ঔষধ নিয়ন্ত্রণ কমিটির ২১ জুন ২০২৩ তারিখে অনুষ্ঠিত ২৫৪ তম সভার কার্যবিবরণী

স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়ের স্বাস্থ্য সেবা বিভাগের সচিব জনাব ড. মু: আনোয়ার হোসেন হাওলাদার এঁর সভাপতিত্বে ঔষধ নিয়ন্ত্রণ কমিটির ২৫৪ তম সভা বিগত ২১ জুন ২০২৩ তারিখ দুপুর ১.০০ ঘটিকায় মন্ত্রণালয়ের সভা কক্ষে অনুষ্ঠিত হয়।

সভায় কমিটির নিম্নবর্ণিত সদস্যগণ উপস্থিত ছিলেন (জ্যেষ্ঠতার ক্রমানুসারে নয়) ঃ

১। মেজর জেনারেল মোহাম্মদ ইউসুফ, মহাপরিচালক, ঔষধ প্রশাসন অধিদপ্তর, ঢাকা
২। অধ্যাপক ডাঃ শারফুদ্দিন আহমেদ, উপাচার্য, বঙ্গবন্ধু শেখ মুজিব মেডিকেল বিশ্ববিদ্যালয়, ঢাকা
৩। অধ্যাপক ডাঃ আবুল বাসার মোহাম্মদ খুরশীদ আলম, মহাপরিচালক, স্বাস্থ্য অধিদপ্তর, ঢাকা
৪। অধ্যাপক ডাঃ মোঃ ইসমাইল খান, উপাচার্য, চট্টগ্রাম মেডিকেল বিশ্ববিদ্যালয়, চট্টগ্রাম
৫। ব্রিগেডিয়ার জেনারেল ডাঃ মোঃ শামীম ইয়াজদানী, ডেপুটি ডিজিএমএস, সামরিক চিকিৎসা সার্ভিস মহাপরিদপ্তর, ঢাকা
৬। অধ্যাপক ড. সীতেশ চন্দ্র বাছার, ডিন ফার্মেসি অনুষদ, ঢাকা বিশ্ববিদ্যালয়
৭। অধ্যাপক ড. শেখ জহির রায়হান, চেয়ারম্যান, ক্লিনিক্যাল ফার্মেসী ও ফার্মাকোলজী বিভাগ, ঢাকা বিশ্ববিদ্যালয়
৮। অধ্যাপক ডাঃ জাকির হোসাইন গালিব, বিভাগীয় প্রধান, চর্ম ও যৌন বিভাগ, স্যার সলিমুল্লাহ মেডিকেল কলেজ, ঢাকা
৯। ডাঃ মোঃ শাহিনুর আলম, পরিচালক (সম্প্রসারন), প্রণিসম্পদ অধিদপ্তর, ঢাকা
১০। ডাঃ শাহিনা আক্তার, সহকারী অধ্যাপক (গাইনী এন্ড অবস), স্যার সলিমুল্লাহ মেডিকেল কলেজ, ঢাকা
১১। জনাব মোঃ মোস্তাফিজুর রহমান, পরিচালক (চ.দা.), ঔষধ প্রশাসন অধিদপ্তর, ঢাকা
১২। জনাব মোহাম্মদ মোস্তাফিজুর রহমান, সহকারী সচিব, স্বাস্থ্য সেবা বিভাগ, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়
১৩। ডাঃ মোঃ জামাল উদ্দিন চৌধুরী, প্রতিনিধি, বাংলাদেশ মেডিকেল এসোসিয়েশন, ঢাকা
১৪। অধ্যাপক ড. মোঃ হাসান কাওসার, বাংলাদেশ ফার্মাসিউটিক্যালস সোসাইটি, ঢাকা
১৫। জনাব মুহাম্মদ মাহবুবুল হক, সচিব, বাংলাদেশ ফার্মেসী কাউন্সিল, ঢাকা
১৬। জনাব এ. কে. মাহবুবুর রহমান, প্রতিনিধি (ইউনানী), বাংলাদেশ ইউনানী ও আয়ুর্বেদিক বোর্ড, ঢাকা
১৭। কবিরাজ শ্রীকৃষ্ণকান্ত রায়, বিশেষজ্ঞ প্রতিনিধি, বাংলাদেশ ইউনানী ও আয়ুর্বেদিক বোর্ড, ঢাকা

পর্যবেক্ষক (জ্যেষ্ঠতার ক্রমানুসারে নয়) ঃ

১। জনাব নাজমুল হাসান, এমপি, সভাপতি, বাংলাদেশ ঔষধ শিল্প সমিতি, ঢাকা
২। জনাব রাব্বুর রেজা, বিশেষজ্ঞ প্রতিনিধি, বাংলাদেশ ঔষধ শিল্প সমিতি এবং সিওও, মেসার্স বেক্সিমকো ফার্মাসিউটিক্যালস লিঃ
৩। মেজর জেনারেল (অবঃ) মোঃ মোস্তাফিজুর রহমান, সিইও, বাংলাদেশ ঔষধ শিল্প সমিতি, ঢাকা
৪। জনাব মোঃ আবদুর রাজ্জাক, বাংলাদেশ ঔষধ শিল্প সমিতি কর্তৃক মনোনীত মেডিকেল ডিভাইস বিশেষজ্ঞ এবং ব্যবস্থাপনা পরিচালক, জেএমআই সিরিঞ্জেস এন্ড মেডিকেল ডিভাইস লিঃ, কুমিল্লা
৫। জনাব মোঃ শাহ জালাল, বিশেষজ্ঞ প্রতিনিধি, বাংলাদেশ ফার্মাসিউটিক্যালস ইম্পোর্টার্স এসোসিয়েশন, ঢাকা

সভার আলোচ্য সূচী :

ক) ঔষধ নিয়ন্ত্রণ কমিটির ২০ মার্চ ২০২২ তারিখে অনুষ্ঠিত ২৫৩ তম সভার কার্যবিবরণী নিশ্চিতকরণ।

খ) Pitolisant HCl & Lumateperone Tosylate এর Antipsychotic জাতীয় ঔষধের অনুমোদনের বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

গ) Paclitaxel 260mg/43.33ml Injection for IV Infusion-এর অনুমোদনের বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

ঘ) **নতুন indication সংযোজন অনুমোদন প্রসঙ্গে:**

(i) M/S Radiant Export Import Enterprise, Uttara, Dhaka নামীয় প্রতিষ্ঠানটি রেজিস্ট্রেশনভুক্ত Empagliflozin INN 10mg Tablet এবং Empagliflozin INN 25mg Tablet পদ দুটির PIL (Patient Information Leaflet) - এ নতুন indication সংযোজন এর বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

(ii) M/S Radiant Export Import Enterprise, Uttara, Dhaka নামীয় প্রতিষ্ঠানটি তাদের রেজিস্ট্রেশনভুক্ত পদ Zavicefta 2.0 g/0.5g Powder for concentrate solution for infusion (**Manufacturer:** ACS Dobfar S.p.A; Via Alessandro Fleming 2, Verona 37135, Italy) নামীয় পদটির নতুন indication সংযোজন এর বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

ঙ) মেসার্স টোটি সেল লিঃ নামীয় প্রতিষ্ঠানটির Human Umbilical Cord Mesenchymal Stem/Stromal Cells পদটি অনুমোদনের বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

চ) ডিসিসি এর রেফারেন্স পাওয়া যাচ্ছে না বিধায় পোস্ট অ্যাপ্রুভালের জন্য অনুমোদনের বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

ছ) **ফর্মুলেশন সংশোধন এর বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে:**

(i) মেসার্স স্কয়ার ফার্মাসিউটিক্যালস কর্তৃক আবেদিত Cinchocaine Hydrochloride + Esculin + Hydrocortisone + Framycetin Sulphate Suppository অনুমোদনের বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

(ii) মেসার্স স্কয়ার ফার্মাসিউটিক্যালস্ লিমিটেড (হার্বাল ডিভিশন) নামীয় প্রতিষ্ঠানটির "ইউরিপাম সফটজেল ক্যাপসুল" নামীয় ক্যাপসুলটির সক্রিয় উপাদানের সংশোধিত ফর্মুলেশন অনুমোদনের বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

জ) ড্রাগ কন্ট্রোল কমিটির ২৫৩ তম সভায় রেফারেন্স না থাকায় বাতিলকৃত ০৪ (চার) টি পদের পূণঃমূল্যায়ন প্রসঙ্গে।

ঝ) Sodium Citrate USP 4% solution (Anticoagulant for blood bank) পদটি অনুমোদনের বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

ঞ) স্থানীয়ভাবে উৎপাদনের জন্য ৪৩৬ টি হিউম্যান ঔষধের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের উপর আলোচনা ও সিদ্ধান্ত গ্রহণ।

ট) স্থানীয়ভাবে উৎপাদনের জন্য ০৩ টি হিউম্যান ভ্যাকসিনের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের উপর আলোচনা ও সিদ্ধান্ত গ্রহণ।

ঠ) আমদানীর জন্য ৫২ টি হিউম্যান ঔষধের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের উপর আলোচনা ও সিদ্ধান্ত গ্রহণ।

ড) আমদানীর জন্য ০৪ টি হিউম্যান ভ্যাকসিনের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের উপর আলোচনা ও সিদ্ধান্ত গ্রহণ।

ঢ) স্থানীয়ভাবে উৎপাদনের জন্য ৫৬ টি ভেটেরিনারি ঔষধের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের উপর আলোচনা ও সিদ্ধান্ত গ্রহণ।

ণ) আমদানীর জন্য ৬৭ টি ভেটেরিনারি ঔষধের বিষয়ে টেকনিক্যাল সাব-কমিটির সুপারিশের উপর আলোচনা ও সিদ্ধান্ত গ্রহণ।

ত) স্থানীয়ভাবে উৎপাদনের জন্য ১৯৮ টি হার্বাল হিউম্যান ঔষধের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের উপর আলোচনা ও সিদ্ধান্ত গ্রহণ।

থ) বিবিধ-১: LDC Graduation পর পেটেন্ট আইনের কারণে ঔষধ রেজিস্ট্রেশনের চ্যালেঞ্জ মোকাবেলার নিমিত্তে নিয়মিত ঔষধ নিয়ন্ত্রণ কমিটি ও এর টেকনিক্যাল সাব-কমিটির সভা আহবান প্রসঙ্গে।

বিবিধ-২: বাংলাদেশের মেডিকেল ডিভাইস শিল্প এদেশের ঔষধ শিল্পের মতো প্রসার না হওয়ার কারণ নির্ণয়পূর্বক সঠিক দিক নির্দেশনা প্রণয়নের জন্য কমিটি গঠন প্রসঙ্গে।

সভার আলোচনাঃ

সবাইকে স্বাগত জানিয়ে সভাপতি সভার কার্যক্রম শুরু করেন। অতঃপর তিনি কমিটির সদস্য সচিব ঔষধ প্রশাসন অধিদপ্তরের মহাপরিচালক-কে সভার আলোচ্যসূচী মোতাবেক বিষয়বস্তু উপস্থাপনের জন্য অনুরোধ করেন।

ক) ঔষধ নিয়ন্ত্রণ কমিটির বিগত ২৫৩ তম সভার কার্যবিবরণী নিশ্চিতকরণ:

বিগত ২০-০৩-২০২২ খ্রিঃ তারিখে অনুষ্ঠিত ঔষধ নিয়ন্ত্রণ কমিটির ২৫৩ তম সভার কার্যবিবরণী নিশ্চিতকরণ করার জন্য সভায় উপস্থাপন করা হল।

সভায় উপস্থিত সদস্যগণ ২৫৩ তম সভার কার্যবিবরণী সঠিকভাবে লিপিবদ্ধ হয়েছে বলে মত প্রকাশ করেন।

সভায় সর্বসম্মতিক্রমে ২৫৩ তম সভার কার্যবিবরণী নিশ্চিত করা হয়।

খ) **Pitolisant HCl & Lumateperone Tosylate এর Antipsychotic জাতীয় ঔষধের অনুমোদনের বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।**

ঔষধ নিয়ন্ত্রণ কমিটির ২৫৩ তম সভায় ১ম দুটি এবং ২৫২ তম সভায় তৃতীয় পদটির বিষয়ে সাইক্রিয়াটিস্ট এর মতামত গ্রহণের জন্য পত্র প্রেরণের সিদ্ধান্ত গৃহীত হয়:

1. Pitolisant Hydrochloride eq. to Pitolisant 4.45 mg Tablet
2. Pitolisant Hydrochloride eq. to Pitolisant 17.8 mg Tablet
3. Lumateperone Tosylate INN 60mg eq. to 42 mg, Lumateperone Capsule

সাইক্রিয়াটিস্ট এর মতামত: অধ্যাপক ডা. বিধান রঞ্জন রায় পোদ্দার, পরিচালক ও অধ্যাপক, জাতীয় মানসিক স্বাস্থ্য ইনস্টিটিউট ও হাসপাতাল পদ তিনটি অনুমোদনের বিষয়ে সুপারিশ করেন।

ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত ঃ পদগুলো অনুমোদন করা হলো।

গ) **Paclitaxel 260mg/43.33ml Injection for IV Infusion-এর অনুমোদনের বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে ।**

মেসার্স বিকন ফার্মাসিউটিক্যালস লিঃ-এর অনুকূলে Paclitaxel 100mg/Vial Injection for IV Infusion and Paclitaxel 300 mg/50 ml Injection অনুমোদিত। প্রতিষ্ঠানটি বর্তমানে Paclitaxel 260mg/43.33ml Injection for IV Infusion, Anticancer এর অনুমোদনের জন্য আবেদন করেছে।

- ABRAXANE for Injectable Suspension (Paclitaxel 100mg/Vial) এর USFDA কর্তৃক অনুমোদিত লেবেল-এ DOSAGE AND ADMINISTRATION -এ Metastatic Breast Cancer (MBC): Recommended dosage of ABRAXANE is 260 mg/m2 intravenously over 30 minutes every 3 weeks উল্লেখ রয়েছে।
- পার্শ্ববর্তী দেশ ভারত হতে এই Paclitaxel 260mg/43.33ml Injection for IV Infusion ঔষধটির দেশে ব্যাপক চাহিদার কারণে স্মাগলিং হয়ে দেশে আসছে মর্মে জানা গেছে। তাই এ বিষয়ে মতামত প্রদানের জন্য সভায় উপস্থাপন করা হয়।

টেকনিক্যাল সাব কমিটির সুপারিশ: মেসার্স বিকন ফার্মাসিউটিক্যালস লিঃ-এর অনুকূলে Paclitaxel 260mg/43.33ml Injection for IV Infusion পদটি অনুমোদনের সুপারিশ করা যেতে পারে।

ঔষধ নিয়ন্ত্রণ কমিটির আলোচনা ঃ ঔষধটির দেশীয় চাহিদা এবং সুলভ মূল্যে জনগণের প্রাপ্তির জন্য পদটি প্রয়োজনীতা রয়েছে মর্মে সভায় উপস্থিত সদস্যগণ মত প্রকাশ করেন।

সভার সিদ্ধান্ত: মেসার্স বিকন ফার্মাসিউটিক্যালস লিঃ-এর অনুকূলে Paclitaxel 260mg/43.33ml Injection for IV Infusion পদটি অনুমোদন করা হলো।

ঘ) **নতুন indication সংযোজন প্রসঙ্গেঃ**

(i) Empagliflozin 10 mg Tablet এবং Empagliflozin 25 mg Tablet পদ দুটির নতুন indication সংযোজনের অনুমোদনের বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

Radiant Export Import Enterprise, Uttara, Dhaka নামীয় প্রতিষ্ঠানটি রেজিস্ট্রেশনভুক্ত Empagliflozin INN 10mg Tablet এবং Empagliflozin INN 25mg Tablet পদ দুটির PIL (Patient Information Leaflet)- এ নতুন indication সংযোজন এর অনুমোদন চেয়ে আবেদন করেছে, যার USFDA এর রেফারেন্স রয়েছে।

Indication টি নিম্নরূপঃ Empagliflozin Tablet is a sodium – glucose co-transporter 2 (SGLT2) inhibitor indicated: To reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure and reduced ejection fraction.

টেকনিক্যাল সাব কমিটির মতামত ঃ Indication টি সংযোজনের সুপারিশ করা হয়।

ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত ঃ Radiant Export Import Enterprise, Uttara, Dhaka নামীয় প্রতিষ্ঠানটি রেজিস্ট্রেশনভুক্ত Empagliflozin INN 10mg Tablet এবং Empagliflozin INN 25mg Tablet পদ দুটির PIL (Patient Information Leaflet) - এ নতুন indication সংযোজন এর অনুমোদন করা হলো।

(ii) Radiant Export Import Enterprise, Uttara, Dhaka নামীয় প্রতিষ্ঠানটি তাদের রেজিস্ট্রেশনভুক্ত পদ Zavicefta 2.0 g/0.5g Powder for concentrate solution for infusion (Ceftazidime Pentahydrate 2329.7mg eq. to 2g ceftazidime + Avibactam Sodium 543.5mg eq. to 0.5g avibactam); **Manufacturer:** ACS Dobfar S.p.A; Via Alessandro Fleming 2, Verona 37135, Italy পদটির নিম্নে বর্ণিত নতুন indication সংযোজনের অনুমোদন চেয়ে আবেদন করেছে:

ঔষধ নিয়ন্ত্রণ কমিটির ২৪৪ তম সভায় অনুমোদিত **Indication:**

For the treatment of patients 18 years or older with following infections caused by the susceptible microorganisms:

- Complicated intra-abdominal infections (cIAI), used in combination with metronidazole.
- Complicated Urinary Tract Infections (cUTI) including Pyelonephritis.

Proposed new Indication:

Zavicefta is indicated in adults and paediatric patients aged 3 months and older for the treatment of the following infections:

- Complicated intra-abdominal infection (cIAI)
- Complicated urinary tract infection (cUTI), including pyelonephritis
- Hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP)
- Treatment of adult patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.
- Zavicefta is also indicated for the treatment of infections due to aerobic Gram-negative organisms in adults and paediatric patients aged 3 months and older with limited treatment.
- Consideration should be given to official guidance on the appropriate use of antibacterial agents.

উল্লিখিত রেফারেন্সের অনুকূলে EMA এর রেফারেন্স রয়েছে।

টেকনিক্যাল সাব কমিটির সভার মতামত: Radiant Export Import Enterprise, Uttara, Dhaka নামীয় প্রতিষ্ঠানটির Zavicefta 2.0 g/0.5g Powder for concentrate solution for infusion (**Manufacturer:** ACS Dobfar S.p.A; Via Alessandro Fleming 2, Verona 37135, Italy) নামীয় পদটির EMA কর্তৃক অনুমোদিত নতুন indication টি অনুমোদনের জন্য সুপারিশ করা যেতে পারে।

ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত ঃ Radiant Export Import Enterprise, Uttara, Dhaka নামীয় প্রতিষ্ঠানটি তাদের রেজিস্ট্রেশনভুক্ত পদ Zavicefta 2.0 g/0.5g Powder for concentrate solution for infusion (**Manufacturer:** ACS Dobfar S.p.A; Via Alessandro Fleming 2, Verona 37135, Italy) নামীয় পদটির নতুন indication টি অনুমোদন করা হলো।

ঙ) মেসার্স টোটি সেল লিঃ নামীয় প্রতিষ্ঠানটির Human Umbilical Cord Mesenchymal Stem/Stromal Cells পদটি অনুমোদনের বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

টোটি সেল লিঃ নামীয় প্রতিষ্ঠানটি Human Umbilical Cord Mesenchymal Stem/Stromal Cells নামীয় পদটির অনুমোদনের জন্য আবেদন করে। এধরনের স্টেম সেল প্রোডাক্ট বাংলাদেশে নতুন। পদটির রেজিস্ট্রেশন অনুমোদনের বিষয়ে ড্রাগ কন্ট্রোল কমিটির ২৫৩ তম সভার সিদ্ধান্ত নিম্নরূপ:

নিম্নোক্ত সদস্যদের সমন্বয়ে একটি পরিদর্শকদল গঠণের সিদ্ধান্ত গৃহীত হয়। উক্ত সদস্যগণ টোটি সেল লিঃ নামীয় প্রতিষ্ঠানটির উৎপাদন ফ্যাসিলিটিজ পরিদর্শনকরতঃ মতামত প্রদান করবেন, যা পরবর্তী ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সভায় উপস্থাপন করা হবে।

১. অধ্যাপক ডাঃ মোঃ টিটো মিঞা, প্রিন্সিপাল, ঢাকা মেডিকেল কলেজ, ঢাকা ।
২. অধ্যাপক সীতেশ চন্দ্র বাছার, ডীন, ফার্মেসী অনুষদ, ঢাকা বিশ্ববিদ্যালয়।
৩. অধ্যাপক ড. এস. এম. আবদুর রহমান, চেয়ারম্যান, ক্লিনিক্যাল ফার্মেসী ও ফার্মাকোলজি, ঢাকা বিশ্ববিদ্যালয়।
৪. প্রফেসর ডা. আহমেদুল কবির, ADG (Admin), স্বাস্থ্য অধিদপ্তর।
৫. জনাব মোঃ মোস্তাফিজুর রহমান, পরিচালক (চঃদাঃ), ঔষধ প্রশাসন অধিদপ্তর।

উক্ত পরিদর্শকদল বিগত ১৬/০৪/২০২২ খ্রিঃ তারিখে প্রতিষ্ঠানটি পরিদর্শন করে নিম্নোক্ত পরামর্শসমূহ বাস্তবায়নের জন্য মতামত প্রদান করে:

১. Human Umbilical Cord-Mesenchymal Stem Cells(HUC-MSCs) এর উৎপাদন প্রক্রিয়ার Process Validation করত: রেকর্ড সংরক্ষণ করতে হবে এবং Validated পদ্ধতিতে উৎপাদন কর্মকান্ড করতে হবে।

২. প্রোডাক্টের ন্যূনতম ০৩টি ব্যাচের Accelerated এবং Real time Stability Study ICH গাইড লাইন অনুযায়ী করতঃ রেকর্ড সংরক্ষণ ও তদানুযায়ী Product এর Shelf Life নির্ধারণ করতে হবে।

৩. Certificate of Analysis এর specification সমূহ Validate করতঃ তা Upgrade করতে হবে।

৪. প্রতিষ্ঠানের জন্য ISO 9001:2015 এবং ICH Q10 অনুযায়ী Quality Manual তৈরীকরতঃ তা অনুসরণ করতে হবে।

৫. Commercial batch উৎপাদনের জন্য উপযুক্ত classified এরিয়ায় Filling-Sealing line সংযোজন করতে হবে।

৬. বর্তমান কারখানাটি ছোট পরিসরে Commercial ভবনে অবস্থিত। প্রতিষ্ঠানটি আগামী ০৫(পাঁচ) বছরের মধ্যে Industrial এলাকায় সুপরিসর clean room concept অনুযায়ী Man Material Uniflow Design-কৃত নির্মিত ভবনে স্থানান্তর করতে হবে।

৭. আবেদিত পদটি Human Umbilical Cord Derived Mesenchymal Stem Cell Allogenic Product. এ জাতীয় পদ USFDA, EMA, TGA, PMDA, MFDS ইত্যাদি Stringent Regulatory

Authority রেজিস্ট্রেশন প্রদান করেছে। এ জাতীয় Advanced Therapy Product এর Safety ও efficacy প্রমাণিত। Pubmed ও Clinical Trial.gov এ ধরণের Product এর উপর অনেক সন্তোষজনক Clinical Trial সম্পন্ন হওয়ার রিপোর্ট প্রকাশিত। পদটি Biological Product, ভিন্ন কাঁচামাল ও Process হতে উদ্ভুত হওয়ায় এই পদের Safety & Therapeutic benefit মূল্যায়ন করা অত্যাবশ্যক।

এমতাবস্থায়, পদটিকে Compassionate use এর জন্য রেজিস্ট্রেশন প্রদান করা যেতে পারে। তবে, Marketing Authorization এর পূর্বে প্রোটকল অনুমোদনের মাধ্যমে যৌক্তিক সংখ্যক Patients এর উপর randomised Control Trial (০১টি Arm-এ Standard Treatment ও ০১টি Arm-এ Allogenic HUC-MSCs এর মাধ্যমে Clinical Trial করতঃ Safety & Therapeutic benefit measure করতে হবে। ট্রায়ালে সন্তোষজনক ফলাফল প্রমাণিত হওয়ার পর indication/label claim সহ পদটির Marketing Authorization প্রদান করা যেতে পারে।

প্রতিষ্ঠানটিকে পরিদর্শকদলের পরামর্শসমূহ অবহিত করা হলে প্রতিষ্ঠানটি নিম্নরূপ উত্তর প্রদান করেছেঃ

১. Process Validation এর জন্য মেসার্স টোটিসেল লিমিটেড-এর R&D বিভাগ Protocol তৈরী করেছে। Protocol অনুযায়ী পর পর তিন ব্যাচের consistent data পাওয়ায় Protocol মোতাবেক Process Validation সম্পন্ন হয়েছে।

২. ICH গাইড লাইন অনুযায়ী ০৩ টি ব্যাচের Accelerated এবং Real Time Stability Study সম্পন্ন হয়েছে।

৩. Certificate of Analysis এর specification সমূহ Validate করতঃ তা Upgrade করা হয়েছে।

৪. ISO 9001:2015 এবং ICH Q10 অনুযায়ী Quality Manual তৈরী করা হয়েছে ও তা অনুসরণ করা হচ্ছে। উল্লেখ্য যে, ইতোমধ্যেই মেসার্স টোটিসেল লিমিটেড ISO 9001:2015 Accreditation অর্জন করেছে।

৫. ইহা একটি বায়োলজিক্যাল প্রোডাক্ট ও Personalized medicine, Individual cord tissue সংগ্রহের মাধ্যমে একটি cord হতে স্বল্প ব্যাচে (একটি cord একটি ব্যাচ) প্রোডাক্ট তৈরী করা হয়। উল্লেখ্য যে, ব্যাচ সাইজ খুবই ছোট (২০-৪০ মিলিলিটার মাত্র) হওয়ায় filling-Sealing line এ সংযোজনের উপযোগী নয়। তাই সর্বোচ্চ সতর্কতার সাথে Biosafety Cabinet এর ভিতর international standard ও যথাযথ SOP মেনে ম্যানুয়াল filling ও sealing করা হচ্ছে।

৬. পরামর্শ মোতাবেক মেসার্স টোটিসেল লিমিটেড-এর কারখানাটি আগামী ০৫(পাঁচ)বছরের মধ্যে Industrial এলাকায় সুপরিসর clean room concept অনুযায়ী Man Material Uniflow Design-কৃত নির্মিত ভবনে স্থানান্তরের পরিকল্পনা চলছে।

৭. ইতোমধ্যে বিগত ০২ জানুয়ারি ২০২৩ তারিখে Bangladesh Medical Research Counncil (BMRC)-এ **"A Prospective, Single-Blinded, Randomized Control, Comparative Study of Allogeneic Umbilical Cord Derived Mesenchymal Stem Cells (UC-MSC) With Standard Treatment for Knee Osteoarthritis (OA)"**- টাইটেলে ৫০ (পঞ্চাশ) জন Human Subject-এ Trial এর Ethical Clearance/অনুমোদনের নিমিত্তে দাখিল করা হয়েছে।

টেকনিক্যাল সাব কমিটির মতামতঃ টোটিসেল লিঃ নামীয় প্রতিষ্ঠানটি কর্তৃক আবেদিত Human Umbilical Cord Mesenchymal Stem/Stromal Cells নামীয় পদটির ক্ষেত্রে পরিদর্শকদল কর্তৃক প্রদেয় পরামর্শসমূহ বাস্তবায়ন এবং "A Prospective, Single-Blinded, Randomized Control, Comparative Study of Allogeneic

Umbilical Cord Derived Mesenchymal Stem Cells (UC-MSC) With Standard Treatment for Knee Osteoarthritis (OA)" ট্রায়ালটি সম্পাদন নিশ্চিত সাপেক্ষে পদটি অনুমোদনের সুপারিশ করা হয়।

বর্তমান কার্যক্রম ঃ "A Prospective, Single-Blinded, Randomized Control, Comparative Study of Allogeneic Umbilical Cord Derived Mesenchymal Stem Cells (UC-MSC) With Standard Treatment for Knee Osteoarthritis (OA)" নামীয় ক্লিনিক্যাল ট্রায়াল প্রটোকলটি ১৬/০৫/২০২৩ খ্রিঃ তারিখে ঔষধ প্রশাসন অধিদপ্তর কর্তৃক অনুমোদিত হয়েছে। ক্লিনিক্যাল ট্রায়ালটি CRO: AMZ Hospital Limited এ শুরু হয়েছে।

ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত ঃ মেসার্স টোটি সেল লিঃ নামীয় প্রতিষ্ঠানটির অনুকূলে Human Umbilical Cord Mesenchymal Stem/Stromal Cells পদটির রেজিস্ট্রেশনের অনুমোদন এবং ক্লিনিক্যাল ট্রায়ালে সন্তোষজনক ফলাফল প্রমাণিত হওয়ার পর indication/label claim সহ পদটির Marketing Authorization প্রদান করার সুপারিশ করা হলো।

চ) ডিসিসি এর রেফারেন্স পাওয়া যাচ্ছে না বিধায় পোস্ট অ্যাপ্রুভালের জন্য অনুমোদনের বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

নিম্নোক্ত পদসমূহ বহুদিন যাবৎ বাজারজাত হয়ে আসছে, কিন্তু ডিসিসি এর রেফারেন্স পাওয়া যাচ্ছে না বিধায় পোস্ট অ্যাপ্রুভালের জন্য টেকনিক্যাল সাব কমিটির সভায় উপস্থাপন করা হলে, পদগুলো সর্বসম্মতিক্রমে অনুমোদনের সুপারিশ করা হয় ঃ

1. Ascorbic Acid USP 500mg/10 gm Sachet
2. Pheniramine Maleate BP 22.70 mg Tablet
3. Calcium Phosphate BP (Milk source) eq. to elemental Calcium 250 mg and Cholecalciferol (Vita. D3) 250 IU Tablet
4. Calcium Carbonate (Algae Source) BP 1500 mg eq. to Calcium 600 mg & Cholecalciferol (Vitamin D3) BP 400 IU Tablet
5. Calcium (Algae Source) 500 mg + Vitamin D 200 IU Tablet
6. Calcium Carbonate (Eggshell Source) BP 1250 mg eq. to Calcium 500 mg + Cholecalciferol (Vitamin D3) BP 200 IU Tablet
7. Calcium Carbonate (Eggshell Source) BP 1500 mg eq. to 600 mg + Cholecalciferol (Vitamin D3) 400 IU Table

ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত ঃ পদগুলোর পোস্ট অ্যাপ্রুভাল করা হলো।

ছ) ফর্মূলেশন সংশোধন এর বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গেঃ

(i) Cinchocaine Hydrochloride + Esculin + Hydrocortisone + Neomycin Sulphate (Suppository) নামীয় কম্বিনেশনটি ডিসিসি ২৩৮ তম সভায় পোস্ট অ্যাপ্রুভাল করা হয়। কিন্তু অনেক প্রতিষ্ঠানই কম্বিনেশনটিতে Neomycin Sulphate এর পরবর্তে Framycetin Sulphate হিসেবে উৎপাদন ও বাজারজাত করে আসছে।

মেসার্স স্কয়ার ফার্মাসিউটিক্যালস কর্তৃক আবেদিত Cinchocaine Hydrochloride + Esculin + Hydrocortisone + Framycetin Sulphate Suppository-এর এর পোস্ট অ্যাপ্রুভাল এর জন্য আবেদন দাখিল করেছে।

ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত ঃ মেসার্স স্কয়ার ফার্মাসিউটিক্যালস কর্তৃক আবেদিত Cinchocaine Hydrochloride + Esculin + Hydrocortisone + Framycetin Sulphate Suppository-নামীয় ঔষধটির পোস্ট অ্যাপ্রুভাল করা হলো।

(ii) মেসার্স স্কয়ার ফার্মাসিউটিক্যালস্ লিমিটেড (হার্বাল ডিভিশন) নামীয় প্রতিষ্ঠানটির "ইউরিপাম সফটজেল ক্যাপসুল" নামীয় ক্যাপসুলটির সক্রিয় উপাদানের সংশোধিত ফর্মুলেশন অনুমোদনের বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

টেকনিক্যাল সাব-কমিটির আলোচনা:

মেসার্স স্কয়ার ফার্মাসিউটিক্যালস্ লিমিটেড (হার্বাল ডিভিশন) নামীয় প্রতিষ্ঠানটি ঔষধ নিয়ন্ত্রণ কমিটির ১৬ এপ্রিল ২০১৮ এ অনুষ্ঠিত ২৪৯ তম সভায় অনুমোদিত রেজিস্ট্রেশন গ্রহণপূর্বক **"ইউরিপাম সফটজেল ক্যাপসুল"** নামে ঔষধটি বাজারজাত করছে। ঔষধটির জেনেরিক নাম ঃ (Saw palmetto 160 mg + Korean ginseng 3.3 mg + Pygeum bark 1.7 mg +Zinc Sulphate 33.10 mg + Copper Gluconate 2mg) Capsule। উল্লেখ্য ঔষধটি বাজারজাত করণ শুরুর ১.৫-২ বছর পর Satbility Chamber হতে নমুনা সংগ্রহ করে আমরা দেখতে পাই যে, এটি ব্লিস্টার প্যাকের ভিতরে আকারে কিছুটা সংকুচিত হয়ে যায়। যা নিয়ে আমাদের ফর্মুলেশন ডেভেলপমেন্ট ডিপার্টমেন্ট সমস্যাটির সমাধানের জন্য কাজ শুরু করে। পরবর্তীতে তারা দেখতে পায় যে, রেসিপি তে ব্যবহৃত Zinc Sulphate Monohydrate এর পরিবর্তে Zinc Oxide ব্যবহার করলে এবং Copper Gluconate এর পরিমাণের সাথে 40% overage সংযোজন করলে এই ঔষধটির ফর্মুলেশনে উপরে উল্লেখিত সমস্যাটি সমাধানের পাশাপাশি এর স্ট্যাবিলিটিও বৃদ্ধি পায়।

ফর্মুলেশনে আবেদনকৃত পরিবর্তন নিম্নরূপঃ

Name of the Active Ingredients	Existing Formula (qty./Cap)	Proposed Formula (qty./Cap)
Saw Palmetto	160.00 mg	160.00 mg
Pygeum Bark	1.70 mg	1.70 mg
Korean Ginseng	3.30 mg	3.30 mg
Zinc Sulphate Monohydrate	33.10 mg	Nil
Zinc Oxide	Nil	15.00
Copper Gluconate	2.00 mg	2.00 mg (With 40% overage)

ফর্মুলেশনে আবেদনকৃত মূল উপাদান সমূহের পরিমাণগত পরিবর্তনের যৌক্তিকতা:

১. আবেদনে উল্লেখিত Zinc Sulphate Monohydrate এবং Zinc Oxide উভয়েই elemental Zinc নিশ্চিত করে যা Pharmacologically active Zinc এর স্ট্যাবল এবং ইউনিফরম dispersion নিশ্চিত করে।

২. পরিবর্তিত ফর্মুলেশনে 33.1 mg of Zinc Sulphate Monohydrate (যা 12 mg elemental Zinc নিশ্চিত করে) এর পরিবর্তে 15.0 mg Zinc Oxide (যা 12 mg elemental Zinc নিশ্চিত করে) ব্যবহার করা হয়েছে।

৩. পরিবর্তিত ফর্মুলেশনে Copper Gluconate এর পরিমান 2.00 mg এর সাথে 40% overage সংযোজন করা হয়েছে যা জিলাটিন অংশে যুক্ত থাকে। যেহেতু এটি সফটজেল ক্যাপসুল এবং জিলাটিন অংশের process loss সাধারণত ৪০%, সেহেতু Copper Gluconate এর পরিমান ৪০% বৃদ্ধি করা হয়েছে। এতে আরও স্ট্যাবল ফর্মুলেশন নিশ্চিত হয়।

টেকনিক্যাল সাব কমিটির সুপারিশ: মেসার্স স্কয়ার ফার্মাসিউটিক্যালস্ লিমিটেড (হার্বাল ডিভিশন) নামীয় প্রতিষ্ঠানটির "ইউরিপাম সফটজেল ক্যাপসুল" নামীয় ক্যাপসুলটির সক্রিয় উপাদানের সংশোধিত ফর্মুলেশন অনুমোদন করা যেতে পারে।

ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত ঃ

মেসার্স স্কয়ার ফার্মাসিউটিক্যালস্ লিমিটেড (হার্বাল ডিভিশন) নামীয় প্রতিষ্ঠানটির "ইউরিপাম সফটজেল ক্যাপসুল" নামীয় ক্যাপসুলটির সক্রিয় উপাদানের সংশোধিত ফর্মুলেশন অনুমোদন করা হলো।

জ) ড্রাগ কন্ট্রোল কমিটির ২৫৩ তম সভায় রেফারেন্স না থাকায় বাতিলকৃত ০৪(চার) টি পদের পূণঃমূল্যায়ন প্রসঙ্গে।

ড্রাগ কন্ট্রোল কমিটির ২৫৩ তম সভায় রেফারেন্স না থাকায় নিম্নোক্ত পদসমূহ বাতিলের সুপারিশ করা হয়:

১. Rabeprazole Sodium BP 20mg Capsule
২. Bromelain 50 mg + Trypsin 1 mg Tablet
৩. Astaxanthin INN 2 mg Soft Gelatin Capsule & Powder filled hard Gelatin Capsule
৪. Astaxanthin INN 4 mg Soft Gelatin Capsule & Powder filled hard Gelatin Capsule

উক্ত পদসমূহ দীর্ঘদিন যাবৎ বাজারজাত হয়ে আসছে। এছাড়া ঔষধ উৎপাদনকারী প্রতিষ্ঠানসমূহ উপর্যুক্ত পদসমূহ বহাল রাখার জন্য আবেদন করেছে বিধায় পদসমূহ পুণঃ বিবেচনার জন্য উপস্থাপন করা হল ।

ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত ঃ Rabeprazole Sodium BP 20mg Capsule পদটির রেজিস্ট্রেশন বহাল রাখার সিদ্ধান্ত গৃহীত হয়। এছাড়া অবশিষ্ট ০৩ (তিন)টি পদ; (১) Bromelain 50 mg + Trypsin 1 mg Tablet, (২) Astaxanthin INN 2 mg Soft Gelatin Capsule & Powder filled hard Gelatin Capsule এবং (৩) Astaxanthin INN 4 mg Soft Gelatin Capsule & Powder filled hard Gelatin Capsule) এর রেজিস্ট্রেশন বাতিলের সিদ্ধান্ত গৃহীত হয়।

ঝ) Sodium Citrate USP 4% solution (Anticoagulant for blood bank) পদটি অনুমোদনের বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

মেসার্স টেকনো ড্রাগস লিঃ নামীয় প্রতিষ্ঠানটি সাইনোভ্যাক বায়োটেক (বাংলাদেশ) লিঃ নামীয় প্রতিষ্ঠানে চুক্তিভিত্তিক সরবরাহের নিমিত্তে Sodium Citrate USP 4% solution (Anticoagulant for blood bank) পদটি অনুমোদনের জন্য ঔষধ প্রশাসন অধিদপ্তরে বিগত ২৪/০৫/২০২৩ তারিখে আবেদন দাখিল করেছে।

ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সর্বশেষ সভা বিগত ১৪/০৩/২০২৩ খ্রিঃ তারিখে অনুষ্ঠিত হয়েছে বিধায়, আবেদনটি টেকনিক্যাল সাব কমিটির সভায় উপস্থাপন করা সম্ভব হয়নি।

আবেদিত পদটি blood bank এর জন্য অতি প্রয়োজনীয় বিধায় অনুমোদনের বিষয়ে সিদ্ধান্তের জন্য উপস্থাপন করা হল।

ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত ঃ মেসার্স টেকনো ড্রাগস লিঃ এর অনুকূলে Sodium Citrate USP 4% solution (Anticoagulant for blood bank) পদটি অনুমোদন করা হলো।

ঞ) স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান ঔষধের অনুমোদনের বিষয়ে টেকনিক্যাল সাব-কমিটির সভার আলোচনা ও সুপারিশ ঃ

স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান ঔষধের রেজিস্ট্রেশনের নিমিত্তে দাখিলকৃত ৪৩৬ (চারশত ছত্রিশ) টি ঔষধ সভায় উপস্থাপন করা হলে বিস্তারিত আলোচনার পর নিম্নলিখিত সুপারিশ করা হয়ঃ

ক।	অনুমোদনের জন্য সুপারিশকৃত	:	২৯৬ টি
খ।	নামঞ্জুরের জন্য সুপারিশকৃত	:	১৩৬ টি
গ।	রেফারেন্স দাখিলের জন্য বলা হয়েছে	:	০৩ টি
ঘ।	চক্ষু বিশেষজ্ঞের মতামত গ্রহণের সিদ্ধান্ত হয়	:	০১ টি

ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত ঃ ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাব-কমিটির সুপরিশ অনুমোদন করা হয় (Annexure-A)।

ট) স্থানীয়ভাবে উৎপাদনের জন্য ০৩টি হিউম্যান ভ্যাকসিনের অনুমোদনের বিষয়ে টেকনিক্যাল সাব-কমিটির সভার আলোচনা ও সুপারিশ ঃ

স্থানীয়ভাবে উৎপাদনের জন্য মেসার্স ইনসেপ্টা ভ্যাকসিন লিঃ, সাভার নামীয় প্রতিষ্ঠানটি রেজিস্ট্রেশনের নিমিত্তে দাখিলকৃত নিম্নলিখিত ০৩(তিন)টি হিউম্যান ভ্যাকসিন সভায় উপস্থাপন করা হলে বিস্তারিত আলোচনার পর নিম্নলিখিত সুপারিশ করা হয় ঃ

1. Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen (s) Content)
2. Diphtheria, Tetanus and Pertussis (Acellular Component) Vaccine (Adsorbed, Reduced Antigen (s) Content)
3. Enterovirus Type 71 Vaccine (Vero cell), Inactivated

টেকনিক্যাল সাব কমিটির সুপারিশ ঃ পদ তিনটি (১) Chemistry Manufacturing & Control and (২) Clinical Trial & Toxicology দুইটি কমিটির সুপারিশসহ ঔষধ নিয়ন্ত্রণ কমিটির সভায় উপস্থাপন করা হবে।

Chemistry Manufacturing & Control and (২) Clinical Trial & Toxicology কমিটির সুপারিশ: বিগত ১৯/০৪/২০২৩ খ্রিঃ তারিখে অনুষ্ঠিত উক্ত কমিটি দু'টির সভায় স্থানীয়ভাবে উৎপাদনের জন্য মেসার্স ইনসেপ্টা ভ্যাকসিন লিঃ, সাভার কর্তৃক আবেদিত ভ্যাকসিন ০৩(তিন)টি অনুমোদনের সুপারিশ করা হয়।

ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত ঃ স্থানীয়ভাবে উৎপাদনের জন্য মেসার্স ইনসেপ্টা ভ্যাকসিন লিঃ, সাভার এর অনুকূলে নিম্নে বর্ণিত ভ্যাকসিন ০৩ (তিন)টি অনুমোদন করা হলো (Annexure-B):

1. Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen (s) Content)
2. Diphtheria, Tetanus and Pertussis (Acellular Component) Vaccine (Adsorbed, Reduced Antigen (s) Content)
3. Enterovirus Type 71 Vaccine (Vero cell), Inactivated

ঠ) আমদানীর জন্য হিউম্যান ঔষধের অনুমোদনের বিষয়ে টেকনিক্যাল সাব-কমিটির সভার আলোচনা ও সুপারিশঃ

আমদানীর জন্য হিউম্যান ঔষধের রেজিস্ট্রেশনের নিমিত্তে আবেদিত ৫৬ (ছাপান্ন) টি ঔষধ সভায় উপস্থাপন করা হলে বিস্তারিত আলোচনার পর নিম্নলিখিত সুপারিশ করা হয়ঃ

ক। অনুমোদনের জন্য সুপারিশকৃত = ৪১ টি
খ। নামঞ্জুরের জন্য সুপারিশকৃত = ১৫ টি;

ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত ঃ

ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাব-কমিটির সুপরিশ অনুমোদন করা হয় (Annexure-C)।

ড) আমদানীর জন্য ০৪(চার) টি হিউম্যান ভ্যাকসিনের অনুমোদনের বিষয়ে টেকনিক্যাল সাব-কমিটির সভার আলোচনা ও সুপারিশ ঃ

আমদানীর জন্য রেজিস্ট্রেশনের নিমিত্তে দাখিলকৃত নিম্নলিখিত ০৪ (চার)টি হিউম্যান ভ্যাকসিন সভায় উপস্থাপন করা হলে বিস্তারিত আলোচনার পর নিম্নলিখিত সুপারিশ করা হয় ঃ

Sl No	Name of the Vaccine	Manufacturer	Importer name
1	PNEUMOSIL Vaccine, Suspension for Injection (2.5ml-5 Dose, 10 Valent)	Serum Institution of India Ltd, India (WHO Prequalified)	Renata Limited

Sl No	Name of the Vaccine	Manufacturer	Importer name
2	PNEUMOSIL Vaccine, Suspension for Injection (0.5ml-1 Dose, 10 Valent)	Serum Institution of India Ltd, India (WHO Prequalified)	Renata Limited
3	**JEEV® - 3 mcg/0.5 ml** Japanese Encephalitis Inactivated Vaccine (Human) (Purified Inactivated Vaccine – (Adsorbed) 3 mcg/0.5 mL	Biological E. Limited, India (WHO Prequalified)	Janata Traders
4	**JEEV® - 6 mcg/0.5 ml** Japanese Encephalitis Inactivated Vaccine (Human) (Purified Inactivated Vaccine – (Adsorbed) 6 mcg/0.5 mL	Biological E. Limited, India (WHO Prequalified)	Janata Traders

আমদানীর জন্য উপর্যুক্ত ০৪(চার)টি হিউম্যান ভ্যাকসিন টেকনিক্যাল সাব-কমিটির সভায় বিস্তারিত আলোচনার পর না মঞ্জুর করার সুপারিশ করা হয়।

ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত ঃ

আমদানীর জন্য উপর্যুক্ত ০৪(চার)টি হিউম্যান ভ্যাকসিন না মঞ্জুর করা হলো (Annexure-D)।

ঢ) স্থানীয়ভাবে উৎপাদনের জন্য ভেটেরিনারি ঔষধের অনুমোদনের বিষয়ে টেকনিক্যাল সাব-কমিটির সভার আলোচনা ও সুপারিশঃ

স্থানীয়ভাবে উৎপাদনের জন্য ভেটেরিনারি ঔষধের রেজিস্ট্রেশনের নিমিত্তে দাখিলকৃত ৫৬(ছাপান্ন) টি ঔষধ সভায় উপস্থাপন করা হলে বিস্তারিত আলোচনার পর নিম্নলিখিত সুপারিশ করা হয় ঃ

ক। অনুমোদনের জন্য সুপারিশকৃত = ৩৬ টি

খ। নামঞ্জুরের জন্য সুপারিশকৃত = ২০ টি;

ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত ঃ

ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাব-কমিটির সুপরিশ অনুমোদন করা হয় (Annexure-E)।

ণ) আমদানীর জন্য ভেটেরিনারি ঔষধের অনুমোদনের বিষয়ে টেকনিক্যাল সাব-কমিটির সভার আলোচনা ও সুপারিশঃ

আমদানীর জন্য ভেটেরিনারি ঔষধের রেজিস্ট্রেশনের নিমিত্তে আবেদিত ৬৭(সাতষট্টি)টি ঔষধ সভায় উপস্থাপন করা হলে বিস্তারিত আলোচনার পর নিম্নলিখিত সুপারিশ করা হয় ঃ

ক। অনুমোদনের জন্য সুপারিশকৃত = ৫১ টি

খ। নামঞ্জুরের জন্য সুপারিশকৃত = ১৬ টি

ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত ঃ

ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাব-কমিটির সুপরিশ অনুমোদন করা হয় (Annexure-F)।

ত) স্থানীয়ভাবে উৎপাদনের জন্য হার্বাল হিউম্যান ঔষধের অনুমোদনের বিষয়ে টেকনিক্যাল সাব-কমিটির সভার আলোচনা ও সুপারিশ ঃ

গত ২২ মে, ২০২৩ তারিখে হার্বাল হিউম্যান ঔষধের আবেদন মূল্যায়নের নিমিত্তে হার্বাল এ্যাডভাইজরী কমিটির সভা অনুষ্ঠিত হয়। উক্ত সভায় ১৯৮ (একশত আটানব্বই) টি ঔষধ সভায় উপস্থাপন করা হলে বিস্তারিত আলোচনার পর নিম্নলিখিত সুপারিশ করা হয় ঃ

ক। অনুমোদনের জন্য সুপারিশকৃত = ১৭৮ টি

খ। নামঞ্জুরের জন্য সুপারিশকৃত = ২০ টি;

ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত ঃ ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাব-কমিটির সুপরিশ অনুমোদন করা হয় (Annexure-G)।

বিবিধ আলোচনা:

১। LDC Graduation পর পেটেন্ট আইনের কারণে ঔষধ রেজিস্ট্রেশনের চ্যালেঞ্জ মোকাবেলার নিমিত্তে নিয়মিত ঔষধ নিয়ন্ত্রণ কমিটি ও এর টেকনিক্যাল সাব-কমিটির সভা আহবান প্রসঙ্গে।

সভার আলোচনা:

বাংলাদেশ ঔষধ শিল্প সমিতি এর সভাপতি জনাব নাজমুল হাসান, এম,পি, সভাকে অবহিত করার জন্য ২০২৬ সালের পর বাংলাদেশ এলডিসি হতে উত্তোরনের পর পেটেন্ট আইনের কারণে পেটেন্টকৃত ঔষধ রেজিস্ট্রেশনের জন্য চ্যালেঞ্জের সম্মুখীন হতে হবে। তাই আমাদেরকে ২০২৬ এর পূর্বেই দেশে অধিক সংখ্যক ঔষধ রেজিস্ট্রেশন করার ব্যবস্থা গ্রহণ করতে হবে। এজন্য বাংলাদেশ ঔষধ শিল্প সমিতি ও ঔষধ প্রশাসন অধিদপ্তরের সমন্বয়ে একটি টাস্কফোর্স গঠন করা যেতে পারে। উক্ত টাস্কফোর্স LDC Graduation এর পরে ঔষধ শিল্পে বর্তমানে পেটেন্টকৃত এবং ভবিষ্যতে পেটেন্টসম্পন্ন ঔষধ (যেমনঃ- Anticancer, Biologics, Antibiotic, NSAIDs) এর প্রাপ্যতা নিশ্চিত করার পরিকল্পনা করতে হবে। এছাড়া টাস্কফোর্স কর্তৃক নতুন জেনেরিকসমূহ চিহ্নিত করে রেজিস্ট্রেশন প্রদান করার ব্যবস্থা করা যেতে পারে এবং ঔষধটি বাজারজাত করার পূর্বে ঔষধ প্রশাসন অধিদপ্তর মার্কেটিং অথোরাইজেশন সনদ ইস্যু করতে পারে। এ লক্ষ্যে তিনি প্রতি মাসে টেকনিক্যাল সাব-কমিটির সভা আহবান করার প্রস্তাব করেন।

অধ্যাপক ডাঃ মোঃ ইসমাইল খান বলেন যে, প্রতি মাসের পরিবর্তে প্রতি দুই মাস পরপর টেকনিক্যাল সাব-কমিটির সভা এবং দুইটি টেকনিক্যাল সাব-কমিটি এর সভার পর একটি ঔষধ নিয়ন্ত্রণ কমিটির সভা আহবান করার প্রস্তাব করেন।

সভাপতি এতদবিষয়ে ঔষধ প্রশাসন অধিদপ্তরকে ব্যবস্থা গ্রহণ করার জন্য অনুরোধ করেন।

ঔষধ প্রশাসন অধিদপ্তরের মহাপরিচালক সভাকে অবহিত করেন যে, অধিদপ্তরে নতুন ঔষধ রেজিস্ট্রেশনের জন্য কিছু আবেদন কোম্পানী কর্তৃক দাখিলের পর আমরা টেকনিক্যাল সাব-কমিটির সভা আহবান করে থাকি। তিনি প্রতি দুই মাস পরপর টেকনিক্যাল সাব-কমিটির সভা এবং দুইটি টেকনিক্যাল সাব-কমিটি এর সভার পর একটি ঔষধ নিয়ন্ত্রণ কমিটির সভা আহবান করার জন্য ব্যবস্থা গ্রহণ করা হবে মর্মে সভাকে অবহিত করেন।

সিদ্ধান্ত:

১। LDC Graduation এর পরে ঔষধ শিল্পের চ্যালেঞ্জের মোকাবেলা করার জন্য বাংলাদেশ ঔষধ শিল্প সমিতি ও ঔষধ প্রশাসন অধিদপ্তরের সমন্বয়ে একটি টাস্কফোর্স গঠন করার নিমিত্তে এর প্রস্তাবনা মন্ত্রণালয় হতে অনুমোদন গ্রহণ করতে হবে।

২। প্রতি দুই মাস পরপর টেকনিক্যাল সাব-কমিটির সভা এবং দুইটি টেকনিক্যাল সাব-কমিটি এর সভার পর একটি ঔষধ নিয়ন্ত্রণ কমিটির সভা আহবান করার নিমিত্তে ব্যবস্থা গ্রহণ করা হবে।

২। বাংলাদেশের মেডিকেল ডিভাইস শিল্প এদেশের ঔষধ শিল্পের মতো প্রসার না হওয়ার কারণ নির্ণয়পূর্বক সঠিক দিক নির্দেশনা প্রণয়নের জন্য কমিটি গঠন প্রসঙ্গে।

সভার আলোচনা:

জনাব মোঃ আবদুর রাজ্জাক, বাংলাদেশ ঔষধ শিল্প সমিতি কর্তৃক মনোনীত মেডিকেল ডিভাইস বিশেষজ্ঞ এবং ব্যবস্থাপনা পরিচালক, জেএমআই সিরিঞ্জেস এন্ড মেডিকেল ডিভাইস লিঃ, কুমিল্লা বলেন যে, বাংলাদেশের ঔষধ শিল্প দেশীয় চাহিদার ৯৮% ঔষধ দেশে উৎপাদন করছে। এছাড়া এদেশ হতে ইউএসএ, ইউকে, ইউরোপীয় দেশসহ দেড় শতাধিক দেশে ঔষধ রপ্তানী হচ্ছে। কিন্তু মেডিকেল ডিভাইস শিল্প দেশীয় চাহিদার মাত্র ৫-৭% মেডিকেল ডিভাইস দেশে উৎপাদিত হয়। অবশিষ্ট মেডিকেল ডিভাইসসমূহ আমদানী করতে হয়। মেডিকেল ডিভাইস সেক্টরে দেশে অনেক কোম্পানী স্থাপিত হলেও, অনেকে কোম্পানী টিকে থাকতে পারে নাই এবং এর কারণগুলো খুজে বের করতে হবে। বাংলাদেশের মেডিকেল ডিভাইস শিল্প এদেশের ঔষধ শিল্পের মতো প্রসার না হওয়ার কারণ নির্ণয় এবং এদেশে মেডিকেল ডিভাইস সেক্টরে চ্যালেঞ্জসমূহ খুজে বের করার জন্য সংশ্লিষ্ট বিশেষজ্ঞদের সমন্বয়ে কমিটি গঠন করার প্রস্তাবনা করেন।

সভাপতি এতদবিষয়ে বাংলাদেশ ঔষধ শিল্প সমিতি এর সভাপতি-কে তাঁর বক্তব্য উপস্থাপনের জন্য অনুরোধ করেন।

বাংলাদেশ ঔষধ শিল্প সমিতি এর সভাপতি জনাব নাজমুল হাসান, এম,পি, বলেন যে, মেডিকেল ডিভাইস শিল্পের এ চ্যালেঞ্জসমূহ নির্ধারনের জন্য পর্যালোচনাপূর্বক একটি প্রস্তাবনা পেশ করা হবে।

সভাপতি বলেন যে, বাংলাদেশ ঔষধ শিল্প সমিতি ও বাংলাদেশ এসোসিয়েশন ফর মেডিকেল ডিভাইস এন্ড সার্জিক্যাল ইন্সট্রুমেন্ট ম্যানুফ্যাকচারার এন্ড এক্সপোর্টার এসোসিয়েশনের প্রস্তাবনার উপর ভিত্তি করে মেডিকেল ডিভাইস শিল্পের চ্যালেঞ্জসমূহ নির্ণয় ও মোকাবেলার করণীয় নির্ধারনের জন্য একটি কমিটি গঠণ করা হবে।

সিদ্ধান্ত:

১। বাংলাদেশ ঔষধ শিল্প সমিতি ও বাংলাদেশ এসোসিয়েশন ফর মেডিকেল ডিভাইস এন্ড সার্জিক্যাল ইন্সট্রুমেন্ট ম্যানুফ্যাকচারার এন্ড এক্সপোর্টার এসোসিয়েশনের প্রস্তাবনার উপর ভিত্তি করে বাংলাদেশের মেডিকেল ডিভাইস শিল্প এদেশের ঔষধ শিল্পের মতো প্রসার না হওয়ার কারণ নির্ণয় এবং এদেশে মেডিকেল ডিভাইস সেক্টরে চ্যালেঞ্জসমূহ নির্ণয় ও মোকাবেলার করণীয় নির্ধারনের জন্য সংশ্লিষ্ট বিশেষজ্ঞদের সমন্বয়ে একটি কমিটি গঠণ করা হবে।

আর কোন আলোচ্য বিষয় না থাকায় সভায় উপস্থিত সবাইকে ধন্যবাদ জানিয়ে সভাপতি সভার সমাপ্তি ঘোষণা করেন।

২৩/৭/২০২৬

মেজর জেনারেল মোহাম্মদ ইউসুফ
মহাপরিচালক
ঔষধ প্রশাসন অধিদপ্তর
ও
সদস্য-সচিব, ঔষধ নিয়ন্ত্রণ কমিটি

ড. মু: আনোয়ার হোসেন হাওলাদার
সচিব
স্বাস্থ্য সেবা বিভাগ
স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়
ও
সভাপতি, ঔষধ নিয়ন্ত্রণ কমিটি

Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
1.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Advanced Chemical Industries Ltd.Narayangang The ACME Laboratories Ltd. Dhamrai, Dhaka General Pharmaceutical Ltd., Gazipur Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Nuvista Pharma Ltd. Navana Pharmaceuticals Ltd., Rupgang, Narayangang M/s Orion Pharma Ltd., D/28/2, Sumilpara, Siddhirgang, Narayangang Ziska Pharmaceuticals Ltd	Ferric maltol INN 231.620 mg eqv. to Iron 30mg Capsule	Ferric maltol INN 231.620 mg eqv. to Iron 30mg	Therapeutic Class: Drug used in Anemia and other Blood disorder Therapeutic code: 045	It is an iron replacement product indicated for the treatment of iron deficiency in adults	Warnings and Precautions: • IBD flare: Avoid use in patients with IBD flare • Iron overload: Accidental overdose of iron products is a leading cause of fatal poisoning in children under 6. Keep out of reach of children Contraindications: • Hypersensitivity to the active substance or any excipient • Hemochromatosis and other iron overload syndromes • Patients receiving repeated blood transfusions Side effects: Gas, diarrhea, constipation, , discolored stools, stomach pain, nausea or vomiting, stomach area discomfort or bloating	Ferric Citrate 1000mg Tablet	USFDA, EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
2.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Beacon Pharmaceuticals Ltd. Beximco Pharmaceutical Ltd, Tongi, Gazipur Drug International Ltd (Unit-3) General Pharmaceutical Ltd.,	Finasteride USP 5mg + Tadalafil USP 5mg Capsule	Finasteride USP 5mg + Tadalafil USP 5mg	Therapeutic Class: Drug used obstratics Therapeutic code: 049	It is a combination of finasteride, a 5α-reductase inhibitor, and tadalafil, a phosphodiesterase 5 (PDE5) inhibitor, and, indicated to initiate treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate for up to 26 weeks.	Contraindications**:** Concomitant use with any form of organic nitrate, either regularly and/or intermittently. It can potentiate the hypotensive effect of nitrates. • Known hypersensitivity to it or any of its components. • Pregnancy. • Concomitant use with guanylate cyclase (GC) stimulators. It may potentiate the hypotensive effects of GC stimulators. **Warnings and Precautions:** Cardiovascular risk, Potential for Drug Interactions when taking it, Consideration of Other Urological Conditions Prior to Initiation of Treatment for BPH, Effects of PSA and the Use of PSA in Prostate Cancer	Finasteride 5 mg Tablet, Tadalafil 5 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Gazipur Pharmasia Ltd., Gojariapara. Bhawal Mirzapur, Gazipur					Detection. **Side effect:** Most common adverse reactions associated with finasteride monotherapy (≥1%) in a 4-year study were impotence, decreased libido, decreased volume of ejaculate, breast enlargement, breast tenderness, and rash. Most common adverse reactions (≥2%) associated with tadalafil were headache, dyspepsia, back pain, myalgia, nasal congestion, flushing, and pain in limb				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
3.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Advanced Chemical Industried Ltd.	Bisoprolol Fumarate 5mg + Perindopril Arginine 5mg Film Coated Tablet	Bisoprolol Fumarate USP 5mg + Perindopril Arginine INN 5mg	Therapeutic Class: Antihypertensive Therapeutic code: 022	It is used to treat high blood pressure (hypertension) and/or to reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) and who have already had a heart attack and/or an operation to improve the blood supply to the heart by widening the vessels that supply it.	**CONTRAINDICATIONS:** • are allergic to Bisoprolol or any other beta-blocker, to Perindopril or any other ACE inhibitor, or to any of the other ingredients of this medicine. • have a heart disease characterized by a slow or irregular heart rate (atrioventricular block second or third degree, sinoatrial block, sick sinus syndrome). **Side-effect:** Dizziness, Vertigo, Headache	**New**	‡idv‡iÝ bvB	রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
4.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Advanced Chemical Industried Ltd.	Bisoprolol Fumarate 5mg + Perindopril Arginine 10mg Film Coated Tablet	Bisoprolol Fumarate USP 5mg + Perindopril Arginine INN 10mg	Therapeutic Class: Antihypertensive Therapeutic code: 022	It is used to treat high blood pressure (hypertension) and/or to reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) and who have already had a heart attack and/or an operation to improve the blood supply to the heart by widening the vessels that supply it.	**CONTRAINDICATIONS:** • are allergic to Bisoprolol or any other beta-blocker, to Perindopril or any other ACE inhibitor, or to any of the other ingredients of this medicine. • have a heart disease characterized by a slow or irregular heart rate (atrioventricular block second or third degree, sinoatrial block, sick sinus syndrome). **SIDE-EFFECT:** • Dizziness • Vertigo • Headache	**New**	‡idv‡iÝ bvB	রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
5.	Renata Limited Mirpur, Dhaka	Escitalopram Oxalate USP 6.39 mg equivalent to Escitalopram 5mg/5ml Solution	Escitalopram Oxalate USP 6.39mg equivalent to Escitalopram 5mg/5ml	Antidepressants Therapeutic Code 014	Escitalopram is a selective serotonin reuptake inhibitor (SSRI) indicated for: • Acute and Maintenance Treatment of Major Depressive Disorder (MDD) in adults and adolescents aged 12-17 years • Acute Treatment of Generalized Anxiety Disorder (GAD) in adults	CONTRAINDICATIONS: Do not use concomitantly. Known hypersensitivity to escitalopram or citalopram or any of the inactive ingredients (WARNINGS AND PRECAUTIONS: Increased risk of suicidal thinking and behavior in children, adolescents and young adults taking antidepressants for major depressive disorder (MDD) and other psychiatric disorders. Lexapro is not approved for use in pediatric patients less than 12 years of age.	Escitalopram 5mg, 10mg, 20 Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
6.	Renata Limited Rajendrapur, Gazipur Ziska Pharmaceuticals Ltd. Beacon Pharmaceuticals Ltd, Bhaluka, Mymensingh	Upadacitinib INN 30mg Extend Release Tablet	Upadacitinib INN 30mg	Therapeutic Class : Nonsteroidal anti-inflamatory and drugs used in arthritis Therapeutic Code 064	**Indication** Upadacitinib is a Janus kinase (JAK) inhibitor indicated for the treatment of • Adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers	**CONTRAINDICATIONS:** Known hypersensitivity to upadacitinib or any of the excipients in RINVOQ. Side Effect upper respiratory tract infections (common cold, sinus infections) • shingles (herpes zoster) • herpes simplex virus infections, including cold sores • bronchitis, nausea, cough, fever, acne, headache **WARNINGS AND PRECAUTIONS:** Serious infections, mortality, Malignancy, major adverse cardiovascular Events (mace), and thrombosis	Upadacitinib 15mg ER Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
7.	Drug International Ltd (Unit-1) 252, Tongi Industrial Area, Tongi, Gazipur, Bangladesh.	Isotretinoin USP 20mg Soft Gelatin Capsule	Isotretinoin USP 20mg Soft Gelatin Capsule	Therapeutic Class: Vitamins Therapeutic Code: 078	It is indicated for the treatment of severe recalcitrant nodular acne in patients 12 years of age and older.	**Contraindication:**Pregnancy, Hypersensitivity to this product or any of its components. **Precaution:** Unacceptable Contraception: Micro-dosed progesterone preparations are not an acceptable method of contraception during therapy. Psychiatric Disorders: Depression, psychosis, suicidal thoughts and behavior, and aggressive and/or violent behaviors. Pseudotumor cerebri, some cases with concomitant tetracycline's. Serious skin reactions: Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis. Acute pancreatitis, rarely fatal hemorrhagic pancreatitis, in patients with either elevated or normal serum triglyceride levels. Lipid Abnormalities: Triglyceridemia, low HDL and elevation of cholesterol. Monitor lipid levels at regular intervals. Hearing Impairment. Hepatotoxicity: Monitor liver function tests at regular intervals. Inflammatory Bowel Disease. Skeletal Abnormalities: Arthralgias, back pain, decreases in bone mineral density	Isotretinoin USP 10mg Capsule	UKMHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						and premature epiphyseal closure. Ocular Abnormalities: corneal opacities, decreased night vision. Glucose and CPK Abnormalities. **Warning: As** per precaution. **Side effects:** Most common side effects are: lip dry, dry skin, back pain, dry eye, arthralgia, epistaxis, headache, nasopharyngitis, chapped lips, dermatitis, blood creatine kinase increased, chelitis, musculoskeletal discomfort, upper respiratory tract infection, visual acuity reduced.				
8.	**GLOBE PHARMACEUTICALS LTD.** **BSCIC Industrial Estate** **Begumgonj‡jv,** **Noakhali.**	Naproxen 220 mg + Diphenhydramine 25 mg Tablet	Naproxen Sodium BP 220 mg equivalent to Naproxen 200 mg + Diphenhydramine Hydrochloride BP 25mg Tablets	Therapeutic Class : Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic Code 064	It is Indicated for Occasional use, for a limited period of time (five days or less), for fast and effective relief of acute night time pain and accompanying sleeplessness caused by aches and pains associated with arthritis, joints, muscles, backache, headache, migraine pain and toothache and, in these circumstances, for increased duration of sleep uninterrupted by pain • Helps you fall asleep and stay asleep.	**Contraindications:** It is contraindicated in patients: • who have previously exhibited allergy or with known hypersensitivity to the active substances naproxen (including naproxen sodium) or diphenhydramine hydrochloride or any of the excipients in the tablet. • with a history of asthma, urticaria, or allergic-type reactions after taking acetylsalicylic acid (ASA) or other NSAIDs (i.e. complete or partial syndrome of ASA-intolerance-rhinosinusitis, urticaria/angioedema, nasal polyps, asthma). Fatal anaphylactoid reactions have occurred in such individuals. Individuals with the above medical problems are at risk of a severe reaction even if they have taken NSAIDs in the past without any adverse reaction. • with active peptic ulcers, a history of recurrent ulceration, or active gastrointestinal bleeding	New Naproxen 250 mg Tablet Esomeprazole 20 mg + Naproxen 500 mg Tablet Diphenhydramine Hydrochloride 50 mg Tablet	USFDA	বর্তমানে প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	বর্তমানে প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						• with inflammatory bowel disease. • with inflammatory bowel disease. • with severe renal impairment (creatinine clearance <30 mL/min or 0.5 mL/sec) or deteriorating renal disease (individuals with lesser degrees of renal impairment are at risk of deterioration of their renal function when prescribed NSAIDs and must be monitored) • in women in their third trimester of pregnancy because of risk of premature closure of the ductus arteriosus and prolonged parturition **Side Effects:** Naproxen Sodium and Diphenhydramine Hydrochloride tablet may cause side effects like heartburn, nausea, vomiting, ringing or buzzing in the ears, bloating, redness or swelling is present in the painful area, choking sensation, diarrhea or constipation.				
9.	Ziska Pharmaceuticals Ltd. Eskayef Pharmaceuticals Limited, Rupgang, Narayangang. DBL Pharmaceuticals Ltd. Surabari, Kashimpur, Gazipur	Icosapent Ethyl 0.5 g soft gelatin capsule	Icosapent Ethyl INN 0.5 g	Therapeutic Class: Lipid Lowering Therapeutic Code:62	It is an ethyl ester of eicosapentaenoic acid (EPA) indicated: as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and o established cardiovascular disease or o diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.	**Contraindications:** Icosapent Ethyl is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to Icosapent Ethyl or any of its components. **Side effects:** The following important adverse reactions are described below and elsewhere in the labeling: • Atrial Fibrillation or Atrial Flutter • Potential for Allergic Reactions in Patients with Fish Allergy • Bleeding **Warning & Precaution:** This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
10.	Ziska Pharmaceuticals Ltd. Eskayef Pharmaceuticals Limited, Rupgan city Narayanganj.	Icosapent Ethyl 1 g soft gelatin capsule	Icosapent Ethyl INN 1 g	Therapeutic Class: Lipid Lowering Therapeutic Code:62	It is an ethyl ester of eicosapentaenoic acid (EPA) indicated: as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and o established cardiovascular disease or o diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.	**Contraindications:** Icosapent Ethyl is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to Icosapent Ethyl or any of its components. **Side effects:** The following important adverse reactions are described below and elsewhere in the labeling: • Atrial Fibrillation or Atrial Flutter • Potential for Allergic Reactions in Patients with Fish Allergy • Bleeding **Warning & Precaution:** This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
11.	Ziska Pharmaceuticals Ltd. Healthcare Pharmaceuticals Ltd Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir,	Imipenem 500 mg+ Cilastatin 500 mg + Relebactam 250 mg In‡jvection	Imipenem INN 500 mg+ Cilastatin INN 500 mg + Relebactam INN 250 mg	Anti-infective Therapeutic Code: 23	It is a combination of imipenem, a penem antibacterial, cilastatin, a renal dehydropeptidase inhibitor, and relebactam, a betalactamase inhibitor, indicated in patients 18 years of age and older who have limited or no alternative treatment options, for the treatment of the following infections caused by susceptible gram-negative bacteria	**Contraindications:** This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. **Side effects:** The most frequently reported adverse reactions occurring in greater than or equal to 2 % of patients treated with imipenem/cilastatin plus relebactam 250 mg were diarrhea, nausea, headache, vomiting, alanine aminotransferase increased, aspartate aminotransferase increased, phlebitis/infusion site reactions, pyrexia, and hypertension. **Warning & Precaution:** This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.	New	USFDA	বর্তমানে প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	বর্তমানে প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
12.	Ziska Pharmaceuticals Ltd. Beacon Pharmaceuticals Limited **The ACME Laboratories Ltd. Dhamrai, Dhaka** Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Abrocitinib 100 mg Tablet	Abrocitinib INN 100 mg	Therapeutic Class : Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic Code 064	It is indicated for the treatment of adults with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.	**Contraindications:** Antiplatelet therapies except for low-dose aspirin (≤81 mg daily), during the first 3 months of treatment. **Side effects:** Most common adverse reactions (≥1%) in subjects receiving 100 mg and 200 mg include: nasopharyngitis, nausea, headache, herpes simplex, increased blood creatinine phosphokinase, dizziness, urinary tract infection, fatigue, acne, vomiting, oropharyngeal pain, influenza, gastroenteritis. Most common adverse reactions (≥1%) in subjects receiving either 100 mg or 200 mg also include: impetigo, hypertension, contact dermatitis, upper abdominal pain, abdominal discomfort, herpes zoster, and thrombocytopenia. **Warning & Precaution:** Laboratory Abnormalities: Laboratory monitoring is recommended due to potential changes in platelets, lymphocytes, and lipids. Immunizations: Avoid use of live vaccines prior to, during, and immediately after CIBINQO treatment.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
13.	Ziska Pharmaceuticals Ltd. Beximco Pharmaceutical Ltd, Tongi, Gazipur Eskayef Pharmaceuticals Limited, Rupgang, Narayangang Popular Pharmaceuticals Ltd. Tongi, Gazipur Navana Pharmaceuticals	Vonoprazan 20 mg Tablet + Amoxicillin 500 mg capsule Combi-pack	Vonoprazan INN 20 mg+ amoxicillin USP 500 mg	Therapeutic Class: Other Classification Therapeutic Code: 075	It is a co-packaged product containing vonoprazan, a PCAB, and amoxicillin, a penicillin class antibacterial, indicated for the treatment of H. pylori infection in adults.	Contraindications: Known hypersensitivity to vonoprazan, amoxicillin or any other beta-lactams, clarithromycin or any other macrolide antimicrobial or any component of Vonoprazan & amoxicillin. Side effects: Most common adverse reactions (≥ 2%) were diarrhea, abdominal pain, vulvovaginal candidiasis and nasopharyngitis Warning & Precaution: Hypersensitivity Reactions: Serious and occasionally fatal reactions (e.g., anaphylaxis) have been reported with components of Vonoprazan 20 mg Tablet + Amoxicillin 500 mg capsule. If	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Ltd., Rupgang, Narayangang Renata Limited Rajendrapur, Gazipur					hypersensitivity reactions occur, discontinue Vonoprazan 20 mg Tablet + Amoxicillin 500 mg capsule and institute immediate therapy (e.g., anaphylaxis management). • Severe Cutaneous Adverse Reactions (SCAR): Discontinue Vonoprazan 20 mg Tablet + Amoxicillin 500 mg capsule at the first signs or symptoms of SCAR or other signs of hypersensitivity and consider further evaluation • Clostridioides difficile-associated diarrhea (CDAD): Evaluate if diarrhea occurs with Vonoprazan 20 mg Tablet + Amoxicillin 500 mg capsule				
14.	Ziska Pharmaceuticals Ltd. Square Pharmaceutical Ltd (Chemical Devision), BSCIC, Pabna. Beximco Pharmaceutical Ltd, Tongi, Gazipur Eskayef Pharmaceuticals Limited, Rupgang, Narayangang. **General Pharmaceutical Ltd., Gazipur** Popular Pharmaceuticals Ltd. Tongi, Gazipur Navana Pharmaceuticals Ltd., Rupgang,	Vonoprazan 20 mg Tablet + Amoxicillin 500 mg capsule+ Clarithromycin 500 mg Tablet Combi-pack	Vonoprazan INN 20 mg+ Amoxicillin USP 500 mg+ Clarithromycin USP 500 mg	Therapeutic Class: Other Classification Therapeutic Code: 075	It is a co-packaged product containing vonoprazan, a potassium-competitive acid blocker (PCAB), amoxicillin, a penicillin class antibacterial, and clarithromycin, a macrolide antimicrobial, indicated for the treatment of Helicobacter pylori (H. pylori) infection in adults.	**Contraindications:** Known hypersensitivity to vonoprazan, amoxicillin or any other beta-lactams, clarithromycin or any other macrolide antimicrobial or any component of Vonoprazan & amoxicillin. **Side effects:** Most common adverse reactions (≥ 2%) were diarrhea, abdominal pain, vulvovaginal candidiasis and nasopharyngitis **Warning & Precaution:** Hypersensitivity Reactions: Serious and occasionally fatal reactions (e.g., anaphylaxis) have been reported with components of Vonoprazan 20 mg Tablet + Amoxicillin 500 mg capsule+ Clarithromycin 500 mg Tablet. If hypersensitivity reactions occur, discontinue Vonoprazan 20 mg Tablet + Amoxicillin 500 mg capsule+ Clarithromycin 500 mg Tablet and institute immediate therapy (e.g., anaphylaxis management). • Severe Cutaneous Adverse Reactions (SCAR): Discontinue Vonoprazan 20 mg Tablet + Amoxicillin 500 mg capsule+ Clarithromycin 500 mg Tablet at the first signs or symptoms of SCAR or other signs of	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Narayangang Renata Limited Rajendrapur, Gazipur					hypersensitivity and consider further evaluation. • Clostridioides difficile-associated diarrhea (CDAD): Evaluate if diarrhea occurs with Vonoprazan 20 mg Tablet + Amoxicillin 500 mg capsule+ Clarithromycin 500 mg Tablet. Vonoprazan 20 mg Tablet + Amoxicillin 500 mg capsule+ Clarithromycin 500 mg Tablet Due to the Clarithromycin Component: • QT Prolongation: Avoid Vonoprazan 20 mg Tablet + Amoxicillin 500 mg capsule+ Clarithromycin 500 mg Tablet in patients with known QT prolongation or receiving drugs known to prolong the QT interval, ventricular arrhythmia (torsades de pointes), hypokalemia/hypomagnesemia, significant bradycardia, or taking Class IA or III antiarrhythmics. • Hepatotoxicity: Discontinue if signs and symptoms of hepatitis occur with Vonoprazan 20 mg Tablet + Amoxicillin 500 mg capsule+ Clarithromycin 500 mg Tablet. • Serious adverse reactions due to concomitant use with other drugs: Serious adverse reactions can occur with Vonoprazan 20 mg Tablet + Amoxicillin 500 mg capsule+ Clarithromycin 500 mg Tablet due to drug interactions of clarithromycin with colchicine, some lipid lowering agents, some calcium channel blockers, and other drugs. • Embryo-Fetal Toxicity: Based on the findings from animal studies and human observational studies in pregnant women treated with clarithromycin, Vonoprazan 20 mg Tablet + Amoxicillin 500 mg capsule+ Clarithromycin 500 mg Tablet is not recommended for use in pregnant women except in clinical circumstances where no alternative therapy is				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						appropriate. • Myasthenia Gravis: Exacerbation of myasthenia gravis can occur with Vonoprazan 20 mg Tablet + Amoxicillin 500 mg capsule+ Clarithromycin 500 mg Tablet since it has been reported in patients receiving clarithromycin tablets.				
15.	Ziska Pharmaceuticals Ltd. The ACME Laboratories Ltd. Beximco Pharmaceutical Ltd, Tongi, Gazipur Aristopharma Ltd. Plot No.14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204 Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Incepta Pharmaceuticals Ltd.; Dhamrai Unit, Dhaka Advanced Chemical Industries Limited, 7 Hajeegang, Godnyl, Narayangong. Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Beacon Pharmaceuticals Ltd, Bhaluka, Mymensingh	Tirzepatide 2.5 mg/0.5 ml in‡jvection or Tirzepatide 2.5 mg pre filled in‡jvection	Tirzepatide INN 2.5 mg/0.5 ml	Antidiabetes Therapeutic Code 015	It is a glucose-dependent insulin tropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contraindications:** Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2. Known serious hypersensitivity to tirzepatide or any of the excipients **Side effects:** The most common adverse reactions, reported in ≥5% of patients treated with tirzepatide are: nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain. WARNING: RISK OF THYROID C-CELL TUMORS See full prescribing information for complete boxed warning. • Tirzepatide causes thyroid C-cell tumors in rats. It is unknown whether Tirzepatide 2.5 mg/0.5 ml Injectioncauses thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as the human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined. • Tirzepatide 2.5 mg/0.5 ml Injectionis contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC and symptoms of thyroid tumors .	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
16.	Ziska Pharmaceuticals Ltd. Beximco Pharmaceutical Ltd, Tongi, Gazipur Aristopharma Ltd. Plot No.14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204 Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Incepta Pharmaceuticals Ltd.; Dhamrai Unit, Dhaka Advanced Chemical Industries Limited, 7 Hajeegang, Godnyl, Narayangong. Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Beacon Pharmaceuticals Ltd, Bhaluka, Mymensingh	Tirzepatide 7.5 mg/0.5 ml in‡jvection	Tirzepatide INN 7.5mg/0.5 ml	Antidiabetes Therapeutic Code 015	It is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contraindications:** Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2. Known serious hypersensitivity to tirzepatide or any of the excipients **Side effects:** The most common adverse reactions, reported in ≥5% of patients treated with tirzepatide are: nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain. WARNING: RISK OF THYROID C-CELL TUMORS See full prescribing information for complete boxed warning. • Tirzepatide causes thyroid C-cell tumors in rats. It is unknown whether Tirzepatide 2.5 mg/0.5 ml Injectioncauses thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as the human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined . • Tirzepatide 2.5 mg/0.5 ml Injectionis contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC and symptoms of thyroid tumors .	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
17.	Ziska Pharmaceuticals Ltd. Beximco Pharmaceutical Ltd, Tongi, Gazipur Incepta Pharmaceuticals Ltd.; Dhamrai Unit,	Tirzepatide 12.5 mg/0.5 ml in‡jvection	Tirzepatide INN 12.5mg/0.5 ml	Antidiabetes Therapeutic Code 015	It is a glucose-dependent insulin tropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contraindications:** Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2. Known serious hypersensitivity to tirzepatide or any of the excipients **Side effects:** The most common adverse reactions, reported in ≥5% of patients	New	USFDA	বর্তমানে প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	বর্তমানে প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Dhaka Advanced Chemical Industries Limited, 7 Hajeegang, Godnyl, Narayangong. Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Beacon Pharmaceuticals Ltd, Bhaluka, Mymensingh					treated with tirzepatide are: nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain. WARNING: RISK OF THYROID C-CELL TUMORS See full prescribing information for complete boxed warning. • Tirzepatide causes thyroid C-cell tumors in rats. It is unknown whether Tirzepatide 2.5 mg/0.5 ml Injectioncauses thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as the human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined . • Tirzepatide 2.5 mg/0.5 ml Injectionis contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC and symptoms of thyroid tumors .				
18.	Ziska Pharmaceuticals Ltd. Beximco Pharmaceutical Ltd, Tongi, Gazipur Incepta Pharmaceuticals Ltd.; Dhamrai Unit, Dhaka Advanced Chemical Industries Limited, 7 Hajeegang, Godnyl, Narayangong. Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Tirzepatide 15 mg/0.5 ml in‡jvection	Tirzepatide INN 15 mg/0.5 ml	Therapeutic Class: Antidiabetes Therapeutic Code 015	It is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contraindications:** Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2. Known serious hypersensitivity to tirzepatide or any of the excipients **Side effects:** The most common adverse reactions, reported in ≥5% of patients treated with tirzepatide are: nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain. WARNING: RISK OF THYROID C-CELL TUMORS See full prescribing information for complete boxed warning. • Tirzepatide causes thyroid C-cell tumors in rats. It is unknown whether Tirzepatide 2.5	New	USFDA	বর্তমানে প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	বর্তমানে প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Beacon Pharmaceuticals Ltd, Bhaluka, Mymensingh					mg/0.5 ml Injectioncauses thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as the human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined . • Tirzepatide 2.5 mg/0.5 ml Injectionis contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC and symptoms of thyroid tumors .				
19.	ACI HealthCare Limited. Treepordi, Sonargaon, Narayangang-1440	Ethambutol HCl USP 100 mg F/C Tablet Dosage Form: F/C Tablet	Ethambutol HCl USP 100 mg	Antitubercular and Antileprotic Therapeutic code: 30	Pulmonary and extrapulmonary tuberculosis	**Contraindication:** It is contraindicated in patients with a history of hypersensitivity to ethambutol hydrochloride or any of its components. It is also contraindicated in patients with known optic neuritis and poor vision unless clinical judgement determines that ethambutol may be used. **Side-effects:** The most important adverse reactions of ethambutol is retrobulbar neuritis with reduced visual acuity. **Warning and precaution:** *Renal impairment:*Toxic effects are more common if renal function is impaired. In particular, visual acuity should be monitored more closely in these patients. *Visual impairment:* Ethambutol causes ocular toxicity and patients should be advised to report any changes of visual acuity. An ophthalmic examination is recommended before starting treatment and every 4 weeks during treatment. It should include visual acuity, color vision, field of vision and ophthalmoscopy. For patients	**Existing molecule**	WHOPQ, UKMHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						with visual defects or renal insufficiency the frequency of tests should be increased to every second or third week. *Hepatic impairment:*Liver function tests should be performed in patients who develop symptoms suggestive of hepatitis or who become generally unwell during treatment. Patients should not drive or operate machinery if affected by possible side effects such as numbness, paraesthesia, dizziness and disorientation.				
20.	ACI HealthCare Limited. Treepordi, Sonargaon, Narayangang-1440	Rifampicin BP 75 mg, Isoniazid BP 50 mg Dispersible tablet Dosage Form: Dispersible Tablet	Rifampicin BP 75 mg, Isoniazid BP 50 mg	Antitubercular and Antileprotic Therapeutic code: 30	Pulmonary and extrapulmonary tuberculosis	**Contraindication:** Hypersensitivity to the active substances or to any of the excipients. Acute liver disease, icterus or severe liver impairment. Co-administration of the product with voriconazole, any HIV protease inhibitor, elvitegravir/cobicistat or any direct acting antiviral for chronic Hepatitis C is contraindicated. **Side-effects:** The most important adverse reactions of rifampicin are hepatotoxicity, particularly cholestatic reactions, and skin reactions. Rifampicin may cause subclinical, uncon‡jvugated hyperbilirubinaemia or jaundice without hepatocellular damage, but occasionally causes hepatocellular in‡jvury. It can also potentiate the hepatotoxicity of the other anti-tuberculosis medications. The most important adverse reactions of isoniazid are peripheral and central neurotoxic effects, and hepatotoxicity. Severe and sometimes fatal hepatitis due to isoniazid therapy has been reported. The majorityof cases have	**Existing molecule**	WHOPQ	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						occurred within the first three months of therapy, but hepatotoxicity may also develop after a longer duration of treatment. **Warnings and precautions**: *Liver toxicity*: Rifampicin and isoniazid may cause hepatotoxicity. *Hypersensitivity*: Rifampicin may cause a hypersensitivity syndrome including 'flu-like' symptoms and/or organ manifestation. The risk is higher in intermittent therapy or if treatment is resumed after discontinuation. *Cross-sensitivity*: Patients hypersensitive to ethionamide, pyrazinamide, niacin (nicotinic acid), or other chemically related medications may also be hypersensitive to isoniazid. *Peripheral neuropathy:*This is the most common toxic effect of isoniazid. The frequency depends on the dose and on predisposing conditions such as malnutrition, alcoholism or diabetes. Concomitant pyridoxine administration largely reduces the risk of developing neuropathy. Therefore, pyridoxine should be co-administered routinely with this combination at doses of 10 mg per day to prevent and at doses of 50-75 mg daily to treat peripheral neuropathy. *Epilepsy and psychotic disorders*: This combination should be used with caution in patients with pre-existing seizure disorders or a history of psychosis. *Hematological toxicity*: Since rifampicin treatment has been associated with hemolytic anemia, leucopenia and thrombocytopenia, full blood count should				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						be monitored regularly throughout therapy with this combination. In case of severe hematological disturbances this combination must be discontinued. *Renal impairment:* Patients with renal impairment, particularly those who are slow acetylators may be at increased risk for isoniazid adverse effects such as peripheral neuropathy, and should be monitored accordingly. As in other patients, adequate supplementation with pyridoxine (see above) should be given to avoid neurotoxicity. *Nephrotoxicity*: This combination should be discontinued in case of clinical signs of nephrotoxicity. *Diabetes Mellitus*: Patients with diabetes should be carefully monitored, since blood glucose control may be affected by isoniazid. *Porphyria*: This combination should be used with caution in patients with porphyria, since the enzyme induction by rifampicin may cause symptoms. *Discoloration of body fluids*: This combination may cause a reddish-orange discoloration of body fluids such as urine, sputum and tears. This is due to rifampicin, and does not require medical attention. *Effects on ability to drive and use machines:* Isoniazid is associated with vertigo, visual disorders and psychotic reactions. Patients should be informed of these, and advised that if affected, they should not drive, operate machinery or take part in any activities where these symptoms may put either the patients or others at risk.				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
21.	ACI HealthCare Limited. Treepordi, Sonargaon, Narayangang-1440	Rifampicin BP 75 mg, Isoniazid BP 50 mg and Pyrazinamide BP 150 mg Dispersible tablet Dosage Form: Dispersible Tablet	Rifampicin BP 75 mg, Isoniazid BP 50 mg, Pyrazinamide BP 150 mg	Therapeutic Class: Antitubercular and Antileprotic Therapeutic code: 30	Pulmonary and extrapulmonary tuberculosis	**Contraindication:** It is contraindicated in patients with a history of hypersensitivity to rifampicin, isoniazid and pyrazinamide or any of its components. It is also contraindicated in patients with history of Acute liver disease, icterus or severe liver impairment. Concomitant use with voriconazole or any HIV inhibitors bictegravir, elvitegravir/cobicistat, etravirine, rilpivirine or with several direct-acting antiviral medicines for treating chronic hepatitis C is contraindicated. **Side-effects:** The most important side effects of rifampicin are hepatotoxicity, particularly cholestatic reactions and skin reactions. Rifampicin may cause subclinical, uncon‡jvugated hyperbilirubinemia or jaundice without hepatocellular damage, but occasionally causes hepatocellular in‡jvury. It can also potentiate the hepatotoxicity of the other antituberculosis medications. The most important side effects of isoniazid are peripheral and central neurotoxic effects and hepatotoxicity. Severe and sometimes fatal hepatitis due to isoniazid therapy has been reported. The majority of cases have occurred within the first 3 months of therapy, but hepatotoxicity may also develop after a longer duration of treatment. The most important adverse effect of pyrazinamide is liver damage, ranging from asymptomatic increase of serum transaminases to symptomatic liver dysfunction, and in rare cases, fatal liver failure. **Warning and precaution:**	**Existing molecule**	WHOPQ	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Liver toxicity: Rifampicin and isoniazid may cause hepatotoxicity. *Hypersensitivity:* Rifampicin may cause a hypersensitivity syndrome including 'flu-like' symptoms and/or organ manifestation. The risk is higher in intermittent therapy or if treatment is resumed after discontinuation. *Cross-sensitivity:* Patients hypersensitive to ethionamide, pyrazinamide, niacin (nicotinic acid), or other chemically related medications may also be hypersensitive to isoniazid or pyrazinamide. *Peripheral neuropathy:*This is the most common toxic effect of isoniazid. The frequency depends on the dose and on predisposing conditions such as malnutrition, alcoholism or diabetes. Concomitant pyridoxine administration largely reduces the risk of developing neuropathy. Therefore, pyridoxine should be co-administered routinely with this combination at doses of 10 mg per day. *Epilepsy and psychotic disorders:* This combination should be used with caution in patients with pre-existing seizure disorders or a history of psychosis. *Hematological toxicity:* Since rifampicin treatment has been associated with hemolytic anemia, leucopenia and thrombocytopenia, full blood count should be monitored regularly throughout therapy with this combination. *Hyperuricaemia and gout*: Pyrazinamide may increase serum levels of uric acid and cause gout. Patients with a history of gout should be carefully monitored. Serum uric acid levels should be determined before				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						starting therapy with this combination. *Renal impairment:*In renal insufficiency, the clearance of pyrazinamide and isoniazid is delayed, leading to increased systemic exposure. In case of renal insufficiency, this combination should not be used, as dose modifications of the active components may be necessary. *Nephrotoxicity*: This combination should be discontinued in case of clinical signs of nephrotoxicity. *Diabetes Mellitus*: Patients with diabetes should be carefully monitored, since blood glucose control may be affected by isoniazid. *Porphyria*: This combination should be used with caution in patients with porphyria, since the enzyme induction by rifampicin may cause symptoms. *Discoloration of body fluids*: This combination may cause a reddish-orange discoloration of body fluids such as urine, sputum and tears. This is due to rifampicin, and does not require medical attention. *Alcohol:*Intake of alcohol beverages should be avoided during treatment with this combination. *Effects on ability to drive and use machines:* Isoniazid is associated with vertigo, visual disorders and psychotic reactions. Patients should be informed of these, and advised that if affected, they should not drive, operate machinery or take part in any activities where these symptoms may put either the patients or others at risk.				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
22.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Miconazole Nitrate BP 0.25gm + Zinc Oxide BP 15gm + White Soft Paraffin BP 81.35gm Ointment	Miconazole Nitrate BP 0.25gm + Zinc Oxide BP 15gm + White Soft Paraffin BP 81.35gm	Therapeutic Class: Skin and Mucous membrane preparations Therapeutic Code:071	• It is indicated for adjunctive treatment of diaper dermatitis when complicated by documented candidiasis (microscopic evidence of pseudohyphae and /or budding yeast) in immunocompetent pediatric patients 4 weeks and older. • It should not be used as a substitute for frequent diaper changes. • It should not be used to prevent the occurrence of diaper dermatitis, since preventative use may result in the development of drug resistance	Warnings and Precautions: If irritation occurs or if the disease worsens, discontinue use of the medication, and contact the health care provider. Contraindications: None Side effects: Irritation. You should call your child's health care provider if irritation appears or if the diaper rash gets worse.	New	USFDA	শুধুমাত্র diaper dermatitis চিকিৎসায় ব্যবহৃত হবে এই শর্তে অনুমোদনের সুপারিশ করা হয়। এ বিষয়ে ড্রাগ কন্ট্রোল কমিটির সভায় চূড়ান্ত সিদ্ধান্ত গৃহীত হবে।	শুধুমাত্র diaper dermatitis চিকিৎসায় ব্যবহৃত হবে এই শর্তে অনুমোদন করা হলো।
23.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Diquafosol Sodium 3% Opthalmic Solution	Diquafosol Sodium 3%	Therapeutic Class: Eye Preparations Therapeutic code: 052	It is indicated for the treatment of dry eye.	Contraindication: It is contraindicated in patients with a history of hypersensitivity to any of the ingredients of this product Side effect: Eye irritation, discharge, pain,con‡jvunctival hyperaemia, itching, foreign body sensation, ocular discomfort.	New	PMDA	চক্ষু বিশেষজ্ঞের মতামত গ্রহণের সিদ্ধান্ত গৃহীত হয়।	চক্ষু বিশেষজ্ঞের মতামতসহ পরবর্তী ডিসিসি-টেকনিক্যাল সাব কমিটির সভায় উপস্থাপিত হবে।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
24.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Ketotifen Fumarate BP 2.75mg eqv. to Ketotifen 2mg Tablet	Ketotifen Fumarate BP 2.75mg eqv. to Ketotifen 2mg	Therapeutic Class: Antihistamine Therapeutic code: 021	It is used for preventive treatment of bronchial asthma especially when associated with atopic symptoms; prevention and treatment of multisystem allergic disorders: chronic urticarial, atopic dermatitis, allergic rhinitis and con‡jvunctivitis.	Side Effects: Drowsiness, dizziness, trouble sleeping or flu- like symptoms might occur. If these persist or worsen, notify your doctor. Unlikely but report promptly: unusual weight gain, stomach pain, rash. Very unlikely but report promptly: unusual bleeding or bruising, irritability, unusual excitability or nervousness. Contraindications: Hypersensitivity to the Ketotifen or to any of the excipients	Ketotifen 1 mg Tablet	EMA	বর্তমানে প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	বর্তমানে প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
25.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Radiant Pharmaceuticals Ltd.	Amlodipine Besilate BP 6.935mg eqv. to Amlodipine 5mg + Bisoprolol Fumarate USP 5mg Tablet	Amlodipine Besilate BP 6.935mg eqv. to Amlodipine 5mg + Bisoprolol Fumarate USP 5mg	Therapeutic Class: Antihypertensive Therapeutic code: 022	It is indicated for the treatment of hypertension, alone or with other antihypertensive agents. (Amlodipine+Bisoprolol) may also be used as initial therapy in patients who are likely to need multiple antihypertensive agents to achieve their blood pressure goals. It is also used to treat angina pectoris, stable chronic heart failure.	Warnings and precautions: Bisoprolol: Overt congestive cardiac failure,abrupt cessation of therapy,peripheral vascular disease, bronchospastic disease, anesthesia and major surgery, diabetes and hypoglycemia and thyrotoxicosis. Amlodipine: Severe aortic stenosis, congestive heart failure and hepatic failure. Contraindications: Cardiogenic shock, overt cardiac failure, second or third degree AV block, marked sinus bradycardia and known sensitivity to amlodipine/bisoprolol Side effects: Edema feet, headache, fatigue ,leg cramps, dry mouth, Other adverse events reported were gastric irritation, angina, asthma ,cold extremities, cough, decrease in libido, dizziness, facial flushing.	Bisoprolol Fumarate 2.50mg + Amlodipine 5mg Film Coated Tablet Bisoprolol 2.5mg, 5mg & 10mg Tablet, Amlodipine 5mg & 10mg Tablet	‡idv‡iÝ bvB	রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
26.	Beximco Pharmaceuticals Ltd. General Pharmaceuticals Ltd. Beacon Pharmaceuticals Ltd. The Ibn SINA Pharmaceuticals Ltd DBL Pharmaceuticals Ltd. Surabari, Kashimpur, Gazipur The ACME Laboratories Ltd. Dhamrai, Dhaka Navana Pharmaceuticals Ltd, Rpugang, Narayangang Organic Healthcare Ltd., Gazipur	Daridorexant 25 mgTablet	Daridorexant INN 25 mg	Therapeutic Class: Antidepressants Therapeutic code: 014	Daridorexant is an orexin receptor antagonist indicated for the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance.	**CONTRAINDICATIONS:** Contraindicated in patients with narcolepsy. **WARNINGS AND PRECAUTIONS:** CNS-Depressant Effects and Daytime Impairment: Impairs alertness and motor coordination including morning impairment. Risk increases when used with other central nervous system (CNS) depressants. For patients taking Daridorexant, caution against next-day driving and other activities requiring complete mental alertness. Worsening of Depression/Suicidal Ideation: Worsening of depression or suicidal thinking may occur. Sleep Paralysis, Hypnagogic/Hypnopompic Hallucinations, and Cataplexy-like Symptoms: Complex Sleep Behaviors: Behaviors including sleepwalking, sleep-driving, and engaging in other activities while not fully awake may occur. Discontinue immediately if complex sleep behavior occurs. Compromised Respiratory Function: Effect on respiratory function should be considered. Need to Evaluate for Co-morbid Diagnoses: Reevaluate if insomnia persists after 7 to 10 days.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
27.	Beximco Pharmaceuticals Ltd Beacon Pharmaceuticals Ltd.. General Pharmaceuticals Ltd. The Ibn SINA Pharmaceuticals Ltd DBL Pharmaceuticals Ltd. Surabari, Kashimpur, Gazipur	Daridorexant 50 mgTablet	Daridorexantl INN 50 mg	Therapeutic Class: Antidepressants Therapeutic code: 014	Daridorexant is an orexin receptor antagonist indicated for the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance.	**CONTRAINDICATIONS:** Contraindicated in patients with narcolepsy. **WARNINGS AND PRECAUTIONS:** CNS-Depressant Effects and Daytime Impairment: Impairs alertness and motor coordination including morning impairment. Risk increases when used with other central nervous system (CNS) depressants. For patients taking Daridorexant, caution against next-day driving and other activities requiring complete mental alertness. Worsening of Depression/Suicidal Ideation: Worsening of depression or suicidal thinking	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	The ACME Laboratories Ltd. Dhamrai, Dhaka Navana Pharmaceuticals Ltd, Rpugang, Narayangang Organic Healthcare Ltd., Gazipur					may occur. Sleep Paralysis, Hypnagogic/Hypnopompic Hallucinations, and Cataplexy-like Symptoms: Complex Sleep Behaviors: Behaviors including sleepwalking, sleep-driving, and engaging in other activities while not fully awake may occur. Discontinue immediately if complex sleep behavior occurs. Compromised Respiratory Function: Effect on respiratory function should be considered. Need to Evaluate for Co-morbid Diagnoses: Reevaluate if insomnia persists after 7 to 10 days.				
28.	Beximco Pharmaceuticals Ltd. The ACME Laboratories Ltd. Dhamrai, Dhaka Advanced Chemical Industried Ltd. Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka. Navana Pharmaceuticals Ltd., Rupgang, Narayangang Beacon Pharmaceuticals Ltd, Bhaluka, Mymensingh	Mavacamten 2.5mg Capsule	Mavacamten INN 2.5mg	Antihypertensive Therapeutic code: 022	Mavacamten is a cardiac myosin inhibitor indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms	CONTRAINDICATIONS • Moderate to strong CYP2C19 inhibitors or strong CYP3A4 inhibitors • Moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
29.	Beximco Pharmaceuticals Ltd. Advanced Chemical Industried Ltd. DBL Pharmaceuticals Ltd., Surabari, Kashimpur, Gazipur	Mavacamten 5mg Capsule	Mavacamten INN 5mg	Antihypertensive Therapeutic code: 022	Mavacamten is a cardiac myosin inhibitor indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms	CONTRAINDICATIONS • Moderate to strong CYP2C19 inhibitors or strong CYP3A4 inhibitors • Moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka. The ACME Laboratories Ltd. Dhamrai, Dhaka Navana Pharmaceuticals Ltd., Rupgang, Narayangang Beacon Pharmaceuticals Ltd, Bhaluka, Mymensingh									
30.	Beximco Pharmaceuticals Ltd. Advanced Chemical Industried Ltd. DBL Pharmaceuticals Ltd., Surabari, Kashimpur, Gazipur Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka. The ACME Laboratories Ltd. Dhamrai, Dhaka Navana Pharmaceuticals Ltd., Rupgang, Narayangang Beacon Pharmaceuticals Ltd, Bhaluka, Mymensingh	Mavacamten 10 mg Capsule	Mavacamten INN 10mg	Therapeutic Class: Antihypertensive Therapeutic code: 022	Mavacamten is a cardiac myosin inhibitor indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms	CONTRAINDICATIONS • Moderate to strong CYP2C19 inhibitors or strong CYP3A4 inhibitors • Moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
31.	Beximco Pharmaceuticals Ltd. The ACME Laboratories Ltd. Dhamrai, Dhaka Advanced Chemical Industried Ltd. Navana Pharmaceuticals Ltd., Rupgang, Narayangang Beacon Pharmaceuticals Ltd, Bhaluka, Mymensingh	Mavacamten 15 mg Capsule	Mavacamten INN 15mg	Antihypertensive Therapeutic code: 022	Mavacamten is a cardiac myosin inhibitor indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms	CONTRAINDICATIONS • Moderate to strong CYP2C19 inhibitors or strong CYP3A4 inhibitors • Moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
32.	Renata Limited Rajendrapur, Gazipur Ziska Pharmaceuticals Ltd. Beacon Pharmaceuticals Ltd, Bhaluka, Mymensingh	Upadacitinib INN 45 mg Extend Release Tablet	Upadacitinib INN 45 mg	NSAIDS used in arthritis Therapeutic Code 064	Upadacitinib is a Janus kinase (JAK) inhibitor indicated for the treatment of • Adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers	**CONTRAINDICATIONS:** Known hypersensitivity to upadacitinib or any of the excipients in RINVOQ. Side Effect : upper respiratory tract infections (common cold, sinus infections), shingles (herpes zoster), herpes simplex virus infections, including cold sores, bronchitis, nausea, cough, fever, acne, headache **WARNINGS AND PRECAUTIONS:** Serious infections, mortality, Malignancy, major adverse cardiovascular Events (mace), and thrombosis	Upadacitinib 15mg ER Tablet	USFDA	বর্তমানে প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	বর্তমানে প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
33.	Aristopharma Ltd. Plot No.14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204 The ACME Laboratories Ltd. Dhamrai, Dhaka DELTA Pharma Ltd Square	Empagliflozin 5 mg + Metformin HCl 1000mg Film Coated Tablet	Empagliflozin INN 5mg + Metformin HCl BP 1000 mg	Antidiabetic Therapeutic Code:015	It is a combination of empagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor and metformin, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing empagliflozin or metformin, or in patients already being treated with both empagliflozin and metformin.	**Contra-indication:** • Moderate to severe renal impairment (eGFR below 45 mL/min/1.73 m2), end stage renal disease, or dialysis • Metabolic acidosis, including diabetic ketoacidosis • History of serious hypersensitivity reaction to empagliflozin or metformin **Side-effect:** The most common side effects of empagliflozin and metformin combination include:	Empagliflozin 10 & 25 mg Tablet, Metformin 500, 750 & 850 mg Tablet, Empagliflozin 5mg + Metformin Hydrochloride 500 mg Tablet	USFDA & BNF-83 Page No.774	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Ziska Pharmaceuticals ltd. Beximco Pharmaceuticals Ltd. Beacon Pharmaceuticals Ltd. General Pharmaceuticals Ltd. Nipro JMI Pharma Ltd.				**Limitation of Use:** Not for the treatment of type-1 diabetes mellitus or diabetic ketoacidosis.	• low blood sugar. • urinary tract infection. • stuffy or runny nose and sore throat. • yeast infections in females. • diarrhea, nausea or vomiting, gas, stomach discomfort, indigestion. • weakness. • headache. **Warnings and Precautions:** Lactic acidosis, Hypotension, Ketoacidosis, Impairment in renal function, Genital mycotic infections, Urinary tract infections				
34.	Popular Pharmaceuticals Ltd.Tongi, Gazipur Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Ziska Pharmaceuticals ltd. The ACME Laboratories Ltd. Dhamrai, Dhaka Beximco Pharmaceuticals Ltd. General Pharmaceuticals Ltd.	Empagliflozin INN 5mg + Metformin HCl BP 1000mg ER Tablet	Empagliflozin INN 5mg + Metformin HCl BP 1000mg	Anti-diabetes Therapeutic Code: 015	It is a combination of empagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor and metformin, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and metformin is appropriate. **Limitation of Use:** Not for the treatment of type-1 diabetes mellitus or diabetic ketoacidosis.	**Contraindications:** Moderate to severe renal impairment (eGFR below 45 mL/min/1.73 m2), end stage renal disease, or dialysis. Metabolic acidosis, including diabetic ketoacidosis. **Side Effects:** The most common adverse reactions associated with this drug (5% or greater incidence) were upper respiratory tract infection, urinary tract infection, nasopharyngitis, diarrhea, constipation, headache, and gastroenteritis. **Warning & Precautions:** Lactic acidosis: Post marketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant Brady arrhythmias. Hypotension: Before initiating assess and correct volume status in patients with renal impairment, the elderly, in patients with low	Empagliflozin 10 & 25 mg Tablet, Metformin 500, 750 & 850 mg Tablet, Empagliflozin 5mg + Metformin Hydrochloride 500 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Nipro JMI Pharma Ltd.					systolic blood pressure, and in patients on diuretics. Monitor for signs and symptoms during therapy. Ketoacidosis: Assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If suspected, discontinue evaluate and treat promptly. Before initiating the drug consider risk factors for ketoacidosis. Patients may require monitoring and temporary discontinuation of therapy in clinical situations known to predispose to ketoacidosis. Acute kidney in‡jvury and impairment in renal function: Consider temporarily discontinuing in settings of reduced oral intake or fluid losses. If an acute kidney in‡jvury occurs, discontinue and promptly treat. Monitor renal function during therapy Urosepsis and Pyelonephritis: Evaluate patients for signs and symptoms of urinary tract infections and treat promptly. Hypoglycemia: Consider lowering the dose of insulin secretagogue or insulin to reduce the risk of hypoglycemia when initiating the drug. Genital mycotic infections: Monitor and treat as appropriate. Vitamin B12 deficiency: Metformin may lower vitamin B12 levels. Monitor hematologic parameters annually. Increased LDL-C: Monitor and treat as appropriate. Macrovascular outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk.				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
35.	Aristopharma Ltd. Plot No.14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204 The ACME Laboratories Ltd. Dhamrai, Dhaka Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Ziska Pharmaceuticals ltd. Beximco Pharmaceuticals Ltd. Beacon Pharmaceuticals Ltd. General Pharmaceuticals Ltd. Nipro JMI Pharma Ltd.	Empagliflozin 12.5 mg + Metformin HCl 1000mg Film Coated Tablet	Empagliflozin INN 12.5 mg + Metformin HCl BP 1000 mg	Antidiabetic Therapeutic Code:015	It is a combination of empagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor and metformin, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing empagliflozin or metformin, or in patients already being treated with both empagliflozin and metformin. **Limitation of Use:** Not for the treatment of type-1 diabetes mellitus or diabetic ketoacidosis.	**Contra-indication:** • Moderate to severe renal impairment (eGFR below 45 mL/min/1.73 m2), end stage renal disease, or dialysis • Metabolic acidosis, including diabetic ketoacidosis • History of serious hypersensitivity reaction to empagliflozin or metformin **Side-effect:** The most common side effects of empagliflozin and metformin combination include: • low blood sugar. • urinary tract infection. • stuffy or runny nose and sore throat. • yeast infections in females. • diarrhea, nausea or vomiting, gas, stomach discomfort, indigestion. • weakness. • headache. **Warnings and Precautions:** Lactic acidosis, Hypotension, Ketoacidosis, Impairment in renal function, Genital mycotic infections, Urinary tract infections	Empagliflozin 10 & 25 mg Tablet, Metformin 500, 750 & 850 mg Tablet, Empagliflozin 5mg + Metformin Hydrochloride 500 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
36.	Aristopharma Ltd. Plot No.14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204 DELTA Pharma Ltd **The ACME Laboratories Ltd. Dhamrai, Dhaka**	Empagliflozin 12.5 mg + Metformin HCl 500mg Film Coated Tablet	Empagliflozin INN 12.5 mg + Metformin HCl BP 500 mg	Antidiabetic Therapeutic Code:015	It is a combination of empagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor and metformin, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing empagliflozin or metformin, or in patients already being treated with both	**Contra-indication:** • Moderate to severe renal impairment (eGFR below 45 mL/min/1.73 m2), end stage renal disease, or dialysis • Metabolic acidosis, including diabetic ketoacidosis • History of serious hypersensitivity reaction to empagliflozin or metformin **Side-effect:** The most common side effects	Empagliflozin 10 & 25 mg Tablet, Metformin 500, 750 & 850 mg Tablet, Empagliflozin 5mg + Metformin Hydrochloride 500 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Beximco Pharmaceuticals Ltd. General Pharmaceuticals Ltd. Nipro JMI Pharma Ltd.				empagliflozin and metformin. **Limitation of Use:** Not for the treatment of type-1 diabetes mellitus or diabetic ketoacidosis.	of empagliflozin and metformin combination include: • low blood sugar. • urinary tract infection. • stuffy or runny nose and sore throat. • yeast infections in females. • diarrhea, nausea or vomiting, gas, stomach discomfort, indigestion. • weakness. • headache. **Warnings and Precautions:** Lactic acidosis, Hypotension, Ketoacidosis, Impairment in renal function, Genital mycotic infections, Urinary tract infections				
37.	Aristopharma Ltd. Plot No.14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204 Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Ziska Pharmaceuticals ltd. The ACME Laboratories Ltd. Dhamrai, Dhaka Beximco Pharmaceuticals Ltd. General Pharmaceuticals Ltd.	Empagliflozin 10mg + Metformin HCl 1000mg Extended Release Tablet	Empagliflozin INN 10mg + Metformin HCl BP 1000 mg	Antidiabetic Therapeutic Code:015	It is a combination of empagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor and metformin, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and metformin is appropriate. **Limitation of Use:** Not for the treatment of type-1 diabetes mellitus or diabetic ketoacidosis.	**Contra-indication:** • Moderate to severe renal impairment (eGFR below 45 mL/min/1.73 m2), end stage renal disease, or dialysis • Metabolic acidosis, including diabetic ketoacidosis • History of serious hypersensitivity reaction to empagliflozin or metformin **Side-effect:** The most common side effects of empagliflozin and metformin combination include: • low blood sugar. • urinary tract infection. • stuffy or runny nose and sore throat. • yeast infections in females. • diarrhea, nausea or vomiting, gas, stomach discomfort, indigestion. • weakness. • headache. **Warnings and Precautions:**	Empagliflozin 10 & 25 mg Tablet, Metformin 500, 750 & 850 mg Tablet, Empagliflozin 5mg + Metformin Hydrochloride 500 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Nipro JMI Pharma Ltd.					Lactic acidosis, Hypotension, Ketoacidosis, Impairment in renal function, Genital mycotic infections, Urinary tract infections				
38.	Aristopharma Ltd. Plot No.14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204 Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur The ACME Laboratories Ltd. Dhamrai, Dhaka Beximco Pharmaceuticals Ltd. General Pharmaceuticals Ltd. Nipro JMI Pharma Ltd.	Empagliflozin 25mg + Metformin HCl 1000mg Extended Release Tablet	Empagliflozin INN 25mg + Metformin HCl BP 1000 mg	Antidiabetic Therapeutic Code:015	It is a combination of empagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor and metformin, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and metformin is appropriate. **Limitation of Use:** Not for the treatment of type-1 diabetes mellitus or diabetic ketoacidosis.	**Contra-indication:** • Moderate to severe renal impairment (eGFR below 45 mL/min/1.73 m2), end stage renal disease, or dialysis • Metabolic acidosis, including diabetic ketoacidosis • History of serious hypersensitivity reaction to empagliflozin or metformin **Side-effect:** The most common side effects of empagliflozin and metformin combination include: • low blood sugar. • urinary tract infection. • stuffy or runny nose and sore throat. • yeast infections in females. • diarrhea, nausea or vomiting, gas, stomach discomfort, indigestion. • weakness. • headache. **Warnings and Precautions:** Lactic acidosis, Hypotension, Ketoacidosis, Impairment in renal function, Genital mycotic infections, Urinary tract infections	Empagliflozin 10 & 25 mg Tablet, Metformin 500, 750 & 850 mg Tablet, Empagliflozin 5mg + Metformin Hydrochloride 500 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
39.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, BANGLADESH General Pharmaceuticals Ltd (Unit-2) Beacon	Pancreatin 70% Enteric Coated Pellets **BP** 300 mg Delayed Release Capsule	Pancreatin 70% Enteric Coated Pellets **BP** 300 mg capsule Contains: Lipase 25,000 Units+Amylase 18,000 Units+Protease 1,000 Units.	Other Classification Therapeutic Code: 075	Exocrine Pancreatic insufficiency due to chronic pancreatitis, cystic fibrosis, obstructive pancreatic tumors, coeliac disease, Zollinger-Ellison syndrome and gastro-intestinal or pancreatic surgical resections or other conditions	**Contraindication:** None **Side effects:** Vomiting, dizziness, cough, hyperglycemia, hypoglycemia, abdominal pain, abnormal feces, flatulence, frequent bowel movements, and nasopharyngitis. **Warnings & Precautions:** ● Fibrosing colonopathy is associated with high-dose use of pancreatic enzyme replacement in the treatment of cystic fibrosis patients. Exercise caution	Pancrelipase 70% EC pellets 540 mg Delayed release Capsule Approved in DCC-252	USFDA BNF-81 Page NO. 103-105	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh Square Pharmaceuticals Ltd., Kaliakoir, Gazipur					when doses of this drug exceed 2,500 lipase units/kg of body weight per meal (or greater than 10,000 lipase units/kg of body weight per day). ● To avoid irritation of oral mucosa, do not chew this drug or retain in the mouth. ● Exercise caution when prescribing this drug to patients with gout, renal impairment, or hyperuricemia. ● There is theoretical risk of viral transmission with all pancreatic enzyme products including this drug. ● Exercise caution when administering pancrelipase to a patient with a known allergy to proteins of porcine origin.				
40.	Drug International Ltd (Unit-3) 31/1, Satrong Road, Gopalpur, Tongi Industrial Area Gazipur, Bangladesh.	Estriol 0.03mg and viable *Lactobacillus acidophilus* 100 million (Eqv. to 50 mg) Vaginal Tablet.	Estriol USP 0.03mg and viable *Lactobacillus acidophilus* USP 100 million (Eqv. to 50 mg).	Hormone Therapeutic Code: 056	This vaginal tablet is indicated for restoration of the lactobacillus flora after local and/or systemic treatment with anti-infective or chemotherapeutic agents, atrophic vaginitis due to estrogen deficiency during menopause and post-menopause or as co medication to systemic hormone replacement therapy, vaginal discharge of unknown origin or mild to intermediate case of vaginosis and candidiasis, where use of anti infective therapy is not absolutely necessary. A further possible application is the prophylactic treatment of recidive vaginal infections.	**Contraindication:** Hypersensitivity to *Lactobacillus acidophilus* and estriol or to any of the excipients of this medicine.Malignant changes (estrogen-dependent tumours) in the breast, uterus or vagina; endometriosis (suspected or manifested); vaginal haemorrhaging of unknown origin. **Precaution:** There is no data available. **Warning:** There is no data available. **Side effects:** General Disorders and Administration Site Conditions: A mild stinging or burning (1.6%) may be experienced shortly after the administration of this medicine. In rare cases, intolerability reactions eg, redness and itching have been reported. In one case, hypersensitivity to the lactobacillus lyophilisate contained in this product observed. If It is accidentally administered orally, no adverse effects are to be expected.	New	□□□□□□ □□□ □□□	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
41.	Incepta Pharmaceuticals Ltd.; Dhamrai Unit, Dhaka Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Drug International Ltd (Unit-3) 31/1, Satrong Road, Gopalpur, Tongi Industrial Area Gazipur, Bangladesh Opsonin Pharma Limited, Rupatali, Barishal Ziska Pharmaceuticals Ltd. Navana Pharmaceuticals Limited	Roflumilast 0.3gm/ 100gm Cream	Roflumilast INN 0.3gm/ 100gm	Skin and Mucous Membrane Preparation Code: 071	Roflumilast is a phosphodiesterase 4 inhibitor indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.	**Contraindication:** It is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C). **Warning & Precaution:** There is no data available. **Side effects:** The most common side effects are diarrhea, headache, insomnia, application site pain, upper respiratory tract infections, and urinary tract infections.	500mcg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
42.	Aristopharma Ltd. Plot No.14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204 Beximco Pharmaceuticals Ltd. DBL Pharmaceuticals	Omarigliptin 12.50mg Film Coated Tablet	Omarigliptin INN 12.50 mg	Antidiabetic Therapeutic Code:015	Omarigliptin is an oral, once-weekly DPP-4 inhibitor indicated for the treatment of adults with type 2 diabetes.	**Contra-indication:** Patients with a history of hypersensitivity to components of this drug. Severe ketosis, diabetic coma or precoma in type-1 diabetes patients. Severe infection in which glycemic control is desired by insulin in‡jvection, before and after surgery. Patients with severe trauma. Efficacy and safety of concomitant administration of this drug and insulin preparations have not	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Ltd., Surabari, Kashimpur, Gazipur The ACME Laboratories Ltd. Dhamrai, Dhaka Advanced Chemical Industries Limited, 7 Hajeegang, Godnyl, Narayangang. Drug International Ltd, Unit-3 Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Navana Pharmaceuticals Ltd., Rupgang, Narayangang Ziska Pharmaceuticals Ltd. General Pharmaceuticals Ltd. EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, BANGLADESH Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka					been studied. **Side-effect:** Hypoglycemia, acute pancreatitis, bowel obstruction and intestinal obstruction. Other side effects are: Gastrointestinal problem, constipation, diarrhea, skin and subcutaneous tissue disorders **Warnings and Precautions:** Since this drug is mainly excreted by the kidneys therefore dose should be adjusted in patients with severe renal impairment, hemodialysis or peritoneal dialysis and end-stage renal failure. Other anti-diabetic drugs (in particular, insulin preparation or sulfonylurea) should be used with caution in combination with Omarigliptin, as they may cause hypoglycemia. Following patients or conditions which might cause low blood sugar: 1. Pituitary dysfunction or adrenal insufficiency 2. Malnutrition, starvation, irregular dietary intake, lack of dietary intake or debilitated state 3. Intense muscle movement 4. Excessive alcohol intake 5. The elderly Caution should be taken in patients engaged in aerial work, operation of an automobile. Precaution must be taken with drugs that enhances the hypoglycemic action (β-blockers, salicylic acid agents, monoamine oxidase inhibitors, etc.). Blood glucose level should be carefully monitored when using drugs that attenuate the hypoglycemic action (adrenaline, adrenocorticotropic hormone,				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	M/s Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirgan‡jv, Narayanagng					thyroid hormone, etc.).				
43.	Aristopharma Ltd. Shampur-Kadamtali I/A, Dhaka-1204 DBL Pharmaceuticals Ltd., Surabari, Kashimpur, Gazipur. The ACME Laboratories Ltd. Dhamrai, Dhaka Advanced Chemical Industries Limited, 7 Hajeegang, Godnyl, Narayanagng. Drug International Ltd, Unit-3 Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Navana Pharmaceuticals Ltd., Rupgang, Narayanagng Ziska Pharmaceuticals	Omarigliptin 25 mg Film Coated Tablet	Omarigliptin INN 25 mg	Antidiabetic Therapeutic Code:015	Omarigliptin is an oral, once-weekly DPP-4 inhibitor indicated for the treatment of adults with type 2 diabetes.	**Contra-indication:** Patients with a history of hypersensitivity to components of this drug. Severe ketosis, diabetic coma or precoma in type 1 diabetes patients. Severe infection in which glycemic control is desired by insulin in‡jvection, before and after surgery. Patients with severe trauma. Efficacy and safety of concomitant administration of this drug and insulin preparations have not been studied. **Side-effect:** Hypoglycemia, acute pancreatitis, bowel obstruction and intestinal obstruction. Other side effects are: Gastrointestinal problem, constipation, diarrhea, skin and subcutaneous tissue disorders **Warnings and Precautions:** Since this drug is mainly excreted by the kidneys therefore dose should be adjusted in patients with severe renal impairment, hemodialysis or peritoneal dialysis and end-stage renal failure. Other anti-diabetic drugs (in particular, insulin preparation or sulfonylurea) should be used with caution in combination with Omarigliptin, as they may cause hypoglycemia. Following patients or conditions which might cause low blood sugar: 1. Pituitary dysfunction or adrenal insufficiency	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Ltd. EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, BANGLADESH Beximco Pharmaceuticals Ltd. Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka. General Pharmaceuticals Ltd. M/s Orion Pharma Ltd.,D/28/2, Sumilpara, Siddhirgan‡jv, Narayanagng					2. Malnutrition, starvation, irregular dietary intake, lack of dietary intake or debilitated state 3. Intense muscle movement 4. Excessive alcohol intake 5.The elderly Caution should be taken in patients engaged in aerial work, operation of an automobile. Precaution must be taken with drugs that enhances the hypoglycemic action (β-blockers, salicylic acid agents, monoamine oxidase inhibitors, etc.). Blood glucose level should be carefully monitored when using drugs that attenuate the hypoglycemic action (adrenaline, adrenocorticotropic hormone, thyroid hormone, etc.).				
44.	Aristopharma Ltd. Gachha, Gazipur Sadar, Gazipur. Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur General Pharmaceuticals (Unit-2)	Dexamethasone 0.10g + Levofloxacin 0.50g/100 ml Eye Drops	(Dexamethasone Sodium Phosphate USP 0.1316 g Eqv.to Dexamethasone 0.10g + Levofloxaxin Hemihydrate USP 0.512 g Eqv.to Levofloxacin 0.50g)/100 ml	Eye Preparations Therapeutic Code: 052	Dexamethasone and Levofloxacin combination product in indicated for prevention and treatment of inflammation, and prevention of infection associated with cataract surgery in adults.	**Contra-indication:** • Hypersensitivity to active substance levofloxacin or to other quinolones, to dexamethasone, or to other steroids, or to any of the excipients listed in section 6.1; • Herpes simplex, keratitis, varicella and other viral disease of the cornea and con‡jvunctiva; • Mycobacterial infections of the eye caused by, but not limited to, acid-fast bacilli such as Mycobacterium tuberculosis, Mycobacterium leprae, or Mycobacterium avium; • Fungal diseases of ocular structures; • Untreated purulent infection of the eye. **Side effects:** This medicine can cause side	Dexamethasone 0.1% Eye Drops & Ointment, 2 mg/ml In‡jvection, Levofloxacin 0.5% & 1.5% Eye Drops, Dexamethasone 0.1% + Gatifloxacin 0.3% Eye Drops, Dexamethasone 0.1% + Tobramycin 0.3% Eye Drops	UK-MHRA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						effects, although not everybody gets them. Most side effects are not serious and affect only the eye. • Very rarely this medicine can cause severe allergic reactions (anaphylactic reactions), accompanied by swelling and tightness in the throat and breathing difficulties. • Stop using Ducressa and contact your doctor immediately if any of these symptoms occurs. • Tendon swelling and rupture have happened in people taking oral or intravenous fluoroquinolones, particularly in older patients and in those treated concurrently with corticosteroids. Stop taking Ducressa if you develop pain or swelling of the tendons (tendinitis). **Very common** (may affect more than 1 in 10 people): • high pressure in the eye. **Common** (may affect up to 1 in 10 people): • discomfort, stinging or irritation, burning, itching in the eye • blurred or decreased vision • mucus in the eye. **Warnings and precautions:** • If you are using any other antibiotic treatment, including oral antibiotics. As with other anti-infectives, prolonged use may induce antibiotic resistance with the result of overgrowth of pathogenic microrganisms. • If you suffer from high pressure in the eye or if you have already had high pressure in the eye after using an eye steroid medicine. You are at risk of having this again if you use Ducressa. If you suffer from high pressure in the eye tell your doctor. • If you have glaucoma. • If you have visual disturbance or blurred				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						vision. • If you are using ocular NSAIDs (Nonsteroidal Anti Inflammatory Drugs) • If you have a disorder causing a thinning of the eye tissues because prolonged steroid treatments may cause further thinning and possible perforation. • If you are diabetic.				
45.	Aristopharma Ltd. Gachha, Gazipur Sadar, Gazipur. Drug International Ltd (Unit-3) 31/1, Satrong Road, Gopalpur, Tongi I/A, Gazipur Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur General Pharmaceuticals (Unit-2) Popular Pharmaceuticals Limited, Tongi, Gazipur	Atropine Sulfate 0.01g /100 ml Ophthalmic Solution	Atropine Sulfate USP 0.01g /100 ml	Eye Preparations Therapeutic Code: 052	Atropine Sulfate 0.01g /100 ml Ophthalmic Solution an eye drop preparation used to deliver atropine directly to the eye for local activity. It reduces the rate of unwanted changes in the eye which may slow the progression of near sightedness (myopia). Atropine Sulfate 0.01g /100 ml Ophthalmic Solution are used as a treatment to slow the progression of myopia in children aged from 4 to 14 years	**Contra-indication:** Patients with glaucoma or a tendency toward glaucoma, and with hypersensitivity to belladonna alkaloids. **Side effects:** The common side effects of Atropine Sulfate include: • Blurred vision • Increased sensitivity to sunlight (photophobia) • Allergy • Sore, swollen, red and itchy eyes • Headache • Fatigue • Serious side effects: flushing, dryness of the skin, rapid and irregular pulse, fever, mental aberrations, psychosis and loss of neuromuscular coordination. **Warnings and precautions:** Do not use it if: • you are allergic to atropine, or any of the ingredients listed at the end of this leaflet. • Always check the ingredients to make sure you can use this medicine. • if you have angle closure glaucoma or a family history of glaucoma. • the expiry date printed on the pack has passed. If you use it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect. • if the packaging is torn or shows signs of tampering.	Atropine Sulphate 1% Eye Drops & Ointment, 1 mg/ml & 0.6 mg/ml In‡jvection,	TGA (Australia)	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
46.	Aristopharma Ltd. Gachha, Gazipur Sadar, Gazipur. The ACME Laboratories Ltd. Dhamrai, Dhaka	Tebipenem Pivoxil 300mg Tablet	Tebipenem Pivoxil Hydrochloride INN 348.774 mg Eqv. to Tebipenem Pivoxil 300 mg	Antiinfective Therapeutic code: 023	Tebipenem is a broad-Spectrum orally-administered antibiotic, from the carbapenem subgroup of β-lactam antibiotics. It was developed as a replacement drug to combat bacteria that had acquired antibiotic resistance to commonly used antibiotics. It is mainly indicated in the following conditions: •Complicated Urinary tract infections • Pyelonephritis	**Contra-indication:** Tebipenem is contraindicated in patients with a history of serious hypersensitivity to tebipenem or any of its components, severe renal impairment, end stage renal disease, ordialysis. **Side effects:** The most common adverse effects associated with Tebipenem are mild diarrhea, headache. **Warnings and precautions:** Tebipenem shouldn't be used with drug which treat epilepsy. Pregnancy: There are no data from the use of tebipenem in pregnant women. Breast-feeding: No data in humans are available on excretion of tebipenem into milk.	New	রেফারেন্স নাই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করা হলো।
47.	M/s. Jenphar Bangladesh Limited. Faridpur,Sreepur, Gazipur, Dhaka EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, BANGLADESH Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Deferasirox 180 mg Tablet	Deferasirox INN 180 mg	DRUG used in Anemia and other Blood disorder Therapeutic code: 045	Deferasirox INN : (deferasirox) is indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older..	**Contraindication:** Serum creatinine greater than 2 times the age-appropriate upper limit of normal (ULN) or creatinine clearance (ClCr) less than 40 mL/min. ·Patients with poor performance status. ·Patients with high-risk myelodysplastic syndromes (MDS). ·Patients with advanced malignancies. · Patients with platelet counts. **WARNINGS AND PRECAUTIONS:** Bone marrow suppression: Neutropenia, agranulocytosis, worsening anemia, and thrombocytopenia, including fatal events; monitor blood counts during Deferasirox therapy. Interrupt therapy for toxicity. · Increased Toxicity in the Elderly: Monitor closely for toxicity. · Hypersensitivity Reactions: Discontinue Deferasirox for severe reactions and institute medical intervention. · Severe skin reactions including Stevens-Johnson syndrome: Discontinue Deferasirox and evaluate.	Deferasirox INN 250 mg & 500mg Dispersible Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
48.	M/s. Jenphar Bangladesh Limited. Faridpur, Sreepur, Gazipur, Dhaka Beacon Pharmaceuticals Ltd.	Deferasirox 360 mg Film coated Tablet	Deferasirox INN 360 mg	DRUG used in Anemia and other Blood disorder Therapeutic code: 045	Deferasirox INN : (deferasirox) is indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older..	**Contraindication:** ● Serum creatinine greater than 2 times the age-appropriate upper limit of normal (ULN) or creatinine clearance (ClCr) less than 40 mL/min. ·Patients with poor performance status. ·Patients with high-risk myelodysplastic syndromes (MDS). ·Patients with advanced malignancies. · Patients with platelet counts. **WARNINGS AND PRECAUTIONS:** ·Bone marrow suppression: Neutropenia, agranulocytosis, worsening anemia, and thrombocytopenia, including fatal events; monitor blood counts during Deferasirox therapy. Interrupt therapy for toxicity. · Increased Toxicity in the Elderly: Monitor closely for toxicity. · Hypersensitivity Reactions: Discontinue Deferasirox for severe reactions and institute medical intervention. · Severe skin reactions including Stevens-Johnson syndrome: Discontinue Deferasirox and evaluate.	Deferasirox INN 250 mg & 500mg **Dispersible Tablet**	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
49.	DBL Pharmaceuticals Ltd., Surabari, Kashimpur, Gazipur.	Liposomal Vitamin C 1000 mg/ 5 ml Syrup	Liposomal Vitamin C 1000 mg/ 5 ml	Vitamins and Combinations Therapeutic Code: 78	Liposomal Vitamin C helps combat oxidative stress, enhances immune function, improves collagen production, boosts iron absorption, and supports overall cardiovascular and brain health	**Contraindication:** Pregnancy or lactation **Side Effects:** Vitamin C doesn't have many serious side effects. The most common one is diarrhoea, but it only occurs when excess dose is consumed. **Precautions & Warnings:** If symptoms persist, seek the advice of a healthcare professional Should not be used in children under 2 years without medical advice High doses of vitamin C may reduce the response to warfarin. Caution and monitoring is advised	New	TGA (Australia)	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
50.	DBL Pharmaceuticals Ltd., Surabari, Kashimpur, Gazipur UniMed UniHealth Pharmaceuticals Ltd. B.K Bari, Gazipur Sadar, Gazipur	Flecainide 50 mg Tablet	Flecainide 50 mg	Anaesthetics (Local) Therapeutic Code: 005	Supraventricular arrhythmias Life threatening ventricular arrhythmias not controlled by other drugs	Contraindication: Contraindicated in patients with pre-existing second- or third-degree AV block, or with right bundle branch block when associated with a left hemiblock (bifascicular block), unless a pacemaker is present to sustain the cardiac rhythm should complete heart block occur. Flecainide Tablet is also contraindicated in the presence of cardiogenic shock or known hypersensitivity to the drug Side-effects: Major side effects are Dizziness, Visual Disturbance, Dyspnea. Precautions & Warning: Flecainide acetate, like other antiarrhythmic agents, can cause new or worsened supraventricular or ventricular arrhythmias. Flecainide acetate has a negative inotropic effect and may cause or worsen CHF, particularly in patients with cardiomyopathy, preexisting severe heart failure (NYHA functional class III or IV) or low ejection fractions (less than 30%).	New	BNF 83 (Page-112)	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
51.	The ACME Laboratories Ltd. Dhamrai, Dhaka Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Ziska Pharmaceuticals Ltd	Teneligliptin INN 20mg Tablet	Teneligliptin (as Hydrobromide Hydrate INN) 20 mg Tablet	Antidiabetic Therapeutic Code:015	Type 2 Diabetes mellitus	**Contra Indications:** Hypersensitivity to the drug or any of the components in the formulation. Severe ketosis, type 1 diabetes, severe infection, surgery, severe trauma and diabetic coma or a history of it. **Side effects:** Upper respiratory tract infection,urinary tract infection (UTI),runny and stuffy nose, diarrhea, constipation, headache and gastroenteritis. **Warning & Precautions:** People who are having a history of severe hepatic impairment should take this medication if prescribed under medical supervision.	**New**	PMDA	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
52.	The ACME Laboratories Ltd. Dhamrai, Dhaka Ziska Pharmaceuticals Ltd Navana Pharmaceuticals Ltd.	Pranlukast Hydrate INN 10% Dry syrup	Pranlukast Hemihydrate INN 10% Dry syrup	Drug used in Bronchial Asthma, Chronic obstructive pulmonary disease(COPD) Therapeutic Code: 044	Asthma, Allergic Rhinitis.	**Contra Indications:** Contraindication can be described as a special circumstance or a disease or a condition where not supposed to use the drug or undergo particular treatment as it can harm the patient; at times, it can be dangerous and life threatening as well. When a procedure should not be combined with other procedure or when a medicine cannot be taken with another medicine, it is called Relative contraindication. Contraindications should be taken seriously as they are based on the relative clinical experience of health care providers or from proven research findings. **Side effects:** Headache, increased incidence of resp. tract infection, GI disturbances, induced generalised pain, fever, myalgia. Warning and Precautions: Renal impairment. Possible elevations in liver enzymes. Withdraw treatment in patients showing signs consistent with Churg-Strauss syndrome.	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
53.	The ACME Laboratories Ltd. Dhamrai, Dhaka Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Advanced Chemical Industries Limited, 7 Hajeegang, Godnyl, Narayangon‡jv. EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng,	Trelagliptin 50 mg Tablet	Trelagliptin Succinate INN 66.50mg eq. to 50 mg Trelagliptin	Antidiabetic Therapeutic Code:015	Type 2 Diabetes mellitus	**Contra Indications:** Trelagliptin should be contraindicated in patients with severe renal impairment and those with end-stage renal failure. Although there would be no major safety problems with recommending a dose regimen of 50 mg once weekly in patients with moderate renal impairment. **Side effects:** Hypoglycaemia, skin disorder-related adverse events and hypersensitivity, cardiovascular risk, proarrhythmic risk associated with QT/QTc interval prolongation, gastrointestinal disorder (including pancreatitis). **Warning & Precautions:** Patients with mild, moderate, or severe renal impairment and patients with end-stage renal	New	PMDA	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	BANGLADESH Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka.					failure.				
54.	The ACME Laboratories Ltd. Dhamrai, Dhaka Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Advanced Chemical Industries Limited, 7 Hajeegang, Godnyl, Narayangon‡jv. EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, BANGLADESH Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka.	Trelagliptin 100 mg Tablet	Trelagliptin Succinate INN 133.0mg eq. to 100mg Trelagliptin	Antidiabetic Therapeutic Code:015	Type 2 Diabetes mellitus	Contra Indications: Trelagliptin should be contraindicated in patients with severe renal impairment and those with end-stage renal failure. Although there would be no major safety problems with recommending a dose regimen of 50 mg once weekly in patients with moderate renal impairment. Side effects: Hypoglycaemia, skin disorder-related adverse events and hypersensitivity, cardiovascular risk, proarrhythmic risk associated with QT/QTc interval prolongation, gastrointestinal disorder (including pancreatitis). Warning & Precautions: Patients with mild, moderate, or severe renal impairment and patients with end-stage renal failure.	New	PMDA	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
55.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Beclometasone Dipropionate BP 200 microgram, Formoterol Fumarate Dihydrate BP 6 micrograms and Glycopyrronium 10 micrograms (as Glycopyrronium bromide BP 12.5 micrograms) HFA Inhaler	Beclometasone Dipropionate BP 200 microgram, Formoterol Fumarate Dihydrate BP 6 micrograms and Glycopyrronium 10 micrograms (as Glycopyrronium bromide BP 12.5 micrograms) HFA Inhaler	Drug used in Bronchial Asthma, Chronic obstructive pulmonary disease(COPD) Therapeutic Code: 044	Maintenance treatment of Asthma	Contraindications: Hypersensitivity to the active substances or to any of the excipients. Warnings and Precautions: Not for acute use. Paradoxical bronchospasm may occur. It should be used with caution in patients with cardiac arrhythmias. Potentially serious hypokalaemia may result from beta2-agonist therapy. Side effects: The most frequently reported adverse reactions in patients with COPD or asthma	New	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						are respectively: dysphonia and oral candidiasis, which are normally associated with inhaled corticosteroids; muscle spasms which can be attributed to the long-acting beta2-agonist component; and dry mouth which is a typical anticholinergic effect.				
56.	The ACME Laboratories Ltd. Dhamrai, Dhaka Everest Pharmaceuticals Ltd. Beximco Pharmaceuticals Ltd. M/s Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirgan‡jv, Narayanagng-1431 Navana Pharmaceuticals Limited	Garenoxacin 200 mg Tablet	Garenoxacin INN 200 mg	Anti-infective Therapeutic Code: 023	Acute bronchitis, pneumonia, secondary infection of chronic respiratory disease, otitis media, sinusitis, Laryngopharyngitis, tonsillitis (including peritonsillitis and peritonsillar abscess).	**Contra indications**: Hypersensitivity. **Side effects**: Diarrhoea, Increased hunger, Stomach pain, Sweating, Nausea and vomiting, Redness of skin, Dizziness and fainting, Headache. **Warning & Precautions**: Do not take, if you are allergic to any of its contents. Consult with doctors before taking Garenoxacin if pregnant or breastfeeding. Avoid alcohol consumption while taking Garenoxacin as it causes increased dizziness. Garenoxacin is not recommended for use in children. Consult with doctors if patients have kidney or liver disease, a joint or tendon disorder, seizures (fits), epilepsy.	**New**	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
57.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Tebipenem Pivoxil Hydrobromide 10% (50 mg/ 0.5 gm) Granules in Sachet	Tebipenem Pivoxil Hydrobromide 10% (50 mg/ 0.5 gm) Granules in Sachet	Antibiotic Therapeutic code: 023	Tebipenem pivoxil is an oral Carbapenem antibiotic, use to treat otolaryngologic and respiratory infections.	**Contra indications**: Tebipenem is contraindicated in patients with a history of serious hypersensitivity to Tebipenem or any of its components, severe renal impairment, end stage renal disease, ordialysis. **Side effects**: The most common adverse effects associated with Tebipenem are mild diarrhea, headache. **Warning & Precautions**: Tebipenem shouldn't be used with drug which treat epilepsy. Pregnancy: There are no data from the use of tebipenem in pregnant women. Breast-feeding: No data in humans are available on excretion of tebipenem into milk.	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
58.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Tofogliflozin Hydrate INN 20 mg Tablet	Tofogliflozin Hydrate INN 20 mg	Antidiabetic Therapeutic Code:015	Treatment of adult patients with type 2 diabetes mellitus.	**Contra Indications:** Pregnant or breastfeeding women, patients with ketosis, diabetic coma or precoma, patients with infection or in‡jvury, patients in the pre-/post-operative period. **Side effects:** Urinary tract infections, hypoglycaemia, dehydration, and skin complications. **Warning & Precautions:** Hypersensitivity to tofogliflozin,eGFR< 30mL/min/1.73m2.	**New**	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
59.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Esaxerenone 1.25 mg tablet	Esaxerenone INN 1.25 mg tablet	Antihypertensive Therapeutic Code:022	Essential Hypertension	**Contra Indications:** It is considered that patients with moderate renal impairment have a particularly high risk of developing hyperkalaemia. **Side effects:** Hyperkalaemia Hypotension-related events **Warning & Precautions:** Appropriate precaution should be given in administering esaxerenone to patients with severe hepatic impairment.	**New**	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
60.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Esaxerenone 2.5 mg tablet	Esaxerenone INN 2.5 mg tablet	Antihypertensive Therapeutic Code:022	Essential Hypertension	**Contra Indications:** It is considered that patients with moderate renal impairment have a particularly high risk of developing hyperkalaemia. **Side effects:** Hyperkalaemia Hypotension-related events **Warning & Precautions:** Appropriate precaution should be given in administering esaxerenone to patients with severe hepatic impairment.	**New**	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
61.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Esaxerenone 5 mg tablet	Esaxerenone INN 5 mg tablet	Antihypertensive Therapeutic Code:022	Essential Hypertension	**Contra Indications:** It is considered that patients with moderate renal impairment have a particularly high risk of developing hyperkalaemia **Side effects:** Hyperkalaemia, Hypotension-related events	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Warning & Precautions: Appropriate precaution should be given in administering esaxerenone to patients with severe hepatic impairment.				
62.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Teneligliptin INN 40mg Tablet	Teneligliptin INN 40mg	Antidiabetic Therapeutic Code:015	Type 2 Diabetes mellitus	**Contra Indications:** Hypersensitivity to the drug or any of the components in the formulation. Severe ketosis, type 1 diabetes, severe infection, surgery, severe trauma and diabetic coma or a history of it. **Side effects:** Upper respiratory tract infection,urinary tract infection (UTI),runny and stuffy nose,diarrhea,constipation,headache, and,gastroenteritis. **Warning & Precautions:** People who are having a history of severe hepatic impairment should take this medication if prescribed under medical supervision.	New	‡idv‡iÝ bvB	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করা হলো।
63.	The ACME Laboratories Ltd. Dhamrai, Dhaka Navana Pharmaceuticals ltd., Rupgang, Narayanagng	Paracetamol 500mg + Metoclopramide 5mg Tablet	Paracetamol BP 500mg + Metoclopramide USP 5mg Tablet	Drug used in migraine Therapeutic Code:047	Acute Migraine	**Contra Indications:** Allergic (hypersensitive) to Paracetamol & Metoclopramide. - Have a blockage or bleeding in your stomach or intestine (gut). - Have had movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs after taking metoclopramide or medicines used to calm emotional and mental problems. - Have had an operation on stomach or intestine (gut). **Side effects:** Diarrhoea, Dizziness, light headedness and fainting. This could be because of low blood pressure. Coughing with wheezing in the chest. This could be a symptom of bronchospasm. **Warning & Precautions:** **-** Treatment should not exceed 3 months due to risk of tardive dyskinesia. - Metoclopramide may induce an abnormal	Metoclopramide HCl 10 mg Tablet & 10mg Suppository 1 mg/ml Drops	BNF 80 (Page 497)	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						heart rhythm, therefore caution is advised in people who may be at risk.				
64.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Telmisartan USP 80mg + Amlodipine BP 5mg + Hydrochlorothiazide BP 12.5mg Tablet	Telmisartan USP 80mg + Amlodipine BP 5mg + Hydrochlorothiazide BP 12.5mg Tablet	Antihypertensive Therapeutic code: 022	Indicated for the treatment of hypertension	**Contraindications**: It is contraindicated in patients who are allergic to Amlodipine, Telmisartan, Hydrochlorothiazide. Also contraindicated in patients who have low potassium, low sodium, high calcium or high uric acid levels in blood. **SideEffect**: Headache, dizziness, nausea, vomiting, stomachpain, diarrhoea, weakness, tiredness, sleepiness, body pain. **Warning & Precautions**: Pregnancy: During pregnancy it may lead to various complications in foetus. Consult with doctor when patient is pregnant or planning a pregnancy. Doctor may advise a safer alternative based on patients' clinical condition. Breast-feeding: It is not recommended while breastfeeding. Doctor may prescribe the medicine if the benefits are greater than the risk or switch to an alternative medicine based on patients condition.	**New**	PMDA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
65.	The ACME Laboratories Ltd. Dhamrai, Dhaka General Pharmaceutical Ltd., Gazipur Drug International Ltd (Unit-3), Gazipur Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria,	Imeglimin Hydrochloride 500mg Tablet	Imeglimin Hydrochloride INN 500mg	Antidiabetic Therapeutic Code:015	Treatment of adult patients with type 2 diabetes mellitus.	**Contraindications:** Contraindicated when the eGFR is <45 mL/min/1.73 m2 **Side effects:** Mild to moderate nausea, Vomiting. **Warning & Precautions:** Use with caution in elderly patients. Do not use for the following categories of patients: pregnant or breastfeeding women, children, patients with pituitary dysfunction or adrenal dysfunction.	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Pabna EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng Navana Pharmaceuticals Ltd., Rupgang, Narayanagng Ziska Pharmaceuticals Ltd. Healthcare Pharmaceuticals Ltd. Beximco Pharmaceuticals Ltd. Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka. Beacon Pharmaceuticals Ltd. M/s Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirgan‡jv, Narayanagng-1431									
66.	The ACME Laboratories Ltd. Dhamrai, Dhaka Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria,	Ipragliflozin 25 mg Tablet	Ipragliflozin L-proline INN 25 mg Tablet	Antidiabetic Therapeutic Code:015	Treatment of adult patients with type 1 & 2 diabetes mellitus.	**Contraindications:** SGLT2 inhibitors also aren't that helpful for someone who already has severe kidney disease **Side effects:** Hypoglycemia • Genital infection • Urinary tract infection	**New**	PMDA	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Pabna					• Pollakiuria/polyuria • Adverse events related to decrease in body fluid volume **Warning & Precautions:** Appropriate precaution should be given in administering ipragliflozin to patients with severe hepatic impairment.				
67.	The ACME Laboratories Ltd. Dhamrai, Dhaka Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Ipragliflozin 50 mg Tablet	Ipragliflozin L-proline INN 50 mg Tablet	Antidiabetic Therapeutic Code:015	Treatment of adult patients with type 1 & 2 diabetes mellitus.	**Contraindications:** SGLT2 inhibitors also aren't that helpful for someone who already has severe kidney disease **Side effects:** Hypoglycemia, Genital infection, Urinary tract infection, Pollakiuria/polyuria, Adverse events related to decrease in body fluid volume **Warning & Precautions:** Appropriate precaution should be given in administering ipragliflozin to patients with severe hepatic impairment.	**New**	PMDA	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
68.	The ACME Laboratories Ltd. Dhamrai, Dhaka DBL Pharma Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka. Everest Pharmaceuticals Ltd. Advanced Chemical Industries Ltd. M/s Orion Pharma Ltd. D/28/2, Sumilpara,	Daprodustat INN 1 mg Tablet	Daprodustat INN 1 mg Tablet	DRUG used in Anemia and other Blood disorder Therapeutic Code:045	It is effective for the treatment of renal anemia in patients with chronic kidney disease. Daprodustat is efficacious and well tolerated for anemia in both dialysis-dependent and non-dialysis-dependent patients.	**Contra Indications:** Pregnant or breastfeeding **Side effects:** Severe headache, chest pain, sudden shortness of breath **Warning & Precautions:** Allergic reactions (itch, rash, etc.) to any medicines or foods, cerebral infarction, myocardial infarction or pulmonary embolism.	**New**	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Siddhirgan‡jv, Narayanagng-1431									
69.	The ACME Laboratories Ltd. Dhamrai, Dhaka Advanced Chemical Industries Ltd. Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh Everest Pharmaceuticals Ltd. Drug International Ltd, Unit-3 Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka. The Ibn SINA Pharmaceuticals Ltd Square Pharmaceuticals Ltd., Salgaria, Pabna M/s Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirgan‡jv, Narayanagng-1431 Navana Pharmaceuticals Limited	Daprodustat 2mg Tablet	Daprodustat INN 2mg Tablet	DRUG used in Anemia and other Blood disorder Therapeutic Code:045	It is effective for the treatment of renal anemia in patients with chronic kidney disease. Daprodustat is efficacious and well tolerated for anemia in both dialysis-dependent and non-dialysis-dependent patients.	**Contra Indications:** Pregnant or breastfeeding **Side effects:** Severe headache, chest pain, sudden shortness of breath **Warning & Precautions:** Allergic reactions (itch, rash, etc.) to any medicines or foods, cerebral infarction, myocardial infarction or pulmonary embolism.	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
70.	The ACME Laboratories Ltd. Dhamrai, Dhaka Advanced Chemical Industries Ltd.	Daprodustat 4 mg Tablet	Daprodustat INN 4 mg Tablet	DRUG used in Anemia and other Blood disorder Therapeutic	It is effective for the treatment of renal anemia in patients with chronic kidney disease. Daprodustat is efficacious and well tolerated for anemia in both	**Contra Indications:** Pregnant or breastfeeding **Side effects:** Severe headache, chest pain, sudden shortness of breath	New	PMDA, Japan	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh DBL Pharma Drug International Ltd, Unit-3 Everest Pharmaceuticals Ltd. Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka. The Ibn SINA Pharmaceuticals Ltd M/s Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirgan‡jv, Narayanagng-1431 Navana Pharmaceuticals Limited			Code:045	dialysis-dependent and non-dialysis-dependent patients.	**Warning & Precautions:** Allergic reactions (itch, rash, etc.) to any medicines or foods, cerebral infarction, myocardial infarction or pulmonary embolism.				
71.	The ACME Laboratories Ltd. Dhamrai, Dhaka Everest Pharmaceuticals Ltd. Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh Drug International Ltd, Unit-3 Incepta pharmaceuticals Ltd,	Daprodustat 6mg Tablet	Daprodustat INN 6mg Tablet	DRUG used in Anemia and other Blood disorder Therapeutic Code:045	It is effective for the treatment of renal anemia in patients with chronic kidney disease. Daprodustat is efficacious and well tolerated for anemia in both dialysis-dependent and non-dialysis-dependent patients.	**Contra Indications:** Pregnant or breastfeeding **Side effects:** Severe headache, chest pain, sudden shortness of breath **Warning & Precautions:** Allergic reactions (itch, rash, etc.) to any medicines or foods, cerebral infarction, myocardial infarction or pulmonary embolism.	New	PMDA, Japan	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Zirabo, Savar, Dhaka. The Ibn SINA Pharmaceuticals Ltd Advanced Chemical Industries Ltd. M/s Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirgan‡jv, Narayanagng-1431									
72.	The ACME Laboratories Ltd. Dhamrai, Dhaka Healthcare Pharmaceuticals Ltd Beximco Pharmaceuticals Ltd. Everest Pharmaceuticals Ltd. M/s Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirgan‡jv, Narayanagng-1431 Navana Pharmaceuticals Limited	Faropenem 150 mg Tablet	Feropenem Sodium INN 161.565 mg eq. to 150mg Faropenem	AntiInfective Therapeutic Code: 023	1. Community acquired pneumonia 2. Skin and skin structure infections 3. Uncomplicated skin and skin 4. Upper and lower respiratory tract infections 5. Ear, Nose and Throat (ENT) infections 6. Acute exacerbations of chronic bronchitis 7. Genito-urinary infections structure infections.	• **Gastrointestinal (common)** - Nausea, Abdominal pain, loose bowel movements, diarrhea **Skin (common)** - Rashes • **Central nervous system** - A headache • **General** - Sweating, vitamin deficiency **Precaution:** Precaution should be taken in case of diabetes patients **Contraindication**: Contraindications History of hypersensitivity to faropenem and other penems, anaphylactic reaction to β-lactams.	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
73.	The ACME Laboratories Ltd. Dhamrai, Dhaka Healthcare Pharmaceuticals Ltd General Pharmaceuticals Ltd. Beximco	Vortioxetine 5mg IR Tablet	Vortioxetine Hydrobromide INN 6.355mg eq to 5.0 mg Vortioxetine	Antidepressants Therapeutic Code:014	Indicated for the treatment of major depressive disorder (MDD).	**Contraindications:** Mavacamten Moderate to strong CYP2C19 inhibitors or strong CYP3A4 inhibitor. Moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers. **Side Effect:** Dizziness and fainting, shortness of breath, chest pain, fatigue, racing heart (palpitations), leg swelling, rapid weight gain.	New	USFDA BNF-83, Page (410-411)	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Pharmaceuticals Ltd. Synovia Pharma PLC UniMed UniHealth Pharmaceuticals Ltd., B.K Bari, Gazipur Sadar, Gazipur EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, BANGLADESH Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka.					**Warning & Precautions:** Mavacamten can cause heart failure due to systolic dysfunction. Echocardiogram assessments of left ventricular ejection fraction(LVEF) required before and during Mavacamten use. Initiation in patients with LVEF <55% not recommended. Interrupt if LVEF <50% or if worsening clinical status. Certain CYP450 inhibitors and inducers are contraindicated in patients taking Mavacamten because of an increased risk of heart failure.				
74.	The ACME Laboratories Ltd. Dhamrai, Dhaka Healthcare Pharmaceuticals Ltd Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka General Pharmaceuticals Ltd. Beximco Pharmaceuticals Ltd. Synovia Pharma PLC. UniMed UniHealth Pharmaceuticals Ltd.,	Vortioxetine 10mg IR Tablet	Vortioxetine Hydrobromide INN 12.71mg eq to 10.0 mg Vortioxetine	Antidepressants Therapeutic Code:014	Indicated for the treatment of major depressive disorder (MDD).	**Contraindications:** Concomitant use with nonselective monoamine oxidase inhibitors (MAOIs) or selective MAO-A inhibitors. **Side Effect:** The most common side effects in short-term studies were nausea, constipation, and vomiting. **Warning & Precautions:** Treatment with serotonergic antidepressants (SSRIs, SNRIs, and others) may increase the risk of abnormal bleeding. Patients should be cautioned about the increased risk of bleeding when Vortioxentine is coadministered with nonsteroidal antiinflammatory drugs (NSAIDs), Aspirin, or other drugs that affect coagulation.	New	USFDA BNF-83, Page (410-411)	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	B.K Bari, Gazipur Sadar, Gazipur EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, BANGLADESH									
75.	The ACME Laboratories Ltd. Dhamrai, Dhaka UniMed UniHealth Pharmaceuticals Ltd., B.K Bari, Gazipur Sadar, Gazipur General Pharmaceuticals Ltd. Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka.	Vortioxetine 15mg IR Tablet	Vortioxetine 15mg	Antidepressants Therapeutic Code:014	Indicated for the treatment of major depressive disorder (MDD).	**Contraindications:** Concomitant use with nonselective monoamine oxidase inhibitors (MAOIs) or selective MAO-A inhibitors. **Side Effect:** The most common side effects in short-term studies were nausea, constipation, and vomiting. **Warning & Precautions:** Treatment with serotonergic antidepressants (SSRIs, SNRIs, and others) may increase the risk of abnormal bleeding. Patients should be cautioned about the increased risk of bleeding when Vortioxentine is coadministered with nonsteroidal antiinflammatory drugs (NSAIDs), Aspirin, or other drugs that affect coagulation.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
76.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Abrocitinib 50mg Tablet	Abrocitinib INN 50mg Tab	Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic Code 064	Indicated for the treatment of adults with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.	**Contraindications:** Antiplatelet therapies except for low-dose aspirin (≤81 mg daily), during the first 3 months of treatment. **Side Effect:** Most common adverse reactions (≥1%) in subjects receiving 100 mg and 200 mg include: nasopharyngitis, nausea, headache, herpes simplex, increased blood creatinine phosphokinase, dizziness, urinary tract infection, fatigue, acne, vomiting, oropharyngeal pain,	**New**	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						influenza, gastroenteritis. Most common adverse reactions (≥1%) in subjects receiving either 100 mg or 200 mg also include: impetigo, hypertension, contact dermatitis, upper abdominal pain, abdominal discomfort, herpes zoster, and thrombocytopenia. **Warning & Precautions:** 1.Laboratory Abnormalities: Laboratory monitoring is recommended due to potential changes in platelets, lymphocytes, and lipids. 2.Immunizations: Avoid use of live vaccines prior to, during, and immediately after CIBINQO treatment.				
77.	The ACME Laboratories Ltd. Dhamrai, Dhaka Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Beacon Pharmaceuticals Limited	Abrocitinib 200mg Tablet	Abrocitinib INN 200mg	Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic Code: 064	Indicated for the treatment of adults with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.	**Contraindications:** Antiplatelet therapies except for low-dose aspirin (≤81 mg daily), during the first 3 months of treatment. **Side Effect:** Most common adverse reactions (≥1%) in subjects receiving 100 mg and 200 mg include: nasopharyngitis, nausea, headache, herpes simplex, increased blood creatinine phosphokinase, dizziness, urinary tract infection, fatigue, acne, vomiting, oropharyngeal pain, influenza, gastroenteritis. Most common adverse reactions (≥1%) in subjects receiving either 100 mg or 200 mg also include: impetigo, hypertension, contact dermatitis, upper abdominal pain, abdominal discomfort, herpes zoster, and thrombocytopenia. **Warning & Precautions:** 1.Laboratory Abnormalities: Laboratory monitoring is recommended due to potential changes in platelets, lymphocytes, and lipids. 2.Immunizations: Avoid use of live vaccines prior to, during, and immediately after CIBINQO treatment.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
78.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Delgocitinib 0.5% Ointment	Delgocitinib INN 0.5% Ointment	Skin and Mucous Membrane Preparations Therapeutic Code: 071	Indicated for the treatment of atopic dermatitis.	**Contraindications:** This medicine inhibits all kinase activities of enzymes called as Janus kinase family (JAK1, JAK2, JAK3 and Tyk2) to suppress the actions of factors involved in immuno/inflammatory actions such as lymphocyte activity and thus to suppress inflammation. **Side Effect:** The most commonly reported side effects include folliculitis (eruption) and acne (pimple). **Warning & Precautions:** 1. Do not apply to mucosa, in‡jvured skin or eroded area. 2. If this medicine gets into eyes by any chance, wash out with water immediately.	**New**	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
79.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Everest Pharmaceuticals Ltd. Beximco Pharmaceuticals Ltd. Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh	Roxadustat 150mg Film Coated Tablet	Roxadustat INN 150mg	Drug used in Anemia and other Blood disorder Therapeutic code: 045	It is a medicine that increases the number of red blood cells and haemoglobin level in your blood. It is used to treat adults with symptomatic anaemia that occurs in patients with chronic kidney disease. Anaemia is when you have too few red blood cells and your haemoglobin level is too low. As a result, your body might not receive enough oxygen. Anaemia can cause symptoms such as tiredness, weakness, or shortness of breath.	**CONTRAINDICATIONS:** Hypersensitivity to the active substances or to any of the excipients. Allergic to peanut or soya, do not use this medicine, as it contains soya lecithin. Pregnancy, Breast-feeding **SIDE-EFFECT:** difficulty in sleeping (insomnia) headache, vomiting, constipation blood clot in the lungs (pulmonary embolism) sepsis, a serious or in rare cases, life-threatening infection seizures and warning signs of seizures (convulsions or fits) blood clot in the veins of your legs (deep vein thrombosis or DVT) blood clot in your haemodialysis access (vascular access thrombosis or VAT) that causes the vascular access to close up or stop working if you are using a fistula or graft for dialysis access. **WARNINGS AND PRECAUTIONS:** if you have a seizure if you get blood clots if you have a liver disorder if you have epilepsy or have ever had convulsions or fits if you have signs and symptoms of an infection, which may include fever, sweating or chills, sore throat, runny nose, shortness of breath, feeling weak, confusion, cough, vomiting, diarrhoea or stomach pain, feeling of burning when you pass urine, red or painful skin or sores on your body.	Roxadustat INN 20mg Tablet Roxadustat INN 50mg Tablet Roxadustat INN 100mg Tablet	**EMA**	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
80.	Eskayef Pharmaceuticals Limited, Mirpur, Dhaka.	Rivaroxaban 1mg/ml Powder for Suspension	Rivaroxaban INN 0.1gm/100ml	Anticoagulants and Fibrinolytic Drug Therapeutic code:	It is a Factor Xa inhibitor (anticoagulant) indicated for: • to reduce risk of stroke and systemic embolism in nonvalvular atrial fibrillation.	**CONTRAINDICATIONS:** • Active pathological bleeding. • Severe hypersensitivity reaction to Rivaroxaban.	Rivaroxaban INN 2.5mg Tablet Rivaroxaban INN 10mg Tablet	**USFDA**	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
				013	• for reduction in the risk of recurrence of DVT or PE. • for prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients. • to reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD). • to reduce the risk of major thrombotic vascular events in patients with peripheral artery disease (PAD), including patients after recent lower extremity revascularization due to symptomatic PAD. **Limitations of Use:** • Renal impairment: Avoid or adjust dose. • Hepatic impairment: Avoid use in Child-Pugh B and C hepatic impairment or hepatic disease associated with coagulopathy.	**SIDE-EFFECT:** • The most common adverse reaction (>5%) in adult patients was bleeding. • The most common adverse reactions (>10%) in pediatric patients were bleeding, cough, vomiting, and gastroenteritis. **WARNINGS AND PRECAUTIONS:** Risk of bleeding: Rivaroxaban can cause serious and fatal bleeding. Pregnancy-related hemorrhage: Use Rivaroxaban with caution in pregnant women due to the potential for obstetric hemorrhage and/or emergent delivery. Prosthetic heart valves: Rivaroxaban use not recommended. Increased Risk of Thrombosis in Patients with Triple Positive Antiphospholipid Syndrome: Rivaroxaban use not recommended.	Rivaroxaban INN 15mg Tablet Rivaroxaban INN 20mg Tablet			

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
81.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Famotidine 10mg Film Coated Tablet	Famotidine USP 10mg	H_2 Receptor Blocker Therapeutic code: 055	Famotidine belongs to a group of medicines called H2−receptor antagonists. These work by reducing the amount of acid you produce in your stomach. It is used to treat the following: • Stomach ulcers (gastric/ duodenal ulcers) • Mild to moderate irritation and inflammation caused by stomach acid leaking up into the gullet (reflux oesophagitis) • Zollinger−Ellison Syndrome (a rare disorder that involves recurrent ulcers and tumours in the stomach and intestines) **Limitations of Use:** • Not recommended for children. • If it has been taking a high dose of Famotidine for a long time. Your doctor may monitor your blood count and liver function.	**CONTRAINDICATIONS:** Allergic to Famotidine, other H2−receptor antagonists or any of the other ingredients of this medicine. **SIDE-EFFECT:** • Headache, Dizziness • Constipation, Diarrhoea • Difficulty in breathing or wheezing (bronchospasm) • Pregnancy and breast−feeding • Allergic reactions: swelling of the face throat or tongue, difficulty in breathing or dizziness (anaphylaxis) • Severe blistering of the skin, mouth, eyes and genitals (Stevens Johnson syndrome, toxic epidermal necrolysis) **WARNINGS AND PRECAUTIONS:** • There is a possibility of a malignant growth (tumor) being present in your stomach. • Suffer from kidney problems.	Famotidine 20mg & 40mg Tablet Famotidine 40mg/5ml Powder for Suspension Famotidine 10 mg/ml USP In‡jvection	**USFDA**	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
82.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Beacon Pharmaceuticals Ltd.	Etoricoxib 30mg Film Coated Tablet	Etoricoxib INN 30mg	Non-steroidal anti-inflammatory and drugs used in arthritis Therapeutic code: 064	Etoricoxib contains the active substance etoricoxib which is one of a group of medicines called selective cyclooxygenase-2 (COX-2) inhibitors. These belong to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs): • Etoricoxib helps to reduce the pain and swelling (inflammation) in the joints and muscles of people 16 years of age and older with osteoarthritis,	**CONTRAINDICATIONS:** intolerance to some sugar if you are allergic to etoricoxib allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including acetylsalicylic acid (aspirin) or COX-2 inhibitors **SIDE-EFFECT:** shortness of breath, severe chest pains, severe headaches with increasing confusion or blurred vision, severe or continual stomach pain, black tar-like stools or bloodstained stool,	Etoricoxib 60mg Tablet Etoricoxib 90mg Tablet Etoricoxib 120mg Tablet	BNF-83 Page:1220	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					rheumatoid arthritis, ankylosing spondylitis and gout. • Etoricoxib is also used for the short term treatment of moderate pain after dental surgery in people 16 years of age and older. **Limitations of Use:** • Do not give this medicine to children and adolescents under 16 years of age. • Drug-drug interaction with blood clotting agent. • Pregnancy, breast-feeding and fertility. • History of high blood pressure, bleeding or ulcers, liver disease. • Have any other problems with your heart, liver or kidneys.	a serious skin condition with severe blisters and bleeding in the lips, eyes, mouth and nose (Stevens-Johnson syndrome) an increase in the number of infections which you may see as fevers, severe chills, sore throat or mouth ulcers. These may indicate you have a low number of white blood cells. an abnormally or dangerously fast heart beat.				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
83.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Fondaparinux Sodium 10mg/0.8ml In‡jvection	Fondaparinux Sodium USP 10mg/Vial	Anticoagulants and Fibrinolytic Drug Therapeutic code: 012	It is a Factor Xa inhibitor (anticoagulant) indicated for: • Prophylaxis of deep vein thrombosis (DVT) in patients undergoing hip fracture surgery (including extended prophylaxis), hip replacement surgery, knee replacement surgery, or abdominal surgery. • Treatment of DVT or acute pulmonary embolism (PE) when administered in con‡jvunction with warfarin.	**CONTRAINDICATIONS:** It is contraindicated in the following conditions: Severe renal impairment. Active major bleeding. Bacterial endocarditis. Thrombocytopenia associated with a positive in vitro test for anti-platelet antibody in the presence of fondaparinux sodium. History of serious hypersensitivity reaction (e.g., angioedema, anaphylactoid / anaphylactic reactions) to Fondaparinux. **SIDE-EFFECT:** The following clinically significant adverse reactions are described elsewhere in the labeling: Hemorrhage Thrombocytopenia Spinal or epidural hematomas Renal impairment and bleeding risk **WARNINGS AND PRECAUTIONS:** Spinal or epidural hematomas, which may result in long-term or permanent paralysis, can occur. Patients taking Fondaparinux with risk factors for bleeding are at increased risk of hemorrhage. Bleeding risk is increased in renal impairment and in patients with low body weight <50 kg. Thrombocytopenia can occur with administration of fondaparinux. Periodic routine complete blood counts (including platelet counts), serum creatinine level, and stool occult blood tests are recommended.	Fondaparinux Sodium INN 2.5mg/0.5ml Fondaparinux Sodium INN 5mg/0.4ml Fondaparinux Sodium INN 7.5mg/0.6ml	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
84.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Calcium 500mg (Algae Source) and Vitamin D3 200IU Powder for Solutions	Calcium Carbonate (Algae Source) USP 1250mg/Sachet (Eqv. to 500mg Elemental Calcium) + Dry Vitamin D3 (Cholecalciferol) USP 2mg/Sachet (Eqv. to 200IU Vitamin D3)	Therapeutic Class: **Vitamins and Combinations** Therapeutic code: **078**	Correction of vitamin D and calcium combined deficiency in elderly people. Vitamin D and calcium supplementation as an adjunct to specific therapy for osteoporosis treatment in patients with established, or at high risk of vitamin D and calcium combined deficiencies. **Limitations of Use:** • Absorption of orally administered tetracycline can be reduced by the simultaneous oral administration of calcium. These two drugs should be taken at least 3 hours apart. • Some diuretics (furosemide, ethacrynic acid), antacids containing aluminium salts and thyroid hormones can inhibit calcium absorption and increase renal and faecal excretion. • Colestyramine, corticosteroids and mineral oils interfere with and reduce Vitamin D absorption, while phenytoin and barbiturates favour its inactivation. • Possible interactions may occur with food (e.g. foods containing phosphate, oxalic or phytinic acid) with a reduction of calcium absorption.	**CONTRAINDICATIONS:** Hypersensitivity to the active substances, soya or to any of the excipients Diseases and/or conditions resulting in hypercalcaemia and/or hypercalciuria Nephrolithiasis/Urolithiasis/Kidney stones Hypervitaminosis D **SIDE-EFFECT:** Immune system disorders: Anaphylactic reaction, allergic dermatitis, Metabolism and nutrition disorders: Hypercalcaemia, hypercalciuria, Gastrointestinal Disorders: Nausea, constipation, diarrhoea, epigastric pain, Skin and subcutaneous tissue disorders: Urticaria **WARNINGS AND PRECAUTIONS:** Used with caution in patients with renal insufficiency. Special caution is also required in the treatment of patients with cardiovascular disease. All other Vitamin D compounds and their derivatives, including food-stuffs which may be fortified with Vitamin D, should be withheld during treatment. Should be prescribed with caution to patients with sarcoidosis because of possible increased metabolism of Vitamin D to its active form. These patients should be monitored for serum and urinary calcium. This medicine contains the colouring agent E110 which can cause allergic type reactions including asthma. Allergy is more common in those people who are allergic to aspirin This medicine contains sucrose: patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine	Calcium 500mg (Algae Source) and Vitamin D3 200IU Tablet Calcium 500mg (Algae Source) and Vitamin D3 400IU Tablet Calcium 600mg (Algae Source) and Vitamin D3 400IU Tablet	‡idv‡iÝ bvB	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করা হল।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
85.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Calcium 600mg (Algae Source) and Vitamin D3 400IU Powder for Solutions	Calcium Carbonate (Algae Source) USP 1500mg/Sachet (Eqv. to 600mg Elemental Calcium) + Dry Vitamin D3 (Cholecalciferol) USP 4mg/Sachet (Eqv. to 400IU Vitamin D3)	Therapeutic Class: **Vitamins and Combinations** Therapeutic code: **078**	Correction of vitamin D and calcium combined deficiency in elderly people. Vitamin D and calcium supplementation as an adjunct to specific therapy for osteoporosis treatment in patients with established, or at high risk of vitamin D and calcium combined deficiencies. **Limitations of Use:** Absorption of orally administered tetracycline can be reduced by the simultaneous oral administration of calcium. These two drugs should be taken at least 3 hours apart. Some diuretics (furosemide, ethacrynic acid), antacids containing aluminium salts and thyroid hormones can inhibit calcium absorption and increase renal and faecal excretion. Colestyramine, corticosteroids and mineral oils interfere with and reduce Vitamin D absorption, while phenytoin and barbiturates favour its inactivation. Possible interactions may occur with food (e.g. foods containing phosphate, oxalic or phytinic acid) with a reduction of calcium absorption.	**CONTRAINDICATIONS:** Hypersensitivity to the active substances, soya or to any of the excipients Diseases and/or conditions resulting in hypercalcaemia and/or hypercalciuria Nephrolithiasis/Urolithiasis/Kidney stones Hypervitaminosis D **SIDE-EFFECT:** Immune system disorders: Anaphylactic reaction, allergic dermatitis Metabolism and nutrition disorders: Hypercalcaemia, hypercalciuria Gastrointestinal Disorders: Nausea, constipation, diarrhoea, epigastric pain, Skin and subcutaneous tissue disorders: Urticaria **WARNINGS AND PRECAUTIONS:** Used with caution in patients with renal insufficiency. Special caution is also required in the treatment of patients with cardiovascular disease. All other Vitamin D compounds and their derivatives, including food-stuffs which may be fortified with Vitamin D, should be withheld during treatment. Should be prescribed with caution to patients with sarcoidosis because of possible increased metabolism of Vitamin D to its active form. These patients should be monitored for serum and urinary calcium. This medicine contains the colouring agent E110 which can cause allergic type reactions including asthma. This medicine contains sucrose: patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.	Calcium 500mg (Algae Source) and Vitamin D3 200IU Tablet Calcium 500mg (Algae Source) and Vitamin D3 400IU Tablet Calcium 600mg (Algae Source) and Vitamin D3 400IU Tablet	‡idv‡iÝ bvB	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
86.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Calcium 500mg (Algae Source) and Vitamin D3 800IU Powder for Solutions	Calcium Carbonate (Algae Source) USP 1250mg/Sachet (Eqv. to 500mg Elemental Calcium) + Dry Vitamin D3 (Cholecalciferol) USP 8mg/Sachet (Eqv. to 800IU Vitamin D3)	Therapeutic Class: **Vitamins and Combinations** Therapeutic code: **078**	Correction of vitamin D and calcium combined deficiency in elderly people. Vitamin D and calcium supplementation as an adjunct to specific therapy for osteoporosis treatment in patients with established, or at high risk of vitamin D and calcium combined deficiencies. **Limitations of Use:** Absorption of orally administered tetracycline can be reduced by the simultaneous oral administration of calcium. These two drugs should be taken at least 3 hours apart. Some diuretics (furosemide, ethacrynic acid), antacids containing aluminium salts and thyroid hormones can inhibit calcium absorption and increase renal and faecal excretion. Colestyramine, corticosteroids and mineral oils interfere with and reduce Vitamin D absorption, while phenytoin and barbiturates favour its inactivation. Possible interactions may occur with food (e.g. foods containing phosphate, oxalic or phytinic acid) with a reduction of calcium absorption.	**CONTRAINDICATIONS:** Hypersensitivity to the active substances, soya or to any of the excipients Diseases and/or conditions resulting in hypercalcaemia and/or hypercalciuria Nephrolithiasis/Urolithiasis/Kidney stones Hypervitaminosis D **SIDE-EFFECT:** Immune system disorders: Anaphylactic reaction, allergic dermatitis Metabolism and nutrition disorders: Hypercalcaemia, hypercalciuria Gastrointestinal Disorders: Nausea, constipation, diarrhoea, epigastric pain Skin and subcutaneous tissue disorders: Urticaria **WARNINGS AND PRECAUTIONS:** Used with caution in patients with renal insufficiency Special caution is also required in the treatment of patients with cardiovascular disease All other Vitamin D compounds and their derivatives, including food-stuffs which may be fortified with Vitamin D, should be withheld during treatment Should be prescribed with caution to patients with sarcoidosis because of possible increased metabolism of Vitamin D to its active form. These patients should be monitored for serum and urinary calcium. This medicine contains the colouring agent E110 which can cause allergic type reactions including asthma. This medicine contains sucrose: patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine	Calcium 500mg (Algae Source) and Vitamin D3 200IU Tablet Calcium 500mg (Algae Source) and Vitamin D3 400IU Tablet Calcium 600mg (Algae Source) and Vitamin D3 400IU Tablet	‡idv‡iÝ bvB	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
87.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Fenoterol Hydrobromide 1.25mg and Ipratropium Bromide 0.5mg/4ml Nebulizer Solution	Fenoterol Hydrobromide BP 1..250mg/4ml + Ipratropium Bromide BP 0.500mg/4ml	Therapeutic Class: **Drug used in Bronchial Asthma, Chronic obstructive pulmonary disease(COPD)** Therapeutic code: **044**	It is anebulizer solution must be administered by means of nebulizer using gas flow (oxygen or compressed air), it is indicated for: Treatment of bronchospasm associated with acute severe exacerbations of bronchial asthma or chronic obstructive pulmonary disease (COPD). It can relieve wheezing, coughing, chest tightness and/or shortness of breath if you have an acute attack of asthma or which includes chronic bronchitis and emphysema. It is important to know that the treatment of asthma and COPD may be different for each patient. Your doctor will discuss with you the best plan for the treatment of your particular condition. This plan may include taking other medication(s) in addition to this drug. **Limitations of Use:** Concomitant use of this drug with other sympathomimetic agents is not recommended since the combined use may lead to deleterious cardiovascular effects. If concomitant use is necessary, this should take place only under strict medical supervision. It is not currently indicated for use in children less than 12 years of age as the dosing regimen and evidence concerning its safety in this age group has not been established.	**CONTRAINDICATIONS:** Patients with a known hypersensitivity to the component drugs, sympathomimetic amines, atropinics or to any of the product components. For a complete listing, see the Dosage Forms, Composition and Packaging section of the product monograph. It is also contraindicated in patients with tachyarrhythmias and hypertrophic obstructive cardiomyopathy. **SIDE-EFFECT:** Fine tremor of skeletal muscles and nervousness, less frequent are tachycardia, increased heart rate, dizziness, palpitations or headache, especially in hypersensitive patients. Potentially serious hypokalemia may result from beta2 agonist therapy dryness of the mouth, throat irritation, pharyngitis or allergic reactions With other β agonist containing products, nausea, vomiting, sweating, weakness and myalgia/muscle cramps may occur because of the low systemic absorption of Ipratropium bromide, ocular accommodation disturbances, gastrointestinal motility disturbances (vomiting, constipation, and diarrhea) and urinary retention are rare and reversible ocular side effects (including accommodation disturbances and glaucoma) may occur Skin reactions or allergic-type reactions such as skin rash, angioedema of the tongue, lips and face, urticaria, laryngospasm and anaphylactic reactions have been reported. **WARNINGS AND PRECAUTIONS:** If you are pregnant or intend to become pregnant. If you are breast feeding. If you have eye problems such as glaucoma or eye pain. If you are taking other medications, including those you can buy without a prescription and including eye drops, or herbal medicines. If you have special allergies or reactions to foods or drugs. If you have other health problems such as difficult urination, enlarged prostate, blood vessel disease, high blood pressure,diabetes mellitus. you have a history of heart disease, irregular heart rhythm (heart skips a beat) or angina (chest pain).	Fenoterol HCl 100mcg + Ipratropium Bromide 40mcg/100 Actuation Inhaler	**রেফারেন্স দাখিল করেনি**	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
88.	Opsonin Pharma Limited, Rupatali, Barishal	Apraclonidine 0.5% (as Hydrochloride USP) Ophthalmic solution	Apraclonidine USP 0.5% (as Hydrochloride USP)	Eye Preparation Therapeutic code: 052	Apraclonidine Hydrochloride Ophthalmic Solution is indicated to control or prevent post-surgical elevations in intraocular pressure that occur in patients after argon laser trabeculoplasty, argon laser iridotomy or Nd:YAG posterior capsulotomy.	**Contraindications:** Apraclonidine Hydrochloride Ophthalmic Solution is contraindicated for patients receiving monoamine oxidase inhibitor therapy and for patients with hypersensitivity to any component of this medication or to clonidine. **Side-effect:** Not Available **Precautions &Warnings:** Since Apraclonidine Hydrochloride Ophthalmic Solution is a potent depressor of intraocular pressure, patients who develop exaggerated reductions in intraocular pressure should be closely monitored. Although the acute administration of two drops of Apraclonidine Hydrochloride Ophthalmic Solution has minimal effect on heart rate or blood pressure in clinical studies evaluating patients undergoing anterior segment laser surgery, the preclinical pharmacologic profile of this drug suggests that caution should be observed in treating patients with severe cardiovascular disease including hypertension. Apraclonidine Hydrochloride Ophthalmic Solution should also be used with caution in patients with severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, chronic renal failure, Raynaud's disease or thromboangiitis obliterans. The possibility of a vasovagal attack occurring during laser surgery should be considered and caution used in patients with history of such episodes. Topical ocular administration of two drops of 0.5%, 1% and 1.5% Apraclonidine Hydrochloride Ophthalmic Solution to New Zealand Albino rabbits three times daily for one month resulted in sporadic and transient instances of minimal corneal cloudiness in the 1.5% group only.	New	রেফারেন্স নাই	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নাই বিধায় বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						No histopathological changes were noted in those eyes. No adverse ocular effects were observed in cynomolgus monkeys treated with two drops of 1.5% Apraclonidine Hydrochloride Ophthalmic Solution applied three times daily for three months. No corneal changes were observed in 320 humans given at least one dose of 1% Apraclonidine Hydrochloride Ophthalmic Solution. Information for Patients: Apraclonidine can cause dizziness and somnolence. Patients who engage in hazardous activities requiring mental alertness should be warned of the potential for a decrease in mental alertness on the day of surgery.				
89.	General Pharmaceutical Ltd., (Unit-2) Gazipur	Apraclonidine 1% Ophthalmic solution	Apraclonidine 1% (as Hydrochloride USP)	Eye Preparation Therapeutic code: 052	Apraclonidine Hydrochloride Ophthalmic Solution is indicated to control or prevent post-surgical elevations in intraocular pressure that occur in patients after argon laser trabeculoplasty, argon laser iridotomy or Nd:YAG posterior capsulotomy.	**Contraindications:** Apraclonidine Hydrochloride Ophthalmic Solution is contraindicated for patients receiving monoamine oxidase inhibitor therapy and for patients with hypersensitivity to any component of this medication or to clonidine. **Side-effect:** Not Available **Precautions &Warnings:** Since Apraclonidine Hydrochloride Ophthalmic Solution is a potent depressor of intraocular pressure, patients who develop exaggerated reductions in intraocular pressure should be closely monitored. Although the acute administration of two drops of Apraclonidine Hydrochloride Ophthalmic Solution has minimal effect on heart rate or blood pressure in clinical studies evaluating patients undergoing anterior segment laser surgery, the preclinical pharmacologic profile of this drug suggests that caution should be observed in treating patients with severe cardiovascular disease including hypertension.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Apraclonidine Hydrochloride Ophthalmic Solution should also be used with caution in patients with severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, chronic renal failure, Raynaud's disease or thromboangiitis obliterans. The possibility of a vasovagal attack occurring during laser surgery should be considered and caution used in patients with history of such episodes. Topical ocular administration of two drops of 0.5%, 1% and 1.5% Apraclonidine Hydrochloride Ophthalmic Solution to New Zealand Albino rabbits three times daily for one month resulted in sporadic and transient instances of minimal corneal cloudiness in the 1.5% group only. No histopathological changes were noted in those eyes. No adverse ocular effects were observed in cynomolgus monkeys treated with two drops of 1.5% Apraclonidine Hydrochloride Ophthalmic Solution applied three times daily for three months. No corneal changes were observed in 320 humans given at least one dose of 1% Apraclonidine Hydrochloride Ophthalmic Solution. Information for Patients: Apraclonidine can cause dizziness and somnolence. Patients who engage in hazardous activities requiring mental alertness should be warned of the potential for a decrease in mental alertness on the day of surgery.				
90.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna General Pharmaceutical Ltd., Gazipur	Tapinarof 1% Cream	Tapinarof INN 1%	Skin & Mucous Membrane Preparations Therapeutic code: 071	It is an aryl hydrocarbon receptor agonist indicated for the topical treatment of plaque psoriasis in adults.	Contraindications: None Side-effect: Most common adverse reactions (incidence ≥ 1%) in subjects treated with Tapinarof cream were folliculitis, nasopharyngitis, contact dermatitis, headache, pruritus, and influenza. Precautions &Warnings: N/A	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Incepta Pharmaceuticals Ltd.; Dhamrai Unit, Dhaka Beximco Pharmaceuticals Ltd Synovia Pharma PLC. Eskayef Pharmaceuticals Limited, Tongi, Gazipur Navana Pharmaceuticals ltd., Rupgang, Narayanagng Ziska Pharmaceuticals Ltd. Opsonin Pharma Limited, Rupatali, Barishal. The ACME Laboratories Ltd. Dhamrai, Dhaka Nuvista Pharma Ltd.									
91.	General Pharmaceutical Ltd., Gazipur Ziska Pharmaceuticals Ltd. The ACME Laboratories Ltd. Dhamrai, Dhaka Beacon Pharmaceuticals Limited Kathali, Bhaluka,	Dotinurad 0.5mg Tablet	Dotinurad INN 0.5mg	Anti-gout Therapeutic code: 076	Dotinurad acts as a selective urate reabsorption inhibitor that has uric acid lowering activity, used to treat of gout and hyperuricemia.	**Contraindications:** The drug is contraindicated in people with tumour lysis syndrome or Lesch–Nyhan syndrome (juvenile gout), as well as severe impairment of kidney function, including kidney transplant and hemodialysis patients **Side-effect:** Get emergency medical help if you have signs of an allergic reaction: hives; difficult breathing; swelling of your face, lips, tongue, or throat. ● gout flare-up symptoms--joint pain,	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Mymensingh EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, BANGLADESH Square Pharmaceuticals Ltd., Salgaria, Pabna					stiffness, redness, or swelling (especially at night); ● kidney problems--little or no urination, swelling in your feet or ankles, feeling tired or short of breath; ● heart problems--chest pain or pressure, pain spreading to your jaw or shoulder; or ● signs of a blood clot--sudden numbness or weakness, problems with vision or speech, swelling or redness in an arm or leg. Common side effects may include: abnormal kidney function tests; heartburn; headache; or flu-like symptoms. **Precautions &Warnings:** *You should not use Dotinurad if you have severe kidney problems, or if you are on dialysis or have received a kidney transplant. Dotinurad can cause kidney failure, especially if you take it without your other prescribed medications. Call your doctor right away if you urinate less than usual or not at all, or if you have swelling in your feet or ankles, or shortness of breath.*				
92.	General Pharmaceutical Ltd., Gazipur Ziska Pharmaceuticals Ltd. The ACME Laboratories Ltd. Dhamrai, Dhaka Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Dotinurad 1mg Tablet	Dotinurad INN 1mg	Anti-gout Therapeutic code: 076	Dotinurad acts as a selective urate reabsorption inhibitor that has uric acid lowering activity, used to treat of gout and hyperuricemia.	**Contraindications:** The drug is contraindicated in people with tumour lysis syndrome or Lesch–Nyhan syndrome (juvenile gout), as well as severe impairment of kidney function, including kidney transplant and hemodialysis patients **Side-effect:** Get emergency medical help if you have signs of an allergic reaction: hives; difficult breathing; swelling of your face, lips, tongue, or throat. ● gout flare-up symptoms--joint pain, stiffness, redness, or swelling (especially at night);	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Square Pharmaceuticals Ltd., Salgaria, Pabna					● kidney problems--little or no urination, swelling in your feet or ankles, feeling tired or short of breath; ● heart problems--chest pain or pressure, pain spreading to your jaw or shoulder; or ● signs of a blood clot--sudden numbness or weakness, problems with vision or speech, swelling or redness in an arm or leg. Common side effects may include: abnormal kidney function tests; heartburn; headache; or flu-like symptoms. **Precautions &Warnings:** *You should not use Dotinurad if you have severe kidney problems, or if you are on dialysis or have received a kidney transplant. Dotinurad can cause kidney failure, especially if you take it without your other prescribed medications. Call your doctor right away if you urinate less than usual or not at all, or if you have swelling in your feet or ankles, or shortness of breath.*				
93.	General Pharmaceutical Ltd., Gazipur The ACME Laboratories Ltd. Dhamrai, Dhaka Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh Square Pharmaceuticals Ltd., Salgaria, Pabna	Dotinurad 2 mg Tablet	Dotinurad INN 2mg	Anti-gout Therapeutic code: 076	Dotinurad acts as a selective urate reabsorption inhibitor that has uric acid lowering activity, used to treat of gout and hyperuricemia.	**Contraindications:** The drug is contraindicated in people with tumour lysis syndrome or Lesch–Nyhan syndrome (juvenile gout), as well as severe impairment of kidney function, including kidney transplant and hemodialysis patients **Side-effect:** Get emergency medical help if you have signs of an allergic reaction: hives; difficult breathing; swelling of your face, lips, tongue, or throat. ● gout flare-up symptoms--joint pain, stiffness, redness, or swelling (especially at night); ● kidney problems--little or no urination, swelling in your feet or ankles,	New	**PMDA**	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						feeling tired or short of breath; ● heart problems--chest pain or pressure, pain spreading to your jaw or shoulder; or ● signs of a blood clot--sudden numbness or weakness, problems with vision or speech, swelling or redness in an arm or leg. Common side effects may include: abnormal kidney function tests; heartburn; headache; or flu-like symptoms. **Precautions &Warnings:** *You should not use Dotinurad if you have severe kidney problems, or if you are on dialysis or have received a kidney transplant. Dotinurad can cause kidney failure, especially if you take it without your other prescribed medications. Call your doctor right away if you urinate less than usual or not at all, or if you have swelling in your feet or ankles, or shortness of breath.*				
94.	General Pharmaceutical Ltd., Gazipur Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh The ACME Laboratories Ltd. Dhamrai, Dhaka Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Imeglimin Hydrochloride INN 1000mg Tablet	Imeglimin Hydrochloride INN 1000mg	Antidiabetes Therapeutic Code: 015	Imeglimin hydrochloride 500 mg Tablet is indicated for the treatment of type 2 diabetes. Imeglimin hydrochloride is an oral glucose-lowering agent. Imeglimin also reduces reactive oxygen species (ROS) production, increases mitochondrial DNA and improves mitochondrial function. Imeglimin hydrochloride 500 mg Tablet is the first member of a completely new class of hypoglycemic drugs, characterized by the advantages of currently available anti-diabetic drugs. At the same time, Imeglimin hydrochloride 500 mg Tablet is free of serious negative adverse effects, which all	**Contraindications:** N/A **Side-effect:** N/A **Precautions &Warnings:** N/A The number of serious AEs (Adverse Events) or SAEs (Serious Adverse Events) and patients reporting them were low for Imeglimin hydrochloride 500 mg Tablet. There was no fatal event because of one SAE (metastatic pancreatic carcinoma, unrelated to study drug) in the Imeglimin hydrochloride 500 mg Tablet group but has one fatal event in the Imeglimin hydrochloride 1500 mg Tablet. The most common AEs (Adverse Events) were infections and infestations with a slight increase in all imeglimin groups. The second most common AEs were gastrointestinal	New	রেফারেন্স নাই	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					the current medications for the treatment of type 2 diabetes without exception come with.	disorders. However, these events, mainly diarrhea, nausea and vomiting, were mostly mild in intensity. A significant decrease of mean aspartate aminotransferase (AST) and alanine aminotransferase (ALT) was observed in imeglimin groups.				
95.	General Pharmaceutical Ltd., Gazipur Beacon Pharmaceuticals Ltd. Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Eskayef Pharmaceuticals Limited, Tongi, Gazipur Ziska Pharmaceuticals Ltd. The ACME Laboratories Ltd. Dhamrai, Dhaka M/s Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirgan‡jv, Narayanagng-1431	Ravuconazole 100mg Capsule	Fosravuconazole L-lysine Ethanolate INN 169.1mg eq. to Ravuconazole 100 mg	Antifungal Therapeutic Code: 020	It is an oral treatment for onychomycosis, which is a fungal infection that induces symptoms such as the clouding and thickening of nails as well as hyperkeratosis in the area surrounding the nail.	Contraindications: - Do not use for pregnant, possibly pregnant or breastfeeding women. -Female patients should use birth control while taking this medicine and for at least 3 months after discontinuing this medicine. -If an allergic reaction occurs, stop taking the medicine and consult with your doctor. -If you're taking any other medication, please consult with your doctor before use. -As this medicine has high hygroscopic property, take the capsules out of the PTP sheet only immediately before you take them. Side-effect: The most commonly reported adverse reactions include stomach discomfort, constipation and angular cheilitis. **Precautions & Warnings:** Trim the lesioned nail with a file or nail clipper as necessary. If you are capable of becoming pregnant, be sure to use birth control while taking this medicine and for at least 3 months after discontinuing this medicine.	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
96.	Healthcare Pharmaceuticals Ltd Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Vortioxetine IR 20mg Tablet	Vortioxetine Hydrobromide INN 25.42mg eq to 20mg Vortioxetine	Antidepressant Therapeutic code: 014	Vortioxetine is used to treat major depressive disorder (MDD). It is an antidepressant and belongs to a group of medicines known as selective serotonin reuptake inhibitors (SSRIs)	**Contraindications:** Hypersensitivity to vortioxetine or any component of the formulation. Hypersensitivity reactions including anaphylaxis, angioedema, and urticarial have. The use of MAOIs intended to treat	New	USFDA BNF-83, Page (410-411)	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Beximco Pharmaceuticals Ltd. Synovia Pharma PLC. UniMed UniHealth Pharmaceuticals Ltd., B.K Bari, Gazipur Sadar, Gazipur The ACME Laboratories Ltd. Dhamrai, Dhaka					psychiatric disorders with Vortioxetine or within 21 days of stopping treatment with Vortioxetine is contraindicated because of an increased risk of serotonin syndrome. The use of Vortioxetine within 14 days of stopping an MAOI intended to treat psychiatric disorders is also contraindicated **Side effects:** Most common adverse reactions (incidence ≥5% and at least twice the rate of placebo) were: nausea, constipation and vomiting. **Warnings and Precautions** : - Serotonin Syndrome has been reported with serotonergic antidepressants (SSRIs, SNRIs, and others), including with Vortioxetine 5 mg. Immediate Release Tablet, both when taken alone, but especially when coadministered with other serotonergic agents (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John's Wort). If such symptoms occur, discontinue Vortioxetine 5 mg Immediate Release Tablet and initiate supportive treatment. If concomitant use of Vortioxetine 5 mg Immediate Release Tablet with other serotonergic drugs is clinically warranted, patients should be made aware of a potential increased risk for serotonin syndrome, particularly during treatment initiation and dose increases . Treatment with serotonergic antidepressants (SSRIs, SNRIs, and others) may increase the risk of abnormal bleeding. Patients should be cautioned about the increased risk of bleeding when Vortioxetine 5 mg Immediate Release Tablet is coadministered with nonsteroidal				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						antiinflammatory drugs (NSAIDs), aspirin, or other drugs that affect coagulation. - Activation of Mania/Hypomania can occur with antidepressant treatment. Screen patients for bipolar disorder .- Hyponatremia can occur in association with the syndrome of inappropriate antidiuretic hormone secretion (SIADH) .				
97.	Healthcare Pharmaceuticals Ltd Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh Drug International Ltd.	Ivosidenib 250 mg Tablet	Ivosidenib INN 250mg	Anticancer Therapeutic code:010	Ivosidenib is an isocitrate dehydrogenase-1 (IDH1) inhibitor indicated for the treatment of adult patients with a susceptible IDH1 mutation as detected by an FDA-approved test with: Acute Myeloid Leukemia (AML) •Newly-diagnosed AML who are ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy • Relapsed or refractory AML. Locally Advanced or Metastatic Cholangiocarcinoma •Locally advanced or metastatic cholangiocarcinoma who have been previously treated.	**Side Effects:** The most common adverse reactions (≥20%) in patients with AML were fatigue, arthralgia, leukocytosis, diarrhea, edema, nausea, dyspnea, mucositis, electrocardiogram QT prolonged, rash, cough, decreased appetite, myalgia, constipation, and pyrexia. The most common adverse reactions (≥15%) in patients with cholangiocarcinoma were fatigue, nausea, abdominal pain, diarrhea, cough, decreased appetite, ascites, vomiting, anemia, and rash **Contraindication:** None **WARNINGS AND PRECAUTIONS:** QTc Interval Prolongation: Monitor electrocardiograms and electrolytes. If QTc interval prolongation occurs, dose reduce or withhold, then resume dose or permanently discontinue	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
98.	Healthcare Pharmaceuticals Ltd Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Cytarabine 2000 mg In‡jvection	Cytarabine USP 2000 mg	Anticancer Therapeutic code:010	Cytarabine may be used alone or in combination with other antineoplastic agents. It is indicated alone or in combination for induction of remission and/or maintenance in patients with acute myeloid leukaemia, acute non-lymphoblastic leukaemias, acute lymphoblastic leukaemias, acute lymphocytic leukaemia, erythroleukaemia, blast crises of	**Side Effects:** Undesirable effects from cytarabine are dose-dependent. Most common are gastrointestinal undesirable effects. Cytarabine is toxic to the bone marrow, and causes haematological undesirable effects. **Contraindication:** Hypersensitivity to cytarabine or to any of the excipients listed in 6.1. Anaemia, leukopenia and thrombocytopenia	100 mg, 500 mg & 1 gm In‡jvection	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					chronic myeloid leukaemia, diffuse histiocytic lymphomas (non-Hodgkin's lymphomas of high malignancy), meningeal leukaemia and meningeal neoplasms. Clinicians should refer to the current literature on combination therapy before initiating treatment.	of non-malignant aetiology (e.g. bone marrow aplasia), unless the benefits outweigh the risk. Degenerative and toxic encephalopathies, especially after the use of methotrexate or treatment with ionizing radiation. During pregnancy, cytarabine should only be administrated on strict indication, where the benefits of the drug to the mother should be weighed against possible hazards to the foetus. **Warnings & Precautions:** Cytarabine is a potent bone marrow suppressant. Therapy should be started cautiously in patients with pre-existing drug-induced bone marrow suppression. Patients receiving the drug should be kept under close medical supervision. Leucocyte and platelet counts should be performed frequently and daily during induction. Bone marrow examinations should be performed frequently after blasts have disappeared from the peripheral blood.				
99.	Healthcare Pharmaceuticals Ltd Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Milk of Magnesia USP 300 mg, Liquid Paraffin BP 1.25 ml and Sodium Picosulfate USP 3.33 mg Per ml	Milk of Magnesia USP 300 mg, Liquid Paraffin BP 1.25 ml and Sodium Picosulfate USP 3.33 mg Per ml	Laxatives Therapeutic code: 060	Liquid Paraffin, Milk Of Magnesia & Sodium Picosulfate belongs to the group of medicines called laxatives used to treat constipation associated with piles, anal fissure, hernia, cardiovascular disorder, endoscopy, bowel clearance before radioscopy, pre/post-operative conditions, elderly and bed-ridden patients. Constipation refers to infrequent bowel movements in which the stools are often dry, painful, and hard to pass.	**Side Effects:** Side effects of Liquid Paraffin, Milk of Magnesia and Sodium Picosulfate-Diarrhoea, Abdominal discomfort, Pain or cramps, Loss of appetite, Dizziness, Fatigue, Itching of skin, Muscle weakness & Vomiting **Contraindication:** Acute Abdominal Surgery, Intestinal Obstruction, Un diagnosed Abdominal Pain and Pregnancy & Lactation.	New	‡idv‡iÝ bvB	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করা হলো।
100.	Healthcare Pharmaceuticals Ltd.	Phendimetrazine Tartrate 35 mg Tablet	Phendimetrazine Tartrate USP 35 mg Tablet	Appetite suppressant	Phendimetrazine is used together with diet and exercise to treat obesity	**Side Effects:** Dizziness, dry mouth, difficulty sleeping, irritability, nausea, vomiting, diarrhea,	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh Ziska Pharmaceuticals Ltd Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka.			Therapeutic code: 075		or constipation may occur. If these effects persist or worsen, notify your doctor or pharmacist promptly. **Contraindication:** Known hypersensitivity or idiosyncratic reactions to sympathomimetics. Advanced arteriosclerosis, symptomatic cardiovascular disease, moderate and severe hypertension, hyperthyroidism, and glaucoma. Highly nervous or agitated patients. Patients with a history of drug abuse. Patients taking other CNS stimulants, including monoamine oxidase inhibitors.				করা হলো।
101.	Healthcare Pharmaceuticals Ltd Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Methotrexate USP Injection20 mg/2 mL (10 mg/ml)	Methotrexate USP Injection20 mg/2 mL (10 mg/ml)	Antimetabolites Therapeutic code:010	Methotrexate inhibits the enzyme dihydrofolate reductase, essential for the synthesis of purines and pyrimidines. Indicated for Severe Crohn's disease; Maintenance of remission of severe Crohn's disease; Moderate to severe active rheumatoid arthritis; Severe active rheumatoid arthritis; Neoplastic diseases; Severe psoriasis unresponsive to conventional therapy (specialist use only)	**Side Effects:** Common or very common ▶ With intrathecal use Necrotising demyelinating leukoencephalopathy . neurotoxicity ▶ With oral use Anaemia .appetite decreased . diarrhoea . drowsiness .fatigue .gastrointestinal discomfort . headache .increased risk of infection . leucopenia . nausea . oral disorders . respiratory disorders . skin reactions . throat ulcer . thrombocytopenia . vomiting ▶ With parenteral use Anaemia .appetite decreased . chest pain .cough .diarrhoea .drowsiness .dyspnoea .fatigue . fever .gastrointestinal discomfort . headache .leucopenia . malaise .nausea .oral disorders . respiratory disorders . skin reactions . throat complaints . thrombocytopenia .	Methotrexate 2.5 mg, 10 mg tablet; 2 mg/ml In‡jvection; 5 mg/2 ml In‡jv; 50 mg/2 ml	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						vomiting ► Uncommon ► With oral use Agranulocytosis .alopecia .arthralgia . bone marrow disorders . chills .confusion .cystitis .depression . diabetes mellitus . dysuria .fever . gastrointestinal disorders .haemorrhage .healing impaired . hepatic disorders .myalgia .neoplasms .nephropathy . osteoporosis .photosensitivity reaction . rheumatoid arthritis aggravated . seizure . severe cutaneous adverse reactions CONTRA-INDICATIONS Active infection .ascites . immunodeficiency syndromes . significant pleural effusion CAUTIONS Photosensitivity—psoriasis lesions aggravated by UV radiation (skin ulceration reported) . diarrhoea . extreme caution in blood disorders (avoid if severe) . peptic ulceration . risk of accumulation in pleural effusion or ascites—drain before				
102.	Healthcare Pharmaceuticals Ltd	Abemaciclib 50 mg Coated Tablet	Abemaciclib INN 50 mg Coated Tablet	Antimetabolites Therapeutic code:010	It is a kinase inhibitor indicated: • in combination with endocrine therapy for the adjuvant treatment of adult patients for early breast cancer, advanced or metastatic breast cancer, metastatic breast cancer with disease progression following endocrine therapy & • as monotherapy for the treatment of adult patients with HRpositive, HER2-negative advanced or metastatic breast cancer with	**Side Effects:** Most common adverse reactions (incidence ≥20%) were diarrhea, neutropenia, nausea, abdominal pain, infections, fatigue, anemia, leukopenia, decreased appetite, vomiting, headache, alopecia, and thrombocytopenia **Contraindication:** None	Abemaciclib 200 mg Tablet Abemaciclib 150 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.					
103.	Healthcare Pharmaceuticals Ltd	Abemaciclib 100 mg Coated Tablet	Abemaciclib INN 100 mg Coated Tablet	Antimetabolites Therapeutic code:010	It is a kinase inhibitor indicated: • in combination with endocrine therapy for the adjuvant treatment of adult patients for early breast cancer, advanced or metastatic breast cancer, metastatic breast cancer with disease progression following endocrine therapy & • as monotherapy for the treatment of adult patients with HRpositive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.	**Side Effects:** Most common adverse reactions (incidence ≥20%) were diarrhea, neutropenia, nausea, abdominal pain, infections, fatigue, anemia, leukopenia, decreased appetite, vomiting, headache, alopecia, and thrombocytopenia **Contraindication:** None	Abemaciclib 200 mg Tablet Abemaciclib 150 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
104.	Healthcare Pharmaceuticals Ltd General Pharmaceuticals (Unit-2)	Daptomycin 350mg/Vial Injection (for infusion)	Daptomycin INN 350mg/Vial	Antiinfective Therapeutic code: 023	It is a lipopeptide antibacterial indicated for the treatment of- [Complicated skin and skin structure infections (cSSSI) in adult patients [Staphylococcus aureus bloodstream infections (bacteremia), including those with right-sided infective endocarditis in adult patients. LIMITATIONS OF USE:] Daptomycin for Injectionis not indicated for the treatment of pneumonia.] Daptomycin for Injectionis not indicated for the 31treatment of left-	CONTRAINDICATIONS: Known hypersensitivity to daptomycin SIDE-EFFECTS:] Adult cSSSI Patients: The most common adverse reactions that occurred in ≥2% of adult cSSSI patients receiving daptomycin4 mg/kg were diarrhea, headache, dizziness, rash, abnormal liver function tests, elevated creatinine phosphokinase (CPK), urinary tract infections, hypotension, and dyspne. [Adult S. aureus bacteremia/endocarditis Patients: The most common adverse reactions that occurred in ≥5% of S. aureus bacteremia/endocarditis patients receiving daptomycin6 mg/kg were sepsis, bacteremia, abdominal pain, chest pain, edema, pharyngolaryngeal pain, pruritus, increased	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					sided infective endocarditis due to S. aureus. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Daptomycin for Injectionand other antibacterial drugs, Daptomycin for Injectionshould be used to treat infections that are proven or strongly suspected to be caused by bacteria	sweating, insomnia, elevated CPK and hypertension. WARNINGS AND PRECAUTIONS: [Anaphylaxis/hypersensitivity reactions (including life-threatening): Discontinue daptomycin and treat signs/symptoms. [Myopathy and rhabdomyolysis: Monitor CPK levels and follow muscle pain or weakness; if elevated CPK or myopathy occurs, consider discontinuation of daptomycin. [Eosinophilic pneumonia: Discontinue daptomycin and consider treatment with systemic steroids.] Peripheral neuropathy: Monitor for neuropathy and consider discontinuation. [Potential nervous system and/or muscular system effects in pediatric patients younger than 12 months: Avoid use of daptomycin in this age group. [Clostridium difficile–associated diarrhea: Evaluate patients if diarrhea occurs.] Persisting or relapsing S. aureusbacteremia/endocarditis: Perform susceptibility testing and rule out sequestered foci of infection. [Decreased efficacy was observed in adult patients with moderate baseline renal impairment.				
105.	Healthcare Pharmaceuticals Ltd General Pharmaceuticals (Unit-2)	Daptomycin 500mg/Vial Injection (for infusion)	Daptomycin INN 500mg/Vial	Anti-infective Therapeutic code: 023	It is a lipopeptide antibacterial indicated for the treatment of- [Complicated skin and skin structure infections (cSSSI) in adult patients [Staphylococcus aureus bloodstream infections (bacteremia), including those with	CONTRAINDICATIONS: Known hypersensitivity to daptomycin SIDE-EFFECTS:] Adult cSSSI Patients: The most common adverse reactions that occurred in ≥2% of adult cSSSI patients receiving daptomycin4 mg/kg were diarrhea, headache, dizziness, rash, abnormal liver function tests, elevated	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					right-sided infective endocarditis in adult patients. LIMITATIONS OF USE:] Daptomycin for Injection is not indicated for the treatment of pneumonia.] Daptomycin for Injectionis not indicated for the treatment of left-sided infective endocarditis due to S. aureus. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Daptomycin for Injectionand other antibacterial drugs, Daptomycin for Injectionshould be used to treat infections that are proven or strongly suspected to be caused by bacteria	creatinine phosphokinase (CPK), urinary tract infections, hypotension, and dyspne. [Adult S. aureus bacteremia/endocarditis Patients: The most common adverse reactions that occurred in ≥5% of S. aureus bacteremia/endocarditis patients receiving daptomycin6 mg/kg were sepsis, bacteremia, abdominal pain, chest pain, edema, pharyngolaryngeal pain, pruritus, increased sweating, insomnia, elevated CPK and hypertension. WARNINGS AND PRECAUTIONS: [Anaphylaxis/hypersensitivity reactions (including life-threatening): Discontinue daptomycin and treat signs/symptoms. [Myopathy and rhabdomyolysis: Monitor CPK levels and follow muscle pain or weakness; if elevated CPK or myopathy occurs, consider discontinuation of daptomycin. [Eosinophilic pneumonia: Discontinue daptomycin and consider treatment with systemic steroids.] Peripheral neuropathy: Monitor for neuropathy and consider discontinuation. [Potential nervous system and/or muscular system effects in pediatric patients younger than 12 months: Avoid use of daptomycin in this age group. [Clostridium difficile–associated diarrhea: Evaluate patients if diarrhea occurs.] Persisting or relapsing S. aureusbacteremia/endocarditis: Perform susceptibility testing and rule out sequestered foci of infection. [Decreased efficacy was observed in adult patients with moderate baseline renal impairment.				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
106.	Healthcare Pharmaceuticals Ltd The ACME Laboratories Ltd. Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, BANGLADESH General Pharmaceuticals Ltd. Navana Pharmaceuticals Limited	Ramosetron Hydrochloride 2.5 mcg. FC Tablet	Ramosetron Hydrochloride INN 2.5 mcg. FC Tablet	Antiemetic Therapeutic code:018	Ramosetron Hydrochloride is a medicine that is used for the treatment of Diarrhea-predominant irritable bowel syndrome in males, Chemotherapy-induced nausea, Chemotherapy-induced vomiting and other conditions. The complete list of uses and indications for Ramosetron Hydrochloride is as follows: ● Diarrhea-predominant irritable bowel syndrome in males ● Chemotherapy-induced nausea ● Chemotherapy-induced vomiting	**Contraindication** If anyone suffering from any of the following diseases, should not take Ramosetron Hydrochloride tablet unless doctor advises to do so - ● Heart Disease ● Liver Disease ● Phenylketonuria (PKU) ● Calcium Deficiency ● Potassium Deficiency	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
107.	Healthcare Pharmaceuticals Ltd Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh General Pharmaceuticals Ltd. The ACME Laboratories Ltd. Navana Pharmaceuticals Limited	Ramosetron Hydrochloride 5 mcg FC Tablet	Ramosetron Hydrochloride INN 5 mcg FC Tablet	Antiemetic Therapeutic code: 018	Ramosetron Hydrochloride is a medicine that is used for the treatment of Diarrhea-predominant irritable bowel syndrome in males, Chemotherapy-induced nausea, Chemotherapy-induced vomiting and other conditions. The complete list of uses and indications for Ramosetron Hydrochloride is as follows: Diarrhea-predominant irritable bowel syndrome in males Chemotherapy-induced nausea Chemotherapy-induced vomiting	**Contraindication:** If anyone suffering from any of the following diseases, should not take Ramosetron Hydrochloride tablet unless doctor advises to do so - ● Heart Disease ● Liver Disease ● Phenylketonuria (PKU) ● Calcium Deficiency ● Potassium Deficiency	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
108.	Healthcare Pharmaceuticals Ltd General Pharmaceuticals Ltd. The ACME Laboratories Ltd.	Ramosetron Hydrochloride 2.5 mcg OD Tablet	Ramosetron Hydrochloride INN 2.5 mcg. OD Tablet	Antiemetic Therapeutic code:018	Ramosetron Hydrochloride is a medicine that is used for the treatment of Diarrhea-predominant irritable bowel syndrome in males, Chemotherapy-induced nausea, Chemotherapy-induced vomiting and other conditions. The complete list of uses and indications for Ramosetron Hydrochloride is as follows: ● Diarrhea-predominant irritable bowel syndrome in males ● Chemotherapy-induced nausea ● Chemotherapy-induced vomiting	**Contraindication:** If anyone suffering from any of the following diseases, should not take Ramosetron Hydrochloride tablet unless doctor advises to do so - ● Heart Disease ● Liver Disease ● Phenylketonuria (PKU) ● Calcium Deficiency ● Potassium Deficiency	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
109.	Healthcare Pharmaceuticals Ltd General Pharmaceuticals Ltd. The ACME Laboratories Ltd.	Ramosetron Hydrochloride INN 5 mcg. OD Tablet	Ramosetron Hydrochloride INN 5 mcg OD Tablet	Antiemetic Therapeutic code: 018	Ramosetron Hydrochloride is a medicine that is used for the treatment of Diarrhea-predominant irritable bowel syndrome in males, Chemotherapy-induced nausea, Chemotherapy-induced vomiting and other conditions. The complete list of uses and indications for Ramosetron Hydrochloride is as follows: ● Diarrhea-predominant irritable bowel syndrome in males ● Chemotherapy-induced nausea ● Chemotherapy-induced vomiting	**Contraindication:** If anyone suffering from any of the following diseases, should not take Ramosetron Hydrochloride tablet unless doctor advises to do so - ● Heart Disease ● Liver Disease ● Phenylketonuria (PKU) ● Calcium Deficiency ● Potassium Deficiency	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
110.	Healthcare Pharmaceuticals Ltd	Rabeprazole Sodium BP 20 mg + Domperidone Maleate Ph Eur 30 mg Capsule	Rabeprazole Sodium BP 20 mg as Rabeprazole Sodium Enteric Coated Pellets and Domperidone EP 30 mg as	Other **Classification** Therapeutic code: 075	symptoms of: Dyspepsia, GERD, Nausia associated with acid peptic disorders, post operative nausea	Contraindication: It is contraindicated in patients with known hypersensitivity to these molecule, substituted benzimidazole, and domperidone or to any component of	Domperidone 10mg Tablet, 15mg & 30mg Suppository,	‡idv‡iÝ bvB	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
			Domperidone Maleate Pellets Sustained Release.			the formulation. It should not be used whenever stimulation of gastric motility is to be avoided or could be harmful, eg. In presence of gastro-intestinal haemorrhage, obatruction or perforation. It is also contraindicated in patients with a prolactinreleasing pituitary tumour (Prolactinomia). Side effects: Adverse effects with Rabeprazole are mild to moderate in intensity and included malaise, diarrhea, nausea, skin eruptions,headache & dizziness, etc. Domperidone has been found to be associated with increased serum prolactin which may be associated with galactorrhea, less frequently gynaecomastia, breast enlargement & soreness. Reduced libido has been reported. Occational rashes & other allergic phenomena are also reported. Domperidone does not cross the blood brain barrier and is therefore less likely to interfere with the central dopaminargic function.	5mg/ml drops and 5mg/5ml Supension Rabeprazole 10mg & 20mg Tablet		যেতে পারে।	
111.	Healthcare Pharmaceuticals Ltd	Brexanolone 5mg/ml (100mg/20 ml)	Brexanolone INN 5 mg /ml (100mg/20 ml)	Antidepressants Therapeutic code: 014	Brexanolone is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of postpartum depression (PPD) in adults	Side-effects: ● Sleepiness ● Dry Mouth ● Passing Out ● Flushing Of The Skin Or Face Contraindications: None	New	USFDA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
112.	Healthcare Pharmaceuticals Ltd Beacon Pharmaceuticals Limited	Phendimetrazine Tartrate USP 105 mg ER Capsule	Phendimetrazine Tartrate USP 105 mg ER Capsule	Appetite suppressant Therapeutic code: 075	Phendimetrazine is used together with diet and exercise to treat obesity	**Side Effects:** Dizziness, dry mouth, difficulty sleeping, irritability, nausea, vomiting, diarrhea, or constipation may occur. If these effects persist or worsen, notify your doctor or pharmacist promptly.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Kathali, Bhaluka, Mymensingh General Pharmaceuticals (Unit-2) EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, BANGLADESH					**Contraindication:** Known hypersensitivity or idiosyncratic reactions to sympathomimetics. Advanced arteriosclerosis, symptomatic cardiovascular disease, moderate and severe hypertension, hyperthyroidism, and glaucoma. Highly nervous or agitated patients. Patients with a history of drug abuse. Patients taking other CNS stimulants, including monoamine oxidase inhibitors.				
113.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Midazolam 5mg/Spray (0.1ml) Nasal Spray	Midazolam USP 5mg/Spray (0.1ml)	Therapeutic Class : Hypnotics, Sedatives & Anxiolytic Therapeutic Code: 057	Midazolam Nasal Spray is a benzodiazepine indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older.	**Contraindication:** Patients with hypersensitivity to midazolam Patients with acute narrow-angle glaucoma **Side-effects:** The most common adverse reactions (≥5% in any Midazolam Nasal spray treatment group) were somnolence, headache, nasal discomfort, throat irritation, and rhinorrhea **Warnings and Precautions**: CNS Depression from Concomitant Use with Other CNS Depressants or Moderate or Strong CYP3A4 Inhibitors: May cause an increased CNSdepressant effect when used with alcohol or other CNS depressants. Concomitant use with moderate or strong CYP3A4 inhibitors may result in prolonged sedation because of a decrease in plasma clearance of midazolam. Suicidal Behavior and Ideation: Antiepileptic drugs increase the risk of suicidal ideation and behavior.	Midazolam 1mg/ml & 15mg/3ml In‡jvection Midazolam 7.5mg, 15mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
114.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Topiramate 25mg/ml Oral Solution	Topiramate USP 25mg/ml	Drug Used in Epilepsy Therapeutic Code:	Topiramate is indicated for: Epilepsy: Initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in	**Contraindication:** Hypersensitivity to trelagliptin or any of its components - Patients with severe renal impairment or end-stage renal failure on	Topiramate 25mg, 50mg, 100mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
				046	patients 2 years of age and older ,adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with LennoxGastaut syndrome in patients 2 years of age and older Preventive treatment of migraine in patients 12 years of age and older	dialysis **Side-effects:** Rash, Itching **Warnings and Precautions:** Acute myopia and secondary angle closure glaucoma: can lead to permanent visual loss; discontinue Topiramate as soon as possible Visual field defects: consider discontinuation of Topiramate Oligohidrosis and hyperthermia: monitor decreased sweating and increased body temperature, especially in pediatric patients	Topiramate 25mg, 50mg, 100mg Er Capsule			
115.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Oxycodone Hydrochloride 10 mg + Naltrexone Hydrochloride BP 1.2 mg Extended Release Capsule	Oxycodone Hydrochloride (20% w/w) ER Pellets* In-house 50mg eqv.to Oxycodone Hydrochloride BP 10 mg + Naltrexone Hydrochloride (2.4% w/w) ER Pellets* In-house 50 mg eqv.to Naltrexone Hydrochloride BP 1.2 mg	Analgesics and Antipyretics Therapeutic Code: 006	Oxycodone+Naltrexone is a combination opioid agonist/opioid antagonist product indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.	**Contraindication:** Significant respiratory depression Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment Known or suspected gastrointestinal obstruction, including paralytic ileus Hypersensitivity to oxycodone or naltrexone **Side-effects:** Most common adverse reactions: nausea, constipation, vomiting, headache, and somnolence**Warnings and Precautions:** Life-T hreatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients: Monitor closely, particularly during initiation and titration. Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid. Severe Hypotension: Monitor during dosage initiation and titration. Avoid use of this in patients with circulatory shock. Risks of Use in Patients with Increased Intracranial Pressure, Brain T umors, Head	New	USFDA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						In‡jvury, or Impaired Consciousness: Monitor for sedation and respiratory depression. Avoid use of it in patients with impaired consciousness or coma.				
116.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Oxycodone Hydrochloride 30 mg + Naltrexone Hydrochloride BP 3.6 mg Extended-Release Capsule	Oxycodone Hydrochloride (20% w/w) ER Pellets* In-house 150mg eqv.to Oxycodone Hydrochloride BP 30 mg + Naltrexone Hydrochloride (2.4% w/w) ER Pellets* In-house 150 mg eqv.to Naltrexone Hydrochloride BP 3.6 mg	Therapeutic Class: Analgesics and Antipyretics Therapeutic Code: 006	Oxycodone+Naltrexone is a combination opioid agonist/opioid antagonist product indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.	**Contraindication:** Significant respiratory depression. Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment Known or suspected gastrointestinal obstruction, including paralytic ileus Hypersensitivity to oxycodone or naltrexone **Side-effects:** Most common adverse reactions: nausea, constipation, vomiting, headache, and somnolence **Warnings and Precautions:** Life-T hreatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients: Monitor closely, particularly during initiation and titration. Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid. Severe Hypotension: Monitor during dosage initiation and titration. Avoid use of this inpatients with circulatory shock. Risks of Use in Patients with Increased Intracranial Pressure, Brain T umors, Head In‡jvury, or Impaired Consciousness: Monitor for sedation and respiratory depression. Avoid use of it in patients with impaired consciousness or coma.	New	USFDA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
117.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Tixagevimab In-house 150mg/1.5ml (100mg/ml) in a single dose vial IM Injection and	Tixagevimab In-house 150mg/1.5ml (100mg/ml) IM Injection and	Therapeutic Class : Unclassified Agents Therapeutic Code:	The U.S. Food and Drug Administration has issued an EUA for the emergency use of the unapproved product (tixagevimab	**Contraindication:** It is contraindicated in individuals with previous severe Hypersensitivity reactions, including anaphylaxis, to any component of it. **Side-effects:** Most common adverse events	New	USFDA-Emergency Use Authorization	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
		Cilgavimab In-house 150mg/1.5ml (100mg/ml) in a single dose vial IM Injection Co-packaged	Cilgavimab In-house 150mg/1.5ml (100mg/ml) IM In‡jvection Co-packaged	075	co-packaged with cilgavimab), SARS-CoV-2 spike protein-directed attachment inhibitor, for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg)	(all grades, incidence ≥3%) are Headache, fatigue, and cough. **Warnings and Precautions:** Hypersensitivity Including Anaphylaxis: Serious hypersensitivity reactions, including anaphylaxis, have been observed with IgG1 monoclonal antibodies like it. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy. Clinically monitor individuals after in‡jvections and observe for at least 1hour. Clinically Significant Bleeding Disorders: As with any other intramuscular in‡jvection, it should be given with caution to individuals with thrombocytopenia or any coagulation disorder. Cardiovascular Events: A higher proportion of subjects who received it versus placebo reported myocardial infarction and cardiac failure serious adverse events. All of the subjects with events had cardiac risk factors and/or a prior history of cardiovascular disease, and there was no clear temporal pattern. A causal relationship between itand these events has not been established. Consider the risks and benefits prior to initiating it in individuals at high risk for cardiovascular events, and advise				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						individuals to seek immediate medical attention if they experience any signs or symptoms suggestive of a cardiovascular event.				
118.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Bebtelovimab 175mg/2ml (87.5 mg/mL) in a single dose vial IV In‡jvection	Bebtelovimab INN 175mg/2ml	Therapeutic Class : Unclassified Agents Therapeutic Code: 075	The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of bebtelovimab for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg): •with positive results of direct SARS-CoV-2 viral testing, and •who are at high risk for progression to severe COVID-19, includinghospitalization or death, and •for whom alternative COVID-19 treatment options approved orauthorized by FDA are not accessible or clinically appropriate.	**Contraindication:** No contraindications have been identified based on the limited available data for the emergency use of bebtelovimab authorized under this EUA. **Side-effects:** Most common adverse reactions are infusion-related reactions (0.3%), pruritus (0.3%), and rash (0.8%). **Warnings and Precautions:** Hypersensitivity Including Anaphylaxis and Infusion-RelatedReactions: Serious hypersensitivity reactions, including anaphylaxis, have been observed with administration of other SARS-CoV-2monoclonal antibodies and could occur with administration ofbebtelovimab. If clinically significant hypersensitivity reactions occur, discontinue and initiate appropriate supportive care. Infusion-relatedreactions may occur up to 24 hours post in‡jvection. These reactionsmay be severe or life threatening. •Clinical Worsening After SARS-CoV-2 Monoclonal AntibodyAdministration: Clinical worsening of COVID-19 after administrationof SARS-CoV-2 monoclonal antibody treatment has been reportedand may include signs or symptoms of fever, hypoxia or increasedrespiratory difficulty, arrhythmia (e.g., atrial fibrillation, sinustachycardia, bradycardia), fatigue, and altered mental status. Someof these events required hospitalization. It is not known if theseevents were related to SARS-CoV-2 monoclonal antibody use orwere due to progression of COVID-19.	New	USFDA-Emergency Use Authorization	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
119.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, BANGLADESH Beximco Pharmaceuticals Ltd. Beacon Pharmaceuticals Ltd, Bhaluka, Mymensingh	Pridinol 3.02mg Tablet	Pridinol Mesilate INN 4mg eqv. to Pridinol 3.02mg	Skeleton Muscle Relaxants Therapeutic Code: 070	Central and peripheral muscle spasms: lumbar pain, torticollis, general muscle pain, in adults.	**Contraindication:** Hypersensitivity to the active substance or to any of the excipients Glaucoma Prostate hypertrophy Syndrome with urinary retention Gastrointestinal obstructions Arrhythmia first trimester of pregnancy **Side-effects:** The following adverse effects may occur, particularly during concomitant administration with other anticholinergic medicinal products Dry mouth, thirst, transient visual disorder (mydriasis, difficulties with accommodation, photosensitivity, slight increase in intraocular pressure), redness and dryness of the skin, bradycardia followed by tachycardia, micturition disorders, constipation and, very rarely, vomiting, dizziness and unsteady gait. **Warnings and Precautions**: The medicinal product must be used with caution in the elderly, and in patients with severe renal and/or hepatic insufficiency, because higher and/or longer-lasting blood levels must be expected. In patients who suffer from hypotension, the risk of circulatory problems (fainting) may be increased. Pridinol contains lactose. Patients with the rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal.	New	UK-MHRA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
120.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Abiraterone Acetate 500mg Tablet	Abiraterone Acetate USP 500mg	Anticancer Therapeutic Code: 010	Is indicated for use in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer who have received prior chemotherapy containing docetaxel	**Contraindication:** Abiraterone is contraindicated in women who are or may become pregnant. **Side-effects:** The most common adverse reactions (≥ 5%) are joint swelling or discomfort, hypokalemia, edema, muscle discomfort, hot flush, diarrhea, urinary tract infection, cough, hypertension, arrhythmia, urinary frequency, nocturia, dyspepsia, and upper respiratory tract infection **Warnings and Precautions:** Mineralocorticoid excess: Use Abiraterone with caution in patients with a history of cardiovascular disease. The safety of Abiraterone in patients with LVEF < 50% or NYHA Class III or IV heart failure is not established. Control hypertension and correct hypokalemia before treatment. Monitor blood pressure, serum potassium and symptoms of fluid retention at least monthly. • Adrenocortical insufficiency: Monitor for symptoms and signs of adrenocortical insufficiency. Increased dosage of corticosteroids may be indicated before, during and after stressful situations. • Hepatotoxicity: Increases in liver enzymes have lead to drug interruption, dose modification and/or discontinuation. Monitor liver function and modify, interrupt, or discontinue Abiraterone dosing as recommended. • Food Effect: Abiraterone must be taken on an empty stomach. Exposure (area under the curve) of Abiraterone increases up to 10 fold when Abiraterone acetate is taken with meals.	250 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
121.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Tebipenem Pivoxil 600mg Tablet	Tebipenem Pivoxil Hydrobromide INN 697.80mg eqv.to 600mg of Tebipenem Pivoxil	Therapeutic Class : Anti-infective Therapeutic Code: 023	Tebipenem Pivoxil Hydrobromide use for infectious disease product designation for complicated urinary tract infections (cUTI), diabetic foot infections (DFI) and community acquired bacterial pneumonia (CABP).	**Contraindication:** History of significant hypersensitivity or allergic reaction to β-lactam antibiotics, product excipients or any contraindication to the use of other carbapenem. **Side-effects:** Diarrhea, headache and nausea. **Warnings and Precautions:** No data available	New	‡idv‡iÝ bvB	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করা হলো।
122.	Incepta Pharmaceuticals Ltd.; Dhamrai Unit, Dhaka Navana Pharmaceuticals Limited	Ammonium Lactate 12% cream	Ammonium Lactate INN 12g/100g	Skin and Mucous Membrane Preparations Therapeutic Code: 071	Ammonium Lactate is indicated for the treatment of dry, scaly skin (xerosis) and ichthyosis vulgaris and for temporary relief of itching associated with these conditions.	**Contraindication:** Ammonium Lactate Cream is contraindicated in those patients with a history of hypersensitivity to any of the label ingredients. **Side-effects:** In controlled clinical trials of patients with ichthyosis vulgaris, the most frequent adverse reactions in patients treated with Ammonium Lactate Cream were rash (including erythema and irritation) and burning/stinging. Each was reported in approximately 10 - 15% of patients. In addition, itching was reported in approximately 5% of patients. In controlled clinical trials of patients with xerosis, the most frequent adverse reactions in patients treated with Ammonium Lactate Cream were transient burning, in about 3% of patients, Stinging, dry skin and rash, each reported in approximately 2% of patients. **Warnings and Precautions:** Sun exposure to areas of the skin treated with Ammonium Lactate (ammonium lactate) Cream, 12% should be minimized or avoided. The use of Ammonium Lactate Cream should be discontinued if hypersensitivity is observed.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
123.	Incepta Pharmaceuticals Ltd., Dhamrai Unit, Dhaka The ACME Laboratories Ltd. Dhamrai, Dhaka	Felbinac 3 % Gel	Felbinac BP/Ph.Eur 3g/100g	Skeleton Muscle Relaxants Therapeutic Code: 070	Felbinac indicated relief of pain in musculoskeletal conditions. Treatment inknee or hand osteoarthritis (adjunct)	**Contraindication:** 1. Use on broken skin or denuded skin. 2. Hypersensitivity to the ingredients. Patients in who attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other non-steroidal anti-inflammatory agents. 3. Use with occlusive dressings. 4. Use simultaneously to the same site with any other topical preparations. 5. Use in the presence of local infection. 6. Use in patients with active peptic ulceration. 7. Pregnancy and breast feeding. **Side-effects:** Bronchospasm, gastrointestinal disorder, hypersensitivity, paraesthesia, photosensitivity reaction, kin reactions **Warnings and Precautions:** Avoid contact with eyes. Avoid contact with inflamed or broken skin, avoid contact with mucous Membranes not for use with occlusive dressings. topical application of large amounts can result in systemic effects, including hypersensitivity	New	BNF-80 Page-1203	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
124.	Incepta Pharmaceuticals Ltd.; Dhamrai Unit, Dhaka	Moxifloxacin Hydrochloride 5.4541mg/ml eqv. to 5mg/ml of Moxifloxacin Intracameral/ Intraocular In‡jvection	Moxifloxacin Hydrochloride USP 5.4541mg/ ml eqv. to 5mg/ml of Moxifloxacin	Anti-infective Therapeutic Code: 023	Moxifloxacin Ophthalmic Solution USP is a topical fluoroquinolone anti-infective indicated for the treatment of bacterial con‡jvunctivitis caused by susceptible strains of the following organisms: Aerococcusviridans*, Corynebacterium macginleyi*, Enterococcus faecalis*, Micrococcus luteus*, Staphylococcus arlettae*, Staphylococcus aureus,	**Contraindication:** None **Side-effects:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to the rates in the clinical trials of another drug and may not reflect the rates observed in practice. The data described below reflect exposure to Moxifloxacin ophthalmic solution in 1263 patients, between 4 months and 92 years of	New	রেফারেন্স নাই	প্রয়োজন রয়েছে বিধায় অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					Staphylococcus capitis, Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus saprophyticus*, Staphylococcus warneri*, Streptococcus mitis*, Streptococcus pneumoniae, Streptococcus parasanguinis*, Escherichia coli*, Haemophilus influenzae, Klebsiella pneumoniae*, Propionibacterium acnes, Chlamydia trachomatis* *Efficacy for this organism was studied in fewer than 10 infections.	age, with signs and symptoms of bacterial con‡jvunctivitis. The most frequently reported adverse reactions were eye irritation, pyrexia and con‡jvunctivitis, reported in 1% to 2% of patients. **Warnings and Precautions:** Not for Intracameral Use or In‡jvection. Moxifloxacin ophthalmic solution will cause damage to the corneal endothelium if introduced directly into the anterior chamber of the eye. Toxic Anterior Segment Syndrome (TASS) has been reported following intraocular administration of Moxifloxacin. TASS is typically characterized by anterior chamber inflammatory reactions, such as fibrin, cell or flare and corneal edema, but other events, such as hypopyon, keratic precipitates or vitreous opacities may also occur.				
125.	Beximco Pharmaceuticals Ltd The ACME Laboratories Ltd. Dhamrai, Dhaka	Indacaterol Acetate 173 mcg (eqv. to Indacaterol 150 mcg) + Glycopyrrolate as Glycopyrronium bromide 63 mcg (eqv. to Glycopyrronium 50 mcg) + Mometasone Furoate 80 mcg DPI Capsule	Indacaterol Acetate INN 173 mcg (eqv. to Indacaterol 150 mcg) + Glycopyrrolate as Glycopyrronium bromide USP 63 mcg (eqv. to Glycopyrronium 50 mcg) + Mometasone Furoate BP 80 mcg	Drug Used in Bronchial Asthma Therapeutic Code: 044	It is indicated as a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta2-agonist and a medium or high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous 12 months.	**Contra-indication:** It is contraindicated in patients who are hypersensitive to this drug or to any ingredients of it. **Side-effects:** Not available **Warnings and Precautions:** Not available	Glycopyrronium Bromide (as Glycopyrrolate) 50 mcg + Mometasone Furoate 160 mcg Dry Powder Inhaler (DPI) Capsule available in the market	TGA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
126.	Beximco Pharmaceuticals Ltd. Advanced Chemical Industried Ltd. The ACME	Chlordiazepoxide 10 mg and Amitriptyline Hydrochloride equivalent to Amitriptyline 25 mg Tablet.	Chlordiazepoxide USP 10 mg and Amitriptyline Hydrochloride BP equivalent to Amitriptyline 25 mg	Antidepressant Therapeutic Code: 014	It is indicated for the treatment of patients with moderate to severe depression associated with moderate to severe anxiety.	**Contra-indication:** It is contraindicated in patients with hypersensitivity to either benzodiazepines or tricyclic antidepressants. It should not be given concomitantly with a monoamine oxidase inhibitor	Chlordizepoxide 5 mg and Amitriptyline Hydrochloride equivalent to Amitriptyline 12.5 mg Tablet.	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Laboratories Ltd.					**Side-effects:** Many symptoms common to the depressive state, such as anorexia, fatigue, weakness, restlessness, and lethargy, have been reported as side effects of treatment with this preparation. **Warnings and Precautions:** It should used with caution in patients with a history of seizures. Close supervision is required when this preparation is given to hyperthyroid patients or those on thyroid medication. The usual precautions should be observed when treating patients with impaired renal or hepatic function. All pediatric patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior.				
127.	Beximco Pharmaceuticals Ltd. Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Diclofenac Diethylamine 2.320 gm eqv. to Diclofenac Sodium 2gm/100gm (2%) Gel	Diclofenac Diethylamine BP 2.320 gm eqv. to Diclofenac Sodium 2 gm/100 gm Gel	Skin & Mucous Membrane Preparation Therapeutic Code: 071	Indicated for the topical treatment of Rheumatoid arthritis, Osteoarthritis, Joint & muscular pains.	**Contra-indication:** It is contraindicated in patient with- - Known hypersensitivity to diclofenac, aspirin, or other NSAIDs. - History of asthma, urticaria. or other allergic-type reactions after taking aspirin or other NSAIDs. - Use during the perioperative period irr the setting of coronary artery bypass graft (CABG). **Side-effects:** Usually very well tolerated. Most common side effects (incidence >2oh of patients treated with Diclofenac Topical Gel and greater than placebo) are application site reactions, including dermatitis.	Diclofenac sodium BP 1 %. Gel	TGA & MHRA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Warnings and Precautions: Serious and potentially fatal cardiovascular (CV) thrombotic events, myocardial infarction, and stroke can occur with NSAID treatment. The lowest possible dose of Diclofenac topical gel should be used in patients with known CV disease or risk factors for CV disease. • NSAIDs, including diclofenac, can cause serious gastrointestinal (GI) adverse events including inflammation, bleeding, ulceration, and perforation. Diclofenac topical gel should be prescribed with caution in those with a prior history of ulcer disease or gastrointestinal bleeding. • Elevation of one or more liver tests may occur during therapy with diclofenac. Diclofenac topical gel should be discontinued immediately if abnormal liver tests persist or worsen. • Long-term administration of NSAIDs can result in renal papillary necrosis and other renal in‡jvury. Diclofenac topical gel should be used with caution in patients at greatest risk of this reaction, including the elderly, those with impaired renal function, heart failure, liver dysfunction, and those taking diuretics and ACE inhibitors.				
128.	Advanced Chemical Industries Limited, 7 Hajeegang, Godnyl, Narayanagng	Perindopril Arginine INN 2.5 mg eq. to 1.697 mg Perindopril FC Tablet	Perindopril Arginine INN 2.5mg eq. to 1.697mg Perindopril	Anti-hypertensive (022)	Hypertention	**Contraindication:** It is contraindicated in patient with hypersensitivity to perindopril arginine or any other components of this product. It is also contraindicated in history of angioedema associated with previous ACE inhibitor therapy, hereditary or idiopathic angioedema, extracorporeal treatments leading to contact of blood with negatively charged surfaces, significant bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney.	New Molecule	UK-MHRA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Side-effects: The most common side effects are dizziness, headache, paresthesia, vertigo, visual disturbances, tinnitus, hypotension, cough, dyspnea, abdominal pain, constipation, diarrhea, dysgeusia, dyspepsia, nausea, vomiting, pruritus, rash, muscle cramps, and asthenia.				
129.	Advanced Chemical Industries Limited, 7 Hajeegang, Godnyl, Narayanagng The ACME Laboratories Ltd. Dhamrai, Dhaka	Diluted Isosorbide Dinitrate USP 80 mg eqv.to 20mg Isosorbide Dinitrate & Hydralazine Hydrochloride BP 37.50 mg tablet	Diluted Isosorbide Dinitrate USP and Hydralazine Hydrochloride BP	Anti-hypertensive (022)	Indicated for the treatment of heart failure as an adjunct to standard in self-identified patients to improve survival, to prolong time to hospitalization for heart and to improve patient-reported functional status.	**Contraindication:** It is contraindicated in patient with hypersensitivity isosorbide dinitrate or hydralazine or any of the components of it. It is also contraindicated in patients who are allergic to organic nitrates. This combination should not use in patients who are taking PDE-5 inhibitors, such as avanafil, sildenafil, tadalafil, or vardenafil. Concomitant use can cause severe hypotension, syncope, or myocardial ischemia. It should not use in patients who are taking the soluble guanylate cyclase (sGC) stimulator riociguat. Concomitant use can cause hypotension. **Side-effects:** The most common side effects are headache, dizziness, asthenia, nausea and hypotension. **Warnings and precautions**: **Hypotension:** Symptomatic hypotension, particularly with upright posture, may occur with even small doses of this combination. **Systemic Lupus Erythematosus** Hydralazine hydrochloride has been reported to cause a drug-induced systemic lupus erythematosus (SLE) syndrome	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
130.	Drug International Ltd (Unit-2) Plot # 13A & 14A,	Enzalutamide 40mg flim coated Tablet	Enzalutamide INN 40.00mg Tablet.	Anticancer Code:10	Enzalutamide is indicated for the treatment of patients with castration-resistant prostate cancer	**Contraindication:** There is no available data. **Precaution:** Caution should be exercised	Enzalutamide 40mg Soft Gelatin Capsule	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Tongi I/A, Tongi, Gazipur.				(CRPC), metastatic castration-sensitive prostate cancer (mCSPC).	when using Enzalutamide in patients with Seizure, Posterior Reversible Encephalopathy Syndrome (PRES), Hypersensitivity, Ischemic Heart Disease, Falls and Fractures. **Warning:** A very bad and sometimes deadly brain problem called posterior reversible encephalopathy syndrome (PRES) has happened with Enzalutamide. **Side effects:** The following clinically significant adverse reactions are described in detail in other labeling sections: Seizure, Posterior Reversible Encephalopathy Syndrome (PRES), Hypersensitivity, Ischemic Heart Disease, Falls and Fractures.				করা হলো।
131.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Enzalutamide 80mg film coated Tablet.	Enzalutamide INN 80.00mg Tablet.	Anticancer Code:10	Enzalutamide is indicated for the treatment of patients with castration-resistant prostate cancer (CRPC), metastatic castration-sensitive prostate cancer (mCSPC).	**Contraindication:** There is no available data. **Precaution:** Caution should be exercised when using Enzalutamide in patients with Seizure, Posterior Reversible Encephalopathy Syndrome (PRES), Hypersensitivity, Ischemic Heart Disease, Falls and Fractures. **Warning:** A very bad and sometimes deadly brain problem called posterior reversible encephalopathy syndrome (PRES) has happened with Enzalutamide. **Side effects:** The following clinically significant adverse reactions are described in detail in other labeling sections: Seizure, Posterior Reversible Encephalopathy Syndrome (PRES), Hypersensitivity, Ischemic Heart Disease, Falls and Fractures.	Enzalutamide 40.00mg Soft Gelatin Capsule.	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
132.	Drug International Ltd. 252, Tongi I/A Tongi, Gazipur	Levothyroxine Sodium 25 mcg Soft Capsule	Levothyroxine Sodium Pentahydrate BP 27.82 mcg Eq. to 25mcg Levothyroxine Sodium	Thyroid & Anti-Thyroid Preparation Therapeutic Code: 074	It is L-thyroxine (T4) indicated for the treatment of **Hypothyroidism:** As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or	**Contraindication:** It is contraindicated in patients with uncorrected adrenal insufficiency. **Precaution:** Caution should be exercised when it is using in patients with Cardiovascular disease,Myxedema coma,	12.5mcg, 25 mcg, 50mcg & 100mcg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					acquired hypothyroidism. Specific indications: Primary (Thyroidal), Secondary (Pituitary), and tertiary (hypothalamic) hypothyroidism and subclinical hypothyroidism.**Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression:** As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.	Acute adrenal crisis in patients with concomitant adrenal insufficiency, Prevention of hyperthyroidism or incomplete treatment of hypothyroidism, Worsening of diabetic control etc. **Warning:** There is no data available. **Side effects:** Adverse reactions associated with Levothyroxine therapy are primarily those of hyperthyroidism due to therapeutic overdosage: arrhythmias, myocardial infarction, dyspnea, muscle spasm, headache, nervousness, irritability, insomnia, tremors, muscle weakness, increased appetite, weight loss, diarrhea, heat intolerance, menstrual irregularities, and skin rash.				
133.	Drug International Ltd. 252, Tongi I/A Tongi, Gazipur	Levothyroxine Sodium 50 mcg Soft Capsule	Levothyroxine Sodium Pentahydrate BP 55.63 mcg eq. to 50mcg Levothyroxine Sodium	Thyroid & Anti-Thyroid Preparation Therapeutic Code: 074	It is L-thyroxine (T4) indicated for the treatment of **Hypothyroidism:** As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. Specific indications: Primary (Thyroidal), Secondary (Pituitary), and tertiary (hypothalamic) hypothyroidism and subclinical hypothyroidism.**Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression:** As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.	**Contraindication:** It is contraindicated in patients with uncorrected adrenal insufficiency. **Precaution:** Caution should be exercised when it is using in patients with Cardiovascular disease,Myxedema coma, Acute adrenal crisis in patients with concomitant adrenal insufficiency, Prevention of hyperthyroidism or incomplete treatment of hypothyroidism, Worsening of diabetic control etc. **Side effects:** Adverse reactions associated with Levothyroxine therapy are primarily those of hyperthyroidism due to therapeutic overdosage: arrhythmias, myocardial infarction, dyspnea, muscle spasm, headache, nervousness, irritability, insomnia, tremors, muscle weakness, increased appetite, weight loss, diarrhea, heat intolerance, menstrual irregularities, and skin rash.	12.5mcg, 25 mcg, 50mcg & 100mcg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
134.	Drug International Ltd. 252, Tongi I/A Tongi, Gazipur.	Levothyroxine Sodium Pentahydrate 14.46 mcg (Eqv. to 13mcg Levothyroxine Sodium) Soft Capsule	Levothyroxine Sodium Pentahydrate BP 14.46 mcg (Eqv. to 13mcg Levothyroxine Sodium)	Thyroid & Anti-Thyroid Preparation Code: 074	It is L-thyroxine (T4) indicated for the treatment of **Hypothyroidism :** As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. Specific indications: Primary (Thyroidal), Secondary (Pituitary), and tertiary (hypothalamic) hypothyroidism and subclinical hypothyroidism.**Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression:** As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.	**Contraindication:** It is contraindicated in patients with uncorrected adrenal insufficiency. **Precaution:**Caution should be exercised when it is using in patients with Cardiovascular disease,Myxedema coma, Acute adrenal crisis in patients with concomitant adrenal insufficiency, Prevention of hyperthyroidism or incomplete treatment of hypothyroidism, Worsening of diabetic control etc. **Warning:** There is no data available. **Side effects:** Adverse reactions associated with Levothyroxine therapy are primarily those of hyperthyroidism due to therapeutic overdosage: arrhythmias, myocardial infarction, dyspnea, muscle spasm, headache, nervousness, irritability, insomnia, tremors, muscle weakness, increased appetite, weight loss, diarrhea, heat intolerance, menstrual irregularities, and skin rash.	12.5mcg, 25 mcg, 50mcg & 100mcg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
135.	Drug International Ltd. 252, Tongi I/A Tongi, Gazipur.	Levothyroxine Sodium Pentahydrate 111.26 mcg (Eqv. to 100 mcg Levothyroxine Sodium) Soft Capsule	Levothyroxine Sodium Pentahydrate BP 111.26mcg (Eqv. to 100mcg Levothyroxine Sodium)	Thyroid & Anti-Thyroid Preparation Code: 074	It is L-thyroxine (T4) indicated for the treatment of **Hypothyroidism :** As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. Specific indications: Primary (Thyroidal), Secondary (Pituitary), and tertiary (hypothalamic) hypothyroidism and subclinical hypothyroidism.**Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression:** As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated	**Contraindication:** It is contraindicated in patients with uncorrected adrenal insufficiency. **Precaution:** Caution should be exercised when it is using in patients with Cardiovascular disease,Myxedema coma, Acute adrenal crisis in patients with concomitant adrenal insufficiency, Prevention of hyperthyroidism or incomplete treatment of hypothyroidism, Worsening of diabetic control etc. **Warning:** There is no data available. **Side effects:** Adverse reactions associated with Levothyroxine therapy are primarily those of hyperthyroidism due to therapeutic overdosage: arrhythmias, myocardial	12.5mcg, 25 mcg, 50mcg & 100mcg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					thyroid cancer.	infarction, dyspnea, muscle spasm, headache, nervousness, irritability, insomnia, tremors, muscle weakness, increased appetite, weight loss, diarrhea, heat intolerance, menstrual irregularities, and skin rash.				
136.	Drug International Ltd (Unit-3) 31/1, Satrong Road, Gopalpur, Tongi Industrial Area Gazipur, Bangladesh Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Aspirin 300mg, Paracetamol 200mg and Caffeine 45mg Tablet.	Aspirin BP 300mg, Paracetamol BP 200mg and Caffeine BP 45mg.	Analgesic Code: 006	It is indicated For the treatment of mild to moderate pain including headache, migraine, neuralgia, toothache, sore throat, period pains, symptomatic relief of sprains, strains, rheumatic pain, sciatica, lumbago, fibrositis, muscular aches and pains, joint swelling and stiffness, influenza, feverishness and feverish colds.	**Contraindication:** Peptic ulceration and those with a history of peptic ulceration; haemophilia; concurrent anti-coagulant therapy; hypersensitivity to aspirin, paracetamol and/or other constituents; children under 16 years and when breast feeding because of possible risk of Reye's Syndrome. **Precaution:** Hypersensitivity-asthma: aspirin may provoke or worsen asthma. There is a possible association between aspirin and Reye's syndrome when given to children. Reye's syndrome is a very rare disease, which affects the brain and liver and can be fatal. For this reason aspirin should not be given to children under 16 years unless specifically indicated (e.g. for Kawasaki's disease). **Warning:** As per precaution. **Side effects:** Side effects include: gastro-intestinal irritation with slight asymptomatic blood loss, Increased bleeding time, Bronchospasm and skin reactions in hypersensitive patients, gastro-intestinal haemorrhage, occasionally major. It may precipitate gout in susceptible individuals. Possible risk of Reye's Syndrome in children, hypersensitivity including skin rash.	New	UK-MHRA	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
137.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh Drug International Ltd, Unit-2	Azacitidine 200mg Tablet	Azacitidine INN 200mg	Therapeutic Class: Anti-cancer Therapeutic Code:010	It is a nucleoside metabolic inhibitor indicated for continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy	**Contraindications:** History of severe hypersensitivity to azacitidine or its components **Side effect:** The most common adverse reactions (≥ 10%) are nausea, vomiting, diarrhea, fatigue/asthenia, constipation, pneumonia, abdominal pain, arthralgia, decreased appetite, febrile neutropenia, dizziness, and pain in extremity. **Warning and Precautions:** • Risks of Substitution with Other Azacitidine Products: Do not substitute ONUREG for intravenous or subcutaneous azacitidine • Myelosuppression: Monitor complete blood counts every other week for the first 2 cycles and prior to the start of each cycle thereafter. Increase monitoring to every other week for the 2 cycles after any dose reduction. Withhold and then resume at same or reduced dose or discontinue ONUREG based on severity	100mg/vial In‡jvection	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
138.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh Drug International Ltd, Unit-2 EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagnj, BANGLADESH	Azacitidine 300mg Tablet	Azacitidine INN 300mg	Anti-cancer Therapeutic Code:010	It is a nucleoside metabolic inhibitor indicated for continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy	**Contraindications:** History of severe hypersensitivity to azacitidine or its components **Side effect:** The most common adverse reactions (≥ 10%) are nausea, vomiting, diarrhea, fatigue/asthenia, constipation, pneumonia, abdominal pain, arthralgia, decreased appetite, febrile neutropenia, dizziness, and pain in extremity. Warning and Precautions: • Risks of Substitution with Other Azacitidine Products: Do not substitute ONUREG for intravenous or subcutaneous azacitidine • Myelosuppression: Monitor complete blood counts every other week for the first 2 cycles and prior to the start of each cycle thereafter. Increase monitoring to every other week for	100mg/vial In‡jvection	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						the 2 cycles after any dose reduction. Withhold and then resume at same or reduced dose or discontinue ONUREG based on severity. • Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of the potential risk to a fetus and use of effective contraception.				
139.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh Drug International Ltd, Unit-2	Panitumumab 400mg/20ml In‡jvection	Panitumumab INN 400mg/20ml	Anti-cancer Therapeutic Code:010	Vectibix is an epidermal growth factor receptor (EGFR) antagonist indicated for the treatment of wild-type RAS (defined as wild-type in both KRAS and NRAS as determined by an FDA-approved test for this use) metastatic colorectal cancer (mCRC): • In combination with FOLFOX for first-line treatment. • As monotherapy following disease progression after prior treatment with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy. • Limitation of Use: Vectibix is not indicated for the treatment of patients with RAS-mutant mCRC or for whom RAS mutation status is unknown.	**Contraindications:** None **Side effect:** Most common adverse reactions (≥ 20%) of Vectibix as monotherapy are skin rash with variable presentations, paronychia, fatigue, nausea, and diarrhea. Most common adverse reactions (≥ 20%) in clinical trials of Vectibix in combination with FOLFOX chemotherapy are diarrhea, stomatitis, mucosal inflammation, asthenia, paronychia, anorexia, hypomagnesemia, hypokalemia, rash, acneiform dermatitis, pruritus, and dry skin. Warning & Precautions: • Dermatologic and Soft Tissue Toxicity: Monitor for dermatologic and soft tissue toxicities and withhold or discontinue Vectibix for severe or life-threatening complications. Limit sun exposure. • Increased tumor progression, increased mortality, or lack of benefit in patients with RAS-mutant mCRC. • Electrolyte Depletion/Monitoring: Monitor electrolytes and institute appropriate treatment. • Infusion Reactions: Terminate the infusion for severe infusion reactions. • Pulmonary Fibrosis/Interstitial Lung Disease (ILD): Permanently discontinue Vectibix in patients developing ILD. • Ocular Toxicities: Monitor for keratitis, ulcerative keratitis, or corneal perforation.	200mg/vial Injection	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Interrupt or discontinue Vectibix for acute or worsening keratitis, ulcerative keratitis, or corneal perforation. • Embryo-fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to the fetus and to use effective contraception during treatment with Vectibix and for 2 months after the last dose.				
140.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh Drug International Ltd, Unit-2 Incepta Pharmaceuticals Ltd.; Savar, Dhaka	Dostarlimab 500mg/10ml Injection or, Dostarlimab 50mg/ml Injection	Dostarlimab INN (as Dostarlimab gxly) 500mg/10ml or, Dostarlimab 50mg/ml Injection	Therapeutic Class: Anti-cancer Therapeutic Code:010	it is a programmed death receptor-1 (PD-1)–blocking antibody indicated for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced: • endometrial cancer, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen, or • solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options. These indications are approved under accelerated approval based on tumor response rate and durability of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial.	**Contraindications:** None **Side effect:** Most common adverse reactions (≥20%) in patients with dMMR solid tumors are fatigue/asthenia, anemia, diarrhea, and nausea. Most common Grade 3 or 4 laboratory abnormalities (≥2%) are decreased lymphocytes, decreased sodium, increased alkaline phosphatase, and decreased albumin. Warning & Precautions: Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue, including the following: immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immune-mediated nephritis with renal dysfunction, immune-mediated dermatologic adverse reactions, and solid organ transplant rejection. Monitor for signs and symptoms of immune-mediated adverse reactions. Evaluate clinical chemistries, including liver enzymes, creatinine, and thyroid function, at baseline and periodically during treatment. Withhold or permanently discontinue JEMPERLI and administer corticosteroids based on the severity of reaction • Infusion-related reactions: Interrupt, slow the rate of infusion, or permanently discontinue JEMPERLI based on severity of	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						reaction. • Complications of allogeneic hematopoietic stem cell transplantation (HSCT): Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after being treated with a PD-1/PD-L1–blocking antibody. • Embryo-fetal toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.				
141.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh Beximco Pharmaceuticals Ltd. Drug International Ltd, Unit-3 The ACME Laboratories Ltd. Dhamrai, Dhaka Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka. EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, BANGLADESH M/s Orion Pharma Ltd. D/28/2, Sumilpara,	Itopride Hydrochloride 50mg Tablet	Itopride Hydrochloride INN 50mg	Antiemetic Therapeutic Code:018	Itopride hydrochloride is used in the treatment of gastrointestinal symptoms of functional, nonulcer dyspepsia (chronic gastritis) i.e., sensation of bloating, early satiety, upper abdominal pain or discomfort, anorexia, heartburn, nausea and vomiting.	**Contraindication:** Itopride hydrochloride is contraindicated in patients with known hypersensitivity to itopride hydrochloride or any of the excipients. Itopride hydrochloride should not be used in patients in whom an increase in gastrointestinal motility could be harmful, e.g. gastrointestinal hemorrhage, mechanical obstruction or perforation. **Side-effects:** The most common side-effects of itopride include mild to moderate abdominal pain and diarrhea. Some other side effects that may occur include: rash, giddiness, exhaustion, back or chest pain, increased salivation, constipation headache, sleeping disorder, dizziness, galactorrhea, andgynecomastia disorders, dizziness, galactorrhea, andgynecomastia. **WARNING AND PRECAUTIONS** Itopride hydrochloride enhances the action of acetylcholine and may produce cholinergic side effects.	New	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Siddhirgan‡jv, Narayanagng-1431 Navana Pharmaceuticals Limited									
142.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh Drug International Ltd, Unit-3	Primidone 25mg Tablet	Primidone USP 25mg	Anti-convulsants	Primidone used alone or concomitantly with other anticonvulsants, is indicated in the control of grand mal, psychomotor, and focal epileptic seizures. It may control grand mal seizures refractory to other anticonvulsant therapy.	**Contra-indication:** Primidone is contraindicated in: 1) patients with porphyria and 2) patients who are hypersensitive to phenobarbital. **Side-effect:** The most frequently occurring early side effects are ataxia and vertigo. These tend to disappear with continued therapy, or with reduction of initial dosage. Occasionally, the following have been reported: nausea, anorexia, vomiting, fatigue, hyperirritability, emotional disturbances, sexual impotency, diplopia, nystagmus, drowsiness, and morbilliform skin eruptions. Granulocytopenia,	New	রেফারেন্স নাই	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করা হলো।
143.	Healthcare Pharmaceuticals Ltd	Azilsartan Kamedoxomil 20mg + Amlodipine 5 mg	Azilsartan Kamedoxomil 20mg + Amlodipine 5 mg	Antihypertensive Therapeutic code:022	Azilsartan Kamedoxomil is an angiotensin II receptor blocker and amlodipine are a calcium channel blocker. It is indicated for the treatment of hypertension to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.	**Side Effects:** The most common adverse reaction in adults was diarrhea (2%). **Contraindication:** Do not co-administer aliskiren-containing products in patients with diabetes. **WARNINGS AND PRECAUTIONS:** Correct volume or salt depletion prior to administration of this drug. Monitor for worsening renal function in patients with renal impairment.	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
144.	Healthcare Pharmaceuticals Ltd	Azilsartan Kamedoxomil 20 mg + Amlodipine BP 2.5 mg	Azilsartan Kamedoxomil 20 mg + Amlodipine BP 2.5 mg	Antihypertensive Therapeutic code: 022	Azilsartan Kamedoxomil is an angiotensin II receptor blocker and amlodipine is a calcium channel blocker. It is indicated for the treatment of hypertension to lower blood pressure. Lowering blood pressure reduces the risk of fatal	**Side Effects:** The most common adverse reaction in adults was diarrhea (2%). **Contraindication:** Do not co-administer aliskiren-containing products in patients with diabetes. **WARNINGS AND PRECAUTIONS:** • Correct volume or salt depletion	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.	prior to administration of this drug. ● Monitor for worsening renal function in patients with renal impairment.				
145.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka Nipro JMI Pharma Ltd. Navana Pharmaceuticals Limited	Erdosteine INN 175mg/5ml Powder for Suspension	Erdosteine INN 175mg/5ml	Antitussives, Expectorants and Mucolytic Therapeutic Code: 031	Erdosteine is indicated for the treatment of acute bronchitis, chronic bronchitis and its exacerbations. Respiratory disorders characterized by abnormal bronchial secretions and impaired mucus transport.	**Contraindication:** Known hypersensitivity towards the product. Because of a possible interference of the product metabolites with the methionine metabolism, Erdosteine is contraindicated in patients suffering from hepatic cirrhosis and deficiency of the cystathionine-synthase enzyme. Phenylketonuria, due to the presence of aspartame. **Side-effects:** No gastro-intestinal nor systemic side effects due to the drug have been observed. **Warnings and Precautions:** The product contains sucrose. Keep this into consideration in case of diabetes or low-calorie diets.	Erdosteine 300mg Capsule	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
146.	Incepta Pharmaceuticals Ltd.; Dhamrai Unit, Dhaka Navana Pharmaceuticals Limited General Pharmaceuticals Ltd.	Allantoin USP 0.5g/100g Gel	Allantoin USP 0.5g/100g	Skin and Mucous Membrane Preparations Therapeutic Code: 071	Temporarily protects and helps relieve chapped or cracked skin. Clinically shown to visibly reduce the appearance of scars. Unique Triple-Action Formula penetrates beneath the surface of the skin to help: Collagen production Cell renewal Lock-in moisture	**Contraindication:** Hypersensitivity to any of the gel ingredients. **Side-effects:** None **Warning & Precaution:** For external use only. When using this product • do not get into eyes. Stop use and ask a doctor if • Condition worsens • Symptoms last more than 7 days or clear	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						up and occur again within a few days. Do not use on • Deep or puncture wounds • Animal bites • Serious burns Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.				
147.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Elemental Calcium 10.0gm + Cholecalciferol 0.0005gm/100ml Oral Liquid	Hydroxyapatite powder Ph. Grade 37.736gm eq. to Elemental Calcium 10.0gm + Cholecalciferol USP 0.0005g/100ml	Metals, Salts, Minerals and Calcium Preparations Therapeutic Code: 062	It can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/ nutrients] should not replace a balanced diet (or words to that effect). Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D	**Contraindication:** Hypercalcemia and hyperparathyroidism, Hypercalciuria and nephrolithiasis, Hypersensitivity to any component of this product, Severe renal insufficiency, Concomitant digoxin therapy (requires careful monitoring of serum calcium level) **Side-effects:** Orally administered Calcium Carbonate may be irritating to the GI tract. It may also cause constipation. Hypercalcemia is rarely produced by administration of calcium alone, but may occur when large doses are given to patients with chronic renal failure.	Cholecalciferol (Vit. D3) 25 mcg/5ml Syrup	TGA	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
148.	Popular Pharmaceuticals Ltd., Tongi, Gazipur Navana Pharmaceuticals Ltd. Rupgang, Narayanagng Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Lornoxicam 8 mg Tablet	Lornoxicam INN 8mg	NSAID Therapeutic Code: 006	It is used for ➢ short term relief of acute mild to moderate pain, ➢ symptomatic relief of pain and inflammation in osteoarthritis and ➢ symptomatic relief of pain and inflammation in rheumatoid arthritis	**Contraindications:** Hypersensitivity to lornoxicam, or any of its excipients, hypersensitivity (symptoms like asthma, rhinitis, angioedema or urticaria) to other non-steroidal anti-inflammatory drugs, including acetylic salicylic acid, gastro-intestinal bleeding, cerebrovascular bleeding or other bleeding disorders, active or history of recurrent peptic ulceration/ hemorrhage (two or more distinct episodes of proven ulceration or bleeding), severe hepatic impairment, severe renal impairment (Serum creatinine >700 µmol/L), Thrombocytopenia, History of	4 mg Tablet; 8 mg/2ml In‡jvection	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	M/s Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirgan‡jv, Narayanagng					gastrointestinal bleeding or perforation, related to previous NSAIDs therapy, severe heart failure, The third trimester of pregnancy. **Side Effects:** The most commonly observed adverse events of NSAIDs are gastrointestinal in nature. Peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, may occur. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease have been reported following administration of NSAIDs. Less frequently, gastritis has been observed. Approximately 20% of patients treated with lornoxicam can be expected to experience adverse reactions. The most frequent adverse effects of lornoxicam include nausea, dyspepsia, indigestion, abdominal pain, vomiting, and diarrhea. These symptoms have generally occurred in less than 10% of patients in available studies. Oedema, hypertension, and cardiac failure, have been reported in association with NSAID treatment. **Warning & Precautions:** : Lornoxicam should be taken carefully when someone has impaired kidney function; • Someone has a history of high blood pressure or heart failure; • Someone suffer from ulcerative colitis or Crohn's disease; • Someone has a history of bleeding tendency; • Someone has a history of asthma;				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						• Someone suffer from SLE (lupus erythematosus, a rare immunological)				
149.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur DBL Pharmaceuticals Ltd., Surabari, Kashimpur, Gazipur Unimed Unihealth Pharmaceuticals Ltd	Dextromethorphan Hydrobromide 45mg + Bupropion HCl 105mg Extended Release Film Coated Bilayer Tablet	Dextromethorphan Hydrobromide USP 45mg + Bupropion HCl USP 105mg	Antidepressants Therapeutic code: 014	It is a combination of dextromethorphan, an uncompetitive N-methyl D-aspartate (NDMA) receptor antagonist and sigma-1 receptor agonist, and bupropion, an aminoketone and CYP450 2D6 inhibitor, indicated for the treatment of major depressive disorder (MDD) in adults.	Warning: Suicidal Thoughts and Behaviors Contraindication: ● Seizure disorder. ● Current or prior diagnosis of bulimia or anorexia nervosa. ● Abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs. ● Use with an MAOI or within 14 days of stopping treatment with it . Do not use it within 14 days of discontinuing an MAOI. ● Known hypersensitivity to bupropion, dextromethorphan, or other components of it. Side Effects: Dizziness, headache, diarrhea, somnolence, dry mouth, sexual dysfunction, and hyperhidrosis	Bupropion Hydrochloride 150mg Sr Tablet & Dextromethorphan Hydrobromide 60 mg + Guaifenesin 1200 mg XR Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
150.	Pharmasia Limited, Gojariapara. Bhawal Mirzapur, Gazipur The ACME Laboratories Ltd. Dhamrai, Dhaka Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Sodium Alginate 10.0gm + Potassium Bicarbonate 2.0gm + Calcium Carbonate 2.0gm)/100ml oral suspension	Sodium Alginate BP 10.0gm + Potassium Bicarbonate USP 2.0 gm + Calcium Carbonate BP 2.0gm/100ml	Antacids Therapeutic Code:007	For the relief of the symptoms associated with reflux oesophagititis, hiatus hernia and all cases of epigastric distress where the underlying causes is gastro-esophageal reflux.	**Contraindication:** Hypersensitivity to sodium alginate, potassium bicarbonate, calcium carbonate or to any of the excipients listed in the product. This product should not be used in patients with moderate or severe renal insufficiency. **Side-effects:** Very rarely (less than 1 in 10,000 patients treated) an allergic reaction to the ingredients may occur. Symptoms of this may include: skin rash itching, difficulty breathing, dizziness, swelling of the face, tongue or throat. If you experience these or any other side effects, stop taking the product and consult your doctor immediately. Other side effects of unknown frequency may include constipation, irritability, muscle twitching or muscle cramps, indigestion that	Sodium Alginate USP 5.0gm + Sodium Bicarbonate USP 2.67 gm + Calcium Carbonate BP 1.6gm)/100ml oral suspension	TGA	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						comes back when you stop taking the tablets and high levels of calcium in the blood. Flatulence, diarrhoea, constipation, upper GI discomfort, allergic reactions etc are rare manifestation. Hypercalcaemia due to prolong use has rarely been reported. **Precaution and Warning:** This medicine contains sodium (9.72 mmol per 4 tablet dose) and calcium (7.5 mmol per 4 tablet dose). If you have been advised to follow a diet restricted in either of these please consult your doctor. The maximum recommended daily dose of this medicinal product contains 894.26 mg sodium (found in table salt). This is equivalent to 44.71% of the adult recommended maximum daily dietary intake for sodium. Talk to your doctor or pharmacist if you need this product on a daily basis for a prolonged period of time, especially if you have been advised to follow a low salt (sodium) diet. This medicine contains 5.6 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. These tablets contain carmoisine lake (E122) which may cause allergic reactions. This product can mask symptoms of other more serious, underlying medical conditions. If symptoms persist, or treatment is required for more than seven days continuously, please speak to your doctor or pharmacist.				
151.	Pharmasia Limited, Gojariapara. Bhawal Mirzapur, Gazipur Square	Sodium Picosulfate 7.5mg/ ml Oral Drops	Sodium Picosulfate BP 7.5 mg/ ml	laxative Therapeutic Code:060	For the treatment of Constipation.	**Contraindication:** It is contraindicated in patient with Ileus or intestinal obstruction. Severe painful and/or feverish acute abdominal conditions (e.g. Appendicitis) potentially associated with nausea and	10 mg Tablet & 0.1% Oral Solution	TGA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Pharmaceuticals Ltd., Salgaria, Pabna Beacon Pharmaceuticals Limited, Kathali, Bhaluka, Mymensingh					vomiting Acute inflammatory bowel diseases. Severe dehydration. ● Known hypersensitivity to sodium Pico sulfate or any other component of the product Rare hereditary conditions that may be incompatible with an excipient of the product. **Side-effects:** Immune system disorders Not known: Hypersensitivity ● Nervous system disorders Uncommon: Dizziness Not known: Syncope Dizziness and syncope occurring after taking sodium picosulfate appear to be consistent with a vasovagal response (for example, due to abdominal spasm, defecation). ● Gastrointestinal disorders Very common: Diarrhea Common: Abdominal discomfort, abdominal pain and abdominal cramps. Uncommon: Nausea, vomiting. ● Skin and subcutaneous tissue disorders Not known: Skin reactions such as angioedema, drug eruption, rash, pruritus. **Warnings and precautions**: ● As with all laxatives, it should not be taken on a continuous daily basis for more than five days without investigating the cause of constipation. ● Prolonged excessive use may lead to fluid and electrolyte imbalance and hypokalemia. ● It should not be taken by children under 10 years without medical advice. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						women, children and high-risk groups such as patients with liver disease, or epilepsy.				
152.	Radiant Pharmaceuticals Limited, B-34 & B-46, BSCIC I/E, Tongi, Gazipur The ACME Laboratories Ltd. Dhamrai, Dhaka	Bromazepam BP 1.5mg Tablet	Bromazepam BP 1.50mg		Bromazepam is indicated for anxiety, tension and other somatic or psychiatric complaints associated with the anxiety syndrome. It can also be used as an adjunct for treatment of anxiety or excitation associated with psychiatric disorders, such as mood disorders or schizophrenia. Benzodiazepines are only indicated when the disorder is severe, disabling or subjecting the individual to extreme distress.	**Contraindications:** Bromazepam is contraindicated in patients with: •Known hypersensitivity to benzodiazepines or any of the excipients. • Severe respiratory insufficiency. •Severe hepatic impairment as benzodiazepines may precipitate hepatic encephalopathy • Sleep apnea syndrome. **Side Effect::** Psychiatric Disorders, Depression, Dependence, Nervous System Disorder, Eye Disorders, Gastrointestinal Disorders, Skin and Subcutaneous Tissue Disorders, Musculoskeletal and Connective Tissue Disorders	3 mg Tablet	রেফারেন্স নাই	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করা হলো।
153.	Synovia Pharma PLC.	Amoxicillin 12 g + Clavulanic Acid 0.858g / 100ml Powder for Suspension	Amoxicillin Trihydrate BP 13.800gm eq. to Amoxicillin 12.00 gm + Diluted Potassium Clavulanate USP 2.059gm eq. to 0.858 gm /100ml	Antibiotic Therapeutic Code: 023	Acute bacterial sinusitis (adequately diagnosed), Acute otitis media, Acute exacerbations of chronic bronchitis (adequately diagnosed), Community acquired pneumonia, Cystitis, Pyelonephritis, Skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis, Bone and joint infections, in particular osteomyelitis.	**Contra-indication**: Hypersensitivity to amoxicillin, other penicillin, or any of the excipients, History of a severe immediate hypersensitivity reaction (e.g., anaphylaxis) to another beta-lactam agent (e.g., a cephalosporin, carbapenem or monobactam), History of jaundice/hepatic impairment due to amoxicillin/clavulanic acid. **Side-effects:** Diarrhoea, indigestion, nausea, vomiting and candidiasis have been reported. Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis) has been reported rarely. Nausea although uncommon, is more often associated with higher oral dosages. Urticarial and erythematous rashes sometimes occur. In common with other beta-lactam antibiotics, angioedema and anaphylaxis may be reported rarely. **Warning and Precautions:** It is strongly	Amoxicillin 125mg + Clavulanic acid 31.25mg /5ml PFS Amoxicillin 400mg + Clavulanic acid 57.5mg /5ml PFS Amoxicillin 500mg + Clavulanic acid 125mg /5ml PFS	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						recommended that amoxicillin is not used to treat concurrent bacterial infections in patients with viral diseases (e.g., infectious mononucleosis) and in patients with lymphatic leukemia, because skin rashes (morbilliform eruptions) occur more frequently in such patients. Beta-lactams, including amoxicillin, predispose the patient to encephalopathy risk (which may include convulsions, confusion, impairment of consciousness, movement disorders), particularly in case of overdose or renal impairment. Acute pancreatitis has been observed within 2 weeks of treatment with amoxicillin + clavulanic acid. Patients should be informed about the signs and symptoms of serious skin manifestations and monitored closely. Treatment should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity. In patients with diabetes mellitus, the sugar content of suspension must be taken into consideration.				
154.	Synovia Pharma PLC General Pharmaceuticals Ltd.	Quetiapine XR 400mg Tablet	Quetiapine Fumarate USP 400 mg	Antipsychotic Therapeutic Code: 028	Quetiapine is indicated for the treatment of Acute and Chronic Psychoses, including Schizophrenia, Bipolar Disorder including treatment of manic episodes satisfying DSM-IV criteria for mania associated with bipolar disorder, treatment of depressive episodes associated with bipolar disorder, maintenance treatment of bipolar I disorder, in combination with a mood stabilizer, for the	**Contra-indication**: Quetiapine is contraindicated in patients who are hypersensitive to it. **Side-effects:** The most commonly reported Adverse Drug Reactions (ADRs) with Quetiapine are somnolence, dizziness, dry mouth, withdrawal (discontinuation) symptoms, elevations in serum triglyceride levels, elevations in total cholesterol (predominantly LDL cholesterol), decreases in HDL cholesterol, Metabolic changes	Quetiapine Fumarate 50mg XR Tablet, Quetiapine Fumarate 200mg XR Tablet	USFDA, BNF-83, Page (432-434)	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					prevention of recurrence of manic, depressive or mixed episodes.	(hyperglycemia, dyslipidemia, weight gain), decreased hemoglobin and extrapyramidal symptoms. **Warning and Precautions:** Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Quetiapine. is not approved for the treatment of patients with dementia-related psychosis. Depression is associated with an increased risk of suicidal thoughts, self-harm and suicide (suicide-related events). This risk persists until significant remission occurs. Quetiapine should be used with caution in patients with known cardiovascular disease, cerebrovascular disease, or other conditions predisposing to hypotension. As with other antipsychotics, caution is recommended when treating patients with a history of seizures. The safety and efficacy of Quetiapine during human pregnancy have not been established. Therefore, Quetiapine should only be used during pregnancy if the benefits justify the potential risks, and the administered dose and duration of treatment should be as low and as short as possible. Women who are breast-feeding should therefore be advised to avoid breast-feeding while taking Quetiapine. Quetiapine is not indicated for use in children and adolescents below 18 years of age.				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
155.	UniMed UniHealth Pharmaceuticals Ltd. B.K Bari, Gazipur Sadar, Gazipur	Mesalazine 500mg Suppository	Mesalazine BP 500mg	Non Steroidal AntiInflammatory Therapeutic Code: 064	It is indicated the management of mild and moderate episodes of ulcerative colitis that is limited to the rectum.	**Contra-indication**: Masalazine is contraindicated in cases of hypersensitivity to the active substance salicylates. Severe impairment of renal or hepatic function. **Side-effects:** The side effects of Mesalazine suppositories may occur severe skin reaction such as skin rash, mucosal lesions or any other sign of hypersensitivity. It also causes acute intolerance reaction such as abdominal cramps, acute abdominal pain, fever, severe headache and rash.	1 gm Suppository 400 mg Tablet 250mg Er Capsule 500 mg Er Capsule	BNF-83 Page:45	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
156.	UniMed UniHealth Pharmaceuticals Ltd. B.K Bari, Gazipur Sadar, Gazipur	Isoxsuprine Hydrochloride 10.00mg Tablet	Isoxsuprine Hydrochloride USP 10.00mg	Peripheral vasodilators Therapeutic Code: 075	It is indicated the cerebral and peripheral hemodynamics by reducing blood viscosity and vasodilation effect, and improves contraction and cramp of uterine muscle by myometrial relaxant effect. It is usually used to treat associated symptoms with sequela of head in‡jvury, peripheral circulatory disorder associated with arteriosclerosis obliterans / thrombophlebitis, dysmenorrhea, and for suppression of uterine contractions.	**Side-effects:** The most commonly reported adverse reactions include nausea, loss of appetite, diarrhea, palpitation, facial flush, headache, dizziness, sleepiness and sweating.	New	‡idv‡iÝ bvB	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করা হলো।
157.	The ACME Laboratories Ltd. Dhamrai, Dhaka The Ibn SINA Pharmaceuticals Ltd	Omeprazole BP 2mg + Sodium Bicarbonate BP 84mg/ml	Omeprazole BP 2 mg + Sodium Bicarbonate BP 84 mg/ mL Suspension, 100 & 200 ml	Unclassified Therapeutic Code: 075	Indicated for the treatment of active benign gastric ulcer & reduction of risk of upper gastrointestinal (GI) bleeding in critically ill patients.	**Contra-indications:** 1. Known hypersensitivity to any components of the formulation. 2. Patients receiving rilpivirine-containing products **Side effect:** Headache or abdominal pain may occur. **Warning & Precautions:** Most common adverse reactions (≥2%) are: headache,	New	USFDA	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						abdominal pain,nausea, diarrhea, vomiting, and flatulence.				
158.	The ACME Laboratories Ltd. Dhamrai, Dhaka General Pharmaceuticals Ltd. M/s Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirgan‡jv, Narayanagng-1431	Azelnidipine 8 mg Tablet	Azelnidipine INN 8 mg	Antihypertensive Therapeutic Code: 022	Hypertension	**Contraindications:** Women who may possibly be pregnant or are pregnant, patients with a history of hypersensitivity to any component of this drug, if combined with azole antifungals, (Itraconazole, Miconazole, etc.), HIV proteaseinhibitors (Ritonavir, Saquinavir, Indinavir, etc.) **Side-effect:** Headache, fast heart rate, the feeling of fast or uneven heartbeat (palpitations), sudden reddening of face, neck or upper chest (flushing), ankle swelling. **Warning & Precautions:** Patients with serious liver and kidney dysfunction. The drug is metabolized in the liver. Also in patients with severe renal dysfunction in general, there is a possibility that the renal function is reduced.	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
159.	The ACME Laboratories Ltd. Dhamrai, Dhaka General Pharmaceuticals Ltd. M/s Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirgan‡jv, Narayanagng-1431	Azelnidipine 16mg Tablet	Azelnidipine INN 16mg	Antihypertensive Therapeutic Code: 022	Hypertension	**Contraindications:** Women who may possibly be pregnant or are pregnant, patients with a history of hypersensitivity to any component of this drug, if combined with azole antifungals, (Itraconazole, Miconazole, etc.), HIV proteaseinhibitors (Ritonavir, Saquinavir, Indinavir, etc.) **Side-effect:** Headache, fast heart rate, the feeling of fast or uneven heartbeat (palpitations), sudden reddening of face, neck or upper chest (flushing), ankle swelling. **Warning & Precautions:** Patients with serious liver and kidney dysfunction. The drug is metabolized in the liver. Also in patients with severe renal dysfunction in general, there is a possibility	**New**	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						that the renal function is reduced.				
160.	The ACME Laboratories Ltd. Dhamrai, Dhaka M/s Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirgan‡jv, Narayanagng-1431	Pridinol Mesilate 3 mg Tablet	Pridinol Mesilate 3mg	Skeleton Muscle Relaxants Therapeutic Code: 070	Indicated for the treatment of cramp like muscle tension/spasm, neck spasm, low back pain, General muscle pain.	**Contraindications:** Contraindicated with certain medications that are used for overactive bladder, urinary incoontinence, asthema treatment and in parkinson disease. **Side effects:** Dry mouth, thirst, temporary visual disorder, hallucinations, problems with urination. **Warning & Precautions:** Take special care if patient has liver/kidney problem, 65 years or older, hypotension.	New	BNF-81	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
161.	The ACME Laboratories Ltd. Dhamrai, Dhaka Navana Pharmaceuticals Ltd.	Lascufloxacin HCl INN 75 mg tablet	Lascufloxacin HCl INN 75 mg tablet	Anti-Infective Therapeutic Code: 023	Indicated for the treatment of otorhinolaryngological infections, Community acquired pneumonia, Respiratory tract infections.	**Contra indications:** Contraindicated in patients with a history of hypersensitivity to lascufloxacin or any other quinolone class of antibiotics and any component of this product. **Side effects:** Nausea, diarrhea, vomiting, abdominal pain or discomfort, and trouble sleeping, hyper sensitivity reactions. **Warning & Precautions:** Renal & hepatic impairement, pregnancy & lactation, if develop symptoms like vomiting, fatigue, dark urine, abdominal pain etc.	New	PMDA	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
162.	The ACME Laboratories Ltd. Dhamrai, Dhaka Incepta Pharmaceuticals Ltd, Dhamrai, Dhaka	Difamilast 0.3% Oint., 10gm	Difamilast 0.3% Oint., 10gm	Skin & Mucous Membrane Preparation Therapeutic Code: 071	Atopic Dermatitis	**Contraindications:** Patients with a history of hypersensitivity to the ingredients of this drug. **Side Effects:** The most commonly reported adverse reactions include pigmentation disorder, folliculitis (furuncle) and pruritus (itching). **Warning & Precautions:** Female patients with a possibility of pregnancy should avoid pregnancy while using this medicine and for a certain period of time after its completion.	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
163.	The ACME Laboratories Ltd. Dhamrai, Dhaka Incepta Pharmaceuticals Ltd, Dhamrai, Dhaka	Difamilast 1.0% Ointment	Difamilast 1.0%	Skin & Mucous Membrane Preparation Therapeutic Code: 071	Atopic Dermatitis	**Contraindications:** Patients with a history of hypersensitivity to the ingredients of this drug. **Side Effects:** The most commonly reported adverse reactions include pigmentation disorder, folliculitis (furuncle) and pruritus (itching). **Warning & Precautions:** Female patients with a possibility of pregnancy should avoid pregnancy while using this medicine and for a certain period of time after its completion.	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
164.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Ferric Citrate INN 250 mg Tab	Ferric Citrate INN 250 mg Tab	Vitamin & Combinations Therapeutic Code: 078	Hyperphosphatemia & Iron deficiency anemia	**Contraindications:** Iron overload syndromes. **Side Effects:** Most common adverse reactions (incidence ≥5%) are discolored feces, diarrhea, constipation, nausea, vomiting, cough, abdominal pain, and hyperkalemia. **Warning & Precautions:** Iron overload: Monitor ferritin and Transferrin saturation. Patients may require a reduction in dose or discontinuation of intravenous iron. Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years of age.	New	PMDA	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
165.	The ACME Laboratories Ltd. Dhamrai, Dhaka Renata Limited Rajendrapur, Gazipur	Valsartan 80mg + Cilnidipine 10 mg Tablet	Valsartan INN 80mg + Cilnidipine INN 10 mg	Antihypertensive Therapeutic Code: 022	Treatment of hypertension	**Contraindications:** Hypersensitive to any components of this product. Pregnant women or women having possibilities of being pregnant. Patients with diabetes mellitus who are receiving Aliskiren. **Side-effect::**Peripheral edema, nasal congestion, sore throat and discomfort when swallowing, upper respiratory tract infection, dizziness etc. **Warning & Precautions:** Avoid fetal or neonatal exposure, assess for hypotension, warn patients with severe obstructive coronary artery disease about the	New	PMDA	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						risk of myocardial infarction or increased angina, titrate slowly in patients with impaired hepatic or severely impaired renal function.				
166.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Aspirin BP 100 mg + Vonoprazan INN 10 mg Tablet	Aspirin BP 100 mg + Vonoprazan INN 10 mg	Unclassified Therapeutic Code: 075	Angina (chronic stable/ unstable angina), myocardial infarction, ischemic cerebrovascular disease (transient ischemic attack, cerebral infarction)	**Contraindications:** • If a long-term administration is performed, endoscopic examination is regularly conducted. • Patients who drink alcohol on a regular basis. •Patients with bronchial asthma or a history of it, renal disorder or a history of it. • Patients scheduled for surgery/cardiac catheter test/tooth extraction. **Side effects:** The most commonly reported adverse reactions include constipation, diarrhea, abdominal bloating, nausea, abdominal pain, itch, anemia, decreased blood pressure and edema. **Warning & Precautions:** ・ Use of this medicine for the treatment of cerebral infarction, try to maintain healthy blood pressure. ・ This medicine may induce or enhance gastrointestinal bleeding; therefore, avoid taking this medicine with any alcoholic beverage. If patients are scheduled for any treatment with bleeding, such as surgery, cardiac catheter test or tooth extraction while taking this medicine, then consultation with doctor is required.	New	PMDA	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
167.	The ACME Laboratories Ltd. Dhamrai, Dhaka Ziska Pharmaceuticals	Elobixibat 5 mg Tablet	Elobixibat INN 5 mg	Laxatives Therapeutic Code:060	Indicated for the treatment of Chronic constipation (excluding constipation caused by organic disease)	**Contra-indications:** None **Side effect:** Most common side effects are diarrhea, abdominal pain & vomiting. **Warning & Precautions:** Liver Test Abnormalities: Obtain baseline liver tests and	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Ltd. Beacon Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka. General Pharmaceuticals Ltd. M/s Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirgan‡jv, Narayanagng-1431					monitor during treatment. Dose reduction or treatment interruption may be required if abnormalities occur. Diarrhea: Treatment interruption or discontinuation may be required for persistent diarrhea.				
168.	The ACME Laboratories Ltd. Dhamrai, Dhaka Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh Ziska Pharmaceuticals Ltd. Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka. General Pharmaceuticals Ltd.	Naftopidil 25 mg Tablet	Naftopidil INN 25mg	Unclassified Therapeutic Code:075	It is used for the treatment of benign prostatic hyperplasia (BPH) and benign prostatic obstruction, associated with lower urinary tract symptoms (LUTS), hypertension, cardiac valve disease, and distal ureteral stones.	**Contraindications:** Naftopidil is contraindicated in patients with allergies to the drug. **Side effects:** The side effects are very few and usually mild with dizziness and low blood pressure. **Warning & Precautions:** Naftopidil should be taken with caution in people with liver or kidney disease, low blood pressure, prostate cancer history, or allergic to Naftopidil. For better results, Naftopidil should be used 30 minutes after a meal. Naftopidil may affect pregnant women and the fetus. This Naftopidil may enhance the risk of temporary loss of consciousness caused by an unexpected decrease in blood pressure. Patients taking Naftopidil should be cautioned about driving, operating machinery, or performing hazardous tasks as	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						it can cause drowsiness or dizziness. Naftopidil should not be used for children less than 18 years of age as safety and efficacy of Naftopidil for children has not established.				
169.	The ACME Laboratories Ltd. Dhamrai, Dhaka Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh General Pharmaceuticals Ltd. Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka.	Naftopidil 50 mg Tablet	Naftopidil INN 50 mg	Unclassified Therapeutic Code:075	It is used for the treatment of benign prostatic hyperplasia (BPH) and benign prostatic obstruction, associated with lower urinary tract symptoms (LUTS), hypertension, cardiac valve disease, and distal ureteral stones.	**Contraindications:** Naftopidil is contraindicated in patients with allergies to the drug. **Side effects:** The side effects are very few and usually mild with dizziness and low blood pressure. **Warning & Precautions:** Naftopidil should be taken with caution in people with liver or kidney disease, low blood pressure, prostate cancer history, or allergic to Naftopidil. For better results, Naftopidil should be used 30 minutes after a meal. Naftopidil may affect pregnant women and the fetus. This Naftopidil may enhance the risk of temporary loss of consciousness caused by an unexpected decrease in blood pressure. Patients taking Naftopidil should be cautioned about driving, operating machinery, or performing hazardous tasks as it can cause drowsiness or dizziness. Naftopidil should not be used for children less than 18 years of age as safety and efficacy of Naftopidil for children has not established.	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
170.	The ACME Laboratories Ltd. Dhamrai, Dhaka General Pharmaceuticals Ltd. Incepta pharmaceuticals Ltd,	Naftopidil 75 mg Tablet	Naftopidil INN 75 mg	Unclassified Therapeutic Code:075	It is used for the treatment of benign prostatic hyperplasia (BPH) and benign prostatic obstruction, associated with lower urinary tract symptoms (LUTS), hypertension, cardiac valve disease, and distal ureteral stones.	**Contraindications:** Naftopidil is contraindicated in patients with allergies to the drug. **Side effects:** The side effects are very few and usually mild with dizziness and low blood pressure. **Warning & Precautions:** Naftopidil should be taken with caution in people with liver or kidney disease, low blood pressure, prostate	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Zirabo, Savar, Dhaka.					cancer history, or allergic to Naftopidil. For better results, Naftopidil should be used 30 minutes after a meal. Naftopidil may affect pregnant women and the fetus. This Naftopidil may enhance the risk of temporary loss of consciousness caused by an unexpected decrease in blood pressure. Patients taking Naftopidil should be cautioned about driving, operating machinery, or performing hazardous tasks as it can cause drowsiness or dizziness. Naftopidil should not be used for children less than 18 years of age as safety and efficacy of Naftopidil for children has not established.				
171.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Efonidipine Hydrochloride Ethanolate 10 mg Tablet	Efonidipine Hydrochloride Ethanolate INN 10 mg	Antihypertensive Therapeutic code: 022	Essential hypertension, Parenchymal hypertension & Angina.	**Contra Indications:** Hypersensitive to Efonidipine or any of the excipients. **Side effects:** Hot flushes, facial flushing and headache, elevation in serum total cholesterol, ALT (SGPT), AST (SGOT). **Warning & Precautions:** Should be administered with caution in patients with hepatic impairment.	New	PMDA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
172.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Efonidipine Hydrochloride Ethanolate 20 mg Tablet	Efonidipine Hydrochloride Ethanolate INN 20 mg	Antihypertensive Therapeutic code: 022	Essential hypertension, Parenchymal hypertension & Angina.	**Contra Indications:** Hypersensitive to Efonidipine or any of the excipients. **Side effects:** Hot flushes, facial flushing and headache, elevation in serum total cholesterol, ALT (SGPT), AST (SGOT). **Warning & Precautions:** Should be administered with caution in patients with hepatic impairment.	New	PMDA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
173.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Renata Limited Rajendrapur, Gazipur Ziska Pharmaceuticals ltd. Organic Health Care Ltd., Gazipur Everest Pharmaceuticals Ltd. Beacon Pharmaceuticals Limited, Kathali, Bhaluka, Mymensingh	Deucravacitinib INN 6mg Tablet	Deucravacitinib INN 6mg	Immune-suppressant Therapeutic Code: 058	Deucravacitinib is a tyrosine kinase 2 (TYK2) inhibitor indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.	**Contraindication:** Known hypersensitivity to deucravacitinib or any of the excipients in Deucravacitinib. **Side-effects:** Most common adverse reactions (≥ 1%) are upper respiratory infections, blood creatine phosphokinase increased, herpes simplex, mouth ulcers, folliculitis and acne. **Warnings and Precautions**: Hypersensitivity: Hypersensitivity reactions such as angioedema have beenreported. Discontinue if a clinically significant hypersensitivity reactionoccurs. Infections: Deucravacitinib may increase the risk of infection. Avoid use inpatients with active or serious infection. If a serious infection develops, discontinue Deucravacitinib until the infection resolves. Tuberculosis: Evaluate for TB prior to initiating treatment with Deucravacitinib. Malignancy: Malignancies including lymphomas were observed in clinicaltrials with Deucravacitinib. Rhabdomyolysis and elevated CPK. Laboratory Abnormalities: Periodically evaluate serum triglycerides. Evaluate liver enzymes at baseline and thereafter in patients with known orsuspected liver disease. Immunizations:Avoid use with live vaccines. Potential Risks Related to JAK Inhibition: It is not known whether TYK2inhibition may be associated with the observed or potential adversereactions of JAK inhibition. Higher rates of all-cause mortality, includingsudden cardiovascular death, major adverse cardiovascular events, overallthrombosis,	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						deep venous thrombosis, pulmonary embolism, and andmalignancies (excluding non-melanoma skin cancer) were observed inpatients treated with a JAK inhibitor compared to those treated with TNFblockers in rheumatoid arthritis (RA) patients. Deucravacitinib is not approvedfor use in RA.				
174.	Beximco Pharmaceuticals Ltd. Tongi, Gazipur Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka.	Loperamide Hydrochloride 1mg/5ml Oral Solution	Loperamide Hydrochloride USP 1mg/5 ml	Therapeutic Class: Anti-diarrheal Therapeutic Code: 016	It is indicated for the control and symptomatic relief of acute nonspecific diarrhea and of chronic diarrhea associated with inflammatory bowel disease. It is also indicated for reducing the volume of discharge from ileostomies.	**Contra-indication:** Loperamide hydrochloride is contraindicated in: • patients with a known hypersensitivity to loperamide hydrochloride or to any of the excipients. • children less than 4 years of age. • when inhibition of peristalsis is to be avoided due to the possible risk of significant sequelae including ileus, megacolon, and toxic megacolon, in particular: -when ileus, constipation or abdominal distension develop, - in patients with acute ulcerative colitis, - in patients with bacterial enterocolitis caused by invasive organisms including Salmonella, Shigella, and Campylobacter, - in patients with pseudomembranous colitis associated with the use of broad-spectrum antibiotics. Loperamide hydrochloride should not be used alone in acute dysentery, which is characterised by blood in stools and elevated body temperatures. **Side-effects:** Loperamide hydrochloride is usually well tolerated, and few undesired effects are likely when it is taken as directed. Constipation may occur. If so, stop Loperamide hydrochloride and if these	2 mg Capsule	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						effects are severe, consult your doctor. Oversensitivity to Loperamide hydrochloride is rare. It can be recognized, for instance, by skin rash or itching. If any of these signs occur, see your doctor. The following complaints sometimes occur, but they may be due to the diarrhea itself: nausea and vomiting, tiredness, dizziness or drowsiness, dry mouth, and flatulence. **Warnings and Precautions:** Diarrhea, Abdominal distention, Anaphylaxis and anaphylactic shock, Tiredness, Dizziness, or Drowsiness may occur in the setting of diarrheal syndromes.				
175.	General Pharmaceutical Ltd., Gazipur The ACME Laboratories Ltd. Everest Pharmaceuticals Ltd. Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Pidotimod 400mg Tablet	Pidotimod INN 400mg	Immune-suppressant Therapeutic Code:058	Pidotimod be used in case of the following ailments: ● -Recurrent respiratory infections ● -Asthma ● -Pneumonia ● -Acute bronchitis ● -Hand–foot–mouth disease	**Contraindications:** Talk to your doctor before using this medicine if you have any of the following conditions: ● -If you are hypersensitive to the active ingredient or any of its ingredients. ● -Not recommended for use during pregnancy and lactation. ● -It should not be administered to people treated with immunosuppressants. Treatment with this drug is only 60 days at the dose prescribed by the doctor. There is an attack phase of 15 days depending on age and it is recommended to be used especially before the start of the winter season. **Side-effect:** The correct use of the drug usually does not cause side effects, but it should be remembered that not every person is the same. The following side effects may occur during the use of Pidotimod: ● -Nausea and vomiting	New	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						● -Diarrhea ● -Stomach ache ● -Mouth dry ● -Fire ● -Chest pain or discomfort ● -Back pain ● -Numbness ● -Headache ● -Difficulty breathing ● -Skin rash and itching ● -Sedation and imbalance ● -Cyanosis (bluish or grayish color of the skin) ● -Difficulty breathing These symptoms usually go away when treatment is stopped, but if they worsen or persist, consult your doctor. Important warning**:** If you have diarrhea that does not go away for a long time, stop the use of the drug and contact your doctor. **Precautions &Warnings:** Pidotimod to be taken with caution, especially if you are children below the age of 12. Your doctor may adjust your dose depending upon your age. Consumption of alcohol along with Pidotimod is not advisable as it may cause unpleasant side effects.				
176.	General Pharmaceutical Ltd., Gazipur Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh The ACME	Pidotimod 800mg Tablet	Pidotimod INN 800mg	Immune-suppressant Therapeutic Code:058	Pidotimod be used in case of the following ailments: ● -Recurrent respiratory infections ● -Asthma ● -Pneumonia ● -Acute bronchitis ● -Hand–foot–mouth disease	**Contraindications:** Talk to your doctor before using this medicine if you have any of the following conditions: ● -If you are hypersensitive to the active ingredient or any of its ingredients. ● -Not recommended for use during pregnancy and lactation. ● -It should not be administered to people treated with immunosuppressants. Treatment with this drug is only 60 days at	New	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Laboratories Ltd. Everest Pharmaceuticals Ltd.					the dose prescribed by the doctor. There is an attack phase of 15 days depending on age and it is recommended to be used especially before the start of the winter season. **Side-effect:** The correct use of the drug usually does not cause side effects, but it should be remembered that not every person is the same. The following side effects may occur during the use of Pidotimod: ● -Nausea and vomiting ● -Diarrhea ● -Stomach ache ● -Mouth dry ● -Fire ● -Chest pain or discomfort ● -Back pain ● -Numbness ● -Headache ● -Difficulty breathing ● -Skin rash and itching ● -Sedation and imbalance ● -Cyanosis (bluish or grayish color of the skin) ● -Difficulty breathing These symptoms usually go away when treatment is stopped, but if they worsen or persist, consult your doctor. Important warning**:** If you have diarrhea that does not go away for a long time, stop the use of the drug and contact your doctor. **Precautions &Warnings:** Pidotimod to be taken with caution, especially if you are children below the age of 12. Your doctor may adjust your dose depending upon your age. Consumption of alcohol along with Pidotimod is not advisable				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						as it may cause unpleasant side effects.				
177.	General Pharmaceutical Ltd., Gazipur	Pidotimod 400mg/7ml Oral Solution	Pidotimod INN 400mg/7ml	Immune suppressant Therapeutic Code:058	Pidotimod be used in case of the following ailments: ● -Recurrent respiratory infections ● -Asthma ● -Pneumonia ● -Acute bronchitis ● -Hand–foot–mouth disease	**Contraindications:** Talk to your doctor before using this medicine if you have any of the following conditions: ● -If you are hypersensitive to the active ingredient or any of its ingredients. ● -Not recommended for use during pregnancy and lactation. ● -It should not be administered to people treated with immunosuppressants. Treatment with this drug is only 60 days at the dose prescribed by the doctor. There is an attack phase of 15 days depending on age and it is recommended to be used especially before the start of the winter season. **Side-effect:** The correct use of the drug usually does not cause side effects, but it should be remembered that not every person is the same. The following side effects may occur during the use of Pidotimod: -Nausea and vomiting ● -Diarrhea -Stomach ache, Mouth dry, Fire, Chest pain or discomfort, Back pain ● Numbness, Headache, Difficulty, breathing, Skin rash and itching, Sedation and imbalance, Cyanosis (bluish or grayish color of the skin) ● Difficulty breathing, These symptoms usually go away when treatment is stopped, but if they worsen or persist, consult your doctor. Important warning**:** If you have diarrhea that does not go away for a long time, stop the use of the drug and contact your doctor. **Precautions &Warnings:** Pidotimod to be taken with caution,	New	†idv‡iÝ †bB	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						especially if you are children below the age of 12. Your doctor may adjust your dose depending upon your age. Consumption of alcohol along with Pidotimod is not advisable as it may cause unpleasant side effects.				
178.	General Pharmaceutical Ltd., Gazipur	Pidotimod INN 800mg/7ml Oral Solution	Pidotimod INN 800mg/7ml	Immune-suppressant Therapeutic Code:058	Pidotimod be used in case of the following ailments: ● -Recurrent respiratory infections ● -Asthma ● -Pneumonia ● -Acute bronchitis ● -Hand–foot–mouth disease	**Contraindications:** Talk to your doctor before using this medicine if you have any of the following conditions: ● -If you are hypersensitive to the active ingredient or any of its ingredients. ● -Not recommended for use during pregnancy and lactation. ● -It should not be administered to people treated with immunosuppressants. Treatment with this drug is only 60 days at the dose prescribed by the doctor. There is an attack phase of 15 days depending on age and it is recommended to be used especially before the start of the winter season. **Side-effect:** The correct use of the drug usually does not cause side effects, but it should be remembered that not every person is the same. The following side effects may occur during the use of Pidotimod: Nausea and vomiting ● Diarrhea, Stomach ache, Mouth dry, Fire ● Chest pain or discomfort ● -Back pain ● -Numbness ● -Headache ● -Difficulty breathing ● -Skin rash and itching ● -Sedation and imbalance ● -Cyanosis (bluish or grayish color of the skin)	New	†idv‡iÝ †bB	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						● -Difficulty breathing These symptoms usually go away when treatment is stopped, but if they worsen or persist, consult your doctor. Important warning**:** If you have diarrhea that does not go away for a long time, stop the use of the drug and contact your doctor. **Precautions &Warnings:** Pidotimod to be taken with caution, especially if you are children below the age of 12. Your doctor may adjust your dose depending upon your age. Consumption of alcohol along with Pidotimod is not advisable as it may cause unpleasant side effects.				
179.	Advanced Chemical Industries Limited, 7 Hajeegang, Godnyl, Narayangon‡jv	Propranolol Hydrochloride 20mg Tablet	Propranolol Hydrochloride BP 20mg	Antihypertensive Therapeutic Code:022	It is indicated in- ● Management of essential and renal hypertension ● Decreasing angina frequency and increasing exercise tolerance in patients with angina pectoris. ● Control of ventricular rate in patients with atrial fibrillation ● Long term prophylaxis after recovery from acute myocardial infarction ● Prophylaxis of migraine ● Anxiety and anxiety tachycardia ● Management of familial or hereditary essential tremor ● Adjunctive management of thyrotoxicosis and thyrotoxic crisis ● Pheochromocytoma (with α-blocker) Hypertrophic subaortic stenosis	**Contraindications:** It is contraindicated in patients with known hypersensitivity to propranolol hydrochloride or any components of this product. It is also contraindicated in cardiogenic shock, sinus bradycardia and greater than first degree block, bronchial asthma. **Side Effects:** The most common side effects are cold extremities, nausea, diarrhea, sleep disturbances, skin rashes dry eyes and lassitude.	10 mg, 40 mg and 80 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
180.	Advanced Chemical Industries Limited, 7 Hajeegang, Godnyl, Narayangon‡jv.	Doxercalciferol 4mcg/2ml Injection	Doxercalciferol USP 4mcg	Thyroid and Anti thyroid Therapeutic Code: 074	It is indicated for treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease (CKD) on dialysis.	**Contraindication:** It is contraindicated in patients with known hypersensitivity to doxercalciferol or any other components of this product. It is also contraindicated hypercalcemia, vitamin D toxicity. **Side-effects:** Most common side effects are edema, headache, malaise, nausea/vomiting, dyspnea and dizziness. **Warnings and precautions**: Hypercalcemia: Can occur during treatment with doxercalciferol Injectionand can lead to cardiac arrhythmias and seizures. The risk may be increased when used concomitantly with high dose calcium preparations, thiazide diuretics or vitamin D and its derivatives. Monitor serum calcium prior to initiation and during treatment and adjust dose accordingly Digitalis toxicity: Hypercalcemia increases the risk of digitalis toxicity. In patients using digitalis compounds, monitor both serum calcium and patients for signs and symptoms of digitalis toxicity. Increase the frequency of monitoring when initiating or adjusting the dose ofdoxercalciferol in‡jvection Serious hypersensitivity reactions: Anaphylaxis with symptoms of angioedema, hypotension, unresponsiveness, chest discomfort, shortness of breath, and cardiopulmonary arrest have been reported in patients on hemodialysis following administration of doxercalciferol in‡jvection. Monitor patients upon initiation of treatment for hypersensitivity reactions. Should a reaction occur, discontinue and treat. Adynamic bone disease: May develop and increase risk of fractures if intact PTH levels	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						are suppressed to abnormally low levels. Monitor intact PTH levels are suppressed to abnormally low levels. Monitor intact PTH levels to avoid oversuppression and adjust dose if needed.				
181.	Advanced Chemical Industries Limited, 7 Hajeegang, Godnyl, Narayangaoj.	Doxercalciferol 2mcg/1ml Injection	Doxercalciferol USP 2mcg/1ml	Thyroid and Anti thyroid Therapeutic Code: 074	It is indicated for treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease (CKD) on dialysis.	**Contraindication:** It is contraindicated in patients with known hypersensitivity to doxercalciferol or any other components of this product. It is also contraindicated hypercalcemia, vitamin D toxicity. **Side-effects:** Most common side effects are edema, headache, malaise, nausea/vomiting, dyspnea and dizziness. **Warnings and precautions**: Hypercalcemia: Can occur during treatment with doxercalciferol Injectionand can lead to cardiac arrhythmias and seizures. The risk may be increased when used concomitantly with high dose calcium preparations, thiazide diuretics or vitamin D and its derivatives. Monitor serum calcium prior to initiation and during treatment and adjust dose accordingly Digitalis toxicity: Hypercalcemia increases the risk of digitalis toxicity. In patients using digitalis compounds, monitor both serum calcium and patients for signs and symptoms of digitalis toxicity. Increase the frequency of monitoring when initiating or adjusting the dose ofdoxercalciferol in‡jvection Serious hypersensitivity reactions: Anaphylaxis with symptoms of angioedema, hypotension, unresponsiveness, chest discomfort, shortness of breath, and cardiopulmonary arrest have been reported in patients on hemodialysis following administration of doxercalciferol in‡jvection.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Monitor patients upon initiation of treatment for hypersensitivity reactions. Should a reaction occur, discontinue and treat. Adynamic bone disease: May develop and increase risk of fractures if intact PTH levels are suppressed to abnormally low levels. Monitor intact PTH levels are suppressed to abnormally low levels. Monitor intact PTH levels to avoid oversuppression and adjust dose if needed.				
182.	Advanced Chemical Industries Limited, 7 Hajeegon‡jv, Godnyl, Narayangon‡jv	Rabeprazole Sodium BP 5mg Delayed Release Capsule	Rabeprazole Sodium BP 5mg Delayed Release Capsule	Proton Pump Inhibitor Therapeutic Code: 067	Duodenal ulcer, gastric ulcer esophagitis & zollinger ellison syndrome	**Contraindication:** It is contraindicated to patient with hypersensitivity to rabeprazole or any of the components of this product. PPIs, including rabeprazole sprinkle, are contraindicated with rilpivirine-containing products. **Side-effects:** The most common side effects are vomiting, abdominal pain, diarrhea, headache and nausea. **Warnings and precautions**: In adults, symptomatic response to therapy with rabeprazole sprinkle does not preclude the presence of gastric malignancy. Consider additional follow-up and diagnostic testing in adult patients who have a suboptimal response or an early symptomatic relapse after completing treatment with a PPI. In older patients, also consider an endoscopy. Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. Rabeprazole sprinkle is indicated for short-term treatment up to 12 weeks. Treatment for longer than 12 weeks is not recommended.	20 mg Tablet 20 mg Capsule, 10mg capsule	USFDA	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
183.	Advanced Chemical Industries Limited, 7 Hajeegon‡jv, Godnyl, Narayangon‡jv.	Rabeprazole Sodium BP 10 mg Delayed Release Capsule	Rabeprazole Sodium BP 10 mg Delayed Release Capsule	Proton Pump Inhibitor Therapeutic Code: 067	Duodenal ulcer, gastric ulcer esophagitis & zollinger ellison syndrome	**Contraindication:** It is contraindicated to patient with hypersensitivity to rabeprazole or any of the components of this product. PPIs, including rabeprazole sprinkle, are contraindicated with rilpivirine-containing products. **Side-effects:** The most common side effects are vomiting, abdominal pain, diarrhea, headache and nausea. **Warnings and precautions**: In adults, symptomatic response to therapy with rabeprazole sprinkle does not preclude the presence of gastric malignancy. Consider additional follow-up and diagnostic testing in adult patients who have a suboptimal response or an early symptomatic relapse after completing treatment with a PPI. In older patients, also consider an endoscopy. Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. Rabeprazole sprinkle is indicated for short-term treatment up to 12 weeks. Treatment for longer than 12 weeks is not recommended.	10 mg Capsule 20mg Capsule	USFDA	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
184.	Advanced Chemical Industries Limited, 7 Hajeegon‡jv, Godnyl, Narayangon‡jv	Olmesartan Medoxomil 40 mg + Amlodipine 10 mg + Hydrochlorothiazide BP 12.5 mg Tablet	Olmesartan Medoxomil USP 40 mg+ Amlodipine Besylate BP 13.87 mg eqv. to Amlodipine 10 mg + Hydrochlorothiazide BP 12.5 mg	Antihypertensive Therapeutic Code: 022	Indicated for the treatment of hypertension	**Contraindication:** It is contraindicated in patient with hypersensitivity to this combination or any other component of this product, to dihydropyridines, to thiazides or to other sulfonamide-derived drugs. Due to the component amlodipine, this combination is also contraindicated in cardiogenic shock, acute myocardial infarction (within the first 4 weeks) and unstable angina pectoris. **Side-effects:** The most common side effects are upper respiratory tract infection, nasopharyngitis, urinary tract infection, hyper triglyceridaemia, hyperuricaemia, dizziness, headache, somnolence, visual disturbance, abdominal pain, dyspepsia, muscle spasm,	Hydrochlorothiazide 12.5 mg + Olmesartan Medoxomil 40 mg Tablet Amlodipine 5 mg + Olmesartan Medoxomil 40 mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						joint swelling, back pain, peripheral edema, fatigue, chest pain. **Warnings and precautions**: Symptomatic hypotension, especially after the first dose, may occur in patients who are volume and/or sodium depleted by vigorous diuretic therapy, dietary salt restriction, diarrhea, or vomiting. Such conditions should be corrected before the administration of this combination.				
185.	Advanced Chemical Industries Limited, 7 Hajeegang, Godnyl, Narayangon‡jv.	Trimetazidine Hydrochloride 60mg Extended Release Tablet	Trimetazidine Hydrochloride BP 60mg	Antihypertensive Therapeutic Code: 022	It is indicated in adults as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled by or intolerant to first-line antianginal therapies.	**Contraindication:** It is contraindicated in patients with hypersensitivity to trimetazidine hydrochloride or any other components of this product. It is also contraindicated parkinson disease, parkinsonian symptoms, tremors, restless leg syndrome, and other related movement disorders, severe renal impairment (creatinine clearance < 30ml/min). **Side-effects:** The most common side effects are dizziness, headache, abdominal pain, diarrhea, dyspepsia, nausea, vomiting, rash, pruritus, urticarial and asthenia **Warnings and precautions**: Trimetazidine should be used with caution in patients who are predisposed to closed-angle glaucoma. It is not a curative treatment for angina attacks, nor is indicated as an initial treatment for unstable angina, or myocardial infarction, nor in the pre-hospital phase or during the first days of hospitalization. In the event of an angina attack, the coronaropathy should be re-evaluated and an adaptation of the treatment considered (medicinal treatment and possible revascularization). Trimetazidine can cause or worsen parkinsonian symptoms (tremor, akinesia, hypertonia), which should be regularly investigated, especially in elderly patients.	20 mg & 35mg Tablet 60 mg Capsule	†idv‡iÝ †bB	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
186.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, BANGLADESH Renata Limited Rajendrapur, Gazipur Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Trifluridine 15 mg + Tipiracil 6.14 mg Tablet	Trifluridine BP 15mg + Tipiracil HCl INN 7.065mg eq. to Tipiracil 6.14mg	Anticancer drug Therapeutic Code: 010	Indicated for the treatment of adult patients with Metastatic Colorectal Cancer, Metastatic Gastric Cancer.	**Contraindication:** None **Side effects:** Asthenia/fatigue, pyrexia, nausea, vomiting, diarrhea, vomiting, abdominal pain, stomatitis, decreased appetite, dysgeusia, alopecia, neutropenia, anemia, thrombocytopenia etc. **Warnings & Precautions:** Severe Myelosuppression: Obtain complete blood counts prior to and on Day 15 of each cycle. Reduce dose and/or hold Trifluridine+Tipiracil as clinically indicated. Embryo-Fetal Toxicity: Fetal harm can occur. Advise women of potential risk to a fetus.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
187.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, BANGLADESH	Olaparib INN 50mg Capsule	Olaparib INN 50 mg	Anticancer drug Therapeutic Code: 010	Olaparib is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated for the treatment of adult patients with deleterious or suspected deleterious germline *BRCA*-mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Olaparib.	**Contraindication:** None **Side effects:**Most common adverse reactions (≥20%) in clinical trials were anemia, nausea, fatigue (including asthenia), omiting,nasopharyngitis/upper respiratory tract infection/influenza, diarrhea,thralgia/myalgia, dysgeusia, headache, dyspepsia, decreased appetite, constipation. and stomatitis. • Most common laboratory abnormalities (≥25%) were decrease in hemoglobin, increase in mean corpuscular volume, decrease in lymphocytes, decrease in leukocytes, decrease in absolute neutrophil count, increase in serum creatinine and decrease in platelets. **Warnings & Precautions:** ● **Myelodysplastic Syndrome/ Acute Myeloid Leukemia:** Do not start Olaparib until patients have recovered from hematological toxicity caused by previous chemotherapy (≤ Grade 1). Monitor complete blood count for cytopenia at baseline and monthly thereafter for clinically	100 mg Tablet 150mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						significant changes during treatment. For prolonged hematological toxicities, interrupt Olaparib and monitor blood counts weekly until recovery. If the levels have not recovered to Grade 1 or less after 4 weeks, refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics. If MDS/AML is confirmed, discontinue Olaparib. ● **Pneumonitis:** If pneumonitis is confirmed, discontinue Olaparib treatment and treat the patient appropriately. **Embryo-Fetal Toxicity:** Olaparib can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings in animals.				
188.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, BANGLADESH	Melatonin BP 2 mg Modified release Tablet	Melatonin BP 2 mg	anxiolytics, sedatives and hypnotics, Therapeutic Code: 057	Indicated for Insomnia	**Contraindication:** Hypersensitivity to the active substance or to any of the excipients. Side effects: Most common adverse reactions were: Mood swings, Aggression, Irritability, Somnolence, Headache, Sudden onset of sleep, Sinusitis, Fatigue, and Hangover. **Warnings & Precautions:** Drowsiness: Melatonin may cause drowsiness. Therefore, the medicinal product should be used with caution if the effects of drowsiness are likely to be associated with a risk to safety. Autoimmune disease: No clinical data exist concerning the use of melatonin in individuals with autoimmune diseases. Therefore, melatonin is not recommended for use in patients with autoimmune diseases. Lactulose: Melatonin contains lactose. Patients with	3 mg Tablet	BNF- 83 Page 521	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine. Precaution with other medicine: Concomitant /non-benzodiazepines hypnotics, thioridazine and imipramine is not recommended.				
189.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, BANGLADESH	Melatonin BP 1 mg Modified release Tablet	Melatonin BP 1 mg	Anxiolytics, sedatives and hypnotics Therapeutic Code: 057	Indicated for Insomnia.	Contraindication: Hypersensitivity to the active substance or to any of the excipients. Side effects: Most common adverse reactions were: Mood swings, Aggression, Irritability, Somnolence, Headache, Sudden onset of sleep, Sinusitis, Fatigue, and Hangover. Warnings & Precautions: Drowsiness: Melatonin may cause drowsiness. Therefore the medicinal product should be used with caution if the effects of drowsiness are likely to be associated with a risk to safety. Autoimmune disease: No clinical data exist concerning the use of melatonin in individuals with autoimmune diseases. Therefore, melatonin is not recommended for use in patients with autoimmune diseases. Lactulose: Melatonin contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine. Precaution with other medicine: Concomitant /non-benzodiazepines hypnotics, thioridazine	3 mg Tablet	BNF- 83, Page 521	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						and imipramine is not recommended.				
190.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng Ziska Pharmaceuticals Ltd. Beximco Pharmaceuticals Ltd. The ACME Laboratories Ltd. Dhamrai, Dhaka Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Navana Pharmaceuticals Limited	Gefapixant INN 45mg Tablet	Gefapixant Citrate INN 69.480mg Eqv. to Gifapixant 45mg Tablet	Antitussives, Expectorants and Mucolytic Therapeutic Code: 031	It's indicated for the treatment of refractory chronic cough.	**Contraindication:** Severe hypersensitivity reactions against one of the ingredients. **Side effects:** The most common adverse events were related to taste disturbance: Ageusia dysgeusia, hypergeusia and taste disorder. **Warnings & Precautions: Gefapixant should be used with caution in patients with known hypersensitivity to sulfonamides.** For patients with refractory chronic Cough (RCC) or unexplained chronic cough (UCC) and comorbid comorbid obstructive sleep apnea (OSA), Gefapixant should not be used	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
191.	Healthcare Pharmaceuticals Ltd	Astaxanthin 2 mg Hard Gelatin Capsule	Astaxanthin INN 2 mg	Unclassified agent Therapeutic code: 075	● Strong antioxidant ● Improves cardiovascular health (Atherosclerosis, reduce cholesterol). ● Improves immune function. ● Improves condition of skin	**Side Effects:** Taking astaxanthin might cause increased bowel movements and red stool color. High doses of astaxanthin might cause stomach pain. **Contraindication:** Contraindicated for those with known allergies to Astaxanthin or any other component of the product.	2mg & 4mg Soft Gelatin Capsule, Liquid filled Hard Gelatin Capsule	TGA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					● Protects skin from damage caused by sun (Reduce wrinkles, pimples and other signs of aging) Improves recovery from central nervous system in‡jvuries Protects from Parkinson 's disease, Dementia and Alzheimer's Protects eyes from cataracts and macular degeneration. Reduces inflammation (Arthritis) Reduces risk of infertility Also Astaxnthin effectively reduce oxidative damage to DNA, decrease the risk for many types of cancer and stabilize blood sugar.					
192.	Healthcare Pharmaceuticals Ltd	Astaxanthin 4 mg Hard Gelatin Capsule	Astaxanthin INN 4mg	Unclassified agent Therapeutic code: 075	● Strong antioxidant ● Improves cardiovascular health (Atherosclerosis, reduce cholesterol). ● Improves immune function. ● Improves condition of skin ● Protects skin from damage caused by sun (Reduce wrinkles, pimples and other signs of aging) ● Improves recovery from central nervous system in‡jvuries ● Protects from Parkinson 's	**Side Effects:** Taking astaxanthin might cause increased bowel movements and red stool color. High doses of astaxanthin might cause stomach pain. **Contraindication:** Contraindicated for those with known allergies to Astaxanthin or any other component of the product.	2mg & 4mg Soft Gelatin Capsule, Liquid filled Hard Gelatin Capsule	TGA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					disease, Dementia and Alzheimer's ● Protects eyes from cataracts and macular degeneration. ● Reduces inflammation (Arthritis) ● Reduces risk of infertility Also Astaxnthin effectively reduce oxidative damage to DNA, decrease the risk for many types of cancer and stabilize blood sugar.					
193.	Healthcare Pharmaceuticals Ltd	Dexamethasone Phosphate 4 mg/ml Injection	Dexamethasone Sodium Phosphate USP 4.372 mg eq. to Dexamethasone Phosphate 4 mg/ml I	Steroidal Anti-inflammatory Therapeutic code: 072	When oral therapy is not feasible and the strength, dosage form, and route of administration of the drug reasonably lend the preparation to the treatment of the condition, those products labelled for intravenous or intramuscular use are indicated as follows: • Endocrine Disorders • Rheumatic Disorders • Collagen Diseases • Dermatologic Diseases • Allergic States • Ophthalmic Diseases • Gastrointestinal Diseases • Respiratory Diseases • Hematologic Disorders • Neoplastic Diseases • Edematous States • Miscellaneous • Diagnostic testing of adrenocortical hyperfunction • Cerebral Edema associated with primary or metastatic brain tumor, craniotomy, or head in‡jvury.	**Side Effects:** Fluid and electrolyte disturbances: Sodium retention Fluid retention, Congestive heart failure in susceptible patients, Potassium loss, Hypokalemic alkalosis, Hypertension, Muscle weakness, Steroid myopathy, Loss of muscle mass, Osteoporosis, Tendon rupture, Peptic ulcer with possible subsequent perforation and hemorrhage, Ulcerative esophagitis, Impaired wound healing, Erythema Increased sweating, Burning or tingling, especially in the perineal area (after IV in‡jvection), Other cutaneous reactions, such as allergic dermatitis, Convulsions, Vertigo, Headache, Psychic disturbances, Increased appetite, Nausea, Malaise, Hiccups etc. **Contraindication:** Systemic fungal infections. Hypersensitivity to any component of this product, including sulfites.	Dexamethasone tablet 0.5 mg, 4 mg, 10 mg (bolus) 20 mg (bolus); Dexamethasone 2 mg/ml In‡jvection	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
194.	Healthcare Pharmaceuticals Ltd	Dexamethasone Phosphate 20mg/5ml Injection	Dexamethasone Sodium Phosphate USP 21.86 mg equivalent to Dexamethasone Phosphate 20mg/5ml	Steroidal Anti-inflammatory Therapeutic code: 072	When oral therapy is not feasible and the strength, dosage form, and route of administration of the drug reasonably lend the preparation to the treatment of the condition, those products labelled for intravenous or intramuscular use are indicated as follows: • Endocrine Disorders • Rheumatic Disorders • Collagen Diseases • Dermatologic Diseases • Allergic States • Ophthalmic Diseases • Gastrointestinal Diseases • Respiratory Diseases • Hematologic Disorders • Neoplastic Diseases • Edematous States • Miscellaneous • Diagnostic testing of adrenocortical hyperfunction • Cerebral Edema associated with primary or metastatic brain tumor, craniotomy, or head in‡jvury.	**Side Effects:** Fluid and electrolyte disturbances: Sodium retention Fluid retention, Congestive heart failure in susceptible patients, Potassium loss, Hypokalemic alkalosis, Hypertension, Muscle weakness, Steroid myopathy, Loss of muscle mass, Osteoporosis, Tendon rupture, Peptic ulcer with possible subsequent perforation and hemorrhage, Ulcerative esophagitis, Impaired wound healing, Erythema Increased sweating, Burning or tingling, especially in the perineal area (after IV in‡jvection), Other cutaneous reactions, such as allergic dermatitis, Convulsions, Vertigo, Headache, Psychic disturbances, Increased appetite, Nausea, Malaise, Hiccups etc. **Contraindication:** Systemic fungal infections. Hypersensitivity to any component of this product, including sulfites.	Dexamethasone tablet 0.5 mg, 4 mg, 10 mg (bolus) 20 mg (bolus); Dexamethasone 2 mg/ml In‡jvection	রেফারেন্স নাই	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করা হলো।
195.	Healthcare Pharmaceuticals Ltd	Dexamethasone Phosphate 120mg/30ml Injection	Dexamethasone Sodium Phosphate USP 131.16 mg eq. to Dexamethasone Phosphate 120mg/30ml	Steroidal Anti-inflammatory Therapeutic code:072	When oral therapy is not feasible and the strength, dosage form, and route of administration of the drug reasonably lend the preparation to the treatment of the condition, those products labelled for intravenous or intramuscular use are indicated as follows: • Endocrine Disorders • Rheumatic Disorders • Collagen Diseases • Dermatologic Diseases • Allergic States • Ophthalmic Diseases	**Side Effects:** Fluid and electrolyte disturbances: Sodium retention Fluid retention, Congestive heart failure in susceptible patients, Potassium loss, Hypokalemic alkalosis, Hypertension, Muscle weakness, Steroid myopathy, Loss of muscle mass, Osteoporosis, Tendon rupture, Peptic ulcer with possible subsequent perforation and hemorrhage, Ulcerative esophagitis, Impaired wound healing, Erythema Increased sweating, Burning or tingling, especially in the perineal area (after IV in‡jvection), Other cutaneous reactions, such as allergic dermatitis, Convulsions, Vertigo,	Dexamethasone tablet 0.5 mg, 4 mg, 10 mg (bolus) 20 mg (bolus); Dexamethasone 2 mg/ml In‡jvection	রেফারেন্স নাই	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					• Gastrointestinal Diseases • Respiratory Diseases • Hematologic Disorders • Neoplastic Diseases • Edematous States • Miscellaneous • Diagnostic testing of adrenocortical hyperfunction • Cerebral Edema associated with primary or metastatic brain tumor, craniotomy, or head in‡jvury.	Headache, Psychic disturbances, Increased appetite, Nausea, Malaise, Hiccups etc. **Contraindication:** Systemic fungal infections. Hypersensitivity to any component of this product, including sulfites.				
196.	Healthcare Pharmaceuticals Ltd	Dexamethasone Phosphate 10 mg/ml Injection	Dexamethasone Sodium Phosphate USP 10.93 mg eq. to Dexamethasone Phosphate 10 mg/ml	Steroidal Anti-inflammatory Therapeutic code: 072	When oral therapy is not feasible and the strength, dosage form, and route of administration of the drug reasonably lend the preparation to the treatment of the condition, those products labelled for intravenous or intramuscular use are indicated as follows: • Endocrine Disorders • Rheumatic Disorders • Collagen Diseases • Dermatologic Diseases • Allergic States • Ophthalmic Diseases • Gastrointestinal Diseases • Respiratory Diseases • Hematologic Disorders • Neoplastic Diseases • Edematous States • Miscellaneous • Diagnostic testing of adrenocortical hyperfunction • Cerebral Edema associated with primary or metastatic brain tumor, craniotomy, or head in‡jvury.	**Side Effects:** Fluid and electrolyte disturbances: Sodium retention Fluid retention, Congestive heart failure in susceptible patients, Potassium loss, Hypokalemic alkalosis, Hypertension, Muscle weakness, Steroid myopathy, Loss of muscle mass, Osteoporosis, Tendon rupture, Peptic ulcer with possible subsequent perforation and hemorrhage, Ulcerative esophagitis, Impaired wound healing, Erythema Increased sweating, Burning or tingling, especially in the perineal area (after IV in‡jvection), Other cutaneous reactions, such as allergic dermatitis, Convulsions, Vertigo, Headache, Psychic disturbances, Increased appetite, Nausea, Malaise, Hiccups etc. **Contraindication:** Systemic fungal infections. Hypersensitivity to any component of this product, including sulfites.	Dexamethasone tablet 0.5 mg, 4 mg, 10 mg (bolus) 20 mg (bolus); Dexamethasone 2 mg/ml In‡jvection	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
197.	Healthcare Pharmaceuticals Ltd	Dexamethasone Sodium Phosphate USP 109.30 mg equivalent to Dexamethasone Phosphate 100mg/10 ml Injection	Dexamethasone Phosphate 100 mg/10 ml In‡jvection (10 mg/ml)	Steroidal Anti-inflammatory Therapeutic code:072	When oral therapy is not feasible and the strength, dosage form, and route of administration of the drug reasonably lend the preparation to the treatment of the condition, those products labelled for intravenous or intramuscular use are indicated as follows: • Endocrine Disorders • Rheumatic Disorders • Collagen Diseases • Dermatologic Diseases • Allergic States • Ophthalmic Diseases • Gastrointestinal Diseases • Respiratory Diseases • Hematologic Disorders • Neoplastic Diseases • Edematous States • Miscellaneous • Diagnostic testing of adrenocortical hyperfunction • Cerebral Edema associated with primary or metastatic brain tumor, craniotomy, or head in‡jvury.	**Side Effects:** Fluid and electrolyte disturbances: Sodium retention Fluid retention, Congestive heart failure in susceptible patients, Potassium loss, Hypokalemic alkalosis, Hypertension, Muscle weakness, Steroid myopathy, Loss of muscle mass, Osteoporosis, Tendon rupture, Peptic ulcer with possible subsequent perforation and hemorrhage, Ulcerative esophagitis, Impaired wound healing, Erythema Increased sweating, Burning or tingling, especially in the perineal area (after IV in‡jvection), Other cutaneous reactions, such as allergic dermatitis, Convulsions, Vertigo, Headache, Psychic disturbances, Increased appetite, Nausea, Malaise, Hiccups etc. **Contraindication:** Systemic fungal infections. Hypersensitivity to any component of this product, including sulfites.	Dexamethasone tablet 0.5 mg, 4 mg, 10 mg (bolus) 20 mg (bolus); Dexamethasone 2 mg/ml In‡jvection	রেফারেন্স নাই	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করা হলো।
198.	Healthcare Pharmaceuticals Ltd. Eskayef Pharmaceuticals Limited, Narayangang.	Cyclophosphamide USP 200 mg/ml Solution for IV Injection	Cyclophosphamide USP 200 mg/ml	Anticancer Therapeutic code: 010	**Malignant Diseases:** malignant lymphomas: Hodgkin's disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitt's lymphoma; multiple myeloma, leukemias, mycosis fungoides, neuroblastoma, adenocarcinoma of ovary, retinoblastoma, breast carcinoma.	**Side-effects:** Adverse reactions reported most often include neutropenia, febrile neutropenia, fever, alopecia, nausea, vomiting, and diarrhea. **CONTRAINDICATIONS** Hypersensitivity to cyclophosphamide, Urinary outflow obstruction	Existing Available as lyophilized form	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
199.	Healthcare Pharmaceuticals Ltd	Cyclophosphamide USP 500 mg/2.5 ml Solution for IV Injection	Cyclophosphamide USP 500 mg/2.5 ml	Anticancer Therapeutic code: 010	**Malignant Diseases:** malignant lymphomas: Hodgkin's disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitt's lymphoma;	**Side-effects:** Adverse reactions reported most often include neutropenia, febrile neutropenia, fever, alopecia, nausea, vomiting, and diarrhea.	Existing Available as lyophilized form	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					multiple myeloma, leukemias, mycosis fungoides, neuroblastoma, adenocarcinoma of ovary, retinoblastoma, breast carcinoma.	**CONTRAINDICATIONS** Hypersensitivity to cyclophosphamide, Urinary outflow obstruction				
200.	Healthcare Pharmaceuticals Ltd	Cyclophosphamide USP 1 gm/5 ml Solution for IV Injection	Cyclophosphamide USP 1 gm/5 ml	Anticancer Therapeutic code: 010	**Malignant Diseases:** malignant lymphomas: Hodgkin's disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitt's lymphoma; multiple myeloma, leukemias, mycosis fungoides, neuroblastoma, adenocarcinoma of ovary, retinoblastoma, breast carcinoma.	**Side-effects:** Adverse reactions reported most often include neutropenia, febrile neutropenia, fever, alopecia, nausea, vomiting, and diarrhea. **CONTRAINDICATIONS** Hypersensitivity to cyclophosphamide, Urinary outflow obstruction	Existing Available as lyophilized form	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
201.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh Everest Pharmaceuticals Ltd.	Roxadustat 70mg Film Coated Tablet	Roxadustat INN 70mg	Drug used in Anemia and other Blood disorder Therapeutic code: 045	It is a medicine that increases the number of red blood cells and haemoglobin level in your blood. It is used to treat adults with symptomatic anaemia that occurs in patients with chronic kidney disease. Anaemia is when you have too few red blood cells and your haemoglobin level is too low. As a result, your body might not receive enough oxygen. Anaemia can cause symptoms such as tiredness, weakness, or shortness of breath. **Limitations of Use:** Do not give to children and adolescents aged less than 18 years because there is not enough information about its use in this age group.	**CONTRAINDIC ATIONS:** • Hypersensitivity to the active substances or to any of the excipients. • Allergic to peanut or soya, do not use this medicine, as it contains soya lecithin. • Pregnancy, Breast-feeding **SIDE-EFFECT:** • difficulty in sleeping (insomnia) • headache, vomiting, constipation • blood clot in the lungs (pulmonary embolism) • sepsis, a serious or in rare cases, life-threatening infection • seizures and warning signs of seizures (convulsions or fits) • blood clot in the veins of your legs (deep vein thrombosis or DVT) • blood clot in your haemodialysis access (vascular access thrombosis or VAT) that causes the vascular access to close up or stop working if you are using a fistula or graft for dialysis access.	Roxadustat INN 20mg Tablet Roxadustat INN 50mg Tablet Roxadustat INN 100mg Tablet	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						WARNINGS AND PRECAUTIONS: • if you have a seizure • if you get blood clots • if you have a liver disorder • if you have epilepsy or have ever had convulsions or fits if you have signs and symptoms of an infection, which may include fever, sweating or chills, sore throat, runny nose, shortness of breath, feeling weak, confusion, cough, vomiting, diarrhoea or stomach pain, feeling of burning when you pass urine, red or painful skin or sores on your body.				
202.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Trandolapril 2mg Tablet	Trandolapril USP 2mg	Anti-hypertensive Therapeutic code: 022	Trandolaprilindicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive medication such as hydrochlorothiazide. Also, it is indicated in stable patients who have evidence of left-ventricular systolic dysfunction (identified by wall motion abnormalities) or who are symptomatic from congestive heart failure within the first few days after sustaining acute myocardial infarction. Administration of trandolapril to Caucasian patients has been shown to decrease the risk of death (principally cardiovascular death) and to decrease the risk of heart failure related hospitalization.	**CONTRAINDICATIONS:** It is contraindicated in patients who are hypersensitive to this product, in patients with hereditary/idiopathic angioedema and in patients with a history of angioedema related to previous treatment with an ACE inhibitor. **SIDE-EFFECT:** • dizziness or headache • low blood pressure • general weakness • cough which may, or may not, produce phlegm. **WARNINGS AND PRECAUTIONS:** • have recently started or been taking diuretics (water tablets) for a long time or are on a low salt diet. • have or have had severe or prolonged vomiting or diarrhoea. • have been told that you have a narrowing of the blood vessels to one or both of your kidneys (renal stenosis).	Trandolapril 1mg Tablet Trandolapril 1mg Capsule Trandolapril 0.5mg Capsule	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						• have a narrowing of one of the valves in the heart (aorta stenosis) or in the outflow from the left chamber of the heart. • suffer from diabetes mellitus. Trandolapril capsules could cause your blood glucose levels to decrease too much. • suffer from heart failure or cirrhosis of the liver with swelling that can also be around your stomach. You are more likely to suffer from a very large drop in your blood pressure (hypotension) when you start to take the tablets which may make you feel faint or light-headed. are on kidney dialysis as you may be at risk of serious allergic reactions (some kinds of dialysis membrane may not be suitable).				
203.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Fluvoxamine Maleate 25mg Film Coated Tablet	Fluvoxamine Maleate USP 25mg	Anti-depressants Therapeutic code:014	Indicated for the treatment of Obsessive Compulsive Disorder (OCD) Major Depressive Episode	**CONTRAINDICATIONS:** Hypersensitivity should not be used with Thioridazine, Terfenadine, Astemizole, Cisapride, Pimozide, Aloestron, Tizanidine, and Lactation. **SIDE-EFFECT:** **Common:** Nausea, Vomiting, Loss of appetite, Upset stomach, Drowsiness, Dizziness Dry mouth, Sore Throat, Headache, Somnolence, Weakness, Insomnia, Diarrhea, Muscle pain. **Less Common:** Absence of or decrease in body movements, Pain, Dyspepsia, Constipation, Heavy menstrual periods, Decreased lipido, Abdominal pain etc. **WARNINGS AND PRECAUTIONS:** As for SSRI in general, Bradycardia with ECG changes has been noted. It is recommended that, Fluvoxamine should be withdrawn in patients who have increased serum liver enzyme concentrations.	Fluvoxamine Maleate 50mg Tablet Fluvoxamine Maleate 100mg Tablet /ER Tablet Fluvoxamine Maleate 150mg Tablet /ER Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Fluvoxamine may need to be given with caution to patients with hepatic or renal impairment, and to the elderly.				
204.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur ZisKa Pharmaceuticals ltd. The ACME Laboratories Ltd.	Sucroferric Oxyhydroxide Eq. to Elemental Iron 500mg Chewable Tablet	Sucroferric Oxyhydroxide INN 2500mg eq. to Elemental Iron 500mg	Vitamins and Combinations Therapeutic code: 078	It is indicated for the control of serum phosphorus levels in adult chronic kidney disease (CKD) patients on haemodialysis (HD) or peritoneal dialysis (PD). This medicine is used to control high blood phosphate levels (hyperphosphataemia) in: • adult patients who undergo haemodialysis or peritoneal dialysis (procedures to eliminate toxic substances from the blood) because of chronic kidney disease children from 2 years of age and adolescents with chronic kidney disease stages 4 and 5 (severe decrease in the ability of the kidneys to work properly) or on dialysis.	**CONTRAINDICATIONS:** • if you are allergic to sucroferric oxyhydroxide or any of the other ingredients of this medicine (listed in section 6) • if you have a history of abnormal iron build-up in your organs (haemochromatosis) • if you have any other disorder associated with too much iron **SIDE-EFFECT:** • Black stools may occur very commonly in patients. If you also have symptoms like increasing tiredness and breathlessness contact your doctor immediately • Very common (may affect more than 1 in 10 people): diarrhoea (generally occurring early on in the treatment, and improving over time) • Common (may affect up to 1 in 10 people): feeling sick (nausea), constipation, vomiting, indigestion, pain in stomach and gut, gas, tooth discolouration, change in taste • Uncommon (may affect up to 1 in 100 people): bloating (abdominal distension), inflammation of the stomach, abdominal discomfort, difficulty swallowing, acid coming back up from the stomach (gastro-oesophageal reflux disease), tongue discolouration, low or high calcium levels in the blood seen in	New	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						tests, tiredness, itch, rash, headache, shortness of breath. **WARNINGS AND PRECAUTIONS:** • if you have had peritonitis, an inflammation of the peritoneum (the thin tissue that lines the inner wall of the abdomen) within the last 3 months • if you have significant stomach and/or liver problems if you have had major surgery on your stomach and/or intestines.				
205.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur Navana Pharmaceuticals Ltd., Rupganj, Narayanganj Everest Pharmaceuticals Ltd.	Itraconazole 65mg Capsule	Itraconazole USP 65mg	Antifungal Agent Therapeutic code:020	It is an azole antifungal indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised adult patients: • Blastomycosis, pulmonary and extrapulmonary • Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis, and • Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy. **Limitations of Use:** • It is not indicated for the treatment of onychomycosis It is not interchangeable or substitutable with other Itraconazole products	**CONTRAINDICATIONS:** • Co-administration with certain drugs that either affect metabolism of Itraconazole or whose metabolism is affected by Itraconazole • Hypersensitivity to Itraconazole **SIDE-EFFECT:** Nausea, rash, vomiting, edema, headache, diarrhea, fatigue, fever, pruritus, hypertension, abnormal hepatic function, abdominal pain, dizziness, hypokalemia, anorexia, malaise, decreased libido, somnolence, albuminuria, impotence. **WARNINGS AND PRECAUTIONS:** • Hepatotoxicity: Serious hepatotoxicity, including liver failure and death were reported with the use of itraconazole. Discontinue treatment if signs of liver dysfunction occur • Cardiac Dysrhythmias: Life-threatening cardiac dysrhythmias and/or sudden death have occurred in patients using certain drugs that are metabolized by human CYP450 enzymes concomitantly with oral itraconazole and/or other CYP3A4	Itraconazole 10 mg/ml oral Solution Itraconazole 100mg Capsule Itraconazole 200mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						inhibitors • Peripheral Neuropathy: This has been reported in patients on long-term therapy with itraconazole. Monitor and promptly evaluate neurologic symptoms Hearing Loss: Reversible or permanent has been reported in patients. Discontinue treatment if hearing loss occurs				
206.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Itraconazole 50mg Capsule	Itraconazole USP 50mg	Antifungal Agent Therapeutic code:020	It is an azole antifungal indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised adult patients: • Blastomycosis, pulmonary and extrapulmonary • Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis, and • Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy. **Limitations of Use:** • It is not indicated for the treatment of onychomycosis It is not interchangeable or substitutable with other Itraconazole products.	**CONTRAINDICATIONS:** • Co-administration with certain drugs that either affect metabolism of Itraconazole or whose metabolism is affected by Itraconazole • Hypersensitivity to Itraconazole **SIDE-EFFECT:** Nausea, rash, vomiting, edema, headache, diarrhea, fatigue, fever, pruritus, hypertension, abnormal hepatic function, abdominal pain, dizziness, hypokalemia, anorexia, malaise, decreased libido, somnolence, albuminuria, impotence. **WARNINGS AND PRECAUTIONS:** • Hepatotoxicity: Serious hepatotoxicity, including liver failure and death were reported with the use of itraconazole. Discontinue treatment if signs of liver dysfunction occur • Cardiac Dysrhythmias: Life-threatening cardiac dysrhythmias and/or sudden death have occurred in patients using certain drugs that are metabolized by human CYP450 enzymes concomitantly with oral itraconazole and/or other CYP3A4 inhibitors • Peripheral Neuropathy: This has been reported in patients on long-term therapy with itraconazole. Monitor and	Itraconazole 10 mg/ml oral Solution Itraconazole 100mg Capsule Itraconazole 200mg Tablet	রেফারেন্স নেই	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						promptly evaluate neurologic symptoms Hearing Loss: Reversible or permanent has been reported in patients. Discontinue treatment if hearing loss occurs.				
207.	Eskayef Pharmaceuticals Limited, Rupgang, Narayanagng	Docosahexaenoic Acid 200mg Soft Gelatin Capsule	Docosahexaenoic Acid 50% Oil INN 400mg eq. to Docosahexaenoic Acid 200mg	Other Classification Therapeutic code: 075	It plays a key role in the development of eye and nerve tissues. DHA might also reduce the risk of heart and circulatory disease by decreasing the thickness of the blood, reducing swelling (inflammation), and lowering blood levels of triglycerides. People commonly use DHA for high levels of cholesterol or other fats in the blood. It is also used for boosting memory and thinking skills, for helping infant and child development, for certain eye disorders, and many other conditions, but there is no good scientific evidence to support many of these uses. **Limitations of Use:** • Decline in memory and thinking skills that occur normally with age. Taking DHA supplements by mouth alone or with other ingredients doesn't improve memory, forgetfulness, or learning ability in people with age-related memory changes. • Alzheimer disease. People who get more DHA from their diet might have a lower risk of Alzheimer disease. But taking DHA supplements by mouth doesn't seem to slow the progression of the disease.	**CONTRAINDICATIONS:** Hypersensitivity **SIDE-EFFECT:** It's been used safely for up to 4 years. Most side effects are mild and involve stomach and intestine issues. **WARNINGS AND PRECAUTIONS:** **Pregnancy and breast-feeding:** DHA is likely safe when taken by mouth in appropriate amounts during pregnancy and breast-feeding. DHA is commonly used during pregnancy and is an ingredient in some prenatal vitamins. DHA is also a normal part of breast milk and added to some infant formulas. It's recommended that 200-300 mg of DHA are consumed daily during pregnancy and breast-feeding, either from supplements or food sources. **Children:** DHA is likely safe when used appropriately. DHA is included in some infant formulas. Also, DHA has been safely given to children 7 years and older at doses of 30 mg/kg daily for up to 4 years. It has also been safely given to children 4 years and older at doses of 0.4-1 gram daily for up to 1 year. But DHA is possibly unsafe when used in preterm infants born at less than 29 weeks. It might worsen breathing in these infants. **Diabetes:** DHA seems to increase blood	New	রেফারেন্স নেই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	রেফারেন্স নাই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					• Attention deficit hyperactivity disorder (ADHD). Taking DHA supplements by mouth doesn't seem to improve ADHD symptoms in children. Memory and thinking skills (cognitive function). Taking DHA supplements by mouth doesn't improve mental performance in healthy adults.	sugar in some people with type 2 diabetes.				
208.	Eskayef Pharmaceuticals Limited, Rupgang, Narayanagng	Desmopressin Acetate 55.3mcg Sublingual Tablet	Desmopressin Acetate USP 55.3mcg	Therapeutic Class: Other Classification Therapeutic code: 075	It is a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.	**CONTRAINDICATIONS:** • Hyponatremia or a history of hyponatremia • Polydipsia • Concomitant use with loop diuretics or systemic or inhaled glucocorticoids • Estimated glomerular filtration rate below 50 mL/min/1.73 m2 • Syndrome of inappropriate antidiuretic hormone secretion (SIADH) • During illnesses that can cause fluid or electrolyte imbalance • Heart failure • Uncontrolled hypertension **SIDE-EFFECT:** It included dry mouth, hyponatremia or blood sodium decreased, and dizziness.	Desmopressin 0.1mg, 0.2mg tablet Desmopressin 0.06mg, 0.12mg sublingual tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
209.	Eskayef Pharmaceuticals Limited, Rupgang, Narayanagng	Desmopressin Acetate 27.7mcg Sublingual Tablet	Desmopressin Acetate USP 27.7mcg	Anti-diuretic Therapeutic code:	It is a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.	**CONTRAINDICATIONS:** Hyponatremia or a history of hyponatremia Polydipsia Concomitant use with loop diuretics or systemic or inhaled glucocorticoids Estimated glomerular filtration rate below 50ml/min/1.73 m2 Syndrome of inappropriate anti-diuretic hormone secretion (SIADH)	Desmopressin 0.1mg, 0.2mg tablet Desmopressin 0.06mg, 0.12mg sublingual tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						During illnesses that can cause fluid or electrolyte imbalance Heart failure Uncontrolled hypertension **SIDE-EFFECT:** It included dry mouth, hyponatremia or blood sodium decreased, and dizziness.				
210.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Quinapril 5mg Film Coated Tablet	Quinapril Hydrochloride USP 5.416mg (Eq. to 5mg Quinapril)	Anti-hypertensive Therapeutic code:022	It is indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.	**CONTRAINDICATIONS:** • hypersensitive to this product and in patients with a history of angioedema related to previous treatment with an ACE inhibitor • contraindicated in combination with a neprilysin inhibitor (e.g., sacubitril) • Do not co-administer with aliskiren in patients with diabetes. **SIDE-EFFECT:** The most frequent clinical adverse reactions in hypertension and congestive heart failure are headache, dizziness, rhinitis, coughing, upper respiratory tract infection, fatigue, and nausea and vomiting. Other less frequent side effects are dyspepsia, myalgia, chest pain, abdominal pain, diarrhoea, back pain, sinusitis, insomnia, paraesthesia, nervousness, asthenia, pharyngitis, hypotension, palpitations, flatulence, depression, pruritus, rash, impotence, oedema, arthralgia, amblyopia. Renal dysfunction, angioedema, hypotension, hyperkalaemia, neutropenia, agranulocytosis see warnings and precautions.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
211.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Quinapril 10mg Film Coated Tablet	Quinapril Hydrochloride USP 10.832mg (Eq. to 10mg Quinapril)	Therapeutic Class: **Anti-hypertensive** Therapeutic code: **022**	It is indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.	**CONTRAINDICATIONS:** • hypersensitive to this product and in patients with a history of angioedema related to previous treatment with an ACE inhibitor • contraindicated in combination with a neprilysin inhibitor (e.g., sacubitril) • Do not co-administer with aliskiren in patients with diabetes. **SIDE-EFFECT:** • The most frequent clinical adverse reactions in hypertension and congestive heart failure are headache, dizziness, rhinitis, coughing, upper respiratory tract infection, fatigue, and nausea and vomiting. Other less frequent side effects are dyspepsia, myalgia, chest pain, abdominal pain, diarrhoea, back pain, sinusitis, insomnia, paraesthesia, nervousness, asthenia, pharyngitis, hypotension, palpitations, flatulence, depression, pruritus, rash, impotence, oedema, arthralgia, amblyopia. Renal dysfunction, angioedema, hypotension, hyperkalaemia, neutropenia, agranulocytosis see warnings and precautions.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
212.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Quinapril 20mg Film Coated Tablet	Quinapril Hydrochloride USP 21.664mg (Eq. to 20mg Quinapril)	Antihypertensive Therapeutic code: 022	It is indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.	**CONTRAINDICATIONS:** • hypersensitive to this product and in patients with a history of angioedema related to previous treatment with an ACE inhibitor • contraindicated in combination with a neprilysin inhibitor (e.g., sacubitril) • Do not co-administer with aliskiren in patients with diabetes.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						SIDE-EFFECT: • The most frequent clinical adverse reactions in hypertension and congestive heart failure are headache, dizziness, rhinitis, coughing, upper respiratory tract infection, fatigue, and nausea and vomiting. Other less frequent side effects are dyspepsia, myalgia, chest pain, abdominal pain, diarrhoea, back pain, sinusitis, insomnia, paraesthesia, nervousness, asthenia, pharyngitis, hypotension, palpitations, flatulence, depression, pruritus, rash, impotence, oedema, arthralgia, amblyopia. Renal dysfunction, angioedema, hypotension, hyperkalaemia, neutropenia, agranulocytosis see warnings and precautions.				
213.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Quinapril 40mg Film Coated Tablet	Quinapril Hydrochloride USP 43.328mg (Eq. to 10mg Quinapril)	Anti-hypertensive Therapeutic code:022	It is indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.	**CONTRAINDICATIONS:** • hypersensitive to this product and in patients with a history of angioedema related to previous treatment with an ACE inhibitor • contraindicated in combination with a neprilysin inhibitor (e.g., sacubitril) • Do not co-administer with aliskiren in patients with diabetes. **SIDE-EFFECT:** • The most frequent clinical adverse reactions in hypertension and congestive heart failure are headache, dizziness, rhinitis, coughing, upper respiratory tract infection, fatigue, and nausea and vomiting. Other less frequent side effects are dyspepsia, myalgia, chest pain, abdominal pain, diarrhoea, back pain, sinusitis, insomnia, paraesthesia, nervousness, asthenia, pharyngitis, hypotension,	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						palpitations, flatulence, depression, pruritus, rash, impotence, oedema, arthralgia, amblyopia. Renal dysfunction, angioedema, hypotension, hyperkalaemia, neutropenia, agranulocytosis see warnings and precautions.				
214.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Molsidomine 2mg Tablet	Molsidomine BP 2mg	Cardiac Glycosides Therapeutic code: 035	It is a long-acting vasodilator used to treat angina pectoris, including in association with left heart failure and acute myocardial infarction. Molsidomine hepatically metabolized to *linsidomine*. Linsidomine releases nitric oxide (NO) from endothelial cells when it decays, and acts as the active vasodilating metabolite. **Limitations of Use:** • Cardiogenic shock • Severe arterial hypotension • Pregnancy, especially in the first trimester • breastfeeding • Simultaneous administration of sildenafil (a medicine for erectile dysfunction) • Patients with low blood pressure and adult patients taking other vasodilators or dehydrated patients (eg. After taking diuretics) due to the risk of a sharp drop in blood pressure. Concomitant use of molsidomine and sildenafil (or other drugs used for erectile dysfunction) is contraindicated due to the risk of a sharp drop in blood pressure, loss	**CONTRAINDICATIONS:** • It is contraindicated in patients with known hypersensitivity to any of the components of the product. • Severe hypotension with shock. • If you are currently treated with molsidomine, do not use sildenafil. The combination of molsidomine and VIAGRA (sildenafil) can induce a marked and sudden fall in blood pressure, possibly causing a Lipothymia (transient malaise), fainting or a cardiac event. • Due to its content in lactose, you should not take this medicine in case of galactosemia, of glucose and galactose and galactose malabsorption syndrome or in case of deficit in lactase (rare metabolic disease) • This medicine is usually not advisable in breastfeeding. **SIDE-EFFECT:** Circulatory disorders: lower blood pressure, especially when standing body Disorders CNS: headache (early treatment, which gradually disappears), dizziness Gastrointestinal disorders: nausea Disorders of the skin and subcutaneous tissue disorders; flushing, skin rash **WARNINGS AND PRECAUTIONS:** This medicinal product must be used	New	রেফারেন্স নেই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					of consciousness and collapse.	cautiously in patients with low blood pressure and elderly subjects, in patients with hypovolaemia and in subjects already treated with a vasodilator substance. The dosage should be increased gradually in patients with impaired liver function. It is not logical to combine Molsidomine with delayed organic nitrates insofar as their way of action is similar. **Side Effects:** Headache and slight blood pressure at the beginning of tr These effects disappear spontaneously within a few days. Exceptionally: postural hypotension (fall of blood pressure on standing up, possibly accompanied by dizziness), gastrointestinal disorders, itching. Inform your doctor or your pharmacist of any unwanted and harmful effects which may not be mentioned in this leaflet.				
215.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Molsidomine 4mg Tablet	Molsidomine BP 4mg	Cardiac Glycosides Therapeutic code:035	It is a long-acting vasodilator used to treat angina pectoris, including in association with left heart failure and acute myocardial infarction. Molsidomine hepatically metabolized to *linsidomine*. Linsidomine releases nitric oxide (NO) from endothelial cells when it decays, and acts as the active vasodilating metabolite. **Limitations of Use:** • Cardiogenic shock • Severe arterial hypotension • Pregnancy, especially in the first trimester • breastfeeding • Simultaneous administration of sildenafil (a	**CONTRAINDICATIONS:** • It is contraindicated in patients with known hypersensitivity to any of the components of the product. • Severe hypotension with shock. • If you are currently treated with molsidomine, do not use sildenafil. The combination of molsidomine and VIAGRA (sildenafil) can induce a marked and sudden fall in blood pressure, possibly causing a Lipothymia (transient malaise), fainting or a cardiac event. • Due to its content in lactose, you should not take this medicine in case of galactosemia, of glucose and galactose and galactose malabsorption syndrome or in case of deficit in lactase (rare metabolic disease) • This medicine is usually not advisable in breastfeeding.	New	রেফারেন্স নেই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					medicine for erectile dysfunction) • Patients with low blood pressure and adult patients taking other vasodilators or dehydrated patients (eg. After taking diuretics) due to the risk of a sharp drop in blood pressure. Concomitant use of molsidomine and sildenafil (or other drugs used for erectile dysfunction) is contraindicated due to the risk of a sharp drop in blood pressure, loss of consciousness and collapse.	**SIDE-EFFECT:** • Circulatory disorders: lower blood pressure, especially when standing body • Disorders CNS: headache (early treatment, which gradually disappears), dizziness • Gastrointestinal disorders: nausea • Disorders of the skin and subcutaneous tissue disorders; flushing, skin rash **WARNINGS AND PRECAUTIONS:** • This medicinal product must be used cautiously in patients with low blood pressure and elderly subjects, in patients with hypovolaemia and in subjects already treated with a vasodilator substance. • The dosage should be increased gradually in patients with impaired liver function. • It is not logical to combine Molsidomine with delayed organic nitrates insofar as their way of action is similar. • Side Effects: Headache and slight blood pressure at the beginning of tr These effects disappear spontaneously within a few days. Exceptionally: postural hypotension (fall of blood pressure on standing up, possibly accompanied by dizziness), gastrointestinal disorders, itching. Inform your doctor or your pharmacist of any unwanted and harmful effects which may not be mentioned in this leaflet.				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
216.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Molsidomine 8mg Tablet	Molsidomine BP 8mg	Cardiac Glycosides Therapeutic code:035	It is a long-acting vasodilator used to treat angina pectoris, including in association with left heart failure and acute myocardial infarction. Molsidomine hepatically metabolized to *linsidomine*. Linsidomine releases nitric oxide (NO) from endothelial cells when it decays, and acts as the active vasodilating metabolite. **Limitations of Use:** • Cardiogenic shock • Severe arterial hypotension • Pregnancy, especially in the first trimester • breastfeeding • Simultaneous administration of sildenafil (a medicine for erectile dysfunction) • Patients with low blood pressure and adult patients taking other vasodilators or dehydrated patients (eg. After taking diuretics) due to the risk of a sharp drop in blood pressure. Concomitant use of molsidomine and sildenafil (or other drugs used for erectile dysfunction) is contraindicated due to the risk of a sharp drop in blood pressure, loss of consciousness and collapse.	**CONTRAINDICATIONS:** • It is contraindicated in patients with known hypersensitivity to any of the components of the product. • Severe hypotension with shock. • If you are currently treated with molsidomine, do not use sildenafil. The combination of molsidomine and VIAGRA (sildenafil) can induce a marked and sudden fall in blood pressure, possibly causing a Lipothymia (transient malaise), fainting or a cardiac event. • Due to its content in lactose, you should not take this medicine in case of galactosemia, of glucose and galactose and galactose malabsorption syndrome or in case of deficit in lactase (rare metabolic disease) This medicine is usually not advisable in breastfeeding. **SIDE-EFFECT:** Circulatory disorders: lower blood pressure, especially when standing body Disorders CNS: headache (early treatment, which gradually disappears), dizziness Gastrointestinal disorders: nausea Disorders of the skin and subcutaneous tissue disorders; flushing, skin rash **WARNINGS AND PRECAUTIONS:** This medicinal product must be used cautiously in patients with low blood pressure and elderly subjects, in patients with hypovolaemia and in subjects already treated with a vasodilator substance. The dosage should be increased gradually in patients with impaired liver function. It is not logical to combine Molsidomine with	New	রেফারেন্স নেই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						delayed organic nitrates insofar as their way of action is similar. **Side Effects:** Headache and slight blood pressure at the beginning of tr These effects disappear spontaneously within a few days. Exceptionally: postural hypotension (fall of blood pressure on standing up, possibly accompanied by dizziness), gastrointestinal disorders, itching. Inform your doctor or your pharmacist of any unwanted and harmful effects which may not be mentioned in this leaflet.				
217.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Tandospirone 10mg Tablet	Tandospirone Citrate INN 15.010mg (Eq. to Tandospirone 10mg)	Antipsychotic Therapeutic code: 028	This medicine, by acting on serotonin receptors (5-HT1A) in the brain, shows effects on physical symptoms, such as psychosomatic diseases, or depression, anxiety, impatience or sleep disorder. It is usually used for the treatment of depression or fear associated with neuroses, physical symptoms associated with psychosomatic diseases (dysautonomia, essential hypertension, peptic ulcer), or depression, anxiety, impatience or sleep disorder.	**CONTRAINDICATIONS:** • If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods. • If you are pregnant or breastfeeding. • If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.) **SIDE-EFFECT:** This medicine may cause sleepiness and/or dizziness. Avoid operating dangerous machinery, such as driving a car. **WARNINGS AND PRECAUTIONS:** • The most commonly reported adverse reactions include sleepiness, lightheadedness, nausea, vomiting, rash, hives, itch, malaise and feeling of discomfort. • general malaise, yellow discoloration of the skin/white of the eyes, loss of appetite[hepatic dysfunction,	New	রেফারেন্স নেই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						jaundice] • excitement, tremor of hands, sweating[serotonin syndrome] fever, consciousness disorder, intense muscle rigidity[malignant syndrome]				
218.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Cranberry 72mg + Ascorbic Acid 100mg + Dry Vitamin E Acetate 12mg + Vitamin D3 5mcg Capsule	Cranberry Extract Ph.Grade 72mg + Ascorbic Acid (Fine Granular) USP 100mg + Dry Vitamin E Acetate (50%) USP 24mg (Eq. to 12mg Dry Vitamin E Acetate) + Dry Vitamin D3 (Cholecalciferol) USP 0.005mg	Therapeutic Class: **Diuretics** Therapeutic code: **042** Therapeutic Class: **Anti-infective** Therapeutic code: **023**	Cranberry is used for the prevention and treatment of Urinary Tract Infections. It is also used for kidney stones, neurogenic bladder, to deodorize urine in people with difficulty controlling urination. Vitamin C and E act as antioxidant and Vitamin D3 maintains the health of bones and teeth.	**CONTRAINDICATIONS:** Hypersensitivity **SIDE-EFFECT:** • Diarrhea • Mild stomach upset • Taken long period of time might increase the chance of getting kidney stones	New	রেফারেন্স নেই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
219.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Cranberry 200mg + D-Mannose 300mg + Potassium Magnesium Citrate 978mg/15ml Syrup	Cranberry Extract Ph.Grade 1.333gm + D-Mannose Ph. Grade 2gm + Potassium Magnesium Citrate Ph. Grade 6.520gm/100ml	Therapeutic Class: **Diuretics** Therapeutic code: **042** Therapeutic Class: **Anti-infective** Therapeutic code: **023**	Cranberry contains high levels of antioxidants which have health promoting properties. It contains special phyto-chemicals which prevent the adherence of bacteria to membranes. Cranberry, D-Mannose & Potassium Magnesium Citrate syrup is used for urinary tract infection.	**CONTRAINDICATIONS:** Hypersensitivity **SIDE-EFFECT:** • Diarrhea • Nausea • Vomiting	New	রেফারেন্স নেই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
220.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Trandolapril 4mg Tablet	Trandolapril USP 4mg	Antihypertensive Therapeutic code:022	Trandolaprilindicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive medication such as hydrochlorothiazide. Also, it is indicated in stable patients who have evidence of left-ventricular systolic dysfunction (identified	**CONTRAINDICATIONS:** It is contraindicated in patients who are hypersensitive to this product, in patients with hereditary/idiopathic angioedema and in patients with a history of angioedema related to previous treatment with an ACE inhibitor. **SIDE-EFFECT:** • dizziness or headache	Trandolapril 1mg Tablet Trandolapril 1mg Capsule Trandolapril 0.5mg Capsule	USFDA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					by wall motion abnormalities) or who are symptomatic from congestive heart failure within the first few days after sustaining acute myocardial infarction. Administration of trandolapril to Caucasian patients has been shown to decrease the risk of death (principally cardiovascular death) and to decrease the risk of heart failure related hospitalization.	• low blood pressure • general weakness • cough which may, or may not, produce phlegm. **WARNINGS AND PRECAUTIONS:** • have recently started or been taking diuretics (water tablets) for a long time or are on a low salt diet. • have or have had severe or prolonged vomiting or diarrhoea. • have been told that you have a narrowing of the blood vessels to one or both of your kidneys (renal stenosis). • have a narrowing of one of the valves in the heart (aorta stenosis) or in the outflow from the left chamber of the heart. • suffer from diabetes mellitus. Trandolapril capsules could cause your blood glucose levels to decrease too much. • suffer from heart failure or cirrhosis of the liver with swelling that can also be around your stomach. You are more likely to suffer from a very large drop in your blood pressure (hypotension) when you start to take the tablets which may make you feel faint or light-headed. are on kidney dialysis as you may be at risk of serious allergic reactions (some kinds of dialysis membrane may not be suitable).				
221.	Opsonin Pharma Limited, Rupatali, Barishal	Azelastine Hydrochloride 140mcg + Mometasone Furoate 50mcg Nasal Spray	Azelastine Hydrochloride USP 140 mcg + Mometasone Furoate USP 50 mcg	Ear & Nose Preparations Therapeutic Code:050	Allergic rhinitis including stuffy nose, runny nose, nasal itching, sneezing, as well as itchy, red and watery eyes	**Contraindications:** Patients with allergic to Azelastine hydrochloride and mometasone furoate should avoid this medication. **Side effects:** Nosebleeds, Pharyngitis, Nasal irritation, Headache **Precautions & warnings:** Concurrent use of this combination nasal spray with alcohol or	New	রেফারেন্স নেই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						other central nervous system depressants should be avoided because additional reductions in alertness and additional impairment of central nervous system performance may occur.				
222.	Opsonin Pharma Limited, Rupatali, Barishal General Pharmaceuticals (Unit-2)	Carbachol 0.01% Intraocular In‡jvection	Carbachol USP 0.01% Carbachol 10 mg/ ml	Eye Preparations Therapeutic Code:052	Indicated to induce miosis during surgery and surgery induced excessive intraocular pressure	**Contraindications:** Contraindicated in those persons showing hypersensitivity to any of the components of this preparation. **Side effects:** Ocular side effects include corneal clouding, persistent bullous keratopathy, retinal detachment and postoperative iritis following cataract extraction. Systemic side effects include flushing, sweating, epigastric distress, abdominal cramps, tightness in urinary bladder, and headache. **Precautions & warnings:** Precautions should be exercised in acute cardiac failure, bronchial asthma, peptic ulcer, hyperthyroidism, Gastrointestinal spasm, urinary tract obstruction and Parkinson's disease.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
223.	Opsonin Pharma Limited, Rupatali, Barishal.	Dequalinium Chloride 250 mcg Chewable Tablet	Dequalinium Chloride BP 250 mcg	Anti-infective Therapeutic Code:023	Relief of sore throat. In addition it is used for the temporary relief of pain of sore throat, throat irritation, ease/relieve nasal congestion, relief of coughs & as antiseptic.	**Contraindications:** Hypersensitivity to any of the ingredients. **Side effects:** Occasional hypersensitivity reactions and soreness of the tongue are possible. **Precautions & warnings:** Do not exceed the stated dose.	10 mg Vaginal Tablet	রেফারেন্স নেই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
224.	Opsonin Pharma Limited, Rupatali, Barishal.	Dipiverfin HCl 0.1% Eye Drops	Dipiverfin HCl USP 0.1%	Eye Preparations Therapeutic Code:052	Indicated for the treatment of Chronic open angle glaucoma.	**Contraindications:** Dipiverfin contraindicated in patients with narrow angles since any dilation of the pupil may predispose the patient to an attack of angle-closure glaucoma. Also contraindicated in patients with hypersensitive to any of components of this product. **Side effects:** The most common side effects of dipivefrine are burning, stinging and other irritations of the eye. Possible, but	New	রেফারেন্স নেই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						uncommon, side effects are those of epinephrine: tachycardia, hypertension and arrhythmias. **Precautions & warnings:** Macular edema may occur in up to 30% of aphakic patients treated with epinephrine. Discontinuation of epinephrine generally results in reversal of the maculopathy. For topical use only.				
225.	Opsonin Pharma Limited, Rupatali, Barishal.	Folinic acid 15 mg + Zinc 20 mg Tablet	Folinic acid BP 15 mg + Zinc USP 20 mg	DRUG used in Anemia and other Blood disorder Therapeutic Code:045	It is indicated in: ● To diminish the toxicity and counteract the effect of impaired Methotrexate elimination. To treat the Megaloblastic anemia due to folate deficiency. To treat the Megaloblastic anemia of pregnancy and infancy. To treatment and prophylaxis of Folinic Acid and Zinc deficiencies.	**Contraindications:** Calcium Folinate therapy is contraindicated for the following: Known hypersensitivity to Calcium Folinate, or to any components of the product formulation. Pernicious anemia or other Megaloblastic anemia where Vitamin B12 is deficient. Zinc is contraindicated in patients having hypersensitivity to Zinc. **Side effects:** Allergic reaction: one may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing). Fits and fainting. **Precautions & warnings:** Calcium Folinate treatment may mask pernicious anemia and other Megaloblastic anemia resulting from Vitamin B12 deficiency. Calcium Folinate should only be used with 5-fluorouracil or Methotrexate under the direct supervision of a clinician experienced in the use of cancer chemotherapeutic agents.	Folinic Acid 5 mg & 15mg Tablet Zinc 10mg & 20 mg Tablet	রেফারেন্স নেই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
226.	Opsonin Pharma Limited, Rupatali, Barishal Square Pharmaceuticals Ltd., Salgaria, Pabna	Sesame Oil 1ml/ml Nasal Drops	Sesame Seed Oil BP 1ml/ml	Ear & Nose Preparation Therapeutic Code:050	Maintenance treatment of patients with: General moisturizing inside the nose, nasal congestion, sinusitis, adjunctive therapy in the treatment of seasonal cold	**Contraindication:** Patients with allergic to Sesame oil **Side effects:** No serious allergic reaction has been reported by using Sesame oil nasal spray. **Precautions & Warnings:** Do not use within an hour before lying down or going to bed at night. Do not use this if you are allergic to	New	TGA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Sesame oil or Vitamin E				
227.	Opsonin Pharma Limited, Rupatali, Barishal Square Pharmaceuticals Ltd., Salgaria, Pabna	Sesame Oil 1ml/ml Nasal Spray	Sesame Seed Oil BP 1ml/ml	Ear & Nose Preparation Therapeutic Code:050	Maintenance treatment of patients with: General moisturizing inside the nose, nasal congestion, sinusitis, adjunctive therapy in the treatment of seasonal cold	**Contraindication:** Patients with allergic to Sesame oil **Side effects:** No serious allergic reaction has been reported by using Sesame oil nasal spray. **Precautions & Warnings:** Do not use within an hour before lying down or going to bed at night. Do not use this if you are allergic to Sesame oil or Vitamin E	New	TGA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
228.	Opsonin Pharma Limited, Rupatali, Barishal Renata Limited Mirpur, Dhaka The ACME Laboratories Ltd.	Tranexamic Acid 650mg Tablet	Tranexamic Acid BP 650mg	Blood Coagulating Therapeutic Code:033	Heavy Menstrual Bleeding	**Contraindications:** Active thromboembolic disease, such as deep vein thrombosis, pulmonary embolism and cerebral thrombosis **Side effects:** Gastrointestinal discomfort **Precautions & warnings:** Concomitant use of Tranexamic acid with Factor IX complex concentrates, anti-inhibitor coagulant concentrates or all-trans retinoic acid (oral tretinoin) may increase the risk of thrombosis.	250mg Tablet & Capsule 500 mg Tablet & Capsule 250 mg/5 ml In‡jvection 500 mg/5 ml In‡jvection 1 gm/10 ml In‡jvection 3 gm/30 ml In‡jvection	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
229.	Opsonin Pharma Limited, Rupatali, Barishal.	Tretinoin 0.1% Cream	Tretinoin USP 100mg/ 100 gm	Skin & mucous membrane preparation Therapeutic Code:071	Tretinoin is used to treat acne vulgaris, Pregnancy-Related Abdominal Striae (Stretch Marks), mottled hyperpigmentation, flat warts, fine wrinkles, dark spots, and roughness associated with photo damage and other skin conditions.	**Contraindications:** It should be discontinued if hypersensitivity to any of its ingredients is noted. **Side effects:** Tretinoin may cause skin dryness, redness, swelling, and blistering. **Precautions & warnings:** Avoid contact with the eyes, ears, nostrils, angles of the nose, and mouth. Wash the skin treated with tretinoin for at least 1 hour after applying it.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
230.	Opsonin Pharma Limited, Rupatali, Barishal	Elinzanetant 120 mg Tablet	Elinzanetant INN 120 mg	Other Classification Therapeutic Code:075	Treatment of hot flashes and sex hormone disorders in postmenopausal women.	Elinzanetant is contraindicated in patients with known hypersensitivity to any components of the formulation.	New	রেফারেন্স নেই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
231.	Opsonin Pharma Limited, Rupatali, Barishal.	Elinzanetant 40 mg Tablet	Elinzanetant INN 40 mg	Other Classification Therapeutic Code:075	Treatment of hot flashes and sex hormone disorders in postmenopausal women.	Elinzanetant is contraindicated in patients with known hypersensitivity to any components of the formulation.	New	রেফারেন্স নেই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
232.	Opsonin Pharma Limited, Rupatali, Barishal.	Elinzanetant 80 mg Tablet	Elinzanetant INN 80 mg	Other Classification Therapeutic Code:075	Treatment of hot flashes and sex hormone disorders in postmenopausal women.	Elinzanetant is contraindicated in patients with known hypersensitivity to any components of the formulation.	New	রেফারেন্স নেই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
233.	Navana Pharmaceuticals Ltd., Rupgang, Narayanagng	Ferric maltol 463.00 mg eq. to Iron 60mg Capsule	Ferric maltol INN 463.00 mg eq. to Iron 60mg	Drug used in Anemia and other Blood disorder Therapeutic code: 045	It is an iron replacement product indicated for the treatment of iron deficiency in adults	Warnings and Precautions: • IBD flare: Avoid use in patients with IBD flare • Iron overload: Accidental overdose of iron products is a leading cause of fatal poisoning in children under 6. Keep out of reach of children Contraindications: • Hypersensitivity to the active substance or any excipient • Hemochromatosis and other iron overload syndromes • Patients receiving repeated blood transfusions Side effects: Gas, diarrhea, constipation, , discolored stools, stomach pain, nausea or vomiting, stomach area discomfort or bloating	New	USFDA EMA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
234.	Navana Pharmaceuticals Ltd., Rupgang, Narayanagng	Carisoprodol 350mg Tablet	Carisoprodol USP 350mg	Skeletal Muscle Relaxant Therapeutic code: 070	It is indicated for the relief of discomfort associated with acute, painful musculoskeletal conditions. **Important Limitations:** •Should only be used for acute treatment periods up to two or three weeks. • Not recommended in pediatric patients less than 16 years of age.	**Contraindications:** Acute intermittent porphyria. Hypersensitivity reactions to a carbamate such as meprobamate. **Side Effects:** Most common adverse reactions (incidence > 2%) are drowsiness, dizziness, and headache. Warnings and Precautions: • Due to sedative properties, may impair ability to perform hazardous tasks such as driving or operating machinery. • Additive sedative effects when used with other CNS depressants including alcohol. • Cases of Drug Dependence, Withdrawal, and Abuse. • Seizures.	250mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
235.	Navana Pharmaceuticals Ltd., Rupgang, Narayanagng General Pharmaceuticals Ltd.	Mafenide 8.5gm% Cream	Mafenide Acetate USP 11.241gm eq. to Mafenide 8.5gm/100gm	Anti-infective Therapeutic Code: 023	Treatment and prophylaxis of infection in second- and third-degree burns.	**Contraindications:** It is contraindicated in patients who are hypersensitive to Mafenide Acetate. It is not known whether there is cross sensitivity to other sulfonamides. Side Effects: Significant: Hyperventilation w/ resulting resp alkalosis, metabolic acidosis, fungal or bacterial superinfection. • Resp: Dyspnoea, decreased pCO2. •Endocrine: Hyperchloraemia. •Haematologic: Eosinophilia, porphyria, bleeding. •Dermatologic: Pain or burning sensation, rash, pruritus, facial oedema, swelling, urticaria, blisters, erythema, excoriation, hives, blisters. Warnings and precautions: Fatal hemolytic anemia with disseminated intravascular coagulation, presumably related to a glucose-6-phosphate dehydrogenase deficiency, has been	5% Topical Solution	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						reported following therapy with Mafenide Cream. Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.				
236.	Navana Pharmaceuticals Ltd., Rupgang, Narayanagng Incepta Pharmaceuticals ltd, Dhamrai, Dhaka	Becaplermin 0.01% Gel	Becaplermin INN 0.01gm/100gm	Metabolic & Endocrine & Wound Care	It is indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply, when used as an adjunct to, and not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief and infection control.	**Contraindications:** is contraindicated in patients with known neoplasm(s) at the site(s) of application. **Side Effects:** The most commonly reported (≥5% incidence) adverse drug reactions (ADRs) are infected skin ulcer, cellulitis and osteomyelitis.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
237.	Navana Pharmaceuticals Ltd., Rupgang, Narayanagng	Revefenacin 175mcg/3 ml Inhalational Nebulizer Solution	Revefenacin INN 175mcg/3 ml	Anticholinergic Therapeutic Code: 011	Revefenacin inhalation solution is an anticholinergic indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).	Contraindications: Revefenacin is contraindicated in patients with hypersensitivity to revefenacin or any component of this product. Side Effects: Most common adverse reactions (incidence greater than or equal to 2% and more common than placebo) include cough, nasopharyngitis, upper respiratory tract infection, headache, and back pain. Warnings and Precautions: • Do not initiate Revefenacin in acutely deteriorating COPD or to treat acute symptoms. • If paradoxical bronchospasm occurs, discontinue Revefenacin and institute alternative therapy. • Worsening of narrow-angle glaucoma may occur. Use with	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						caution in patients with narrow-angle glaucoma and instruct patients to contact a healthcare provider immediately if symptoms occur. • Worsening of urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction and instruct patients to contact a healthcare provider immediately if symptoms occur. • Immediate hypersensitivity reactions may occur. If such a reaction occurs, therapy with Revefenacin should be stopped at once and alternative treatments should be considered.				
238.	Navana Pharmaceuticals Ltd., Rupgang, Narayanagng	Glycopyrrolate 1.7 mg OD Tablet	Glycopyrrolate INN 1.7 mg	Anticholinergic Therapeutic Code: 011	Glycopyrrolate is an anticholinergic indicated in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer. **Limitations of use:** Not indicated as monotherapy for treatment of peptic ulcer because effectiveness in peptic ulcer healing has not been established.	**Contraindications:** Patients at risk for anticholinergic toxicity due to various underlying medical conditions. • Hypersensitivity to glycopyrrolate or the inactive ingredients. **Side Effects:** Adverse reactions include blurred vision, drowsiness, decreased sweating, flushing, vomiting, constipation, dry mouth, tachycardia and urinary retention.	New	USFDA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
239.	Navana Pharmaceuticals Ltd., Rupgang, Narayanagng Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh The ACME Laboratories Ltd.	Anamorelin HCl 50mg Tablet	Anamorelin HCl INN 50mg	Agents affecting metabolism Therapeutic Code: 075	A drug with a new active ingredient indicated for the treatment of cancer cachexia in the following malignancies: non-small cell lung cancer, gastric cancer, pancreatic cancer, and colorectal cancer.	**Contraindications:** The combined use with potent CYP3A4 inhibitors should be contraindicated. **Side Effects:** Blood glucose increase, Drug-Related Hepatic Disorders, Cardiovascular events, ECG abnormalities, Oedema, Phototoxicity	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
240.	Renata Limited Rajendrapur, Gazipur	Cabozantinib 40mg Film Coated Tablet	Cabozantinib (S)-Malate INN 51mg eq. to Cabozantinib 40mg	Anticancer Therapeutic Code: 010	It is a kinase inhibitor indicated for the treatment of patients with rogressive, metastatic medullary thyroid cancer	**Contraindications:** It is contraindicated in patients with known hypersensitivity to Cabozantinib or any other components of this product. **Side effects:** The most common side effects of Cabozantinib include: Tiredness, Decreased appetite, Weight loss, Nausea, Vomiting, Changes in certain blood tests **Warning & Precaution:** The following clinical conditions require special caution and frequent patient monitoring is necessary:	20 mg, 80mg Capsule, 60mg Tabet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
241.	Renata Limited Rajendrapur, Gazipur	Dasatinib 70mg Film Coated Tablet	Dasatinib Monohydrate INN 72.583mg eq. to Dasatinib 70mg	Anticancer Therapeutic Code: 010	Dasatinib is a kinase inhibitor indicated for the treatment of ● Newly diagnosed adults with Philadelphia chromosome -positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. ● Adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib. Adults with Philadelphia chromosome -positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy.	**Contra indications:** It is contraindicated in patients with known hypersensitivity to Dasatinib or to any component of the formulation. **Side effects:** Myelosuppression, bleeding-related events, fluid retention, cardiovascular events, pulmonary arterial hypertension, QT prolongation, severe dermatologic reactions, tumor lysis syndrome, effects on growth and development in pediatric patients.	20mg, 50mg, 100 mg & 140mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
242.	Renata Limited Rajendrapur, Gazipur	Dasatinib 80mg Film Coated Tablet	Dasatinib Monohydrate INN 82.953mg eq. to Dasatinib 70mg	Anticancer Therapeutic Code: 010	Dasatinib is a kinase inhibitor indicated for the treatment of ● Newly diagnosed adults with Philadelphia chromosome -positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. ● Adults with chronic, accelerated, or myeloid or lymphoid	**Contra indications:** It is contraindicated in patients with known hypersensitivity to Dasatinib or to any component of the formulation. **Side effects:** Myelosuppression, bleeding-related events, fluid retention, cardiovascular events, pulmonary arterial hypertension, QT prolongation, severe dermatologic reactions, tumor lysis syndrome, effects on growth and	20mg, 50mg, 100 mg & 140mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib. Adults with Philadelphia chromosome -positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy.	development in pediatric patients.				
243.	Renata Limited Rajendrapur, Gazipur	Estradiol 0.5mg + Progesterone 100mg Soft Gelatine Capsule	Estradiol Hemihydrate BP 0.517mg eq. to Estradiol 0.5mg + Progesterone BP 100mg	Hormone Therapeutic Code: 056	It is a combination of an estrogen and progesterone indicated in a woman with a uterus for the treatment of moderate to severe vasomotor symptoms due to menopause.	**Contraindications:** Undiagnosed abnormal genital bleeding Known, suspected, or history of breast cancer Known or suspected estrogen-dependent neoplasia Active DVT, PE, or history of these conditions Active arterial thromboembolic disease (for example, stroke and MI), or a history of these conditions Known anaphylactic reaction or angioedema with BIJUVA Known liver impairment or disease Known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders **Adverse Reactions:** In a single, prospective, randomized, placebo-controlled, double-blind trial, the most common adverse reactions with (estradiol and progesterone) capsules (incidence ≥ 3% of women and greater than placebo) were breast tenderness, headache, vaginal bleeding, vaginal discharge and pelvic pain	Estradiol 2mg, 4mg & 25mg Tablet Progesterone 100mg & 200mg Soft Gelatin Capsule	USFDA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
244.	Renata Limited Rajendrapur, Gazipur	Estradiol 1.0mg + Progesterone 100mg Soft Gelatine Capsule	Estradiol Hemihydrate BP 1.033 mg eq. to Estradiol 1.0mg + Progesterone BP 100mg	Hormone Therapeutic Code: 056	It is a combination of an estrogen and progesterone indicated in a woman with a uterus for the treatment of moderate to severe vasomotor symptoms due to menopause.	**Contraindications:** Undiagnosed abnormal genital bleeding Known, suspected, or history of breast cancer Known or suspected estrogen-dependent neoplasia Active DVT, PE, or history of these conditions Active arterial thromboembolic disease (for example, stroke and MI), or a history of these conditions Known anaphylactic reaction or angioedema with BIJUVA Known liver impairment or disease	Estradiol 2mg, 4mg & 25mg Tablet Progesterone 100mg & 200mg Soft Gelatin Capsule	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders **Adverse Reactions:** In a single, prospective, randomized, placebo-controlled, double-blind trial, the most common adverse reactions with (estradiol and progesterone) capsules (incidence ≥ 3% of women and greater than placebo) were breast tenderness, headache, vaginal bleeding, vaginal discharge and pelvic pain				
245.	Renata Limited Rajendrapur, Gazipur	Temozolomide 100mg/Vial Lyophilized Powder for In‡jvection	Temozolomide USP 100mg/Vial	Anticancer Therapeutic Code: 010	It is an alkylating drug indicated for the treatment of adult patients with: ● Newly diagnosed glioblastoma multiforme (GBM) concomitantly with radiotherapy and then as maintenance treatment. ● Refractory anaplastic astrocytoma patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine.	**Contraindications:** Temozolomide is contraindicated in patients who have a history of hypersensitivity reaction (such as urticaria, allergic reaction including anaphylaxis, toxic epidermal necrolysis, and Stevens-Johnson syndrome) to any of its components. Temozolomide is also contraindicated in patients who have a history of hypersensitivity to dacarbazine (DTIC), since both drugs are metabolized to 5-(3-methyltriazen-1-yl)-imidazole-4-carboxamide (MTIC). **Side effects:** Nausea, vomiting, taste perversion, constipation, diarrhoea, abdominal pain, stomatitis, anorexia, headache, fatigue, convulsions, dizziness, memory impairment, impaired concentration, tremors, blurred vision, hearing impairment, speech disorder, rash, infection, oral candidiasis, dyspnoea, coughing, neutropenia, thrombocytopenia, leucopenia, anaemia, hyperglycemia, decreased weight, insomnia, anxiety, alopecia, muscle weakness, urinary incontinence, increased alanine aminotransferase. Rarely, myelodysplastic syndrome and secondary	5mg, 100mg & 250mg Capsule	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						malignancies.				
246.	Renata Limited Rajendrapur, Gazipur	Temozolomide 140mg Capsule	Temozolomide USP 140mg	Anticancer Therapeutic Code: 010	It is an alkylating drug indicated for the treatment of adult patients with: ● Newly diagnosed glioblastoma multiforme (GBM) concomitantly with radiotherapy and then as maintenance treatment. ● Refractory anaplastic astrocytoma patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine.	**Contraindications:** Temozolomide is contraindicated in patients who have a history of hypersensitivity reaction (such as urticaria, allergic reaction including anaphylaxis, toxic epidermal necrolysis, and Stevens-Johnson syndrome) to any of its components. Temozolomide is also contraindicated in patients who have a history of hypersensitivity to dacarbazine (DTIC), since both drugs are metabolized to 5-(3-methyltriazen-1-yl)-imidazole-4-carboxamide (MTIC). **Side effects:** Nausea, vomiting, taste perversion, constipation, diarrhoea, abdominal pain, stomatitis, anorexia, headache, fatigue, convulsions, dizziness, memory impairment, impaired concentration, tremors, blurred vision, hearing impairment, speech disorder, rash, infection, oral candidiasis, dyspnoea, coughing, neutropenia, thrombocytopenia, leucopenia, anaemia, hyperglycemia, decreased weight, insomnia, anxiety, alopecia, muscle weakness, urinary incontinence, increased alanine aminotransferase. Rarely, myelodysplastic syndrome and secondary malignancies.	5mg, 100mg & 250mg Capsule	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
247.	Renata Limited Rajendrapur, Gazipur	Temozolomide 180mg Capsule	Temozolomide USP 180mg	Anticancer Therapeutic Code: 010	It is an alkylating drug indicated for the treatment of adult patients with: ● Newly diagnosed glioblastoma multiforme (GBM) concomitantly with radiotherapy and then as maintenance treatment. ● Refractory anaplastic astrocytoma patients who have experienced disease progression	**Contraindications:** Temozolomide is contraindicated in patients who have a history of hypersensitivity reaction (such as urticaria, allergic reaction including anaphylaxis, toxic epidermal necrolysis, and Stevens-Johnson syndrome) to any of its components. Temozolomide is also contraindicated in patients who have a history of hypersensitivity to dacarbazine (DTIC), since both drugs are metabolized to	5mg, 100mg & 250mg Capsule	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					on a drug regimen containing nitrosourea and procarbazine.	5-(3-methyltriazen-1-yl)-imidazole-4-carboxamide (MTIC). **Side effects:** Nausea, vomiting, taste perversion, constipation, diarrhoea, abdominal pain, stomatitis, anorexia, headache, fatigue, convulsions, dizziness, memory impairment, impaired concentration, tremors, blurred vision, hearing impairment, speech disorder, rash, infection, oral candidiasis, dyspnoea, coughing, neutropenia, thrombocytopenia, leucopenia, anaemia, hyperglycemia, decreased weight, insomnia, anxiety, alopecia, muscle weakness, urinary incontinence, increased alanine aminotransferase. Rarely, myelodysplastic syndrome and secondary malignancies.				
248.	Renata Limited Rajendrapur, Gazipur Ziska Pharmaceuticals Ltd.	Testosterone Undecanoate 112.5mg Soft Gelatin Capsule	Testosterone Undecanoate INN 112.5mg	Hormone Therapeutic Code: 056	Testosterone undecanoate is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: ● Primary hypogonadism (congenital or acquired). ● Hypogonadotropic hypogonadism (congenital or acquired).	**Contra indications:** Men with breast cancer or known or suspected prostate cancer. Women who are pregnant. Testosterone may cause fetal harm. Known hypersensitivity or with any of its ingredients. Men with hypogonadal conditions not associated with structural or genetic etiologies. **Side effects:** ● Polycythemia ● Diarrhea ● Dyspepsia ● Eructation ● Peripheral Edema ● Nausea ● Increased Hematocrit ● Headache	40mg Capsule	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						● Prostatomegaly Hypertension **Warnings & Precautions:** Monitor hematocrit approximately every 3 months to detect increased red blood cell mass and polycythemia. Monitor patients with benign prostatic hyperplasia (BPH) for worsening of signs and symptoms of BPH. Venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients using testosterone. Exogenous administration of androgens may lead to azoospermia. Edema, with or without congestive heart failure, may occur in patients with pre-existing cardiac, renal, or hepatic disease. Sleep apnea may occur in those with risk factors. Monitor prostate specific antigen (PSA) and lipid concentrations periodically.				
249.	Renata Limited Rajendrapur, Gazipur Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Trifluridine 20mg + Tipiracil 8.19mg Film Coated Tablet	Trifluridine USP 20mg + Tipiracil HCl INN 9.420mg eq.to Tipiracil 8.19mg	Anticancer Therapeutic Code: 010	Indicated for the treatment of adult patients with: x metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy. (1.1) x metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted	**Contraindications:** Hypersensitivity to the active substances or to any of the excipients used **Side effects:** The most frequently observed adverse drug reactions in patients receiving Trifluridine and Tipiracil are neutropenia, nausea, fatigue, anaemia. **Warnings & Precautions:** The following clinical conditions require special caution and frequent patient monitoring is necessary: • Bone marrow suppression: Trifluridine and Tipiracil caused an increase in the incidence of myelosuppression including anaemia, neutropenia, leukopenia, and	Trifluridine 1% Eye Drops	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					therapy.	thrombocytopenia. • Gastrointestinal toxicity Trifluridine and Tipiracil caused an increase in the incidence of gastrointestinal toxicities including nausea, vomiting and diarrhoea. • Proteinuria Monitoring of proteinuria by dipstick urinalysis is recommended prior to starting and during therapy. • Embryo-Fetal Toxicity: Based on animal studies and its mechanism of action, trifluridine and tipiracil can cause fetal harm when administered to a pregnant woman.				
250.	Renata Limited Rajendrapur, Gazipur Beacon Pharmaceuticals Ltd.	Cabazitaxel 60mg/1.5ml In‡jvection For Dilution 13% (w/w) Etahnol in WFI	Cabazitaxel BP 60mg/1.5ml	Anticancer Therapeutic Code: 010	It is a microtubule inhibitor indicated in combination with prednisone for treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen	**Contraindications:** Cabazitaxel is contraindicated in the following conditions: Neutrophil counts <1,500/mm³: platelets >100,000/mm³, haemoglobin >10 g/dL, creatinine <1.5 x ULN, hepatic impairment (bilirubin 21 x ULN, or AST &/or ALT 21.5 x ULN); concomitant vaccination with yellow fever vaccine. **Side effects:** The most common side effects of Cabazitaxel in all grade: Anaemia, Leukopenia, Neutropenia, Thrombocytopenia, Diarrhoea, Most common side effects of Cabazitaxel in grade ≥3 or higher: Neutropenia, Leukopenia, Anaemia, Febrile Neutropenia, Diarrhoea **Warnings & Precautions:** The following clinical conditions require special caution and frequent patient monitoring is necessary: • Hypersensitivity reactions • Bone marrow suppression • Risk of neutropenia • Gastrointestinal disorders • Risk of nausea, vomiting, diarrhoea and dehydration • Risk of serious gastrointestinal reactions	Cabazitaxel 10mg/ml Infusion	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						• Peripheral neuropathy • Anaemia • Risk of renal failure • Respiratory disorders • Risk of cardiac arrhythmias • Patients with liver impairment • Pregnancy and Lactation • Caution in Elderly Use				
251.	Renata Limited Mirpur, Dhaka. Beacon Pharmaceuticals Ltd.	Deflazacort 36mg Film Coated Tablet	Deflazacort INN 36mg	Steroidal Anti Inflammatory Therapeutic code: 072	it is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older.	**Contraindications:** Deflazacort is contraindicated in patients with known hypersensitivity to Deflazacort or to any of the inactive ingredients. Instances of hypersensitivity, including anaphylaxis, have occurred in patients receiving corticosteroid therapy **Side-effects:** GI disturbances, musculoskeletal, endocrine, neuropsychiatric, ophthalmic, fluid and electrolyte disturbances; susceptible to infection, impaired healing, hypersensitivity, skin atrophy, striae, telangiectasia, acne, myocardial rupture following recent MI, thromboembolism. Warning & Precaution: The following clinical conditions require special caution and frequent patient monitoring is necessary: • Cardiac disease or congestive heart failure (except in the presence of active rheumatic carditis), hypertension, thromboembolic disorders. Glucocorticoids can cause salt and water retention and increased excretion of potassium. Dietary salt restriction and potassium supplementation may be necessary. • Gastritis or oesophagitis, diverticulitis, ulcerative colitis if there is probability of	6mg, 18mg, 24mg & 30mg Tablet and 120mg/100ml Suspension	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						impending perforation, abscess or pyogenic infections, fresh intestinal anastomosis, active or latent peptic ulcer. • Diabetes mellitus or a family history, osteoporosis, myasthenia gravis, renal insufficiency. • Emotional instability or psychotic tendency, epilepsy. • Previous corticosteroid-induced myopathy. • Liver failure. • Hypothyroidism and cirrhosis, which may increase glucocorticoid effect. • Ocular herpes simplex because of possible corneal perforation.				
252.	Renata Limited Mirpur, Dhaka.	Ferrous Sulfate 325mg + Sodium Ascorbate 562.40mg Prolonged Release Tablet	Dried Ferrous Sulfate USP 325mg eq to Elemental Iron 105mg + Sodium Ascorbate USP 562.40mg eq. to Ascorbic Acid 500mg	Drug used in anaemia Therapeutic code: 045	It is used to prevent and treat iron-deficiency anaemia and vitamin C deficiency when the two are present together. It should be taken by pregnant women after the first 13 weeks of pregnancy	**Contraindications**: ● The absorption of Dried ferrous sulfate & Vitamin C may also be decreased when taken with tea, coffee, milk, eggs, wholegrain cereals and dietary fiber, therefore, it should be taken at least 1 hour before or 2 hours after ingestion of these products. ● In case of concomitant administration of Dried ferrous sulfate & Vitamin C with Antibiotics for infections such as tetracycline antibiotics, Indigestion remedies such as antacids and preparations of calcium, zinc and phosphorous, Quinolone anti-infective agents such as ciprofloxacin, norfloxacin and ofloxacine, Levothyroxine as a thyroid hormone medication, Methyldopa for high blood pressure, Levodopa for Parkinson's disease, Penicillamine for arthritis, please allow 2 – 3 hours between taking Dried ferrous sulfate & Vitamin C and the other medications (or 4 hours for the quinolone anti-infective agents).	Ferrous Sulphate 200 mg Tablet Ferrous Sulphate 200 mg + Folic Acid 200 mcg Tablet	TGA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Side-effects: ● Stools may turn black whilst taking the medication. If you have a test for the detection of blood in your stools, tell your doctor you are taking Dried ferrous sulfate & Vitamin C PR Tablet as black stools may cause an incorrect result to the test. ● Allergic reaction (itchy skin and in rare cases swelling of the face and oral mucosa and difficulty in breathing or fainting). ● If you develop any of these symptoms stop taking the tablets and contact your doctor ✓ Feeling sick ✓ Vomiting ✓ Stomach Pain ✓ Diarrhoea ✓ Constipation Haematemesis (blood in vomiting) and ileus (intestinal obstruction) have been reported Warning & Precaution: Due to the risk of mouth ulceration and tooth discoloration, tablets should not be sucked, chewed or kept in the mouth but swallowed whole with water				
253.	Renata Limited Mirpur, Dhaka.	Hydrocortisone 5mg Tablet	Hydrocortisone BP 5mg	Steroidal Anti Inflammatory Therapeutic code: 072	Replacement therapy in congenital adrenal hyperplasia in children. Treatment of adrenal insufficiency in children and adolescents < 18 years of age. Emergency treatment of severe bronchial asthma, drug hypersensitivity reactions, serum sickness, angioneurotic oedema and anaphylaxis in adults and children.	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients used in the tablet formulation, Systemic fungal infections, and patients with systemic infections (unless specific anti-infective therapy is employed) and patients vaccinated with live vaccines. **Side-effects:** Hydrocortisone is generally well tolerated except in prolonged high doses. It may predispose to esophageal	10mg & 20mg Tablet and 100mg Injection, 1% Cream and 1% Ointment	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						candidiais and cause menstrual irregularity, weight gain, euphoria, mood swings, depression, insomnia and acne Warning & Precaution: Hydrocortisone should be used with caution in patients with a history of peptic ulceration as it increases the incidence of peptic ulceration. This drug should be used with caution in patients with cardiac failure, hypertension, glaucoma, diabetic mellitus and epilepsy				
254.	Renata Limited Mirpur, Dhaka.	Methylprednisolone 32mg Film Coated Tablet	Methylprednisolone USP 32mg	Steroidal Anti Inflammatory Therapeutic code: 072	It is a steroid that prevents the release of substances in the body that cause inflammation. It is used to treat many different inflammatory conditions such as arthritis, lupus, psoriasis, ulcerative colitis, allergic disorders, gland (endocrine) disorders, and conditions that affect the skin, eyes, lungs, stomach, nervous system, or blood cells.	**Contraindications:** Methylprednisolone contraindications include patients with documented hypersensitivity to the drug or components, systemic fungal infection, live or attenuated virus vaccine, idiopathic thrombocytopenic purpura, or in premature infants. Like other glucocorticoids, Methylprednisolone must be used with great caution in patients with peptic ulcers, heart disease or hypertension with heart failure, certain infectious illnesses such as varicella and tuberculosis psychoses, diabetes, osteoporosis, or glaucoma. Side Effects: Short courses of Methylprednisolone are usually well-tolerated with few, mild side effects. Long term, high doses of Methylprednisolone may produce predictable and potentially serious side effects. Whenever possible, the lowest effective doses of Methylprednisolone should be used for the shortest length of time to minimize side effects. Alternate day dosing also can help to reduce side effects. Side effects of Methylprednisolone and other corticosteroids range from mild annoyances to serious irreversible bodily damage. Side	2mg, 4mg, 8mg, & 16mg Tablet	USFDA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						effects include fluid retention, weight gain, high blood pressure, potassium loss, headache, muscle weakness, hair growth on the face, glaucoma, cataracts, peptic ulceration, growth retardation in children, convulsions and psychic disturbances including depression, euphoria, insomnia etc. Prolonged use of Methylprednisolone can depress the ability of the body's adrenal glands to produce corticosteroids. Abruptly stopping Methylprednisolone in these individuals can cause symptoms of corticosteroid insufficiency with accompanying nausea, vomiting, and even shock. Therefore, withdrawal of Methylprednisolone usually is accomplished by gradually lowering the dose. Gradually tapering Methylprednisolone not only minimizes the symptoms of corticosteroid insufficiency, it also reduces the risk of an abrupt flare of the disease being treated. Warning & Precaution: Adrenocortical insufficiency may persist for months after discontinuation of therapy; therefore, in any situation of stress occurring during that period, hormone therapy should be reinstituted. Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently. There is an enhanced effect of corticosteroids on patients with hypothyroidism and in those with cirrhosis. Corticosteroids should be used cautiously in patients with ocular herpes simplex because of possible corneal perforation. Aspirin should be used cautiously in con‡jvunction with corticosteroids in hypoprothrombinemia. Growth and development of infants and children on prolonged corticosteroid therapy				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						should be carefully observed.				
255.	Renata Limited Mirpur, Dhaka.	Risperidone 0.5mg Orally Disintegrating Tablet	Risperidone USP 0.5mg	Antipsychotic Therapeutic code: 028	Indicated for the management of the manifestation of psychotic disorders	Contraindication: Hypersensitivity to the active substance or to any of the excipients Side Effects: Postural orthostatic tachycardia syndrome As with other antipsychotics, very rare cases of QT prolongation have been reported post-marketing with risperidone. Other class-related cardiac effects reported with antipsychotics which prolong QT interval include ventricular arrhythmia, ventricular fibrillation, ventricular tachycardia, sudden death, cardiac arrest.	1mg, 2mg & 4mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
256.	Renata Limited Mirpur, Dhaka.	Topiramate 150mg Extended Release Capsule	Topiramate ER Pellets Pharma Grade 375mg containg Topiramate USP 150mg	Epilepsy Therapeutic code: 046	It is an antiepileptic drug indicated for: ♣ Partial Onset Seizures and Primary Generalized Tonic-Clonic Seizures initial monotherapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures and adjunctive therapy in patients 2 years of age and older with partial onset or primary generalized tonic-clonic seizures ♣ Lennox-Gastaut Syndrome (LGS) - adjunctive therapy in patients 2 years of age and older with seizures associated with Lennox-Gastaut syndrome	**Contraindication:** Topiramate XR is contraindicated in patients with metabolic acidosis who are taking concomitant metformin. **Side Effects:** Tingling of the arms and legs (paresthesia), not feeling hungry, weight loss, nervousness, nausea, speech problems, tiredness, dizziness, sleepiness/drowsiness, a change in the way foods taste, upper respiratory tract infection, slow reactions, difficulty with memory, fever, abnormal vision, diarrhea, pain in the abdomen	25mg, 50mg & 100mg Tablet and ER Capsule	US FDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
257.	Renata Limited Mirpur, Dhaka.	Topiramate 200mg Extended Release Capsule	Topiramate ER Pellets Pharma Grade 500mg containg Topiramate USP 200mg	Epilepsy Therapeutic code: 046	Epilepsy Therapeutic code: 046	It is an antiepileptic drug indicated for: ♣ Partial Onset Seizures and Primary Generalized Tonic-Clonic Seizures initial monotherapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures and adjunctive therapy in patients 2 years of age and older with partial onset or primary generalized tonic-clonic seizures	25mg, 50mg & 100mg Tablet and ER Capsule	US FDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						♣ Lennox-Gastaut Syndrome (LGS) - adjunctive therapy in patients 2 years of age and older with seizures associated with Lennox-Gastaut syndrome				
258.	Renata Limited Mirpur, Dhaka.	Dinoprostone 0.5mg Tablet	Dinoprostone BP 0.5mg	Drug Used in obstratics and Geniourinary Disease Therapeutic code: 049	It is used to cause an abortion during weeks 12-20 of pregnancy. It is also used up to week 28 of pregnancy to help vaginally remove any remaining material in the womb from a miscarriage/missed abortion. This medication causes the womb to contract and push out its contents, including the placenta and the fetus/unborn baby, whether living or not	**Contraindications:** This drug should not be used if patient is carrying more than one baby, if the labor has already started, or if your water has broken Side Effects: **More common:** upset stomach, vomiting, diarrhea, dizziness, flushing of the skin, headache, fever Warning & Precaution Allergic to Dinoprostone or any other drugs. asthma; anemia; a cesarean section or any other uterine surgery; diabetes; high or low blood pressure; placenta previa; a seizure disorder; six or more previous term pregnancies; glaucoma or increased pressure in the eye; cephalopelvic disproportion; previous difficult or traumatic deliveries; unexplained vaginal bleeding; or heart, liver, or kidney disease.	50 mg/10 ml Injection 0.5mg/3gm Cervical gel	রেফারেন্স নাই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
259.	Renata Limited Mirpur, Dhaka The ACME Laboratories Ltd.	Dinoprostone BP 3mg Vaginal Tablet	Dinoprostone BP 3mg	Prostaglandin Therapeutic code: 077	DO	DO	50 mg/10 ml Injection 0.5mg/3gm Cervical gel	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
260.	Renata Limited Mirpur, Dhaka	Omeprazole USP 2mg/ml Dry Powder for Suspension	Omeprazole USP 2mg/ml	Proton Pump Inhibitor Therapeutic code: 067	• Treatment of duodenal ulcers • Prevention of relapse of duodenal ulcers • Treatment of gastric ulcers • Prevention of relapse of gastric ulcers • In combination with appropriate antibiotics, *Helicobacter pylori (H. pylori)* eradication in peptic ulcer disease	**Contraindications:** Hypersensitivity to the active substance, substituted benzimidazoles or to any of the excipients. Omeprazole must not be used with nelfi navir. **Side Effects:** Adults and children: Common: headache, abdominal pain, constipation, diarrhoea, fl atulence, nausea/vomiting, fundic gland polyps. Uncommon: Insomnia, dizziness, paraesthesia, somnolence,	20 mg & 40 mg Capsule	EMA MHRA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					• Treatment of NSAID-associated gastric and duodenal ulcers • Prevention of NSAID-associated gastric and duodenal ulcers in patients at risk • Treatment of reflux esophagitis • Long-term management of patients with healed reflux esophagitis • Treatment of symptomatic gastro-esophageal reflux disease Paediatric use *Children over 1 month of age* • Treatment of reflux esophagitis • Symptomatic treatment of heartburn and acid regurgitation in gastro-esophageal reflux disease *Children over 4 years of age and adolescents* In combination with antibiotics in treatment of duodenal ulcer caused by *H. pylori*	vertigo, increased liver enzymes, dermatitis, pruritus, rash, urticaria, fracture of the hip, wrist or spine, malaise, peripheral oedema. Rare: leukopenia, thrombocytopenia, hypersensitivity reactions, hyponatraemia, agitation, confusion, depression, taste disturbance, blurred vision, bronchospasm, dry mouth, stomatitis, gastrointestinal candidiasis, hepatitis, alopecia, photosensitivity, arthralgia, myalgia, interstitial nephritis, increased sweating Warning & Precaution: Malignancy, reduced vitamin B12 absorption, severe hypomagnesaemia, increased risk of bone fracture, subacute cutaneous lupus erythematosus (SCLE), gastrointestinal infections may occur, treatment should be stopped for at least 5 days before CgA measurement .				
261.	Renata Limited Mirpur, Dhaka	Omeprazole USP 4mg/ml Dry Powder for Suspension	Omeprazole USP 4mg/ml	Proton Pump Inhibitor Therapeutic code: 067	• Treatment of duodenal ulcers • Prevention of relapse of duodenal ulcers • Treatment of gastric ulcers • Prevention of relapse of gastric ulcers • In combination with appropriate antibiotics, *Helicobacter pylori (H. pylori)* eradication in peptic ulcer disease • Treatment of NSAID-associated gastric and duodenal ulcers • Prevention of NSAID-associated gastric and duodenal ulcers in patients at risk • Treatment of reflux esophagitis • Long-term management of	**Contraindications:** Hypersensitivity to the active substance, substituted benzimidazoles or to any of the excipients. Omeprazole must not be used with nelfi navir. **Side Effects:** Adults and children: Common: headache, abdominal pain, constipation, diarrhoea, fl atulence, nausea/vomiting, fundic gland polyps. Uncommon: Insomnia, dizziness, paraesthesia, somnolence, vertigo, increased liver enzymes, dermatitis, pruritus, rash, urticaria, fracture of the hip, wrist or spine, malaise, peripheral oedema. Rare: leukopenia, thrombocytopenia, hypersensitivity reactions, hyponatraemia, agitation, confusion, depression, taste disturbance, blurred vision, bronchospasm,	20 mg & 40 mg Capsule	EMA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					patients with healed reflux esophagitis • Treatment of symptomatic gastro-esophageal reflux disease Paediatric use *Children over 1 month of age* • Treatment of reflux esophagitis • Symptomatic treatment of heartburn and acid regurgitation in gastro-esophageal reflux disease *Children over 4 years of age and adolescents* In combination with antibiotics in treatment of duodenal ulcer caused by *H. pylori*	dry mouth, stomatitis, gastrointestinal candidiasis, hepatitis, alopecia, photosensitivity, arthralgia, myalgia, interstitial nephritis, increased sweating Warning & Precaution: Malignancy, reduced vitamin B12 absorption, severe hypomagnesaemia, increased risk of bone fracture, subacute cutaneous lupus erythematosus (SCLE), gastrointestinal infections may occur, treatment should be stopped for at least 5 days before CgA measurement .				
262.	UniMed UniHealth Pharmaceuticals Ltd. B.K Bari, Gazipur Sadar, Gazipur	Calcium Glubionate 21.80g + Calcium Lactobionate 14.54g	Calcium Glubionate INN 21.80g + Calcium Lactobionate USP 14.54g	Metals, Salts, Minerals & Calcium Preparations Therapeutic Code: 062	It is indicated in the treatment of neonatal tetany and a therapeutic supplement in osteoporosis, post-gastrectomy malabsorption, osteomalacia, rickets, pregnancy and lactation.	**Contraindications:** Severe hypercalcaemia and hypercalciuria (e.g. in hyperparathyroidism, vitamin D overdosage, decalcifying tumour such as plasmacytoma and skeletal metastases, immobilisation osteoporosis; sarcoidosis), severe renal failure and mild alkali syndrome. Due to its galactose component should not be given to patients with galactosaemic. **Side effects:** Mild gastrointestinal disturbances have occurred rarely (e.g. constipation, diarrhoea). Although hypercalcaemia would not be expected in patients unless their renal function were impaired, the following symptoms could indicate possibility of hypercalcaemia; nausea, vomiting, anorexia, constipation, abdominal pain, bone pain, thirst, polyimide muscle weakness, drowsiness or confusion.	New	রেফারেন্স নাই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
263.	UniMed UniHealth Pharmaceuticals Ltd.	Terbinafine Hydrochloride 500 mg Tablet	Terbinafine Hydrochloride BP 500 mg Tablet	Antifungal agent Therapeutic Code: 020	It is used to treat a wide range of fungal infections of the skin and nails, including ringworm. It works by killing the fungi that cause the infection.	**Contraindications:** Hypersensitivity Chronic or active liver disease **Side effects:** Headache, Diarrhea, Rash, Indigestion, Abnormal liver enzyme, Itching,	125mg Tablet 250mg Tablet	রেফারেন্স নাই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Taste change, Nausea, Abdominal pain & Flatulence				
264.	Renata Limited Rajendrapur, Gazipur	Norethisterone 10mg Tablet	Norethisterone Acetate BP 11.41mg eq. to Norethisterone 10mg	Contraceptive Therapeutic Code: 039	Norethisterone is indicated as an oral contraceptive when given as monotherapy14 or in combination with an estrogen component, such as ethinylestradiol or estradiol	**Contraindications:** ● Hypersensitivity to the active substance or any of the excipients listed in section 6.1 ● Pregnancy ● Previous idiopathic or current venous thromboembolism (deep vein thrombosis, pulmonary embolism) ● Active or recent arterial thromboembolic disease (e.g. angina, myocardial infarction) ● Disturbance of liver function ● History during pregnancy of idiopathic jaundice ● Severe pruritus or pemphigoid gestationis ● Undiagnosed irregular vaginal bleeding Porphyria **Side effects**: Amongst those recorded are slight nausea, exacerbation of epilepsy and migraine. With extremely high dosage there may be cholestatic liver changes **Warnings & Precautions:** There is a general opinion, based on statistical evidence that users of combined oral contraceptives experience, more often than non-users, venous thromboembolism, arterial thrombosis, including cerebral and myocardial infarction, and subarachnoid haemorrhage. Full recovery from such disorders does not always occur, and it should be realized that in a few cases they are fatal. Although norethisterone does not	5mg Tablet	রেফারেন্স নাই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						contain oestrogen, one should keep the possibility of an increased thromboembolic risk in mind, particularly where there is a history of thromboembolic disease or in the presence of severe diabetes with vascular changes or sickle-cell anemia				
265.	Renata Limited Rajendrapur, Gazipur	Norethisterone 15mg Tablet	Norethisterone Acetate BP 17.11 mg eq. to Norethisterone 15mg	Contraceptive Therapeutic Code: 039	Norethisterone is indicated as an oral contraceptive when given as monotherapy14 or in combination with an estrogen component, such as ethinylestradiol or estradiol	**Contraindications:** ● Hypersensitivity to the active substance or any of the excipients listed in section 6.1 ● Pregnancy ● Previous idiopathic or current venous thromboembolism (deep vein thrombosis, pulmonary embolism) ● Active or recent arterial thromboembolic disease (e.g. angina, myocardial infarction) ● Disturbance of liver function ● History during pregnancy of idiopathic jaundice ● Severe pruritus or pemphigoid gestationis ● Undiagnosed irregular vaginal bleeding Porphyria **Side effects**: Amongst those recorded are slight nausea, exacerbation of epilepsy and migraine. With extremely high dosage there may be cholestatic liver changes **Warnings & Precautions:** There is a general opinion, based on statistical evidence that users of combined oral contraceptives experience, more often than non-users, venous thromboembolism, arterial thrombosis, including cerebral and myocardial infarction, and subarachnoid	5mg Tablet	রেফারেন্স নাই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						haemorrhage. Full recovery from such disorders does not always occur, and it should be realized that in a few cases they are fatal. Although norethisterone does not contain oestrogen, one should keep the possibility of an increased thromboembolic risk in mind, particularly where there is a history of thromboembolic disease or in the presence of severe diabetes with vascular changes or sickle-cell anemia				
266.	Silva Pharmaceuticals Ltd.	Glycerin 0.75 ml + Honey 1.11 gm (0.4 g as glucose) + Liquid Sugar 2.2 ml/5ml Syrup	Glycerin BP 0.75 ml + Honey BP 1.11 gm (0.4 g as glucose) + Liquid Sugar BP 2.2 ml/5ml	Antitussive Therapeutic Code: 031	For the relief of coughs and sore throats.	**Contraindication:** Hypersensitivity or intolerance to any of the ingredients. **Common Side-effects:** This medicine is unlikely to cause side effects unless the patient is allergic to the ingredients. **Precautions:** Diabetics should take note of the carbohydrate content of this product. Do not give to children under one year. Keep all medicines out of the reach of children.	Glycerine .75 ml + Liquid Sugar 1.93 ml/5 ml Syrup	MHRA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
267.	Orion Infusion Limited Maikuli, Rupgang, Narayanagng	Potassium Chloride 0.3% + Sodium Chloride 0.45% + Anhydrous Glucose 5.0% Solution for IV Infusion **Pack Size:** 500ml, 1000ml	Potassium Chloride BP 0.3% + Sodium Chloride BP 0.45% + Anhydrous Glucose BP 5.0%	Electrolytes Therapeutic Code: 079	Prevention and treatment of potassium depletion and/or hypokalaemia in cases where supply of water and carbohydrates is required, due to restriction of the intake of fluids and electrolytes by normal routes.	**Contraindication:** ● Where the administration of sodium, potassium or chloride could be clinically detrimental. ● Solutions containing Glucose may be contraindicated in patients with hypersensitivity to corn products. **Side effects:** Diarrhea, Allergic reactions like skin rash, itching, Confusion Nausea &Vomiting	Calcium Chloride 0.033% + Potassium Chloride 0.03% + Sodium Chloride 0.86% IV Infusion	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
268.	Organic Health Care Ltd., Gilarchala, 7 Kewa Mouza, Sreepur, Gazipur Beacon Pharmaceuticals	Tiaprofenic Acid 300mg Tablet	Tiaprofenic Acid INN 300 mg	NSAID Therapeutic Code: 064	Relief of signs and symptoms of rheumatoid arthritis and osteoarthritis (degenerative joint disease)	**Contraindications:** Known hypersensitivity to **Tiaprofenic** or any of the excipients **Side effects:** Agranulocytosis, Alopecia, angioedema, aplastic anemia, Loss of appetite, asthma and bronchospasm, depression, dizziness, drowsiness, fatigue, female infertility, fluid retention, GI discomfort	New	BNF-84 Page: 1244	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Limited Kathali, Bhaluka, Mymensingh					etc **Warning and Precaution**: Allergic disorder, cardiac impairment, cerebrovascular disease, connective tissue disorder, risk of renal impairment, IHD, Heart failure, CVD, uncontrolled hypertension				
269.	Beacon Pharmaceuticals Limited, Kathali, Bhaluka, Mymensingh	Evocalcet 1mg Tablet	Evocalcet INN 1mg	Metals, Salts, Minerals & calcium Perparetions Therapeutic Code:062	It is indicated for the Secondary hyperparathyroidism in patients on maintenance dialysis	**Contraindication**: Patients with a history of hypersensitivity to the ingredients of this drug. **Side-Effect:** Low incidence of myocardial infarction, congestive heart failure and GI related issues.	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
270.	Beacon Pharmaceuticals Limited, Kathali, Bhaluka, Mymensingh	Evocalcet 2mg Tablet	Evocalcet INN 2mg	Metals, Salts, Minerals & calcium Perparetions Therapeutic Code:062	It is indicated for the Secondary hyperparathyroidism in patients on maintenance dialysis	**Contraindication**: Patients with a history of hypersensitivity to the ingredients of this drug. **Side-Effect:** Low incidence of myocardial infarction, congestive heart failure and GI related issues.		PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
271.	Beacon Pharmaceuticals Limited, Kathali, Bhaluka, Mymensingh	Rebamipide 100mg Tablet	Rebamipide INN 100mg	Antacid Therapeutic Code:007	In is prescribed for the treatment of peptic ulcer, gastroduodenal ulcers and gastric disorder. It is indicated during bleeding, erosion, redness and edema that occur in acute gastritis and acute exacerbation of chronic gastritis.	**Contraindication**: it is contraindicated in patients who are allergic to the drug. **Side-Effect:** Skin: Rash, Pruritsus, drug-eruption-like eczema. Constipation, Bloating, Diarrhea, nausea and Vomiting.	New	রেফারেন্স নাই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
272.	Beacon Pharmaceuticals Limited, Kathali, Bhaluka, Mymensingh General Pharmaceuticals Ltd.	Olopatadine Hydrochloride 5mg Tablet	Olopatadine Hydrochloride USP 5mg	Antihistamine Therapeutic Code:021	Olopatadine is indicated for the symptomatic treatment of ocular itching associated with allergic con‡jvunctivitis as ophthalmic solution. As an antihistaminr, Olopatadine in indicated for the symptomatic relief of seasonal allergic rhinitis in patients 12 years of age and older.	**Contraindication**: there are no known contraindications for olopatadine. But proven hypersensitivity to olopatadine is a contraindication. **Side-Effect:** Blurred vision, Burning, redness or stinging, dry eyes, taste changes andabnormal sensation in eye.	0.1%, 0.2%, 0.7% Eye Drops 0.6% Nasal Spray	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
273.	Beacon Pharmaceuticals Limited, Kathali, Bhaluka, Mymensingh	Levosimendan 12.5mg/5ml Concentrate Solution for Infusion	Levosimendan INN 12.5mg/5ml	Cardiac Glvcosides Therapeutic Code:035	It is indicated for the short-term treatment of acutely decompensated severe chronic heart failure (ADHF) in situations where conventional therapy is not sufficient, and in cases where inotropic support is considered appropriate.	**Contraindications:** Hypersensitivity to levosimendan or to any of the excipients. Severe hypotension and tachycardia (see sections 4.4 and 5.1). Significant mechanical obstructions affecting ventricular filling or outflow or both. Severe renal impairment (creatinine clearance **Side effect**: In placebo-controlled clinical trials for ADHF (REVIVE programme), 53% of patients experienced adverse reactions, the most frequent of which were ventricular tachycardia, hypotension, and headache. In a dobutamine-controlled clinical trial for ADHF (SURVIVE), 18% of patients experienced adverse reactions, the most frequent of which were ventricular tachycardia, atrial fibrillation, hypotension, ventricular extrasystoles, tachycardia, and headache. The following table describes the adverse reactions observed in 1% or greater of patients during REVIVE I, REVIVE II, SURVIVE, LIDO, RUSSLAN, 300105, and 3001024 clinical trials. If the incidence of any particular event in an individual trial was greater than that seen across the other trials, then the higher incidence is reported in the tableThe events considered at least possibly related to levosimendan are displayed by system organ class and frequency, using the following convention: very common (≥ 1/10), common (≥ 1/100, < 1/10).	New	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
274.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Levosimendan 25mg/10ml Concentrate Solution for Infusion	Levosimendan INN 25mg/10ml	Cardiac Glvcosides Therapeutic Code:035	It is indicated for the short-term treatment of acutely decompensated severe chronic heart failure (ADHF) in situations where conventional therapy is not sufficient, and in cases where inotropic support is	**Contraindications**: Hypersensitivity to levosimendan or to any of the excipients. Severe hypotension and tachycardia (see sections 4.4 and 5.1). Significant mechanical obstructions affecting ventricular filling or outflow or both. Severe renal impairment	New	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					considered appropriate.	(creatinine clearance **Side effect:** In placebo-controlled clinical trials for ADHF (REVIVE programme), 53% of patients experienced adverse reactions, the most frequent of which were ventricular tachycardia, hypotension, and headache. In a dobutamine-controlled clinical trial for ADHF (SURVIVE), 18% of patients experienced adverse reactions, the most frequent of which were ventricular tachycardia, atrial fibrillation, hypotension, ventricular extrasystoles, tachycardia, and headache. The following table describes the adverse reactions observed in 1% or greater of patients during REVIVE I, REVIVE II, SURVIVE, LIDO, RUSSLAN, 300105, and 3001024 clinical trials. If the incidence of any particular event in an individual trial was greater than that seen across the other trials, then the higher incidence is reported in the tableThe events considered at least possibly related to levosimendan are displayed by system organ class and frequency, using the following convention: very common (≥ 1/10), common (≥ 1/100, < 1/10).				
275.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, BANGLADESH Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Nalfurafine Hydrochloride INN 2.50 mcg OD Tablet	Nalfurafine Hydrochloride INN 2.50 mcg OD Tablet	Unclassified Agents Therapeutic Code: 075	Improvement of pruritus in the following patients (use only when sufficient efficacy is not obtained with the existing therapies or treatments): hemodialysis patients, patients with chronic liver disease.	**Contraindication:** Nalfurafine Hydrochloride is contraindicated in patients with a history of a hypersensitivity reaction to Nalfurafine Hydrochloride or any of its components. **Side effects:** Nasopharyngitis, Insomnia, Dizziness, Somnolence, Hepatic encephalopathy, Diarrhoea, Constipation, Nausea, Nocturia, Blood prolactin increased, Blood antidiuretic hormone increased, Blood thyroid stimulating hormone increased, Total bile acids increased, Blood glucose increased, Blood testosterone free decreased. **Warning and Precaution:** Before starting	New	PMDA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						the treatment with Nalfurafine Hydrochloride in a patient with severe (Child-Pugh class C) hepatic impairment, the risks and benefits of the treatment should be considered, and the patient should be carefully monitored throughout the treatment.				
276.	Concord Pharmaceuticals Ltd., Narayanagng	Naproxen 220mg + Diphenhydramine 25mg Tablet	Naproxen Sodium BP 220 mg + Diphenhydramine Hydrochloride BP 25mg Tablet	Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic Code 064	It is Indicated for occasional use, for a limited period of time (five days or less), for fast and effective relief of acute nighttime pain and accompanying sleeplessness caused by aches and pains associated with arthritis, joints, muscles, backache, headache, migraine pain and toothache and, in these circumstances, for increased duration of sleep uninterrupted by pain · Helps you fall asleep and stay asleep.	**Contraindication:** It is contraindicated in patients: · who have previously exhibited allergy or with known hypersensitivity to the active substances' naproxen or diphenhydramine hydrochloride or any of the excipients in the tablet. · with a history of asthma, urticaria, or allergic-type reactions after taking acetylsalicylic acid (ASA) or other NSAIDs (i.e. complete or partial syndrome of ASAintolerance - rhinosinusitis, urticaria/angioedema, nasal polyps, asthma). Fatal anaphylactoid reactions have occurred in such individuals. Individuals with the above medical problems are at risk of a severe reaction even if they have taken NSAIDs in the past without any adverse reaction. **Side-effects:** Stop use and contact a doctor if you experience: heartburn, nausea, vomiting, ringing or buzzing in the ears, bloating,redness or swelling is present in the painful area, choking sensation,diarrhea or constipation.	Naproxen 250 mg Tablet Esomeprazole 20 mg + Naproxen 500 mg Tablet Diphenhydramine Hydrochloride 50 mg Tablet	USFDA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
277.	Eskayef Pharmaceuticals	Acetylcystiene 100mg/5ml Syrup	N-acetylcystiene BP 2gm/100ml	Therapeutic Class: Antitussives,	It is indicated for the Mucolytic therapy and in the management of	CONTRAINDICATIONS: Hypersensitivity to the active substance or to	100mg/ml & 200mg/ml	রেফারেন্স নাই	আবেদন না মঞ্জুর করার	আবেদন না

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Limited, Tongi, Gazipur			Expectorants and Mucolytic Therapeutic code: 031	acetaminophen overdose.	any of the excipients. The drug is contraindicated in children less than 2 years. SIDE-EFFECT: Like all medicines, this mucolytic can cause side effects, although not everybody gets them. The following is a table showing the frequency of adverse reactions reported after taking N-acetylcystiene by mouth.	Respiratory Solution 100mg & 200mg Effervescent Granules 600mg Tablet		সুপারিশ করা যেতে পারে।	মঞ্জুর করা হলো।
278.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Bisoprolol Fumarate 2.5mg + Perindopril Arginine 5mg Film Coated Tablet	Bisoprolol Fumarate USP 2.5mg + Perindopril Arginine INN 5mg	Therapeutic Class: Anti-hypertensive Therapeutic code: 022	It is used to treat high blood pressure (hypertension) and/or to reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) and who have already had a heart attack and/or an operation to improve the blood supply to the heart by widening the vessels that supply it.	CONTRAINDICATIONS: • are allergic to Bisoprolol or any other beta-blocker, to Perindopril or any other ACE inhibitor, or to any of the other ingredients of this medicine. • have a heart disease characterized by a slow or irregular heart rate (atrioventricular block second or third degree, sinoatrial block, sick sinus syndrome). SIDE-EFFECT: • vertigo • dizziness • headache	Bisoprolol Fumarate + Amlodipine: 5mg/5mg, 5mg/10mg, 10mg/5mg, 10mg/10mg Perindopril + Amlodipine: 3.5mg/2.5mg, 7mg/5mg, 14mg/10mg, 5mg/5mg, 5mg/10mg, 10mg/5mg, 10mg/10mg	রেফারেন্স নাই	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
279.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Neomycin Sulfate USP 500 mg Tablet	Neomycin Sulfate USP 500 mg	Anti-infective Therapeutic Code: 023	Neomycin tablet (Neomycin Sulfate USP) is indicated for pre-operative sterilisation of the bowel and may be useful in the treatment of impending hepatic coma, including portal systemic encephalopathy	**Contraindication:** Neomycin tablets should not be given when intestinal obstruction is present. Hypersensitivity to aminoglycosides. Infants under 1 year. Myasthenia gravis **Side-effects:** Nausea, vomiting, diarrhoea, increased salivation, stomatitis, nephrotoxicity, ototoxicity, rise in serum levels of hepatic enzymes and bilirubin, blood dyscrasias, haemolyticanaemia, confusion, paraesthesia, disorientation, nystagmus, hypersensitivity	Neomycin Sulphate 0.5% Ointment, Neomycin Sulphate 0.5% Eye and Ear Drops	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						reactions including dermatitis, pruritus, drug fever and anaphylaxis. Cross-sensitivity with other aminoglycosides may occur. Malabsorption syndrome with steatorrhoea and diarrhoea, which can be severe, may be caused by prolonged oral therapy. Superinfection may occur, especially with prolonged oral treatment. Electrolyte disturbances (notably hypomagnesaemia but also hypocalcaemia and hypokalaemia) have occurred with other aminoglycosides. **Warnings and Precautions**: The absorption of neomycin is poor from the alimentary tract, with about 97% of an orally administered dose being excreted unchanged in the faeces. Impaired G.I. motility however may increase absorption of the drug and it is therefore possible, as with other broad spectrum antibiotics that prolonged therapy could result in ototoxicity and nephrotoxicity, particularly in patients with a degree of renal failure. In such patients, and infants and the elderly, it is generally desirable to determine dosage requirements of aminoglycosides by individual monitoring. Some authorities consider that monitoring is also important in obese patients and those with cystic fibrosis. Impaired hepatic function or auditory function, bacteraemia, fever, and possibly exposure to loud noises have been reported to increase the risk of ototoxicity, while volume depletion or hypotension, liver disease, or female sex have reported as additional risk factors for nephrotoxicity. Regular assessment of auditory, vestibular				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						and renal function is particularly necessary in patients with additional risk factors. When used as an adjunct in the management of hepatic coma, care should be taken that administration is of the minimal period necessary, since prolonged exposure to the drug may result in malabsorption. Neomycin should be used with caution in patients with neuromuscular disorders and Parkinsonism. There is almost complete cross-resistance between neomycin, kanamycin, paromomycin and framycetin. Cross-resistance with gentamicin has also been reported. Since prolonged therapy may result in the overgrowth of non-sensitive organisms, treatment should not be continued longer than necessary to prevent superinfection due to the over growth of non-sensitive organisms.				
280.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Teplizumab-mzwv (1mg/ml) ready to fill bulk* INN 2ml/Vial eqv. to Teplizumab-mzwv 2mg/2mL (1mg/mL) single dose vial for IV Infusion	Teplizumab-mzwv (1mg/ml) ready to fill bulk* INN 2ml/Vial eqv. to Teplizumab-mzwv 2mg/2mL (1mg/mL)	Antidiabetes Therapeutic Code: 015	Teplizumab-mzwv is a CD3-directed antibody indicated to delay the onset of Stage 3 type 1 diabetes (TI D) in adults and pediatric patients aged 8 years and older with Stage 2 TI D.	**Contraindication:** Known hypersensitivity to Teplizumab-mzwv or excipients. **Side-effects:** Most common adverse reactions (>10%) were lymphopenia, rash, leukopenia, and headache. **Warnings and Precautions**: No data available	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
281.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Dextromethorphan Hydrobromide USP 45mg eqv. to Dextromethorphan 32.98mg + Bupropion Hydrochloride USP 105mg eqv. to Bupropion	Dextromethorphan Hydrobromide USP 45mg eqv. to Dextromethorphan 32.98mg + Bupropion Hydrochloride USP 105mg eqv. to Bupropion	Antidepressants Therapeutic Code: 014	Dextromethorphan Hydrobromide and Bupropion Hydrochloride is a combination of dextromethorphan, an uncompetitive N-methyl D-aspartate (NMDA) receptor	**Contraindication:**Seizure disorder. Current or prior diagnosis of bulimia or anorexia nervosa. Abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	General Pharmaceuticals Ltd.	91.14mg Extended Release Tablet	91.14mg		antagonist and sigma-1 receptor agonist, and bupropion, an aminoketone and CYP450 2D6 inhibitor, indicated for the treatment of major depressive disorder (MDD) in adults.	antiepileptic drugs. Use with an MAOI or within 14 days of stopping treatment with Dextromethorphan Hydrobromide and Bupropion Hydrochloride. Do not use Dextromethorphan Hydrobromide and Bupropion Hydrochloride within 14 days of discontinuing an MAOI. Known hypersensitivity to bupropion, dextromethorphan, or other components of Dextromethorphan Hydrobromide and Bupropion Hydrochloride. **Side-effects:** Most common adverse reactions (≥5% and more than twice as frequently as placebo): dizziness, headache, diarrhea, somnolence, dry mouth, sexual dysfunction, and hyperhidrosis. **Warnings and Precautions**: Seizure: Risk is dose-related. Discontinue if seizure occurs. Increased Blood Pressure and Hypertension: Dextromethorphan Hydrobromide and Bupropion Hydrochloride can increase blood pressure and cause hypertension. Assess blood pressure before initiating treatment and monitor periodically during treatment. Activation of Mania or Hypomania: Screen patients for bipolar disorder. Psychosis and Other Neuropsychiatric Reactions: Instruct patients to contact a healthcare provider if such reactions occur. Angle-Closure Glaucoma: Angle-closure glaucoma has occurred in patients with untreated anatomically narrow angles treated with antidepressants. Dizziness: Dextromethorphan Hydrobromide and Bupropion Hydrochloride may cause dizziness. Take precautions to reduce falls				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						and use caution when operating machinery. Serotonin Syndrome: Use of Dextromethorphan Hydrobromide and Bupropion Hydrochloride with selective serotonin reuptake inhibitors (SSRIs) or tricyclic antidepressants increases the risk. Discontinue if occurs. Embryo-fetal Toxicity: May cause fetal harm. Advise pregnant females of the potential risk to a fetus. Discontinue treatment in pregnant females and use alternative treatment for females who are planning to become pregnant.				
282.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka Beacon Pharmaceuticals Ltd.	Eslicarbazepine Acetate INN 200mg Tablet	Eslicarbazepine Acetate INN 200mg	Therapeutic Class : Drug Used in Epilepsy Therapeutic Code: 046	Eslicarbazepine Acetate is indicated for the treatment of partial-onset seizures in patients 4 years of age and older.	**Contraindication:** Eslicarbazepine Acetate is contraindicated in patients with a hypersensitivity to eslicarbazepine acetate or oxcarbazepine. **Side-effects:** Most common adverse reactions in adult patients receiving Eslicarbazepine Acetate (≥4% and ≥2% greater than placebo): dizziness, somnolence, nausea, headache, diplopia, vomiting, fatigue, vertigo, ataxia, blurred vision, and tremor. Adverse reactions in pediatric patients are similar to those seen in adult patients. **Warnings and Precautions**: Suicidal Behavior and Ideation: Monitor for suicidal thoughts or behavior. Serious Dermatologic Reactions, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), Anaphylactic Reactions and Angioedema: Monitor and discontinue if another cause cannot be established. Hyponatremia: Monitor sodium levels in patients at risk or patients experiencing	400 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						hyponatremia symptoms. Neurological Adverse Reactions: Monitor for dizziness, disturbance in gait and coordination, somnolence, fatigue, cognitive dysfunction, and visual changes. Use caution when driving or operating machinery. Withdrawal of Eslicarbazepine Acetate: Withdraw Eslicarbazepine Acetate gradually to minimize the risk of increased seizure frequency and status epilepticus. Drug Induced Liver In‡jvury: Discontinue Eslicarbazepine Acetate in patients with jaundice or evidence of significant liver in‡jvury. Hematologic Adverse Reactions: Consider discontinuing.				
283.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka Beacon Pharmaceuticals Ltd.	Eslicarbazepine Acetate INN 600mg Tablet	Eslicarbazepine Acetate INN 600mg	Therapeutic Class : Drug Used in Epilepsy Therapeutic Code: 046	Eslicarbazepine Acetate is indicated for the treatment of partial-onset seizures in patients 4 years of age and older.	**Contraindication:**Eslicarbazepine Acetate is contraindicated in patients with a hypersensitivity to eslicarbazepine acetate or oxcarbazepine. **Side-effects:** Most common adverse reactions in adult patients receiving Eslicarbazepine Acetate (≥4% and ≥2% greater than placebo): dizziness, somnolence, nausea, headache, diplopia, vomiting, fatigue, vertigo, ataxia, blurred vision, and tremor. Adverse reactions in pediatric patients are similar to those seen in adult patients. **Warnings and Precautions**: Suicidal Behavior and Ideation: Monitor for suicidal thoughts or behavior. Serious Dermatologic Reactions, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), Anaphylactic Reactions and Angioedema: Monitor and discontinue if another cause cannot be established. Hyponatremia: Monitor sodium levels in	400 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						patients at risk or patients experiencing hyponatremia symptoms. Neurological Adverse Reactions: Monitor for dizziness, disturbance in gait and coordination, somnolence, fatigue, cognitive dysfunction, and visual changes. Use caution when driving or operating machinery. Withdrawal of Eslicarbazepine Acetate: Withdraw Eslicarbazepine Acetate gradually to minimize the risk of increased seizure frequency and status epilepticus. Drug Induced Liver In‡jvury: Discontinue Eslicarbazepine Acetate in patients with jaundice or evidence of significant liver in‡jvury. Hematologic Adverse Reactions: Consider discontinuing.				
284.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka Beacon Pharmaceuticals Ltd.	Eslicarbazepine Acetate INN 800mg Tablet	Eslicarbazepine Acetate INN 800mg	Therapeutic Class : Drug Used in Epilepsy Therapeutic Code: 046	Eslicarbazepine Acetate is indicated for the treatment of partial-onset seizures in patients 4 years of age and older.	**Contraindication:** Eslicarbazepine Acetate is contraindicated in patients with a hypersensitivity to eslicarbazepine acetate or oxcarbazepine. **Side-effects:**Most common adverse reactions in adult patients receiving Eslicarbazepine Acetate (≥4% and ≥2% greater than placebo): dizziness, somnolence, nausea, headache, diplopia, vomiting, fatigue, vertigo, ataxia, blurred vision, and tremor. Adverse reactions in pediatric patients are similar to those seen in adult patients. **Warnings and Precautions**: Suicidal Behavior and Ideation: Monitor for suicidal thoughts or behavior. Serious Dermatologic Reactions, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), Anaphylactic Reactions and Angioedema: Monitor and discontinue if another cause cannot be established. Hyponatremia: Monitor sodium levels in	Eslicarbazepine Acetate 400 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						patients at risk or patients experiencing hyponatremia symptoms. Neurological Adverse Reactions: Monitor for dizziness, disturbance in gait and coordination, somnolence, fatigue, cognitive dysfunction, and visual changes. Use caution when driving or operating machinery. Withdrawal of Eslicarbazepine Acetate: Withdraw slicarbazepine Acetate gradually to minimize the risk of increased seizure frequency and status epilepticus. Drug Induced Liver In‡jvury: Discontinue Eslicarbazepine Acetate in patients with jaundice or evidence of significant liver in‡jvury. Hematologic Adverse Reactions: Consider discontinuing.				
285.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Paclitexel 260mg/43.33ml Injectionfor IV Infusion	Paclitexel USP 260mg/43.33ml	Anticancer Therapeutic Code: 010	It is a microtubule inhibitor indicated for the treatment of: •Metastatic breast cancer, after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated. •Locally advanced or metastatic non-small cell lung cancer (NSCLC), as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy. •Metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine.	CONTRAINDICATIONS: ·Neutrophil counts of < 1,500 cells/mm^3. •Severe hypersensitivity reactions to paclitaxel **Side-effect:** The most common adverse reactions (≥ 20%) in metastatic breast cancer are alopecia, neutropenia, sensory neuropathy, abnormal ECG, fatigue/asthenia, myalgia/arthralgia, AST elevation, alkaline phosphatase elevation, anemia, nausea, infections, and diarrhea. •The most common adverse reactions (≥ 20%) in NSCLC are anemia, neutropenia, thrombocytopenia, alopecia, peripheral neuropathy, nausea, and fatigue. •The most common (≥ 20%) adverse reactions of ABRAXANE in adenocarcinoma of the pancreas are neutropenia, fatigue, peripheral neuropathy, nausea, alopecia,	30mg/6m, 100mg/16.67ml, 300mg/50ml	রেফারেন্স নাই	আবেদন করার সুপারিশ করা যেতে পারে।	আবেদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						peripheral edema, diarrhea, pyrexia, vomiting, decreased appetite, rash, and dehydration.				
286.	Beacon Pharmaceuticals Limited, Kathali, Bhaluka, Mymensingh	Guaifenesin 100mg/5ml Syrup	Guaifenesin USP 100mg/5ml	Antitussives, Expectorants and Mucolytic Therapeutic code: 031	It is indicated for the symptomatic relief of productive cough and chest congestion.	CONTRAINDICATIONS Hypersensitivity to the active ingredient Side-effect:Common guaifenesin side effects may include: dizziness, headache; •drowsiness; •rash; or nausea, vomiting, stomach upset.	Dextromethorphan Hydrobromide 60mg + Guaifenesin 1200mg ER Tablet	UKMHRA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
287.	Renata Limited Rajendrapur, Gazipur Ziska Pharmaceuticals Ltd.	Progesterone 25mg/1.112ml solution for Injectionvials	Progesterone BP 25mg/1.112ml	Hormone Therapeutic code: 056	It is indicated in adults for luteal support as part of an Assisted Reproductive Technology (ART) treatment program in infertile women who are unable to use or tolerate vaginal preparations. Source: Rx Reasoner	Contraindications: should not be used in individuals with any of the following conditions: Hypersensitivity to progesterone or to any of the excipients. Undiagnosed vaginal bleeding. Known missed abortion or ectopic pregnancy. Severe hepatic dysfunction or disease. Known or suspected breast or genital tract cancer. Active arterial or venous thromboembolism or severe thrombophlebitis, or a history of these events. Porphyria. A history of idiopathic jaundice, severe pruritus or pemphigoid gestationis during pregnancy. Source: Rx Reasoner Adverse events: The most frequently reported adverse drug reactions during treatment with Lubionduring clinical trial are administration site reactions, breast and vulvo-vaginal disorders. Source: Rx Reasoner	100mg Soft Gelatine Capsule 200mg Soft Gelatine Capsule	BNF-83 Page:824 Lubion 25mg/1.112ml solution for Injectionvials	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
288.	Drug International Ltd. 31/1, Satrong Road, Gopalpur,Tongi IndustrialArea, Gazipur, Bangladesh. Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka.	Peficitinib Hydrobromide INN 50mg Film Coating Tablet.	Peficitinib HydrobromideINN 62.4 mg (eqv.to Peficitinib 50mg).	Immunosuppre-ssant Code: 58	It is indicated for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have an inadequate response to conventional therapies.	**Contraindication:** It is contraindicated in patients with known hypersensitivity to Peficitinib or any other components of this product and pregnancy. Women of childbearing potential should beadvised to use effective contraception during the treatment with peficitinib and a certain period after the completion of the treatment. **Precaution:** RA patients with moderate hepatic impairment should be treated with Peficitinib 50 mg once daily. **Warning:** As per precaution. **Side effects:** The most frequently reported adverse reactions are nasopharyngitis, diarrhea, nausea, pharyngitis, upper respiratory tract infection (URTI), constipation, headache and back pain.	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
289.	Drug International Ltd 31/1, Satrong, Tongil/A, Gazipur.Bangladesh General Pharmaceuticals Ltd. The ACME Laboratories Ltd.	Pemafibrate INN 0.10mg Tablet.	Pemafibrate INN 0.10mg	Selective Peroxisome Proliferator-Activated Receptor Alpha Modulators (SPPARMα)	It is indicated for the treatment of Hyperlipidemia (including familial hyperlipidemia).	**Contraindication:** It is contraindicated with the patients with hypersensitivity to Pemafibrate or any component of this medicine. **Precaution:** Use in patients with Hepatic impairment: Exposure to pemafibrate in subjects with hepatic cirrhosis was higher than that in subjects with normal hepatic function. Use in patients with renal impairment: For use of the existing fibrates in patients with renal impairment, warnings and precautions for contraindication or careful administration are applicable depending on severity of renal impairment.	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Warning: As per precaution. **Side effects:** The most common side effects are diarrhoea, constipation, nausea, abdominal distention or discomfort, stomatitis, taste abnormality.				
290.	Drug International Ltd. 31/1, Satrong Road, Gopalpur, Tongi Industrial Area Gazipur, Bangladesh. Beacon Pharmaceuticals Ltd., Incepta Pharmaceuticals Ltd., Savar, Dhaka	Peficitinib Hydrobromide INN 100mg Film Coating Tablet	Peficitinib HydrobromideINN 124.8 mg (eqv.to Peficitinib 100mg).	Immunosuppre-ssant Code: 58	It is indicated for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have an inadequate response to conventional therapies.	**Contraindication:** It is contraindicated in patients with known hypersensitivity to Peficitinib or any other components of this product and pregnancy. Women of childbearing potential should beadvised to use effective contraception during the treatment with peficitinib and a certain period after the completion of the treatment. **Precaution:** RA patients with moderate hepatic impairment should be treated with Peficitinib 50 mg once daily. **Warning:** As per precaution. **Side effects:** The most frequently reported adverse reactions are nasopharyngitis, diarrhea, nausea, pharyngitis, upper respiratory tract infection (URTI), constipation, and headache and back pain.	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
291.	Nuvista Pharma Ltd.	Estradiol Hemihydrate BP 2.07mg eqv. to Estradiol 2mg Tablet **and** Estradiol Hemihydrate BP 2.07mg eqv. to Estradiol 2mg &Dydrogesterone USP 10mg Tablet	Estradiol Hemihydrate BP 2.07mg eqv. to Estradiol 2mg Tablet **and** Estradiol Hemihydrate BP 2.07mg eqv. to Estradiol 2mg & Dydrogesterone USP 10mg Tablet	Hormone Therapeutic Class: 056	Hormone replacement therapy (HRT) in estrogen deficiency associated with natural or artificial menopause in women with an intact uterus. Prevention of postmenopausal bone mineral density loss in women. For initiation and continuation of treatment of postmenopausal symptoms, the	Contraindication • Women who have had a hysterectomy • Known or suspected carcinoma of the breast, endometrium or other estrogen dependent neoplasia • Known or suspected progestogen dependent neoplasms • Untreated endometrial hyperplasia	NEW	BNF-80	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
		(1 to 14 days 2mg Estradiol Tablet After then 15 to 28 days Estradiol 2mg + Dydrogesterone 10mg Tablet)	(1 to 14 days 2mg Estradiol Tablet After then 15 to 28 days Estradiol 2mg + Dydrogesterone 10mg Tablet)		lowest effective dose for the shortest duration should be used with the goal being short term use.	• Active or chronic liver disease or a history of liver disease where the liver function tests have failed to return to normal. • Cerebrovascular accident or a past history of these conditions associated with previous estrogen use • Previous idiopathic or current venous thromboembolism (deep venous thrombosis, pulmonary embolism) or cerebrovascular accident • Known thrombophilic disorders (e.g., protein C, protein S or antithrombin deficiency) • Active or recent arterial thromboembolic disease (e.g., angina, myocardial infarction) • Abnormal genitourinary tract bleeding of unknown etiology • Porphyria • Known or suspected pregnancy • Lactation • Known hypersensitivity to any ingredients Side Effects: The most common side effects include headache, abdominal pain, back pain and breast tenderness. The common side effects can include vaginal candidiasis, depression, nervousness, migraine, dizziness, nausea, vomiting, flatulence, allergic skin reactions, menstrual disorders, weight gain, cervical discharge and pelvic pain. Please refer to the Summary of Product Characteristics for full information.				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
292.	Nuvista Pharma Ltd. The ACME Laboratories Ltd. Ziska Pharmaceuticals Ltd. Renata Limited	Estradiol Valerate 2mg Tablet	Estradiol Valerate BP 2mg	Hormone Therapeutic Class: 056	Relief of symptoms occurring after menopause: During the menopause, the amount of the oestrogen produced by a woman's body drops. This can cause symptoms such as hot face, neck and chest ("hot flushes"). Estradiol Valerate alleviates these symptoms after menopause. Prevention of osteoporosis: After the menopause some women may develop fragile bones (osteoporosis). If you are at an increased risk of fractures due to osteoporosis and other medicines are not suitable for you, you can use Estradiol Valerate to prevent osteoporosis after menopause.	**Contraindication:** It include coagulation problems, cardiovascular diseases, liver disease, and certain hormone-sensitive cancers such as breast cancer and endometrial cancer, among others. **Side Effects:** • Breast pain, • Headache, • Vaginal itching or discharge, changes in your menstrual periods, breakthrough bleeding, • Thinning scalp hair; or. • Nausea, vomiting, bloating, stomach cramps.	NEW	BNF-80	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
293.	Nuvista Pharma Ltd.	Nomegestrol acetate INN 2.5mg & Estradiol Hemihydrate BP eq. to Estradiol 1.5mg Tablet (With 4 yellow placebo tablet)	Nomegestrol acetate INN 2.5mg & Estradiol Hemihydrate BP eq. to Estradiol 1.5mg Tablet (With 4 yellow placebo tablet)	Contraceptives Therapeutic Class: 039	Oral contraception. The decision to prescribe This combination should take into consideration the individual woman's current risk factors, particularly those for venous thromboembolism (VTE), and how the risk of VTE with This combination compares with other combined hormonal contraceptives (CHCs)	**Contraindication:**Combined hormonal contraceptives (CHCs) must not be used in the following conditions. Should any of the conditions appear for the first time during This combination use, the medicinal product should be stopped immediately. •Presence or risk of venous thromboembolism (VTE) • Venous thromboembolism – current VTE (on anticoagulants) or history of (e.g. deep venous thrombosis [DVT] or pulmonary embolism [PE]). • Known hereditary or acquired predisposition for venous thromboembolism, such as APC-resistance (including Factor V Leiden), antithrombin-III-deficiency, protein C deficiency, protein S deficiency. • Major surgery with prolonged immobilization (see section 4.4).	NEW	BNF-80	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						o A high risk of venous thromboembolism due to the presence of multiple risk factors (see section 4.4). • Presence or risk of arterial thromboembolism (ATE) **Side Effects:** There have been no reports of serious harmful effects from taking too many This combination tablets at one time. If you have taken several tablets at a time, you may have nausea, vomiting or vaginal bleeding. If you discover that a child has taken This combination, ask your doctor for advice.				
294.	Nuvista Pharma Ltd. General Pharmaceuticals Ltd.	Tretinoin 0.1% + Benzoyl Peroxide 3% Cream	Tretinoin 0.1% + Benzoyl Peroxide 3%	Skin and Mucous Membrane Preparations Therapeutic Class: 071	Tretinoin and benzoyl peroxide cream is indicated for the topical treatment of acne vulgaris in adults and pediatric patients 9 years of age and older.	**Contraindication:** Tretinoin and benzoyl peroxide cream is contraindicated in patients with a history of hypersensitivity reaction to benzoyl peroxide or any components of Tretinoin and benzoyl peroxide cream. **Side Effects:** In clinical studies, Tretinoin and benzoyl peroxide cream was proven to have fewer side effects. The most common side effects reported by people - all at the application site (AKA where they applied the cream) - were: • Stinging or burning • Dryness • Exfoliation (scaling) • Erythema (redness) • Dermatitis • Pruritus (itching) and irritation	NEW	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
295.	Nuvista Pharma Ltd.	Solifenacin Succinate 6mg + Tamsulosin Hydrochloride 0.4mg Modified Release Tablet	Solifenacin Succinate 6mg + Tamsulosin Hydrochloride 0.4mg	Drug used in obstratics and Genitourinary disease Therapeutic Class:	Treatment of moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia (BPH) in men who are not	**Contraindication:** Patients with hypersensitivity to the active substance(s) or to any of the excipients •Patients undergoing hemodialysis •Patients with severe hepatic impairment •Patients with severe renal impairment who	NEW	BNF-80	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
				049	adequately responding to treatment with monotherapy.	are also treated with a strong cytochrome P450 (CYP) 3A4 inhibitor, e.g., ketoconazole •Patients with moderate hepatic impairment who are also treated with a strong CYP3A4 inhibitor, e.g., ketoconazole •Patients with severe gastrointestinal conditions (including toxic megacolon), myasthenia gravis or narrow-angle glaucoma and patients at risk for these conditions •Patients with a history of orthostatic hypotension. **Side Effects:** Constipation • Dry mouth • Indigestion (dyspepsia) • Dizziness • Blurred vision • Tiredness (fatigue) • Abnormal ejaculation (ejaculation disorder). This means that semen does not leave the body via the urethra, but instead goes into the bladder (retrograde ejaculation) or the ejaculation volume is reduced or absent (ejaculation failure) This phenomenon is harmless. • Feeling sick (nausea) • Abdominal pain				
296.	Ziska Pharmaceuticals Ltd.	Recombinant Follicle stimulating hormone (rFSH) 75 IU/0.125ml prefilled syringe Injection	Recombinant Follicle stimulating hormone (rFSH) USP 75 IU/0.125ml	Therapeutic Class: Hormone Therapeutic Code: 056	Induction of ovulation in women who have previously received pituitary suppression intramuscular and subcutaneous administration, development of multiple follicles as part of an assisted reproductive technology (ART) cycle in ovulatory women who have previously received pituitary suppression	**Contraindications:** Follicle stimulating hormone is contraindicated in women who exhibit prior hypersensitivity to follicle stimulating hormone or urofollitropins, high levels of FSH indicating primary ovarian failure, presence of uncontrolled non-gonadal endocrinopathies, sex hormone dependent tumors of the reproductive tract and accessory organ, tumors of pituitary gland or hypothalamus, abnormal uterine bleeding of undetermined origin, ovarian cysts or enlargement of undetermined origin, not due to polycystic ovary syndrome	Follicle Stimulating Hormone (Urofollitrophin) 75IU/Vial	BNF-83 Page: 801	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Side-effects: headache, hot flashes, OHSS, pain, and respiratory disorder Warnings and Precautions: Hypersensitivity and anaphylactic reaction, abnormal ovarian enlargement ovarian hyperstimulation syndrome				
297.	Ziska Pharmaceuticals Ltd.	Recombinant Follicle stimulating hormone (rFSH) 150 IU/0.25ml prefilled syringe Injection	Recombinant Follicle stimulating hormone (rFSH) USP 150 IU/0.25ml	Therapeutic Class: Hormone Therapeutic Code : 056	Induction of ovulation in women who have previously received pituitary suppression intramuscular and subcutaneous administration, development of multiple follicles as part of an assisted reproductive technology (ART) cycle in ovulatory women who have previously received pituitary suppression	**Contraindications:** Follicle stimulating hormone is contraindicated in women who exhibit prior hypersensitivity to follicle stimulating hormone or urofollitropins, high levels of FSH indicating primary ovarian failure, presence of uncontrolled non-gonadal endocrinopathies, sex hormone dependent tumors of the reproductive tract and accessory organ, tumors of pituitary gland or hypothalamus, abnormal uterine bleeding of undetermined origin, ovarian cysts or enlargement of undetermined origin, not due to polycystic ovary syndrome Side-effects: headache, hot flashes, OHSS,pain, and respiratory disorder **Warnings and Precautions:** Hypersensitivity and anaphylactic reaction, abnormal ovarian enlargement ovarian hyper stimulation syndrome	Follicle Stimulating Hormone (Urofollitrophin) 75IU/Vial	BNF-83 Page: 801	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
298.	Ziska Pharmaceuticals Ltd.	Recombinant Follicle stimulating hormone (rFSH) 225 IU/0.375ml prefilled syringe Injection	Recombinant Follicle stimulating hormone (rFSH) USP 225 IU/0.375ml	Therapeutic Class: Hormone Therapeutic Code: 056	Induction of ovulation in women who have previously received pituitary suppression intramuscular and subcutaneous administration, development of multiple follicles as part of an assisted reproductive technology (ART) cycle in ovulatory women who have previously received pituitary suppression	Contraindications: Follicle stimulating hormone is contraindicated in women who exhibit prior hypersensitivity to follicle stimulating hormone or urofollitropins, high levels of FSH indicating primary ovarian failure, presence of uncontrolled non-gonadal endocrinopathies, sex hormone dependent tumors of the reproductive tract and accessory organ, tumors of pituitary gland or hypothalamus, abnormal uterine bleeding of undetermined origin, ovarian cysts or enlargement of undetermined origin, not due to polycystic ovary syndrome	Follicle Stimulating Hormone (Urofollitrophin) 75IU/Vial	BNF-83 Page: 801	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Side-effects:headache, hot flashes, OHSS, pain, and respiratory disorder Warnings and Precautions: Hypersensitivity and anaphylactic reaction, abnormal ovarian enlargement ovarian hyper stimulation syndrome				
299.	Ziska Pharmaceuticals Ltd.	Recombinant Follicle stimulating hormone (rFSH) 300 IU/0.5ml prefilled syringe Injection	Recombinant Follicle stimulating hormone (rFSH) USP 300 IU/0.5ml	Therapeutic Class: Hormone Therapeutic Code: 056	Induction of ovulation in women who have previously received pituitary suppression intramuscular and subcutaneous administration, development of multiple follicles as part of an assisted reproductive technology (ART) cycle in ovulatory women who have previously received pituitary suppression	Contraindications: Follicle stimulating hormone is contraindicated in women who exhibit prior hypersensitivity to follicle stimulating hormone or urofollitropins, high levels of FSH indicating primary ovarian failure, presence of uncontrolled non-gonadal endocrinopathies, sex hormone dependent tumors of the reproductive tract and accessory organ, tumors of pituitary gland or hypothalamus, abnormal uterine bleeding of undetermined origin, ovarian cysts or enlargement of undetermined origin, not due to polycystic ovary syndrome Side-effects: headache, hot flashes, OHSS, pain, and respiratory disorder Warnings and Precautions: Hypersensitivity and anaphylactic reaction, abnormal ovarian enlargement ovarian hyper stimulation syndrome	Follicle Stimulating Hormone (Urofollitrophin) 75IU/Vial	BNF-83 Page: 801	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
300.	Ziska Pharmaceuticals Ltd.	Human chorionic gonadotropin (HCG) 10,000 IU/Vial Injection	Human Chorionic Gonadotropin USP 10000IU/Vial	Therapeutic Class: Hormone Therapeutic Code: 056	**In the female:** Ovulation induction in infertility due to anovulation or impaired follicle-ripening. Preparation of follicles for puncture in controlled ovarianhyperstimulation programs (ART). Luteal phase support.	Contraindications: Known or suspected androgen-dependent tumors, such as prostatic carcinoma or breast carcinoma in the male. Side effects: Allergic reactions have occasionally been reported with the use of urinary gonadotrophin preparations. These	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					Threatened and habitualabortion. **In the male:** Hypogonadotropic hypogonadism (also cases of idiopathic dysphemism have shown a positive responsetogonadotropins). Delayed puberty associated with insufficient gonadotropic pituitary function. Cryptorchidism, (not due to anatomical obstruction) Used to treat oligospermia	mostly involve local reactions such as pain and rash at the Injectionsite, and generalized reactions such as rash and fever. Warning & Precautions: Multiplets are more likely to be born in pregnancies that occur following stimulation of ovulation using gonadotropic medications. Unwanted ovarian hyperstimulation: Prior administration of an FSH-containing preparation to patients being treated for infertility due to anovulation or inadequate follicular ripening may result in unwanted ovarian hyperstimulation. As a result, ultrasonic follicular development assessment and estrogen level assessments should be done before to FSH treatment and at frequent intervals during FSH treatment. Estrogen levels can rise very quickly, e.g., more than a daily doubling for two or three days in a row, and can reach dangerously high levels				
301.	Ziska Pharmaceuticals Ltd.	Human chorionic gonadotropin (HCG) 250mcg/0.5ml prefilled syringe	Human Chorionic Gonadotropin USP 250mcg/0.5ml	Therapeutic Class: Hormone Therapeutic Code: 056	In the female: Ovulation induction in infertility due to anovulation or impaired follicle-ripening. Preparation of follicles for puncture in controlled ovarianhyperstimulation programs (ART). Luteal phase support. Threatened and habitualabortion. In the male: Hypogonadotropic hypogonadism (also cases of idiopathic dysspermias have shown a positive responsetogonadotropins). Delayed puberty associated with insufficient gonadotropic pituitary function. Cryptorchidism, (not due to anatomical obstruction)	**Contraindications:** Known or suspected androgen-dependent tumors, such as prostatic carcinoma or breast carcinoma in the male. **Side effects:** Allergic reactions have occasionally been reported with the use of urinary gonadotrophin preparations. These mostly involve local reactions such as pain and rash at the Injectionsite, and generalized reactions such as rash and fever. Warning & Precautions: Multiplets are more likely to be born in pregnancies that occur following stimulation of ovulation using gonadotropic medications. Unwanted ovarian hyperstimulation: Prior administration of an	New	BNF-83 Page: 801	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					Used to treat oligospermia	FSH-containing preparation to patients being treated for infertility due to anovulation or inadequate follicular ripening may result in unwanted ovarian hyperstimulation. As a result, ultrasonic follicular development assessment and estrogen level assessments should be done before to FSH treatment and at frequent intervals during FSH treatment. Estrogen levels can rise very quickly, e.g., more than a daily doubling for two or three days in a row, and can reach dangerously high levels				
302.	Drug International Ltd. 31/1, Satrong Road, Gopalpur, Tongi I/A Gazipur, Bangladesh.	Lecanemab-irmb INN 500.00mg/5ml In‡jvection	Lecanemab-irmb INN 500.00mg/5ml	Anti-psychotic Therapeutic Code: 028	It is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment with Lecanemab should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with Lecanemab.	**Contraindication:** It is contraindicated in patients with known hypersensitivity to Lecanemab or any other components of this product. **Precaution: Amyloid Related Imaging Abnormalities (ARIA):** Enhanced clinical vigilance for ARIA is recommended during the first 14 weeks of treatment with Lecanemab. Risk of ARIA, including symptomatic ARIA, was increased in apolipoprotein E ε4 homozygotes compared to heterozygotes and noncarriers. **Infusion-Related Reactions:** The infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy administered as clinically indicated. Consider pre-medication at subsequent dosing with antihistamines, non-steroidal anti-inflammatory drugs, or corticosteroids. **Warning:** There is no data available. **Side effects:** • Amyloid Related Imaging Abnormalities; • Infusion-Related Reactions.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
303.	Drug International Ltd. 13A & 14A, Tongi I/A, Tongi, Gazipur, Bangladesh.	Elacestrant INN 100.00mg (Eqv. to 86.00mg Elacestrant)	Elacestrant INN 100.00mg (Eqv. to 86.00mg Elacestrant) Tablet	Anticancer Therapeutic Code: 010	It is indicated for the treatment of postmenopausal women or adult men with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, *ESR1*-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.	**Contraindication:** It is contraindicated in patients with hypersensitivity to Elacestrant or any component of the product. **Precaution:** Caution shold be exercised when Elacestrant is used in patients with Dyslipidemia and Embryo-Fetal Toxicity. **Warning:** There is no data available. **Side effects:** • Dyslipidemia.		USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
304.	Advanced Chemical Industries Limited	Olanzapine 3mg + Fluoxetine 25mg Capsule	Olanzapine USP 3 mg + Fluoxetine HCl USP 27.95 mg eq. to 25 mg Fluoxetine	Antipsychotic (028) + Antidepressant (014)	It combines olanzapine, an atypical antipsychotic and fluoxetine, a selective serotonin reuptake inhibitor, indicated for acute treatment of depressive Episodes Associated with Bipolar I Disorder and treatment Resistant Depression	Contraindication: MAOI: Because of the risk of serotonin syndrome, do not use MAOIs intended to treat psychiatric disorders with Ii or within 5 weeks of stopping treatment with it. Do not use it within 14 days of stopping an MAOI intended to treat psychiatric disorders. In addition, do not start it in a patient who is being treated with linezolid or intravenous methylene blue. Pimozide: Do not use. Risk of QT interval prolongation Thioridazine: Do not use. Risk of QT interval prolongation. Do not use thioridazine within 5weeks of discontinuing it. Adverse Reactions Most common adverse reactions (≥5% and at least twice that for placebo) in adults: sedation, weight increased, appetite increased, dry mouth, fatigue, edema, tremor, disturbance in attention, blurred vision. Children and adolescents: sedation, weight increased, appetite increased, tremor, triglyceride increased, hepatic enzymes increased.	Olanzapine 5 mg Tablet Olanzapine 10 mg Tablet	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
305.	Advanced Chemical Industries Limited	Olanzapine 6 mg + Fluoxetine 25mg Capsule	Olanzapine USP 6 mg + Fluoxetine HCl USP 27.95 mg eq. to 25 mg Fluoxetine	Antipsychotic (028) + Antidepressant (014)	It combines olanzapine, an atypical antipsychotic and fluoxetine, a selective serotonin reuptake inhibitor, indicated for acute treatment of depressive Episodes Associated with Bipolar I Disorder and treatment Resistant Depression	Contraindication: MAOI: Because of the risk of serotonin syndrome, do not use MAOIs intended to treat psychiatric disorders with Ii or within 5 weeks of stopping treatment with it. Do not use it within 14 days of stopping an MAOI intended to treat psychiatric disorders. In addition, do not start it in a patient who is being treated with linezolid or intravenous methylene blue. Pimozide: Do not use. Risk of QT interval prolongation Thioridazine: Do not use. Risk of QT interval prolongation. Do not use thioridazine within 5weeks of discontinuing it. Adverse Reactions Most common adverse reactions (≥5% and at least twice that for placebo) in adults: sedation, weight increased, appetite increased, dry mouth, fatigue, edema, tremor, disturbance in attention, blurred vision. Children and adolescents: sedation, weight increased, appetite increased, tremor, triglyceride increased, hepatic enzymes increased.	Olanzapine 5 mg Tablet Olanzapine 10 mg Tablet	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
306.	Advanced Chemical Industries Limited	Tolvaptan 45 mg Tablet	Tolvaptan INN	Diuretics Therapeutic Code: 042	Indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)	Contraindication: • Hypersensitivity to tolvaptan or any components of the product • Patients with autosomal dominant polycystic kidney disease (ADPKD) • Unable to sense or respond to thirst • Hypovolemic hyponatremia • Taking strong CYP3A inhibitors • Anuria Adverse Reactions The most common side effects are diarrhea, constipation, thirst, hyperglycemia and	15mg Tablet and 30mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						polyuria.				
307.	Advanced Chemical Industries Limited	Tolvaptan 60 mg Tablet	Tolvaptan INN	Diuretics Therapeutic Code: 042	Indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)	Contraindication: • Hypersensitivity to tolvaptan or any components of the product • Patients with autosomal dominant polycystic kidney disease (ADPKD) • Unable to sense or respond to thirst • Hypovolemic hyponatremia • Taking strong CYP3A inhibitors • Anuria Adverse Reactions The most common side effects are diarrhea, constipation, thirst, hyperglycemia and polyuria.	15mg Tablet and 30mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
308.	Advanced Chemical Industries Limited 7, Hajeegonj, Godnyl, Narayangonj	Bisoprolol Fumarate 10 mg + Perindopril Arginine 5 mg Tablet	Bisoprolol Fumarate USP 10mg + Perindopril Arginine INN 5mg	Anti hypertensive Therapeutic Code: 022	This combination is indicated for the treatment of hypertension to lower blood pressure	**Contraindication:** This combination is contraindicated to patients with known hypersensitivity to bisoprolol fumarate or perindopril arginine or any other components of this product. It is also contraindicated to patients with acute heart failure or during episodes of heart failure decompensation requiring i.v. inotropic therapy, cardiogenic shock, second or third degree AV block, severe bronchial asthma or severe chronic obstructive pulmonary disease **Side-effects:** The most common side effects to bisoprolol include headache, dizziness, worsening of heart failure, hypotension, cold extremities, nausea, vomiting, abdominal pain, diarrhea. **Warnings and precautions**: ACE inhibitors may cause a fall in blood pressure. Angioedema of the face,	New	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						extremities, lips, mucous membranes, tongue, glottis and/or larynx has been reported rarely in patients treated with ACE inhibitors, including perindopril. *Hepatic failure:* ACE inhibitors have been associated with a syndrome that starts with cholestatic jaundice and progresses to fulminant hepatic necrosis and (sometimes) death.				
309.	Advanced Chemical Industries Limited 7, Hajeegonj, Godnyl, Narayangonj	Bisoprolol Fumarate 10 mg + Perindopril Arginine 10 mg Tablet.	Bisoprolol Fumarate USP 10mg Perindopril Arginine INN 10mg	Anti hypertensive Therapeutic Code: 022	This combination is indicated for the treatment of hypertension to lower blood pressure	**Contraindication:** This combination is contraindicated to patients with known hypersensitivity to bisoprolol fumarate or perindopril arginine or any other components of this product. It is also contraindicated to patients with acute heart failure or during episodes of heart failure decompensation requiring i.v. inotropic therapy, cardiogenic shock, second or third degree AV block, severe bronchial asthma or severe chronic obstructive pulmonary disease **Side-effects:** The most common side effects to bisoprolol include headache, dizziness, worsening of heart failure, hypotension, cold extremities, nausea, vomiting, abdominal pain, diarrhea. **Warnings and precautions**: ACE inhibitors may cause a fall in blood pressure. Angioedema of the face, extremities, lips, mucous membranes, tongue, glottis and/or larynx has been reported rarely in patients treated with ACE inhibitors, including perindopril. *Hepatic failure:* ACE inhibitors have been associated with a syndrome that starts with cholestatic jaundice and progresses to fulminant hepatic necrosis and (sometimes) death.	New	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
310.	Advanced Chemical Industries Limited 7, Hajeegonj, Godnyl, Narayangonj	Amlodipine Besilate BP eq. to Amlodipine 10 mg + Perindopril Arginine 10 mg Tablet.	Amlodipine Besilate BP 10mg + Perindopril Arginine INN 10mg	Anti hypertensive Therapeutic Code: 022	This combination is indicated for the treatment of hypertension to lower blood pressure	**Contraindication:** It is contraindicated in patients with known hypersensitivity to Perindopril or Amlodipine or any other components of this product. This combination is also contraindicated in patients with hereditary or idiopathic angioedema, with or without previous ACE inhibitor treatment, and in patients who are hypersensitive to perindopril, to any other ACE inhibitor, or to amlodipine. **Side-effects:** The most common side effects are edema, cough, headache and dizziness. **Warnings and precautions**: Patients with rare hereditary problems of galactose intolerance, glucose galactose malabsorption or total lactase deficiency should not take this combination.Since ACE inhibitors reduce angiotensin II formation resulting in decreased production of aldosterone, increases in serum potassium have been observed in some patients treated with ACE inhibitors including Perindopril. Serum electrolytes (including sodium potassium and urea) should be measured from time to time when ACE inhibitors are given especially in combination with diuretics.	Perindopril 3.395 mg (as Perindopril Arginine INN 5 mg) + Amlodipine 10 mg (as Amlodipine Besilate Eur. Ph. 13.870 mg) & Perindopril 3.395 mg (as Perindopril Arginine INN 5 mg) + Amlodipine 5 mg (as Amlodipine Besilate Eur. Ph. 6.935 mg) **(DCC240)**	TGA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
311.	Advanced Chemical Industries Limited 7, Hajeegonj, Godnyl, Narayangonj DBL Pharma	Daprodustat 8 mg Tablet	Daprodustat INN 8mg	Drug used in Anemia and other Blood disorder. Therapeutic Code: 045	Indicated for the treatment of anemia due to chronic kidney disease (CKD)	**Contraindication:** It is contraindicated in patients with known hypersensitivity to it or any other components of this product. It is also contraindicated in patients receiving a strong CYP2C8 inhibitor such as gemfibrozil and with uncontrolled hypertension. **Side-effects:** The most common side effects are hypertension, thrombotic vascular events	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						and abdominal pain. **Warnings and precautions**: Daprodustat increases the risk of arterial and venous thrombotic events that may be fatal, including myocardial infarction, stroke, venous thromboembolism and vascular access thrombosis. Risk of hospitalization for heart failure: Increased in patients with a history of heart failure. Hypertension: Worsening hypertension, including hypertensive crisis may occur. Monitor blood pressure. Adjust anti-hypertensive therapy as needed. Malignancy: May have unfavorable effects on cancer growth. Not recommended if active malignancy.				
312.	Advanced Chemical Industries Limited 7, Hajeegonj, Godnyl, Narayangonj	Amlodipine Besilate BP eq. to Amlodipine 2.5 mg & Perindopril Arginine INN 3.5 mg Tablet.	Amlodipine Besilate BP 2.5mg + Perindopril Arginine INN 3.5mg	Anti hypertensive Therapeutic Code: 022	This combination is indicated for the treatment of hypertension to lower blood pressure	**Contraindication:** It is contraindicated in patients with known hypersensitivity to Perindopril or Amlodipine or any other components of this product. This combination is also contraindicated in patients with hereditary or idiopathic angioedema, with or without previous ACE inhibitor treatment, and in patients who are hypersensitive to perindopril, to any other ACE inhibitor, or to amlodipine. **Side-effects:** The most common side effects are edema, cough, headache and dizziness. **Warnings and precautions**: Patients with rare hereditary problems of galactose intolerance, glucose galactose malabsorption or total lactase deficiency should not take this combination.Since ACE inhibitors reduce angiotensin II formation resulting in decreased production of aldosterone, increases in serum potassium	Perindopril 3.395 mg (as Perindopril Arginine INN 5 mg) + Amlodipine 10 mg (as Amlodipine Besilate Eur. Ph. 13.870 mg) & Perindopril 3.395 mg (as Perindopril Arginine INN 5 mg) + Amlodipine 5 mg (as Amlodipine Besilate Eur. Ph. 6.935 mg)	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						have been observed in some patients treated with ACE inhibitors including Perindopril. Serum electrolytes (including sodium potassium and urea) should be measured from time to time when ACE inhibitors are given especially in combination with diuretics.				
313.	Advanced Chemical Industries Limited 7, Hajeegon‡jv, Godnyl, Narayangon‡jv.	Amlodipine Besilate BP eqv. to Amlodipine 5 mg & Perindopril Arginine INN 7 mg Tablet.	Amlodipine Besilate BP 5mg + Perindopril Arginine INN 7mg	Anti hypertensive Therapeutic Code: 022	This combination is indicated for the treatment of hypertension to lower blood pressure	**Contraindication:** It is contraindicated in patients with known hypersensitivity to Perindopril or Amlodipine or any other components of this product. This combination is also contraindicated in patients with hereditary or idiopathic angioedema, with or without previous ACE inhibitor treatment, and in patients who are hypersensitive to perindopril, to any other ACE inhibitor, or to amlodipine. **Side-effects:** The most common side effects are edema, cough, headache and dizziness. **Warnings and precautions**: Patients with rare hereditary problems of galactose intolerance, glucose galactose malabsorption or total lactase deficiency should not take this combination.Since ACE inhibitors reduce angiotensin II formation resulting in decreased production of aldosterone, increases in serum potassium have been observed in some patients treated with ACE inhibitors including Perindopril. Serum electrolytes (including sodium potassium and urea) should be measured from time to time when ACE inhibitors are given especially in combination with diuretics.	Perindopril 3.395 mg (as Perindopril Arginine INN 5 mg) + Amlodipine 10 mg (as Amlodipine Besilate Eur. Ph. 13.870 mg) & Perindopril 3.395 mg (as Perindopril Arginine INN 5 mg) + Amlodipine 5 mg (as Amlodipine Besilate Eur. Ph. 6.935 mg)	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
314.	Advanced Chemical Industries Limited 7, Hajeegon‡jv, Godnyl, Narayangon‡jv.	Amlodipine Besilate BP eqv. to Amlodipine 10 mg & Perindopril Arginine INN 14 mg Tablet.	Amlodipine Besilate BP 10mg + Perindopril Arginine INN 14mg	Anti hypertensive Therapeutic Code: 022	This combination is indicated for the treatment of hypertension to lower blood pressure	**Contraindication:** It is contraindicated in patients with known hypersensitivity to Perindopril or Amlodipine or any other components of this product. This combination is also contraindicated in patients with hereditary or idiopathic angioedema, with or without previous ACE inhibitor treatment, and in patients who are hypersensitive to perindopril, to any other ACE inhibitor, or to amlodipine. **Side-effects:** The most common side effects are edema, cough, headache and dizziness. **Warnings and precautions**: Patients with rare hereditary problems of galactose intolerance, glucose galactose malabsorption or total lactase deficiency should not take this combination.Since ACE inhibitors reduce angiotensin II formation resulting in decreased production of aldosterone, increases in serum potassium have been observed in some patients treated with ACE inhibitors including Perindopril. Serum electrolytes (including sodium potassium and urea) should be measured from time to time when ACE inhibitors are given especially in combination with diuretics.	Perindopril 3.395 mg (as Perindopril Arginine INN 5 mg) + Amlodipine 10 mg (as Amlodipine Besilate Eur. Ph. 13.870 mg) & Perindopril 3.395 mg (as Perindopril Arginine INN 5 mg) + Amlodipine 5 mg (as Amlodipine Besilate Eur. Ph. 6.935 mg)	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
315.	Advanced Chemical Industries Limited 7, Hajeegon‡jv, Godnyl, Narayangon‡jv.	Trovafloxacin Mesylate INN 123.083 mg eqv. to Trovafloxacin 100 mg	Trovafloxacin INN	Anti-infective Therapeutic Code: 023	Indicated for the treatment of patients initiating therapy in in-patient health care facilities (i.e., hospitals and long term nursing care facilities) with serious, life- or limb-threatening infections caused by susceptible strains of microorganisms.	**Contraindication:** Trovafloxacin is contraindicated to patients with known hypersensitivity to it or any other components of this product. **Side-effects:** The most common side effects are dizziness, nausea, headache, vomiting, abdominal pain, symptomatic pancreatitis, anaphylaxis, Stevens-Johnson syndrome,	New	USFDA	অনুমোদনের সুপাশি করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						agranulocytosis, aplastic anemia, pancytopenia, symptomatic hepatitis. **Warnings and precautions**: Trovafloxacin -associated liver enzyme abnormalities, symptomatic hepatitis, jaundice, and liver failure (including rare reports of acute hepatic necrosis with eosinophilic infiltration, liver transplantation and/or death) have been reported with both short-term and long-term drug exposure in men and women. Trovafloxacin use exceeding 2 weeks in duration is associated with a significantly increased risk of serious liver in‡jvury. Trovafloxacin should be used with caution in patients with known or suspected CNS disorders, such as severe cerebral atherosclerosis, epilepsy, and other factors that predispose to seizures. Serious and occasionally fatal hypersensitivity and/or anaphylactic reactions have been reported in patients receiving therapy with Trovafloxacin.				
316.	Advanced Chemical Industries Limited 7, Hajeegon‡jv, Godnyl, Narayangon‡jv.	Trovafloxacin Mesylate INN 246.166 mg eqv. to Trovafloxacin 200 mg	Trovafloxacin INN	Anti-infective Therapeutic Code: 023	Indicated for the treatment of patients initiating therapy in in-patient health care facilities (i.e., hospitals and long term nursing care facilities) with serious, life- or limb-threatening infections caused by susceptible strains of microorganisms.	**Contraindication:** Trovafloxacin is contraindicated to patients with known hypersensitivity to it or any other components of this product. **Side-effects:** The most common side effects are dizziness, nausea, headache, vomiting, abdominal pain, symptomatic pancreatitis, anaphylaxis, Stevens-Johnson syndrome, agranulocytosis, aplastic anemia, pancytopenia, symptomatic hepatitis. **Warnings and precautions**: Trovafloxacin -associated liver enzyme	New	USFDA	অনুমোদনের সুপাশি করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						abnormalities, symptomatic hepatitis, jaundice, and liver failure (including rare reports of acute hepatic necrosis with eosinophilic infiltration, liver transplantation and/or death) have been reported with both short-term and long-term drug exposure in men and women. Trovafloxacin use exceeding 2 weeks in duration is associated with a significantly increased risk of serious liver in‡jvury. Trovafloxacin should be used with caution in patients with known or suspected CNS disorders, such as severe cerebral atherosclerosis, epilepsy, and other factors that predispose to seizures. Serious and occasionally fatal hypersensitivity and/or anaphylactic reactions have been reported in patients receiving therapy with Trovafloxacin.				
317.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Brotizolam BP 0.25mg Tablet	Brotizolam BP 0.25mg Tablet	Hvonotics. Sedatives& Anxiolitic Therapeutic Code:057	Brotizolam demonstrates anxiolytic, anticonvulsant, sedative and skeletal muscle relaxant effect. Brotizolam is indicated for 2-4 weeks of treatment for severe or debilitating insomnia.	**Contraindication**: It is contraindicated in patients with myasthenia gravis, severe respiratory insufficiency, sleep apnoea syndrome and severe hepatic insufficiency. LENDORMIN is contraindicated in patients with a known hypersensitivity to the active ingredient brotizolam, any of the excipients or to other benzodiazepines. The available dosage forms are only suitable for adults and no investigations have been performed in children. Therefore, LENDORMIN is contraindicated in children. In case of rare hereditary conditions that may be incompatible with an excipient of the product (see section “Special precautions”) the use of the product is contraindicated. **Side-Effect:** Most adverse reactions that have been	New	EMA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						observed so far, relate to the product's pharmacological action. These phenomena are predominantly at the start of therapy and usually disappear with continued administration. The risk of drug dependence (e.g. rebound effect, altered mood, anxiety and restlessness) increases with the duration of therapy with LENDORMIN, which should not exceed two weeks. In particular, the following adverse reactions may occur				
318.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Maralixibat 0.950gm/100ml Oral Solution	Maralixibat Chloride INN 1.00mg eqv. to Maralixibat 0.950gm/100ml Oral Solution, 30 mL	Unclassified Agents Therapeutic code:075	It is indicated for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 2 months of age and older.	Contraindication: Hypersensitivity to the active substance Side-effects: Bloody or black, tarry stools. bone fractures. itching, rash.light-colored stools.stomach pain.	New	EMA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
319.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Troxipide INN 100mg Extended-Release Tablet	Troxipide INN 100mg	Unclassified Agents Therapeutic code:075	Troxipide is used for the treatment of peptic ulcer, gastroesophageal reflex disease, to manage gastric mucosal lesions (erosion, hemorrhage, redness and edema) in acute exacerbation of chronic gastritis. Troxipide is a novel gastroprotective agent with anti-ulcer, anti-inflammatary and mucus secreting properties; its action does not depent on the pH of stomach or duodenum.	CONTRAINDICATIONS Troxipide is contraindicated in patients allergic to the drug and in pregnant women. Side-effect: Mostly mild to moderate. • Gastrointestinal: Constipation • CNS: Headache • Others: Slight increase in level of liv er enzymes, fatigue Warning & Precautions: Use with caution in children, old patients, pregnant and breastfeeding women. Use with caution while treating women in the reproductive age group.	New	JP	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
320.	Beacon Pharmaceuticals Limited Kathali, Bhaluka,	Iguratimod 25mg Tablet	Iguratimod INN 25mg	Immunosuppre-ssant Therapeutic Code: 58	It is used to treat rheumatoid arthritis. It works by improving abnormal immunological responses and suppressing the production of substances that cause redness and	Contraindication: Side-effects: Diarrhea, Nausea, Rash, Abdominal pain, Vomiting, Stomatitis (Inflammation of the mouth), Photosensitivity,	New	PMDA	অনুমোদনের সুপাশি করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Mymensingh Beximco Pharmaceuticals Ltd.				swelling.	Decreased appetite, Itching.				
321.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Lafutidine 10mg Tablet	Lafutidine INN 10mg	Proton Pump Inhibitor Therapeutic Code: 67	Lafutidine is used to treat gastric ulcers, duodenal ulcers, as well as wounds in the lining of the stomach associated with acute gastritis and acute exacerbation of chronic gastritis	Contraindication: Contraindications to loratadine include patients with documented hypersensitivity to the drug or components of the formulation, with strong contraindications in children under the age of 2 due to its antihistamine properties, which may cause CNS stimulation or seizures in young patients Side-effects: Adverse events observed during clinical trials included constipation, diarrhea, drug rash, nausea, vomiting and dizziness	New	PMDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
322.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Tranexamic Acid USP 750mg+Ibuprofen USP 450mg+Clemastine Fumarate USP 1.34mg eqv. to 1mg of Clemastine + Bromhexine Hydrochloride INN 12mg + dl-Methylephedrine Hydrochloride INN 60mg + Dihydrocodeine Phosphate INN 24mg + Thiamin Nitrate (Vitamin B1 Nitrate) BP 25mg + Riboflavin (Vitamin B2) BP 15.249mg Film Coated Tablet.	Tranexamic Acid USP 750mg+Ibuprofen USP 450mg+Clemastine Fumarate USP 1.34mg eqv. to 1mg of Clemastine + Bromhexine Hydrochloride INN 12mg + dl-Methylephedrine Hydrochloride INN 60mg + Dihydrocodeine Phosphate INN 24mg + Thiamin Nitrate (Vitamin B1 Nitrate) BP 25mg + Riboflavin (Vitamin B2) BP 15.249mg	Common Cold Preparations Therapeutic code:038	Relief of cold symptoms (throat pain, fever, chills, headache, runny nose, stuffy nose, sneezing, coughing, tan, joint pain, muscle pain)	**CONTRAINDICATIONS:** It is contraindicated in patients allergic to the drug and in pregnant women. **Side-effect:** Skin: Rash/redness, itching, bruising Disinfectent: Nausea, vomiting, loss of appetite, stomach discomfort, gastritis, mouth ulcer, stomach upset, gastrointestinal bleeding, abdominal pain, diarrhea, bloody stools, Psycho-nervous system: Dizziness, excitement, convulsion. **Warning & Precautions:** • Persons who have had a allergic symptopms due to this drug or the ingredients of this drug • Person who have had asthma after taking this drug, other cold remedies, antipyretic analgesics • Children under 15 years old Pregnant women within 12 weeks of the	New	PMDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						expected delivery date.				
323.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Bepotastine 10 mg Tablet	Bepotastine INN 10 mg	Antihistamine Therapeutic Code: 021	Allergic rhinitis, urticaria, and pruritus associated with skin disorders (eczema/dermatitis, prurigo, cutaneous pruritus).	Contraindication: If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods. Side-effects: The most commonly reported adverse reactions include sleepiness, dry mouth, nausea, gastric pain, diarrhea, gastric distress, malaise and vomiting. If any of these symptoms occur, consult with your doctor or pharmacist. The symptoms described below are rarely	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
324.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Pancretin BP 150mg Capsule	Pancreatin 70% Enteric Coated Pellets BP 150 mg capsule Contains: Lipase 10,000 Units+Amylase 10,000 Units+Protease 1,000 Units.	Unclassified Agents Therapeutic Code: 075	Exocrine Pancreatic insufficiency due to chronic pancreatitis, cystic fibrosis, obstructive pancreatic tumors, coeliac disease, Zollinger-Ellison syndrome and gastro-intestinal or pancreatic surgical resections or other conditions	**Contraindication:** None **Side effects:** Vomiting, dizziness, cough, hyperglycemia, hypoglycemia, abdominal pain, abnormal feces, flatulence, frequent bowel movements, and nasopharyngitis. **Warnings & Precautions:** • Fibrosing colonopathy is associated with high-dose use of pancreatic enzyme replacement in the treatment of cystic fibrosis patients. Exercise caution when doses of this drug exceed 2,500 lipase units/kg of body weight per meal (or greater than 10,000 lipase units/kg of body weight per day). • To avoid irritation of oral mucosa, do not chew this drug or retain in the mouth. • Exercise caution when prescribing this drug to patients with gout, renal impairment, or hyperuricemia. • There is theoretical risk of viral	Pancrelipase 70% EC pellets 540 mg Delayed release Capsule Approved in DCC-252	TGA BNF-81 Page NO. 103-105	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						transmission with all pancreatic enzyme products including this drug. • Exercise caution when administering pancrelipase to a patient with a known allergy to proteins of porcine origin.				
325.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Romiplostim 125 microgram lyophilized powder for in‡jvection	Romiplostim 125 mcg in‡jvection	Drug used in Anemia and other Blood disorder Therapeutic Code: 045	Romiplostin is indicated for the treatment of thrombocytopenia in patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, and adults.	Contraindication: None Side-effects: The following serious adverse reactions are discussed in greater detail in other sections: Progression of Myelodysplastic Syndromes Thrombotic/Thromboembolic Complications Loss of Response to Romiplostin Laboratory Monitoring Warnings and Precautions: No data available	500mcg, 250mg	UKMHRA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
326.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Vibegron 75mg Tablet	Vibegron INN 75mg	Adrenergic Therapeutic Code:001	Vibegron is indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults.	**Contraindication**: None **Side-Effect:** Urinary tract infection (6.6%), Headache (4%), Bronchitis (2.9%), Nasopharyngitis (2.8%), Diarrhea (2.2%), Nausea (2.2%)	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
327.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Oxycodone Hydrochloride 80mg + Naltrexone Hydrochloride 9.6mg ER Capsule	Oxycodone Hydrochloride 80mg + Naltrexone Hydrochloride BP 9.6mg	Analgesics and Antipyretics Therapeutic Code: 006	Oxycodone+Naltrexone is a combination opioid agonist/opioid antagonist product indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.	**Contraindication:** Significant respiratory depression Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment Known or suspected gastrointestinal obstruction, including paralytic ileus Hypersensitivity to oxycodone or naltrexone **Side-effects:** Most common adverse reactions: nausea, constipation, vomiting, headache, and somnolence**Warnings and Precautions:** Life-T hreatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients: Monitor closely, particularly during initiation and titration.	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid. Severe Hypotension: Monitor during dosage initiation and titration. Avoid use of this in patients with circulatory shock. Risks of Use in Patients with Increased Intracranial Pressure, Brain T umors, Head In‡jvury, or Impaired Consciousness: Monitor for sedation and respiratory depression. Avoid use of it in patients with impaired consciousness or coma.				
328.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Aspirin 325mg+Dextromethorphan Hydrobromide 10mg + Phenylephrine Bitartrate 7.8mg Tablet	Aspirin BP 325mg+Dextromethorphan Hydrobromide BP 10mg + Phenylephrine Bitartrate USP 7.8mg	Unclassified Agents Therapeutic code:075	It is used temporarily to relieve these symptoms due to a cold with a cough: minor aches and pains, headache, cough, nasal and sinus congestion, sore throat, and temporarily reduces fever.	Contraindication: Aspirin is contraindicated in patients with known allergy to NSAIDS and in patients with asthma, rhinitis and nasal polyps. It may cause anaphylaxis, laryngeal edema, severe urticaria, angioedema, or bronchospasm (asthma). All salicylate products also carry the traditional Reye's syndrome warning to prevent use in children or teenagers who have any viral infection, with or without fever. Side-effects: Abdominal or stomach pain, cramping, burning, black or tarry stools, bloody or cloudy urine, change in consciousness, chest pain or discomfort, convulsions, severe or continuing, decreased frequency or amount of urine, difficulty breathing.	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
329.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Dofetilide 500mcg Capsule,	Dofetilide USP 500mcg Capsule	Antiarrhythmic Therapeutic code:009	Dofetilide is indicated for the maintenance of normal sinus rhythm (delay in time to recurrence of atrial fibrillation/atrial flutter [AF/Afl]) in patients with atrial fibrillation/atrial flutter of greater than one week duration who have	Contraindications: Dofetilide is contraindicated in patients with congenital or acquired long QT syndromes. Dofetilide should not be used in patients with a baseline QT interval or QTc >440 msec (500 msec in patients with ventricular conduction abnormalities). Dofetilide is also	125mcg, 250mcg	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					been converted to normal sinus rhythm. Because Dofetilide can cause life threatening ventricular arrhythmias, it should be reserved for patients in whom atrial fibrillation/atrial flutter is highly symptomatic. In general, antiarrhythmic therapy for atrial fibrillation/atrial flutter aims to prolong the time in normal sinus rhythm. Recurrence is expected in some patient. Conversion of Atrial Fibrillation/Flutter Dofetilide is indicated for the conversion of atrial fibrillation and atrial flutter to normal sinus rhythm. Dofetilide has not been shown to be effective in patients with paroxysmal atrial fibrillation.	contraindicated in patients with severe renal impairment (calculated creatinine clearance <20 mL/min).The concomitant use of verapamil or the cation transport system inhibitors cimetidine, trimethoprim (alone or in combination with sulfamethoxazole), or ketoconazole with Dofetilide is contraindicated, as each of these drugs cause a substantial increase in dofetilide plasma concentrations. In addition, other known inhibitors of the renal cation transport system such as prochlorperazine, dolutegravir and megestrol should not be used in patients on Dofetilide.The concomitant use of hydrochlorothiazide (alone or in combinations such as with triamterene) with Dofetilide is contraindicated because this has been shown to significantly increase dofetilide plasma concentrations and QT interval prolongation Side Effects: The most frequent adverse events were headache, chest pain				
330.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Tirofiban HCl Monohydrate INN 14.045mg eqv. to 12.5mg Tinofiban/250ml IV In‡jvection.	Tirofiban HCl Monohydrate INN 14.045mg eqv. to 12.5mg Tinofiban/250ml IV In‡jvection.	Coronary Vasodilators and Antianginal drug Therapeutic code:040	It is a platelet aggregation inhibitor indicated to reduce the rate of thrombotic cardiovascular events (combined endpoint of death, myocardial infarction, or refractory ischemia/repeat cardiac procedure) in patients with non-ST elevation acute coronary syndrome	Contraindication: • Known hypersensitivity to any component of AGGRASTAT. • History of thrombocytopenia with prior exposure to AGGRASTAT. • Active internal bleeding, or history of bleeding diathesis, major surgical procedure or severe physical trauma within the previous month Side-effects: Bleeding is the most commonly reported adverse reaction	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
331.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Adagrasib 200mg Tablet	Adagrasib INN 200mg	Anti-cancer Therapeutic code: 010	It is an inhibitor of the RAS GTPase family indicated for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA approved test, who have received at least one prior systemic therapy. This indication is approved under accelerated approval based on objective response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of a clinical benefit in a confirmatory trial(s)	Contraindication: None. Side-effects: The most common (≥ 25%) adverse reactions were nausea, diarrhea, vomiting, fatigue, musculoskeletal pain, hepatotoxicity, renal impairment, edema, dyspnea, and decreased appetite. • The most common Grade 3 or 4 (≥ 2%) laboratory abnormalities were decreased lymphocytes, decreased hemoglobin, increased alanine aminotransferase, increased aspartate aminotransferase, hypokalemia, hyponatremia, increased lipase, decreased leukocytes, decreased neutrophils and increased alkaline phosphatase.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
332.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Glycerol Phenylbutyrate 1.1gm/ml Oral Liquid	Glycerol Phenylbutyrate INN 110gm/100ml Oral Liquid	Unclassified Agents Therapeutic code:075	It (glycerol phenylbutyrate) is a nitrogen-binding agent indicated for chronic management of patients 2 years of age and older with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. RAVICTI must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements). Limitations of Use: • RAVICTI is not indicated for treatment of acute hyperammonemia in patients with UCDs. (1) • Safety and efficacy for treatment of N-acetylglutamate synthase (NAGS) deficiency has not been established	CONTRAINDICATIONS: Patients less than 2 months of age. (4) • Known hypersensitivity to phenylbutyrate. Side-effect: Most common adverse reactions (≥10%) are: diarrhea, flatulence, and headache WARNINGS AND PRECAUTIONS: • Neurotoxicity: Phenylacetate (PAA), the active moiety of RAVICTI, may be toxic; reduce dosage for symptoms of neurotoxicity. • Pancreatic Insufficiency or Intestinal Malabsorption: Monitor ammonia levels closely	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
333.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh Incepta Pharmaceuticals Ltd, Savar, Dhaka	Adalimumab INN 40mg/0.4ml Pre-filled syringe	Adalimumab INN 40mg/0.4ml Pre-filled syringe	Immune-suooressant Therapeutic code:058	It is a tumor necrosis factor (TNF) blocker indicated for treatment of: • Rheumatoid Arthritis (RA) : Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA. • Juvenile Idiopathic Arthritis (JIA) (1.2): Reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older. • Psoriatic Arthritis (PsA) (1.3): Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA. • Ankylosing Spondylitis (AS) (1.4): Reducing signs and symptoms in adult patients with active AS. • Adult Crohn's Disease (CD) (1.5): Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. Reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab. • Pediatric Crohn's Disease (1.6): Reducing signs and symptoms and inducing and maintaining clinical	**CONTRAINDICATIONS:** None **Side-effect:** Most common adverse reactions (incidence >10%): infections (e.g. upper respiratory, sinusitis), Injectionsite reactions, headache and rash. WARNINGS AND PRECAUTIONS: Serious infections: Do not start HUMIRA during an active infection. If an infection develops, monitor carefully, and stop HUMIRA if infection becomes serious • Invasive fungal infections: For patients who develop a systemic illness on HUMIRA, consider empiric antifungal therapy for those who reside or travel to regions where mycoses are endemic • Malignancies: Incidence of malignancies was greater in HUMIRA-treated patients than in controls • Anaphylaxis or serious allergic reactions may occur	Adalimumab 20mg/.2ml	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					remission in patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate. • Ulcerative Colitis (UC) (1.7): Inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine (6-MP). The effectiveness of HUMIRA has not been established in patients who have lost response to or were intolerant to TNF blockers. • Plaque Psoriasis (Ps) (1.8): The treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. • Hidradenitis Suppurativa (HS) (1.9): The treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older. • Uveitis (UV) (1.10): The treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older.					

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
334.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Sodium Phenylbutyrate USP 500mg Tablet	Sodium Phenylbutyrate USP 500mg Tablet	Unclassified Agents Therapeutic code:075	BUPHENYL® is indicated as adjunctive therapy in the chronic management of patients with urea cycle disorders involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS). It is indicated in all patients with neonatal-onset deficiency (complete enzymatic deficiency, presenting within the first 28 days of life). It is also indicated in patients with late-onset disease (partial enzymatic deficiency, presenting after the first month of life) who have a history of hyperammonemic encephalopathy. It is important that the diagnosis be made early and treatment initiated immediately to improve survival. Any episode of acute hyperammonemia should be treated as a lifethreatening emergency	**CONTRAINDICATIONS:** BUPHENYL® should not be used to manage acute hyperammonemia, which is a medical emergency **Side-effect:** The assessment of clinical adverse events came from 206 patients treated with sodium phenylbutyrate. Adverse events (both clinical and laboratory) were not collected systematically in these patients, but were obtained from patient-visit reports by the 65 co-investigators. Causality of adverse effects is sometimes difficult to determine in this patient population because they may result from either the underlying disease, the patient's restricted diet, intercurrent illness, or BUPHENYL® . Furthermore, the rates may be under-estimated because they were reported primarily by parent or guardian and not the patient	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
335.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Sodium Phenylbutyrate USP 5gm/sachet	Sodium Phenylbutyrate USP 5gm/sachet	Unclassified Agents Therapeutic code:075	It is indicated as adjunctive therapy in the chronic management of patients with urea cycle disorders involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS). It is indicated in all patients with neonatal-onset deficiency (complete enzymatic deficiency, presenting within the first 28 days of life). It is also indicated in patients with late-onset disease (partial enzymatic deficiency, presenting after the first month of life) who have a history of	CONTRAINDICATIONS: BUPHENYL® should not be used to manage acute hyperammonemia, which is a medical emergency Side-effect: The assessment of clinical adverse events came from 206 patients treated with sodium phenylbutyrate. Adverse events (both clinical and laboratory) were not collected systematically in these patients, but were obtained from patient-visit reports by the 65 co-investigators. Causality of adverse effects is sometimes difficult to determine in this patient population because they may result from either the underlying disease, the patient's restricted diet, intercurrent illness, or BUPHENYL® . Furthermore, the rates	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					hyperammonemic encephalopathy. It is important that the diagnosis be made early and treatment initiated immediately to improve survival. Any episode of acute hyperammonemia should be treated as a lifethreatening emergency	may be under-estimated because they were reported primarily by parent or guardian and not the patient. WARNINGS AND PRECAUTIONS: . Neurotoxicity of Phenylacetate: Increased exposure to phenylacetate, the major metabolite of PHEBURANE, may be associated with neurotoxicity in patients with UCDs. Consider reducing the dose if neurotoxicity symptoms are present. • Hypokalemia: Renal excretion of phenylacetylglutamine may induce urinary loss of potassium. Monitor serum potassium during therapy and initiate appropriate treatment when necessary. • Conditions Associated with Edema: Calculate the total amount of sodium patients will be exposed to based on their weight or body surface area. If a patient develops new-onset edema or worsening edema while on treatment, discontinue administration of PHEBURANE and initiate appropriate therapy. • Diabetes Mellitus, Hereditary Fructose Intolerance, GlucoseGalactose Malabsorption or Sucrase-Isomaltase Insufficiency: Avoid use of PHEBURANE in patients with rare hereditary problems of fructose intolerance, glu				
336.	Beximco Pharmaceuticals Ltd., Tongi, Gazipur	Topiroxostat 60 mg Tablet	Topiroxostat INN 60 mg	Uricosuric and Anti-Gout Agents. Therapeutic Code:076	Gout and hyperurcemia	**Contraindications:** There are no known contraindications for Topiroxostat. **Side Effect:** The most reported adverse reactions include gouty arthritis. Liver dysfunction: Generalized fatigability, nausea, yellowness in skin or con‡jvunctiva Erythema multiforme: Round or oval red	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						rash, fever, joint pain **Warnings and Precautions:** If there is previous history of any allergic reactions (itch, rash, etc.) to any medicines or foods. **Pregnant or breastfeeding:** If there is history of taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)				
337.	Beximco Pharmaceuticals Ltd., Tongi, Gazipur The ACME Laboratories Ltd. Dhamrai, Dhaka	Faropenem 200 mg tablet	Faropenem Sodium Hydrate JP 247.000 mg equivalent to Faropenem 200mg	Anti-infective Therapeutic Code: 023	**Lower respiratory tract infections**: E.g., acute bronchitis, pneumonia, pulmonary suppuration. **Ear, nose, and throat (ENT) infections**: E.g., otitis externa, tympanitis, sinusitis. **Genito-urinary infections**: E.g., pyelonephritis, cystitis, prostatitis, seminal gland inflammation. **Upper respiratory tract infections**: E.g., pharyngitis, tonsillitis. **Skin and skin structure infections**: E.g., pustular acne, folliculitis, contagious impetigo, erysipelas, lymphangitis, suppurative nail inflammation, subcutaneous abscess, hidradenitis (sweat gland inflammation), infective sebaceous cyst, chronic pyoderma, secondary infection of	**Contraindication:** Faropenem is contraindicated in patients with known hypersensitivity to any of the components of this product or to other drugs in the same class, or in patients who have demonstrated anaphylactic reactions to beta-lactams. **Side effect:** Common side effects of this drug are: • Headache • Nausea • Vomiting • Stomach pain • Diarrhea **Warnings and Precautions:** Faropenem should be administered with caution in the following: 1. Patients with a history of hypersensitivity to penicillin, cephem or carbapenem drugs. 2. Patients with a family history of atopy. 3. Patients with renal impairment. The dosage should be reduced or the interval between doses should be increased. 4. Geriatric patients. 5. Patients with poor oral intake or poor general state (since there are cases that	Faropenem 150 mg tablet |	PMDA, JP	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					external wounds or surgical wounds. **Gynecological infections**: E.g., adnexitis, Bartholin gland inflammation.	show symptoms of vitamin K deficiency, proper monitoring should be done).				
338.	Beximco Pharmaceuticals Ltd., Tongi, Gazipur Drug International Ltd 31/1,Satrong, Tongi I/A, Gazipur. The ACME Laboratories Ltd. Renata Limited, Bhaluka DBL Pharmaceuticals Ltd.	Salbutamol 90 mcg and Budesonide 80 mcg inhalation Aerosol	Salbutamol sulfate BP eq. to 90 mcg Salbutamol and Budesonide BP 80 mcg per actuation	Drug used in Bronchial Asthma Therapeutic Code: 044	Salbutamol and Budesonide Inhalation Aerosol is indicated for the as-needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations in patients with asthma 18 years of age and older.	**Contraindication**: Hypersensitivity to Salbutamol, Budesonide, or to any of the excipients. **Side effect:** Most common adverse reactions (incidence ≥ 1%) are headache, oral candidiasis, cough, dysphonia. **Warnings and Precautions** ▪ If symptoms continue after using combination, this may be a marker of destabilization of asthma and requires reevaluation of treatment. ▪ If paradoxical bronchospasm occurs, discontinue combination immediately and institute alternative therapy. ▪ Cardiovascular effects may occur. Use with caution in patient's sensitive to sympathomimetic drugs and patients with cardiovascular disorders. ▪ Excessive use may be fatal. Do not exceed maximum recommended dosage. ▪ Hypersensitivity reactions may occur. Discontinue combination immediately. ▪ Use with caution in patients with convulsive disorders, hyperthyroidism, diabetes mellitus, and ketoacidosis. ▪ Hypokalemia may occur. ▪ Potential worsening of infections (e.g., existing tuberculosis; fungal, bacterial,	Budesonide inhaler and Salbutamol inhaler	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						viral, or parasitic infections; or ocular herpes simplex). Use with caution in patients with these infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients. ▪ Oropharyngeal candidiasis may occur. Advise patients to rinse mouth with water, if available, without swallowing after use. Monitor patients periodically. ▪ Hypercorticism and adrenal suppression may occur with very high dosages in susceptible individuals. If such changes occur, consider appropriate therapy. ▪ Monitor patients with major risk factors for decreased bone mineral content. ▪ Glaucoma and cataracts may occur. Consider referral to an ophthalmologist in patients who develop ocular symptoms				
339.	Beximco Pharmaceuticals Ltd., Tongi, Gazipur	Phentermine 3.75 mg and Topiramate 23 mg extended-release capsules	Phentermine Hydrochloride USP 3.75 mg equivalent to Phentermine 3.75 mg and Topiramate USP 23 mg	Appetite suppressant agents Therapeutic Code: 075	Weight management for Obese or Overweight adults in the presence of at least one comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia	**Contraindications:** Pregnancy, Glaucoma, Hyperthyroidism, During or within 14 days of taking monoamine oxidase inhibitor Known hypersensitivity or idiosyncrasy to sympathomimetic amines **Side effect:** Most common adverse reactions (incidence greater than or equal to 5%) are: paraesthesia, dizziness, dysgeusia, insomnia, constipation, and dry mouth. **Warnings & Precautions** Fetal Toxicity: Females of reproductive potential: Obtain negative pregnancy test before treatment and monthly thereafter; use effective contraception. It is available through a limited program under a Risk Evaluation	Topiramate 25 & 50 mg Tablet	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						and Mitigation Strategy (REMS) • Increase in Heart Rate: Monitor heart rate in all patients, especially those with cardiac or cerebrovascular disease • Suicidal Behavior and Ideation: Monitor for depression or suicidal thoughts. Discontinue if symptoms develop. • Acute Myopia and Secondary Angle Closure Glaucoma: Discontinue it. • Mood and Sleep Disorders: Consider dose reduction or withdrawal for clinically significant or persistent symptoms. • Cognitive Impairment: May cause disturbances in attention or memory. Caution patients about operating automobiles or hazardous machinery when starting treatment. • Metabolic Acidosis: Measure electrolytes before/during treatment. • Elevated Creatinine: Measure creatinine before/during treatment. • Use of Antidiabetic Medications: Weight loss may cause hypoglycemia. Measure serum glucose before/during treatment				
340.	Beximco Pharmaceuticals Ltd., Tongi, Gazipur	Phentermine 7.5 mg and Topiramate 46 mg extended-release capsules	Phentermine Hydrochloride USP 9.33 mg equivalent to Phentermine 7.5 mg and Topiramate USP 46 mg	Appetite suppressant agents Therapeutic Code: 075	Weight management for Obese or Overweight adults in the presence of at least one comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia	**Contraindication:** Pregnancy, Glaucoma, Hyperthyroidism, During or within 14 days of taking monoamine oxidase inhibitor Known hypersensitivity or idiosyncrasy to sympathomimetic amines **Side effect:** Most common adverse reactions (incidence greater than or equal to 5%) are: paraesthesia, dizziness, dysgeusia, insomnia, constipation, and dry mouth. **Warnings & Precautions** Fetal Toxicity: Females of reproductive potential: Obtain negative pregnancy test before treatment and monthly thereafter; use effective contraception. It is available through	Topiramate 25 & 50 mg Tablet	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						a limited program under a Risk Evaluation and Mitigation Strategy (REMS) • Increase in Heart Rate: Monitor heart rate in all patients, especially those with cardiac or cerebrovascular disease • Suicidal Behavior and Ideation: Monitor for depression or suicidal thoughts. Discontinue if symptoms develop. • Acute Myopia and Secondary Angle Closure Glaucoma: Discontinue it. • Mood and Sleep Disorders: Consider dose reduction or withdrawal for clinically significant or persistent symptoms. • Cognitive Impairment: May cause disturbances in attention or memory. Caution patients about operating automobiles or hazardous machinery when starting treatment. • Metabolic Acidosis: Measure electrolytes before/during treatment. • Elevated Creatinine: Measure creatinine before/during treatment. • Use of Antidiabetic Medications: Weight loss may cause hypoglycemia. Measure serum glucose before/during treatment				
341.	DBL Pharmaceuticals Ltd. Surabari, Kashimpur, Gazipur	Sodium Zirconium Cyclosilicate 10 gm/ Sachet Powder for oral suspension.	Sodium Zirconium Cyclosilicate INN 10 gm Equivalent to 800 mg of Sodium)/ Sachet	Electrolytes Therapeutic Code No.: 062	Sodium Zirconium Cyclosilicate is a potassium binder indicated for the treatment of hyperkalemia in adults. Limitation of Use Sodium Zirconium Cyclosilicate should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action	**Contraindications:** None **Side effects:** Edema **Warnings and Precautions** Serum potassium levels Serum potassium should be monitored when clinically indicated, including after changes are made to medicinal products that affect the serum potassium concentration (e.g. renin-angiotensin-aldosterone system (RAAS) inhibitors or diuretics) and after the Sodium Zirconium Cyclosilicate dose is titrated. Hypokalaemia Hypokalaemia may be observed. Dose titration as described under maintenance posology	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						may be required in such cases to prevent moderate to severe hypokalaemia. In patients with severe hypokalaemia, Sodium Zirconium Cyclosilicate should be discontinued and the patient re-evaluated. QT Prolongation During correction of hyperkalaemia, a lengthening of the QT interval can be observed as the physiologic result of a decline in serum potassium concentration. The risk of interaction with X-rays Sodium zirconium cyclosilicate may be opaque to X-rays. If the patient is having abdominal X-rays, radiographers should keep this in mind. Intestinal perforation The risk for intestinal perforation with the use of Sodium Zirconium Cyclosilicate is currently unknown. Since intestinal perforation has been reported with potassium binders including Lokelma, specific attention should be paid to signs and symptoms related to intestinal perforation. Sodium content This medicinal product contains approximately 400 mg sodium per 5 g dose, equivalent to 20% of the WHO recommended maximum daily intake of 2 g sodium for an adult. Sodium Zirconium Cyclosilicate is considered high in sodium. This should be particularly taken into account for those on a low salt diet. Limitations of the clinical data Severe hyperkalaemia There is limited experience in patients with serum potassium concentrations greater than 6.5 mmol/L. Long-term exposure Clinical trials with Sodium Zirconium Cyclosilicate have not included exposure				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						longer than one year.				
342.	DBL Pharmaceuticals Ltd. Surabari, Kashimpur, Gazipur	Methocarbamol 500 mg Tablet	Methocarbamol 500 mg Tablet	Muscle relaxant Therapeutic Code: 070	Indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions.	**Contraindications:** contraindicated in patients hypersensitive to methocarbamol or to any of the tablet components. **Side effects:** Body as a whole: Anaphylactic reaction, angioneurotic edema, fever, headache Cardiovascular system: Bradycardia, flushing, hypotension, syncope, thrombophlebitis Digestive system: Dyspepsia, jaundice (including cholestatic jaundice), nausea and vomiting Nervous system: Amnesia, confusion, Diplopia, dizziness or lightheadedness, drowsiness, insomnia, mild muscular incoordination, nystagmus, sedation, seizures (including grand mal), vertigo Skin and special senses: Blurred vision, con‡jvunctivitis, nasal congestion, metallic taste, pruritus, rash, urticaria **Precautions** Patients should be cautioned that methocarbamol may cause drowsiness or dizziness, which may impair their ability to operate motor vehicles or machinery. Because methocarbamol may possess a general CNS-depressant effect, patients should be cautioned about combined effects with alcohol and other CNS depressants. **Warnings** Since methocarbamol may possess a general CNS depressant effect, patients receiving Methocarbamol should be cautioned about combined effects with alcohol and other CNS depressants. Safe use of Methocarbamol has	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						not been established with regard to possible adverse effects upon fetal development. There have been reports of fetal and congenital abnormalities following in utero exposure to methocarbamol. Therefore, Methocarbamol should not be used in women who are or may become pregnant and particularly during early pregnancy unless in the judgment of the physician the potential benefits outweigh the possible hazards				
343.	DBL Pharmaceuticals Ltd. Surabari, Kashimpur, Gazipur	Methocarbamol 750 mg Tablet	Methocarbamol 750 mg Tablet	Muscle relaxant Therapeutic Code: 070	Indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions.	**Contraindications:** contraindicated in patients hypersensitive to methocarbamol or to any of the tablet components. **Side effects:** Body as a whole: Anaphylactic reaction, angioneurotic edema, fever, headache Cardiovascular system: Bradycardia, flushing, hypotension, syncope, thrombophlebitis Digestive system: Dyspepsia, jaundice (including cholestatic jaundice), nausea and vomiting Nervous system: Amnesia, confusion, Diplopia, dizziness or lightheadedness, drowsiness, insomnia, mild muscular incoordination, nystagmus, sedation, seizures (including grand mal), vertigo Skin and special senses: Blurred vision, con‡jvunctivitis, nasal congestion, metallic taste, pruritus, rash, urticaria **Precautions** Patients should be cautioned that methocarbamol may cause drowsiness or dizziness, which may impair their ability to operate motor vehicles or machinery. Because methocarbamol may possess a general CNS-depressant effect, patients should be cautioned about combined effects with alcohol and other CNS depressants. **Warnings**	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Since methocarbamol may possess a general CNS depressant effect, patients receiving Methocarbamol should be cautioned about combined effects with alcohol and other CNS depressants. Safe use of Methocarbamol has not been established with regard to possible adverse effects upon fetal development. There have been reports of fetal and congenital abnormalities following in utero exposure to methocarbamol. Therefore, Methocarbamol should not be used in women who are or may become pregnant and particularly during early pregnancy unless in the judgment of the physician the potential benefits outweigh the possible hazards				
344.	Drug International Ltd 31/1,Satrong, Tongi I/A, Gazipur.	Lenacapavir Sodium INN.375.00 mg (Eqv. to Lenacapavir300mg)	Lenacapavir Sodium INN.375.00 mg (Eqv. to Lenacapavir300mg) Tablet	Antiviral Therapeutic code: 032	It is in combination with other antiretroviral(s), is indicated for the treatment of adults with multidrug resistant HIV-1 infection forwhom it is otherwise not possible to construct a suppressive anti-viral regimen, for oral loading prior to administration of long-actinglenacapavir in‡jvection	**Contraindication:** Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Co-administration with strong inducers of CYP3A, P-gp, and UGT1A1, such as: • antimycobacterials: rifampicin • anticonvulsants: carbamazepine, phenytoin • herbal products: St. John's wort (*Hypericumperforatum*). **Precaution:** If Lencapavir is discontinued, to minimise the risk of developing viral resistance it is essential to adopt an alternative, fully suppressiveantiretroviral regimen where possible, no later than 28 weeks after the final Injectionof Lencapavir. **Warning:**There is no data available. **Side effects:** The common adverse reactions are anaphylaxis, “red man syndrome”, acute kidney In‡jvury, hearing loss, neutropenia.	New	UKMHRA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
345.	Drug International Ltd 31/1, Satrong Road, Gopalpur, Tongi Industrial Area.Gazipur, Bangladesh.	Inclisiran Sodium INN 300.00mg (Eqv to 284.00 mg)/1.5ml Pre-filled Syringe.	Inclisiran Sodium INN 300.00mg (Eqv to 284.00 mg)/1.5ml	Lipid Lowering Agent Therapeutic code:061	Inclisiran Sodium is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol(LDL-C).	**Contraindications:** It is contraindicated in patients known to have hypersensitivity to the active substance or to any of the excipients. **Precautions:** There is no data available. **Warning:** There is no data available. **Side effects:** Common adverse reactions in clinical trials (≥ 3%): Injectionsite reaction, arthralgia, urinary tract infection, diarrhea, bronchitis, pain in extremity, and dyspnea.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
346.	Drug International Ltd 31/1,Satrong, Tongi I/A, Gazipur.	Bictegravir INN 50.00mg, Emtricitabine INN 200.00mg and TenofovirAlafenamideFumarate INN 28.00 mg (Eqv. to 25.00mg TenofovirAlafenamide	Bictegravir INN 50.00mg, Emtricitabine INN 200.00mg and TenofovirAlafenamideFumarate INN 28.00 mg (Eqv. to 25.00mg TenofovirAlafenamideTablet	Antiviral Therapeutic code:032	It is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 14 kg who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components.	**Contraindication:** It is contraindicated to be co-administered with: dofetilide and rifampin. **Precaution:** Immune reconstitution syndrome: May necessitate further evaluation and treatment. New onset or worsening renal impairment: Assess serum creatinine, estimated creatinine clearance, urine glucose and urine protein when initiating and during therapy as clinically appropriate in all patients. Also assess serum phosphorus in patients with chronic kidney disease. Lactic acidosis/severe hepatomegaly with steatosis: Discontinue treatment in patients who develop symptoms or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity. **Warning:** As precausion **Side effects:** The most common side effects are diarrhea, nausea, and headache.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
347.	Drug International Ltd. 252, Tongi Industrial Area, Tongi, Gazipur, Bangladesh.	Bisacodyl USP 10.00 mg suppository	Bisacodyl USP 10.00 mg	Laxative Therapeutic code:060	Bisacodyl Suppositories is indicated for Relief of occasional constipation Under medical supervision, for the preparation of diagnostic procedures, in pre- and postoperative treatment, and in conditions which require defecation to be facilitated.	**Contraindication:** Patients with ileus, intestinal obstruction, acute abdominal conditions like acute appendicitis, acute inflammatory bowel diseases, severe abdominal pain associated with nausea and vomiting which may be indicative of more severe conditions. **Precaution:** The use of suppositories may lead to painful sensations and local irritation, especially in patients with anal fissures and ulcerative proctitis and should be used in these conditions under medical advice or as directed by a physician **Warning:** There is no data available. **Side effects:** The most commonly reported adverse reactions during treatment are abdominal pain and diarrhoea.	Bisacodyl 5.00mg Tablet	UK-MHRA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
348.	Drug International Ltd. 13A & 14A, Tongi I/A, Tongi, Gazipur, Bangladesh.	Pirtobrutinib INN 50.00 mg	Pirtobrutinib INN 50.00 mg Tablet	Anticancer Therapeutic code:010	It is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor.	**Contraindication:** It is contraindicated in patients with known hypersensitivity to Pirtobrutinib or any other components of this product. **Precaution:** Caution shold be exercised when Pirtobrutinib is used in patients with Infections, Hemorrhage, Cytopenias, Atrial Fibrillation and Atrial Flutter, Second Primary Malignancies, Embryo-Fetal Toxicity. **Warning:** There is no data available.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Side effects: •Hemorrhage, •Cytopenias, • Atrial Fibrillation and •Atrial Flutter, •Second Primary Malignancies				
349.	Drug International Ltd. 13A & 14A, Tongi I/A, Tongi, Gazipur, Bangladesh.	Pirtobrutinib INN 100.00 mg	Pirtobrutinib INN 100.00 mg Tablet	Anticancer Therapeutic code:010	It is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor.	**Contraindication:** It is contraindicated in patients with known hypersensitivity to Pirtobrutinib or any other components of this product. **Precaution:** Caution shold be exercised when Pirtobrutinib is used in patients with Infections, Hemorrhage, Cytopenias, Atrial Fibrillation and Atrial Flutter, Second Primary Malignancies, Embryo-Fetal Toxicity. **Warning:** There is no data available. **Side effects:** •Hemorrhage, •Cytopenias, • Atrial Fibrillation and •Atrial Flutter, •Second Primary Malignancies.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
350.	Drug International Ltd. 31/1, Satrong Road, Gopalpur, Tongi Industrial Area.Gazipur, Bangladesh.	Pegcetacoplan INN 150.00 mg/ml In‡jvection	Pegcetacoplan INN 150.00 mg/ml.	Eye preparation Therapeutic code:052	It indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).	**Contraindication:** It is contraindicated in Ocular or Periocular Infection and Active Intraocular Inflammation. **Precaution:** It should be given with caution in Endophthalmitis and Retinal Detachments, Neovascular AMD, Intraocular inflammation and Increased Intraocular Pressure. **Warning:** It should be given with caution in Endophthalmitis and Retinal Detachments, Neovascular AMD, Intraocular inflammation and Increased Intraocular Pressure. **Side effects:** Most common adverse reactions: ocular discomfort, neovascular age-related macular degeneration, vitreous floaters and con‡jvunctival hemorrhage.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
351.	Drug International Ltd. 31/1, Satrong Road, Gopalpur, Tongi Industrial Area.Gazipur, Bangladesh. Advanced Chemical Industries Limited	Sparsentan USP 200mg Tablet.	Sparsentan USP 200.00 mg.	Nephropathy Therapeutic code:075	Sparsentan is an endothelin and angiotensin II receptor antagonist indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.	**Contraindication:** Do not coadminister Sparsentan with angiotensin receptor blockers, endothelin receptor antagonists, or aliskiren. **Precaution:** Caution should be exercised when using Sparsentan in patients with Hepatotoxicity, Embryo-Fetal Toxicity, Hypotension, Acute Kidney In‡jvury, Hyperkalemia, Fluid Retention. **Warning:** There is no data available. **Side effects:** Most common adverse reactions are peripheral edema, hypotension (including orthostatic hypotension), dizziness, hyperkalemia, and anemia.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
352.	Drug International Ltd. 31/1, Satrong Road, Gopalpur, Tongi Industrial Area.Gazipur, Bangladesh. Advanced Chemical Industries Limited	Sparsentan USP 400.00 mg Tablet.	Sparsentan USP 400.00 mg	Nephropathy Therapeutic code:075	Sparsentan is an endothelin and angiotensin II receptor antagonist indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.	**Contraindication:** Do not coadminister Sparsentan with angiotensin receptor blockers, endothelin receptor antagonists, or aliskiren. **Precaution:** Caution should be exercised when using Sparsentan in patients with Hepatotoxicity, Embryo-Fetal Toxicity, Hypotension, Acute Kidney In‡jvury, Hyperkalemia, Fluid Retention. **Warning:** There is no data available. **Side effects:** Most common adverse reactions are peripheral edema, hypotension (including orthostatic hypotension), dizziness, hyperkalemia, and anemia.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
353.	Drug International Ltd. 13A & 14A, Tongi I/A, Tongi, Gazipur, Bangladesh.	Ceftolozane Sulfate INN 1.147 gm (Eqv. to 1.00gm Ceftolozane) and Tazobactam Sodium INN 0.537 gm (Eqv. to 0.5gm Tazobactam)/ Vial	Ceftolozane Sulfate INN 1.147 gm (Eqv. to 1.00gm Ceftolozane) and Tazobactam Sodium INN 0.537 gm (Eqv. to 0.5gm Tazobactam)/ Vial In‡jvection	Antibiotic Therapeutic code:023	It is indicated for the treatment of the following infections caused by designated susceptible microorganisms: Complicated Intra-abdominal Infections (cIAI), used in combination with metronidazole, in adult and pediatric patients (birth to less than 18 years old). Complicated Urinary Tract Infections (cUTI), Including Pyelonephritis, in adult and pediatric patients (birth to less than 18 years old). Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP), in adult patients 18 years and older. To reduce the development of drug-resistant bacteria and maintain the effectiveness and other antibacterial drugs. It should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.	**Contraindication:** It is contraindicated in patients with known serious hypersensitivity to the components (ceftolozane and tazobactam), piperacillin/ tazobactam, or other members of the beta lactam class. **Precaution:** Decreased efficacy was observed in a Phase 3 cIAI trial in a subgroup of patients with baseline CrCl of 30 to 50 mL/min. Monitor CrCl at least daily in patients with changing renal function and adjust the dose accordingly. • Serious hypersensitivity (anaphylactic) reactions have been reported with beta-lactam antibacterial drugs. Exercise caution in patients with known hypersensitivity to beta-lactam antibacterial drugs. If an anaphylactic reaction occurs, discontinue the drug and institute appropriate therapy. • *Clostridioides difficile*-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents. Evaluate if diarrhea occurs. **Warning:** There is no data available. **Side effects:** Adult cIAI, cUTI and HAB/VABP Patients: The most common adverse reactions in adult patients are	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						nausea, diarrhea, headache, and pyrexia. The most common adverse reactions (≥5% in the HABP/VABP indication) are increase in hepatic transaminases, renal impairment/renal failure, and diarrhea. Pediatric cIAI and cUTI Patients: The most common adverse reactions in pediatric patients (≥7% in either the cIAI or cUTI indication) are thrombocytosis, diarrhea, pyrexia, leukopenia, abdominal pain, vomiting, increased aspartate aminotransferase, and anemia.				
354.	Drug International Ltd. 13A & 14A, Tongi I/A, Tongi, Gazipur, Bangladesh.	Elacestrant INN 400.00mg (Eqv. to 345.00mg Elacestrant)	Elacestrant INN 400.00mg (Eqv. to 345.00mg Elacestrant) Tablet	Anticancer Therapeutic code:010	It is indicated for the treatment of postmenopausal women or adult men with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, *ESR1*-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.	**Contraindication:** It is contraindicated in patients with hypersensitivity to Elacestrant or any component of the product. **Precaution:** Caution shold be exercised when Elacestrant is used in patients with Dyslipidemia and Embryo-Fetal Toxicity. **Warning:** There is no data available. **Side effects:** • Dyslipidemia.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
355.	Drug International Ltd. 31/1, Satrong Road, Gopalpur, Tongi Industrial Area.Gazipur, Bangladesh.	Ursodeoxyc-holic Acid BP 500.00 mg Film Coated tablet.	Ursodeoxycho-lic Acid BP 500.00 mg.	Secondary Bile acid Therapeutic code:075	These tablets are indicated for the treatment of patients with primary biliary cirrhosis (PBC).	**Contraindication:** It is contraindicated in case of non-functioning gall-bladder calcified and pigmented gallstones, inflammatory bowel disease. **Precaution:** Patients with variceal bleeding, hepatic encephalopathy, ascites or in need of an urgent liver transplant, should receive appropriate specific treatment. **Warning:** It should be usedcautiously in those with liver	Ursodeoxycho-lic Acid BP 300.00 mgtablet.	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						disease. **Side effects:** Commonly reported side effects are nausea, vomiting, diarrhoea, gallstone opacilication, pruritus.				
356.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Terlipressin 0.85mg for In‡jvection	Terlipressin Acetate BP 1mg (Eq. to Terlipressin 0.85mg)	Hormone Therapeutic code: 056	It is a vasopressin receptor agonist indicated to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function. **Limitations of Use:** Patients with a serum creatinine >5mg/dL are unlikely to experience benefit.	**CONTRAINDICATIONS:** • In patients experiencing hypoxia or worsening respiratory symptoms. • In patients with ongoing coronary, peripheral, or mesenteric ischemia. **SIDE-EFFECT:** Abdominal pain, nausea, diarrhea, dyspnea and respiratory failure. **WARNINGS AND PRECAUTIONS:** • Serious or fatal respiratory failure • Ineligibility of liver transplant • Ischemic events • Embryo-fetal toxicity	Terlipressin Acetate 0.2 mg/ml solution for in‡jvection	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
357.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, Bangladesh	Avacopan INN 10 mg Capsule	Avacopan INN 10 mg Capsule	Other Classification Therapeutic Code: 075	Chronic Inflammatory conditions of the blood vessels (vasculitis)	**Contraindication:** Serious hypersensitivity to avacopan or to any of the excipients **Side effects:** The most common adverse reactions (≥5%) are: nausea, headache, hypertension, diarrhea, vomiting, rash, fatigue, upper abdominal pain, dizziness, blood creatinine increased, and paresthesia. **Warnings & Precautions: Hepatotoxicity:** Increase in liver function tests occurred in clinical trials. Obtain liver function tests before initiation of therapy and monitor as clinically indicated **Serious Hypersensitivity Reactions:** Cases of angioedema occurred in a clinical trial. Observe for signs and symptoms of angioedema and manage accordingly. **Hepatitis B Virus (HBV) Reactivation:** Cases of HBV reactivation occurred in a clinical trial. Withhold avacopan and institute	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						appropriate anti-infective therapy. **Serious Infections:** Avoid use of avacopan in patients with active, serious infection, including localized infections.				
358.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, Bangladesh	Patiromer INN 16.8 gm/Sachet for Oral Suspension	Patiromer Sorbitex Calcium INN 33.600 gm Eqv. to Patiromer 16.8 gm/Sachet	Potassium Binders Therapeutic Code: 075	Patiromer is a potassium binder indicated for the treatment of hyperkalemia.	**Contraindication:** Patiromer is contraindicated in patients with a history of a hypersensitivity reaction to Patiromer or any of its components. **Side effects:** During the clinical studies, the most commonly reported adverse reactions leading to discontinuation of Patiromer were gastrointestinal adverse reactions (2.7%), including vomiting (0.8%), diarrhea (0.6%), constipation (0.5%) and flatulence (0.5%). Mild to moderate hypersensitivity reactions were reported in 0.3% of patients treated. **Warning and Precaution:** Binding to Other Orally Administered Medications Patiromer binds many orally administered medications, which could decrease their gastrointestinal absorption and lead to reduced efficacy. Worsening of Gastrointestinal Motility Avoid use of Patiromer in patients with severe constipation, bowel obstruction or impaction, including abnormal post-operative bowel motility disorders.	Patiromer 8.40 gm/ Sachet for Oral Suspension	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
359.	General Pharmaceutical Ltd., Gazipur	Benzoic acid 0.050gm + Malic acid 0.70gm + Salicylic acid 0.0133gm/100gm Ointment	Benzoic acid BP 0.050gm + Malic acid USP 0.70gm + Salicylic acid BP 0.0133gm/100gm Ointment	Anti-burn & wound Therapeutic code: 023	To treat superficial skin lesions such as burns, scalds, sunburns, wounds and abrasions in infants, children, adolescents and adults. It has a disinfecting and analgesic effect (pain relieving effect) and supports wound healing. Burns,	There is no documented experience on the use of Malic acid+ benzoic acid + salicylic acid in human pregnancy or lactation. Careful consideration should therefore be given before its use during the first trimester of pregnancy. Avoid getting this medicine in your eyes. If the medicine does get in your eyes, flush	New	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					Chronic Skin Ulcers, Varicose ulcers and other benign indolent ulcers: Trophic ulcers including pressure sores. Traumatic in‡jvury. Crushed limb in‡jvuries: Multiple lesions. Also indicated in surgical procedures where slough may be a problem. Preparation of skin grafting: Mastectomies: Amputations: Post-surgical incisions.	them with water and call doctor right away. This medicine should not be given to children under 12 years of age without a doctor's approval.				
360.	General Pharmaceutical Ltd., Gazipur	Etofenamate 5% Topical gel	Etofenamate INN 5%	Topical Non-Steroidal Anti-Inflammatory Drug (NSAID) Therapeutic code: 072	Local symptomatic relief of painful or inflammatory conditions, of traumatic or degenerative origin of the joints, tendons, ligaments and muscles, periarthritis, arthrosynovitis,, distortions, meniscal lesions of the knee.	**Contraindications:** - Hypersensitivity to Etofenamate or to any of the components of this medicine. Its use is not recommended in patients who have presented allergic reactions (rhinitis, asthma, pruritus, angioedema, urticaria, shock or other), caused by acid acetylsalicylic or other NSAIDs due to the possibility of cross hypersensitivity. **Side-effect:** No side effect found **Precautions &Warnings:** This medication because it contains dimethyl sulfoxide can cause skin irritation.	New	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
361.	General Pharmaceutical Ltd., Gazipur	Ossein-hydroxyapatite 600mg Tablet	Ossein-hydroxyapatite Compound Ph. Gr. 622.5mg (Equivalent to Ossein-hydroxyapatite 600 mg)Tablet	Vitamins & Combinations Therapeutic code: 078	Treatment of osteoporosis in various origin Regulation of calcium & phosphate balance during pregnancy & lactation Stimulation of recovery process in subjects presenting bone fractures	Contraindications: Ossein-hydroxyapatite must not be used by patients who are sensitive to any constituent of the product: hypercalcemia and hypercalciuria Calcium Lithiasis Long-lasting immobilization Children up to 6 years old because of the pharmaceuticals form Patients suffering from severe renal failure and hemodialysis patients	New	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Side-effect: Precautions & Warnings: Special warnings and special precautions for use For patients treated with combination of Ossein-hydroxyapatite Calcium and Vitamin D hypercalcemia and hypercalciuria have to be monitored. For patients with raised blood and urine calcium levels, the dosage has to be adapted. For patients with high risk of renal calcium stone formation, and patients suffering from nephritic disorders, a prolonged treatment with Ossein-hydroxyapatite should be avoided. For patients suffering from renal insufficiency, blood and urine calcium levels should be regularly monitored and the high dose should be avoided In the event of long-term treatment and/or renal impairment, it is necessary to check urinary calcium levels and reduce or temporarily discontinue treatment if these exceed 7.5mmol/24 hours (300mg/24h) in adults and 0.12 to 0.15mmol/24h in children. In patients suffering from moderate renal failure, monitoring of serum phosphorus level is recommended.				
362.	General Pharmaceutical Ltd., Gazipur	Ossein-hydroxyapatite 800mg Tablet	Ossein-hydroxyapatite Compound Ph. Gr. 830.00mg (Equivalent to Ossein-hydroxyapatite 800 mg)Tablet	Vitamins & Combinations Therapeutic code: 078	Treatment of osteoporosis in various origin Regulation of calcium & phosphate balance during pregnancy & lactation Stimulation of recovery process in subjects presenting bone fractures	**Contraindications:** Ossein-hydroxyapatite must not be used by patients who are sensitive to any constituent of the product: hypercalcemia and hypercalciuria Calcium Lithiasis Long-lasting immobilization Children up to 6 years old because of the pharmaceuticals form Patients suffering from severe renal failure and hemodialysis patients	New	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Side-effect: **Precautions & Warnings:** Special warnings and special precautions for use For patients treated with combination of Ossein-hydroxyapatite Calcium and Vitamin D hypercalcemia and hypercalciuria have to be monitored. For patients with raised blood and urine calcium levels, the dosage has to be adapted. For patients with high risk of renal calcium stone formation, and patients suffering from nephritic disorders, a prolonged treatment with Ossein-hydroxyapatite should be avoided. For patients suffering from renal insufficiency, blood and urine calcium levels should be regularly monitored and the high dose should be avoided In the event of long-term treatment and/or renal impairment, it is necessary to check urinary calcium levels and reduce or temporarily discontinue treatment if these exceed 7.5mmol/24 hours (300mg/24h) in adults and 0.12 to 0.15mmol/24h in children. In patients suffering from moderate renal failure, monitoring of serum phosphorus level is recommended.				
363.	General Pharmaceutical Ltd., Gazipur	Ramipril 2.5 mg +Felodipine 2.5mg Prolongred Release Tablet	Ramipril BP 2.5mg +Felodipine BP 2.5mg	Antihypertensive Therapeutic Code:022	For the management of hypertension	**Contraindications:** -history of angioedema. - concomitant use with sacubitril/valsartan therapy. - unstable haemodynamic conditions: cardiovascular shock, untreated heart failure, acute myocardial infarction, unstable angina pectoris, stroke. - haemodynamically significant cardiac valvular obstruction.	Ramipril 2.5 mg & 5mg Tablet Felodipine USP 2.5mg & 10mg Tablet	TGA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						- dynamic cardiac outflow obstruction. - AV block II or III. - severely impaired hepatic function. - severely impaired renal function (creatinine clearance less than 20 ml/min) and in patients on dialysis. - pregnancy. - lactation. - The concomitant use of Triapin with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR <60 ml/min/1.73 m^2). **Side effects:** - Headache or feeling tired - Feeling dizzy - Dry tickly cough, inflammation of your sinuses (sinusitis) or bronchitis, shortness of breath - Stomach or gut pain, diarrhoea, indigestion, feeling or being sick - Skin rash with or without raised area - Chest pain - Cramps or pain in your muscles -Blood tests showing more potassium than usual in blood.				
364.	General Pharmaceutical Ltd., Gazipur	Ramipril 5 mg +Felodipine 5mg Prolongred Release Tablet	Ramipril BP 25mg +Felodipine BP 5mg	Antihypertensive Therapeutic Code:022	For the management of hypertension	**Contraindications:** -history of angioedema. - concomitant use with sacubitril/valsartan therapy. - unstable haemodynamic conditions: cardiovascular shock, untreated heart failure, acute myocardial infarction, unstable angina pectoris, stroke. - haemodynamically significant cardiac valvular obstruction. - dynamic cardiac outflow obstruction. - AV block II or III. - severely impaired hepatic function.	Ramipril 2.5 mg & 5mg Tablet Felodipine USP 2.5mg & 10mg Tablet	TGA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						- severely impaired renal function (creatinine clearance less than 20 ml/min) and in patients on dialysis. - pregnancy. - lactation. - The concomitant use of Triapin with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR <60 ml/min/1.73 m^2). **Side effects:** - Headache or feeling tired - Feeling dizzy - Dry tickly cough, inflammation of your sinuses (sinusitis) or bronchitis, shortness of breath - Stomach or gut pain, diarrhoea, indigestion, feeling or being sick - Skin rash with or without raised area - Chest pain - Cramps or pain in your muscles -Blood tests showing more potassium than usual in blood.				
365.	General Pharmaceutical Ltd., Gazipur	Benzydamine HCL 150 mg + Chlorhexidine Gluconate 120 mg)/100ml Sore Throat gargle Mouth Solution	Benzydamine HCL BP 150 mg + Chlorhexidine Gluconate BP 120 mg)/100ml (Mouth Solution)	Oral mouth Solution Therapeutic code: 073	Fast temporary relief of painful conditions of the mouth and throat including the symptoms of sore throat; pharyngitis; tonsillitis; mouth ulcers swelling, redness and inflammatory conditions; pain following mouth & throat surgery; pain following dental procedures including orosurgical & periodontal procedures.	**Contraindications:** Contraindicated in patients with known hypersensitivity to chlorhexidine or benzydamine. **Side-effect: S**tinging feeling or numbness in mouth after using benzydamine **Precautions &Warnings:** This Solution is indicated for use as a rinse or gargle. It should not be swallowed but rather should be expectorated after each use. Solution contains chlorhexidine. Chlorhexidine is known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock. The prevalence of chlorhexidine	New	TGA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						hypersensitivity is unknown, but available literature suggests this is likely to be very rare. It should not be administered to anyone with a possible history of an allergic reaction to chlorhexidine. If any signs or symptoms of a suspected hypersensitivity reaction such as itching, skin rash, redness, swelling, breathing difficulties, light headedness, and rapid heart rate develop, immediately stop using the product. Appropriate therapeutic countermeasures must be instituted as clinically indicated. This Solution should generally be used undiluted but if burning or stinging occur, it may be diluted with water. If a sore throat is either caused or complicated by a bacterial infection, appropriate antibacterial therapy should be considered in addition to the use of Solution. For use in patients with hepatic or renal impairment see Dosage & Administration. Use in Children: Because of the lack of sufficient clinical experience, this is not recommended in children under 6 years of age. Use in Pregnancy: Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of fetal damage. The safety benzydamine hydrochloride has not been established in pregnant patients. Risk to benefit ratio should be established if it is used in these patients.				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
366.	General Pharmaceutical Ltd., Gazipur The ACME Laboratories Ltd Drug International Ltd 31/1, Satrong Road, Gopalpur, Tongi Industrial Area Gazipur, Bangladesh The Ibn sina Pharmaceuticals ltd	Bexagliflozin INN 20 mg Tablet	Bexagliflozin INN 20 mg	Antidiabetic Therapeutic Code:015	Bexagliflozin is a sodium-glucose co-transporter 2 (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	Contraindication: Hypersensitivity to bexagliflozin or any excipient • Patients on dialysis **Side effects: Ketoacidosis,** nausea, vomiting, stomach-area (abdominal) pain, tiredness, trouble breathing, Amputations, **Dehydration, Vaginal yeast infection.** **Warning and precautions:** Ketoacidosis, Lower limb amputation, Volume depletion, Urosepsis and pyelonephritis, Hypoglycemia, Necrotizing Fasciitis of the Perineum (Fournier's Gangrene), Genital mycotic infection.	**New**	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
367.	General Pharmaceutical Ltd., Gazipur	Lumateperone Tosylate 42mg Capsule	Lumateperone Tosylate INN 60.00mg (Equivalent to Lumateperone 42 mg)	Antipsychotic Therapeutic code: 028	It is an atypical antipsychotic indicated for the treatment of: • Schizophrenia in adults. • Depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate.	**Contra-indications:** Known hypersensitivity to lumateperone or any components of Lumateperone Tosylate **Side Effects:** Most common adverse reactions in clinical trials (incidence > 5% and greater than twice placebo) were somnolence/sedation and dry mouth. **Warning & Precautions:** Cerebrovascular Adverse Reactions in Elderly Patients with Dementia Related Psychosis: Increased incidence of cerebrovascular adverse reactions (e.g., stroke and transient ischemic attack) Neuroleptic Malignant Syndrome: Manage with immediate discontinuation and close monitoring Tardive Dyskinesia: Discontinue treatment if clinically appropriate. Metabolic Changes: Monitor for hyperglycemia/diabetes mellitus, dyslipidemia, and weight gain.	**New**	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
368.	General Pharmaceutical Ltd., unit-2, Gazipur The Ibn Sina Pharmaceuticals ltd	Omidenepag isopropyl 0.002% ophthalmic solution	Omidenepag isopropyl INN 0.002% ophthalmic solution	Eye Preparation Therapeutic code: 052	Omidenepag isopropyl ophthalmic solution 0.002% is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.	**Contraindications:** None. **Side-effect:** The most common adverse reactions are con‡jvunctival hyperemia, photophobia, vision blurred, dry eye, instillation site pain, eye pain, ocular hyperemia, punctate keratitis, headache, eye irritation, and visual impairment **Precautions & Warnings:** • Pigmentation • Eyelash Changes • Ocular Inflammation • Macular Edema	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
369.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Temazepam 7.5mg Capsule	Temazepam USP 7.5mg	Hypnotics, Sedatives & Anxiolytic Therapeutic Code: 057	Temazepam is indicated for the short-term treatment of insomnia (generally 7 to 10 days). For patients with short-term insomnia, instructions in the prescription should indicate that temazepam should be used for short periods of time (7 to 10 days). The clinical trials performed in support of efficacy were 2 weeks in duration with the final formal assessment of sleep latency performed at the end of treatment.	**Contraindication:** Benzodiazepines may cause fetal harm when administered to a pregnant woman. An increased risk of congenital malformations associated with the use of diazepam and chlordiazepoxide during the first trimester of pregnancy has been suggested in several studies. Transplacental distribution has resulted in neonatal CNS depression following the ingestion of therapeutic doses of a benzodiazepine hypnotic during the last weeks of pregnancy. Reproduction studies in animals with temazepam were performed in rats and rabbits. In a perinatal-postnatal study in rats, oral doses of 60 mg/kg/day resulted in increasing nursling mortality. Teratology studies in rats demonstrated increased fetal resorptions at doses of 30 and 120 mg/kg in one study and increased occurrence of rudimentary ribs, which are considered skeletal variants, in a second study at doses of 240 mg/kg or higher. In rabbits, occasional abnormalities such as exencephaly and fusion or asymmetry of ribs	Temazepam 10 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						were reported without dose relationship. Although these abnormalities were not found in the concurrent control group, they have been reported to occur randomly in historical controls. At doses of 40 mg/kg or higher, there was an increased incidence of the 13th rib variant when compared to the incidence in concurrent and historical controls. Temazepam is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus. Patients should be instructed to discontinue the drug prior to becoming pregnant. The possibility that a woman of childbearing potential may be pregnant at the time of institution of therapy should be considered. **Side-effects:** The more common side effects of temazepam can include: drowsiness headache tiredness nervousness dizziness nausea **Warnings and Precautions:** Since the risk of the development of over sedation, dizziness, confusion, and/or ataxia increases substantially with larger doses of benzodiazepines in elderly and debilitated patients, 7.5 mg of temazepam is recommended as the initial dosage for such patients. Temazepam should be administered with caution in severely depressed patients or those in whom there is any evidence of latent depression; it should				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						be recognized that suicidal tendencies may be present and protective measures may be necessary. The usual precautions should be observed in patients with impaired renal or hepatic function and in patients with chronic pulmonary insufficiency. If temazepam is to be combined with other drugs having known hypnotic properties or CNS depressant effects, consideration should be given to potential additive effects. The possibility of a synergistic effect exists with the co-administration of temazepam l and diphenhydramine. One case of stillbirth at term has been reported 8 hours after a pregnant patient received temazepam and diphenhydramine. A cause and effect relationship has not yet been determined.				
370.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Temazepam 15mg Capsule	Temazepam USP 15mg	Hypnotics, Sedatives & Anxiolytic Therapeutic Code: 057	Temazepam is indicated for the short-term treatment of insomnia (generally 7 to 10 days). For patients with short-term insomnia, instructions in the prescription should indicate that temazepam should be used for short periods of time (7 to 10 days). The clinical trials performed in support of efficacy were 2 weeks in duration with the final formal assessment of sleep latency performed at the end of treatment.	**Contraindication:** Benzodiazepines may cause fetal harm when administered to a pregnant woman. An increased risk of congenital malformations associated with the use of diazepam and chlordiazepoxide during the first trimester of pregnancy has been suggested in several studies. Transplacental distribution has resulted in neonatal CNS depression following the ingestion of therapeutic doses of a benzodiazepine hypnotic during the last weeks of pregnancy. Reproduction studies in animals with temazepam were performed in rats and rabbits. In a perinatal-postnatal study in rats, oral doses of 60 mg/kg/day resulted in increasing nursling mortality. Teratology studies in rats demonstrated increased fetal resorptions at doses of 30 and 120 mg/kg in one study and increased occurrence of rudimentary ribs, which are considered skeletal variants, in a second	Temazepam 10 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						study at doses of 240 mg/kg or higher. In rabbits, occasional abnormalities such as exencephaly and fusion or asymmetry of ribs were reported without dose relationship. Although these abnormalities were not found in the concurrent control group, they have been reported to occur randomly in historical controls. At doses of 40 mg/kg or higher, there was an increased incidence of the 13th rib variant when compared to the incidence in concurrent and historical controls. Temazepam is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus. Patients should be instructed to discontinue the drug prior to becoming pregnant. The possibility that a woman of childbearing potential may be pregnant at the time of institution of therapy should be considered. **Side-effects:** The more common side effects of temazepam can include: drowsiness headache tiredness nervousness dizziness nausea **Warnings and Precautions:** Since the risk of the development of over sedation, dizziness, confusion, and/or ataxia increases substantially with larger doses of benzodiazepines in elderly and debilitated patients, 7.5 mg of temazepam is recommended as the initial dosage for such patients. Temazepam should be				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						administered with caution in severely depressed patients or those in whom there is any evidence of latent depression; it should be recognized that suicidal tendencies may be present and protective measures may be necessary. The usual precautions should be observed in patients with impaired renal or hepatic function and in patients with chronic pulmonary insufficiency. If temazepam is to be combined with other drugs having known hypnotic properties or CNS depressant effects, consideration should be given to potential additive effects. The possibility of a synergistic effect exists with the co-administration of temazepam l and diphenhydramine. One case of stillbirth at term has been reported 8 hours after a pregnant patient received temazepam and diphenhydramine. A cause and effect relationship has not yet been determined.				
371.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Temazepam USP 22.5 mg Capsule	Temazepam 22.5 mg	Hypnotics, Sedatives & Anxiolytic Therapeutic Code: 057	Temazepam is indicated for the short-term treatment of insomnia (generally 7 to 10 days). For patients with short-term insomnia, instructions in the prescription should indicate that temazepam should be used for short periods of time (7 to 10 days). The clinical trials performed in support of efficacy were 2 weeks in duration with the final formal assessment of sleep latency performed at the end of treatment.	**Contraindication:** Temazepam may cause fetal harm when administered to a pregnant woman. An increased risk of congenital malformations associated with the use of diazepam and chlordiazepoxide during the first trimester of pregnancy has been suggested in several studies. Transplacental distribution has resulted in neonatal CNS depression following the ingestion of therapeutic doses of a benzodiazepine hypnotic during the last weeks of pregnancy. Reproduction studies in animals with temazepam were performed in rats and rabbits. In a perinatal-postnatal study in rats, oral doses of 60 mg/kg/day resulted in increasing nursling mortality. Teratology studies in rats demonstrated increased fetal resorptions at doses of 30	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						and 120 mg/kg in one study and increased occurrence of rudimentary ribs, which are considered skeletal variants, in a second study at doses of 240 mg/kg or higher. In rabbits, occasional abnormalities such as exencephaly and fusion or asymmetry of ribs were reported without dose relationship. Although these abnormalities were not found in the concurrent control group, they have been reported to occur randomly in historical controls. At doses of 40 mg/kg or higher, there was an increased incidence of the 13th rib variant when compared to the incidence in concurrent and historical controls. Temazepam is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus. Patients should be instructed to discontinue the drug prior to becoming pregnant. The possibility that a woman of childbearing potential may be pregnant at the time of institution of therapy should be considered. **Side-effects:** The more common side effects of temazepam can include: drowsiness, headache, tiredness, nervousness, dizziness, nausea **Warning & Precaution:** Since the risk of the development of over sedation, dizziness, confusion, and/or ataxia increases substantially with larger doses of benzodiazepines in elderly and debilitated patients, 7.5 mg of temazepam is recommended as the initial dosage for such patients. Temazepam should be administered with caution in severely depressed patients or those in whom there is				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						any evidence of latent depression; it should be recognized that suicidal tendencies may be present and protective measures may be necessary. The usual precautions should be observed in patients with impaired renal or hepatic function and in patients with chronic pulmonary insufficiency. If temazepam is to be combined with other drugs having known hypnotic properties or CNS depressant effects, consideration should be given to potential additive effects. The possibility of a synergistic effect exists with the co-administration of temazepam l and diphenhydramine. One case of stillbirth at term has been reported 8 hours after a pregnant patient received temazepam and diphenhydramine. A cause and effect relationship has not yet been determined.				
372.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Temazepam USP 30 mg Capsule	Temazepam 30 mg	Hypnotics, Sedatives & Anxiolytic Therapeutic Code: 057	Temazepam is indicated for the short-term treatment of insomnia (generally 7 to 10 days). For patients with short-term insomnia, instructions in the prescription should indicate that temazepam should be used for short periods of time (7 to 10 days). The clinical trials performed in support of efficacy were 2 weeks in duration with the final formal assessment of sleep latency performed at the end of treatment.	**Contraindication:** Temazepam may cause fetal harm when administered to a pregnant woman. An increased risk of congenital malformations associated with the use of diazepam and chlordiazepoxide during the first trimester of pregnancy has been suggested in several studies. Transplacental distribution has resulted in neonatal CNS depression following the ingestion of therapeutic doses of a benzodiazepine hypnotic during the last weeks of pregnancy. Reproduction studies in animals with temazepam were performed in rats and rabbits. In a perinatal-postnatal study in rats, oral doses of 60 mg/kg/day resulted in increasing nursling mortality. Teratology studies in rats demonstrated increased fetal resorptions at doses of 30 and 120 mg/kg in one study and increased occurrence of rudimentary ribs, which are	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						considered skeletal variants, in a second study at doses of 240 mg/kg or higher. In rabbits, occasional abnormalities such as exencephaly and fusion or asymmetry of ribs were reported without dose relationship. Although these abnormalities were not found in the concurrent control group, they have been reported to occur randomly in historical controls. At doses of 40 mg/kg or higher, there was an increased incidence of the 13th rib variant when compared to the incidence in concurrent and historical controls. Temazepam is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus. Patients should be instructed to discontinue the drug prior to becoming pregnant. The possibility that a woman of childbearing potential may be pregnant at the time of institution of therapy should be considered. **Side-effects:** The more common side effects of temazepam can include: drowsiness, headache, tiredness, nervousness, dizziness, nausea **Warning & Precaution:** Since the risk of the development of over sedation, dizziness, confusion, and/or ataxia increases substantially with larger doses of benzodiazepines in elderly and debilitated patients, 7.5 mg of temazepam is recommended as the initial dosage for such patients. Temazepam should be administered with caution in severely depressed patients or those in whom there is any evidence of latent depression; it should be recognized that suicidal tendencies may				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						be present and protective measures may be necessary. The usual precautions should be observed in patients with impaired renal or hepatic function and in patients with chronic pulmonary insufficiency. If temazepam is to be combined with other drugs having known hypnotic properties or CNS depressant effects, consideration should be given to potential additive effects. The possibility of a synergistic effect exists with the co-administration of temazepam l and diphenhydramine. One case of stillbirth at term has been reported 8 hours after a pregnant patient received temazepam and diphenhydramine. A cause and effect relationship has not yet been determined.				
373.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Methylphenidate Hydrochloride USP 0.1gm/100ml (5mg/5ml) Oral Solution, 100 ml	Methylphenidate Hydrochloride USP 0.1gm/100ml (5mg/5ml)	Antipsychotic Therapeutic Code: 028	Attention Deficit Disorders: Narcolepsy Attention Deficit Disorders (previously known as Minimal Brain Dysfunction in Children). Other terms being used to describe the behavioral syndrome below include: Hyperkinetic Child Syndrome, Minimal Brain Damage, Minimal Cerebral Dysfunction, Minor Cerebral Dysfunction. Methylphenidate Oral Solution 5 mg/5 mL is indicated as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate-to-severe distractibility, short	**Contraindication:** Marked anxiety, tension, and agitation are contraindications to Methylphenidate Oral Solution 5 mg/5 mL, since the drug may aggravate these symptoms. Methylphenidate Oral Solution 5 mg/5 mL is contraindicated also in patients known to be hypersensitive to the drug, in patients with glaucoma, and in patients with motor tics or with a family history or diagnosis of Tourette's syndrome. Methylphenidate Oral Solution 5 mg/5 mL is contraindicated during treatment with monoamine oxidase inhibitors, and also within a minimum of 14 days following discontinuation of a monoamine oxidase inhibitor (hypertensive crises may result). **Side-effects:** Common side effects include: nervousness, nausea, trouble sleeping, decreased appetite, headache, dizziness, stomach ache, weight loss and fast heart beat.	Methylphenidate Hydrochloride 5mg, 10mg, 27mg Tablet, 18 mg Er Tablet; 20 mg, 30mg, 40mg Capsule	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					attention span, hyperactivity, emotional lability, and impulsivity. The diagnosis of this syndrome should not be made with finality when these symptoms are only of comparatively recent origin. Nonlocalizing (soft) neurological signs, learning disability, and abnormal EEG may or may not be present, and a diagnosis of central nervous system dysfunction may or may not be warranted. Special Diagnostic Considerations: Specific etiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use not only of medical but of special psychological, educational, and social resources. Characteristics commonly reported include: chronic history of short attention span, distractibility, emotional lability, impulsivity, and moderate-to-severe hyperactivity; minor neurological signs and abnormal EEG. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the child and not solely on the presence of one or more of these characteristics. Drug treatment is not indicated for all children with this syndrome. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and/or primary psychiatric disorders, including psychosis. Appropriate	Other serious side effects include: slowing of growth (height and weight) in children, seizures mainly in patients with a history of seizures, eyesight changes or blurred vision. **Warning & Precaution:** Patients with an element of agitation may react adversely; discontinue therapy if necessary. Periodic CBC, differential, and platelet counts are advised during prolonged therapy. Drug treatment is not indicated in all cases of this behavioral syndrome and should be considered only in light of the complete history and evaluation of the child. The decision to prescribe. Methylphenidate Oral Solution 5 mg/5 mL should depend on the physician's assessment of the chronicity and severity of the child's symptoms and their appropriateness for his/her age. Prescription should not depend solely on the presence of one or more of the behavioral characteristics. When these symptoms are associated with acute stress reactions, treatment with Methylphenidate Oral Solution 5 mg/5 mL is usually not indicated. Long-term effects of Methylphenidate Oral Solution 5 mg/5 mL in children have not been well established.				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					educational placement is essential and psychosocial intervention is generally necessary. When remedial measures alone are insufficient the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the child's symptoms.					
374.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Lecanemab-irmb (100mg/ml) INN/In-house 500mg/Vial, 5ml IV In‡jvection	Lecanemab-irmb (100mg/ml) INN/In-house 500mg/Vial, 5ml	Cholinergic Therapeutic Code: 037	Lecanemab is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment with Lecanemab should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with Lecanemab. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.	**Contraindication:** None. **Side-effects:** Most common adverse reactions (at approximately 10% and higher incidence compared to placebo): infusion-related reactions, headache, and ARIA-edema. **Warning & Precaution:** Amyloid Related Imaging Abnormalities (ARIA): Enhanced clinical vigilance for ARIA is recommended during the first 14 weeks of treatment with Lecanemab. Risk of ARIA, including symptomatic ARIA, was increased in apolipoprotein E ε4 homozygotes compared to heterozygotes and noncarriers. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI scanning if indicated. Infusion-Related Reactions: The infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy administered as clinically indicated. Consider pre-medication at subsequent dosing with antihistamines, non-steroidal anti-inflammatory drugs, or corticosteroids.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
375.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Lecanemab-irmb (100mg/ml) INN/In-house 200mg/Vial, 2ml IV In‡jvection	Lecanemab-irmb (100mg/ml) INN/In-house 200mg/Vial,	Cholinergic Therapeutic Code: 037	Lecanemab is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment with Lecanemab should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with Lecanemab. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.	**Contraindication:** None. **Side-effects:** Most common adverse reactions (at approximately 10% and higher incidence compared to placebo): infusion-related reactions, headache, and ARIA-edema. **Warning & Precaution:** Amyloid Related Imaging Abnormalities (ARIA): Enhanced clinical vigilance for ARIA is recommended during the first 14 weeks of treatment with Lecanemab. Risk of ARIA, including symptomatic ARIA, was increased in apolipoprotein E ε4 homozygotes compared to heterozygotes and noncarriers. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI scanning if indicated. Infusion-Related Reactions: The infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy administered as clinically indicated. Consider pre-medication at subsequent dosing with antihistamines, non-steroidal anti-inflammatory drugs, or corticosteroids.	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
376.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Tezepelumab-ekko (110mg/ml) INN/In-house 210mg/PFS, 1.91ml SC In‡jvection	Tezepelumab-ekko (110mg/ml) INN/In-house 210mg/PFS, 1.91ml	Drug Used in Bronchial Asthma Therapeutic Code: 044	Tezepelumab is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody (IgG2λ), indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.	**Contraindication:** Known hypersensitivity to tezepelumab-ekko or excipients **Side-effects:** No evaluated **Warning & Precaution:** 1. Hypersensitivity Reactions: Hypersensitivity reactions (e.g., rash, allergic con‡jvunctivitis) can occur after	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						administration of tezepelumab-ekko. Initiate appropriate treatment as clinically indicated in the event of a hypersensitivity reaction. 2. Risk Associated with Abrupt Reduction in Corticosteroid Dosage: Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with tezepelumab-ekko. Decrease corticosteroids gradually, if appropriate. 3. Parasitic (Helminth) Infection: Treat patients with pre-existing helminth infections before therapy with tezepelumab-ekko. If patients become infected while receiving tezepelumab-ekko and do not respond to antihelminth treatment, discontinue tezepelumab-ekko until the parasitic infection resolves. 4. Vaccination: Avoid use of live attenuated vaccines				
377.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Aprepitant 32mg/4.4ml (7.2 mg/ml) In‡jvectable emulsion	Aprepitant 32mg/4.4ml (7.2 mg/ml)	Antiemetic Therapeutic Code:018	Aprepitant is a substance P/neurokinin-1 (NK 1) receptor antagonist, indicated in adults, in combination with other antiemetic agents, for the prevention of: Acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin. Nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).	**Contraindication:** Aprepitant is contraindicated in patients: Who are hypersensitive to any component of the product. Hypersensitivity reactions including anaphylaxis have been reported. Taking pimozide. Inhibition of CYP3A4 by aprepitant could result in elevated plasma concentrations of pimozide, which is a CYP3A4 substrate, potentially causing serious or life-threatening reactions, such as QT prolongation, a known adverse reaction of pimozide. **Side-effects:** Most common adverse reactions with the 3-day oral aprepitant regimen in con‡jvunction with MEC (≥1% and greater than standard therapy) were: fatigue and eructation.	Aprepitant 40mg, 80mg, 125 mg Capsule	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Most common adverse reactions with the single-dose fosaprepitant regimen in con‡jvunction with HEC were generally similar to that seen in prior HEC studies with oral aprepitant. In addition, infusion site reactions (3%) occurred. Most common adverse reactions with single-dose aprepitant (≥2%) were: headache and fatigue. **Warning & Precaution:** Most common adverse reactions with the 3-day oral aprepitant regimen in con‡jvunction with MEC (≥1% and greater than standard therapy) were: fatigue and eructation. Most common adverse reactions with the single-dose fosaprepitant regimen in con‡jvunction with HEC were generally similar to that seen in prior HEC studies with oral aprepitant. In addition, infusion site reactions (3%) occurred. Most common adverse reactions with single-dose aprepitant (≥2%) were: headache and fatigue.				
378.	Navana Pharmaceuticals Limited	Vancomycin 125 mg Capsule	Vancomycin USP 125mg	Antibiotic Therapeutic Code: 023	Treatment of: *C. difficile*-associated diarrhea • Enterocolitis caused by *Staphylococcus aureus* (including methicillinresistant strains). Important Limitations: Orally administered it is not effective for other types of infections.	**Contraindications:** Hypersensitivity to vancomycin. **Side Effects:** The most common adverse reactions (≥ 10%) were nausea (17%), abdominal pain (15%) and hypokalemia (13%). **Warnings and precautions:** • It must be given orally for treatment of *C. difficile*-associated diarrhea and staphylococcal enterocolitis. Orally administered vancomycin hydrochloride is not effective for treatment of other types of infections. • Clinically significant serum concentrations have been reported in some patients who have taken multiple oral doses	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						of vancomycin hydrochloride for *C. difficile*-associated diarrhea. Monitoring of serum concentrations may be appropriate in some instances. • Nephrotoxicity has occurred following oral vancomycin hydrochloride therapy and can occur either during or after completion of therapy. The risk is increased in geriatric patients. Monitor renal function. • Ototoxicity has occurred in patients receiving vancomycin hydrochloride. Assessment of auditory function may be appropriate in some instances. • Prescribing it in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug resistant bacteria.				
379.	NIPRO JMI Pharma Ltd, Rajandrapur, Chaddagram, Cumilla	Empagliflozin 5 mg + Metformin Hydrochloride 850mg Tablet	Empagliflozin INN 5 mg + Metformin Hydrochloride BP 850 mg	Antidiabetic Therapeutic Code: 015	This combination is indicated for the treatment of adults with type 2 diabetes mellitus as an adjunct to diet and exercise: • in patients insufficiently controlled on their maximally tolerated dose of metformin alone. • in combination with other medicinal products for the treatment of diabetes, in patients insufficiently controlled with metformin and these medicinal products. • in patients already being treated with the combination of empagliflozin and metformin as separate tablets.	**Contraindications:** Severe renal impairment (eGFR below 30 mL/min/1.73 m^2), end-stage renal disease, or on dialysis. Metabolic acidosis, including diabetic ketoacidosis. Hypersensitivity to empagliflozin, linagliptin, metformin, or any of the excipients in this product. **Side Effects:** The most commonly reported side effects in clinical trials were hypoglycaemia in combination with insulin and/or sulphonylurea, and gastrointestinal symptoms (nausea, vomiting, diarrhoea, abdominal pain and loss of appetite). No additional side effects were identified in clinical trials with empagliflozin as add-on to metformin compared to the side effects of the single components. **Warnings And Precautions:** **Lactic acidosis:** Lactic acidosis, a very rare but serious metabolic complication, most often occurs at acute worsening of renal function or cardiorespiratory illness or sepsis. Metformin accumulation occurs at the acute	Empagliflozin 5 mg + Metformin Hydrochloride 500 mg Tablet	BNF-83 Page:774 TGA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						worsening of renal function and increases the risk of lactic acidosis. Patients and/or caregivers should be informed of the risk of lactic acidosis. **Diabetic ketoacidosis:** Rare cases of diabetic ketoacidosis (DKA), including life-threatening and fatal cases, have been reported in patients treated with SGLT2 inhibitors, including empagliflozin. In patients where DKA is suspected or diagnosed, treatment with empagliflozin should be discontinued immediately. It should not be used for treatment of patients with type 1 diabetes. Data from a clinical trial program in patients with type 1 diabetes showed increased DKA occurrence with common frequency in patients treated with empagliflozin 10 mg and 25 mg as an adjunct to insulin compared to placebo. **Administration of iodinated contrast agent:** Intravascular administration of iodinated contrasaat agents may lead to contrast induced nephropathy, resulting in metformin accumulation and an increased risk of lactic acidosis. Metformin should be discontinued prior to or at the time of the imaging procedure and not restarted until at least 48 hours after, provided that renal function has been re-evaluated and found to be stable. **Renal impairment:** Due to the mechanism of action, decreased renal function will result in reduced glycaemic efficacy of empagliflozin. **Cardiac function:** Patients with heart failure are more at risk of hypoxia and renal insufficiency. In patients with stable chronic heart failure, it may be used with a regular monitoring of cardiac and renal function.				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Surgery: Metformin must be discontinued at the time of surgery under general, spinal or epidural anaesthesia. Therapy may be restarted no earlier than 48 hours following surgery or resumption of oral nutrition and provided that renal function has been re-evaluated and found to be stable. **Risk for volume depletion:** Based on the mode of action of SGLT2 inhibitors, osmotic diuresis accompanying therapeutic glucosuria may lead to a modest decrease in blood pressure. Therefore, caution should be exercised in patients for whom a empagliflozin-induced drop in blood pressure could pose a risk, such as patients with known cardiovascular disease, patients on anti-hypertensive therapy with a history of hypotension or patients aged 75 years and older. **Elderly:** The effect of empagliflozin on urinary glucose excretion is associated with osmotic diuresis, which could affect the hydration status. Patients aged 75 years and older may be at an increased risk of volume depletion. Therefore, special attention should be given to their volume intake in case of co-administered medicinal products which may lead to volume depletion (e.g. diuretics, ACE inhibitors). **Urinary tract infections:** Post-marketing cases of complicated urinary tract infections including pyelonephritis and urosepsis have been reported in patients treated with empagliflozin. Temporary interruption of treatment should be considered in patients with complicated urinary tract infections. **Necrotising fasciitis of the perineum (Fournier's gangrene)**: Post-marketing cases of necrotising fasciitis of the perineum,				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						(also known as Fournier's gangrene), have been reported in female and male patients taking SGLT2 inhibitors. This is a rare but serious and potentially life-threatening event that requires urgent surgical intervention and antibiotic treatment. **Lower limb amputations:** An increase in cases of lower limb amputation (primarily of the toe) has been observed in long-term clinical studies with another SGLT2 inhibitor. It is unknown whether this constitutes a class effect. Like for all diabetic patients it is important to counsel patients on routine preventative foot care. **Hepatic in‡jvury:** Cases of hepatic in‡jvury have been reported with empagliflozin in clinical trials. **Cardiac failure:** Experience in New York Heart Association (NYHA) class I-II is limited, and there is no experience in clinical studies with empagliflozin in NYHA class III-IV. **Elevated haematocrit:** Haematocrit increase was observed with empagliflozin treatment.				
380.	NIPRO JMI Pharma Ltd, Rajandrapur, Chaddagram, Cumilla	Empagliflozin 12.5mg + Metformin Hydrochloride 850mg Tablet	Empagliflozin INN 12.5 mg + Metformin Hydrochloride BP 850 mg	Antidiabetic Therapeutic Code: 015	This combination is indicated for the treatment of adults with type 2 diabetes mellitus as an adjunct to diet and exercise: • in patients insufficiently controlled on their maximally tolerated dose of metformin alone. • in combination with other medicinal products for the treatment of diabetes, in patients insufficiently controlled with metformin and these medicinal products. • in patients already being treated with the combination of	**Contraindications:** Severe renal impairment (eGFR below 30 mL/min/1.73 m^2), end-stage renal disease, or on dialysis. Metabolic acidosis, including diabetic ketoacidosis. Hypersensitivity to empagliflozin, linagliptin, metformin, or any of the excipients in this product. **Side Effects:** The most commonly reported side effects in clinical trials were hypoglycaemia in combination with insulin and/or sulphonylurea, and gastrointestinal symptoms (nausea, vomiting, diarrhoea, abdominal pain and loss of appetite). No additional side effects were identified in	Empagliflozin 5 mg + Metformin Hydrochloride 500 mg Tablet	BNF-83 Page:774, TGA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					empagliflozin and metformin as separate tablets.	clinical trials with empagliflozin as add-on to metformin compared to the side effects of the single components. **Warnings And Precautions:** **Lactic acidosis:** Lactic acidosis, a very rare but serious metabolic complication, most often occurs at acute worsening of renal function or cardiorespiratory illness or sepsis. Metformin accumulation occurs at acute worsening of renal function and increases the risk of lactic acidosis. Patients and/or care-givers should be informed of the risk of lactic acidosis. **Diabetic ketoacidosis:** Rare cases of diabetic ketoacidosis (DKA), including life-threatening and fatal cases, have been reported in patients treated with SGLT2 inhibitors, including empagliflozin. In patients where DKA is suspected or diagnosed, treatment with empagliflozin should be discontinued immediately. It should not be used for treatment of patients with type 1 diabetes. Data from a clinical trial program in patients with type 1 diabetes showed increased DKA occurrence with common frequency in patients treated with empagliflozin 10 mg and 25 mg as an adjunct to insulin compared to placebo. **Administration of iodinated contrast agent:** Intravascular administration of iodinated contrasaat agents may lead to contrast induced nephropathy, resulting in metformin accumulation and an increased risk of lactic acidosis. Metformin should be discontinued prior to or at the time of the imaging procedure and not restarted until at least 48 hours after, provided that renal function has been re-evaluated and found to be stable.				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Renal impairment: Due to the mechanism of action, decreased renal function will result in reduced glycaemic efficacy of empagliflozin. **Cardiac function:** Patients with heart failure are more at risk of hypoxia and renal insufficiency. In patients with stable chronic heart failure, it may be used with a regular monitoring of cardiac and renal function. **Surgery:** Metformin must be discontinued at the time of surgery under general, spinal or epidural anaesthesia. Therapy may be restarted no earlier than 48 hours following surgery or resumption of oral nutrition and provided that renal function has been re-evaluated and found to be stable. **Risk for volume depletion:** Based on the mode of action of SGLT2 inhibitors, osmotic diuresis accompanying therapeutic glucosuria may lead to a modest decrease in blood pressure. Therefore, caution should be exercised in patients for whom a empagliflozin-induced drop in blood pressure could pose a risk, such as patients with known cardiovascular disease, patients on anti-hypertensive therapy with a history of hypotension or patients aged 75 years and older. **Elderly:** The effect of empagliflozin on urinary glucose excretion is associated with osmotic diuresis, which could affect the hydration status. Patients aged 75 years and older may be at an increased risk of volume depletion. Therefore, special attention should be given to their volume intake in case of co-administered medicinal products which may lead to volume depletion (e.g. diuretics, ACE inhibitors). **Urinary tract infections:** Post-marketing				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						cases of complicated urinary tract infections including pyelonephritis and urosepsis have been reported in patients treated with empagliflozin. Temporary interruption of treatment should be considered in patients with complicated urinary tract infections. **Necrotising fasciitis of the perineum (Fournier's gangrene)**: Post-marketing cases of necrotising fasciitis of the perineum, (also known as Fournier's gangrene), have been reported in female and male patients taking SGLT2 inhibitors. This is a rare but serious and potentially life-threatening event that requires urgent surgical intervention and antibiotic treatment. **Lower limb amputations:** An increase in cases of lower limb amputation (primarily of the toe) has been observed in long-term clinical studies with another SGLT2 inhibitor. It is unknown whether this constitutes a class effect. Like for all diabetic patients it is important to counsel patients on routine preventative foot care. **Hepatic in‡jvury:** Cases of hepatic in‡jvury have been reported with empagliflozin in clinical trials. **Cardiac failure:** Experience in New York Heart Association (NYHA) class I-II is limited, and there is no experience in clinical studies with empagliflozin in NYHA class III-IV. **Elevated haematocrit:** Haematocrit increase was observed with empagliflozin treatment.				
381.	Renata Limited, Mirpur	Misoprostol 25mcg Tablet	Misoprostol Dispersion USP (Misoprostol with Hypromellose 1:100) 2.5 mg eq. to Misoprostol 25mcg	Drug Used Obstratics Therapeutic	Misoprostol Dispersion is indicated for induction of labour.	**Contraindication:** - When there is hypersensitivity to the active substance or to any of the excipients listed in section 6.1 - When labour has started	Misoprostol 100mcg, 200mcg, 600mcg Tablet	UKMHRA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
				Code: 049		- When there is suspicion or evidence of foetal compromise prior to induction (e.g., failed non-stress or stress test, meconium staining or diagnosis or history of non-reassuring foetal status) - When oxytocic drugs and/or other labour induction agents are being given (see section 4.2, 4.4, 4.5 and 5.2) - When there is suspicion or evidence of uterine scar resulting from previous uterine or cervical surgery, e.g. caesarean delivery - When there is uterine abnormality (e.g. bicornuate uterus) preventing vaginal delivery - When there is placenta praevia or unexplained vaginal bleeding after 24 weeks gestation with this pregnancy - When there is foetal malpresentation, contraindicating vaginal delivery - In patients with kidney failure (GFR <15 ml/min/1.73 m). **Side-effects:** Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may occur when using Misoprostol. Very Common: may affect more than 1 in 10 people – Nausea - Vomiting - Meconium stain (early faeces (stool) passed by the unborn baby into the amniotic fluid) - Postpartum bleeding2) (loss of over 500 ml blood after delivery) 1) Reported as very common for Misoprostol 50 µg every 4 hours. 2) Reported as very common for Misoprostol 25 µg every 2 hours. 4				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Common: may affect up to 1 in 10 people - Apgar score low*1) (test performed at the baby at 1 and 5 minutes after birth, where the score of the test determines how well the baby is doing after being born) - Foetal heart rate abnormal*1) - Uterine hyperstimulation2) (uterine contractions are too strong, too frequent, or last too long) - Diarrhoea - Nausea3) - Vomiting3) - Postpartum bleeding1) (loss of over 500 ml blood after delivery) - Chills - Elevation of body temperature * Side effect in the baby 1) Reported as common for Misoprostol 50 µg every 4 hours. 2) Uterine hyperstimulation was reported both with and without foetal heart rate changes. 3) Reported as common for Misoprostol 25 µg every 2 hours. Uncommon: may affect up to 1 in 100 people - Apgar score low*1) (test performed at the baby at 1 and 5 minutes after birth, where the score of the test determines how well the baby is doing after being born) - Foetal heart rate abnormal*1) * Side effect in the baby 1) Reported as uncommon for Misoprostol 25 µg every 2 hours. Not known: Frequency cannot be estimated from the available data - Dizziness - Convulsion neonatal* (seizures in the newborn baby) - Neonatal asphyxia* (lack of oxygen to the baby's brain and organs during the birth) - Cyanosis neonatal* (also called "blue baby syndrome" characterised by blue coloration of the skin and mucous membranes in the newborn baby) - Rash pruritic (itchy rash) - Foetal acidosis* (high acid level in the unborn baby's blood) - Premature separation of placenta (separation of the placenta from the wall of the uterus before birth) - Uterine (uterus) rupture * Side effect in the baby				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Warnings and precautions: Talk to your midwife, doctor or nurse before taking Misoprostol. Misoprostol must only be given by a trained professional in a hospital where facilities for monitoring you and your baby are available. Your cervix will be assessed carefully before you take Misoprostol. Misoprostol can cause excessive stimulation of the womb. In case the womb contractions are prolonged or too strong or your doctor or nurse is concerned for you and your baby, you will not be given more tablets and your midwife or doctor will decide if you should be given medicines to reduce the strength or to slow down the frequency of your contractions. The effect of Misoprostol has not been studied in women with severe pre-eclampsia (a condition where pregnant women suffer from high blood pressure, protein in the urine and possibly other complications). Infections of the membranes surrounding the baby (chorioamnionitis) may necessitate fast delivery. The physician will take the necessary decisions regarding treatment with antibiotics, inducing labour or caesarean section. There are no or limited experience with the use of Misoprostol in women whose membranes have been ruptured for more than 48 hours before the use of Misoprostol. If your doctor finds that you need treatment with oxytocin (medicine used to facilitate birth), this will be carefully considered, as the treatment with oxytocin may affect the way Misoprostol works. It is recommended to wait 4 hours after the last dose of Misoprostol				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						before giving oxytocin (see "Do not take Misoprostol" above, and "Other medicines and Misoprostol" and "How to take Misoprostol" below). There is no experience with the use of Misoprostol to start the birth process in women who are pregnant with more than one baby and there is no experience with the use of Misoprostol in women who have had 5 or more previous babies delivered vaginally. There is limited experience with the use of Misoprostol to start the birth process in women less than 37 weeks pregnant (see "Pregnancy, breast-feeding and fertility" below). You should only take Misoprostol if your midwife or doctor judge that you have a medical need for help to start the birth process. There is no or limited information with the use of Misoprostol in pregnant women with a Bishop Score >6 (Bishop Score is the most commonly used method to rate the readiness of the cervix). An increased risk of formation of blood clots in the small blood vessels throughout the body (disseminated intravascular coagulation) after delivery has been described in patients whose labour has been induced by any method. Dose adjustments may be needed in pregnant women with reduced kidney or liver function (see "How to take Misoprostol below). Misoprostol contains sodium This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
382.	Renata ltd. Mirpur	Bisoprolol Fumerate 7.5 mg FC Tablet	Bisoprolol Fumerate 7.5 mg FC Tablet	Antihypertensive Therapeutic Code: 022	Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides.	**Contraindication:** Bisoprolol is contraindicated in chronic heart failure patients with: - acute heart failure or during episodes of heart failure decompensation requiring i.v. inotropic therapy - cardiogenic shock - second or third degree AV block (without a pacemaker) - sick sinus syndrome - sinoatrial block - bradycardia with less than 60 beats/min before the start of therapy - hypotension (systolic blood pressure less than 100 mm Hg) - severe bronchial asthma or severe chronic obstructive pulmonary disease - late stages of peripheral arterial occlusive disease and Raynaud's syndrome **Side-effects:** **Warnings and precautions**: The treatment of stable chronic heart failure with bisoprolol has to be initiated with a special titration phase. Especially in patients with ischaemic heart disease the cessation of therapy with bisoprolol must not be done abruptly unless clearly indicated, because this may lead to transitional worsening of heart condition. The initiation and cessation of treatment with bisoprolol necessitates regular monitoring. There is no therapeutic experience of bisoprolol treatment of heart failure in patients with the following diseases and conditions: • insulin dependent diabetes mellitus (type I) • severely impaired renal function • severely impaired hepatic function • restrictive cardiomyopathy	2.5mg, 5mg, 10mg Tablet	UKMHRA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						• congenital heart disease • haemodynamically significant organic valvular disease • myocardial infarction within 3 months Bisoprolol must be used with caution in: - bronchospasm (bronchial asthma, obstructive airways diseases) - diabetes mellitus with large fluctuations in blood glucose values; symptoms of hypoglycaemia can be masked - strict fasting - ongoing desensitisation therapy - first degree AV block - Prinzmetal's angina - peripheral arterial occlusive disease (intensification of complaints might happen especially during the start of therapy) - general anaesthesia				
383.	Renata ltd. Mirpur Ziska Pharmaceticals ltd.	Estradiol Valerate 2mg Film Coated Tablet	Estradiol Valerate USP 2mg	Hormone Therapeutic Code: 056	It is indicated for- Constipation of any etiology, relief from prolonged & recurrent constipation, bowel clearance before surgery, childbirth or radio-logical investigations.	**Contraindication:** It is contraindicated in patient withIleus or intestinal obstruction Severe painful and/or feverish acute abdominal conditions (e.g.appendicitis) potentially associated with nausea and vomiting Acute inflammatory bowel diseases. Severe dehydration. Known hypersensitivity to sodium picosulfate or any other component of the product editary conditions that may be incompatible with an excipient of the product. **Side-effects:** **Warnings and precautions**: Talk to your doctor or pharmacist before taking Progynova before you start the treatment, as these may return or become worse during treatment with Progynova [If so, you should see your doctor more	1mg, 3mg Tablet	UKMHRA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						often for check-ups:] fibroids inside your womb] growth of womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia)] increased risk of developing blood clots (see "Blood clots in a vein (thrombosis)")] increased risk of getting an oestrogen-sensitive cancer (such as mother, sister or grandmother who has had breast cancer) [high blood pressure] a liver disorder, such as a benign liver tumour] diabetes [gallstones] migraine or severe headaches [a disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE)] epilepsy [asthma				
384.	Renata ltd. Rajendrapur	Valproic Acid 250mg Soft Gel Capsule	Valproic Acid BP 250mg	Drug used in Epilepsy Therapeutic Code: 046	Valproic Acid is an anti-epileptic drug indicated for: • Monotherapy and adjunctive therapy of complex partial seizures; sole and adjunctive therapy of simple and complex absence seizures; adjunctive therapy in patients with multiple seizure types that include absence seizures.	**Contraindications:** • Hepatic disease or significant hepatic dysfunction • Known mitochondrial disorders caused by mutations in mitochondrial DNA polymerase γ (POLG) • Suspected POLG-related disorder in children under two years of age • Known hypersensitivity to the drug • Urea cycle disorders **Side-effects:** • Most common adverse reactions (reported >5%) are abdominal pain alopecia, amblyopia/blurred vision, amnesia, anorexia,	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						asthenia, ataxia, bronchitis, constipation, depression, diarrhea, diplopia, dizziness, dyspepsia, dyspnea, ecchymosis, emotional lability, fever, flu syndrome, headache, increased appetite, infection, insomnia, nausea, nervousness, nystagmus, peripheral edema, pharyngitis, rhinitis, somnolence, thinking abnormal, thrombocytopenia, tinnitus, tremor, vomiting, weight gain, weight loss. • The safety and tolerability of valproate in pediatric patients were shown to be comparable to those in adults. **Precaution and Warnings:** • Hepatotoxicity; evaluate high risk populations and monitor serum liver tests • Birth defects and decreased IQ following in utero exposure; only use to treat pregnant women with epilepsy if other medications are unacceptable; should not be administered to a woman of childbearing potential unless essential • Pancreatitis; Depakene should ordinarily be discontinued • Suicidal behavior or ideation; Antiepileptic drugs, including Depakene, increase the risk of suicidal thoughts or behavior • Bleeding and other hematopoietic disorders; monitor platelet counts and coagulation tests • Hyperammonemia and hyperammonemic encephalopathy; measure ammonia level if unexplained lethargy and vomiting or changes in mental status, and also with concomitant topiramate use; consider discontinuation of valproate therapy • Hypothermia; Hypothermia has been reported during valproate therapy with or				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						without associated hyperammonemia. This adverse reaction can also occur in patients using concomitant topiramate • Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan hypersensitivity reaction; discontinue Depakene • Somnolence in the elderly can occur. Depakene dosage should be increased slowly and with regular monitoring for fluid and nutritional intake				
385.	Renata Ltd., Mirpur	Methylphenidate 50mg MR Capsule	Methylphenidate USP 50mg MR	Antidepressants Therapeutic Code: 014	This medicinal product is indicated as part of a comprehensive treatment programme for attention-deficit/hyperactivity disorder (ADHD) in children aged 6 years of age and over when remedial measures alone prove insufficient.	**Contraindication:** Hypersensitivity to the active substance or to any of the excipients listed in section. • Glaucoma • Phaeochromocytoma • During treatment with non-selective, irreversible monoamine oxidase (MAO) inhibitors, or within a minimum of 14 days following discontinuing those drugs, due to risk of hypertensive crises. • Hyperthyroidism or thyrotoxicosis • Diagnosis or history of severe depression, anorexia nervosa/anorexic disorders, suicidal tendencies, psychotic symptoms, severe mood disorders, mania, schizophrenia, psychopathic/borderline personality disorder. • Diagnosis or history of severe and episodic (Type I) Bipolar (affective) disorder (that is not well-controlled). • Pre-existing cardiovascular disorders including severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias and channelopathies (disorders caused by the dysfunction of ion channels). • Pre-existing cerebrovascular disorders,	5mg, 10mg Tablet 18mg, 27mg ER Tablet 30mg, 40mg Tablet	UKMHRA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						cerebral aneurysm, vascular abnormalities including vasculitis or stroke. **Side-effects:** The most common side effects are nasopharyngitis, anorexia, decreased appetite, moderately reduced weight and height gain during prolonged use in children* etc. **Warnings and precautions**: The safety and efficacy of long-term use of methylphenidate has not been systematically evaluated in controlled trials. Methylphenidate treatment should not and need not be indefinite. Methylphenidate treatment is usually discontinued during or after puberty. Patients on long-term therapy (i.e., over 12 months) must have careful ongoing monitoring according to the guidance in section 4.2 and 4.4 for cardiovascular status, growth, appetite, development of de novo or worsening of pre-existing psychiatric disorders. Psychiatric disorders to monitor for are described below, and include (but are not limited to) motor or vocal tics, aggressive or hostile behaviour, agitation, anxiety, depression, psychosis, mania, delusions, irritability, lack of spontaneity, withdrawal and excessive perseveration. The physician who elects to use methylphenidate for extended periods (over 12 months) in children and adolescents with ADHD should periodically re-evaluate the long-term usefulness of the drug for the individual patient with trial periods off medication to assess the patient's functioning without pharmacotherapy. It is				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						recommended that methylphenidate is de-challenged at least once yearly to assess the child's condition (preferably during times of school holidays). Improvement may be sustained when the drug is either temporarily or permanently discontinued.				
386.	Renata Ltd., Mirpur	Methylphenidate 60mg MR Capsule	Methylphenidate 60mg MR	Antidepressants Therapeutic Code: 014	This medicinal product is indicated as part of a comprehensive treatment programme for attention-deficit/hyperactivity disorder (ADHD) in children aged 6 years of age and over when remedial measures alone prove insufficient.	**Contraindication:** Hypersensitivity to the active substance or to any of the excipients listed in section. • Glaucoma • Phaeochromocytoma • During treatment with non-selective, irreversible monoamine oxidase (MAO) inhibitors, or within a minimum of 14 days following discontinuing those drugs, due to risk of hypertensive crises. • Hyperthyroidism or thyrotoxicosis • Diagnosis or history of severe depression, anorexia nervosa/anorexic disorders, suicidal tendencies, psychotic symptoms, severe mood disorders, mania, schizophrenia, psychopathic/borderline personality disorder. • Diagnosis or history of severe and episodic (Type I) Bipolar (affective) disorder (that is not well-controlled). • Pre-existing cardiovascular disorders including severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias and channelopathies (disorders caused by the dysfunction of ion channels). • Pre-existing cerebrovascular disorders, cerebral aneurysm, vascular abnormalities including vasculitis or stroke. **Side-effects:** The most common side effects are nasopharyngitis, anorexia, decreased	5mg, 10mg Tablet 18mg, 27mg ER Tablet 30mg, 40mg Tablet	UKMHRA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						appetite, moderately reduced weight and height gain during prolonged use in children* etc. **Warnings and precautions**: The safety and efficacy of long-term use of methylphenidate has not been systematically evaluated in controlled trials. Methylphenidate treatment should not and need not be indefinite. Methylphenidate treatment is usually discontinued during or after puberty. Patients on long-term therapy (i.e., over 12 months) must have careful ongoing monitoring according to the guidance in section 4.2 and 4.4 for cardiovascular status, growth, appetite, development of de novo or worsening of pre-existing psychiatric disorders. Psychiatric disorders to monitor for are described below, and include (but are not limited to) motor or vocal tics, aggressive or hostile behaviour, agitation, anxiety, depression, psychosis, mania, delusions, irritability, lack of spontaneity, withdrawal and excessive perseveration. The physician who elects to use methylphenidate for extended periods (over 12 months) in children and adolescents with ADHD should periodically re-evaluate the long-term usefulness of the drug for the individual patient with trial periods off medication to assess the patient's functioning without pharmacotherapy. It is recommended that methylphenidate is de-challenged at least once yearly to assess the child's condition (preferably during times of school holidays). Improvement may be				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						sustained when the drug is either temporarily or permanently discontinued.				
387.	Renata Ltd., Mirpur	Tacrolimus 0.75mg XR Tablet	Tacrolimus USP 0.75mg	Skin and Mucous Membrane Preparations Antacids Therapeutic Code: 071	Tacrolimus is a calcineurin-inhibitor immunosuppressant indicated for: • The prophylaxis of organ rejection in de novo kidney transplant patients in combination with other immunosuppressant's • The prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations in combination with other immunosuppressants	**Contraindication:** Known hypersensitivity to tacrolimus. **Side-effects:** De novo kidney transplant patients: Most common adverse reactions (incidence ≥15%) include: diarrhea, anemia, urinary tract infection, hypertension, tremor, constipation, diabetes mellitus, peripheral edema, hyperkalemia and headache. • Conversion of kidney transplant patients from immediate-release to extended-release tacrolimus: Most common adverse reactions (incidence ≥10%) include: diarrhea and blood creatinine increased. **Precautions and Warnings:** • Not Interchangeable with Other Tacrolimus Products: Instruct patients or caregivers to recognize appearance of TACROLIMUS tablets. • New Onset Diabetes after Transplant: Monitor blood glucose. • Nephrotoxicity (acute and/or chronic): May occur due to TACROLIMUS, drug interactions or concomitant nephrotoxic drugs. Monitor renal function; consider dosage reduction. • Neurotoxicity: Including risk of posterior reversible encephalopathy syndrome (PRES); monitor for neurologic abnormalities; reduce dosage or discontinue TACROLIMUS. • Hyperkalemia: Risk may be increased with	0.5mg, 1mg, 5mg Capsule 1mg Tablet 2mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						other agents associated with hyperkalemia; monitor serum potassium levels. • Hypertension: May require antihypertensive therapy; monitor relevant drug interactions. • QT Prolongation: Consider obtaining electrocardiograms and monitoring electrolytes in patients at high risk. • Immunizations: Avoid live vaccines. • Pure Red Cell Aplasia: Consider discontinuation.				
388.	Renata Ltd., Mirpur	Tacrolimus 4mg XR Tablet	Tacrolimus 4 mg	Skin and Mucous Membrane Preparations Antacids Therapeutic Code: 071	Tacrolimus is a calcineurin-inhibitor immunosuppressant indicated for: • The prophylaxis of organ rejection in de novo kidney transplant patients in combination with other immunosuppressant's • The prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations in combination with other immunosuppressants	**Contraindication:** Known hypersensitivity to tacrolimus. **Side-effects:** De novo kidney transplant patients: Most common adverse reactions (incidence ≥15%) include: diarrhea, anemia, urinary tract infection, hypertension, tremor, constipation, diabetes mellitus, peripheral edema, hyperkalemia and headache. • Conversion of kidney transplant patients from immediate-release to extended-release tacrolimus: Most common adverse reactions (incidence ≥10%) include: diarrhea and blood creatinine increased. **Precautions and Warnings:** • Not Interchangeable with Other Tacrolimus Products: Instruct patients or caregivers to recognize appearance of TACROLIMUS tablets. • New Onset Diabetes after Transplant: Monitor blood glucose. • Nephrotoxicity (acute and/or chronic): May occur due to TACROLIMUS, drug interactions or concomitant nephrotoxic drugs. Monitor renal function; consider dosage reduction. • Neurotoxicity: Including risk of posterior	0.5mg, 1mg, 5mg Capsule 1mg Tablet 2mg Tablet	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						reversible encephalopathy syndrome (PRES); monitor for neurologic abnormalities; reduce dosage or discontinue TACROLIMUS. • Hyperkalemia: Risk may be increased with other agents associated with hyperkalemia; monitor serum potassium levels. • Hypertension: May require antihypertensive therapy; monitor relevant drug interactions. • QT Prolongation: Consider obtaining electrocardiograms and monitoring electrolytes in patients at high risk. • Immunizations: Avoid live vaccines. • Pure Red Cell Aplasia: Consider discontinuation.				
389.	Beacon Pharmaceuticals Limited, Kathali, Bhaluka, Mymensingh	Roflumilast 250mcg tablet.	Roflumilast INN 250mcg	Druq used in Bronchial Asthma Therapeutic Code: 044	Roflumilast is indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. This medication is not a bronchodilator, and it is not indicated for the treatment of acute bronchospasm	Contraindication: Roflumilast is contraindicated in patients with moderate to severe hepatic disease **Side-effects:** Diarrhea, Weight loss, Nausea (4.7%), Headache (4.4%), Back pain (3.2%), Insomnia (2.4%)	500mcg Tablet	BNF-81 Page-287	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
390.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Ertugliflozin USP 5 mg + Sitagliptin USP 100 mg Tablet	Ertugliflozin USP 5 mg + Sitagliptin USP 100 mg	Antidiabetic Therapeutic Code: 015	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes	**Contra-Indications:** Severe renal impairment, end stage renal disease, or dialysis. **Side-effects:** Female genital mycotic infections, upper respiratory tract infection, nasopharyngitis and headache. In the add-on to sulfonylurea and add-on to insulin studies, hypoglycemia was also more commonly reported in patients treated with sitagliptin compared to placebo. **Warning & Precautions:** Pancreatitis, Hypotension, Ketoacidosis,	NEW	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Acute Kidney In‡jvury and Impairment in Renal Function				
391.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Ertugliflozin USP 15 mg + Sitagliptin USP 100 mg Tablet	Ertugliflozin USP 15 mg + Sitagliptin USP 100 mg	Antidiabetic Therapeutic Code: 015	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes	**Contra-Indications:** Severe renal impairment, end stage renal disease, or dialysis. **Side-effects:** Female genital mycotic infections, upper respiratory tract infection, nasopharyngitis and headache. In the add-on to sulfonylurea and add-on to insulin studies, hypoglycemia was also more commonly reported in patients treated with sitagliptin compared to placebo. **Warning & Precautions:** Pancreatitis, Hypotension, Ketoacidosis, Acute Kidney In‡jvury and Impairment in Renal Function	NEW	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
392.	The IBN SINA Pharmaceutical Industries Ltd.	Balsalazide Disodium 750 mg Capsule	Balsalazide Disodium USP 750 mg Capsule	Nonsteroidal Antiinflamatory Therapeutic Code: 064	Balsalazide is an aminosalicylate indicated for the treatment of mildly to moderately active ulcerative colitis in patients 5 years of age and older.	**Contraindication:** Known or suspected hypersensitivity to salicylates, aminosalicylates, or any of the components of Balsalazide capsules or Balsalazide metabolites. **Side effect:** Most common adverse reactions (≥3%) are: headache, abdominal pain, diarrhea, nausea, vomiting, respiratory infection, and arthralgia. Adverse reactions in pediatric patients were similar. **Warnings & Precautions: Renal Impairment:** Assess renal function at the beginning of treatment and periodically during treatment. Evaluate the risks and benefits in patients with known renal impairment or taking nephrotoxic drugs; monitor renal function. • **Mesalamine-Induced Acute Intolerance Syndrome:**	New	USFDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Symptoms may be difficult to distinguish from an exacerbation of ulcerative colitis; monitor for worsening symptoms; discontinue treatment, if acute intolerance syndrome is suspected. • **Hypersensitivity Reactions, including Myocarditis and Pericarditis:** Evaluate patients immediately and discontinue if a hypersensitivity reaction is suspected • **Hepatic Failure:** Evaluate the risks and benefits in patients with known liver impairment • **Upper Gastrointestinal Tract Obstruction:** Avoid in patients with pyloric stenosis or other organic or functional obstruction • **Photosensitivity:** Advise patients with pre-existing skin conditions to avoid sun exposure, wear protective clothing, and use a broad-spectrum sunscreen when outdoors • **Nephrolithiasis:** Stones containing mesalamine, the active moiety in Balsalazide, are undetectable by standard radiography or computed tomography (CT). Ensure adequate fluid intake during treatment with Balsalazide • **Interference with Laboratory Tests:** Use of mesalamine may lead to spuriously elevated test results when measuring urinary normetanephrine by liquid chromatography with electrochemical detection.				
393.	UniMed UniHealth Pharmaceuticals Ltd.	Paricalcitol 0.0005gm/100ml Solution for IV In‡jvection	Paricalcitol USP 0.0005gm/100ml	Other Classification Therapeutic Code: 075	Prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease.	**Side effects:** Common or very common Electrolyte imbalance. hypoparathyroidism. taste altered. Uncommon Asthenia. diarrhea. dizziness. dry mouth. malaise. muscle complaints. pain.	New	BNF 84 (Page-1182-83)	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
394.	UniMed UniHealth Pharmaceuticals Ltd.	Phenazone 4.00gm + Lidocaine hydrochloride 1.00gm/100gm Ear Drops, Solution	Phenazone BP 4.00gm + Lidocaine HCl BP 1.00gm/100gm	Ear and Nose Preparations Therapeutic Code: 050	This medicinal product is intended for local symptomatic treatment and relief of pain in the following diseases of the middle ear without tympanic perforation: - acute,	**Contraindications:** Hypersensitivity to the active substances or to any of the excipients (Sodium thiosulfate, Ethanol, Glycerol, Purified water). Infectious or traumatic perforation of the	New	BNF 84 (Page-1291)	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					congestive otitis media; - otitis in influenza, the so called viral bullous otitis; - barotraumatic otitis.	tympanic membrane (including myringotomy).				
395.	UniMed UniHealth Pharmaceuticals Ltd., B.K Bari, Gazipur Sadar, Gazipur	Amisulpride 10.00gm/100ml Oral Solution	Amisulpride BP 10.00gm/100ml Oral Solution	Antipsychotic Therapeutic Code: 028	It is used for acute psychotic episode in schizophrenia.	**Contraindications:** CNS depression. comatose states. phaeochromocytoma. prolactin-dependent tumors. **Side effects: C**ommon or very common: Anxiety. breast pain. hypersalivation. muscle rigidity. nausea. oculogyric crisis. orgasm abnormal. Trismus, Uncommon: Hyperglycemia, Frequency not known: Angioedema. bone disorders. cardiac arrest. confusion. dyslipidemia. hyponatremia. nasal congestion. neoplasms. SIADH. urticaria. vision blurred.	50mg, 100mg, 200mg Tablet 2.5 mg/ml In‡jvection 5 mg/2 ml In‡jvection	BNF 84 (Page-426-27)	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
396.	Beximco Pharmaceuticals Ltd., Tongi, Gazipur	Topiroxostat 20 mg tablet	Topiroxostat INN 20 mg	Uricosuric and Anti-Gout Agents. Therapeutic Code:076	Gout and hyperurcemia	**Contraindication:** There are no known contraindications for Topiroxostat. **Side Effect:** The most reported adverse reactions include gouty arthritis. Liver dysfunction: Generalized fatigability, nausea, yellowness in skin or con‡jvunctiva Erythema multiforme: Round or oval red rash, fever, joint pain **Warnings and Precautions:** If there is previous history of any allergic reactions (itch, rash, etc.) to any medicines or foods. **Pregnant or breastfeeding.** If there is history of taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
397.	Beximco Pharmaceuticals Ltd., Tongi, Gazipur	Topiroxostat 40 mg tablet	Topiroxostat INN 40 mg	Uricosuric and Anti-Gout Agents. Therapeutic Code:076	Gout and hyperurcemia	**Contraindication:** There are no known contraindications for Topiroxostat. **Side Effect:** The most reported adverse reactions include gouty arthritis. Liver dysfunction: Generalized fatigability, nausea, yellowness in skin or con‡jvunctiva Erythema multiforme: Round or oval red rash, fever, joint pain **Warnings and Precautions:** If there is previous history of any allergic reactions (itch, rash, etc.) to any medicines or foods. **Pregnant or breastfeeding.** If there is history of taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
398.	General Pharmaceutical Ltd., Gazipur	Silver Sulfadiazine 1.0gm + Sodium Hyaluronate 0.002gm/100gm Cream	Silver Sulfadiazine + Sodium Hyaluronate (0.2%+1%)	Anti-burn Therapeutic code: 023	Mainly used for treating wounds, ulcers and burns. Treating skin lesions, varicose ulcers.	**Contraindications:** Some medical conditions may interact with Sulfadiazine: planning to become pregnant, taking any prescription or nonprescription medicine, herbal preparation, or dietary supplement, allergies to medicines, foods, or other substances. Diarrhea, a sore throat, or a stomach or intestinal infection. Having a history of asthma, liver problems, kidney problems, glucose-6-phosphate dehydrogenase (G-6-PD) deficiency, the blood disease porphyria, or other blood problems. Some medicine may interact with Sulfadiazine: Indomethacin, probenecid, or salicylates (e.g., aspirin) because the side effects of Sulfadiazine may be increased. Anticoagulants (e.g., warfarin) because the risk of bleeding may be increased. Methotrexate or thiazide	New	রেফারেন্স নাই	প্রয়োজন রয়েছে বিধায় অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						diuretics (e.g., hydrochlorothiazide) because side effects may be increased by Sulfadiazine Sulfonylureas (e.g., glyburide) because the risk of low blood sugar may be increased				
399.	General Pharmaceutical Ltd., Gazipur	Thiamine Mononitrate BP 100mg + Pyridoxine HCl BP 100mg + Cyanocobalamin BP 5mg Tablet	Thiamine Mononitrate BP (Vitamin B1) 100mg + Pyridoxine HCl BP (Vitamin B6)100mg + Cyanocobalamin BP (Vitamin B12) 5mg Tablet	Vitamins & Combinations Therapeutic code: 078	Diabetic polyneuropathy, neuralgia, nerve compression syndrome, migraine & other circulatory disorders.	side-effects that may occur from all constituting ingredients of Thiamine Mononitrate (Vit B1) + Pyridoxine Hydrochloride (Vit B6) + Cyanocobalamin (Vit B12) Tablet. This is not a comprehensive list. These side-effects are possible, but do not always occur. Some of the side-effects may be rare but serious. Consult your doctor if you observe any of the following side-effects, especially if they do not go away. • Pruritus • Urticaria • Weakness • Sweating • Nausea • Restlessness	Cyanocobalamin 200 mcg+Pyridoxine Hydrochloride 200 mg+Vitamin B1 100 mg Tablet	রেফারেন্স নাই	রেফারেন্স নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
400.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Calcium 350mg (Coral Source) and Vitamin D3 300IU Chewable Tablet	Calcium Carbonate (Coral Source) USP 875mg (Eq. to 350mg Elemental Calcium) and Dry Vitamin D3 (Cholecalciferol) USP 3mg (Eq. to 300IU Vitamin D3)	Vitamins and Combinations Therapeutic code: 078	It is indicated in the treatment of Calcium and Vitamin D3 deficiency. Vitamin D3 increases Calcium absorption in the GIT hence improves bone framework.	**CONTRAINDIC ATIONS:** Hypercalcemia, kidney stone, calcium depositions in kidneys. Hypervitaminosis D, severely impaired kidney function/kidney failure. **SIDE-EFFECT:** Swollen face, lips, tongue or throat; difficult to swallow; hives and difficulty breathing. **WARNINGS AND PRECAUTIONS:** • Suffer from sarcoidosis • Are taking other medicines containing vitamin D or calcium • Have poor kidney function or high tendency of kidney stone formation • Are immobilized with osteoporosis.	Calcium 600mg + Cholecalciferol 400IU Tablet Calcium 500mg + Cholecalciferol 200IU Tablet	রেফারেন্স নাই	রেফারেন্স নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
401.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Ramosetron Hydrochloride INN 100 mcg Tablet	Ramosetron Hydrochloride INN 100 mcg Tablet	Antiemetic Therapeutic code: 018	Ramosetron Hydrochloride is a medicine that is used for the treatment of Diarrhea-predominant irritable bowel syndrome in males, Chemotherapy-induced nausea, Chemotherapy-induced vomiting and other conditions. The complete list of uses and indications for Ramosetron Hydrochloride is as follows: • Diarrhea-predominant irritable bowel syndrome in males • Chemotherapy-induced nausea • Chemotherapy-induced vomiting	**Contraindication** If anyone suffering from any of the following diseases, should not take Ramosetron Hydrochloride tablet unless doctor advises to do so - • Heart Disease • Liver Disease • Phenylketonuria (PKU) • Calcium Deficiency Potassium Deficiency	New	রেফারেন্স নাই	রেফারেন্স নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
402.	Beacon Pharmaceuticals Limited Kathali, Bhaluka,	Loxoprofen INN 60mgTablet	Laxoprofen Sodium Hydrate INN 68.100mg eqv. to Loxoprofen Sodium 60mg Tablet	Analgesics and Antipyretics Therapeutic Code: 006	Loxoprofen is non-steroidal anti-inflammatory Medication (NSAID) indicated for pain and inflammation related to musculoskeletal and joint disorders. In addition to its effects	Contraindication: History of aspirin-induced asthma attack , History of nonsteroidal antiinflammatory drugs [NSAIDs]-induced asthma attack ,	New	রেফারেন্স নাই	রেফারেন্স নেই বিধায় নামঞ্জুরের সুপারিশ করা	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Mymensingh				on pain, it is an antipyretic and anti-inflammatory medication.	Hypersensitivity to arylcarboxylic acids, Hypersensitivity to nonsteroidal anti-inflammatory drugs [NSAIDs], Hypersensitivity to one of the components, Hypersensitivity to salicylates, Progressive peptic ulcer,Se vere congestive heart failure, Severe hematologic disease, Severe hepatic failure, Severe renal failure, Lactation, Last 4 months of pregnancy. Side-effects: The most commonly reported side effect include gastric discomfort, pain in the pit of the stomach, stomachache, nausea/vomiting, loss of appetite, edema/swelling, rash, hives, drowsiness, fever, and itch.			যেতে পারে।	
403.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Calcium Carbanate BP 1250mg eqv. to Elemental Calcium 500mg- + Cholecalciferol (Vit-D3, 100000IU) BP 2mg + Menaquinone-7 (Vit. K2) USP 9.00mg eqv. to 90mcg Vitamin K2 Film Coated Tablet.	Calcium Carbanate BP 1250mg eqv. to Elemental Calcium 500mg- + Cholecalciferol (Vit-D3, 100000IU) BP 2mg + Menaquinone-7 (Vit. K2) USP 9.00mg eqv. to 90mcg Vitamin K2	Vitamins and Combinations Therapeutic Code: 078	Helps enhance and support bone healths Assists in healthy bone and development, growth and building Helps promote bone strength and mineralization Maintains and supports blood & heart health and muscle & neuromuscular function Prevent Oteoporosis when dietary intake in inadequate	**CONTRAINDICATIONS:** It is contraindicated in case of hypercalcemia, hyperthyroidismt, renal calculi, & nephrolithiasis and Zollinger-ellison syndrome. **Side-effect:** If there is experience loike nausea , vomiting, stomach crams, dry mouth, increase thirst, increase urination while taking, noticed to physicians. Side effect from micronutrient are rare. **Warning & Precautions:** If tehre is any heart disease or kidney disease, precautions should be taken.		রেফারেন্স নাই	রেফারেন্স নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
404.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Olmesartan Medoximil 10mg + Amlodipine 5mg Tablet	Olmesartan Medoximil USP 10mg + Amlodipine Besilate BP 6.94mg eqv. to Amlodipine 5mg	Antihypertensive Therapeutic code:022	Indicated for dihydropyridine calcium channel blocker and angiotensin II receptor blocker combination product indicated for the treatment of hypertension, alone or with other antihypertensive	**Contraindications:** It is contraindicated with aliskiren in patients with diabetes and hypersensitivity to the active substance or to any of the excipients. **Side effects:** The most common side effects	Amlodipin e Besilate 6.640mg equivalent to Amlodipin	রেফারেন্স নাই	রেফারেন্স নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					agents.	include edema, dizziness, flushing, palpitation. Other side effects may include vomiting, diarrhoea, rhabdomyolysis, alopecia, pruritus, urticaria etc. **Warnings and Precautions**: Hypotension in volume- or saltdepleted patients with treatment initiation may be anticipated. Start treatment under close supervision. Increased angina or myocardial infarction may occur upon dosage initiation or increase. Impaired renal function: changes in renal function may be anticipated in susceptible individual. Sprue-like enteropathy has been reported. Consider discontinuation of this medication in cases where no other etiology is found.	e 5 mg and Olmesarta n Medoxomi l 40 mg tablet			
405.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Olmesartan Medoximil 20mg + Amlodipine Besilate 6.945mg eqv. to Amlodipine 5mg+Hydrochlorothiazide 25mg Tablet	Olmesartan Medoximil USP 20mg + Amlodipine Besilate BP 6.945mg eqv. to Amlodipine 5mg+Hydrochlorothiazide USP 25mg	Antihypertensive Therapeutic Code: 022	Indicated for the treatment of hypertension	**Contraindication:** It is contraindicated in patient with hypersensitivity to this combination or any other component of this product, to dihydropyridines, to thiazides or to other sulfonamide-derived drugs. Due to the component amlodipine, this combination is also contraindicated in cardiogenic shock, acute myocardial infarction (within the first 4 weeks) and unstable angina pectoris. **Side-effects:** The most common side effects are upper respiratory tract infection, nasopharyngitis, urinary tract infection, hyper triglyceridaemia, hyperuricaemia, dizziness, headache, somnolence, visual disturbance, abdominal pain, dyspepsia, muscle spasm, joint swelling, back pain, peripheral edema, fatigue, chest pain. **Warnings and precautions**:	Hydrochlorothiazide 12.5 mg + Olmesartan Medoxomil 40 mg Tablet Amlodipine 5 mg + Olmesartan Medoxomil 40 mg Tablet	রেফারেন্স নাই	রেফারেন্স নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Symptomatic hypotension, especially after the first dose, may occur in patients who are volume and/or sodium depleted by vigorous diuretic therapy, dietary salt restriction, diarrhea, or vomiting. Such conditions should be corrected before the administration of this combination.				
406.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Peficitinib Hydrobromide 150mg Tablet.	Peficitinib Hydrobromide INN 150mg	Immunosuppre-ssant Therapeutic Code: 58	It is indicated for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have an inadequate response to conventional therapies.	**Contraindication:** It is contraindicated in patients with known hypersensitivity to Peficitinib or any other components of this product and pregnancy. Women of childbearing potential should beadvised to use effective contraception during the treatment with peficitinib and a certain period after the completion of the treatment. **Precaution:** RA patients with moderate hepatic impairment should be treated with Peficitinib 50 mg once daily. **Side effects:** The most frequently reported adverse reactions are nasopharyngitis, diarrhea, nausea, pharyngitis, upper respiratory tract infection (URTI), constipation, headache and back pain.	New	রেফারেন্স নাই	রেফারেন্স দাখিলের জন্য বলা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
407.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	(Ascorbic Acid 500mg + Anhydrous Glucose (Dextrose) 25gm + Thiamin HCl 125mg + Riboflavin Sodium Phosphate 25mg + Pyridoxine HCl 25mg + Nicotinamide 125mg + D-Pantothenol 250mg)/500ml IV Infusion	Ascorbic Acid BP 500mg + Anhydrous Glucose (Dextrose) BP 25gm + Thiamin HCl BP 125mg + Riboflavin Sodium Phosphate 25mg + Pyridoxine HCl BP 25mg + Nicotinamide BP 125mg + D-Pantothenol BP 250mg/500ml	Water for In‡jvection, Electrolytes, Blood Volume Restorers and Caloric Agents. Therapeutic code: 079	It should be given to post-surgery (due to malignant tumor, burns, febrile disease, thyrotoxicosis, peritonitis, wound infection) patients when Vitamin B complex and Vitamin C supplements are needed. Also, it is suitable for those alcoholic or gastrointestinal disease patients who cannot easily swallow to combine administration with amino acid complex and glucose infusions	Contraindication: Vitamin C supplementation is contraindicated in blood disorders like thalassemia, G6PD deficiency, sickle cell disease, and hemochromatosis. Avoid taking supplements immediately before or following angioplasty. Diabetic patients should take vitamin C supplements with care as it raises blood sugar levels. Side-effects: Constipation, diarrhea, or upset stomach may occur. These effects are usually temporary and may disappear as	New	রেফারেন্স নাই	রেফারেন্স নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						your body adjusts to this medication. If any of these effects last or get worse, tell your doctor or pharmacist promptly.				
408.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Fudosteine INN 400mg Film Coated Tablet	Fudosteine INN 400mg	Druq used in Bronchial Asthma Therapeutic Code: 44	bronchial asthma, chronic bronchitis, pulmonary emphysema, bronchiectasis, pulmonary tuberculosis, pneumoconiosis, atypical mycobacterial disease and diffuse panbronchiolitis	**CONTRAINDICATIONS:** Due to prospensity to cause emesis, N-Acylcysteine in contraindicated in patients with peptic ulcers. It is also contraindicated in patients with esophageal varices and Mallory-Weiss tear due tp similar reasons .It Must be strictly avoided in patients who have had an anaphylactic reation to the drug in the past. The only contraindicated for dornase alfa is known hypersensitivity to the drug in past or if the patient is hypersensitive to Chinese hamster ovary (CHO) cell products. **Side-effect:** Mild gastric discomfort, Gastric ulceration, and fixed drug eruption have been reported with carbocisteine. Epigastralgia, headache, erythema, and nausea, have been reported in patients receiving erdosteine, the latter two of which led to treatment discontinuation. **Warning & Precautions:** Reanal impairment: Contraindicated for the patient creatinine clearance rate less than 25ml/min Hepatic Impaiment: Mild to moderate: max: 300mg daily. Severe: Contraindicated.	New	রেফারেন্স নাই	রেফারেন্স নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
409.	Beacon Pharmaceuticals Limited Kathali, Bhaluka,	Propanthelline Bromide 7.5 mg Tablet	Propanthelline Bromide 7.5 mg Tablet	Anticholinerqic Therapeutic Code: 011	Propantheline bromide USP is indicated as an adjunctive therapy in the treatment of peptic ulcer (gastric and duodenal) and for the relief of the symptoms of gastritis.	Contraindications: Propantheline is contraindicated in patients with: 1. Glaucoma, since mydriasis is to be avoided. 2. Obstructive disease of the gastrointestinal	15mg Tablet	রেফারেন্স নাই	রেফারেন্স নেই বিধায় নামঞ্জুরের সুপারিশ করা	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Mymensingh				Propantheline bromide is also indicated for Spastic and inflammatory disease of GI and urinary tracts such as the symptomatic treatment of the irritable bowel syndrome (irritable colon, spastic colon, mucous colitis, acute enterocolitis, nervous diarrhoea and functional gastrointestinal disorders). Other indications include renal colic, hyperhidrosis, as adjunctive therapy in ulcerative colitis, diverticulitis, cholecystitis and pancreatitis and for certain gastrointestinal diagnostic procedures (Duodenography). Control of salivation and enuresis. Second-line therapy for urinary incontinence.	tract (pyloroduodenal stenosis, achalasia, paralytic ileus, etc.). 3. Obstructive uropathy (e.g., bladder-neck obstruction due to prostatic hypertrophy). 4. Intestinal atony of elderly or debilitated patients. 5. Severe ulcerative colitis or toxic megacolon complicating ulcerative colitis. 6. Unstable cardiovascular adjustment in acute hemorrhage. 7. Myasthenia gravis. Side-effects: Common side effects of Propantheline include: dry mouth, increased sensitivity of the eyes to light, dizziness, nervousness. difficulty sleeping, headache, loss of sense of taste, upset stomach, vomiting, bloating, confusion (especially in the elderly), blurred vision, constipation			যেতে পারে।	হলো।
410.	UniMed UniHealth Pharmaceuticals Ltd. B.K Bari, Gazipur Sadar, Gazipur	Disodium Edetate 15gm + Cetrimide 0.75gm/100ml Solution Root Canal Chelating Agent	Disodium Edetate BP 15gm + Cetrimide BP 0.75gm/100ml Solution Root Canal Chelating Agent	Other Classification Therapeutic code:075	• Locating canal orifices. • Facilitating root canal preparation. • Aiding in the removal of pulp stones.	**Contraindications:**		রেফারেন্স নাই	প্রয়োজন রয়েছে বিধায় অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
411.	UniMed UniHealth Pharmaceuticals Ltd.	Sodium Hypochlorite 3.00gm/100gm Canal irrigation	Sodium Hypochlorite 5% Solution USP 60.00g eq. to Sodium Hypochlorite 3.00gm/100gm Canal irrigation	Other Classification Therapeutic code:075	Canal irrigation for root canal preparation.			রেফারেন্স নাই	প্রয়োজন রয়েছে বিধায় অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
412.	UniMed UniHealth Pharmaceuticals Ltd.	Chlorhexidine Gluconate Solution 0.2% Root-canal Solution	Chlorhexidine Gluconate 20% Solution BP 0.20gm/100gm Root-canal Solution	Other Classification Therapeutic code:075	Root-canal irrigation when endodontic re-treatment is required and/or when root-canal treatment requires several sessions due to infected canal.	**Contraindications:** Hypersensitivity to any component.		রেফারেন্স নাই	প্রয়োজন রয়েছে বিধায় অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
413.	Popular Pharmaceuticals Limited, Tongi, Gazipur	Citicoline 2.00gm + Hyaluronic Acid 0.200gm + Cyanocobalamin 0.055gm/100ml Ophthalmic Solution	Citicoline Sodium USP 2.094gm Eq. to Citicoline 2.00gm + Sodium Hyaluronate BP 0.211gm Equivalent to Hyaluronic Acid 0.200gm + Cyanocobalamin BP 0.055gm/100ml	Eye Preparations Therapeutic Code: 052	For its structural action on retinal ganglion cells, is indicated as coadjuvant to antihypertensive therapy in glaucomatous patients & patients with incipient diabetic retinopathy. It promotes the physiological processes of corneal re-epithelialization after eye surgery, laser or small abrasions of the corneal surface. The wetting and protective properties of this drug ensures ocular relief in case of irritation, burning and foreign body sensation caused by environmental factors or prolonged use of video terminals.	**Contra-indication:** If anyone has known hypersensitivity to any of the components of the product. **Side effects:** It's may cause pain, redness, itching, swelling, blurred vision, tunnel vision & bruising.	Citicoline 500mg Tablet Citicoline 500mg/4 ml In‡jvection	রেফারেন্স নাই	রেফারেন্স নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
414.	Popular Pharmaceuticals Limited, Tongi, Gazipur	Esomeprazole 20mg + Domperidone 30mg Capsule	Esomeprazole Magnesium, Trihydrate USP 22.300mg eq. to Esomeprazole 20mg + Domperidone BP 30 mg	PPI + Antiemetic Therapeutic code: 067	ESOMEPRAZOLE + DOMPERIDONE is indicated for the management of: 1. Functional Dyspepsia (Non-ulcer Dyspepsia) 2. Dyspeptic symptom complex associated with gastroesophageal reflux disease (GERD): epigastric sense of fullness, feeling of abdominal distension, upper	**CONTRAINDICATIONS:** ESOMEPRAZOLE + DOMPERIDONE is contraindicated in patients with known hypersensitivity to Esomeprazole or other substituted benzimidazoles or to Domperidone or other dopamine antagonists. ESOMEPRAZOLE + DOMPERIDONE should not be used whenever stimulation of gastrointestinal motility might be dangerous such as in the presence of gastrointestinal haemorrhage, mechanical obstruction, or perforation.	Esomeprazole 20mg Capsule Domperidone 10mg Tablet	রেফারেন্স নাই	রেফারেন্স নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					abdominal pain, nausea, vomiting, belching, flatulence, and early satiety,	ESOMEPRAZOLE + DOMPERIDONE is contraindicated in patients with prolactinoma (a prolactin releasing pituitarytumour). **Side Effect:** Esomeprazole:Common adverse events reported with Esomeprazole in clinical trials include headache, nausea, vomiting, diarrhoea, abdominal pain, flatulence, constipation and dry mouth. Other less commonly reported adverse effects include dizziness, insomnia, allergic reactions, asthenia, bowel irregularity, urlicaria, etc. The incidence of treatment-related adverse events during 6-month maintenance treatment with Esomeprazole was similar to placebo. There were no differences in types of related adverse events seen during maintenance treatment up to 12 months compared to short-term treatment. Domperidone The most frequent reactions to Domperidone are those related to elevated prolactin levels including breast tenderness, galactorrhoea, gynaecomaslia and amenorrhoea. These effects are dose-related and gradually resolve after lowering the dose or discontinuing treatment. Other rarely reported adverse reactions include headache, diarrhoea, dirziness, mild and transient abdominal cramps, dry mouth and drowsiness. Rare allergic reactions, such as rash and urticaria, have also been reported. Extrapyramidal reactions occur very rarely in adults and usually resolve completely and spontaneously after				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						cessation of treatment				
415.	Popular Pharmaceuticals Limited, Tongi, Gazipur	Esomeprazole 40mg + Domperidone 30mg Capsule	Esomeprazole Magnesium, Trihydrate USP 44.60mg eq. to Esomeprazole 40mg + Domperidone BP 30 mg	PPI + Antiemetic Therapeutic code: 067	ESOMEPRAZOLE + DOMPERIDONE is indicated for the management of: 1. Functional Dyspepsia (Non-ulcer Dyspepsia) 2. Dyspeptic symptom complex associated with gastroesophageal reflux disease (GERD): epigastric sense of fullness, feeling of abdominal distension, upper abdominal pain, nausea, vomiting, belching, flatulence, and early satiety,	**CONTRAINDICATIONS** ESOMEPRAZOLE + DOMPERIDONE is contraindicated in patients with known hypersensitivity to Esomeprazole or other substituted benzimidazoles or to Domperidone or other dopamine antagonists. ESOMEPRAZOLE + DOMPERIDONE should not be used whenever stimulation of gastrointestinal motility might be dangerous such as in the presence of gastrointestinal haemorrhage, mechanical obstruction, or perforation. ESOMEPRAZOLE + DOMPERIDONE is contraindicated in patients with prolactinoma (a prolactin releasing pituitarytumour). **Side Effect:** Esomeprazole; Common adverse events reported with Esomeprazole in clinical trials include headache, nausea, vomiting, diarrhoea, abdominal pain, flatulence, constipation and dry mouth. Other less commonly reported adverse effects include dizziness, insomnia, allergic reactions, asthenia, bowel irregularity, urlicaria, etc. The incidence of treatment-related adverse events during 6-month maintenance treatment with Esomeprazole was similar to placebo. There were no differences in types of related adverse events seen during maintenance treatment up to 12 months	Esomeprazole 20mg Capsule Domperidone 10mg Tablet	রেফারেন্স নাই	রেফারেন্স নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						compared to short-term treatment. Domperidone The most frequent reactions to Domperidone are those related to elevated prolactin levels including breast tenderness, galactorrhoea, gynaecomaslia and amenorrhoea. These effects are dose-related and gradually resolve after lowering the dose or discontinuing treatment. Other rarely reported adverse reactions include headache, diarrhoea, dirziness, mild and transient abdominal cramps, dry mouth and drowsiness. Rare allergic reactions, such as rash and urticaria, have also been reported. Extrapyramidal reactions occur very rarely in adults and usually resolve completely and spontaneously after cessation of treatment				
416.	Renata ltd. Mirpur	Calcium Carbonate (from Coral Calcium) 1500 mg eq. to coral Calcium 600mg and Vitamin-D_3 (Cholecalciferol) 800IU Chewable Tablets	Calcium Carbonate USP (from Coral Calcium) 1500 mg equivalent to coral Calcium 600 mg and Vitamin-D_3 (Cholecalciferol) USP 800 IU	Metals, Salts, Minerals and Calcium Preparations Code: 062	1. Treatment of osteoporosis, rickets, osteomalacia and tetany. 2. Reduction of secondary hyperparathyroidism in post-menopausal women. 3. As supplement during pregnancy & lactation. 4. For prevention and treatment of Calcium and Vitamin D deficiency.	**Caution:** Do not exceed the recommended daily dose. In case of accidental overdose contact a physician or poison control centre immediately. Keep out of reach of children.	500mg+200IU, 500mg+400IU, 600mg+400IU, Tablet	রেফারেন্স নাই	রেফারেন্স নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
417.	NIPRO JMI Pharma Ltd, Rajandrapur, Chaddagram, Cumilla	Domperidone 30 mg Sustained Release capsule	Domperidone BP 30 mg	Antiemetic Therapeutic Code: 018	Domperidone is indicated for the relief of the symptoms of nausea and vomiting, abdominal fullness and discomfort.	**Contraindications:** It is contraindicated in patients with known hypersensitivity to Domperidone or any components of the preparation. Domperidone should not be used whenever gastro-intestinal stimulation might be dangerous (i.e., gastro-intestinal hemorrhage, mechanical obstruction or perforation). It is also contraindicated in prolactinoma. **Side Effects:** Major & minor side effects for Domperidone 30 mg sustained release	10 mg Tablet, 5 mg/ml Drop, 10 mg & 20 mg Oro-dispersible Tablet, 15 mg, 30 mg Suppository, 5 mg/ 5 ml Oral Suspension.	রেফারেন্স নাই	রেফারেন্স নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						capsule is swelling of face, lips, eyelids, tongue, hands and feet; difficulty in breathing; skin rash; convulsions; heart rhythm disorders; disrupted menstrual cycle; breast pain and tenderness; dry mouth; loss of libido; breast like growth in men.				
418.	Navana Pharmaceuticals Limited	Etrasimod 2mg Tablet	Etrasimod INN 2 mg	Ulcerative Colitis Therapeutic Code: 0	It is indicated for the treatment of Ulcerative Colitis.	**Contraindication:** No data found. **Side effects:** The most common adverse reactions are Headache, worsening of COVID-19 infection, dizziness, pyrexia, arthralgia, abdominal pain, and nausea. **Warning & Precaution:** No data found.	New	রেফারেন্স নাই	রেফারেন্স দাখিলের জন্য বলা যেতে পারে।	রেফারেন্স দাখিলের জন্য বলা হলো।
419.	Ziska Pharmaceuticals Ltd.	Myo-Inositol 2000 BP mg + D-Chiro Inositol 50mg Capsule	Myo-Inositol 2000mg + D-Chiro Inositol 50mg	Vitamin and Combination Therapeutic Code: 078	It is commonly used supplements for Polycystic ovary syndrome (PCOS), supports and maintains Healthy hormone levels, Menstrual cycles, Ovarian health, Reproductive health, Healthy fetal development, Bone health and Insulin sensitivity.	Contraindications: Contraindicated in patients with known hypersensitivity to D-chiro-inositol. Side-effects: Nausea, Vomiting, headache, tiredness, dizziness **Warnings and Precautions:** Do not use D CHIRO INOSITOL+MYO INOSITOL if patients have allergic to any of its contents.Inform doctor if patients have diabetes, heart, kidney or liver problems. Consult with doctor if patients are pregnant or breastfeeding. Keep doctors informed about healthcondition and medications to rule out any interactions/side effects.	New	রেফারেন্স নাই	রেফারেন্স নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
420.	Ziska Pharmaceuticals Ltd.	Myo-Inositol 2000mg + D-Chiro Inositol 50mg + MTHF Folate 500mcg + Vitamin D3 25mcg Capsule	Myo-Inositol 2000mg + D-Chiro Inositol 50mg + MTHF Folate 500mcg + Vitamin D3 25mcg	Vitamin and Combination Therapeutic Code: 078	It is commonly used supplements for Polycystic ovary syndrome (PCOS), supports and maintains Healthy hormone levels, Menstrual cycles, Ovarian health, Reproductive health, Healthy fetal development, Bone health and Insulin sensitivity.	**Contraindications:** Contraindicated in patients with known hypersensitivity to D-chiro-inositol. **Side-effects:** Nausea, Vomiting, headache, tiredness, dizziness, Warnings and Precautions Do not use D CHIRO INOSITOL+MYO INOSITOL if patients have allergic to any of its contents. Inform doctor if patients have diabetes, heart, kidney or liver problems. Consult with doctor if patients are pregnant or breastfeeding. Keep doctors informed about	New	রেফারেন্স নাই	রেফারেন্স নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						healthcondition and medications to rule out any interactions/side effects.				
421.	Ziska Pharmaceuticals Ltd.	Anlotinib Hydrochloride INN 12.00 mg Capsule	Anlotinib Hydrochloride INN 12.00 mg Capsule	Anticancer Therapeutic code: 010	It is indicated in adults for the treatment of Non-small Cell Lung Cancer and Metastatic Colorectal Cancer.	**Contraindications:** Some cases of ICC may be responsive to the antiangiogenic drug, anlotinib, when combined with microwave ablation. Randomized clinical studies are required to further confirm the efficacy and safety of anlotinib in the clinical treatment of ICC. **Adverse events:** The tolerability profile of anlotinib is similar to that of other tyrosine kinase inhibitors that target VEGFR and other tyrosine kinase-mediated pathways; however, anlotinib has a significantly lower incidence of grade 3. Unusual bruising or bleeding, Bloody or black and tarry stools, Blood in the urine, Vomit that is bright red or looks like coffee grounds, coughing up blood, Stomach pain, swelling, or tenderness, Headache, Fever, Swelling, tenderness, warmth, or redness of a leg, Swelling of the feet or ankles.		রেফারেন্স নাই	রেফারেন্স দাখিলে জন্য বলা যেতে পারে।	রেফারেন্স দাখিলের জন্য বলা হলো।
422.	Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh	Zinc Oxide BP 6.225mg eqv. to Zinc 5mg + Coated Ascorbic Acid BP 100.3mg eqv. to 100mg Ascorbic Acid + Sodium Ascorbate BP 371.250mg eqv. to Ascorbic Acid 300mg Film Coated Tablet.	Zinc 5mg + Ascorbic Acid 400mg	Vitamins and Combinations Therapeutic Code: 078	It is indicated for the boost up the immunity.	**CONTRAINDICATIONS:** It is contraindicated inpatients with iron metabolism disorder, sickle cell anemia, decreased kidney function. **Side-effect:** Headache, Dizziness, nausea, Stomach Upset **Warning & Precautions:**In some people, vitamin C might cause side effect such as stomach cramps, nausea, heartburn, and headache. The change of getting these side effect increases with higher doses.		□□□□□□ □□□ □□□	রেফারেন্স নেই বিধায় নামঞ্জুরের সুপারিশ করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
423.	Aristopharma Ltd, Sampur, Dhaka. Square Pharmaceuticals Ltd., Salgaria, Pabna Eskayef Pharmaceuticals Limited, Tongi, Gazipur The ACME Laboratories Ltd. Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirgan‡jv, Narayanagng Renata Limited, Mirpur, Dhaka Ziska Pharmaceuticals Ltd. Beacon Pharmaceuticals Ltd. Beximco Pharmaceuticals Ltd. Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka. General Pharmaceuticals Ltd. Popular Pharmaceuticals Limited, Tongi, Gazipur	Mirogabalin 2.5mg Film Coated Tablet	Mirogabalin Besylate INN 4.390mg (Eq. to Mirogabalin 2.5 mg)	Drug Used in Epilepsy Therapeutic code: 046	Mirogabalin has been used in the treatment of peripheral neuropathic pain.	**Contraindication:** If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines. If you have renal dysfunction. If you are pregnant or breastfeeding. If you are taking any other medicinal products. **Side Effects:** Dizziness, Sleepiness, Sleeping for unusually long periods, Headache	**New**	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
424.	Aristopharma Ltd. Eskayef Pharmaceuticals Limited, Tongi, Gazipur Nuvista Pharma Ltd. The ACME Laboratories Ltd. Dhamrai, Dhaka Drug International Ltd (Unit-3) 31/1,Satrong, Tongi I/A, Gazipur Orion Pharma Ltd.; D/28/2, Sumilpara, Siddhirgan‡jv, Narayanagng Renata Limited, Mirpur, Dhaka Ziska Pharmaceuticals Ltd. Beacon Pharmaceuticals Ltd. Beximco Pharmaceuticals Ltd. Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka. General Pharmaceuticals Ltd. Popular Pharmaceuticals Limited, Tongi, Gazipur	Mirogabalin 5mg Film Coated Tablet	Mirogabalin Besylate INN 8.780mg (Eq. to Mirogabalin 5mg)	Drug Used in Epilepsy Therapeutic code: 046	Mirogabalin has been used in the treatment of peripheral neuropathic pain.	**Contraindication:** If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines. If you have renal dysfunction. If you are pregnant or breastfeeding. If you are taking any other medicinal products. **Side Effects:** Dizziness, Sleepiness, Sleeping for unusually long periods, Headache	**New**		অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Square Pharmaceuticals Ltd., Salgaria, Pabna									
425.	Aristopharma Ltd. Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Renata Limited Mirpur, Dhaka Ziska Pharmaceuticals Ltd. Beacon Pharmaceuticals Ltd. Beximco Pharmaceuticals Ltd. Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka. General Pharmaceuticals Ltd. Popular Pharmaceuticals Limited, Tongi, Gazipur Square Pharmaceuticals Ltd., Salgaria, Pabna The ACME Laboratories Ltd. Dhamrai, Dhaka	Mirogabalin 15mg Film Coated Tablet	Mirogabalin Besylate INN 26.340mg (Eq. to Mirogabalin 15mg)	Drug Used in Epilepsy Therapeutic code: 046	Mirogabalin has been used in the treatment of peripheral neuropathic pain.	CONTRAINDICATIONS: Hypersensitivity, Pregnancy **SIDE-EFFECTS:** General malaise Loss of appetite Nausea, vomiting Jaundice (liver dysfunction)	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
426.	Aristopharma Ltd. Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Nuvista Pharma Ltd. Square Pharmaceuticals Ltd., Salgaria, Pabna The ACME Laboratories Ltd. Dhamrai, Dhaka Drug International Ltd (Unit-3) 31/1,Satrong, Tongi I/A, Gazipur Renata Limited Mirpur, Dhaka Ziska Pharmaceuticals Ltd. Beacon Pharmaceuticals Ltd. Beximco Pharmaceuticals Ltd. General Pharmaceuticals Ltd. Incepta pharmaceuticals Ltd, Zirabo, Savar, Dhaka. Popular Pharmaceuticals Limited, Tongi, Gazipur	Mirogabalin 10mg Film Coated Tablet	Mirogabalin Besylate INN 17.560mg (Eq. to Mirogabalin 10mg)	Therapeutic Class: Drug Used in Epilepsy Therapeutic code: 046	Mirogabalin has been used in the treatment of peripheral neuropathic pain.	Contraindication: If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines. If you have renal dysfunction. If you are pregnant or breastfeeding. If you are taking any other medicinal products. Side Effects: Dizziness Sleepiness Sleeping for unusually long periods **Headache**	New	PMDA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
427.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur The Ibn SINA Pharmaceuticals Ltd Beximco Pharmaceutical Ltd, Tongi, Gazipur Aristopharma Ltd. Plot No.14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204 Incepta Pharmaceuticals, Savar, Dhaka EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, BANGLADESH Delta Pharma Ltd. Eskayef Pharmaceuticals Limited, Tongi, Gazipur. The ACME Laboratories Ltd. Dhamrai, Dhaka General Pharmaceutical Ltd., Gazipur Healthcare Pharmaceuticals Ltd Advanced Chemical Industries Limited, 7	Vonoprazan 10mg Tablet	Vonoprazan Fumarate INN 13.36mg eq. to Vonoprazan 10mg	Therapeutic Class: Other Classification Therapeutic code: 075	It is used for the treatment of gastric ulcer, duodenal ulcer or reflux esophagitis; prevention of recurrent gastric or duodenal ulcer associated with low-dose aspirin administration; and prevention of recurrent gastric or duodenal ulcer associated with non-steroidal anti-inflammatory drug administration. Adjunct therapy to Helicobacter pylori eradication.	Contraindications: Hypersensitivity to the active substance or to any of the excipients. Vonoprazan tablets should not be co-administered with Atazanavir & Rilpivirine. Side-effects: The most common adverse reaction was constipation, diarrhoea, skin rash & nausea.	New	PMDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Hajeegang, Godnyl, Narayanagng. Beacon Pharmaceuticals Limited, Kathali, Bhaluka, Mymensingh Drug International Ltd, Unit-3 Popular Pharmaceuticals Ltd. Tongi, Gazipur Pharmasia Limited, Gojariapara. Bhawal, Mirzapur, Gazipur M/s Orion Pharma Ltd., D/28/2, Sumilpara, Siddhirgan‡jv, Narayangang Radiant Pharmaceuticals Limited, B-34 & B-46, BSCIC I/E, Tongi, Gazipur UniMed UniHealth Pharmaceuticals Ltd., B.K Bari, Gazipur Sadar, Gazipur Renata Limited Mirpur, Dhaka Silva Pharmaceuticals Ltd. Ziska Pharmaceuticals Ltd. Navana Pharmaceuticals Ltd, Narayangang.									

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
428.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur The Ibn SINA Pharmaceuticals Ltd Beximco Pharmaceutical Ltd, Tongi, Gazipur Aristopharma Ltd. Plot No.14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204 EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagng, BANGLADESH Delta Pharma Ltd. The ACME Laboratories Ltd. Dhamrai, Dhaka Eskayef Pharmaceuticals Limited, Tongi, Gazipur. General Pharmaceutical Ltd., Gazipur Healthcare Pharmaceuticals Ltd Advanced Chemical Industries Limited, 7 Hajeegang, Godnyl, Narayanagng. Beacon	Vonoprazan 20mg Tablet	Vonoprazan Fumarate INN 26.72mg eq. to Vonoprazan 20mg	Therapeutic Class: Other Classification Therapeutic code: 075	It is used for the treatment of gastric ulcer, duodenal ulcer or reflux esophagitis; prevention of recurrent gastric or duodenal ulcer associated with low-dose aspirin administration; and prevention of recurrent gastric or duodenal ulcer associated with non-steroidal anti-inflammatory drug administration. Adjunct therapy to Helicobacter pylori eradication.	Contraindications: Hypersensitivity to the active substance or to any of the excipients. Vonoprazan tablets should not be co-administered with Atazanavir & Rilpivirine. Side-effects: The most common adverse reaction was constipation, diarrhoea, skin rash & nausea.	New	PMDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh Drug International Ltd, Unit-3 Popular Pharmaceuticals Ltd. Tongi, Gazipur Pharmasia Limited, Gojariapara. Bhawal Mirzapur, Gazipur M/s Orion Pharma Ltd., D/28/2, Sumilpara, Siddhirgan‡jv, Narayanagng Radiant Pharmaceuticals Limited, B-34 & B-46, BSCIC I/E, Tongi, Gazipur UniMed UniHealth Pharmaceuticals Ltd., B.K Bari, Gazipur Sadar, Gazipur Renata Limited Mirpur, Dhaka Silva Pharmaceuticals Ltd. Ziska Pharmaceuticals Ltd. Incepta Pharmaceuticals Ltd.									

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Savar, Dhaka Navana Pharmaceuticals Ltd, Narayangang.									

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
429.	Nuvista Pharma Ltd. Beximco Pharmaceuticals Ltd. Aristopharma Ltd. Plot No.14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204 Healthcare Pharmaceuticals Ltd Beacon Pharmaceuticals Limited Kathali, Bhaluka, Mymensingh Drug International Ltd, Unit-3 Eskayef Pharmaceuticals Limited, Tongi, Gazipur Orion Pharma Ltd., Narayanagng Incepta Pharmaceuticals, Savar, Dhaka.	Acotiamide Hydrochloride Hydrate 100mg Tablet	Acotiamide Hydrochloride Hydrate INN 100mg	Drug used in Antiemetic Therapeutic Class: 018	Indications: A drug indicated for the treatment of postprandial fullness, upper abdominal bloating, and early satiation in functional dyspepsia.	Contraindication: Hypersensitivity Side Effects: Diarrhea, Constipation, Dizziness, Rash, Abnormal liver function	NEW	PMDA, FY-2012 Japan	বর্তমানে প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	বর্তমানে প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।
430.	Nuvista Pharma Ltd. Incepta Pharmaceuticals, Dhamrai, Dhaka.	Relugolix 40mg Tablet	Relugolix INN 40mg	Hormone Therapeutic Class: 056	Indications: Relief of the following symptoms associated with uterine fibroids: menorrhagia, lower abdominal pain, lumbar pain, and anemia.	Contraindication: The most commonly reported adverse reactions include Hot flush, Abnormal uterine bleeding Menorrhagia, Headache, Excessive amount of sweat and genital bleeding, Depressed mood, Pessimistic, decline of thinking ability Insomnia, Loss of appetite, General malaise Easy fatigability, General malaise, Weakness, nausea, Loss of appetite **Side Effects:** Side effects of Relugolix include menstrual abnormalities, hot flashes, excessive sweating, headache, and decreased bone mineral density.	NEW	PMDA, FY-2018 Japan	বর্তমানে প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	বর্তমানে প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
431.	Beximco Pharmaceutical Ltd, Tongi, Gazipur Beacon Pharmaceuticals Ltd. Aristopharma Ltd. Plot No.14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204 DBL Pharmaceuticals Ltd., Surabari, Kashimpur, Gazipur The ACME Laboratories Ltd. Dhamrai, Dhaka Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Opsonin Pharma Limited, Rupatali, Barishal Navana Pharmaceuticals Ltd., Rupgang, Narayangang Silva Pharmaceuticals Ltd. Organic Health care delta Ltd. Renata Ltd, Mirpur.	Oteseconazole 150mg Capsule	Oteseconazole INN 150 mg	Antifungal Agent Therapeutic Code: 020	Oteseconazole has been used in trials studying the treatment of Tinea Pedis, Onychomycosis, Candidiasis, Vulvovaginal, and Recurrent Vulvovaginal Candidiasis	**Contraindication:** Hypersentivity to any of the ingredient **Side-effects:** Patients associate RVVC with oppression, isolation, embarrassment, frustration, powerlessness, sadness, and hopelessness to the point of despair **Warnings and Precautions:** No data available	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
432.	Beximco Pharmaceutical Ltd, Tongi, Gazipur Healthcare Pharmaceuticals Ltd Drug International Ltd	Cholecalciferol 400 IU/ ml Oral Solution	Cholecalciferol BP 400 IU/ ml	Therapeutic Class: Vitamins and Combination Therapeutic	Recommended for infants and children under 12 years of age as a prevention/treatment for vitamin D deficiency in those at risk.	**Contraindication:** It is contraindicated in all diseases associated with hypercalcemia. It is also contraindicated in patients with known hypersensitivity to Cholecalciferol (or medicines of the same class) and any of the constituent excipients.	New	TGA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	(Unit-3) 31/1, Satrong Road, Gopalpur, Tongi Industrial Area Gazipur, Bangladesh			Code:078		Cholecalciferol is contraindicated if there is evidence of vitamin D toxicity. **Side-effect:** Generally, all nutritional supplements are considered to be safe and well tolerable. However, few side-effects can generally occur including hypercalcaemia syndrome or Calcium intoxication (depending on the severity and duration of hypercalcaemia), occasional acute symptoms include anorexia, headache, nausea, vomiting, abdominal pain or stomach ache and constipation **Warning and Precautions:** Cholecalciferol is usually nontoxic in physiologic doses. Chronic or acute administration of excessive doses may lead to hypervitaminosis D, manifested by hypercalcemia and its sequelae. The use of vitamin D in excess of the recommended dietary allowance during normal pregnancy should be avoided unless, in the judgment of the physician, potential benefits in a specific case outweigh the significant hazards involved.				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
433.	Beximco Pharmaceutical Ltd, Tongi, Gazipur The ACME Laboratories Ltd. Aristopharma Ltd. Plot No.14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204 Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Incepta Pharmaceuticals Ltd.; Dhamrai Unit, Dhaka Advanced Chemical Industries Limited, 7 Hajeegang, Godnyl, Narayangong. Eskayef Pharmaceuticals Limited, Tongi, Gazipur Ziska Pharmaceuticals Ltd. Beacon Pharmaceuticals Ltd.	Tirzepatide 5mg/0.5 ml Injection or Tirzepatide 5mg prefilled Injection	Tirzepatide INN 5mg/0.5ml In‡jvection	Antidiabetes Therapeutic Code:015	Type 2 Diabetes mellitus	Contra Indications: Tirzepatide is under investigation in clinical trial NCT03311724 (A Study of Tirzepatide (LY3298176) in Participants With Type 2 Diabetes). Side effects: Nausea, vomiting, diarrhea, abdominal pain, and constipation. Warning & Precautions: Tirzepatide is under investigation in clinical trial NCT03311724 (A Study of Tirzepatide (LY3298176) in Participants With Type 2 Diabetes).	NEW	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
434.	Beximco Pharmaceutical Ltd, Tongi, Gazipur The ACME Laboratories Ltd. Aristopharma Ltd. Plot No.14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204	Tirzepatide 10mg/0.5ml Injection or Tirzepatide 10mg prefilled Injection	Tirzepatide INN 10mg/0.5ml	Antidiabetes Therapeutic Code:015	Type 2 Diabetes mellitus	Contra Indications: Tirzepatide is under investigation in clinical trial NCT03311724 (A Study of Tirzepatide (LY3298176) in Participants with Type 2 Diabetes). Side effects: Nausea, vomiting, diarrhea, abdominal pain, and constipation. Warning & Precautions: Tirzepatide is under investigation in clinical trial NCT03311724 (A Study of Tirzepatide (LY3298176) in Participants with Type 2	NEW	USFDA	বর্তমানে প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	বর্তমানে প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Incepta Pharmaceuticals Ltd.; Dhamrai Unit, Dhaka Advanced Chemical Industries Limited, 7 Hajeegang, Godnyl, Narayangong. Eskayef Pharmaceuticals Limited, Tongi, Gazipur Ziska Pharmaceuticals Ltd. Beacon Pharmaceuticals Ltd.					Diabetes).				

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
435.	Pharmasia Limited, Gojariapara. Bhawal Mirzapur, Gazipur Advanced Chemical Industries Limited, 7 Hajeegang, Godnyl, Narayangong Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Sodium Alginate 250mg + Sodium Bicarbonate 106.5mg + Calcium Carbonate 187.50mg Chewable Tablet	Sodium Alginate BP 250 mg + Sodium Bicarbonate BP 106.5 mg + Calcium Carbonate BP 187.50 mg	Antacids Therapeutic Code:007	Relief of the symptoms associated with reflux oesophagititis, hiatus hernia and all cases of epigastric distress where the underlying causes is gastro-esophageal reflux. Fast, soothing relief of heartburn and acid indigestion due to gastro-esophageal reflux.	**Contraindication:** Hypersensitivity to sodium alginate, potassium bicarbonate, calcium carbonate or to any of the excipients listed in the product. This product should not be used in patients with moderate or severe renal insufficiency. **Side-effects:** Very rarely (less than 1 in 10,000 patients treated) an allergic reaction to the ingredients may occur. Symptoms of this may include: skin rash itching, difficulty breathing, dizziness, swelling of the face, tongue or throat. If you experience these or any other side effects, stop taking the product and consult your doctor immediately. Other side effects of unknown frequency may include constipation, irritability, muscle twitching or muscle cramps, indigestion that comes back when you stop taking the tablets and high levels of calcium in the blood. **Precaution and Warning:** This medicine contains sodium (9.72 mmol per 4 tablet dose) and calcium (7.5 mmol per 4 tablet dose). If you have been advised to follow a diet restricted in either of these please consult your doctor. The maximum recommended daily dose of this medicinal product contains 894.26 mg sodium (found in table salt). This is equivalent to 44.71% of the adult recommended maximum daily dietary intake for sodium. Talk to your doctor or pharmacist if you need this product on a daily basis for a prolonged period of time, especially if you have been advised to follow a low salt (sodium) diet. This medicine contains 5.6 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. These tablets contain carmoisine lake (E122) which may cause allergic reactions. This product can mask symptoms of other more serious, underlying medical conditions. If symptoms persist, or treatment is required for more than seven days continuously, please speak to your doctor or pharmacist.	Sodium Alginate 250.00mg + Sodium Bicarbonate 133.500mg + Calcium Carbonate 80.00mg Chewable Tablet	TGA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl.	Name of the manufacturer	Name of the Product	Generic Name	Therapeutic Class and code	Indication	Contra-indication & Side-effect	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
436.	Pharmasia Limited, Gojariapara. Bhawal Mirzapur, Gazipur	Sodium Alginate 500mg + Sodium Bicarbonate 267mg + Calcium Carbonate 160mg Chewable Tablet	Sodium Alginate BP 500mg + Sodium Bicarbonate BP 267mg + Calcium Carbonate BP 160mg	Antacids Therapeutic Code:007	Relief of the symptoms associated with reflux oesophagititis, hiatus hernia and all cases of epigastric distress where the underlying causes is gastro-esophageal reflux. Fast, soothing relief of heartburn and acid indigestion due to gastro-esophageal reflux.	**Contraindication:** Hypersensitivity to sodium alginate, potassium bicarbonate, calcium carbonate or to any of the excipients listed in the product. This product should not be used in patients with moderate or severe renal insufficiency. **Side-effects:** Very rarely (less than 1 in 10,000 patients treated) an allergic reaction to the ingredients may occur. Symptoms of this may include: skin rash itching, difficulty breathing, dizziness, swelling of the face, tongue or throat. If you experience these or any other side effects, stop taking the product and consult your doctor immediately. Other side effects of unknown frequency may include constipation, irritability, muscle twitching or muscle cramps, indigestion that comes back when you stop taking the tablets and high levels of calcium in the blood. **Precaution and Warning:** This medicine contains sodium (9.72 mmol per 4 tablet dose) and calcium (7.5 mmol per 4 tablet dose). If you have been advised to follow a diet restricted in either of these please consult your doctor. The maximum recommended daily dose of this medicinal product contains 894.26 mg sodium (found in table salt). This is equivalent to 44.71% of the adult recommended maximum daily dietary intake for sodium. Talk to your doctor or pharmacist if you need this product on a daily basis for a prolonged period of time, especially if you have been advised to follow a low salt (sodium) diet. This medicine contains 5.6 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. These tablets contain carmoisine lake (E122) which may cause allergic reactions. This product can mask symptoms of other more serious, underlying medical conditions. If symptoms persist, or treatment is required for more than seven days continuously, please speak to your doctor or pharmacist.	Sodium Alginate 250.00mg + Sodium Bicarbonate 133.500mg + Calcium Carbonate 80.00mg Chewable Tablet	TGA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Annexure - B: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান ভ্যাকসিন এর তালিকা

No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Therapeutic Class	Indication	Source of Product (Fill Finished/ API)	Registration Status of the Product (Fill Finished manufacturing Country)	Certificate	Registration Status of the Product (Internationally)/ Name of the Countries where this Product Export	WHO Prequalification (If any)	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	CMC & Clinical Trial & Toxicology committee এর সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
1.	Incepta Vaccine Ltd. ; Zirabo, Savar, Dhaka	Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen (s) Content)	Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen (s) Content) Each 0.5 ml contain: Purified Tetanus Toxoid BP 7.5 Lf + Purified Diptheria Toxoid BP 2 Lf	Vaccines Therapeutic Code: 069	Purified Tetanus Toxoid and Purified Diptheria Toxoid vaccine is an immunogenic and safe option for booster immunization against tetanus and diptheria in adolescent and adults.	PT BIO FARMA (PERSERO)., Indonesia	Indonesia	**GMP Certificate :** Yes **Lot Release Certificate of the Product: Yes**	Internationally registered: Eygpt Thailand Name of the Countries where this Product Export: Central africa, China, Ghana, Haiti, Thailand, Saudi Arabia	No	Purified Diptheria Toxoid BP 2 Lf (≥2 IU and <30 IU) + Purified Tetanus Toxoid BP 7Lf (≥40 IU)/ 0.5ml DCC 252	রেফারেন্স নাই	CMC & Clinical Trial & Toxicology committee এর সভার সুপারিশসহ ডিসিসি-র সভায় উপস্থাপন করা হবে।	ভ্যাক্সিনটি অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
2.	Incepta Vaccine Ltd. ; Zirabo, Savar, Dhaka	Diphtheria, Tetanus and Pertussis (Acellular Component) Vaccine (Adsorbed, Reduced Antigen (s) Content)	Diphtheria, Tetanus and Pertussis (Acellular Component) Vaccine (Adsorbed, Reduced Antigen (s) Content) Each 0.5 ml contain:Tetan	Vaccines Therapeutic Code: 069	This vaccine indicated for active booster immunization against tetanus, diphtheria and whooping cough in individuals from the age of 9 years onwards.	BioNet-Asia Co. Ltd., Thailand	Thailand	**Certificate :** Yes **Lot Release Certificate of the Product: Yes**		No	Tetanus Toxoid, reduced Diphtheria Toxoid and Acellular Pertussis (Tdap) Suspension for intramuscular injection Each dose of 0.5 ml contains:	রেফারেন্স নাই	CMC & Clinical Trial & Toxicology committee এর সভার সুপারিশসহ ডিসিসি-র সভায় উপস্থাপন করা হবে।	ভ্যাক্সিনটি অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Therapeutic Class	Indication	Source of Product (Fill Finished/ API)	Registration Status of the Product (Fill Finished manufacturing Country)	Certificate	Registration Status of the Product (Internationally)/ Name of the Countries where this Product Export	WHO Prequalification (If any)	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	CMC & Clinical Trial & Toxicology committee এর সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
			us Toxoid BP 7.5 Lf + Diphtheria Toxoid BP 2 Lf + Recombinant Pertussis Toxin (rPT) BP 2mcg + Filamentous Haemagglutinin (FHA) BP 5mcg								Diphtheria Toxoid 2 Lf, Tetanus Toxoid 5 Lf, Acellular Pertussis, Partusis Toxioid (PT) 2.5 mcg Filamentous Haemagglutinin (HFA) 5 mcg, Perfaction (PRN) 3 mcg Fimbriae Types 2 and 3 (FIM) 5 mcg DCC-242				

No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Therapeutic Class	Indication	Source of Product (Fill Finished/ API)	Registration Status of the Product (Fill Finished manufacturing Country)	Certificate	Registration Status of the Product (Internationally)/ Name of the Countries where this Product Export	WHO Prequalification (If any)	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	CMC & Clinical Trial & Toxicology committee এর সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
03	Incepta Vaccine Ltd. ; Zirabo, Savar, Dhaka	Enterovirus Type 71 Vaccine (Vero cell), Inactivated	Enterovirus Type 71 Vaccine (Vero Cell), Inactivated Each 0.5 ml contains EV71 neutralizing antibody titer no less than 3.0 EU	Vaccines Therapeutic Code: 069	Vaccination of EV71 vaccine can stimulate the body to produce immunity against EV71, and is used to prevent hand, foot and mouth disease caused by EV71 infection.	SINOVAC BIOTECH CO., LTD., China	China	**Certificate :** Yes **Lot Release Certificate of the Product: Yes**	Yes	Indonesia	No	রেফারেন্স নাই	CMC & Clinical Trial & Toxicology committee এর সভার সুপারিশসহ ডিসিসি-র সভায় উপস্থাপন করা হবে।	ভ্যাক্সিনটি অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Annex-C: আমদানির জন্য হিউম্যান মেডিসিন এর তালিকা

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
1	Manufacturer: Eli Lilly & Company, Indianapolis, IN 46285, USA' Local Agent: Healthcare Pharmaceuticals Ltd	Trulicity 3 mg/0.50 ml (Dulaglutide 3 mg/0.50 ml) Prefilled Pen & Cartridge	Dulaglutide 3 mg/0.50 ml Prefilled Pen & Cartridge	Antidiabetes Therapeutic code: 015	TRULICITY® is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated: as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. • to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors	**Side Effects:** The most common adverse reactions, reported in ≥5% of patients treated with TRULICITY are: nausea, diarrhea, vomiting, abdominal pain, and decreased appetite **Contraindication:** TRULICITY is contraindicated in patients with a personal or family history of medullary thyroid carcinoma or in patients with MultipleEndocrine Neoplasia syndrome type 2. • TRULICITY is contraindicated in patients with a prior serious hypersensitivity reaction to TRULICITY or any of the product components	0.75mg/0.50 ml 1.5mg/0.50 ml	USFDA- CPP EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
2	Manufacturer: Eli Lilly & Company, Indianapolis, IN 46285, USA' Local Agent: Healthcare Pharmaceuticals Ltd	Trulicity 4.5 mg/0.50 ml (Dulaglutide 4.5 mg/0.50 ml) Prefilled Pen & Cartridge	Dulaglutide 4.5 mg/0.50 ml Prefilled Pen & Cartridge	Antidiabetes Therapeutic code: 015	TRULICITY® is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated: as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. • to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors	**Side Effects:** The most common adverse reactions, reported in ≥5% of patients treated with TRULICITY are: nausea, diarrhea, vomiting, abdominal pain, and decreased appetite **Contraindication:** TRULICITY is contraindicated in patients with a personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2. • TRULICITY is contraindicated in patients with a prior serious hypersensitivity reaction to TRULICITY or any of the product components	0.75mg/0.50 ml 1.5mg/0.50 ml	USFDA- CPP EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
3.	**Manufacturer:** Getinge Stericool Medikal Aletler Sanayi Ve Ticaret Anonim Sirketi, Bestepe Mahallesi Nergiz Sk. No. 7/2/71 Yenimahalle, Ankara, Turkey **Exported By:** Getinge South East Asia Pte. Ltd., #06-01/02, BS Bendemeer Center, 20 Bendemeer Road, Singapore-339914 **Local Agent:** Globex Marketing Co. Ltd. 74/B/1, Green Road, RH Home Center (6th Floor) , Dhaka	Stericool Hydrogen Peroxide Plasma Sterilizer	Hydrogen Peroxide (59%)	Others Classifications Therapeutic code: 075	Cleaning/ Disinfecting of reusable Surgical/ Medical Instruments	N/A	New	FSC – Turkey মেডিকেল ডিভাইস হিসেবে অনুমোদিত।	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
4.	**Manufacture:** Biotest AG Landsteinerstraße 5 D-63303 Dreieich Germany **Local Agent:** Eon Pharmaceuticals Ltd 304, tejgaon I/A,Dhaka-1208	Fovepta	Human hepatitis B Immunoglobulin 500IU/ml solution for In‡jvection	Immunoglobulin Therapeutic code: 069	Therapeutic indications Immunoprophylaxis of hepatitis B - In case of accidental exposure in non-immunised subjects (including persons whose vaccination is incomplete or status unknown). - In haemodialysed patients, until vaccination has become effective. - In the newborn of a hepatitis B virus carrier-mother.	**Contraindication:** Hypersensitivity to human immunoglobulins, especially in patients with antibodies against IgA. Side effect: fever, mouth sores, red or swollen gums; a light-headed feeling, like you might pass out; liver problems--upper stomach pain, loss of appetite, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes); symptoms of fluid buildup around your lungs--chest pain, pain when you breathe, rapid heart		CPP-Germany	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					- In subjects who did not show an immune response (no measurable hepatitis B antibodies) after vaccination and for whom a continuous prevention is necessary due to the continuous risk of being infected with hepatitis B.	rate, feeling light-headed or short of breath (especially when lying down); or symptoms of a blood clot or stroke--sudden numbness or weakness (especially on one side of the body); chest pain, trouble breathing, rapid heart rate, coughing up blood; or pain, swelling, warmth, or redness in your arms or legs. Common side effects may include: nausea, vomiting, diarrhea, upset stomach; back pain, tired feeling; tremors, memory problems, agitation, vision problems; cold symptoms such as stuffy nose, sneezing, sore throat; mild rash; or pain, redness, bruising, or tenderness where the medicine was in‡jvected.				
5.	Manufacture: Biotest AG Landsteinerstraße 5 D-63303 Dreieich Germany Local Agent: Eon Pharmaceuticals Ltd 304, tejgaon I/A,Dhaka-1208 Factory: 217/5,Chandana,Joydevpur,Gazipur	Hepatect CP	Human Hepatitis B Immunoglobulin 50IU/ml solution for Infusion	Immunoglobulin Therapeutic code: 069	Therapeutic indications Immunoprophylaxis of hepatitis B - In case of accidental exposure in non-immunised subjects (including persons whose vaccination is incomplete or status unknown). - In haemodialysed patients, until vaccination has become effective. - In the newborn of a hepatitis B virus carrier-mother. - In subjects who did not show an immune response (no measurable hepatitis B antibodies) after vaccination and for whom a continuous prevention is necessary due to the continuous risk of being infected with hepatitis B.	Contraindication: Hypersensitivity to human immunoglobulins, especially in patients with antibodies against IgA. Side effect:fever, mouth sores, red or swollen gums; a light-headed feeling, like you might pass out; liver problems--upper stomach pain, loss of appetite, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes); symptoms of fluid buildup around your lungs--chest pain, pain when you breathe, rapid heart rate, feeling light-headed or short of breath (especially when lying down); or symptoms of a blood clot or stroke--sudden numbness or weakness (especially on one side of the body); chest pain, trouble breathing, rapid heart rate, coughing up blood; or pain, swelling, warmth, or redness in your arms or legs. Common side effects may include: nausea, vomiting, diarrhea, upset		CPP-Germany	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						stomach; back pain, tired feeling; tremors, memory problems, agitation, vision problems; cold symptoms such as stuffy nose, sneezing, sore throat; mild rash; or pain, redness, bruising, or tenderness where the medicine was inactive.				
6.	**Manufacturer:** LES LABORATOIRES SERVIER INDUSTRIE 905 ROUTE DE SARAN 45520 GIDY FRANCE **Local Representative:** Transcom Distribution Co. Ltd 52, Motijheel C/A Dhaka 1000	COSYREL 5MG/5MG, film-coated tablets	Bisoprolol Fumarate 5mg + Perindopril Arginine 5 mg	Antihypertensive Therapeutic Code: 022	Substitution therapy for treatment of hypertension and/or stable coronary artery disease and/or chronic heart failure	**Contraindications:** Acute heart failure or during episodes of heart failure decompensation requiring i.e. inotropic therapy • Cardiogenic shock • Second- or third-degree atrioventricular block (without pacemaker) • Sick sinus syndrome • Sinoatrial block • Symptomatic bradycardia • Symptomatic hypotension • Severe bronchial asthma or severe chronic obstructive pulmonary disease • Severe forms of peripheral arterial occlusive disease or severe forms of Raynaud's syndrome • Untreated phaeochromocytoma • Metabolic acidosis • History of angioedema associated with previous ACE inhibitor therapy • Hereditary or idiopathic angioedema • Second and third trimesters of pregnancy • Concomitant use of COSYREL with aliskiren-containing products in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73m²) **Side Effects:** Headache, dizziness, vertigo,	Bisoprolol Hemifumarate 1.25mg, 2.5mg, 5.0mg & 10mg Tablet Perindopril Erbumine 2mg, 4mg & 8mg Tablet	- CPP of France, Switzerland	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						taste disturbances, pins and needles, tingling or numbness of the hands of feet, vision disturbances, tinnitus, feeling of coldness in hands or feet, cough, shortness of breath, gastro-intestinal disorders such as nausea, vomiting, abdominal pain, difficulty of digestion or dyspepsia, diarrhoea, constipation, allergic reactions such as skin rashes, itching, muscle cramps, feeling of tiredness, fatigue.				
7.	**Manufacturer:** LES LABORATOIRES SERVIER INDUSTRIE 905 ROUTE DE SARAN 45520 GIDY FRANCE **Local Representative:** Transcom Distribution Co. Ltd 52, Motijheel C/A Dhaka 1000	COSYREL 5MG/10MG, film-coated tablet	Bisoprolol Fumarate 5mg + Perindopril Arginine 10mg	Antihypertensive Therapeutic Code: 022	Substitution therapy for treatment of hypertension and/or stable coronary artery disease and/or chronic heart failure	**Contraindications**: Acute heart failure or during episodes of heart failure decompensation requiring i.e. inotropic therapy • Cardiogenic shock • Second- or third-degree atrioventricular block (without pacemaker) • Sick sinus syndrome • Sinoatrial block • Symptomatic bradycardia • Symptomatic hypotension • Severe bronchial asthma or severe chronic obstructive pulmonary disease • Severe forms of peripheral arterial occlusive disease or severe forms of Raynaud's syndrome • Untreated phaeochromocytoma • Metabolic acidosis • History of angioedema associated with previous ACE inhibitor therapy • Hereditary or idiopathic angioedema • Second and third trimesters of pregnancy • Concomitant use of COSYREL with	Bisoprolol Hemifumarate 1.25mg, 2.5mg, 5.0mg & 10mg Tablet Perindopril Erbumine 2mg, 4mg & 8mg Tablet	- CPP of France, Switzerland	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						aliskiren-containing products in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73m²) **Side Effects:** headache, dizziness, vertigo, taste disturbances, pins and needles, tingling or numbness of the hands of feet, vision disturbances, tinnitus, feeling of coldness in hands or feet, cough, shortness of breath, gastro-intestinal disorders such as nausea, vomiting, abdominal pain, difficulty of digestion or dyspepsia, diarrhoea, constipation, allergic reactions such as skin rashes, itching, muscle cramps, feeling of tiredness, fatigue.				
8.	**Manufacturer:** ALIVE PTY LTD. UNIT 1-45 KENWAY DRIVE UNDERWOOD QLD 4119 AUSTRALIA **Local Representative:** JMI HOSPITAL REQUISITE Mfg. Ltd. Kazi Nazrul Islam Avenue Dhaka-1212	98 Alive Immune	Zinc Amino acid Chelate -75mg, Melaleuca Alternifolia leaf Oil Essential - 150mg	Others Classifications Therapeutic code: 075	1.Antioxidant/Reduce free radicals formed in the body 2. Maintain/ Support Immune system Health.	1. May be dangerous if taken in large amounts or for a long period. 2. Contains Zinc which may be dangerous if taken in large amounts or for a long period.	New	TGA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
9.	**Manufacturer name:** Laboratorios Rubio, S.A., Industria 29, Pol. Ind. Comte de Sert. 08755 Castellbisbal (Barcelona), Spain **Local Agent:** City Overseas Ltd 218,Mitford Road,Dhaka	Methylphenidate Hydrochloride 20mg Tablet	Methylphenidate Hydrochloride 20mg	Antidepressants Therapeutic Code:014	Treatment of attention deficit hyper activity disorder (ADHD).	**Contraindications:** Methylphenidate is contraindicated in patients with severe hypertension, angina pectoris, cardiac arrhythmias, heart failure, recent myocardial infarction, hyperthyroidism or thyrotoxicosis **Side effect:** Nervousness, irritability, difficulty falling asleep or staying asleep, dizziness, nausea, vomiting.	5mg, 10mg Tab., 10mg, 20mg Capsule	COPP-Spain (Country of Origin) COPP-UK	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
10	**Manufacturer name:** Panpharma GmbH, Bunsenstrasse 4, 22946 Trittiu, Germany **Local Agent:** City Overseas Ltd 218,Mitford Road,Dhaka	Fentanyl Panpharma 0.5mg Solution for Injection	Fentanyl 0.5mg/10ml	Opioid Analgesics Therapeutic Code:065	Short duration analgesia during pre-medication, induction and maintenance of anaesthesia, and in the immediate post-operative period. Opioid analgesic supplement to general and regional anaesthesia. Combination with a neuroleptic as an anaesthetic pre-medication for the induction of anaesthesia, and as an adjunct in the maintenance of general and regional anaesthesia.	**Contraindication:** Known hypersensitivity or intolerance to Fentanyl, other opioid analgesics, or to any of the excipients. As for any opioid analgesic, Fentanyl should not be used in patients susceptible to respiratory depression, use of Fentanyl in patients who have received MAO inhibitors within 14 days is not recommended. Fentanyl may cause muscle rigidity upon IV administration. Therefore, the need for reversal and muscle relaxants contraindicates its use in patients with a history of myasthenia gravis. For Children two years of age or younger Safe conditions for use have not been established. Use in patient after operative interventions in the biliary tract is not recommended. **Side Effect:** Fentanyl Injection may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. Common Side Effects	100mcg, 200mcg -Tablet 0.10mcg/2 ml In‡jvection 2.5mg/50ml Injection	Germany	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						are, An Unusual Sense Of Well Being Sedation, Headaches, Post-Operative Confusion Or Agitation, Neurological Or Airway, Complications Of Anesthesia, Vein Pain O Inflammation, Chills Or Lowered Body Temperature, Visual Disturbance.				
11	**Manufacturer name:** Octapharma AB, Lars Forssells gata 23, S-112 75 Stockholm, Sweden **Local Agent:** City Overseas Ltd 218,Mitford Road,Dhaka	NUWIQ 250 IU powder and solvent for solution for injection	Simoctocog alfa, Human Coagulation Factor VIII (rDNA) 250 IU	Blood Coagulating Therapeutic Code:033	Treatment and prophylaxis of bleeding in patients with hemophilia A (congenital factor VIII deficiency). NUWIQ can be used for all age groups.	**Contraindication**: Hypersensitivity to the active substance or to any of the excipients. **Side Effect:** Hypersensitivity or allergic reactions (which may include angioedema, burning and stinging at the infusion site, chills, flushing, headache, hives, hypotension, lethargy, nausea, rash, restlessness, tachycardia, tightness of the chest, tingling, urticarial, including generalized urticarial, vomiting, wheezing) have rarely been observed with FVIII preparations and may in some cases progress to severe anaphylaxis (including shock). Development of neutralizing antibodies (inhibitors) may occur in patients with haemophilia A treated with factor VIII, including with NUWIQ. If such inhibitors occur, the condition will manifest itself as an insufficient clinical response. In such cases, it is recommended that a specialized haemophilia centre be contacted.	NEW BNF 78, Page 113	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
12	**Manufacturer name:** Octapharma AB, Lars Forssells gata 23, S-112 75 Stockholm, Sweden	NUWIQ 500 IU powder and solvent for solution for injection	Simoctocog alfa, Human Coagulation Factor VIII (rDNA) 500 IU	Blood Coagulating Therapeutic Code:033	Treatment and prophylaxis of bleeding in patients with hemophilia A (congenital factor VIII deficiency). NUWIQ can be used for all age groups.	**Contraindication**: Hypersensitivity to the active substance or to any of the excipients. **Side Effect:** Hypersensitivity or allergic reactions (which may include angioedema, burning and stinging at the infusion site, chills, flushing, headache, hives, hypotension,	NEW BNF 78, Page 113	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Local Agent: City Overseas Ltd 218,Mitford Road, Dhaka					lethargy, nausea, rash, restlessness, tachycardia, tightness of the chest, tingling, urticarial, including generalized urticarial, vomiting, wheezing) have rarely been observed with FVIII preparations and may in some cases progress to severe anaphylaxis (including shock). Development of neutralizing antibodies (inhibitors) may occur in patients with haemophilia A treated with factor VIII, including with NUWIQ. If such inhibitors occur, the condition will manifest itself as an insufficient clinical response. In such cases, it is recommended that a specialized hemophilia center be contacted.				
13.	**Manufacturer name:** Octapharma AB, Lars Forssells gata 23, S-112 75 Stockholm, Sweden **Local Agent:** City Overseas Ltd 218,Mitford Road,Dhaka	NUWIQ 1000 IU powder and solvent for solution for injection	Simoctocog alfa, Human Coagulation Factor VIII (rDNA) 1000 IU	Blood Coagulating Therapeutic Code:033	Treatment and prophylaxis of bleeding in patients with hemophilia A (congenital factor VIII deficiency). NUWIQ can be used for all age groups.	**Contraindication**: Hypersensitivity to the active substance or to any of the excipients. **Side Effect:** Hypersensitivity or allergic reactions (which may include angiooedema, burning and stinging at the infusion site, chills, flushing, headache, hives, hypotension, lethargy, nausea, rash, restlessness, tachycardia, tightness of the chest, tingling, urticaria, including generalized urticaria, vomiting, wheezing) have rarely been observed with FVIII preparations and may in some cases progress to severe anaphylaxis (including shock). Development of neutralizing antibodies (inhibitors) may occur in patients with hemophilia A treated with factor VIII, including with NUWIQ. If such inhibitors occur, the condition will manifest itself as an insufficient clinical response. In such cases, it	NEW BNF 78, Page 113	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						is recommended that a specialized hemophilia center be contacted.				
14	**Manufacturer:** Dr. Reddy's Laboratories Limited FTO Unit-VII, Plot No. P1- P9, Phase- III, V SEZ, Duvvada, Visakhapatnam, Andhra Pradesh 530046 India. **Local Agent:** ZAS Corporation Ltd., 80/22 Mymenshing Road, Nurjehan Tower (3rd Floor) Dhaka-1000,	a) Sirolimus 1 mg Film Coated Tablet	Sirolimus USP 1mg	Immune-suppressant Therapeutic Code:058	Sirolimus is indicated for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving a renal transplant. It is recommended that Sirolimus be used initially in combination with cyclosporine microemulsion and corticosteroids for 2 to 3 months. Sirolimus may be continued as maintenance therapy with corticosteroids only if cyclosporine microemulsion can be progressively discontinued. Sirolimus is indicated for the treatment of patients with sporadic lymphangioleiomyomatosis with moderate lung disease or declining lung function.	**Contraindication:** Hypersensitivity to the active substance or to any of the excipients. **Side effects:** The most frequently reported adverse reactions (frequency common (≥ 1/100 to < 1/10)) are: Fungal infections, urinary tract infection, candida infection, anaemia, anxiety, insomnia, dizziness, headache, hypertension, hypotension, gastrointestinal and abdominal pain, nausea, vomiting, constipation, diarrhoea, flatulence, bloating and distension, liver function tests abnormal (increased alanine aminotransferase (ALT), aspartate aminotransferase (AST) or alkaline phosphatase (ALP)), rash, pruritus, limb pain, serum creatine phosphokinase (CPK) increased, infusion site reactions, pyrexia, asthenia.	New	CPP- India & USA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
		b) Sirolimus 2 mg Film-Coated Tablet	Sirolimus USP 2mg	Immune-suppressant Therapeutic Code:058	Sirolimus is indicated for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving a renal transplant. It is recommended that Sirolimus be used initially in combination with cyclosporine microemulsion and corticosteroids for 2 to 3 months. Sirolimus may be continued as maintenance therapy with corticosteroids only if	**Contraindication:** Hypersensitivity to the active substance or to any of the excipients. **Side effects:** The most frequently reported adverse reactions (frequency common (≥ 1/100 to < 1/10)) are: Fungal infections, urinary tract infection, candida infection, anaemia, anxiety, insomnia, dizziness, headache, hypertension, hypotension, gastrointestinal and abdominal pain, nausea, vomiting, constipation,	New	CPP- India & USA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					cyclosporine microemulsion can be progressively discontinued. Sirolimus is indicated for the treatment of patients with sporadic lymphangioleiomyomatosis with moderate lung disease or declining lung function.	diarrhoea, flatulence, bloating and distension, liver function tests abnormal (increased alanine aminotransferase (ALT), aspartate aminotransferase (AST) or alkaline phosphatase (ALP)), rash, pruritus, limb pain, serum creatine phosphokinase (CPK) increased, infusion site reactions, pyrexia, asthenia.				
15	**Manufacturer:** Waymade Plc Josselin Road, Burnt Mills Industrial Estate, Basildon, SS13 1QF, United Kingdom **Local Agent:** ZAS Corporation Ltd., 80/22 Mymenshing Road, Nurjehan Tower (3rd Floor) Dhaka-1000	Synacthen 250mcg/ml ampoule Solution for Injection	Tetracosactide Acetate Ph. Eu 250mcg/ml	Hormone Therapeutic Code: 056	Diagnostic test for the investigation of adrenocortical insufficiency.	**Contraindication:** Synacthen is contra-indicated in patients with allergic disorders (e.g. asthma), acute psychosis, infectious diseases, peptic ulcer, refractory heart failure, Cushing's syndrome, treatment of primary adrenocortical insufficiency and adrenocongenital syndrome. **Side Effect:** Anaphylactic shock or severe allergic reaction (symptoms may include redness or pain at the injection site, rash, itching, hives or flushing, dizziness, feeling or being sick, difficulty breathing, and swelling of the face, lips, tongue or other parts of the body, feeling very unwell). This tends to be more severe in people, who suffer from allergies (especially asthma). For these reasons, you should be monitored carefully for 30 minutes after the injection. If you have had an allergic reaction, you should never be treated with Synacthen Ampoules or similar medicines again.	New	CPP- UK	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
16	**Manufacturer:** Andersonbrecon (UK) Limited Units 2-7, Wye Valley Business Park, Brecon Road, Hay-Onwye, Hereford, Hr3 5pg, United Kingdom **Local Agent:** ZAS Corporation Ltd., 80/22 Mymenshing Road, Nurjehan Tower (3rd Floor) Dhaka-1000,	Bijuva 1mg/100mg Soft Capsule	Estradiol Hemihydrate Ph. Eu 1.00mg + Progesterone Ph. Eu 100.0mg	Hormone Therapeutic Code: 056	BIJUVE is a Hormone Replacement Therapy (HRT). It contains two types of female hormones, an oestrogen and a progestogen. BIJUVE is used in postmenopausal women with at least 12 months (1 year) since their last natural period. Continuous combined hormone replacement therapy (HRT) for estrogen deficiency symptoms in postmenopausal women with intact uterus and with at least 12 months since last menses. The experience in treating women older than 65 years is limited.	**Contraindications:** Known, past or suspected breast cancer; Known or suspected estrogen-dependent malignant tumours (e.g. endometrial cancer); Undiagnosed genital bleeding; Untreated endometrial hyperplasia; Previous or current venous thromboembolism (deep vein thrombosis, pulmonary embolism); Known thrombophilic disorders (e.g. protein C, protein S, or antithrombin deficiency, Active or recent arterial thromboembolic disease (e.g. angina, myocardial infarction); Acute liver disease or a history of liver disease as long as liver function tests have failed to return to normal; Porphyria; Known hypersensitivity to the active substances or to any of the excipients. **Side effects:** The most commonly reported related adverse drug reactions for Bijuve in clinical trials were breast tenderness (10.4%), headache (3.4%), nausea (2.2%), pelvic pain (3.1%), vaginal hemorrhage (3.4%), and vaginal discharge (3.4%).	New	CPP- UK	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
17	**Manufacturer:** OM Pharma SA Rue du Bois-du-Lan 22 1217 Meyrin Switzerland **Local Agent:** ZAS Corporation Ltd., 80/22	Dicynone 500 Capsule	Etamsylate Ph. Eur 500mg	Antihemorrhagic agent Therapeutic Code: 019	**In surgery**: Prophylaxis and treatment of pre-operative and post-operative capillary haemorrhages in all delicate surgeries or in highly vascularised tissue: ENT, gynaecology, obstetrics, urology, dentistry, ophthalmology, plastic surgery and reconstructive surgery. **In Internal Medicine:** Prophylaxis and treatment of capillary haemorrhages, regardless	**Contraindications:** Acute porphyria. Hypersensitivity to any of the ingredients of the medicinal product. **Side effects:** Gastralgia, nausea, headache, skin rash. Dicynone 500 tablets contains sulphite as antioxidant that may cause allergic reactions, nausea and diarrhea in susceptible patients.	New	CPP- Switzerland	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Mymenshing Road, Nurjehan Tower (3rd Floor) Dhaka-1000,				of their origin and location: haematuria, haematemesis and melena, epistaxis, gingivorrhagia. In Gynecology Metrorrhagia, primary menorrhagia or menorrhagia due to intrauterine devices, where there is no organic pathology					
18	**Manufacturer:** LTS Lohmann Therapie-Systeme AG Lohmannstraße 2, 56626 Andernach, Germany **Product License Holder:** Theramex ireland Ltd. Ireland **Local Agent:** ZAS Corporation Ltd., 80/22 Mymenshing Road, Nurjehan Tower (3rd Floor) Dhaka-1000,	**Fem7- Sequi** 50mcg+ 50mcg/10mcg/24hours Transdermal patch	Phase 1: Each patch contains Estradiol Hemihydrate Ph. Eur 1.5 mg Phase 2: Each patch contains Estradiol Hemihydrate Ph. Eur 1.5 mg + levonorgestrel Ph. Eur 1.5 mg	Hormone Therapeutic Code: 056	Fem7 is a Hormone Replacement Therapy (HRT) containing an oestrogen, estradiol hemihydrate, which is a sexual female hormone. Fem7 is used in postmenopausal women more than one year after menopause. FemSeven is used for: 1. Relief of symptoms occurring after menopause. 2. Prevention of osteoporosis The experience in treating women older than 65 years is limited.	**Contraindications:** Known, past or suspected breast cancer; Known or suspected oestrogen-dependent malignant tumours (e.g. endometrial cancer);Undiagnosed genital bleeding; Untreated endometrial hyperplasia; Previous idiopathic or current venous thromboembolism (deep venous thrombosis, pulmonary embolism); Active or recent arterial thromboembolic disease, (e.g. angina, myocardial infarction);Acute liver disease, or a history of liver disease as long as liver function tests have failed to return to normal;Known hypersensitivity to the active substances or to any of the excipients;Porphyria. **Side effects:** The following diseases are reported more often in women using HRT compared to women not using HRT: breast cancer; abnormal growth or cancer of the lining of the womb (endometrial hyperplasia or cancer); ovarian cancer; blood clots in the veins of the legs or lungs (venous thromboembolism); heart disease; stroke; probable memory loss if HRT is started over the age of 65.	New	CPP- Germany	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
		b) Fem7-50µg Transdermal patch	Each patch contains Estradiol Hemihydrate Ph. Eur 1.5 mg	Hormone Therapeutic Code: 056	It is a Hormone Replacement Therapy (HRT) containing an oestrogen, estradiol hemihydrate, which is a sexual female hormone. It is used in postmenopausal women more than one year after menopause. FemSeven is used for: 1. Relief of symptoms occurring after menopause. The experience in treating women older than 65 years is limited. 2. Prevention of osteoporosis	**Contraindications:** Known, past or suspected breast cancer; Known or suspected oestrogen-dependent malignant tumours (e.g. endometrial cancer);Undiagnosed genital bleeding; Untreated endometrial hyperplasia; Previous idiopathic or current venous thromboembolism (deep venous thrombosis, pulmonary embolism);Known thrombophilia disorders (e.g. protein C, protein S, or antithrombin deficiency, Active or recent arterial thromboembolic disease, (e.g. angina, myocardial infarction);Acute liver disease, or a history of liver disease as long as liver function tests have failed to return to normal; Known hypersensitivity to the active substances or to any of the excipients; Porphyria. **Side effects:** The following diseases are reported more often in women using HRT compared to women not using HRT: • breast cancer; • abnormal growth or cancer of the lining of the womb (endometrial hyperplasia or cancer); • ovarian cancer; • blood clots in the veins of the legs or lungs (venous thromboembolism); • heart disease; • stroke; • probable memory loss if HRT is started over the age of 65	New	CPP- Germany.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
		c) Fem7- Conti 50mcg/7mcg/24hours Transdermal patch	Each patch contains Estradiol Hemihydrate Ph.	Hormone Therapeutic	It is a Hormone Replacement Therapy (HRT) containing an oestrogen, estradiol hemihydrate,	**Contraindications:** Known, past or suspected breast cancer; Known or suspected oestrogen-dependent malignant tumours (e.g.	New	CPP- Germany	আবেদন না মঞ্জুর করার সুপারিশ করা	আবেদন না মঞ্জুর করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
			Eur 1.5 mg + levonorgestrel Ph. Eur 0.525mg	Code: 056	which is a sexual female hormone. It is used in postmenopausal women more than one year after menopause. FemSeven is used for: 1. Relief of symptoms occurring after menopause. 2. Prevention of osteoporosis The experience in treating women older than 65 years is limited.	endometrial cancer);Undiagnosed genital bleeding; Untreated endometrial hyperplasia; Previous idiopathic or current venous thromboembolism (deep venous thrombosis, pulmonary embolism); Active or recent arterial thromboembolic disease, (e.g. angina, myocardial infarction);Acute liver disease, or a history of liver disease as long as liver function tests have failed to return to normal; Known hypersensitivity to the active substances or to any of the excipients; Porphyria. **Side effects:** The following diseases are reported more often in women using HRT compared to women not using HRT: breast cancer; abnormal growth or cancer of the lining of the womb (endometrial hyperplasia or cancer); ovarian cancer; blood clots in the veins of the legs or lungs (venous thromboembolism); heart disease; stroke; probable memory loss if HRT is started over the age of 65.			যেতে পারে।	
19	**Manufacturer:** Pancap Pharma Inc., 50 Valleywood Drive, Unit 6, Markham, Ontario L3R 6E9 Canada. **Local Agent:** ZAS Corporation Ltd., 80/22 Mymenshing Road,	Provocholine Powder for Solution 100 mg/Vial	Methacholine Chloride USP 100 mg/Vial	Cholinergic Receptor Agonist Therapeutic Code: 011	Provocholine indicated for the diagnosis of bronchial airway hyperreactivity in subjects who do not have clinically apparent asthma.	**Contraindications:** It is contraindicated in patients with known hypersensitivity to this drug or to other parasympathomimetic agents. Repeated administration of Provocholine by inhalation other than on the day that a patient undergoes challenge with increasing doses is contraindicated Inhalation challenge should not be performed in patients receiving any beta-adrenergic blocking agent because in such patients' responses to methacholine chloride can be exaggerated or prolonged, and may not respond as readily to accepted modalities of treatment.	New	CPP- Canada & USA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Nurjehan Tower (3rd					**Side effects:** Side Effects associated with 153 inhaled methacholine chloride challenges include one occurrence each of headache, throat irritation, light-headedness and itching. Provocholine is to be administered only by inhalation. When administered orally or by injection, methacholine chloride is reported to be associated with nausea and vomiting, substernal pain or pressure, hypotension, fainting and transient complete heart block.				
20	**Manufacturer:** OM Pharma SA Rue du Bois-du-Lan 22 1217 Meyrin Switzerland. **Local Agent:** ZAS Corporation Ltd., 80/22 Mymenshing Road, Nurjehan Tower (3rd Floor) Dhaka-1000.	Uro-Vaxom Capsule	OM-89 lyophilizate Ph. Eur 60.00 mg corresponding to Lysates of E.coli Ph .Eur 6.00 mg+ Anhydrous propyl gallate Ph. Eur 0.08mg + Anhydrous sodium glutamate USP 3.03mg + Mannitol Ph. Eur 60.00mg.	Immunostimulant Therapeutic Code: 075	Uro-Vaxom is a medicine of biological origin used as an immunostimulant to increase your natural defences. Uro-Vaxom can prevent recurring urinary tract infections, particularly cystitis. It can also be used in combination with other possible treatments prescribed during the acute phase of urinary infections.	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Side effects:** Adverse reactions are presented by organ class and the frequency with which they were observed in clinical trials and/or during post-market surveillance during application of Uro-Vaxom. Frequencies are defined as: Common: <1/10 to ≥1/100; Uncommon: <1/100 to ≥1/1,000; Rare: <1/1,000 to ≥1/10,000; Very rare: <1/10,000. Diarrhea, nausea, headache, skin rash. Abdominal Pain, Skin and subcutaneous tissue disorders.	New	CPP-Switzerland	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
21	**Manufacturer:** OM Pharma SA Rue du Bois-du-Lan 22 1217 Meyrin Switzerland. **Local Agent:** ZAS Corporation Ltd., 80/22	Broncho-Vaxom Enfants Capsule	Standardized OM-89 lyophilizate Ph.Eur 20.00 mg corresponding to Lyophilized Bacterial Lysate of (Haemophilus influenzae, Streptococcus pneumoniae, Klebsiella	Immunostimulant Therapeutic Code: 075	➢ Immunotherapy. ➢ Prevention of recurrent infections of the airways and acute infectious exacerbations of chronic bronchitis. ➢ Co-medication in the treatment of acute airway infections.	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Side effects:** Common: Diarrhea, nausea, headache, skin rash. Abdominal Pain, Skin and subcutaneous tissue disorders, Vomiting. uncommon: hypersensitivity (rash erythematous, rash generalised, erythema, oedema, eyelid oedema, face oedema, peripheral oedema, swelling, face swelling, pruritus, generalised pruritus, dyspnoea).	Lyophilized Bacterial Lysates 50mg Sublingual Tablet Lyophilized Bacterial Lysates INN 50mg (Lyophilized Bacterial	CPP-Switzerland	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000.		pneumoniae ssp. Pneumoniae and ozaenae, Staphylococcus aureus, Streptococcus pyogenes and sanguinis, Moraxella (Branhamella) catarrhalis Ph. Eur 3.50 mg + Anhydrous propyl gallate Ph.Eur 0.042mg + Monosodium glutamate USP 1.515mg+ Mannitol Ph. Eur 20.00 mg				Lysates of Staphylococcus aureus, Streptococcus pyogenes and viridans, Klebsiella pneumonia and ozaenae, Haemophilus influenzae, Neisseria catarrhalis Diplococcus pneumonia: 7 mg and 43mg of which corresponded to lyophilization substrate: Glycine) Bacterial Lysate			
22	**Manufacturer:** VETTER Pharma-Fertigung GmbH & Co. KG, Schuetzenstr. 87 and 99-101-88212 Ravensburg, Germany **Local Agent:**	Remsima 120mg/ml Pre-Filled Syringe	Infliximab Ph. Eur 120mg/ml	Immune-suppressant Therapeutic Code:058	Remsima is indicated for: Rheumatoid arthritis, Adult Crohn's disease, Pediatric Crohn's disease, Ulcerative colitis, Pediatric ulcerative colitis, Ankylosing spondylitis Psoriatic arthritis,	**Contraindications:** Hypersensitivity to the active substance, to other murine proteins, or to any of the excipients. Patients with tuberculosis or other severe infections such as sepsis, abscesses, and opportunistic infections. Patients with moderate or severe heart failure (NYHA class III/IV). **Side effects:** Viral infection (e.g. influenza, herpes virus infection).		EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	ZAS Corporation 80/22 Mymenshing Road, Nurjehan Tower (3rd Floor) Dhaka-1000.					Bacterial infections (e.g. sepsis, cellulitis, abscess). Meningitis, opportunistic infections (such as invasive fungal infections [pneumocystosis, histoplasmosis, aspergillosis, coccidioidomycosis, cryptococcosis, blastomycosis], bacterial infections [atypical mycobacterial, listeriosis, salmonellosis], and viral infections [cytomegalovirus]), parasitic infections, hepatitis B reactivation				
23	**Manufacturer:** VETTER Pharma-Fertigung GmbH & Co. KG, Schuetzenstr. 87 and 99-101-88212 Ravensburg, Germany. **Local Agent:** ZAS Corporation 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000.	Remsima Pre-Filled 120mg/ml Pen	Infliximab Ph. Eur 120mg/ml	Immune-suppressant Therapeutic Code:058	Remsima is indicated for: Rheumatoid arthritis, Adult Crohn's disease, Pediatric Crohn's disease, Ulcerative colitis, Pediatric ulcerative colitis, Ankylosing spondylitis Psoriatic arthritis,	**Contraindications:** Hypersensitivity to the active substance, to other murine proteins, or to any of the excipients. Patients with tuberculosis or other severe infections such as sepsis, abscesses, and opportunistic infections. Patients with moderate or severe heart failure (NYHA class III/IV). **Side effects:** Viral infection (e.g. influenza, herpes virus infection). Bacterial infections (e.g. sepsis, cellulitis, abscess). Meningitis, opportunistic infections (such as invasive fungal infections [pneumocystosis, histoplasmosis, aspergillosis, coccidioidomycosis, cryptococcosis, blastomycosis], bacterial infections [atypical mycobacterial, listeriosis, salmonellosis], and viral infections [cytomegalovirus]), parasitic infections, hepatitis B reactivation		EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
24	**Manufacturer:** Celltrion Pharma Inc. 82, 2 Sandan-ro,	Yuflyma 80mg /0.8ml Pre-Filled Pen	Adalimumab Ph. Eur 80mg /0.8ml	Immune-suppressant Therapeutic	Yuflyma in combination with methotrexate, is indicated for: the treatment of moderate to severe, active rheumatoid arthritis in adult	**Contraindications:** Hypersensitivity to the active substance, to other murine proteins, or to any of the excipients. Patients with tuberculosis or other severe		CPP-Korea EMA	আবেদন না মঞ্জুর করার সুপারিশ করা	আবেদন না মঞ্জুর করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea. . **Local Agent:** ZAS Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000.			Code:058	patients when the response to disease-modifying anti-rheumatic drugs including methotrexate has been inadequate. the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate. Yuflyma can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Adalimumab has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with methotrexateetc.	infections such as sepsis, abscesses, and opportunistic infections. Patients with moderate or severe heart failure (NYHA class III/IV). **Side effects:** Respiratory tract infections (including lower and upper respiratory tract infection, pneumonia, sinusitis, pharyngitis, nasopharyngitis and pneumonia herpes viral) Systemic infections (including sepsis, candidiasis and influenza), intestinal infections (including gastroenteritis viral), skin and soft tissue infections (including paronychia, cellulitis, impetigo, necrotising fasciitis and herpes zoster), ear infections, oral infections (including herpes simplex, oral herpes and tooth infections), reproductive tract infections (including vulvovaginal mycotic infection), urinary tract infections (including pyelonephritis), fungal infections, joint infections.			যেতে পারে।	
25	**Manufacturer:** Celltrion Pharma Inc. 82, 2 Sandan-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea. **Local Agent:**	Yuflyma 80mg /0.8ml Pre-Filled Syringe	Adalimumab Ph.Eur 80mg /0.8ml	Immune-suppressant Therapeutic Code:058	Yuflyma in combination with methotrexate, is indicated for: the treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drugs including methotrexate has been inadequate. the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate. Yuflyma can be given as monotherapy in case of intolerance	**Contraindications:** Hypersensitivity to the active substance, to other murine proteins, or to any of the excipients. Patients with tuberculosis or other severe infections such as sepsis, abscesses, and opportunistic infections. Patients with moderate or severe heart failure (NYHA class III/IV). **Side effects:** Respiratory tract infections (including lower and upper respiratory tract infection, pneumonia, sinusitis, pharyngitis, nasopharyngitis and pneumonia herpes viral)		CPP Korea EMA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	ZAS Corporation 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000				to methotrexate or when continued treatment with methotrexate is inappropriate. Adalimumab has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with methotrexates.	Systemic infections (including sepsis, candidiasis and influenza), intestinal infections (including gastroenteritis viral), skin and soft tissue infections (including paronychia, cellulitis, impetigo, necrotising fasciitis and herpes zoster), ear infections, oral infections (including herpes simplex, oral herpes and tooth infections), reproductive tract infections (including vulvovaginal mycotic infection), urinary tract infections (including pyelonephritis), fungal infections, joint infections.				
26	**Manufacturer:** Catalent Belgium S.A Font Saint landry 10, Brussels, B -1120, Belgium. **Local Agent:** ZAS Corporation 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000torony, Hungary	Yuflyma 40mg/0.4ml Pre-Filled Pen	Adalimumab Ph. Eur 40mg/0.4ml	Immune-suppressant Therapeutic Code:058	Yuflyma in combination with methotrexate, is indicated for: the treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drugs including methotrexate has been inadequate. the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate. Yuflyma can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Adalimumab has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with	**Contraindications:** Hypersensitivity to the active substance, to other murine proteins, or to any of the excipients. Patients with tuberculosis or other severe infections such as sepsis, abscesses, and opportunistic infections. Patients with moderate or severe heart failure (NYHA class III/IV). **Side effects:** Respiratory tract infections (including lower and upper respiratory tract infection, pneumonia, sinusitis, pharyngitis, nasopharyngitis and pneumonia herpes viral) Systemic infections (including sepsis, candidiasis and influenza), intestinal infections (including gastroenteritis viral), skin and soft tissue infections (including paronychia, cellulitis, impetigo, necrotising fasciitis and herpes zoster), ear infections, oral infections (including herpes simplex, oral herpes and tooth infections), reproductive tract infections (including vulvovaginal mycotic infection),		EMA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					methotrexates.	urinary tract infections (including pyelonephritis), fungal infections, joint infections.				
27	**Manufacturer:** Cyndea Pharma S.L. Poligono Industrial Emiliano Revilla Sanz, Avda. De Agreda 31, Olvega 42110 (Soria), Spain **Local Agent:** ZAS Corporation 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000torony, Hungary	Utrogestan 300mg Soft Capsule	Progesterone Ph.Eur 300mg	Hormone Therapeutic Code:056	It is indicated in adult women for supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles.	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Jaundice, Severe hepatic dysfunction, Undiagnosed vaginal bleeding, Mammary or genital tract carcinoma, Thrombophlebitis, Thromboembolic diseases, Cerebral haemorrhage, Porphyria, missed abortion, Allergy to nuts or soya. **Side effects:** Local intolerance (burning, itching or oily discharge) has been observed in clinical studies and has been reported in publications, but the incidence is extremely rare. When used as recommended, transient fatigue or dizziness may occur within 1 – 3 hours of taking the medicine.	100mg & 200mg Soft Capsule	CPP Spain & France.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
28	**Manufacturer:** Laboratoire AGUETTANT SAS Olivier CESBRON Address: 1 rue Alexander Fleming, 69007-LYON-FRANCE **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan	NUTRYELT. Concentrate for solution for Infusion	Zine (Zn) 10000 ug (as Zinc gluconate)+ Copper (Cu) 300ug (as Copper gluconate) + Manganese (Mn) 55 ug (as Manganese gluconate) + Fluorine (F) 950ug (as sodium fluoride) + Iodine (I) 130ug (as	Trace Element Therapeutic Code:079	NUTRYELT is a concentrate for solution for infusion. It contains 9 essential trace elements (iron, copper, manganese, zinc, fluorine, iodine, selenium, chromium, molybdenum). These trace elements are considered as essential because the body cannot produce them but needs them in very small quantities in order to function properly. NUTRYELT is used to provide trace elements in adults need in intravenous (into a vein) feeding..	**Contraindication:** Hypersensitivity to Nutryelt Tartrate or to any of the excipients Special warnings and precautions for use If anyone has allergic (hypersensitive) to any of the ingredients of NUTRYELT If anyone has abnormally high level of any of the ingredients of the product in your blood. (If you have any doubt, ask your doctor). If anyone has pronounced cholestasis (yellowing of the skin or whites of the eyes caused by liver or blood problem). If anyone has an excess of copper (wilson's disease) or iron in the body (hemochromatosis).	New	CPP- France	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Tower (3rd Floor) Dhaka-1000, Bangladesh.		potassium iodide)+ Selenium (se) 70 ug (as sodium selenite)+ Molybdenum (Mo) 20ug (as sodium molybdate), Chromium (Cr) 10ug (as chromium chloride) + Iron (Fe) 1000 ug (as ferrous gluconate)			**Side effects** Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor you notice any of the following: Frequency not known (cannot be estimated from the available data): pain at the application site. Case of hypersensitivity reactions including fatal anaphylactic reactions have been reported in patients receiving IV iron-containing products. If anyone gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national.				
29	**Manufacturer:** Anfarm Hellas S.A 61st km Nat Road. Athens-Lamia, Schimatari Viotias 32009, Greece. **Local Agent:** Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-	a) Daptomycin 500 mg/Vial Powder for Solution for In‡jvection or Infusion	Daptomycin Ph.Eur 500 mg/vial	Antibiotic Therapeutic Code:023	It is indicated for the treatment of Complicated skin and skin structure infections (cSSSI) in adult and paediatric patients (1 to 17 years of age) and, Staphylococcus aureus bloodstream infections (bacteremia), in adult patients including those with right-sided infective endocarditis Staphylococcus aureus bloodstream infections (bacteremia) in pediatric patients (1 to 17 years of age).	**Contraindications:** Daptomycin for In‡jvection is contraindicated in patients with known hypersensitivity to daptomycin. **Side effects:** Fungal infections, urinary tract infection, candida infection, anaemia, anxiety, insomnia, dizziness, headache, hypertension, hypotension, gastrointestinal and abdominal pain, nausea, vomiting, constipation, diarrhoea, flatulence, bloating and distension, liver function tests abnormal (increased alanine aminotransferase (ALT), aspartate aminotransferase (AST) or alkaline phosphatase (ALP)), rash, pruritus, limb pain,		CPP -Greece & UK	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	1000.					serum creatine phosphokinase (CPK) increased, infusion site reactions, pyrexia, asthenia.				
		b) Daptomycin 350mg/Vial Powder for Solution for In‡jvection or Infusion	Daptomycin Ph.Eur 350 mg/vial	Antibiotic Therapeutic Code:023	It is indicated for the treatment of Complicated skin and skin structure infections (cSSSI) in adult and paediatric patients (1 to 17 years of age) and, Staphylococcus aureus bloodstream infections (bacteremia), in adult patients including those with right-sided infective endocarditis Staphylococcus aureus bloodstream infections (bacteremia) in pediatric patients (1 to 17 years of age).	**Contraindications:** Daptomycin for In‡jvection is contraindicated in patients with known hypersensitivity to daptomycin. **Side effects:** Fungal infections, urinary tract infection, candida infection, anaemia, anxiety, insomnia, dizziness, headache, hypertension, hypotension, gastrointestinal and abdominal pain, nausea, vomiting, constipation, diarrhoea, flatulence, bloating and distension, liver function tests abnormal (increased alanine aminotransferase (ALT), aspartate aminotransferase (AST) or alkaline phosphatase (ALP)), rash, pruritus, limb pain, serum creatine phosphokinase (CPK) increased, infusion site reactions, pyrexia, asthenia		CPP -Greece & UK	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
30	Made for F. Hoffmann-La Roche Ltd Basel, Switzerland by Roche Diagnostics GmbH, Sandhofer 116, 68305 mannheim, Germany **Local agent:** Roche Bangladesh	**Ocrevus** concentrate for solution for infusion	Ocrelizumab INN 300mg/10ml vial	Immune-suppressant Therapeutic Code:058	Ocrevus is indicated for the treatment of patients with relapsing forms of multiple sclerosis (RMS) to suppress relapses and disease progression (clinical and subclinical disease activity). Ocrevus is indicated for the treatment of patients with primary progressive multiple sclerosis (PPMS) to delay disease progression and reduce deterioration in walking	**Contraindication**: Ocrevus is contraindicated in patients with a known hypersensitivity to ocrelizumab or to any of the excipients. **Side effects**: Relapsing Forms of MS Primary Progressive MS Infusion-Related Reactions Respiratory Tract Infections Herpes infections	New	USFDA & EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Limited Ninakabbo, Level-2, 227/A, Gulshan-Tejgaon Link Road, Tejgaon I/A, Dhaka-1208, Bangladesh				speed					
31	Made for F. Hoffmann-La Roche Ltd, Basel, Switzerland by F. Hoffmann-La Roche AG Wurmisweg, CH-4303, Kaiseraugst, Switzerland **Local agent:** Roche Bangladesh Limited, Ninakabbo, Level-2, 227/A, Gulshan-Tejgaon Link Road,Tejgaon I/A, Dhaka-1208,	Vabysmo Solution for intravitreal In‡jvection 6mg/0.05ml	Faricimab INN 6mg/0.05ml	Eye Preparations Therapeutic Code:052	It is a bispecific angiopoietin-2 (Ang-2) and vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of: a) Neovascular (wet) age-related macular degeneration (nAMD) b) Diabetic macular edema (DME)	**Contraindication**: VABYSMO is contraindicated in patients with ocular or periocular infections. VABYSMO is contraindicated in patients with active intraocular inflammation. VABYSMO is contraindicated in patients with known hypersensitivity to faricimab or any of the excipients. Hypersensitivity reactions may manifest as rash, pruritus, urticaria, erythema, or severe intraocular inflammation **Side effects**: uveitis, endophthalmitis, vitritis, retinal tear, rhegmatogenous retinal detachment and traumatic cataract	New	USFDA, & EMA CPP-Switzerland	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
32	**Manufacturer:** Novartis Pharma Stein AG, Switzerland **Local Representative:**	Scemblix 20mg Film-Coated tablet	Asciminib INN 20mg	Anticancer Therapeutic Code: 010	Scemblix is indicated for the treatment of adult patients with: • **Philadelphia chromosome**-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) previously treated with two or more tyrosine kinase inhibitors.	**Contraindication:** None **Side Effects** **Very common (≥10%)*:*** Upper respiratory tract infection, thrombocytopenia, neutropenia, anaemia, dyslipidaemia, headache, dizziness, hypertension, cough, pancreatic enzymes increased, vomiting, diarrhoea, nausea,	New Molecule	CPP-Switzerland	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Novartis (Bangladesh) Limited Tower One One Seven (Level 5) Plot # 117/A, Tejgaon I/A Dhaka 1208, Bangladesh.				• Ph+ CML in CP harboring the T315I mutation.	abdominal pain, hepatic enzyme increased, rash, musculoskeletal pain, arthralgia, fatigue, pruritus. **Common (≥1 to <10%):** Lower respiratory tract infection, influenza, decreased appetite, vision blurred, dry eye, palpitations, pleural effusion, dyspnoea, non-cardiac chest pain, pancreatitis, blood bilirubin increased, urticaria, pyrexia, oedema, blood creatine phosphokinase increased. **Uncommon (≥0.1 to <1%):** Febrile neutropenia, electrocardiogram QT prolonged.				
33	**Manufacturer:** Novartis Pharma Stein AG, Switzerland **Local Representative:** Novartis (Bangladesh) Limited Tower One One Seven (Level 5) Plot # 117/A, Tejgaon I/A Dhaka 1208, Bangladesh.	Scemblix 40mg Film-coated tablet	Asciminib INN 40mg	Anticancer Therapeutic Code: 010	Scemblix is indicated for the treatment of adult patients with: • **Philadelphia chromosome**-positive chronic myeloid leukaemia in chronic phase (CP) previously treated with two or more tyrosine kinase inhibitors. • positive chronic myeloid leukaemia in CP harboring the T315I mutation.	**Contraindication:** None **Side Effects** **Very common (≥10%)*:*** Upper respiratory tract infection,thrombocytopenia, neutropenia, anaemia, dyslipidaemia, headache, dizziness, hypertension, cough, pancreatic enzymes increased, vomiting, diarrhoea, nausea, abdominal pain, hepatic enzyme increased, rash, musculoskeletal pain, arthralgia, fatigue, pruritus. **Common (≥1 to <10%):** Lower respiratory tract infection, influenza, decreased appetite, vision blurred, dry eye, palpitations, pleural effusion, dyspnoea, non-cardiac chest pain, pancreatitis, blood bilirubin increased, urticaria, pyrexia, oedema, blood creatine phosphokinase increased. **Uncommon (≥0.1 to <1%):** Febrile neutropenia, electrocardiogram QT prolonged.	New Molecule	CPP-Switzerland	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
34	**Manufacturer:** Sandoz S.R.L, Targu Mures, Romania **Local Representative:** Novartis (Bangladesh) Limited. Tower One One Seven (Level 5) Plot # 117/A, Tejgaon I/A, Dhaka 1208, Bangladesh	Jadenu 90mg Film-coated tablet	Deferasirox INN 90mg	Others Classification Therapeutic Code: 074	Jadenu is indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in adult and paediatric patients (aged 2 years and over) It is also indicated for the treatment of chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes aged 10 years and older.	**Contraindication:** Creatinine clearance <40 mL/min or serum creatinine >2 times the age-appropriate upper limit of normal. High-risk myelodysplastic syndrome (MDS) patients and patients with other haematological and non-haematological malignancies who are not expected to benefit from chelation therapy due to the rapid progression of their disease. **Side Effects:** In patients with transfusional iron overload, the most frequently occurring (greater than 5%) adverse reactions are diarrhoea, vomiting, nausea, abdominal pain, skin rashes, and increases in serum creatinine. In deferasirox-treated patients with NTDT syndromes, the most frequently occurring (greater than 5%) adverse reactions are diarrhoea, rash, and nausea.	New Molecule	CPP-Switzerland	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
35	**Manufacturer:** Sandoz S.R.L, Targu Mures, Romania **Local Representative:** Novartis (Bangladesh) Limited. Tower One One Seven	Jadenu 180mg Film-coated tablet	Deferasirox INN 180mg	Others Classification Therapeutic Class: 074	Jadenu is indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in adult and paediatric patients (aged 2 years and over) It is also indicated for the treatment of chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes aged 10	**Contraindication:** Creatinine clearance <40 mL/min or serum creatinine >2 times the age-appropriate upper limit of normal. High-risk myelodysplastic syndrome (MDS) patients and patients with other haematological and non-haematological malignancies who are not expected to benefit from chelation therapy due to the rapid progression of their disease.	New Molecule	CPP-Switzerland	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	(Level 5) Plot # 117/A, Tejgaon I/A, Dhaka 1208, Bangladesh				years and older.	**Side Effects:** In patients with transfusional iron overload, the most frequently occurring (greater than 5%) adverse reactions are diarrhoea, vomiting, nausea, abdominal pain, skin rashes, and increases in serum creatinine. In deferasirox-treated patients with NTDT syndromes, the most frequently occurring (greater than 5%) adverse reactions are diarrhoea, rash, and nausea.				
36	**Manufacturer:** Sandoz S.R.L, Targu Mures, Romania **Local Representative:** Novartis (Bangladesh) Limited. Tower One One Seven (Level 5) Plot # 117/A, Tejgaon I/A, Dhaka 1208, Bangladesh	Jadenu 360mg Film-coated tablet	Deferasirox INN 360mg	Others Classification Therapeutic Class: 074	Jadenu is indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in adult and paediatric patients (aged 2 years and over) It is also indicated for the treatment of chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes aged 10 years and older.	**Contraindication:** Creatinine clearance <40 mL/min or serum creatinine >2 times the age-appropriate upper limit of normal. High-risk myelodysplastic syndrome (MDS) patients and patients with other haematological and non-haematological malignancies who are not expected to benefit from chelation therapy due to the rapid progression of their disease. **Side Effects:** In patients with transfusional iron overload, the most frequently occurring (greater than 5%) adverse reactions are diarrhoea, vomiting, nausea, abdominal pain, skin rashes, and increases in serum creatinine. In deferasirox-treated patients with NTDT syndromes, the most frequently occurring (greater than 5%) adverse reactions are diarrhoea, rash, and nausea.	New	CPP-Switzerland	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
37	**Manufacturer:** Bieffe Medital S.A, Spain	Plasmalyte-A (Plasmalyte-148) ($P^{H\ 7.4}$) Solution for infusion	Sodium Gluconate 0.502% W/V + Magnesium Chloride	Electrolytes Therapeutic Code: 079	This In‡jvection pH 7.4 (Multiple Electrolytes In‡jvection) is indicated as a source of water and electrolytes or as an alkalinizing agent.	**Contraindications:** Not Known **Side Effects:** The most common side effects of Plasma-Lyte A include: back pain,	New	CPP-Spain & UK	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	MA Holder: Baxter, SL, Spain **Local Agent:** Swadesh, 30 Bijoynagar Road, 3 rd floor, Dhaka.		Hexahydrate 0.030% W/V + Sodium Acetate Trihydrate 0.368% W/V + Potassium Chloride 0.037% W/V + Sodium Chloride 0.526 W/V		PLASMA-LYTE A In‡jvection pH 7.4 (Multiple Electrolytes In‡jvection) is compatible with blood or blood components. It may be administered prior to or following the infusion of blood through the same administration set (i.e., as a priming solution), added to or infused concurrently with blood components, or used as a diluent in the transfusion of packed erythrocytes. PLASMA-LYTE A (multiple electrolytes in‡jvection) In‡jvection and 0.9% Sodium Chloride In‡jvection, USP are equally compatible with blood or blood components.	weakness, acid or sour stomach, burping, heartburn, indigestion, and abdominal pain.				
38	**Manufacturer:** Baxter S.A., Bd. René Branquart 80, 7860, Lessines, Belgium **MAH:** Baxter S.A., France **Local Agent** Unicorn Healthcare Solution Limited. Suit: A-1 & B-1, 8 th Floor, Dynasty Wahed Tower 56/2 Panthapath	**OLIMEL N9E, emulsion for infusion** 3-compartment plastic bags of 1000ml (200 ml + 400 ml + 400 ml) 1000 ml bag: 1 carton with 6 bags	(Refined olive oil & Refined soya-bean oil) 40.00g + Alanine 8.24g + Arginine 5.58g + Aspartic acid 1.65g + lutamic acid 2.84g + Glycine 3.95g + Histidine 3.40 g + Isoleucine 2.4g + Leucine 3.95 g + Lysine (equivalent to Lysine acetate) 4.48 g (6.32 g) + Méthionine 2.84 g + Phenylalanine 3.95 g + Proline	Amino Acids Therapeutic Codes: 003	OLIMEL is indicated for parenteral c for adults and children greater than 2 years of age when oral or enteral nutrition is impossible, insufficient or contraindicated.	The use of OLIMEL is contraindicated in the following situations: • In premature neonates, infants and children less than 2 years of age Hypersensitivity to egg, soya-bean, peanut proteins, or corn/corn products or to any of the active substances or excipients. • Congenital abnormalities of amino acid metabolism, • Severe hyperlipidemia or severe disorders of lipid metabolism characterized by hypertriglyceridemia • Severe hyperglycemia • Pathologically-elevated plasma concentration of sodium, potassium, magnesium, calcium and/or phosphorus. **Side Effect:** Potential undesirable effects may occur as a result of inappropriate use (for	New	France	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	(Kalabagan Lake Circus) Dhaka-1205		3.40 g + Serine 2.25 g + Threonine 2.84 g +Tryptophan 0.95 g + Tyrosine 0.15 g + Valine 3.64 g + Sodium acetate, trihydrate 1.50 g + Sodium glycerophosphate, hydrated 3.67 g + Potassium chloride 2.4 g + Magnesium chloride, hexahydrate 0.81 g + Calcium chloride, dihydrate 0.52g + Glucose (equivalent to Glucose monohydrate) 110.00 g (121.00 g)/1000ml			example: overdose, excessively fast infusion rate). At the beginning of the infusion, any of the following abnormal signs (sweating, fever, shivering, headache, skin rashes, dyspnea) should be cause for immediate discontinuation of the infusion: The adverse drug reactions (ADRs) reported with OLIMEL N9-840 in a randomized, double-blind, active-controlled, efficacy and safety study, are listed in the table below. Twenty-eight patients with various medical conditions (i.e., postsurgical fasting, severe malnutrition, enteral intake insufficient or forbidden) were included and treated; patients in the OLIMEL group received drug product up to 40 mL/kg/d over 5 days.				
39	**Manufacturer:** Baxter S.A., Bd. René Branquart 80, 7860 Lessines, Belgium **MAH:** Baxter S.A., France	**OLIMEL N9E, emulsion for infusion** 3-compartment plastic bags of 2000ml (400 ml + 800 ml + 800 ml) 2000 ml bag: 1 carton with 4 bags	(Refined olive oil & refined soya-bean oil) 80.00 g + Alanine 16.48 g + Arginine 11.16 g + Aspartic acid 3.30 g + lutamic acid 5.69 g + Glycine 7.90 g + Histidine 6.79 g + Isoleucine	Amino Acids Therapeutic Codes: 003	OLIMEL is indicated for parenteral c for adults and children greater than 2 years of age when oral or enteral nutrition is impossible, insufficient or contraindicated.	The use of OLIMEL is contraindicated in the following situations: • In premature neonates, infants and children less than 2 years of age Hypersensitivity to egg, soya-bean, peanut proteins, or corn/corn products or to any of the active substances or excipients. • Congenital abnormalities of amino acid metabolism, • Severe hyperlipidemia or severe disorders of lipid metabolism	New	France	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Local Agent Unicorn Healthcare Solution Limited. Suit: A-1 & B-1, 8 th Floor, Dynasty Wahed Tower 56/2 Panthapath (Kalabagan Lake Circus) Dhaka-1205		5.69 g + Leucine 7.90 g + Lysine (equivalent to Lysine acetate) 8.96 g (12.64g) + Méthionine 5.69 g + Phénylalanine 7.90 g + Proline 6.79 g + Serine 4.50 g + Threonine 5.69 g +Tryptophan 1.90 g + Tyrosine 0.30 g + Valine 7.29 g + Sodium acetate, trihydrate 2.99 g + Sodium glycerophosphate, hydrated 7.34 g + Potassium chloride 4.47 g + Magnesium chloride, hexahydrate 1.62 g + Calcium chloride, dihydrate 1.03 g + Glucose (equivalent to Glucose monohydrate) 220.00 g (121.00 g)/2000ml			characterized by hypertriglyceridemia• Severe hyperglycemia • Pathologically-elevated plasma concentration of sodium, potassium, magnesium, calcium and/or phosphorus. **Side Effect:** Potential undesirable effects may occur as a result of inappropriate use (for example: overdose, excessively fast infusion rate). At the beginning of the infusion, any of the following abnormal signs (sweating, fever, shivering, headache, skin rashes, dyspnea) should be cause for immediate discontinuation of the infusion: The adverse drug reactions (ADRs) reported with OLIMEL N9-840 in a randomized, double-blind, active-controlled, efficacy and safety study, are listed in the table below. Twenty-eight patients with various medical conditions (i.e., postsurgical fasting, severe malnutrition, enteral intake insufficient or forbidden) were included and treated; patients in the OLIMEL group received drug product up to 40 mL/kg/d over 5 days.				

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
40	**Manufacturer:** Baxter S.A., Bd. René Branquart 80, 7860 Lessines, Belgium **MAH:** Baxter S.A., France **Local Agent** Unicorn Healthcare Solution Limited. Suit: A-1 & B-1, 8 th Floor, Dynasty Wahed Tower 56/2 Panthapath (Kalabagan Lake Circus) Dhaka-1205	**Periolimel N4E, emulsion for infusion,** 3-compartment plastic bags of 1000 ml (200 ml + 400 ml + 400 ml) 1000 ml bag: 1 carton with 6 bags	Refined olive oil & refined soya-bean oil 30.00 g + Alanine 3.66 g + Arginine 2.48 g + Aspartic acid 0.73 g + Glutamic acid 1.26 g + Glycine 1.76 g + Histidine 1.51 g + Isoleucine 1.26 g Leucine 1.76 g + Lysine (equivalent to Lysine acetate) 1.99 g (2.81 g) + Methionine 1.26 g + Phenylalanine 1.76 g + Proline 1.51 g + Serine 1.00 g + Threonine 1.26 g + Tryptophan 0.42 g Tyrosine 0.06 g + Valine 1.62 g + Sodium acetate, trihydrate 1.16 g + Sodium glycerophosphate, hydrated 1.91 g + Potassium chloride 1.19 g + Magnesium chloride, hexahydrate 0.45	Amino Acids Therapeutic Codes: 003	PERIOLIMEL is indicated for parenteral nutrition for adults and children greater than 2 years of age when oral or enteral nutrition is impossible, insufficient or contraindicated.	The use of PERIOLIMEL is contraindicated in the following situations: • In premature neonates, infants and children less than 2 years of age Hypersensitivity to egg, soya-bean, peanut proteins, or corn/corn products or to any of the active substances or excipients. • Congenital abnormalities of amino acid metabolism, • Severe hyperlipidemia or severe disorders of lipid metabolism characterized by hypertriglyceridemia • Severe hyperglycemia • Pathologically-elevated plasma concentration of sodium, potassium, magnesium, calcium and/or phosphorus. **Side Effect:** Potential undesirable effects may occur as a result of inappropriate use (for example: overdose, excessively fast infusion rate). At the beginning of the infusion, any of the following abnormal signs (sweating, fever, shivering, headache, skin rashes, dyspnoea) should be cause for immediate discontinuation of the infusion: The adverse drug reactions (ADRs) reported with PERIOLIMEL N9-840 in a randomized, double-blind, active-controlled, efficacy and safety study, are listed in the table below. Twenty-eight patients with various medical conditions (i.e., postsurgical fasting, severe malnutrition, enteral intake insufficient or forbidden) were included and treated; patients in the PERIOLIMEL group received drug product up to 40 mL/kg/d over 5 days.	New	France	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
			g + Calcium chloride, dihydrate 0.30 g +Glucose (equivalent to Glucose monohydrate) 75.00 g (82.50 g)/1000ml							
41	**Manufacturer:** Baxter S.A., Bd. René Branquart 80, 7860 Lessines, Belgium **MAH:** Baxter S.A., France **Local Agent** Unicorn Healthcare Solution Limited. Suit: A-1 & B-1, 8 th Floor, Dynasty Wahed Tower 56/2 Panthapath (Kalabagan Lake Circus) Dhaka-1205	Periolimel N4E, emulsion for infusion, 3-compartment plastic bags of 2000ml (400 ml + 800 ml + 800 ml) 2000 ml bag: 1 carton with 4 bags	Refined olive oil & refined soya-bean oil 60.00 g + Alanine 7. 33 g +Arginine 4.96 g + Aspartic acid 1.46 g + Glutamic acid 2,53 g + Glycine 3. 51 g + Histidine 3.02 g + Isoleucine 2.53 g + Leucine 3.51 g + Lysine (equivalent to Lysine acetate) 3.98 g (5.62 g) + Methionine 2.53 g + Phenylalanine 3.51 g + Proline 3.02 g + Serine 2.00 g + Threonine 2.53 g + Tryptophan 0.85 g Tyrosine 0.13 g + Valine 3.24 g + Sodium acetate, trihydrate 2.31 g +	Amino Acids Therapeutic Codes: 003	PERIOLIMEL is indicated for parenteral nutrition for adults and children greater than 2 years of age when oral or enteral nutrition is impossible, insufficient or contraindicated.	**Contraindications:** The use of PERIOLIMEL is contraindicated in the following situations: • In premature neonates, infants and children less than 2 years of age Hypersensitivity to egg, soya-bean, peanut proteins, or corn/corn products or to any of the active substances or excipients. • Congenital abnormalities of amino acid metabolism, • Severe hyperlipidemia or severe disorders of lipid metabolism characterized by hypertriglyceridemia • Severe hyperglycemia • Pathologically-elevated plasma concentration of sodium, potassium, magnesium, calcium and/or phosphorus. **Side Effect:** Potential undesirable effects may occur as a result of inappropriate use (for example: overdose, excessively fast infusion rate). At the beginning of the infusion, any of the following abnormal signs (sweating, fever, shivering, headache, skin rashes, dyspnea) should be cause for immediate discontinuation of the infusion: The adverse drug reactions (ADRs) reported with PERIOLIMEL N9-840 in a randomized, double-blind, active-controlled,	New	France	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
			Sodium glycerophosphate, hydrated 3.82 g + Potassium chloride 2.38 g Magnesium chloride, hexahydrate 0.90 g + Calcium chloride, dihydrate 0.59 g + Glucose (equivalent to Glucose monohydrate) 150.00 g (165.00 g)/2000ml			efficacy and safety study, are listed in the table below. Twenty-eight patients with various medical conditions (i.e., postsurgical fasting, severe malnutrition, enteral intake insufficient or forbidden) were included and treated; patients in the PERIOLIMEL group received drug product up to 40 mL/kg/d over 5 days.				
42	Merck Serono SPA Via Delle Magnolie 15, (loc. frazione Zona Industriale) Modugno (BA), I-70026, Italy **Local Agent:** Janata Traders 62/2 Purana Paltan Dhaka 1000	**SAIZEN 6mg** (5.83mg/ml) Solution for in‡jvection, 1 Cartridge of 1.03ml	Somatropin 6mg (5.83mg/ml)	**Growth Hormone**	Saizen is indicated in the treatment of: Children and adolescents: - Growth failure in children caused by decreased or absent secretion of endogenous growth hormone. - Growth failure in girls with gonadal dysgenesis - Growth failure in prepubertal children due to chronic renal failure - Growth disturbance Adults: Replacement therapy in adults with pronounced growth hormone deficiency as diagnosed by a single dynamic test for growth hormone deficiency.	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients listed in section Somatropin should not be used for growth promotion in children with closed epiphyses. Somatropin must not be used when there is any evidence of activity of a tumour. Intracranial tumours must be inactive and antitumour therapy must be completed prior to starting growth hormone therapy. Treatment should be discontinued if there is evidence of tumour growth. **Side-effects:** Up to 10% of patients may experienceredness and itching at the site of in‡jvection. Fluid retention is expected during growth hormone replacement therapy in adults. Oedema, joint swelling, arthralgias, myalgias	**Somatropin 5mg, 8mg, 10mg**	Italy & UK	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						and paraesthesias may be clinical manifestations of fluid retention. However, these symptoms / signs are usually transient and dose dependent.				
43	Merck Serono SPA Via Delle Magnolie 15, (loc. frazione Zona Industriale) Modugno (BA), I-70026, Italy **Local Agent:** Janata Traders 62/2 Purana Paltan Dhaka 1000	**SAIZEN 12mg** (8mg/ml) Solution for in‡jvection, 1 Cartridge of 1.5ml	Somatropin 12mg (8mg/ml)	**Growth Hormone**	Saizen is indicated in the treatment of: Children and adolescents: - Growth failure in children caused by decreased or absent secretion of endogenous growth hormone. - Growth failure in girls with gonadal dysgenesis - Growth failure in prepubertal children due to chronic renal failure - Growth disturbance Adults: Replacement therapy in adults with pronounced growth hormone deficiency as diagnosed by a single dynamic test for growth hormone deficiency.	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients listed in section Somatropin should not be used for growth promotion in children with closed epiphyses. Somatropin must not be used when there is any evidence of activity of a tumour. Intracranial tumours must be inactive and antitumour therapy must be completed prior to starting growth hormone therapy. Treatment should be discontinued if there is evidence of tumour growth. **Side-effects:** Up to 10% of patients may experience redness and itching at the site of in‡jvection. Fluid retention is expected during growth hormone replacement therapy in adults. Oedema, joint swelling, arthralgias, myalgias and paraesthesias may be clinical manifestations of fluid retention. However, these symptoms / signs are usually transient and dose dependent.	Do	Do	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
44	Merck Serono SPA Via Delle Magnolie 15, (loc. frazione Zona Industriale) Modugno (BA), I-70026, Italy **Local Agent:** Janata Traders	**SAIZEN 20mg** (8mg/ml) Solution for in‡jvection, 1 Cartridge of 2.5ml	**Somatropin 20mg (8mg/ml)**	**Growth Hormone**	Saizen is indicated in the treatment of: Children and adolescents: - Growth failure in children caused by decreased or absent secretion of endogenous growth hormone. - Growth failure in girls with gonadal dysgenesis	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients listed in section Somatropin should not be used for growth promotion in children with closed epiphyses. Somatropin must not be used when there is any evidence of activity of a tumour. Intracranial tumours must be inactive and	Do	Do	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	62/2 Purana Paltan Dhaka 1000				- Growth failure in prepubertal children due to chronic renal failure - Growth disturbance Adults: - Replacement therapy in adults with pronounced growth hormone deficiency as diagnosed by a single dynamic test for growth hormone deficiency.	antitumour therapy must be completed prior to starting growth hormone therapy. Treatment should be discontinued if there is evidence of tumour growth. **Side-effects:** Up to 10% of patients may experience redness and itching at the site of in‡jvection. Fluid retention is expected during growth hormone replacement therapy in adults. Oedema, joint swelling, arthralgias, myalgias and paraesthesias may be clinical manifestations of fluid retention. However, these symptoms / signs are usually transient and dose dependent.				
45	**Legal manufacturer:** Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg, Germany **Production Site:** Fresenius Medical Care Deutschland GmbH 66606 St. Wendel, Frankfurter Straße 6-8, Germany **Local Agent:** Fresenius Medical Care Bangladesh	**multiBic** Potassium free solution for haemodialysis/ haemofiltration Ph. Eur.	*After mixing, each 1000ml ready to use solution contains:* Sodium chloride 6.136 gm + Sodium hydrogen carbonate 2.940 gm + Calcium chloride dihydrate 0.2205 gm + Magnesium chloride hexahydrate 0.1017 gm + Glucose monohydrate 1.100 gm	Solution for haemodialysis/ haemofiltration	In patients with acute kidney in‡jvury requiring continuous renal replacement therapy. For intravenous use as substation solution in haemofiltration & haemodiafiltration, and as dialysis solution in haemodialysis & haemodiafiltration.	Solution dependent contraindications: multiBic® potassium-free/2/3/4 mmol/L potassium: hypokalaemia, metabolic alkalosis; multiBic® 4 mmol/L potassium: hyperkalaemia, metabolic alkalosis; Haemofiltration dependent contraindications due to the technical procedure itself: Renal failure with increased hypercatabolism in cases where uraemic symptoms can no longer be relieved by haemofiltration; Inadequate blood flow from vascular access; If there is a high risk of haemorrhage on account of systemic anticoagulation.	NEW	Germany	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Ltd., Level-10, Tower1, Police Plaza Concord, Gulshan-1, Dhaka									
46	**Legal manufacturer:** Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg, Germany **Production Site:** Fresenius Medical Care Deutschland GmbH 66606 St. Wendel, Frankfurter Straße 6-8, Germany **Local Agent:** Fresenius Medical Care Bangladesh Ltd., Level-10, Tower1, Police Plaza Concord, Gulshan-1, Dhaka, Bangladesh	**multiBic 2** solution for haemodialysis/ haemofiltration Ph. Eur.	**After mixing, each 1000ml solution contains:** Sodium chloride 6.136 gm + Potassium chloride 0.1491 gm + Sodium hydrogen carbonate 2.940 gm + Calcium chloride dihydrate 0.2205 gm + Magnesium chloride hexahydrate 0.1017 gm + Glucose monohydrate 1.100 gm	Solution for hemodialysis/h emofiltration	In patients with acute kidney in‡jvury requiring continuous renal replacement therapy. For intravenous use as substation solution in haemofiltration & haemodiafiltration, and as dialysis solution in haemodialysis & haemodiafiltration.	Solution dependent contraindications: multiBic® potassium-free/2/3/4 mmol/L potassium: hypokalaemia, metabolic alkalosis; multiBic® 4 mmol/L potassium: hyperkalaemia, metabolic alkalosis; Haemofiltration dependent contraindications due to the technical procedure itself: Renal failure with increased hypercatabolism in cases where uraemic symptoms can no longer be relieved by haemofiltration; Inadequate blood flow from vascular access; If there is a high risk of haemorrhage on account of systemic anticoagulation.	NEW	Germany	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
47	**Legal manufacturer:** Fresenius Medical Care AG & Co. KGaA,	**multiBic 3** solution for haemodialysis/ haemofiltration Ph. Eur.	**After mixing, each 1000ml solution contains:** Sodium chloride	Solution for haemodialysis/ haemofiltration	In patients with acute kidney in‡jvury requiring continuous renal replacement therapy. For intravenous use as substation solution in haemofiltration &	Solution dependent contraindications: multiBic® potassium-free/2/3/4 mmol/L potassium: hypokalaemia, metabolic alkalosis; multiBic® 4 mmol/L potassium: hyperkalaemia, metabolic alkalosis;	NEW	Germany	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	61346 Bad Homburg, Germany **Production Site:** Fresenius Medical Care Deutschland GmbH 66606 St. Wendel, Frankfurter Straße 6-8, Germany **Local Agent:** Fresenius Medical Care Bangladesh Ltd., Level-10, Tower1, Police Plaza Concord, Gulshan-1, Dhaka		6.136 gm + Potassium chloride 0.2237 gm + Sodium hydrogen carbonate 2.940 gm + Calcium chloride dihydrate 0.2205 gm + Magnesium chloride hexahydrate 0.1017 gm + Glucose monohydrate 1.100 gm		haemodiafiltration, and as dialysis solution in haemodialysis & haemodiafiltration.	Haemofiltration dependent contraindications due to the technical procedure itself: Renal failure with increased hypercatabolism in cases where uraemic symptoms can no longer be relieved by haemofiltration; Inadequate blood flow from vascular access; If there is a high risk of haemorrhage on account of systemic anticoagulation.				
48	**Legal manufacturer:** Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg, Germany **Production Site:** Fresenius Medical Care Deutschland GmbH 66606 St. Wendel, Frankfurter Straße	**multiBic 4** solution for haemodialysis/ haemofiltration Ph. Eur.	**After mixing, each 1000ml solution contains:** Sodium chloride 6.136 gm + Potassium chloride 0.2982 gm + Sodium hydrogen carbonate 2.940 gm + Calcium chloride dihydrate 0.2205 gm + Magnesium	Solution for haemodialysis/ haemofiltration	In patients with acute kidney in‡jvury requiring continuous renal replacement therapy. For intravenous use as substation solution in haemofiltration & haemodiafiltration, and as dialysis solution in haemodialysis & haemodiafiltration.	Solution dependent contraindications: multiBic® potassium-free/2/3/4 mmol/L potassium: hypokalaemia, metabolic alkalosis; multiBic® 4 mmol/L potassium: hyperkalaemia, metabolic alkalosis; Haemofiltration dependent contraindications due to the technical procedure itself: Renal failure with increased hypercatabolism in cases where uraemic symptoms can no longer be relieved by haemofiltration; Inadequate blood flow from vascular access; If there is a high risk of haemorrhage on account of systemic anticoagulation.	NEW	Germany	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	6-8, Germany **Local Agent:** Fresenius Medical Care Bangladesh Ltd., Level-10, Tower1, Police Plaza Concord, Gulshan-1, Dhaka		chloride hexahydrate 0.1017 gm + Glucose monohydrate 1.100 gm							
49	**Manufacturer:** River Pharma Srl; Address: Viale Stazione 6, 26863 Orio Litta (LO), Italy **Importer:** Benvue International Ltd. Address: 1512, O. R. Nizam Road, Chittagong, Bangladesh.	**Epaset Tablet**	N-Acetyl Cysteine 200 mg & D-Glucoronic Acid 100 mg	Liver disease	It is indicated for treatment of fatty liver disease, hepatomegaly	**Contraindications:** Contraindicated in patients with known hypersensitivity to any of its components. Keep out of the reach of children under 3 years of age. Do not take during pregnancy. Do not exceed the recommended daily dose. Store in cool dry place. The use by date refers to a correctly stored unopened product. **Side Effects:** N-acetyl cysteine is likely safe for most adults. N-acetyl cysteine is an FDA-approved prescription drug. It can cause side effects such as dry mouth, nausea, vomiting, and diarrhea. It has an unpleasant odor that some people find hard to tolerate.	New	Italy	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
50	**Manufacturer:** River Pharma Srl; Address: Viale Stazione 6, 26863 Orio Litta (LO), Italy **Importer:** Benvue International Ltd. Address: 1512, O.	**Lenifast 100 ml Gel**	Dimethyl Sulfoxide 9% + Methyl Salicylate 5% + N-Acetyl Glucosamine 3%	joint pain	It is indicated for treatment of joint pain, muscle pain, painful shoulder, back pain, algia ankle & cervical brachialgia	**Contraindications:** Contraindicated in patients with known hypersensitivity to any of its components. Not to be used on children under 6 years old. Do not apply to skin abrasions. Do not apply to irritated skin. If irritation develops, use of the product should be discontinued. **Side Effects:** Use sparingly on tender skin and do not cover immediately after	New	Italy	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	R. Nizam Road, Chittagong					application. If an adverse reaction occurs discontinue use immediately. Known side effects of menthol – contact dermatitis or eczema, hypersensitivity reactions characterized by urticaria, flushing and headache. Irritation of the skin may also be caused.				
51	**Manufacturer:** Pound International Ltd, UK **Importer:** Bioart Bangladesh, 290, Middle Pirer Bag, Mirpur, Dhaka.	Stud 100 Desensitizing Spray for Men	Lidocaine INN 9.6% w/w	Therapeutic class: Anesthetics (Local) Therapeutic code: 005	It is indicated for pruritus, pruritic eczemas, abrasions, minor burns, insect bites, pain, soreness and discomfort due to pruritus ani, pruritus vulvae, hemorrhoids, anal fissures and similar conditions of the skin and mucous membranes.	**Contraindications:** Traumatized mucosa, Secondary bacterial infction, known hypersensitivity. **Side effects:** Erythema or edema, Abnormal sensation.	2% Gel 1% Solution 4% In‡jvection	USFDA, TGA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
52	Merck Serono S.p.A., Via Delle Magnolie 15, (loc. Frazione Zona Industriale) 70026, Modugno (BA), Italy and Merck Serono S.A Switzerland. **Local Agent:** Janata Traders 62/2 Purana Paltan Dhaka 1000	Gonal-f 150 IU/0.25ml (11 µg) solution for in‡jvection in pre-filled pen	Follitropin alfa 150 IU/0.25ml (11 µg)	Hormone	**In adult women** • Anovulation (including polycystic ovarian syndrome) in women who have been unresponsive to treatment with clomiphene citrate. • Stimulation of multifollicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilisation (IVF), gamete intra-fallopian transfer and zygote intra-fallopian transfer. • GONAL-f in association with a luteinising hormone (LH) preparation is recommended for the stimulation of follicular development in women with severe LH and FSH deficiency. In clinical trials these patients were	**Side Effects:** Summary of the safety profile The most commonly reported adverse reactions are headache, ovarian cysts and local in‡jvection site reactions (e.g. pain, erythema, haematoma, swelling and/or irritation at the site of in‡jvection). Mild or moderate ovarian hyperstimulation syndrome (OHSS) has been commonly reported and should be considered as an intrinsic risk of the stimulation procedure. Severe OHSS is uncommon . **Contra Indications/ Warnings** • hypersensitivity to the active substance or to any of the excipients listed in section 6.1 • tumours of the hypothalamus or pituitary gland • ovarian enlargement or ovarian cyst not due	75 IU, 300IU, 450 IU	EMA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/ EMA)	টেকনিক্যাল সাব কমিটি সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					defined by an endogenous serum LH level < 1.2 IU/L. **In adult men** • GONAL-f is indicated for the stimulation of spermatogenesis in men who have congenital or acquired hypogonadotrophic hypogonadism with concomitant human Chorionic Gonadotropin (hCG) therapy	to polycystic ovarian syndrome • gynaecological haemorrhages of unknown aetiology				

Annex-D: আমদানির জন্য হিউম্যান ভ্যাক্সিন এর অনুমোদন

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/EMA)	টেকনিক্যাল সাব কমিটির সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
1.	**Manufacturer:** Serum Institution of India Ltd, 212/2 Hadapsar, Pune-411 0028, Maharashtra State, India **Local Agent:** Renata Limited	PNEUMOSIL Vaccine, In‡jvectable, Suspension for In‡jvection (2.5ml-5 Dose, 10 Valent)	Each dose of 0.5ml contains: Saccharide for serotypes 1, 5, 9V, 14, 19A, 19F, 23F, 7F, 6A 2mcg each + Saccharide for serotype 6B 4mcg + Con‡jvugated to CRM197 carrier protein Aluminium (as Aluminium phosphate) 0.125mg + Thiomersal: 0.005 %	Human Vaccine **Therapeutic code:** 069	Active immunization against invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* serotypes 1,5, 6A, 6B, 7F, 9V, 14, 19A, 19F and 23F in infants and toddlers from 6 weeks up to 2 years of age. The use of vaccine should be determined on the basis of relevant recommendations and take into consideration the disease impact by age and regional epidemiology	**CONTRAINDICATIONS:** Hypersensitivity to any component of the vaccine, including diphtheria toxoid. **Side Effects:** Safety assessment of Pneumococcal Polysaccharide Con‡jvugate Vaccine (Adsorbed) (10-valent) was based on clinical trials involving the administration of 5,416 doses to 1,828 healthy children as primary immunization. Furthermore, 428 children received a booster dose of Pneumococcal Polysaccharide Con‡jvugate Vaccine (Adsorbed) (10-valent) following a primary vaccination course. Pneumococcal Polysaccharide Con‡jvugate Vaccine (Adsorbed) (10-valent) was administered concomitantly with recommended childhood vaccines, as appropriate. Safety was also assessed in 57 previously unvaccinated children during the second year of life; all children received 2 doses of vaccine. Pneumococcal Polysaccharide Con‡jvugate Vaccine (Adsorbed) (10-valent) has also been used for booster vaccination in 56 children who received another pneumococcal con‡jvugate vaccine for the primary course. The vast majority of the reactions observed following vaccination were of mild or moderate severity and were of short duration. In the largest study in infants, the most common adverse reactions observed after primary vaccination were tenderness at the	New	COPP-India WHO Pre-qualified Certificate	আবেদন নামঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/EMA)	টেকনিক্যাল সাব কমিটির সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						in‡jvection site, fever and irritability, which were reported for approximately 49%, 52% and 32% of all infants, respectively. No increase in the incidence or severity was observed following subsequent doses of the primary vaccination course. Following booster vaccination, the most common adverse reaction was tenderness at the in‡jvection site, which was reported for approximately 8% of all infants. The Indian Phase 3 licensure study in infants similarly showed tenderness at the in‡jvection site, fever and irritability as the most common adverse reactions observed after primary vaccination, with no change in the incidence or severity observed following subsequent doses of the primary vaccination course. Majority of the solicited AEs were of mild to moderate intensity and resolved completely. The in‡jvection site and systemic reactions following catch-up vaccination or booster vaccination during the second year of life were similar to those reported after primary vaccination. In all studies, the incidence and severity of local and general adverse reactions reported within 7 days of vaccination were similar to those after vaccination with the licensed comparator PCV. **Tabulated list of adverse reactions** Adverse reactions (i.e. events considered as related to vaccination) have been categorized by frequency for all age groups. Frequencies are reported as: Very common (≥1/10 vaccinees) Common (≥1/100 vaccinees but < 1/10 vaccinees) Uncommon (≥1/1000 vaccinees but < 1/100 vaccinees) Rare (≥1/10,000 vaccinees but < 1/1,000 vaccinees)				

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/EMA)	টেকনিক্যাল সাব কমিটির সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
2.	**Manufacturer:** Serum Institution of India Ltd, 212/2 Hadapsar, Pune-411 0028, Maharashtra State, India **Local Agent:** Renata Limited	PNEUMOSIL Vaccine, In‡jvectable, Suspension for In‡jvection (0.5ml-1 Dose, 10 Valent)	Each dose of 0.5ml contains: Saccharide for serotypes 1, 5, 9V, 14, 19A, 19F, 23F, 7F, 6A (2mcg each) + Saccharide for serotype 6B 4mcg + Con‡jvugated to CRM197 carrier protein Aluminium (as Aluminium phosphate) 0.125 mg	Human Vaccine **Therapeutic code:** 069	Active immunization against invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* serotypes 1,5, 6A, 6B, 7F, 9V, 14, 19A, 19F and 23F in infants and toddlers from 6 weeks up to 2 years of age. The use of vaccine should be determined on the basis of relevant recommendations and take into consideration the disease impact by age and regional epidemiology	**CONTRAINDICATIONS:** Hypersensitivity to any component of the vaccine, including diphtheria toxoid. **Side Effects:** Safety assessment of Pneumococcal Polysaccharide Con‡jvugate Vaccine (Adsorbed) (10-valent) was based on clinical trials involving the administration of 5,416 doses to 1,828 healthy children as primary immunization. Furthermore, 428 children received a booster dose of Pneumococcal Polysaccharide Con‡jvugate Vaccine (Adsorbed) (10-valent) following a primary vaccination course. Pneumococcal Polysaccharide Con‡jvugate Vaccine (Adsorbed) (10-valent) was administered concomitantly with recommended childhood vaccines, as appropriate. Safety was also assessed in 57 previously unvaccinated children during the second year of life; all children received 2 doses of vaccine. Pneumococcal Polysaccharide conjugate Vaccine (Adsorbed) (10-valent) has also been used for booster vaccination in 56 children who received another pneumococcal conjugate vaccine for the primary course. The vast majority of the reactions observed following vaccination were of mild or moderate severity and were of short duration. In the largest study in infants, the most common adverse reactions observed after primary vaccination were tenderness at the injection site, fever and irritability, which were reported for approximately 49%, 52% and 32% of all infants, respectively. No	New	COPP-India WHO Pre-qualified Certificate	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/EMA)	টেকনিক্যাল সাব কমিটির সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						increase in the incidence or severity was observed following subsequent doses of the primary vaccination course. Following booster vaccination, the most common adverse reaction was tenderness at the in‡jvection site, which was reported for approximately 8% of all infants. The Indian Phase 3 licensure study in infants similarly showed tenderness at the in‡jvection site, fever and irritability as the most common adverse reactions observed after primary vaccination, with no change in the incidence or severity observed following subsequent doses of the primary vaccination course. Majority of the solicited AEs were of mild to moderate intensity and resolved completely. The in‡jvection site and systemic reactions following catch-up vaccination or booster vaccination during the second year of life were similar to those reported after primary vaccination. In all studies, the incidence and severity of local and general adverse reactions reported within 7 days of vaccination were similar to those after vaccination with the licensed comparator PCV. **Tabulated list of adverse reactions** Adverse reactions (i.e. events considered as related to vaccination) have been categorized by frequency for all age groups. Frequencies are reported as: Very common (≥1/10 vaccinees) Common (≥1/100 vaccinees but < 1/10 vaccinees) Uncommon (≥1/1000 vaccinees but < 1/100 vaccinees) Rare (≥1/10,000 vaccinees but < 1/1,000 vaccinees)				

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/EMA)	টেকনিক্যাল সাব কমিটির সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
3.	M/s Biological E. Limited Plot No. 1, Biotech Park, Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri (District), Telangana, INDIA-500 078. **Local Agent:** Janata Traders 62/2 Purana Paltan Dhaka 1000	**JEEV® - 3 mcg/0.5 ml** Suspension for Intramuscular In‡jvection. Single dose Vial of 0.5 mL & Five dose Vial of 2.5 mL	Japanese Encephalitis Inactivated Vaccine (Human) (Purified Inactivated Vaccine – (Adsorbed) 3 mcg/0.5 mL **Vaccine**	Human Vaccine **Therapeutic code:** 069	JEEV® is indicated for active immunization against Japanese Encephalitis in children (between ≥ 1 to < 3 years of age). The vaccine should be used in children at risk of exposure through travel into areas where JE is endemic, spending a month or longer in endemic areas during the transmission season, especially if travel will include rural areas or residing in areas where JE is endemic or epidemic. JE Vaccine should also be considered for short-term (< 1 month) travelers whose itinerary or activities might increase their risk for exposure to JE virus.	**Contraindication:** Hypersensitivity to any component of vaccine Administration must be postponed in persons with acute severe febrile conditions. **Side effects:** The safety of JEEV® was assessed in a controlled clinical trials ≥ 1 to <3 Years old healthy indian children. Adverse events usually within first three days after vaccination and are usually mild or occasionally moderate in intensity and disappear within a few days.	New	India WHO Prequalified	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
4.	M/s Biological E. Limited Plot No. 1, Biotech Park, Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri	**JEEV® - 6 mcg/0.5 ml** Suspension for Intramuscular In‡jvection. Single dose Vial of 0.5 mL & Five dose Vial of 2.5 ml	Japanese Encephalitis Inactivated Vaccine (Human) (Purified Inactivated Vaccine – (Adsorbed) 6 mcg/0.5 mL **Vaccine**	Human Vaccine **Therapeutic code:** 069	JEEV® is indicated for active immunization against Japanese Encephalitis in children (between ≥ 3 to ≤ 49 years of age). The vaccine should be used in children at risk of exposure through travel	**Contraindication:** Hypersensitivity to any component of vaccine Administration must be postponed in persons with acute severe febrile conditions. **Side effects:** The safety of JEEV® was assessed in a controlled clinical trials ≥ 3 to ≤ 49 Years old children and adults. Adverse events usually within first three days after vaccination and are usually mild	New	India WHO Prequalified	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl. No	Name of the Manufacturer	Name of the Product	Generic Name with Strength	Therapeutic Class	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/FSC (UK/USA/Switzerland /Germany/France/ Japan/Australia/EMA)	টেকনিক্যাল সাব কমিটির সভার মতামত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	(District), Telangana, INDIA-500 078. **Local Agent:** Janata Traders 62/2 Purana Paltan Dhaka 1000				into areas where JE is endemic, spending a month or longer in endemic areas during the transmission season, especially if travel will include rural areas or residing in areas where JE is endemic or epidemic	or occasionally moderate in intensity and disappear within a few days. No increase in the number of adverse events reported was noted between first and second doses.				

Annex-E: স্থানীয়ভাবে উৎপাদনের জন্য ভেটেরিনারী মেডিসিন এর তালিকা

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
1.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Furosemide 50 mg/ml (5ml Injection)	Furosemide 50 mg/ml Injection	Therapeutic Class: Diuretic Therapeutic Code:042	It is indicated for the treatment of oedemata associated with cardiac insufficiency, renal dysfunction, trauma and parasitic disease. It is also recommended for the treatment of mammary oedema and limb oedemata .	**Contraindication:** 1. Excessive amounts may result in dehydration 2. increased thirst, lethargy, drowsiness or may happen 3. Restlessness, fatigue, oliguria, gastrointestinal disturbances and tachycardia may occur **Side Effects:** Common: thirst, lethargy, drowsiness etc. Rare: gastrointestinal disturbances and tachycardia. **Warning & Precaution:** It may lower serum calcium levels.	2000mg Bolus	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
2.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Furosemide 50 mg/ml (10ml Injection)l	Furosemide 50 mg/ml Injection	Therapeutic Class: Diuretic Therapeutic Code:042	It is indicated for the treatment of oedemata associated with cardiac insufficiency, renal dysfunction, trauma and parasitic disease. It is also recommended for the treatment of mammary oedema and limb oedemata .	**Contraindication:** 1. Excessive amounts may result in dehydration 2. Excessive amounts may result in dehydration 3. increased thirst, lethargy, drowsiness or may happen 4. Restlessness, fatigue, oliguria, gastrointestinal disturbances and tachycardia may occur **Side Effects:** Common: thirst, lethargy, drowsiness or etc. Rare: gastrointestinal disturbances and tachycardia. **Warning & Precaution:** It may lower serum calcium levels.	2000mg Bolus	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
3.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Eprinomectin 20 mg + Vitamin E 50 mg/ml Injection (50ml Injection)	Eprinomectin 20 mg + Vitamin E 50 mg/ml	Therapeutic Class: Anthelmintic Therapeutic Code:053	It is indicated for effective treatment & control of the common mature & immature gastro intestinal worms, lungworm, sucking lice & mange mites in beef & dairy cattle & as supportive therapy for poor immunity, poor growth rates, lower feed efficiency & poor fertility.	**Contra Indications:** Patients who are hypersensitive to this drug or to any ingredient in the formulation. Ibrexafungerp use is contraindicated in pregnancy because it may cause fetal harm. **Side-effects:** The most common side effects of Ibrexafungerp include: loose stools, nausea, stomach pain, dizziness, and vomiting. **Warning & Precautions:** Prior to initiating treatment with Ibrexafungerp, verify the pregnancy status in females of reproductive potential. Advise females of reproductive potential to use effective contraception during treatment with Ibrexafungerp and for 4 days after the last dose.	Eprinomectin 500 mg/10 ml Injection	No Reference Medsafe (New Zealand)	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
4.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Eprinomectin 20 mg + Vitamin E 50 mg/ml Injection (100ml Injection)	Eprinomectin 20 mg + Vitamin E 50 mg/ml	Therapeutic Class: Anthelmintic Therapeutic Code:053	It is indicated for effective treatment & control of the common mature & immature gastro intestinal worms, lungworm, sucking lice & mange mites in beef & dairy cattle & as supportive therapy for poor immunity, poor growth rates, Lower feed efficiency & poor fertility.	**Contra Indications:** Patients who are hypersensitive to this drug or to any ingredient in the formulation. Ibrexafungerp use is contraindicated in pregnancy because it may cause fetal harm. **Side-effects:** The most common side effects of Ibrexafungerp include: loose stools, nausea, stomach pain, dizziness, and vomiting. **Warning & Precautions:** Prior to initiating treatment with Ibrexafungerp, verify the pregnancy status in females of reproductive potential. Advise females of reproductive potential to use effective contraception during treatment with Ibrexafungerp and for 4 days after the last dose.	Eprinomectin 500 mg/10 ml Injection	No Reference Medsafe (New Zealand)	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
5.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Eprinomectin 20 mg + Vitamin E 50 mg/ml Injection (500ml Injection)	Eprinomectin 20 mg + Vitamin E 50 mg/ml	Therapeutic Class: Anthelmintic Therapeutic Code:053	It is indicated for effective treatment & control of the common mature & immature gastro intestinal worms, lungworm, sucking lice & mange mites in beef & dairy cattle & as supportive therapy for poor immunity, poor growth rates, Lower feed efficiency & poor fertility.	Contra Indications: Patients who are hypersensitive to this drug or to any ingredient in the formulation. Ibrexafungerp use is contraindicated in pregnancy because it may cause fetal harm. Side-effects: The most common side effects of Ibrexafungerp include: loose stools, nausea, stomach pain, dizziness, and vomiting. Warning & Precautions: Prior to initiating treatment with Ibrexafungerp, verify the pregnancy status in females of reproductive potential. Advise females of reproductive potential to use effective contraception during treatment with Ibrexafungerp and for 4 days after the last dose.	Eprinomectin 500 mg/10ml Injection	No Reference Medsafe (New Zealand)	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
6.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Apramycin Sulfate Water Soluble Powder (WSP)	Apramycin 552000 IU/584.75 mg (as apramycin sulfate)/g, Water Soluble Powder (WSP)	Therapeutic Class: Antibiotic Therapeutic Code:051	**Poultry:** For the treatment of Colibacillosis by Escherichia coli susceptible to apramycin. **Calves:** For the treatment of bacterial enteritis caused by Escherichia coli and clinical outbreaks due to Salmonella enterica subsp. enterica serovar Dublin (Salmonella Dublin) susceptible to apramycin. Treatment should be based on prior confirmation of the Salmonella serovars involved. **Rabbits/Pigs:** For the treatment of bacterial enteritis caused by Escherichia coli.	**Contra Indications:** 1. Do not use in case of hypersensitivity to apramycin. 2. Do not use in calves with functional rumen. 3. Do not use in animals suffering from kidney disorders. **Side effects**: No adverse reactions have been reported with the use of this product at recommended levels. **Warning & Precautions**: When handling the product, avoid inhalation, oral exposure and direct contact with skin or eyes. In the event of skin contact, wash thoroughly with soap and water. In the event of accidental eye contact, wash the affected eye with fresh running water	New	USFDA, UKMHRA	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						and seek medical attention if irritation persists.				
7.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Doramectin 10 mg/ml Injection (5ml Injection)	Doramectin 10 mg/ml Injection	Therapeutic Class: Anthelmintic Therapeutic Code:053	For the treatment and control of both internal & external parasites in animal.	**Contra Indications:** Do not use in dogs, as severe adverse reactions may occur. **Side effects:** None. **Warning & Precautions:** Dectomax has been developed specifically for use in cattle and swine only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
8.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Doramectin 10 mg/ml Injection (10ml Injection)	Doramectin 10 mg/ml Injection	Therapeutic Class: Anthelmintic Therapeutic Code:053	For the treatment and control of both internal & external parasites in animal.	**Contra Indications:** Do not use in dogs, as severe adverse reactions may occur. **Side effects:** None. **Warning & Precautions:** Dectomax has been developed specifically for use in cattle and swine only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
9.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Doramectin 10 mg/ml Injection (30ml Injection)	Doramectin 10 mg/ml Injection	Therapeutic Class: Anthelmintic Therapeutic Code:053	For the treatment and control of both internal & external parasites in animal.	**Contra Indications:** Do not use in dogs, as severe adverse reactions may occur. **Side effects:** None. **Warning & Precautions:** Dectomax has been developed specifically for use in cattle and swine only. This product should not be used in other animal species as	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						severe adverse reactions, including fatalities in dogs, may result.				
10.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Doramectin 10 mg/ml Injection (50ml Injection)	Doramectin 10 mg/ml Injection	Therapeutic Class: Anthelmintic Therapeutic Code:053	For the treatment and control of both internal & external parasites in animal.	**Contra Indications:** Do not use in dogs, as severe adverse reactions may occur. **Side effects:** None. **Warning & Precautions:** Dectomax has been developed specifically for use in cattle and swine only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
11.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Mupirocin 20 mg/ml.	Mupirocin 20 mg/ml Ointment	Therapeutic Class: Antibiotic Therapeutic Code:051	Topical treatment of bacterial infections caused by susceptible microorganisms.	**Contra Indications:** This drug is contraindicated in animals with a history of sensitivity reactions to any of its components. **Side effects:** No adverse reactions have been reported with this product **Warning & Precautions:** Care should be taken when using this product in treating extensive deep lesions where absorption of large quantities of polyethylene glycol is possible.	New	USFDA	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
12.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Amoxycillin trihydrate 150 mg + Gentamicin 40 mg/ml Injection (10ml Injection)	Amoxycillin trihydrate 150 mg + Gentamicin 40 mg/ml Injection	Therapeutic Class: Antibiotic Therapeutic Code:051	**Cattle**- Gastrointestinal, respiratory and intramammary infections, pneumonia, diarrhoea, bacterial enteritis, mastitis, metritis and cutaneous abscesses. **Swine**- Respiratory and gastrointestinal infections & bacterial enteritis and mastitis metritis-agalactia syndrome (MMA)	**Contra Indications:** Do not use in cases of known hypersensitivity to the active substance, or to any of excipients. **Side effects:** Prolonged treatment with doses greater than recommended may cause renal disorder. **Warning & Precautions:** It may cause severe pain &	New	EMA Brand: Biogenta (Interchemie), The Netherlands Brand: GENTAMOX (Hipra), Spain	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						inflammation in the case of accidental self-Injection.				
13.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Amoxycillin trihydrate 150 mg + Gentamicin 40 mg/ml Injection (30ml Injection)	Amoxycillin trihydrate 150 mg + Gentamicin 40 mg/ml Injection	Therapeutic Class: Antibiotic Therapeutic Code:051	**Cattle**- Gastrointestinal, respiratory and intramammary infections, pneumonia, diarrhoea, bacterial enteritis, mastitis, metritis and cutaneous abscesses. **Swine**- Respiratory and gastrointestinal infections & bacterial enteritis and mastitis metritis-agalactia syndrome (MMA)	**Contra Indications:** Do not use in cases of known hypersensitivity to the active substance, or to any of excipients. **Side effects:** Prolonged treatment with doses greater than recommended may cause renal disorder. **Warning & Precautions:** It may cause severe pain & inflammation in the case of accidental self-Injection.	New	EMA Brand: Biogenta (Interchemie), The Netherlands Brand: GENTAMOX (Hipra), Spain	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
14.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Butylscopolamine Bromide 4 mg + Metamizole 500 mg/m (15ml Injection)l	Butylscopolamine Bromide 4 mg + Metamizole 500 mg/ml Injection	Therapeutic Class: Analgesic & Antipyretics Therapeutic Code:058	Spasmolytic and Analgesic for cattle, horse and dog	**Contra Indications:** Do not use in cases of known hypersensitivity to the active substance, or to any of excipients. **Side effects:** Studies in laboratory animals (rabbit, rat) have not produced any evidence of a teratogenic effect. No information on use during pregnancy in the target species is available and therefore should not be used. **Warning & Precautions:** Due to a risk of local reactions, do not use the intramuscular route in horses.	New	UKMHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
15.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Butylscopolamine Bromide 4 mg + Metamizole 500 mg/ml (30ml Injection)	Butylscopolamine Bromide 4 mg + Metamizole 500 mg/ml Injection	Therapeutic Class: Analgesic & Antipyretics Therapeutic Code:058	Spasmolytic and Analgesic for cattle, horse and dog	**Contra Indications:** Do not use in cases of known hypersensitivity to the active substance, or to any of excipients. **Side effects:** Studies in laboratory animals (rabbit, rat) have not produced any evidence of a teratogenic effect. No information on use during pregnancy in the target species is available and therefore should not be used. **Warning & Precautions:** Due to a risk of local reactions, do not use the intramuscular route in horses.	New	UKMHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
16.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Butylscopolamine Bromide 4 mg + Metamizole 500 mg/ml 50ml Injection)	Butylscopolamine Bromide 4 mg + Metamizole 500 mg/ml Injection	Therapeutic Class: Analgesic & Antipyretics Therapeutic Code:058	Spasmolytic and Analgesic for cattle, horse and dog	**Contra Indications:** Do not use in cases of known hypersensitivity to the active substance, or to any of excipients. **Side effects:** Studies in laboratory animals (rabbit, rat) have not produced any evidence of a teratogenic effect. No information on use during pregnancy in the target species is available and therefore should not be used. **Warning & Precautions:** Due to a risk of local reactions, do not use the intramuscular route in horses.	New	UKMHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
17.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Xylazine hydrochloride 20 mg/ml (5ml Injection)	Xylazine hydrochloride 20 mg/ml Injection	Therapeutic Class: Anesthetic Therapeutic Code:058	It is used as a preanesthetic, sedative, analgesic, muscle relaxant, premedication agent & induce vomition.	**Contra Indications:** Do not use in case of respiratory diseases, ventricular arrhythmia, hypotension and in a shock. **Side effects:** Respiratory weakness with concomitant acidosis, bradycardia, hypotension, frequent urination. **Warning & Precautions:** Gas accumulation in GIT, inhibit intestinal motility etc.	Existing	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
18.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Xylazine hydrochloride 20 mg/ml (10ml Injection)	Xylazine hydrochloride 20 mg/ml Injection	Therapeutic Class: Anesthetic Therapeutic Code:058	It is used as a preanesthetic, sedative, analgesic, muscle relaxant, premedication agent & induce vomition.	**Contra Indications:** Do not use in case of respiratory diseases, ventricular arrhythmia, hypotension and in a shock. **Side effects:** Respiratory weakness with concomitant acidosis, bradycardia, hypotension, frequent urination. **Warning & Precautions:** Gas accumulation in GIT, inhibit intestinal motility etc.	Existing	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
19.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Xylazine Hydrochloride 20 mg/ml (30ml Injection)	Xylazine Hydrochloride 20 mg/ml Injection	Therapeutic Class: Anesthetic Therapeutic Code:058	It is used as a preanesthetic, sedative, analgesic, muscle relaxant, premedication agent & induce vomition.	**Contra Indications:** Do not use in case of respiratory diseases, ventricular arrhythmia, hypotension and in a shock. **Side effects:** Respiratory weakness with concomitant acidosis, bradycardia, hypotension, frequent urination. **Warning & Precautions:** Gas accumulation in GIT, inhibit intestinal motility etc.	Existing	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
20.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Xylazine hydrochloride 20 mg/ml (50ml Injection)	Xylazine hydrochloride 20 mg/ml Injection	Therapeutic Class: Anesthetic Therapeutic Code:058	It is used as a preanesthetic, sedative, analgesic, muscle relaxant, premedication agent & induce vomition.	**Contra Indications:** Do not use in case of respiratory diseases, ventricular arrhythmia, hypotension and in a shock. **Side effects:** Respiratory weakness with concomitant acidosis, bradycardia, hypotension, frequent urination. **Warning & Precautions:** Gas accumulation in GIT, inhibit intestinal motility etc.	Existing	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
21.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Cefoperazone sodium 250 mg/10 ml vial Injection (10ml Injection)	Cefoperazone sodium 250 mg/10 ml vial Injection.	Therapeutic Class: Antibiotic Therapeutic Code:051	Cefoperazone Intramammary Suspension is indicated for the treatment of clinical mastitis in lactating cows.	**Contra Indications:** Contraindicated in animals hypersensitive to cephalosporin's or to have severe disturbance of kidney function. **Side effects:** In some cases skin rash, fever, diarrhoea, transient elevation of serum transaminases and transient eosinophilia. **Warning & Precautions:** • It is not envisaged for this product to be administrated to species other than lactating cattle. • Special precautions for use in animals • Special precautions to be taken by the person administering the veterinary medicinal product to animals.	New	UKMHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
22.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Cefoperazone sodium 250 mg/10 ml vial Injection (20ml Injection)	Cefoperazone sodium 250 mg/10 ml vial Injection.	Therapeutic Class: Antibiotic Therapeutic Code:051	Cefoperazone Intramammary Suspension is indicated for the treatment of clinical mastitis in lactating cows.	**Contra Indications:** Contraindicated in animals hypersensetive to cephalosporins or to have severe disturbance of kidney function. **Side effects:** In some cases skin rash, fever, diarrhoea, transient elevation of serum transaminases and transient eosinophilia. **Warning & Precautions:** • It is not envisaged for this product to be administrated to species other than lactating cattle. • Special precautions for use in animals • Special precautions to be taken by the person administering the veterinary medicinal product to animals.	New	UKMHRA	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
23.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Difloxacin (as hydrochloride) 100 mg/ml	Difloxacin (as hydrochloride) 100 mg/ml Oral Solution	Therapeutic Class: Antibiotic Therapeutic Code:051	Chronic Respiratory Disease (CRD) caused by susceptible microorganisms in poultry. It is also indicated for the treatment of infections caused by *Pasteurella multocida* in poultry.	**Contra Indications:** Do not use in laying hens. Do not use in cases of known hypersensitivity to the active substance, or to any of excipients. Do not administer with NSAIDS. **Side effects:** Nausea, Vomiting, Diarrhea, lack of appetite etc. **Warning & Precautions:** Do not use another drink tray during the medication period. Keep the product in its original container. The solution is recommended to use with protective equipment (gloves .glasses, etc.)	New	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
24.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Guaifenesin 128 mg/ml	Guaifenesin 128 mg/ml Oral Solution	Therapeutic Class: Expectorant Therapeutic Code:059	As supportive therapy in common cold, dry cough, chronic bronchitis, bronchial congestion, upper respiratory tract infections and other respiratory diseases.	**Contra Indications:** Anticholinesterase drugs such as physostigmine are contraindicated. **Side effects:** Guaifenesin may cause a mild decrease in blood pressure and an increase in heart rate. **Warning & Precautions:** Signs of overdose include apneustic breathing, nystagmus, hypotension and increased muscle rigidity if overdose exceeds three times.	New	USFDA	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
25.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Halofuginone 0.50 mg/ml	Halofuginone 0.50 mg/ml Oral solution	Therapeutic Class: Antiprotozoal Therapeutic Code:051	For the treatment of Diarrhoea due to Cryptosporodiosis in new born calves	**Contraindication:** 1. Do not use on an empty stomach 2. Do not use in cases of diarrhoea estabiashed for more than 24 hrs and in weak animals. 3. Do not use in cases of hypersensitivity to the active substance or to any of the excipients. **Side Effects:** Common: Anorexia, Vomiting, allergic reactions etc. Rare: An increase in the level of diarrhoea has been observed in	New	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						treated animals. **Warning & Precaution:** Wash skin thoroughly after handling.				
26.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Paromomycin sulfate 200 mg, equivalent to paromomycin base 140 mg/ml Oral solution	Paromomycin sulfate 200 mg, eq. to paromomycin base 140 mg/ml	Therapeutic Class: Anthelmintic Therapeutic Code:053	Treatment of gastro-intestinal infections caused by Escherichia coli susceptible to paromomycin.	**Contra Indications:** Do not use in animals with known hypersensitivity to paromomycin, other aminoglycosides or any of the excipients. Do not use in cases with impaired function of the kidneys or liver. **Side effects:** In some cases ototoxicity, nephrotoxicity & soft faeces may occur. **Warning & Precautions:** Reuptake of medication by animal can be altered as a consequence of illness. In some cases Paromomycin may cause allergic reactions in some people. Do not eat, drink and smoke when handling the product.	New	UKMHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
27.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Tilmicosin 300 mg/ml Injection (10ml Injection)	Tilmicosin 300 mg/ml	Therapeutic Class: Antibiotic Therapeutic Code:051	Treatment and control of Bovine & Swine respiratory diseases, foot rot & mastitis caused by susceptible microorganisms in animals.	**Contra Indications:** Do not use in cases of known hypersensitivity to the active substance, or to any of excipients. **Side effects:** Soft tissue swelling may occur. Hypersensitivity reactions may occur in very rare cases. **Warning & Precautions:** To avoid self-Injection do not use automatic Injection equipment.	New	USFDA, EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
28.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Tilmicosin 300 mg/ml Injection (30ml Injection)	Tilmicosin 300 mg/ml	Therapeutic Class: Antibiotic Therapeutic Code:051	Treatment and control of Bovine & Swine respiratory diseases, foot rot & mastitis caused by susceptible microorganisms in animals.	**Contra Indications:** Do not use in cases of known hypersensitivity to the active substance, or to any of excipients. **Side effects:**	New	USFDA, EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Soft tissue swelling may occur. Hypersensitivity reactions may occur in very rare cases. **Warning & Precautions:** To avoid self-Injection do not use automatic Injection equipment.				
29.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Tilmicosin 300 mg/ml Injection (100ml Injection)	Tilmicosin 300 mg/ml	Therapeutic Class: Antibiotic Therapeutic Code:051	Treatment and control of Bovine & Swine respiratory diseases, foot rot & mastitis caused by susceptible microorganisms in animals.	**Contra Indications:** Do not use in cases of known hypersensitivity to the active substance, or to any of excipients. **Side effects:** Soft tissue swelling may occur. Hypersensitivity reactions may occur in very rare cases. **Warning & Precautions:** To avoid self-Injection do not use automatic Injection equipment.	New	USFDA, EMA Approved by DCC-242	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
30.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Nystatin 100000 units + Neomycin (as sulfate) 2.5 mg + Gramicidin 0.25 mg + Triamcinolone Acetonide 1mg/gm Cream	Nystatin 100000 units + Neomycin (as sulfate) 2.5 mg + Gramicidin 0.25 mg + Triamcinolone acetonide 1mg/gm	Therapeutic Class: Antibiotic Therapeutic Code:051	It is indicated in acute atopic dermatitis, exfoliative erythroderm-neurodermatitis, nummular eczema, acute contact dermatitis, chronic eczema, chronic familial benign pemphigus and intertriginous.	**Contra Indications:** Do not use in cases of known hypersensitivity to the active substance of this products or to any of excipients. **Side effects**: Burning, stinging, redness, or irritation may occur in some cases. **Warning & Precautions**: For Skin Contact: Wash with soap and water. Eye Contact: Flush with copious amounts of water.	New	NO REFERENCE (Health Canada's HPFB, Canada)	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
31.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Carprofen 200 mg Bolus	Carprofen USP 200mg	Therapeutic Class: Analgesic & Antipyretics Therapeutic Code:058	It is indicated in fever, pain, inflammatory diseases and acute infectious respiratory disease & acute mastitis in cattle as supportive therapy. It is also recommended in synovitis, bursitis, arthritis, tendinitis, sprains, twist, traumatic in‡jvuries.	**Contraindications:** Animals with cardiac, renal or hepatic disease, where there is the possibility of gastro-intestinal ulceration or bleeding, hypersensitivity to the drug; treatment with other NSAIDs concurrently or within 24 hours: race horses prior racing; pregnant mares.	Carprofen USP 100 mg Bolus, Carprofen USP 500 mg Bolus	NO REFERENCE	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Side effects: Common side effects: Prolonged use may cause gastro-intestinal lesions, inappetance, vomiting and diarrhea. Rare Side effects: Not known. **Warning & precaution** Caution with use in animals less than 6 weeks of age or aged animals; avoid used in dehydrated, hypovolunlaemic or hypotensive patients; avoid concurrent, potentially nephrotoxic drugs.				
32.	Advanced Chemical Industries Limited, 7 Hajeegan‡jv, Godnyl, Narayangan‡jv.	Danofloxacin 5% Injection (25ml)	Danofloxacin Mesylate INN 63.44mg eqv. to Danofloxacin 50 mg/ml,	Anti-biotic (023) Veterinary (077)	Danofloxacin is indicated for the treatment of respiratory and digestive tract infections caused by gram positive, gram negative bacteria and Mycoplasma.	**Contraindication:** Danofloxacin is not recommended for use in the case of resistant bacteria to other fluoroquinolones. **Side-effects:** Hypersensitivity reaction causing lameness.	**New Molecule**	**No reference**	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
33.	Advanced Chemical Industries Limited, 7 Hajeegan‡jv, Godnyl, Narayangon‡jv.	Ronidazole 12.0 % Oral Powder	Ronidazole BP 12.0 %,	Veterinary Drugs (077)	Indicated in the treatment of Trichomoniasis and hexamitiasis and Canker it's highly effective against other protozoa, which affect pigeons.	**Contraindication:** Ronidazole should not be used with the Oxytetracyclines, Phenobarbital, Rifampin, or Phenytoin. **Side-effects:** Common side effects: No side effects observed at recommended doses. Rare side effects: No side effects observed at recommended doses.	**New Molecule**	**No reference** American Pharmaceutical Ingredients (Dailymed)	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
34.	Navana Pharmaceuticals Limited	Itraconazole 10 mg/ml Oral Solution (Veterinary)	Itraconazole 10 mg/ml	Antifungal 077	It is indicated for the treatment of dermatophytosis caused by Microsporum canis in cats.	Contraindication: Hypersensitivity Side-effects: Salivation, vomiting, diarrhea, anorexia, depression and apathy may occasionally occur. These effects are usually mild and transient. Warnings: Wash hands after use. Precautions: it is recommended to administer the product without food.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
35.	Navana Pharmaceuticals Limited	Furosemide 1500 mg/30 ml (Veterinary)	Furosemide 1500 mg/30 ml Injection (30ml Vial)	Diuretic 077	Edema, ascites	Contraindication: Hypersensitivity, or seriously depleted electrolytes Side-effects: Increased urination alkalosis, uric acid retention and may rarely produce acute gout, hyperglycemia & glycosuria. Warnings: Do not use in animals with pre-existing electrolyte or water imbalance, impaired hepatic function. Precautions: Do not mix with other medicines.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
36.	Navana Pharmaceuticals Limited	Furosemide 1500mg/30ml Injection (Veterinary)	Furosemide 1500 mg/30 ml	Diuretic 077	Edema, ascites	Contraindication: Hypersensitivity, or seriously depleted electrolytes Side-effects: Increased urination alkalosis, uric acid retention and may rarely produce acute gout, hyperglycemia & glycosuria. Warnings: Do not use in animals with pre-existing electrolyte or water imbalance, impaired hepatic function. Precautions: Do not mix with other medicines.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
37.	**Navana Pharmaceuticals Limited**	Furosemide 10 mg/ml (Veterinary)	Furosemide 10 mg/ml Syrup	Diuretic 077	Edema, ascites	**Contraindication:** Hypersensitivity, or seriously depleted electrolytes Side-effects: Increased urination alkalosis, uric acid retention and may rarely produce acute gout, hyperglycemia & glycosuria. **Warnings:** Do not use in animals with pre-existing electrolyte or water imbalance, impaired hepatic function. Precautions: Do not mix with other medicines.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
38.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgari, Pabna	Difloxacin 150mg Bolus (For Veterinary Use)	Difloxacin Hydrochloride Trihydrate BP 185.120mg eq. to 150mg Difloxacin	Therapeutic Class: Veterinary Drugs Therapeutic code: 077	Prevention and treatment of infections caused by microorganisms sensitive to Difloxacin, among these; digestive tract, genital and urinary tract, respiratory tract, ear canal and skin infections. This drug is recommended for the treatment of acute infections. Withdrawal period: Meat and offal: 46 days.	Side effects: Adverse reactions were rare treated with Difloxacin. The observed reactions were inappetence, emesis, diarrhea, and anal irritation. These adverse reactions were selflimiting within one or two days and did not require additional treatment. Contraindications and warnings: Difloxacin is not recommended in animals with hypersensitivity to the active ingredient. Do not administrate by other route different than the indicated. Do not administer along with NSA|Ds. Difloxacin must not be used in growing dogs under the fast growing stage due to possible adverse effects on the joints cartilage. Must not be used in small and medium breed dogs up to the 8 months old, in big breed dogs up to 12 months old and in giant breed dogs up to 18 months old.	New	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
39.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgari, Pabna	Difloxacin 10g /100ml Injection (For Veterinary Use)	Difloxacin Hydrochloride Trihydrate BP 12.3413g (eq. to 10 g Difloxacin)/100ml	Therapeutic Class: Veterinary Drugs Therapeutic code: 077	Prevention and treatment of infections caused by microorganisms sensitive to Difloxacin, among these; digestive tract, genital and urinary tract, respiratory tract, ear canal and skin infections. This drug is recommended for the treatment of acute infections. Withdrawal period: Meat and offal: 46 days.	Side effects: Occasionally, pruritus and or local inflammation has been observed in the Injection site. These reactions are transient and comparable to the ones observed with other antibiotics. In dogs, pain on the Injection site had been reported rarely. General adverse reactions had not been observed with the Injection drug, in doses up to 4 times the recommended dose. It can manifest infrequently hypersensitivity reactions, if they occur, discontinue treatment. Local reaction (swelling) may occur at the Injection site in animals for up to a week.	New	No Reference	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Contraindications and warnings: Difloxacin is not recommended in animals with hypersensitivity to the active ingredient. Do not administrate by other route different than the indicated. Do not administer along with NSA|Ds. Difloxacin must not be used in growing dogs under the fast growing stage due to possible adverse effects on the joints cartilage. Must not be used in small and medium breed dogs up to the 8 months old, in big breed dogs up to 12 months old and in giant breed dogs up to 18 months old.				
40.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgari, Pabna	Difloxacin 10g/ 100ml Oral Solution (For Veterinary Use)	Difloxacin Hydrochloride Trihydrate BP 12.3413gm eq. to 10 g Difloxacin/100ml	Therapeutic Class: Veterinary Drugs Therapeutic code: 077	Prevention and treatment of infections caused by microorganisms sensitive to Difloxacin, among these; digestive tract, genital and urinary tract, respiratory tract, ear canal and skin infections. This drug is recommended for the treatment of acute infections. Withdrawal period: Meat and offal: (chickens and turkeys): 24 hours.	Side effects: Adverse reactions were rare treated with Difloxacin. The observed reactions were inappetence, emesis, diarrhea, and anal irritation. These adverse reactions were selflimiting within one or two days and did not require additional treatment. Contraindications and warnings: Since no studies were performed in clinically lame birds, Difloxacin should not be used in birds with existing leg-weakness or in birds suffering from osteoporosis.	New	No Reference	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
41.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgari, Pabna	Bacitracin Zinc BP 0.667 g (eqv. to 40000 IU) + Neomycin Sulphate (Micronized) BP 0.35 g + Polymyxin B Sulphate (Micronized) BP 0.077 g (eqv. to 500000 IU)/100g Ointment (For Veterinary Use)	Bacitracin Zinc BP 0.667 g eq. to 40000 IU) + Neomycin Sulphate (Micronized) BP 0.35 g + Polymyxin B Sulphate (Micronized) BP 0.077 g (eqv. to 500000 IU)/100g	Therapeutic Class: Veterinary Drugs Therapeutic code: 077	It is used in the treatment of infected wounds, burns or skin grafts and in the prevention of infection of extensive burns and contaminated wounds.	Side effects: Itching or inflammation may occur in animal's sensitive to the product. Contraindications: Animals with a hypersensitivity to Neomycin Sulphate, Bacitracin zinc & Polymyxin B Sulphate should not receive this medication	New	No Reference	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
42.	Eskayef Pharmaceuticals Limited, Murapara, Rupgan‡jv, Narayangan‡jv	Tolfenamic Acid 200mg Bolus	Tolfenamic Acid BP 200mg	Therapeutic Class: **NSAID** Therapeutic code: **064**	**It is indicated for rapid relief of Pain, Inflammation & fever in the following conditions:** • Mastitis • Metritis • Osteoarthritis • Muscular fatigue • Bovine Respiratory Disease (BRD) **DOSAGE & ADMINISTRATION:** • **Species:** Cattle • **Dose:** 1 Bolus/ 100Kg (2 mg/Kg) body weight • **Route:** Oral administration • **Interval:** Once Daily • **Duration:** 3-5 days Or, as per direction of a registered Veterinarian/Consultant. **WITHDRAWAL PERIOD:** • Meat: 12 days • Milk: Zero (0) day **STORAGE CONDITION:** Keep in a dry place and away from light. Store at or below 25 °C temperature. Keep out of reach of children.	**CONTRAINDICATIONS:** Should not be administered with glucocorticoids as well as the animals hypersensitive to Tolfenamic Acid. **SIDE-EFFECT:** There are relatively few side effects assorted with Tolfenamic Acid. The most common side effects are diarrhea, vomiting & loss of appetite. **OVERDOSE:** Tolfenamic Acid is well tolerated as dose up to 3 to 5 times at recommended dose for cattle.	**Tolfenamic Acid 200mg Bolus (Suspended)** **Tolfenamic Acid 400mg/10ml Injection** **Tolfenamic Acid 1gm/25ml Injection**	No Reference	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
43.	**Eskayef Pharmaceuticals Limited, Murapara, Rupgan‡jv, Narayangan‡jv**	Triclabendazole 900mg + Ivermectin 15mg Bolus	Triclabendazole BP 900mg + Ivermectin BP 15mg	Therapeutic Class: **Other Classification** Therapeutic code: **075**	It is indicated for Prevention & Treatment of Liver fluke, Round worm & Ectoparasites of Cattle, Buffalo & Sheep/Goat. **DOSAGE & ADMINISTRATION:** • **Dose:** 1 Bolus / 41-75 Kg body weight (Ivermectin 0.2 mg	**CONTRAINDICATIONS:** It is contraindicated in animals hypersensitive to active ingredients. **SIDE-EFFECT:** It is well tolerated. At the recommended doses there is no side effect.	Levamisole 150mg + Triclabendazole 225mg Bolus Levamisole 600mg + Triclabendazole 900mg Bolus	No Reference	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					and Triclabendazole 12 mg/ kg body weight) • **Route:** Oral administration Or, as per direction of a registered Veterinarian/Consultant. **WITHDRAWAL PERIOD:** • Meat: 12 days • Milk: 28 days **STORAGE CONDITION:** Store at or below 25°C temperature. Store in a dry place, away from light. Keep out of the reach of children.	**OVERDOSE:** Triclabendazole 16 times & Ivermectin 10 time's safe than the recommended dosages. **DRUG INTERACTIONS:** This combination should not be used with Pyrantel, Morantel and Diethylcarbamazine. **USE IN PREGNANCY AND LACTATION:** **There is no effect on pregnant animals if given in recommended dosage. It has no embryonic or teratogenic effect reported in fetus.** **WARNINGS AND PRECAUTIONS:** • The animal should be given adequate fluid during and after therapy. • There is no adverse effect but sometimes diarrhoea may occur in over dosages.	Levamisole 750mg + Triclabendazole 1.2gm Bolus Levamisole 1.2gm + Triclabendazole 1.8gm Bolus Triclabendazole 900mg Bolus Ivermectin 500mg/100ml Solution Ivermectin 1gm/100gm Solution Ivermectin 1gm/100ml Injection Ivermectin 10mg/ml Injection			
44.	**Eskayef Pharmaceuticals Limited, Murapara, Rupgan‡jv, Narayangan‡jv.**	Zinc 900mg Bolus	Zinc Sulphate Monohydrate USP 2470.095mg (eq. to 900mg Zinc)	Therapeutic Class: **Other Classification** Therapeutic code**:** **075**	**INDICATIONS:** **Poultry:** Increases growth and egg production Increases the Hatchability and productivity of Breeder and parent stock Helps to prevent any types of Diarrhea Decrease the rate of sudden death. **Dairy:** Helps to cure the infection of FMD Increases the fertility of Bull Increases body weight Helps to prevent any types of Diarrhea.	**CONTRAINDICATIONS:** Hypersensitive to Zinc. **SIDE-EFFECT:** It is well tolerated. At the recommended doses there is no side effect.	**Zinc 200mg Bolus** **Zinc 600mg Bolus** **Zinc 2gm/100ml Liquid**	No Reference	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					DOSAGE & ADMINISTRATION: • **Cattle:** 300-400kg body weight; 1 bolus in each cattle for 3-5 days. • **Poultry:** *Prevention* - 1 bolus in 200liter water for 3-5 days. *Treatment* - 1 bolus in 150liter water for 3-5 days. **WITHDRAWAL PERIOD:** Zero (0) day **STORAGE CONDITION:** Store in a cool & dry place, away from light. Keep out of the reach of children.					
45.	**Al-Madina Pharmaceuticals Ltd., Tilargati, Tongi, Gazipur**	Enrofloxacin+ Bromhexine Oral Solution (For Veterinary Use)	Enrofloxacin USP 200mg + Bromhexine HCl BP 10mg/ml	Therapeutic Class: Veterinary Drugs Therapeutic code: 077	For the treatment of primary and secondary infectious processes in poultry, produced by Gram positive, Gram negative and/or mycoplasmas. The Product is a combination of a fluoroquinolone and a mucolytic for oral administration in drinking water for chicken's broilers, brood stock and replacement chicks up to 16 weeks of life. **Withdrawal period:** Do not slaughter poultry until 10 days passed from last administration. Do not administer to layers or lifting cocks. Do not administer after the 16 weeks.	**CONTRAINDICATIONS:** Do not use in animals hypersensitive to Enrofloxacin and Bromhexine. **SIDE-EFFECT:** As with all veterinary products some unwanted effects can occur. Always consult veterinary physician or animal care specialist for medical advice before use. Common side effects include: diarrhea or loose stools. On very rare occasions, an animal may experience a seizure, while younger animals may experience swollen joints. If any symptom persists or gets worse, or you notice any other symptom, then please seek veterinary medical treatment immediately.	**New**	No reference	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
46.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Drotaverine Hydrochloride 20 mg Injection 10ml Injection	Each ml Injection contains Drotaverine Hydrochloride INN 20 mg	Therapeutic Class Antispasmodic Therapeutic Code:075	As antispastic in adjuvant treatment of digestive conditions (abdominal colic, gastric or duodenal ulcer, gastritis, enteritis, colitis, pancreatitis, spastic constipation, meteorism, spasms of cardia and pyloric sphincter, spasms of the biliary smooth muscles, biliary lithiasis, cholecystitis); spasms of urinary tract smooth muscles (renal urethral lithiasis, pyelitis, cystitis); genital disorders (uterine tetanic contractions, severe pains, abortion imminence) in dog, cat, horse and cattle. The spasmolytic action of the product also causes pain killing up to removal.	**Contra Indications:** Contraindicated in animal having severe hepatic, renal or cardiac failure. **Side effects:** Arterial blood pressure may drop following too rapid intravenous Injection. **Warning & Precautions:** This drug is not to be administered to horses that are to be slaughtered for use in food. If administering by intravenous route, in‡jvect the product very slowly.	**Existing** **Brand:** **Espa (Square, Popular)**	HUMAN DCC 238 Reference available	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
47.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Ciprofloxacin + Dexamethason Eye drop	Each ml contains Dexamethasone BP 1 mg + Ciprofloxacin Hydrochloride BP equivalent to Ciprofloxacin 3 mg. Eye drop	Therapeutic Class: Anti-infective Therapeutic Code:023	Treatment of animals with acute and chronic inflammation of the eyes and ears that are the result of bacterial, chemical or traumatic effects-con‡jvunctivitis, blepharitis, keratitis, keratocon‡jvunctivitis, iritis, iridocyclitis, ulcers and erosion of the cornea, eye diseases after in‡jvuries or ingress of foreign bodies or aggressive compounds in the after and preoperative periods, as well as otitis media, otorrhoea, in particular, caused by the extraneous intervention.	**Contra Indications:** Do not administer to animals with hypersensitivity to the active ingredients of this mdicin. Do not administer in the day of vaccination. **Side-effects:** Some effects like photophobia, con‡jvunctivitis/keratitis, Periocular/facial edema, foreign body sensation, blurred vision, tearing, dryness, and eye pain. may occur in som cases. **Warning & Precautions:** Prolonged use may result in overgrowth of non-susceptible organisms including fungi; in ocular hypertension, damage to the optic nerve, defects in visual acuity and posterior subcapsular cataract formation may occur. Patients wearing contact lenses must not use the drops	**Existing** **Brand: Civodex Vet (Popular Pharmaceutics Ltd.)** Brand: Ciflodex (German-Ukraine Researce Institute) Brand: Cipronorm (Ukrainian	HUMAN DCC 226 Reference available	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						during the time the lenses are worn. Avoid contaminating with the tip with material from fingers or other sources.				
48.	Incepta Pharmaceuticals Ltd.; Dhamrai Unit, Dhaka	(Tiamulin Hydrogen Fumarate BP/Ph.Eur 45g + Chlortetracycline Hydrochloride BP/Ph.Eur 21.5210g eqv. to Chlortetracycline 20.00g)/100g Powder (VET)	(Tiamulin Hydrogen Fumarate BP/Ph.Eur 45g + Chlortetracycline Hydrochloride BP/Ph.Eur 21.5210g eq. to Chlortetracycline 20.00g)/100g	Therapeutic Class: Veterinary Drugs Therapeutic Code: 077	It can be used for the treatment and prevention of Mycoplasmal and other infections of poultry like CRD, CCRD, sinusitis, airsacculitis, enteritis, pneumonia etc. It is Clinically Effective especially against Mycoplasmas and a large number of gram-positive as well as some gram negative organisms. Chlortetracycline Hydrochloride is indicated for gastrointestinal and respiratory tract infections caused by chlortetracycline sensitive bacteria, like Bordetella, Campylobacter, Chlamydia, E. coli, Haemophilus, Mycoplasma, Pasteurella, Rickettsia, Salmonella, Staphylococcus and Streptococcus spp., in calves, goats, poultry, sheep and swine.	**Contraindication & Precaution:** Do not use in Birds hypersensitive to the active ingredient **Side-effects:** No information available.	New	No reference	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
49.	Opsonin Pharma Limited, Rupatali, Barishal.	Amoxicillin Trihydrate 150 mg + Gentamycin 40 mg/ml Suspension for Injection.	Amoxicillin Trihydrate 150 mg + Gentamycin 40 mg/ml	Anti-infective Code: 023	○ Pneumonia ○ Diarrhoea ○ Bacterial enteritis ○ Mastitis & Metritis ○ To treat serious bacterial infection such as- bacteremia, urinary tract infection, chest infection etc.	**Contraindication:** Hypersensitivity towards amoxycillin and/or gentamicin. Administration to animals with a seriously impaired hepatic and/or renal function. Concurrent administration of tetracyclines, chloramphenicol, macrolides and lincosamides. Concurrent administration of nephrotoxic and/or ototoxic preparations, intravenous calcium supplementation, iron	New	LABORATORIOS HIPRA, S.A., Spain.	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						supplementation and non-steroidal antiinflammatory preparations. **Side effects:** Hypersensitivity reactions. **Precautions & warnings:** The uptake of medication by animals may be altered as a consequence of illness. In case of insufficient water uptake, animals should be treated parenterally instead using a suitable in‡jvectable product prescribed by the veterinarian. The use of the product should be combined with good management practices e.g. good hygiene, proper ventilation, no overstocking.				
50.	Opsonin Pharma Limited, Rupatali, Barishal.	Nitroxynil 340 mg + Clorsulon 67 mg + Ivermectin 6.7 mg/ml Injection	Nitroxynil 340 mg + Clorsulon 67 mg + Ivermectin 6.7 mg/ml	Anthelmintic Code: 008	○ Endectocide and Flukicide ○ Nitroxynil, ivermectin and clorsulon sensitive strains of internal and external parasites of cattle. ○ Triclabendazole resistant strains of early immature (including 2-week old stages). ○ Immature and adult liver fluke (Fasciola hepatica).	**Contraindication:** Do not use in cases of hypersensitivity to the active substance or to any of the excipients. **Side effects:** Stomach upset, vomiting, diarrhea, dilated pupils, hyperthermia, hypercapnia, unsteadiness when walking may occur. **Precautions & warnings:** In‡jvect high on the neck behind the ear. If required, the dose can be divided and administered in two sites. Note: Swelling at the site of Injection is a possibility. This product is not to be used intravenously or intramuscularly	New	Virbac, Australia	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
51.	Opsonin Pharma Limited, Rupatali, Barishal.	Nitroxynil 340 mg + Clorsulon 67 mg/ml Injection	Nitroxynil USP 340 mg + Clorsulon USP 67 mg/ml	Anthelmintic Code: 008	In Cattle Internal Parasites & External Parasites	**Contraindication:** Do not use in cases of hypersensitivity to the active substance or to any of the excipients. **Side effects:** Small swellings at the Injection site, skin irritation; eye irritation may be rare but serious. In the event of accidental overdose or adverse reaction, the symptoms	New	Virbac, Australia	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						include hyperthermia, hyperpnoea, hypercapnea and increased excitability and high blood pressure. **Precautions & warnings:** In‡jvect high on the neck behind the ear. If required, the dose can be divided and administered in two sites. Note: Swelling at the site of Injection is a possibility. This product is not to be used intravenously or intramuscularly				
52.	Opsonin Pharma Limited, Rupatali, Barishal.	Cloxacillin 16.7% Eye Ointment.	Cloxacillin USP 16.7%	Anti-infective Code: 023	Indicated for the treatment of eye infection in cattle, sheep and horses caused by Staphylococcus spp. and Bacillus spp.	**Contraindication:** Do not use in cases of hypersensitivity to the active substance or to any of the excipients. **Side effects:** Allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue. Burning, stinging, or itching of the eyes or eyelids. Changes in vision. Redness, swelling, or pain. **Precautions & warnings:** Penicillins may occasionally cause severe allergic reactions.	New	UK MHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
53.	Opsonin Pharma Limited, Rupatali, Barishal.	Itraconazole 10 mg/ml Oral Solution	Itraconazole USP 10 mg/ml	Antifungal **Code:** 020	Indicated for the treatment of dermatophyte infections in pet animal and bird.	**Contradiction:** Hypersensitivity to Itraconazole hepatic impairment, pregnant or lactating queens. **Side effects:** Mild Transient salivation, vomiting diarrhea and anorexia. **Warnings & Precautions:** Not for use in humans. Keep out of reach of children. Wash Hands after use. Use with caution in cats with renal dysfunction. Itraconazole is metabolized by the liver (mainly CYP3A) and can cause elevated liver enzymes. Use with caution in cats with impaired liver function. If clinical signs suggestive of liver dysfunction	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						develop, treatment should be discontinued.				
54.	Opsonin Pharma Limited, Rupatali, Barishal.	Moxidectin 0.5% Pour-On	Moxidectin USP 0.5%	Anthelmintic Code: 008	Indicated for External parasites e.g. Mites, Lice, Horn Flies & Internal parasites e.g. Gastrointestinal Roundworms, Lungworms.	**Contraindication:** Do not use in cases of hypersensitivity to the active substance or to any of the excipients. **Side effects:** Digestive tract disorders such as diarrhoea, neurological disorders such as ataxia, hypersensitivity/allergic reactions and skin irritation at application site may be observed very rarely. **Precautions & warnings:** Not for Use In Humans. Keep this and all drugs out of the reach of children. This product can cause irritation to skin, eyes, or mucous membranes. In case of accidental skin contact and/or clothing contamination, wash skin thoroughly with soap and water and launder clothing with detergent. In case of accidental eye contact, flush eyes with copious amounts of water. When direct inhalation occurs, cleanse lungs and respiratory passages with fresh air. In case of ingestion, do not induce vomiting and seek medical attention immediately. If irritation or any other symptom attributable to exposure to this product persists, consult your physician.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
55.	Opsonin Pharma Limited, Rupatali, Barishal.	Nystatin 10 million units + Neomycin 2.5 mg + Thiostrepton 2500 units + Triamcinolone Acetonide 1.0 mg/ml Topical Ointment	Nystatin 10 million + Neomycin 2.5 mg + Thiostrepton 2500 units + Triamcinolone Acetonide 1.0 mg/ml	Anti-infective Code: 023	Indicated in the management of dermatologic disorders characterized by inflammation and dry or exudative dermatitis, Particularly those caused, complicated or threatened by bacterial or candidal (Candida albicans) infections otitis in dog, cats & livestock.	**Contraindications:** Do not use in case of hypersensitivity to the neomycin or any other active substances. **Side effects:** Vomiting and diarrhea (occasionally bloody) have been observed in dogs. Cushing's Syndrome in dogs has been reported in association with prolonged or repeated steroid therapy. **Precautions & warnings:** Not for use in humans. Keep out of reach of children. Corticosteroids administered to dogs during pregnancy have also resulted in other congenital anomalies including deformed forelegs, phocomelia and anasarca.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
56.	Popular Pharmaceuticals Limited, Tongi, Gazipur	Sulfadiazine BP 15gm + Neomycin Sulfate BP equivalent to neomycin 2.5gm/100ml Oral Suspension (for Veterinary Use)	Sulfadiazine BP 15gm + Neomycin Sulfate BP equivalent to neomycin 2.5gm/100ml Oral Suspension (for Veterinary Use)	Therapeutic Class: Antibiotic Therapeutic Code:077	For the treatment of diarrhoea in pre-ruminant calves associated with infections caused by organisms known to be, or suspected of being, susceptible to the combination of sulfadiazine and neomycin.	**Contra Indications:** **Do not use in animals with known hypersensitivity to the active ingredient. Do not exceed the recommended dosage or the period of treatment. Do not use local anaesthetics of the procaine group or vitamin B complex during treatment they are antagonistic to the sulphonamide component. Do not use in calves with a functional rumen. Do not use in lactating cows. Do not use in foals and horses.** **Side effects: Chronic usage of oral neomycin may result in bacterial or fungal superinfections.** **Warning & Precautions:** **1. Do not handle this product if you know you are sensitive to sulphonamides.**	New	VMD, UK	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Name of the Medicine with Dosage Form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effect, Warnings and Precautions	Status (New Molecule / Existing)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/TGA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						2. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning.				

Annex-F: আমদানির জন্য ভেটেরিনারী মেডিসিন এর তালিকা

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
1.	M/s NEXUS Distributor, 56/Kha, Jail Road, Mymensing,	Laboratorios Calier, S.A Plo.In.De Leon.ED.CEEI-	Primun Gumboro W2512 Vaccine	Avian infectious Bursal Disease (IBD) Virus, Live Attenuated, Intermediate Plus IBDV_W2512 Strain min 1.5 log 10 EID50	Vaccine For the active immunization of broiler chickens with maternally-derived antibodies (MDA) to reduce mortality,	None	New	Spain	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Bangladesh.	Onzonilla(Leon)-24231, Spain.		max 3.0 log 10 EIDI50	clinical disease, weight loss and acute lesions in the bursa of Fabricius associated with infection caused by very virulent strains of infectious Bursal disease viruses.					
2.	M/s NEXUS Distributor, 56/Kha, Jail Road, Mymensing, Bangladesh.	Laboratorios Calier, S.A Plo.In.De Leon.ED.CEEI-Onzonilla(Leon)-24231, Spain.	Primun Newcastle HB1 Vaccine	Live Newcastle Disease (NDV) Virus, Lentogenic strain NDV-HB1 min 6.0 log 10 EID50 max 7.0 log 10 EID50	Vaccine For the active immunization of chickens against Newcastle disease (ND) to reduce clinical signs and mortality	None	New	Spain	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
3.	M/s NEXUS Distributor, 56/Kha, Jail Road, Mymensing, Bangladesh.	Laboratorios Calier, S.A Plo.In.De Leon.ED.CEEI-Onzonilla (Leon)-24231, Spain.	Primun Newcastle C30 Vaccine	Live Newcastle Disease (NDV) Virus, lentogenic strain NDV-CLS min 6.0 log 10 EID50 max 7.0 log 10 EID50	Vaccine For the active immunization of chickens against Newcastle disease (ND) to reduce clinical signs and mortality	None	New	Spain	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
4.	M/s NEXUS Distributor, 56/Kha, Jail Road, Mymensing, Bangladesh.	Laboratorios Calier, S.A Plo.In.De Leon.ED.CEEI-Onzonilla (Leon)-24231, Spain.	Primun Gumboro Vaccine	Avian Infections bursal disease (IBD) Virus, live attenuated intermediate IBDV_IGS Strain min 3.0 log 10 EID50 max 4.5 log 10 EID50	Vaccine For the active immunization of chickens with maternally derived antibodies (MDA) against infectious bursal diseases (Gumboro disease) to reduce mortality, clinical disease and acute lesions in the bursa of Fabricius.	None	New	Spain	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
5.	M/s NEXUS Distributor,	Laboratorios Calier, S.A	Primun IB-ND DUO Vaccine	Live Newcastle Disease (NDV) virus, lentogenic	Vaccine For the active immunization of chickens against Newcastle disease (ND) and	None	New	Spain	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	56/Kha, Jail Road, Mymensing, Bangladesh.	Plo.In.De Leon.ED.CEEI-Onzonilla (Leon)-24231, Spain.		strain NDV-HB1 min 6.0 log 10 EID50 max 7.0 log 10 EID50 Live Infectious Bronchitis (IBV) virus, Strain IBV_H120 min 3.0 log 10 EID50 max 4.0 log 10 EID50	Massachusetts serotype of infectious bronchitis (IB) to reduce clinical signs and mortality.					
6.	M/s NEXUS Distributor, 56/Kha, Jail Road, Mymensing, Bangladesh.	Laboratorios Calier, S.A Plo.In.De Leon.ED.CEEI-Onzonilla(Leon)-24231, Spain.	Primun Salmonella E Vaccine	Live, attenuated salmonella enterica, subsp.enterica serovar enteritidis, strain CAL10 Sm+RIF+/Ssq- 1-6 x 10^8 CFU/dose	Vaccine Replacement chicks (future layer and breeders) active immunization to reduce colonization of internal organs (spleen, liver, caeca and ovaries) and feacal excretion of salmonella enteritidis field strains.	None Meat & offal: 21days. after 1st & 3rd vaccination Meat & offal: 14days after 4th vaccination Eggs: Zero days after 4th vaccination.	New	Spain	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
7.	Elanco Bangladesh Limited Praasad Trade Center, 11th Floor),6 Kemal Ataturk Avenue, Banani Dhaka-1213 Bangladesh	**Manufacturer:** Elanco US Inc. 375 China Road, Winslow, Maine 04901 USA	**AviPro 304 ND-IB-MG** Oil emulsion for Injection	**Quantity/dose(0.5ml)** Newcastle disease virus: B1 type, LaSota strain ≥ $10^{7.6}$ EID_{50}// + Infectious bronchitis virus: Mass. type, Holland 52 strain ≥ $10^{6.9}$ EID_{50} +Mycoplasma gallisepticum: R strain ≥ $10^{6.0}$ CCU	Vaccine This product has been shown to be effective for the vaccination of healthy chickens 6 weeks of age or older against Newcastle disease, infectious bronchitis (Mass. type), and *Mycoplasma* *gallisepticum*. Onset of immunity for Newcastle disease: 2 weeks following vaccination Onset of immunity for *Mycoplasma gallisepticum*: 3 weeks following the 2nd vaccination	Do not use in clinically ill or weakened animals. **Side Effects:** As with any oil emulsion, mild local reaction may occur. **Withdrawal Period:** Do not vaccinate within 42 days before slaughter.	New	USA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Target Species: Chickens				
8.	M/s.ESKAYEF Pharmaceuticals Limited, Operation HQ.Plot 82, Road 14, Block B, Banani, Dhaka, Bangladesh.	DAE SUNG MICROBIOLOGICAL LABS 103, Deogyneong, Uiwang-si, Gyeonggi-do, Korea.	DS Gumboro K7Chicken Vac	Infectious Bursal Disease Virus Over $10^{2.0}$ EID^{50} IBD K7 Strain	Therapeutic Class: Vaccine. Indication: For the Prevention or Decrease of infectious Bursal Disease in Chickens.	Contraindication: Do not use to chickens that have fever, severe nutritional disorders and stressed. Side effect: After administration, vaccination reaction as mild loss of appetite may occur depends on hygienic conditions or individual.	New	Republic Of Korea	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
9.	M/s.ESKAYEF Pharmaceuticals Limited, Operation HQ.Plot 82, Road 14, Block B, Banani, Dhaka, Bangladesh.	DAE SUNG MICROBIOLOGICAL LABS 103, Deogyneong, Uiwang-si, Gyeonggi-do, Korea.	DS NDS Chicken Vac	Newcastle Disease Virus Over $10^{6.0}$ EID^{50} NDRL0901 Strain	Therapeutic Class: Vaccine. Indication: For the Prevention of Decrease of Newcastle Disease (ND) in Chickens.	Contraindication: Do not use to chickens that have fever, severe nutritional disorders and stressed. Side effect: After administration, vaccination reaction as mild loss of appetite may occur depends on hygienic conditions or individual.	New	Republic Of Korea	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
10.	M/s..ESKAYEF Pharmaceuticals Limited, Operation HQ.,Plot 82, Road 14, Block B, Banani, Dhaka, Bangladesh.	DAE SUNG MICROBIOLOGICAL LABS 103, Deogyneong, Uiwang-si, Gyeonggi-do, Korea.	DS IB-QX Chicken Vac	Infectious Bronchitis Virus Over $10^{2.5}$ EID^{50} Nephropathogenic Type, K40/09 HP Strain	Therapeutic Class: Vaccine. Indication: For the Prevention or Decrease of Infectious Bronchitis(IB) in Chickens	Contraindication: Do not use to chickens that have fever, severe nutritional disorders and stressed. Side effect: After administration, vaccination reaction as mild loss of appetite may occur depends on hygienic conditions or individual.	New	Republic Of Korea	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
11.	M/s.ESKAYEF Pharmaceuticals Limited, Operation HQ.,Plot 82, Road 14, Block B, Banani, Dhaka, Bangladesh.	DAE SUNG MICROBIOLOGICAL LABS 103, Deogyneong, Uiwang-si, Gyeonggi-do, Korea.	DS BNE-Q Chicken Vac	Infectious Bronchitis Virus Over $10^{7.0}$ EID_{50} Nephropathogenic Type, K40/09 HP Strain Newcastle Disease Virus Over $10^{9.0}$ EID_{50} Lasota Strain Egg Drop Syndrome Virus Over $10^{7.0}$ EID_{50} K-11 Strain	Therapeutic Class: Vaccine. Indication: For the Prevention or Decrease of Infectious Bronchitis(IB), Newcastle Disease(ND) and Egg Drop Syndrome(EDS) in Chickens	Contraindication: Do not use to chickens that have fever, severe nutritional disorders and stressed. Side effect: After administration, vaccination reaction as mild loss of appetite may occur depends on hygienic conditions or individual.	New	Republic Of Korea	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
12.	M/s.ESKAYEF Pharmaceuticals Limited, Operation HQ.,Plot 82, Road 14, Block B, Banani, Dhaka, Bangladesh.	DAE SUNG MICROBIOLOGICAL LABS 103, Deogyneong, Uiwang-si, Gyeonggi-do, Korea.	DS ANBBE-Q Oil Chicken Vac	Low Pathogenic Avian Influenza virus Over $10^{8.0}$ EID_{50} H9N2 Type (LPAIV, A/Chicken/Korea/01310/2001 CE20 Strain) Newcastle Disease Virus Over $10^{9.0}$ EID_{50} Lasota Strain Infectious Bronchitis Virus Over $10^{6.5}$ EID_{50} Respiratory Type, M41 Strain Infectious Bronchitis Virus	Therapeutic Class: Vaccine. Indication: For the Prevention of Newcastle Disease(ND), Infectious Bronchitis(IB), Egg Drop Syndrome(EDS) and Low Pathogenic Avian Influenza(LPAI, H9N2 type) in Chickens	Contraindication: Do not use to chickens that have fever, severe nutritional disorders and stressed. Side effect: After administration, vaccination reaction as mild loss of appetite may occur depends on hygienic conditions or individual.	New	Republic Of Korea	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
				Over $10^{7.0}$ EID_{50} Nephropathogenic Type, K40/09 HP Strain						
13.	M/s.ESKAYEF Pharmaceuticals Limited, Operation HQ.,Plot 82, Road 14, Block B, Banani, Dhaka, Bangladesh.	DAE SUNG MICROBIOLOGICAL LABS 103, Deogyneong, Uiwang-si, Gyeonggi-do, Korea.	DS Fowl Pox Chicken Vac	FowlPox Virus Over 50% FowlPox Virus adapted strain	Therapeutic Class: Vaccine. Indication: For the Prevention of Fowl Pox	Contraindication: Do not use to chickens that have fever, severe nutritional disorders and stressed. Side effect: After administration, vaccination reaction as mild loss of appetite may occur depends on hygienic conditions or individual.	New	Republic Of Korea	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
14.	KAAS Trade& 80/22, Mymensingh Road, Nurjehan Tower (8th Floor) Bangla Motor, Dhaka-1000, Bangladesh Phone: +88-02-223361435	Synthese elevage 11 rue Marie Curie- 35137 PLEUMELEUC, France	SPECTRAGEN®	Benzylalkyl (C12-C16) dimethyl ammonium chloride (CAS 68424-85-1): 18.96% Glutaraldehyde (CAS 111-30-8): 16.11%, Didecyl dimethyl ammonium chloride (CAS 7173-51-5): 6.63%	**Therapeutic Class:** **Disinfectant** **&** **Indication: Disinfection on hard surfaces in livestock areas**: Use water solution of SPECTRAGEN® on previously cleaned and rinsed surfaces. **Bactericidal, Virucidal and Fungicidal-Yeastcidal**: (Efficacy against additional strains): 1. Salmonella senftenberg, Listeria monocytogenes, Salmonella enteritidis, Salmonella typhimurium 2. Newcastle virus, myxoma virus, H5N1 virus, PRRS virus, PED virus, duck parvovirus, Coronavirus.	**Contraindication:** **Sensitivity against ingredients:** 1.SPECTRAGEN® may cause skin and respiratory sensitivity. Therefore, the disinfectant is not recommended to be used by workers/users that react sensible against the active ingredients Glutaraldehyde.This might lead to unwanted reactions of the skin and respiratory tract. 2. Should be kept away from children and animals.	New	France	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					3. Aspergillus fumigatus.					
15.	Bengal Overseas Ltd.; Paragon House (6th Floor) 5, Mohakhali C/A, Dhaka-1212.	**Manufacturer:** Intervet GesmbH, Siemensstraße 107, 1210 Wien, Austria **Marketing Autorization Holder:** Intervet International B.V.; Wim de korverstraat, 5831 AN Boxmeer, The Netherlands	**Bravecto,** Chewable tablet	Fluralaner; 112.5 mg, 250 mg, 500 mg, 1000 mg, 1400 mg; 1,2,4 tablet(s)	Isoxazoline drug (potent acaricide and insecticide) **Indication:** For the treatment of tick and flea infestations on dogs for 12 weeks. This veterinary medicinal product is a systemic insecticide and acaricide with a long duration of action that provides immediate and persistent tick (adult and juvenile Ixodes ricinus, Ixodes hexagonus, Ixodes scapularis, Ixodes holocyclus, Dermacentor reticulatus, Dermacentor variabilis and Rhipicephalus sanguineus) and flea (Ctenocephalides felis and Ctenocephalides canis) killing activity for 12 weeks. Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance. The onset of effect is within 8 hours of attachment for fleas (C. felis) and 12 hours of attachment for ticks (I. ricinus). The product provides protection against transmission of Babesia canis by Dermacentor reticulatus ticks by killing the ticks before disease transmission occurs. This has been shown over a 12-week period after treatment. The product effectively controls environmental flea populations in areas to which treated dogs have access. Can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).	**Contraindication:** Do not use in case of hypersensitivity to the active substance or to any of the excipients. **Side-effect:** Singular cases (1.6%) of mild and transient gastrointestinal symptoms such as diarrhoea/ vomiting/ inappetence/ drooling related to the route of administration of the product were observed in clinical studies.	New	EMA certificate	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					For the treatment of Demodicosis caused by Demodex spp. mites. For the treatment of Sarcoptic mange and Otodectes spp. mite infestations.					
16.	M/S Rafique Medicine College Road Ishurdi, Pabna	Komipharm International Co, Ltd. 1236-6, Chongwang-Dong,Shihung-Si Kyonggi-Do, The Republic of Korea.	**PRO-VAC™ CORYZA-3**	Vacccine Contains Inactivated bactarial of serotype A (0083 Strain) B (0222 Strain) & C (modesto Strain) of aviabactrim paragallinarum	**Therapeutic Class:** **Vaccine** **Indication:** Pro-Vac™ Coryza-3 an inactivate trivalent bacterial vaccine for the prevention of infectious Coryza (IC) & alleviation of Clinical Sign in chicken.	**Contraindication:** • Do not use this product to those with fever of serious nutritional disorder. • Do not use this product to those with infectious disease, parasite infections or stress. • Do not use this product to those with weakened immunity due to mold of bacterial toxin. • Do not use this product to those with shock or hypersensitivity to this product. **Side effect:** According to hygiene and /or health condition of the animal, vaccination may arouse following reaction i.e. anorexia, coughing, sneezing, reduced egg production, and e.t.c., and it is recommended to observe the presence of hypersensitivity post-vaccination, and consult with the veterinarian in taking necessary action when treating with antibiotics and /or nutrients.	New	Republic of Korea.	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
17.	M/S Rafique Medicine College Road Ishurdi, Pabna	Komipharm International Co, Ltd. 1236-6, Chongwang-Dong,Shihung-Si Kyonggi-Do, The Republic of Korea.	**PRO-VAC CRDF**	Mycoplasma gallisepticum culture (F strain)	**Therapeutic Class:** **Vaccine** **Indication:** Prevention for infection by Mycoplasma gallisepticum.	**Contraindication:** Do not administer this product to the following ones| • Those with fever or serious nutritional disorder • Those with infectious disease, parasite infection of stress. • Those with shock or hypersensitiveness to this vaccine. **Side effect:** Those administered with this product may show anorexia, cough, sneeze, spawn, rate decline. If so it is recommended to administrate antibiotic and nutrient and please consult with the veterinarian and take the necessary action.	New	Republic of Korea.	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
18.	M/S Rafique Medicine College Road Ishurdi, Pabna	Komipharm International Co, Ltd. 1236-6, Chongwang-Dong,Shihung-Si Kyonggi-Do, The Republic of Korea.	**PRO-VAC™ H5-AINK**	HA recombinant antigen of H5-type highly pathogenic avian influenza virus (HA protein derived from A/Duck/Korea/Chenoa/2010 (H5N1), A/Duck/Korea/ES2/2016(H5N6)) + Newcastle disease virus before inactivation (NDV, Ulster 2C strain)	**Therapeutic Class:** **Vaccine** **Indication:** For the prevention of Highly pathogenic Avian Influenza (H5N1 & H5N6) infection & Newcastle Disease infection.	**Contraindication:/Warning** • Do not administer to the animal with shock and/or hypersensitivity to this product • Do not administer to the animal with other disease infected of or incubation period, with fever of serious nutritional disorder, infectious disease, parasite infection or stress and weakened immunity due to mold or bacterial toxin. **Side effect:**	New	Republic of Korea.	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						According to the hygiene and/or health condition of the animal, vaccination may arouse following reaction i.e.; anorexia, coughing, sneezing, reduce egg production and etc., and it is recommended to observe the presence of hypersensitivities post vaccination and consult with the veterinarian in taking necessary action when treating with antibiotic and/or nutrients.				
19.	M/S Rafique Medicine College Road Ishurdi, Pabna	Komipharm International Co, Ltd. 1236-6, Chongwang-Dong,Shihung-Si Kyonggi-Do, The Republic of Korea.	**PRO-VAC EDS**	Inactivated Egg Drop syndrome'76 (EDS'76 : K-11 Strain) antigent	**Therapeutic Class:** **Vaccine** **Indication:** For the prevention of egg drop syndrome infection in chicken.	**Contraindication:/Warning** Do not administer this product is to the following ones • Use this product according to vererinarians' instruction • Those with infection disease, Parasite infection or stress • Those with shock or Hypersensitivity to this vaccine **Side Effect:** Vaccination may arouse following reaction according to the hygiene and/ or health condition of the chicken such as anorexia, coughing, sneezing, reduced egg production and etc., and it is recommended to observe the presence of hypersensitivity after vaccination and consult with the veterinarian in taking necessary action when	New	Republic of Korea.	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						treating with antibiotics and/or nutrients.				
20.	M/S Rafique Medicine College Road Ishurdi, Pabna	Komipharm International Co, Ltd. 1236-6, Chongwang-Dong,Shihung-Si Kyonggi-Do, The Republic of Korea.	**PRO-VAC FP**	Live monovalent (TCH strain) viral vaccine for the active immunization against fowl pox in chicken and turkey.	**Therapeutic Class:** **Vaccine** **Indication:** For the active immunization against Fowl pox in chickens and turkeys.	**Contraindication:/Warning** Do not administer this product is to the following ones • Those with fever or serious nutrition lesion. • Those with infection disease parasite infection or stress. • Those with weakened immunity due to mold or bacterial toxin (aflatoxin of toxin produced by E coli or salmonella SPP) • Those with hypersensitiveness to this kind of vaccine. **Side effect:** According to the hygiene of the poultry, those administered with this product may show anorexia, vomiting, redness, collapse, convulsions, or other hypersensitive reaction. If so, it is recommended to administer epinephrine and do enough massage and consult with veterinarian and take the necessary action.	New	Republic of Korea.	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
21.	M/S Rafique Medicine College Road	Komipharm International Co, Ltd.	**KOMI TRIMISOLE 19.5%**	Triclabendazole 120g Levamisole Hydrochloride 75mg	**Therapeutic Class:** Anthelmintics **Indication:** A parasiticide for the treatment and control of internal parasite	**Contraindication:/Warning** • Do not use to those animals which have sensitive reactions against this product • Do not use at layer.	New	Republic of Korea.	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Ishurdi, Pabna	1236-6, Chongwang-Dong,Shihung-Si Kyonggi-Do, The Republic of Korea.			like Gastrointestinal nematodes lung worm and etc. in cattle and ship. • Gastrointestinal nematodes: Haemonchus ssp. Trichostronglylus spp, Cooperia spp, Ostertagia spp and oesophagostromum sps • Lungworms: Dictyocaulus spp • Trematoda: Faciola hepatica.	**Side effect:** Frequently administration of this medicine cattle can cause temporary pain reaction and local edema at the Injection site which can last up to 30 days. When used at high concentration, temporary anxiety and reduced feed intake may occur in the target animal.				
22.	M/S Rafique Medicine College Road Ishurdi, Pabna	Komipharm International Co, Ltd. 1236-6, Chongwang-Dong,Shihung-Si Kyonggi-Do, The Republic of Korea.	**T-Raxxin Inǂjv.**	Tulathromycine 100.00 mg	**Therapeutic Class:** Antibiotics. **Indication:** For the treatment of bacterial diseases susceptible to tulathromycine.	**Contraindication:** • Do not use to those animals which have sensitive reactions against this product • Do not use at layer. **Side effect:** •Frequent administration of this medicine cattle can cause temporary pain reaction and local edema at the Injection site which can last up to 30 days. • When used at high concentration, temporary anxiety and reduced feed intake may occur in the target animal.	New	Republic of Korea.	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
23.	M/S Rafique Medicine College Road Ishurdi, Pabna	Komipharm International Co, Ltd. 1236-6, Chongwang-Dong,Shihung-Si	**KOMI TIAMULIN 125 SOL.**	Tiamulin Hydrogen Fumarate 125g	**Therapeutic Class:** Antibiotics **Indication:** Liquid Concentrate, when administered in the drinking water for five consecutive days, is an effective antibiotic for the treatment of swine dysentery associated	**Contraindication:** • This product is a veterinary medicine and should never be used to humans • Use the drug by Veterians instruction • Read the instruction manual thoroughly before using it	New	Republic of Korea.	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
		Kyonggi-Do, The Republic of Korea.			with Brachyspira (formerly Serpulina or Treponema) hyodysenteriae susceptible to tiamulin at a dose level of 3.5 mg tiamulin hydrogen fumarate per pound of body weight daily and for treatment of swine pneumonia due to Actinobacillus pleuropneumoniae susceptible to tiamulin when given at 10.5 mg tiamulin hydrogen fumarate per pound of body weight daily	• Do not use this product except designated species as safety and efficacy have not been established. • Observe the prescribed dosages as it may cause drug accidents or economic loss due to mix or abuse. • If you do not comply with the withdrawal period medicines may remain in livestock product such as meal. so please calculate and comply by the time • If you have any question about the product. Please contact the manufacturer.				
24.	M/S SP Vet Care limiter 382/H/3, East Nakhalpara, Tejgaon, Dhaka, Bangladesh.	FATRO S.p.A Via Emilla, 285-40064 Ozzano Emilia (BO) Italy	**OLVAC** **A+B+HG**	Inactivated virus of Newcastle disease not less than $50PD_{50}$ Inactivated virus of infectious bronchitis not less than $10^{7.5}$ EID_{50} Inactivated Adeno EDS, 76 not less than 1000HU Inactivated H.paragallinaurm serovar A: not less than 3X 109 CFU Inactivated H.paragallinaurm serovar C: not less than 3X 109 CFU	**Therapeutic Class:** **Vaccine** **Indication:** **OLVAC** **A+B+HG is indicated for active immunization to prevent mortality, Clinical signs and lesions of the Newcastle Disease, Infectious bronchitis, Infectious Coryza and Egg drop syndrome in poultry.** **Protection starts 2 weeks after vaccination and last for the entire productive life of the birds (60 weeks)**	**Contraindication:/Warning** There are no known contra-indications	New	Italy	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
25.	Local Agent: Solver Agropharma Ltd House # 770 (2nd Floor), Road # 10 (New), Avenue # 6, Mirpur DOHS, Dhaka-1216	Manufacturer: Samu Median Co. Ltd, 235-15 Chusa-ro Sinam-Myeon, Yesan-Gun, Chungcheongnam-do, Republic of Korea	MOXI-150 LA Injection	Amoxicillin Trihydrate USP 150mg (as base)/ml	Antibiotic For treatment of various diseases caused by bacteria susceptible to amoxicillin Cattle, Swine, Sheep: Respiratory infection by Gram-positive bacteria and Pasteurella spp., and gastrointestinal tract infection by Enterobacteriaceae Dogs : Gastrointestinal tract, respiratory, genitourinary and skin infection	**Contraindications:** The use of this drug is contraindicated in animals with a history of hypersensitivity to penicillin **Special precautions:** 1. Discontinue the use for 25days in cattle, swine before slaughter and for 96 hours before milking 2. Treat in accordance with the direction of veterinarian. 3. Do not use to animals having hypersensitivity to Penicillin. 4. Keep out of the reach of children **Withdrawal period:** Cattle - 28 days, Milk - 4 days, Swine, Sheep - 21 days.	New	Republic of Korea	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
26.	Local Agent: Solver Agro pharma Ltd House # 770 (2nd Floor), Road # 10 (New), Avenue # 6, Mirpur DOHS, Dhaka-1216	Manufacturer: Samu Median Co. Ltd, 235-15 Chusa-ro Sinam-Myeon, Yesan-Gun, Chungcheongnam-do, Republic of Korea	Samu P Injection	Samu PYRIN in‡jv.	Analgesic & Antipyretic Analgesic and antipyretic efficacy at the time of treatment of various infectious diseases accompanied by fever or pains. Pyrectic disease: flu, bronchitis, inflammatory disease, distemper, pneumonia, pyrexia(fever) of unknown etiology Allergic disease: eczema Dolorific(Painful) disease : muscular pain, arthritis, neuralgia, bruise, distortion, claudication	**Contraindications:** Unknown **Special precautions:** ñ Treat in accordance with the direction of veterinarian. ñ There may be hypersensitivity according to the individual and do not use to animals having hypersensitive to group of pyrin. ñ Do not use it with other products which contains central nervous system depressants (chlorpromazine, phenylbutazone, barbiturates) and anticoagulant. ñ Keep out of reach of children. ñ Store in airtight container at room temperature (1~30 °C), avoiding light.	New	Republic of Korea	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Withdrawal period : Cattle, Horses, Sheep - 10 days, Swine - 5 days, Milk - 48 hours.				
27.	Local Agent: M/s. Hesper Pharma, 168, East Razabazar, Sher E-Bangla Nagar, Tejgaon, Dhaka	Manufacturer: M/s. Biowet Puławy Sp. z o.o. ul. H. Arciucha 2, 24-100 Puławy, Poland	In‡jvectio Glucosi 40% Solution for Injection	Glucose Monohydrate Ph. Eur. 400mg/ml	Therapeutic Lass- Blood substitutes and perfusion solutions, solutions for parenteral nutrition, carbohydrates • Treatment of energy deficiency. • Treatment of hypoglycaemia and ketosis. • Liver diseases as an adjuvant therapy. • Preparation increasing duresis.	**Contraindication:** :Hyperglycaemia, Overhydration, Acidosis and hypotonic dehydration **Special warnings for each target species:** None. **Withdrawal** period : Dogs, cats – not applicable Cattle, horses, sheep, swine, goats Edible tissues – zero days Milk – zero days.	New	Poland	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
28.	Local Agent M/s. INTER-AGRO BD Ltd., 718/A.1st Floor, West Nakhalpara, Tejgaon, Dhaka-1215, Bangladesh	Manufacturer: COD Beck Blenders Limited, Dalton, Thirsk, North Yorkshire Y07 3HR, UK. MA Holder: ECO Animal Health Limited, UK	Aivlosin 425 Powder	Tylvalosin (as Tylvalosin tartrate) Manufacturer's specification 42.5mg/gm	Macrolide Antibiotic. For the treatment of respiratory disease associated with Mycoplasma gallisepticum in chicken. For the treatment of disease associated with Mycoplasma synoviae and Mycoplasma gallisepticum in chicken laying hens producing eggs for human consumption	**Contraindication**: None **Special warnings:** None **Withdrawal period:** Meat and offal: 1 day. Eggs (chicken): zero days	New	UK	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
29.	Local Agent M/s. INTER-AGRO BD Ltd., 718/A.1st Floor, West Nakhalpara, Tejgaon,	Manufacturer: Alfasan International B.V. Address: Kuipersweg 9, 3449 JA	Finiworm Powder for Oral Administration	Each gram of hydrosoluble powder contains: Piperazine Citrate 1000mg	Antibiotic. Piperazine is used for the treatment of ascarids in dogs, cats, horses, swine and poultry. Piperazine is considered safe to use in animals with concurrent gastroenteritis and during	**Contraindication**: Piperazine should be considered contraindicated in patients with chronic liver or kidney disease, and those with gastrointestinal hypomotility. **Special warnings:** None **Withdrawal period:**	New	The Netherlands	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Dhaka-1215, Bangladesh	Woerden, The Netherlands			Pregnancy	Meat and offal: 1 day. Eggs (chicken): zero days				
30.	Local Agent: M/s. Phibro Animal Health Corporation, Crystal Palace, House : SE (D) 22, Level-3, R # 140, Gulashan-1, Dhaka,	Manufacturer: M/s. Phibro Animal Health Limited, Finisklin Business Park, Sligo, Ireland	Phivax IB Var 206 Effervescent tablets for suspension	Live attenuated Avian Infectious Bronchitis virus (IBV), variant strain 206 ≥ $10^{3.2}$ EID_{50} per dose	Vaccine For the active immunization of chickens to reduce mortality and clinical signs associated with infection caused by virulent variant 2 strains of IB virus.	**Contraindication**: None **Special warnings for each target species:** Vaccinate healthy chickens only. **Withdrawal** period: Zero days.	New	Ireland	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
31.	Local Agent : M/s Phibro Animal Health Corporation Crystal Palace, House : SE (D) 22, Level-3, R # 140, Gulashan-1, Dhaka	Manufactured By: Bio Agri Mix LP, 52 Wellington Street, Mitcheel, ON NOK 1NO, Canada	Stafac® 500	Virginiamycin 500g/Kg	Antibiotic For prevention of broiler chickens of necrotic enteritis caused by microorganisms susceptible to virginiamycin.	**Contraindication:** In case of hypersensitivity to virginiamycin. Not permitted for use in laying hens producing eggs for human consumption. **Side-effect:** No adverse effects on recommended dose. Withdrawal Period: Zero days	New	Canada	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
32.	M/S Univet Limited 1302, Park Road, APPt.401,Block -K, Baridhara Diplomatic Zone, Dhaka.	M/S Artevet 1000 N. West Street, Suite-1200 Wilmington, DE 19801, USA.	SANITAB One tube Contains 15 tablets	Sodium Dichloroisoc Yanurate	Water Purifier	**Sanitab in 600 1 of water** **1 tablet in 30 1 of water for moderate to heavy contaminant**	USA	Existing	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
33.	Future Dream Enterprise 49, Shantinagar	Samu Median Co.Ltd 235-15 Chuso-ro	Vitaton Forte In‡jv. (Vet)	Vitamin A 500000 IU Cholecalciferol 50000IU	General **Indication-**	**Not known**	Korea	New	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Dhaka-1217	Sinam-myeon, Yesan-gun, Chungcheongnam-do, Korea		Tocopherrol 50 mg//ml	For promotion of growth For increase of resistance against infectious For prevention and treatment of osteomalacia, rickets and deficiencies of Vitamin A, D3 and E.			diseases		
34.	M/S R R Agro Traders Ka-229, Second floor, Progoti shoroni kuril Vatara Dhaka-1229	M/S Biocidas Biodegradables ZIX, S.L Poligono los Leones, Nave O, 50298, Pineseque, Zaragoza, Spain	Aquazix Plus	Hydrogen Peroxide 50% Silver 0.038%	Disinfectant **Uses:** to be applied by trained staff only. can be used with livestock, food industry and water treatment. For use on all farms or Livestock holdings. Clean Water pipe and tanks. Cleaning agent for treating surfaces and surroundings in firms Cleanser elements biofilm.	**May intensify fire, oxidizer, harmful if swallowed of if inhaled.**	Spain		অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
35.	ACI Ltd. 245, Tejgaon Industrial Area, Dhaka-1208.	M/S Bimeda Animal Health Limited 2, 3 & 4 Airton Close, Tallaght, Dublin 24, Ireland.	Multimast Dry Cow Intramammary Suspension 120X4.5gm In‡jvectors	Neomycin sulphate 100mg + Penethamate hydrochloride 100mg + Procaine benzylpenicillin 400mg/4.5gm syringe	Antibiotic **Indication-** For routine use in cows at drying off, to treat existing intramammary infections	**Contraindication**: Do not use in lactating cow. Do not use within 50 days prior calving. **Side Effect:** Other than the possibility of sensitivity reactions, it is not anticipated that the product will cause any undesirable effects due to the low toxicity of the	IRELAND	New IRELAND	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					and to assist in preventing new infections occurring during the dry period.	actives and the method of administration of the product.				
36.	ACI Ltd. 245, Tejgaon Industrial Area, Dhaka-1208.	CEVA-PHYLAXIA Veterinary Biologicals Co. Ltd. 1107 Budapest, Szallas u. 5 Hungary	Newflend ND H9 Live, Frozen Vaccine	Cell associated live recombinant rHVT/ND/H9….min. 3000 PFU/Dose	Vaccine Newflend ND H9 vaccine, for active immunization of chickens against Newcastle disease and H9-subtype of Low Pathogenic Avian Influenza.	**Contraindication:** No contraindications are known. **Side effects:** No contraindications are known.	HUNGARY	New HUNGARY	প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
37.	ACI Ltd. 245, Tejgaon Industrial Area, Dhaka-1208.	FILAVIE 20 La Corbiere-Roussay 49450 Sevremoine, France	CEVAC IBH-8 K Inactivated oil-adjuvant Vaccine.	Inactivated Inclusion-Body Hepatitis, FAdV-8b strain…min. log10 TCID50/Dose (0.5mL)	Vaccine Cevac IBH-8 K vaccine, for active immunization of chickens against Inclusion-Body Hepatitis, Strain FAdV-8b	**Contraindication:** No contraindications are known. **Side effects**: No contraindications are known.	FRANCE	New FRANCE	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
38.	Advance Animal Science Co. Ltd.; 149/A, DIT Extension Road, Motijheel, Dhaka- 1000, Bangladesh	Vetpharm Laboratories (S) Pte Ltd. 27 Tuas Avenue 13, #01-25 Singapore	Florcol 30% (Vet)	Florfenicol 300gm/L	Antibiotic <u>Indications</u>: For use in infections caused by both Gram-positive and gram-negative bacteria like Pasteurella multocida, Pasteurella haemolytica, Haemophilus parasuis, Actinobacillus pleuroneumoniae, Bordetella broachiseptics, Streptococcus, Staphylococcus, E. coli, Mycoplasma, Salmonella, Clostridium etc.	**Contraindication:** Excessive use of Florfenicol can cause hypersensitivity. Don't administer to animals with renal impairment. Don't administer while vaccination is given or narcotic is given. **Side-effect:** Hypersensitivity, stomatitis and GIT disturbances may occur in some cased. This is as a result of atrophy of the intestinal villi. Prolonged and excessive overdose treatment may lead to bone marrow suppression and immune suppression. **Withdrawal Period:**	Singapore	Florfenicol 200g/L (DCC- 240) Singapore	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						7 days prior to slaughter. 10 days for layers laying eggs for human consumption. **Pharmaceutical Form:** Water Soluble Powder				
39.	Advance Animal Science Co. Ltd.; 149/A, DIT Extension Road, Motijheel, Dhaka- 1000, Bangladesh	Vetpharm Laboratories (S) Pte Ltd. 27 TUAS AVENUE13, #01-25 Singapore 638993	Lincostine 25% (Vet)	Lincomycin HCl 62.5gm/250gm	Antibiotic Indications: It is highly effective against C.R.D. caused by Mycoplasma. It is also effective against infections caused by Streptococci, Staphylococci and Bacillus anthracis.	**Contraindication:** Solution of lincomycin salts have an acid pH and incompatibility may reasonably be expected with alkaline preparations or with drugs unstable at low pH. **Side-effect:** When given parenterally or in excessive oral dosage, the major adverse effects of the Lincomycin are dose-related neurotoxicity and nephrotoxicity, Hypersensitivity reactions are rare, although rashes and fever have been reported. **Withdrawal Period:** 5 days before slaughter for human consumption 7 days for laying hens laying eggs for human consumption. **Pharmaceutical Form:** Water Soluble Powder	Singapore	Lincomycin HCl 44 gm/kg (DCC- 244) Singapore	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
40.	Advance Animal Science Co. Ltd.; 149/A, DIT Extension Road, Motijheel,	Vetpharm Laboratories (S) Pte Ltd. 27 Tuas Avenue 13, #01-25 Singapore	Tilmicosin 50% (Vet)	Tilmicosin Phosphate 250gm/500 gm	**Antibiotic** Indications: Tilmicosin 50% Water Soluble Powder is highly effective against C.R.D. caused by Mycoplasma, Actinobacillus, Haemophilus, Pasteurella multocida as well as for usage in secondary infections	**Contraindication:** Solutions of Tilmicosin salts have an acid pH and incompatibility may reasonable be expected with alkaline preparation or with drugs unstable at low pH **Side-effect:**	Singapore	Tilmicosin Phosphate 250 gm/L (DCC- 238) Singapore	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Dhaka- 1000, Bangladesh					Tilmicosin is reported to produce diarrhea in many animals after systemic use; in some animals, severe antibiotic-associated or pseudomembranous colitis may develop, and has proved fatal. Other gastrointestinal effects reported with tilmocosin include nausea, vomiting, abdominal pain or cramps, and unpleasant or metallic taste after high intravenous doses. **Withdrawal Period:** Poultry: 7 daysEggs: 10 days **Pharmaceutical Form:** Water Soluble Powder				
41.	Advance Animal Science Co. Ltd.; 149/A, DIT Extension Road, Motijheel, Dhaka- 1000, Bangladesh	Vetpharm Laboratories (S) Pvt Ltd. 27 Tuas Avenue 13, #01-25 Singapore	Farm Fly-Clean (Vet)	Cyromazine 100 gm/1kg	**Insecticide/Fly controller** Indications: Cyromazine, the active ingredient of Farm Fly-Clean is an insect growth regulator belonging to the group of trizine derivatives Cyromazine interferes with the chitin metabolism of the insect. Treated larvae will not moult to the next stage and so the cycle of the fly is interrupted. The effect of the fly population becomes visible at least 2 weeks after first administration.	**Contraindication:** Cyromazine is considered of low acute oral, dermal and inhalation toxicity. **Side-effect:** No classification of concern has been assigned to cyromazine based on the available mammalian toxicity data, i.e. carcinogen, germ cell mutagen, reproductive toxicant. Therefore, the interim criteria for the determination of endocrine disrupting properties are not fulfilled, However, these conclusions may be revised pending on the outcome of the RAC on the potential classification of cyromazine as		Singapore	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						toxic for reproduction category 2 and/or the availability of specific criteria for the determination of endocrine-disrupting properties. **Withdrawal Period:** Not required using the prescribed dosage. **Pharmaceutical Form:** Premix				
42.	Protimax Nutrivet Ltd. AWR U-Tower, Plot 35, Road 133, Gulshan South Avenue, Gulshan-1, Dhaka-1212, Bangladesh.	SOMVITAL, SL. Calle Manfredonia 10, ships 1-2, Zaragoza, Spain	**ANCOR PED**	Sodium bisulphate- 5.0%, Sodium chlorite- 1.5%, Disodium peroxodisulphate- 2.5%, Zeolites- 27.8%, MMT (Montmorillonite)- 63.2%	Solid disinfectant For use in footbaths: eases shoe hUygienization at the entrance of livestock farming. Use in bedding: improves its hygienization. ANCOR PED is an effective mixture of natural ingredients such as Montmorillonite, inorganic silicon and Magnesium salts and aluminum silicates in powder format. Genuine composition of ANCOR PED, along with its particle size prompts and eases an efficient and uniform distribution.	**No Contra indication**	SPAIN		প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
43.	Protimax Nutrivet Ltd. AWR U-Tower, Plot 35, Road 133, Gulshan South Avenue, Gulshan-1, Dhaka-1212,	SOMVITAL, SL. Calle Manfredonia 10, ships 1-2, Zaragoza, Spain	**GOITASAN**	Formaldehyde. Formol- 10.8%, Alkyl dimethyl benzyl ammonium chloride- 12.0%, Demineralized water- s.q.100%	Disinfection of Livestock installation: surfaces, machines, tools etc. Disinfection of vehicles, foot baths, disinfection tunnels and sanitary gates. Disinfection of slurry pits. Due to its high disinfectant power, it is a very suitable product for use in Hygiene	**No Contra indication**	SPAIN		প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Bangladesh.				and Disinfection Protocols against Ascaris suum.					
44.	Protimax Nutrivet Ltd. AWR U-Tower, Plot 35, Road 133, Gulshan South Avenue, Gulshan-1, Dhaka-1212, Bangladesh.	SOMVITAL, SL. Calle Manfredonia 10, ships 1-2, Zaragoza, Spain	**MEVIPOW**	Potassium monopersulphate-51.96%, Sodium hexametaphosphate-24%, Sulphamic acid- 4.5%, Dodecylbnzene sodium sulphonate- 11.4%, Malic acid- 6.6%, Sodium chloride- 1.5%, Food colouring E-123 - 0.04%	Disinfection of Livestock facilities of any Kind: surfaces, Hatcheries, equipment, tanks, tools, pipes. Disinfection of vehicles and footbaths. Mevipow is highly effective in preventing and containing animal diseases as porcine epidemic diarrhea.	**No Contra indication**	SPAIN		প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
45.	Protimax Nutrivet Ltd. AWR U-Tower, Plot 35, Road 133, Gulshan South Avenue, Gulshan-1, Dhaka-1212, Bangladesh.	SOMVITAL, SL. Calle Manfredonia 10, ships 1-2, Zaragoza, Spain	**MEVIBACTER**	Peracetic Acid- 5.0%, Hydrogen peroxide- 23%, Acetic Acid- 10%, Distilled water- 62%	Disinfection of facilities, surfaces, equipment, disinfection arches, tools, circuits, tanks, cooling, food industry, pipes, etc. for professional use. Disinfection of the environment by nebulization. Exclusive use of specialized personnel.	**No Contra indication**	SPAIN		প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
46.	Protimax Nutrivet Ltd. AWR U-Tower, Plot 35, Road 133, Gulshan South Avenue,	SOMVITAL, SL. Calle Manfredonia 10, ships 1-2, Zaragoza, Spain	**MEVISAN**	Glutaraldehyde. Glutaral- 11.5%, Alkyl dimethyl benzyl ammonium chloride- 16.5%, Demineralized water- s.q.100%	Disinfection of Livestock installations, surfaces, equipment, tanks, tools etc Disinfection of vehicles, foot baths, disinfection tunnels and sanitary gates.	**No Contra indication**			প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Gulshan-1, Dhaka-1212, Bangladesh.									
47.	Protimax Nutrivet Ltd. AWR U-Tower, Plot 35, Road 133, Gulshan South Avenue, Gulshan-1, Dhaka-1212,	SOMVITAL, SL. Calle Manfredonia 10, ships 1-2, Zaragoza, Spain	**FOGGERSAN FORTE**	2- Phenylphenol- 10%, N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine- 1%, Excipients and Solvents – q.s.100%	Disinfection of facilities in the Livestock environment, in the food industry, sheds, surfaces and environments. Disinfection the interior of vehicles, cameras and ducts.	**No Contra indication**	SPAIN		প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
48.	Protimax Nutrivet Ltd. AWR U-Tower, Plot 35, Road 133, Gulshan South Avenue, Gulshan-1, Dhaka-1212, Bangladesh.	SOMVITAL, SL. Calle Manfredonia 10, ships 1-2, Zaragoza, Spain	**GRASS**	Sodium hydroxide- 4%, Anionic surfactants- <5%, Amphoteric surfactants - <5%, Demineralized water- s.q.100%	With a foaming formulation, product suitable for cleaning all types of installations. For professional use only	**No Contra indication**	SPAIN		প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।
49.	Protimax Nutrivet Ltd. AWR U-Tower, Plot 35, Road 133, Gulshan South Avenue, Gulshan-1, Dhaka-1212, Bangladesh.	SOMVITAL, SL. Calle Manfredonia 10, ships 1-2, Zaragoza, Spain	**DIXCLOR**	Sodium bisulphate – 40.0%, Sodium chlorite- 24.0%, Sodium sulphate – 13.0%, Magnesium sulphate – 9.0%, Sodium chloride – 7.0%, Sodium alginate – 4.5%,	Disinfection of water in tanks, rafts, pipes, troughs, etc. Removal of biofilm formed in the pipes and prevention of its appearance. The product is processed in accordance with RD 140/2003 of 7th February, in which the sanitary criteria of the quality of	**No Contra indication**	SPAIN		প্রয়োজনীয় রেফারেন্স না থাকায় না মঞ্জুরের সুপারিশ করা হয়।	রেফারেন্স নেই বিধায় আবেদন না মঞ্জুর করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
				Sodium percarbonate – 2.5%	water for human consumption are established. It is in accordance with the European Regulation REACH 1907/2006/CE, 453/2010/EC and 830/2015 EU. Notified formula as future TP5 biocide for the disinfection of drinking water, according to the second transitory provision of RD 1054/2002. It fluffiness the criteria of the standards for chemical products used for treatment of water intended for human consumption UNE-EN 16037 (sodium sulphate), UNE-EN 938 (sodium chlorite) and UNE-EN 12671 (chlorine dioxide generated in situ).					
50.	**Beaphar B.V.** Drostenkamp 3, 8101 BX Raalte, Netherlands Importer: Shombhob Health Ltd. House-131, Road-4, Block-A, Banani, Dhaka-1213.	Fiprotec Spot on Solution for Cats	1 pipette of 0.5ml contains Fipronil 50mg	Antiparasites	To be used against infestations with fleas, alone or in association with ticks and/or biting lice. -Treatment of fleas (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 4 weeks. Prevention of the multiplication of fleas by inhibiting the development of eggs (ovicidal activity), larvae and pupae (larvicidal activity) originating from eggs laid by adult fleas for 6 weeks after application. -Treatment of ticks (*Ixodes ricinus, Dermacentor variabilis, Rhipicephalus sanguineus*). The product has a	**Contra-indication** *The product should not be used on kittens less than 8 weeks old and/or weighing less than 1kg*. **Side Effects** If licking occurs, a brief period of hyper salivation may be observed due mainly to the nature of the carrier. Among the very rare suspected adverse reactions, transient cutaneous reactions at the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Exceptionally,	New	Netherlands	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					persistent acaricidal efficacy for up to 2 weeks against ticks (based on experimental data). -Treatment of biting lice (*Felicola subrostratus*).	hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have been observed after use. **Special warnings & Precautions** For optimal control of flea, infestation in multi-pet household, all cats in the household should be treated with a suitable insecticide. Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in cases of massive infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.				
51.	**Beaphar B.V.** Drostenkamp 3, 8101 BX Raalte, Netherlands Importer: Shombhob Health Ltd. House-131, Road-4, Block-	Fiprotec Spot on Solution for Small Dogs	1 pipette of 0.67ml contains Fipronil 67mg	Antiparasites	The treatment and prevention of flea (Ctenocephalides felis) infestations in dogs. The duration of protection against flea infestations is 5 weeks. The product protects against new tick (Dermacentor reticulatus, Rhipicephalus sanguineus) infestations in dogs from day 7 to day 28 after application of the product.	**Contra-indications** Do not use on dogs less than 8 weeks old and/or weighing less than 2kg. Do not use in cases of hypersensitivity to the active substance or to any of the excipients. Do not use on sick (e.g. systemic disease, fever) or convalescent animals. Do not use in rabbits, as adverse reactions and even death could occur. Do not use in cats, as this could lead to overdosing.	New	Netherlands	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	A, Banani, Dhaka-1213.					**Side Effects** If licking occurs, a brief period of hyper salivation may be observed due mainly to the nature of the carrier. Among the very rare suspected adverse reactions, transient cutaneous reactions at the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have been observed after use. **Special warnings & Precaution** For optimal control of flea infestation in multi-pet household, all dogs in the household should be treated with a suitable insecticide. Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in cases of massive infestation and at the beginning of the control measures, with a				

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						suitable insecticide and vacuumed regularly.				
52.	**Beaphar B.V.** Drostenkamp 3, 8101 BX Raalte, Netherlands Importer: Shombhob Health Ltd. House-131, Road-4, Block-A, Banani, Dhaka-1213.	Fiprotec Spot on Solution for Medium Dogs	1 pipette of 1.34ml contains Fipronil 134mg	Antiparasites	The treatment and prevention of flea (Ctenocephalides felis) infestations in dogs. The duration of protection against flea infestations is 5 weeks. The product protects against new tick (Dermacentor reticulatus, Rhipicephalus sanguineus) infestations in dogs from day 7 to day 28 after application of the product.	**Contra-indications** Do not use on dogs less than 8 weeks old and/or weighing less than 2kg. Do not use in cases of hypersensitivity to the active substance or to any of the excipients. Do not use on sick (e.g. systemic disease, fever) or convalescent animals. Do not use in rabbits, as adverse reactions and even death could occur. Do not use in cats, as this could lead to overdosing. **Side Effects** If licking occurs, a brief period of hyper salivation may be observed due mainly to the nature of the carrier. Among the very rare suspected adverse reactions, transient cutaneous reactions at the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have been observed after use.	New	Netherlands	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Special warnings & Precaution For optimal control of flea infestation in multi-pet household, all dogs in the household should be treated with a suitable insecticide. Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in cases of massive infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.				
53.	**Beaphar B.V.** Drostenkamp 3, 8101 BX Raalte, Netherlands Importer: Shombhob Health Ltd. House-131, Road-4, Block-A, Banani, Dhaka-1213.	Fiprotec Spot on Solution for Large Dogs	1 pipette of 2.68ml contains Fipronil 268mg	Antiparasites	The treatment and prevention of flea (Ctenocephalides felis) infestations in dogs. The duration of protection against flea infestations is 5 weeks. The product protects against new tick (Dermacentor reticulatus, Rhipicephalus sanguineus) infestations in dogs from day 7 to day 28 after application of the product.	**Contra-indications** Do not use on dogs less than 8 weeks old and/or weighing less than 2kg. Do not use in cases of hypersensitivity to the active substance or to any of the excipients. Do not use on sick (e.g. systemic disease, fever) or convalescent animals. Do not use in rabbits, as adverse reactions and even death could occur. Do not use in cats, as this could lead to overdosing. **Side Effects** If licking occurs, a brief period of hyper salivation may be observed due mainly to the nature of the carrier. Among the very rare suspected adverse reactions,	New	Netherlands	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						transient cutaneous reactions at the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have been observed after use. **Special warnings & Precaution** For optimal control of flea infestation in multi-pet household, all dogs in the household should be treated with a suitable insecticide. Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in cases of massive infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.				
54.	Renata Limited Plot No. 1, Milk Vita Road, Section-7 Mirpur, Dhaka-1216	IZO S.r.l. a socio unico S.S. 234 per Cremona Km 28,2 27013 Chignolo Po (PV) Italy	IZOVAC FC - Emulsion for Injection. Homogeneous oily, white and milky emulsion.	Each dose of 0.5 ml contains: Active substances: - Inactivated *Pasteurella multocida* serotype 1: ≥ 7.3 log_2 SAT*	Vaccine Active immunization of chickens against Fowl Cholera	Do not use in unhealthy birds. Do not use in cases of hypersensitivity to the active substance or to any of the excipients.	New	CPP: Italy	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
				- Inactivated *Pasteurella multocida* serotype 3: ≥ 7.3 log_2 SAT* -Inactivated *Pasteurella multocida* serotype 4: ≥ 7.3 log_2 SAT* * SAT = Serum Agglutination Test units after Injection of chickens with 1 dose						
55.	Renata Limited Plot No. 1, Milk Vita Road, Section-7 Mirpur, Dhaka-1216	IZO S.r.l. a socio unico S.S. 234 per Cremona Km 28,2 27013 Chignolo Po (PV) Italy	IZOVAC CHB - Lyophilisate for drinking water/oculonasal suspension for chickens.	Each dose of reconstituted vaccine contains: Active substance: − Live attenuated Newcastle Disease virus, strain Clone: ≥ 6.0 log_{10} EID_{50}* − Live attenuated Infectious Bronchitis virus, strain Massachusetts H120: ≥ 3.0 log_{10} EID_{50}* − Live attenuated Infectious Bronchitis virus, strain 28/86: ≥ 3.0 log_{10} EID_{50}* *EID_{50}=embryo infectious dose 50%	Vaccine For the active immunization of chickens against Newcastle disease and respiratory and nephropathy forms of Infectious Bronchitis.	Do not use in unhealthy birds. Do not use in the case of hypersensitivity on the active substances or any of excipients.	New	CPP: Italy	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
56.	Renata Limited Plot No. 1, Milk Vita Road, Section-7	IZO S.r.l. a socio unico S.S. 234 per Cremona Km	IZOVAC ENCEPHALOMYELITIS – Lyophilized for oral	Each dose of reconstituted vaccine contains: Active substance:	Vaccine For the active immunization of chickens from 10 weeks of age against avian	Vaccinate healthy animals only. The vaccine virus can spread from vaccinated to non-vaccinated chickens and	New	CPP: Italy	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Mirpur, Dhaka-1216	28,2 27013 Chignolo Po (PV) Italy	suspension, Nut-brown lyophilized tablet	- Live attenuated avian Encephalomyelitis virus, strain Calnek 1143: 10^3 ≤R≤ $10^{4.5}$ EID_{50}* *EID_{50}=embryo infectious dose – as Ph.Eur.	encephalomyelitis to prevent mortality, clinical signs and lesions of disease.	appropriate care should be taken to separate vaccinated from non-vaccinated.				
57.	Renata Limited Plot No. 1, Milk Vita Road, Section-7 Mirpur, Dhaka-1216	IZO S.r.l. a socio unico S.S. 234 per Cremona Km 28,2 27013 Chignolo Po (PV) Italy	IZOVAC MAREK MD – Frozen suspension for Injection.	Each dose of reconstituted vaccine (0.2 ml) contains: Active substance: - Live apathogenic virus of Marek disease, strain Rispens CVI 988 (serotype 1) ≥ 2.000 PFU* *PFU= Plaque forming units	Vaccine For active immunization of one-day-old chickens to reduce mortality, clinical signs and lesions caused by Marek's disease virus.	Do not use in unhealthy birds. Do not use in cases of hypersensitivity to the active substances or to Aby‡gv`‡bi mycvwik Kiv nq|any of the excipients.	New	CPP: Italy	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
58.	Renata Limited Plot No. 1, Milk Vita Road, Section-7 Mirpur, Dhaka-1216	IZO S.r.l. a socio unico S.S. 234 per Cremona Km 28,2 27013 Chignolo Po (PV) Italy	IZOVAC ND-EDS-IB - Emulsion for Injection. Homogeneous oily, white and milky emulsion.	Each dose of 0.5 ml contains: Active substances: - Inactivated virus of Newcastle Disease, strain Ulster: ≥ 4.0 log_2 HI units * - Inactivated Adenovirus EDS '76, strain 127 ≥ 7.0 log_2 HI units ** - Inactivated avian Infectious bronchitis virus, strain M41: ≥ 6.0 log2 HI units **	Vaccine For the vaccination of chickens against infection with Newcastle disease virus, Egg Drop Syndrome'76 and Avian Infectious Bronchitis in order to reduce the decline in egg caused by adenovirus EDS'76. For the booster vaccination of layers and breeders previously vaccinated with live attenuated vaccines homologous Avian Infectious Bronchitis and Newcastle disease.	Do not use in unhealthy birds. Do not use in cases of hypersensitivity to the active substances, to the adjuvant or to any of the excipients.	New	CPP: Italy	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
				- Inactivated avian Infectious bronchitis virus, strain D274: ≥ 4.0 log_2 HI units ** - Inactivated avian Infectious bronchitis virus, strain D1466: ≥ 4.0 log_2 HI units ** * HI units after Injection of chickens with 1/50 dose ** HI units after Injection of chickens with 1 dose						
59.	Renata Limited Plot No. 1, Milk Vita Road, Section-7 Mirpur, Dhaka-1216	IZO S.r.l. a socio unico S.S. 234 per Cremona Km 28,2 27013 Chignolo Po (PV) Italy	IZOVAC MAREK BIVALENT– Frozen suspension for Injection.	Each dose of reconstituted vaccine (0.2 ml) contains: Active substance: - -Live apathogenic virus of Marek's disease, strain HVT FC-126 (serotype 3) ≥ 2.000 PFU* - Live apathogenic virus of Marek's disease, strain Rispens CVI 988 (serotype 1) ≥ 2.000 PFU* *PFU= Plaque forming units	Vaccine For active immunization of one-day-old chickens to reduce mortality, clinical signs and lesions caused by Marek's disease virus.	Do not use in unhealthy birds. Do not use in cases of hypersensitivity to the active substances or to any of the excipients.	New	CPP: Italy	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
60.	Renata Limited Plot No. 1, Milk Vita Road, Section-7 Mirpur, Dhaka-1216	IZO S.r.l. a socio unico S.S. 234 per Cremona Km 28,2 27013 Chignolo Po (PV) Italy	IZOVAC FOWL POX - Lyophilisate and solvent for suspension for wing web administration.	Each dose of reconstituted vaccine contains: Active substance: -Live attenuated Fowlpox virus strain Brescia P1: ≥ 3.0 log_{10} $TCID_{50}$* *$TCID_{50}$ =	Vaccine For active immunization of chickens against Fowlpox virus.	Do not use in unhealthy birds. Do not use in the case of hypersensitivity to the active substance or to the excipient.	New	CPP: Italy	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
				Tissue Culture Infectious Dose 50%						
61.	Renata Limited Plot No. 1, Milk Vita Road, Section-7 Mirpur, Dhaka-1216	IZO S.r.l. a socio unico S.S. 234 per Cremona Km 28,2 27013 Chignolo Po (PV) Italy	Vaxxon ND-FLU – Homogeneous oily in‡jvectable emulsion, white and milky.	Each dose of 0.5 ml contains: - Inactivated Newcastle Disease virus, strain Ulster: ≥ 4.0 log_2 HI units* - Inactivated Avian Influenza A virus, subtype H9N2: ≥ 5.0 log_2 HI units* * HI units after Injection of chickens with 1/50 dose ** HI units after Injection of chickens with 1 dose	Vaccine Active immunization against Newcastle Disease and Avian Influenza A.	None.	New	CPP: Italy	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
62.	Renata Limited Plot No. 1, Milk Vita Road, Section-7 Mirpur, Dhaka-1216	IZO S.r.l. a socio unico S.S. 234 per Cremona Km 28,2 27013 Chignolo Po (PV) Italy	Vaxxon Coccivet R Suspension	Each 1000 doses contains attenuated strains of - *Eimeria tenella* strain BV 25: 1,0 to 6.0 x 10^5 sporulated oocysts - *Eimeria acervulina* strain BV 45: 1.0 to 6.0 x 10^5 sporulated oocysts - *Eimeria maxima* strain BV 47: 1.0 to 8.0 x 10^5 sporulated oocysts	Vaccine VAXXON COCCIVET R is a polyvalent vaccine against Coccidiosis in layer and breeder chickens.	The vaccine should not be used in chickens with malnourishment, weakness or with intercurrent diseases (coryza, salmonellosis, DCR and others), since their physiological resistance may be much lowered and may not respond satisfactorily to the immunization process.	New	CPP: Brazil FSC: Singapore Registration: Singapore	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
				- *Eimeria maxima* strain BV 52: 1,0 to 8.0 x 10^5 sporulated oocysts - *Eimeria brunetti* strain BV 300: 2,0 to 7.0 x 10^5 sporulated oocysts - *Eimeria necatrix* strain BV 302: 1,0 to 6.0 x 10^5 sporulated oocysts - *Eimeria mitis* strain BV 44: 1,0 to 5.0 x 10^5 sporulated oocysts - *Eimeria praecox* strain BV 41: 1,0 to 5.0 x 10^5sporulated oocysts						

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
63.	M/S Rafique Medicine College Road Ishurdi, Pabna	Komipharm International Co, Ltd. 1236-6,Chongwang-Dong,Shihung-Si Kyonggi-Do, The Republic of Korea	**PRO-VAC ND IB (Q)**	Newcastle Disease Virus (Ulster 2C Strain) Infectious Bronchitis Virus (KM-QXE 120 Strain)	Vaccine For the immunization against newcastle disease and infectious bronchitis virus infection in broiler chicken.	Contraindication: Do not administer the product to the following ones| • Those with fever or serious nutritional disorder • Those with infectious disease, parasite infection of stress. • Those with weakened immunity due to mold or bacterial toxin (aflatoxin or toxin produced by E. coli or salmonella spp.) • Those with shock or hypersensitiveness to this vaccine	New	FSC: Korea	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
64.	**Local Agent:** Bengal Overseas Ltd.; Paragon House (6th Floor) 5, Mohakhali C/A,	Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands	**NOBILIS INFLUENZA H5N2**	**Avian Influenza Type A; Subtype H5N2** inducing per dose ≥ 6.0 log_2 HI unit	Vaccine Nobilis Influenza H5N2 is meant to be used for active immunisation of healthy poultry as an aid in the control of Avian Influenza type A subtype H5.	**Contraindication:** None **Side-effect:** None	New	The Netherlands	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।
65.	**Local Agent:** Bengal Overseas Ltd.; Paragon House (6th Floor) 5, Mohakhali C/A,	Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands	**NOBILIS INFLUENZA H9N2+ND**	**Inactivated Avian Influenza Virus Type A; Subtype H9N2,** strain AG415: inducing per dose ≥ 7.0 log_2 HI unit and **InactivatedNewcastle Disease Virus, strain Clone 30:** inducing ≥ 4.0 log_2 HI units per 1/50 dose	Vaccine Nobilis Influenza H9N2+ND is meant to be used for active immunisation of healthy poultry as an aid in the prevention of Avian Influenza type A subtype H9 and Newcastle Disease.	**Contraindication:** None **Side-effect:** In healthy animals no clinical reactions. Slight transient reactions at the site of Injection may occur.	New	The Netherlands	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
				or containing ≥ 50 PD_{50} units per dose.						
66.	**Local Agent:** Bengal Overseas Ltd.; Paragon House (6th Floor) 5, Mohakhali C/A,	Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands	**BRAVECTO PLUS,** **SPOT-ON SOLUTION**	Fluralaner/Moxidectin; 112.5 mg/5.6 mg, 250 mg/ 12.5 mg or 500 mg/ 25mg; 1 or 2 pipette(s)	Spot-on Solution For cats with, or at risk from, mixed parasitic infestations by ticks and fleas, gastrointestinal nematodes (4th stage larvae, immature adults and adults of *Toxocaracati*and *Ancylostomatubaeforme*), heartworm or lungworm. The veterinary medicinal product is exclusively indicated when use against ticks or fleas and one or more of the other target parasites is indicated at the same time.	**Contraindication:** Do not use in case of hypersensitivity to the active substance or to any of the excipients. **Side-effect:** Mild and transient skin reactions at the application site (alopecia, flaking skin, redness and pruritus) were commonly observed in clinical trials. Dyspnoea after licking the application site, hypersalivation, emesis, haematemesis, diarrhoea, lethargy, pyrexia, tachypnoea and mydriasis were uncommonly observed in clinical trials shortly after administration. Anorexia as well as neurological manifestations such as tremors and ataxia have been reported very rarely after the use of this product based on post marketing safety experience. The frequency of adverse reactions is defined using the following convention:	New	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

SL No	Name of Local Agent/ Importer.	Name of Manufacturing Company/ Supplier	Brand Name	Generic Name	Therapeutic Class & Indication	Contra-indication & Side effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						- very common (more than 1 in 10 animals treated displaying adverse reaction(s)) - common (more than 1 but less than 10 animals in 100 animals treated) - uncommon (more than I but less than 10 animals in 1,000 animals treated) - rare (more than 1 but less than 10 animals in 10,000 animals treated) - very rare (less than 1 animal in 10,000 animals treated, including isolated reports)				
67.	Pharma & Firm,3/2, Nayapalton, Dhaka.	SB-Shinil Co. Ltd. (Shinil Biogen Co. LTd. 235-18, Chusa-rp,Sinam-Myeon, Yesan Gun, Chungcheongnam-do 32417Republic Of Korea.	**SB Chlor-T**	Each 1 Tablet (5 gm) contains Sodium Dichloisoyanurate 2.5 gm	disinfectent 1) For the disinfection of a livestock body, shed, instrument and other. 2) For the purification of the drinking water (except layer).	1) For the disinfection of a livestock body, shed, instrument and other. 2) For the purification of the drinking water (except layer).	**Contraindication:** None **Side-effect:** None	New	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হলো।

Annex-G: স্থানীয়ভাবে উৎপাদনের জন্য হার্বাল মেডিসিন এর তালিকা

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
1.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai.	Tart Cherry extract 250 mg + Celery seed 60 mg	Capsule	•Uric acid reduction •Balance muscle recovery & joint mobility	**Contraindications:** The drug is contraindicated in patients with kidney infections. **Side Effect:** This drug is usually well tolerated.	New	**Product Reference:** Bronson Tart Cherry Extract + Celery Seed Capsules, USA **Book Reference:** American botanical Council & PDR 4th edition G-8, Page -182	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
2.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai.	Calcium (as MCHC and dicalcium phosphate) 206.67 mg mg, Phosphorus (as MCHC and dicalcium phosphate)120 mg, Microcrystalline Hydroxyapatite Concentrate (MCHC) 0.5 g	Tablet	•Reducing the rate of bone loss or bone thinning and in protecting bone strength, •Supports bone mass •Slow age-related bone loss	**Contraindications**: May contraindicate with the following medications: Biphosphates, Anti-hypertensives & Cholesterol-lowering medications. **Side effects**: This drug is usually well tolerated.	New	**Product Reference:** Bone builder, Metagenics, USA **Book Reference:** US pharmacopoeia, US Patent, Current Medical Research	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
3.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai.	Magnesium 120 mg (from 665 mg of Magnesium Glycinate, chelate buffered Magnesium-Bisglycinate chelate, Magnesium oxide)	Capsule	•Osteoporosis, •Type 2 diabetes •Migraine •headaches •Depression •chronic fatigue syndrome •Fibromyalgia •risk of stroke •heart failure, diabetes, and all-cause mortality	**Contraindications:** It is contraindicated in those patients who are hypersensitive to any component of this product. **Side-effects**: Taking large or frequent doses of dietary magnesium supplements can cause adverse effects, including diarrhea, nausea, and stomach cramps.	New	**Product Reference:** Nature's Truth High Absorption buffered Magnesium Glycinate, USA **Book Reference:** US pharmacopoeia	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
4.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai.	Boswellia serrata 300 mg (Boswellia acid> 65%) & Turmeric Extract (rhizome) (Circumalonga Linn.) (95% Curcuminoids, 190 mg) 200 mg	Capsule	•Bone & Joint wellness •supports healthy inflammation •oxidative stress and deterioration •cardiovascular and joint health	**Contraindication:** Contraindicated in patients with a known hypersensitivity to curcuminoids. Curcuminoids is contraindicated in obstruction of bile passages. **Side Effects:** The combination is well tolerated in recommended dose.	New	**Product Reference:** Morpheme Remedies Boswellia Curcumin (95% Curcuminoids), India **Book Reference:** US Pharmacopoeia, PDR Herbal Medicine 4th Edition Page 775,	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
5.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai.	Manganese (as manganese amino acid chelate) 0.335 mg, Soluble keratin) 83.335 mg, MSM (methylsulfonylmethane) 66.665 mg, L-Arginine 66.665 mg, L-Proline 41.665 mg, Glycine 41.665 mg, Boswellia serrata Extract 16.665 mg (20% AKBA), Strawberry Fruit Extract (Fragaria X ananassa, standardized to 2% polyphenols) 4.165 mg, Spinach Leaf Extract (Spinacia oleracea, standardized to 1.5% polyphenols) 4.165 mg, Silicon (as silicon amino acid chelate)2.5 mg, Extract from the bark of Pinus radiata trees, standardized to 80% proanthocyanidins 1.665 mg , Hyaluronic Acid (as sodium hyaluronate) 0.835 mg	Capsule	•Support joint function and the ligament structure	**Contraindication:** It is contraindicated in patients taking blood thinning medication such as Coumadin. **Side Effects**: No adverse effects have been reported.	New	**Product Reference:** Joint, Tendon, Ligament, Douglas, USA **Book Reference:** US Pharmacopoeia, Europian food Safty Authority, American Botanical Council, PDR 4th Edition Page 712, 674,	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
6.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai.	Gurmaar *(Gymnema sylvestre)*-150 mg, Karela (*Momordica charantia*)-150 mg, Saptrangi (*Salacia chinensis*)-50 mg, Vizaysaar (*Pterocarpus marsupium*)-50 mg, Ashwagandha *(Withania somnifera*)-50 mg & Tulsi *(Ocimum tenuiflorum*)-50 mg	Capsule	•Type-2 Diabetes and its complains	**Contra-Indications:** Gurmaar might affect blood sugar levels and could interfere with blood sugar control during and after surgery. Stop using Gurmaar at least 2 weeks before a scheduled surgery **Side effects**: Generally well tolerated in recommended dose.	New	**Product Reference:** Dia-Beta Plus, Planet -India, Export to USA **Book Reference:** American Botanical Council, Indian Medicinal Plant (Springer Text Book), PDR 4th edition Page - 182. British Pharmacopoeia	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
7.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai.	Maca Root Extract 125 mg, Myo-Inositol 100 mg, Vitex agnus-castus (Chaste Tree Berry) 50 mg, Ginkgo biloba leaf extract 37.5 mg, Tribulus Terrestris Fruit Extract (std. to 45% Steroidal Saponsis) 18.75 mg, Epimedium (std. to 10% Icariin, aerial parts) 12.5 mg, Organic Shatavari Root 12.5 mg, 5-Hydroxytryptophan (5-HTP) 12.5 mg, Dong quai root extract (Angelica sinensis 2:1) 11.25 mg, Melatonin 1.25 mg & Zinc 3.75 mg, Riboflavin 2.5 mg, Niacin 5 mg, Folate (as 200 mcg Folic Acid) 166.75 mcg DFE	Capsule	•Decreases stress, •Improves ovulation, •Strengthens egg quality, •Optimizes reproductive health in female.	**Contra indication**: It is contraindicated in patients with inflammatory kidney disease. **Side Effects**: It may cause side effects of upset stomach, headaches etc.	New	**Product Reference:** Concepta's Women's Fertility Boost, USA **Book Reference:** US Pharmacopoeia , European Pharmacopeia, American botanical council , PDR 4th Edition, American Herbal Pharmacopoeia , European Medical Council	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
8.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai.	Rhapontic Rhubarb (Rheum rhaponticum L.) Root Extract [Providing 2.2 mg rhaponticin and 1 mg desoxy-rhaponticin] 4 mg	Tablet	•Multiple menopausal symptoms, including hot flashes, sleep disturbances, mood swings, irritability, anxiety, and sexual problems	**Contraindications**: It is not recommended for women who are pregnant or breastfeeding. **Side effect:** Generally safe and well-tolerated by most people, some people may have Stomach upset,Rash, Slowheart, rate, Headaches, Dizziness or feeling light-headed, Joint pain	New	**Product Reference:** Estrovera, Metagenics, USA **Book Reference:** American botanical council	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
9.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai.	Co-enzyme Q10 (as Ubidecarenone) 150 mg, Magnesium (derived from Magnesium oxide) 150 mg, Vitamin D3 as Cholecalciferol 1000 IU	Capsule	•Cardiovascular Support •Migraine Support •Adjunct to Chronic Medication such as Statins •Muscle Relaxant Energy	**Contraindications**: Hypersensitivity to any of the ingredients, including excipients. **Side effects:** Some people as rare exception may experience gastrointestinal discomfort such as diarrhea.	New	**Product Reference:** VasQ10, AnaStellar Brands, South Africa **Book Reference:** British Pharmacopeia, US Pharmacopeia	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
10.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai.	Magnesium (as Magnesium oxide) 66.67 mg, Zinc (as Zinc oxide) 10 mg, Tribulus Terrestris (fruit) 250 mg, Chrysin (Oroxylum indicum) (seed) 25 mg, Horny Goat Weed (Epimedium sagittatum) (aerial) 16.67 mg, Longjack (Eurycoma longifolia) (root) 16.67 mg, Saw Palmetto Berries (Serenoa repens) (berry) 16.67 mg, Hawthorn Berries (Crataegus pinnatifida Bunge) (stem) 16.67 mg, Cissus quadrangularis (stem) 16.67 mg	Capsule	•Increases Testosterone production, •Burns fat •Builds lean muscle fast •Boosts stamina & •Enhances performance in Male	**Contra-Indications:** Consumption of herbal ingredients may cause allergies to certain individuals, please talk physician before taking any herbal supplements. **Side effects:** Possible side effects include headaches, nausea, stomachaches, high/low blood pressure and increased heart rate.	New	**Product Reference:** TestoBoost, Arazo Nutrition, USA **Book Reference:** US Pharmacopoeia, British Pharmacopeia, American botanical council, PDR 4th edition Page -664 & 271, Drugs.com	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
11.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai.	Saw Palmetto Berry Extract-125 mg, Cranberry Fruit Extract-125mg, Pumpkin Seed Extract-100 mg & Pygeum Bark Extract-100 mg	Capsule	•BPH •Treatment and prevention of UTI	**Contraindication:** You may not be able to use saw palmetto if you have certain medical conditions., such as: a bleeding or blood clotting disorder (such as hemophilia). **Side effects**: Possible side effects includes allergic reaction: hives; difficulty breathing; swelling of your face, lips, tongue, or throat.	New	**Product Reference:** Saw Palmetto Plus Cranberry, Eurobio-UK **Book Reference:** PDR 4th edition Page - 664,618, American botanical council, WHO Monograph on Selected Medicinal Plants. V-2, Page: 246-247	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
12.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai.	Xanthigen proprietory blend (Wakame Seaweed) 300 mg , Green select phytosome (From Green tea of Camellia Sinensis Extract) 150 mg	Capsule	•Healthy weight management support •fat metabolism and metabolic rate support	**Contraindication:** Take with food. If you have liver problems, consult your health professional before use. **Side Effects:** In rare cases, green tea can cause dizziness, insomnia, agitation or fatigue. Consult your physician for more information.	New	**Product Reference:** Xanthitrim, Pure encapsulations, USA, **Book Reference:** US Pharmacopeia-DSC, PDR 4th edition Page-369	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
13.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai.	Vitamin C (as ascorbic acid) 166.66 mg, Vitamin E (as vitamin E succinate) 89.33 mg, Zinc (as monomethionine) 8.33 mg, Lutein (as marigold (Tagetes erecta) flower) 3.33 mg, Zeaxanthin 0.66 mg	Capsule	•Support for eye health •Antioxidant support for retinal health	**Contraindications**: It is contraindicated in those patients who are hypersensitive to any component of this product. **Side effects:** No health hazards or side effects are known in con‡jvunction with the proper administration of designated therapeutic dosages.	New	**Book Reference:** PDR for Herbal Medicines (Page- 497-500), US Pharmacopeia, American Botanical Council, Health Cnada, **Product Reference:** Macu-Support, Douglas Laboratories,USA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
14.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai.	Vitamin A (Beta carotene) 4 mg, vitamin C (Ascorbic acid) 240 mg, Choline (bitartrate) 22 mg, Inositol 55 mg, Milk thistle seed extract (Silybum marianum) 175 mg, Silymarin 140 mg, Proprietary Blend 410 mg [N-Acetyl-L-Cysteine and Dandelion root (Taraxacum officinale)]	Tablet	•Supports the hepatic system. •Stabilizes liver cell membranes. •Facilitates elimination of toxins in the body. •Acts as a powerful antioxidant.	**Contraindication**: Contraindications include closure of the biliary ducts, gallbladder empyema, and ileus. **Side effect**s: No health hazards or side effects are known in con‡jvunction with the proper administration of designated therapeutic dosages.	New	**Reference:** PDR for Herbal Medicines (Page- 516-520, 245-246), US Pharmacopeia **Ref. Product:** Milk Thistle Combination, Natures Sunshine, USA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
15.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai.	Cassia angustifolia-140 mg, Ipomoea Turpethum-50 mg, Rheum emodi-50 mg, Glycyrrhiza Glabra-30 mg, powder of Erandbhrisht Haritaki- 200 mg & Zingiber Officinale-30 mg	Tablet	•Constipation, •Bowel Regulation, •Colic Pain & Discomfort, •Digestive Disturbance •Loss of Appetite	**Contraindication:** The effects of some drugs can change if you take other drugs or herbal products at the same time. **Side Effects**: Stomach/abdominal pain or cramping, nausea, diarrhea, or weakness may occur.	New	**Reference:** PDR 4th edition Page -339, 469, 684 & 772 , American Botanical Council, **Ref Product:** Laximer, Healwell Nutraceuticals - India	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
16.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai.	Lactiplantibacillus plantarum 6.6 BLB (3.3+3.3 Billion Live Bacteria) and Lacticaseibacillus paracasei 3.3 BLB & Vitamin D3 (Cholecalciferol) 60 IU (1.5 mcg)	Capsule	•Age related bone loss	**Contraindication:** No known interaction with other medicine **Side effects:** No serious side effects have been reported	New	**Reference:** PDR for Herbal Medicine 4th Edition Page 996-999 **Ref. Product:** Probi Osteo, Sweden	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
17.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai.	Palmitoylethanolamide 300 mg	Capsule	Chronic and neuropathic pain	**Contraindications:** No known contraindications exist, though safety during pregnancy and lactation has not been established. **Side effects:** There is no significant side effects.	New	**Reference:** FDA GRAS (generally recognized as safe) **Ref. Product:** Levagen, Gencor Pacific - USA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
18.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai.	Natural Eggshell Membrane 500 mg & Calcium (Dicalcium phosphate) 34 mg	Capsule	Joint comfort and flexibility Supports healthy cartilage Supports overall joint health	**Contraindications:** No known contraindications exist, though safety during pregnancy and lactation has not been established. **Side effects:** There is no significant side effects.	New	**Reference:** FDA GRAS (generally recognized as safe) **Ref. Product:** NEM Natural Eggshell Membrane, Natural Factors, USA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
19.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai.	Natural Eggshell Membrane 500 mg	Capsule	Reduces joint pain and improves joint flexibility. Helps maintain good cartilage and joint health. Helps to reduce joint pain and reduce joint stiffness.	**Contraindications**: No known contraindications exist. **Side effects:** There is no known side effects.	New	**Reference:** FDA GRAS (generally recognized as safe) **Ref. Product:** NEM, Jamieson, USA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
20.	Aristopharma Ltd. (Herbal Division), Gachha, Gazipur Sadar, Gazipur.	Ginkgo Biloba Extract 60mg + Ginseng Extract (Panax ginseng) 170 mg Contains Panax Ginseng 100 mg Capsule	Capsule	It is used for the treatment of Improvement of brain function and memory, Brain and its blood vessels activator, Fatigue, Stress, Aging, Blood pressure drop and other conditions. The complete list of uses and indications as follows: • Improvement of brain function and	**Contra-indication:** It is should not be used if you have the following conditions: •Hypersensitivity to ginkgo preparations **Side-effect:** The most common side effects of Ginkgo Biloba and Ginseng Capsule include:	New	PDR For Herbal Medicines-4th Edition, Pages-371-390. The American Journal of Chinese Medicine, Vol. 31, No.6, pp. 841-855 (2003). **Reference product:** GINCOSAN, Switzerland	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
				memory • Brain and its blood vessels activator • Fatigue • Stress • Aging • Blood pressure drop • Inflammation • Mental disorder • Diabetes • Cancer • Oxidative stress • Tumour • Hypotension	•Palpitations •Diarrhea •Headaches •Nausea •Vomiting •Dizziness •Restlessness •Weakness •Skin rash				
21.	Aristopharma Ltd. (Herbal Division), Gachha, Gazipur Sadar, Gazipur.	Lactobacillus rhamnosus GG blend with Inulin 500 mg (Eqv.to not less than 20 billion CFU and Inulin 200 mg) Capsule	Capsule	In the prevention and treatment of gastrointestinal infection, it is likely a combination of direct competetion between pathogenic bacteria in the gut, and immune modulation and treatment. • Improves immune system • Acute Diaarhoea • Reduces gastrointestinal side effects of antibiotics Promote gut health	**Contra-indication:** Use with caution when Short-gut Syndrome and severe immunocompromised condition. **Side-effect:** • Flatulence Mild abdominal discomfort, usually self-limited.	New	PDR For Herbal Medicines-4th Edition, Pages-996-1001. PDR For Nutritional Supplements-2nd Edition, Pages-517-522. AP&T Alimentary Pharmacology and Therapeutics 2015; Pages-1149-1157 **Reference Product:** Culturelle-Ultimate Balance for Antibiotics, i-Health, inc./Culturelle, 55 Sebethe Drive Cromwell, USA (Company Web: https//www.cuturelle.com)	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
22.	Aristopharma Ltd. (Herbal Division), Gachha, Gazipur Sadar, Gazipur.	Omega-3 Fatty Acids 500 mg + Zeaxanthin 1 mg + Lutein 5 mg + Ascorbic Acid 250 mg + Vitamin E 147.06 mg Eqv.to Vitamin E 200 IU+ Zinc Oxide 15.5625 mg Eqv.to Zinc 12.5 mg+ Cupric Oxide 1.259 mg Eqv.to Copper 1 mg Softgel Capsule	Capsule	This preperation is indicated for Eye Disease. This is an advanced new antioxidant supplement formulated to provide nutritional support for the eye.	**Contra-indication:** This preperation should not be used in any patient known to be allergic to it or any of its contituents. **Side-effect:** Large doses of Vitamin C are reported to cause diarrhoea and other gastrointestinal disturbance. Large doses of Vitamin E may cause diarrhoea, abdominal pain, and other gastrointestinal disturbances. Fatigue and weakness have also been reported. Side effects of Zinc salt are abdominal pain and dyspepsia.	New	PDR For Nutritional Supplements-2nd edition, Omega-3 Fatty Acids-Pages-208-213, Leutin & Zeaxanthin, Pages-390, 395, Vitamin C, Pages-654-669. JAMA. 2013; 309(19):2005-2015 Published Online May 5, 2013, Doi:10.1001/jama.2013.4997. AREDS2 formulla https://eyeamfinethankyou.com/334 **Reference Product:**PreserVision (AREDS2), Bausch & Lomb	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
23.	Aristopharma Ltd. (Herbal Division), Gachha, Gazipur Sadar, Gazipur.	Svarjiksara52.20g+ Nimbukamlam43.60g + Ajwain Extract 1.28g/100g Effervesscent Powder	Effervesscent Powder	It is used in the treatment of- • Beneficial in case of indigesion, loss of appetite, flatulence. • Facilitates aid in case of gastrointestinal functions. Helps to enhance the digestive function.	**Contra-indication:** Sodium bicarbonate is contraindicated certain conditions such as renal failure, respiratory or metabolic alkalosis, hypoventilation, hypernatraemia, hypertension, oedema, congestive heart failure, eclampsia, aldosteronism, a history of the urinary stones and consistent potassium depletion or hypocalcemia. It is generally contraindicated in patients with excessive chloride loss. **Side-effect:** Generally, well tolerated. It may cause fluid retention.	New	WHO Monographs on Selected Medicinal Plants-Volume-3, Pages-33-41. International Journal of Ayurbedic Medicine, 2017, 8(3), Pages-138-142 **Reference Product:** GASOFAST, MANKIND PHARMA, INDIA, AP Antacid, APOLLO HOSPITALS ENTERPRISE LTD.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
24.	Aristopharma Ltd. (Herbal Division), Gachha, Gazipur Sadar, Gazipur.	Bacillus Subtilis HU58 0.80g (Eqv.to less than 40 billion) /100 ml Syrup	Syrup	As an adjuvant therapy in the treatment of diseases- • Digestive and immune health • Antibiotic associated diarrhea • Acute/Chronic diarrhea • Traveler's diarrhea • Indigestion • Irritable bowel syndrome Urinary tract infection (UTI)	**Contra-indication:** Probiotics are contraindicated in those hypersensitive to any component of a probiotic-containing product. **Side-effect:** Generally, well tolerated. Only minor transient side events such as nausea, flatulence and bloating were reported.	New	PDR For Nutritional Supplements-2nd edition. Pages-517-522. World Journal of Gastrointestinal Pathophysiology 2017 August 15; 8(3), Pages-117-126. Biomedical Journal of Scientific & Technical Research DOI:10.26717/BJSTR.2020.29.004839 **Reference Product:** Bacilliq Probiotic Liquid, Synergia Life Sciences (Company Web: https://www.synergialifesciences.com/index.html)	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
25.	Aristopharma Ltd. (Herbal Division), Gachha, Gazipur Sadar, Gazipur.	Arginine (L-Arginine) 2 g + Glycine 1 g + Ascorbic Acid 60 mg + Pyridoxine Hydrochloride 2.431 mg Eqv.to Pyridoxine 2 mg + Cyanocobalamin 1 mcg+ Calcium Pantothenate 6 mg + Folic Acid 200 mcg + Zinc Sulphate Monohydrate 16.673 mg Eqv.to Zinc Sulfat 15 mg + Malic Acid 2 g+ Glycyrrhizinic Acid 0.10g + Glucosamine Sulfate Potassum Chloride 3.38mg Eqv.to Glucosamine 2g+ Neohespedine Dihydrochalcone 10.033 mg Eqv.to Neohesperidine 10 mg /100ml Oral Solution	Oral Solution	Adjuvant therapy in the treatment of diseases that require immunostimulant activity such as Hepatitis C virus related cirrhosis, degenerative diseases, and general anemia	**Contra-indication:** Hypersensitive to any of the components of the medication. Do not exceed the expressly recommended daily dose. Not recommended for chlidren under 3 years old. Do not use for more than 6 weeks without medical advice. **Side-effect:** Generally, well tolerated. Only minor transient adverse events such as nausea and diarrhoea were reported.	New	PDR For Nutritional Supplemnents-2nd Edition, Malic Acid, Pages-412-413, Glucosamine, Pages-267-272, Glycine, Pages279-281, Vitamin C, Pages-654-669, Folic Acid, Pages-225-237, Vitamin B6, Pages-634-644, Vitamin B12, Pages-644-653. PDR For Herbal Medicines-4th Edition, Lemon, Pages-460-461. **Reference Product:** Viusid, Unica Pharmaceuticals	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
26.	Aristopharma Ltd. (Herbal Division), Gachha, Gazipur Sadar, Gazipur.	Elderberry Flower Extract 207mg + Primrose Flowers Extract 207mg + Common Sorrel 207mg + European Vervain Extract & Gentian Root Extract 69g/100ml Syrup.	Syrup	Swollen nose and throat, Upper respiratory cold infections, Cough, Bronchitis, Headache, Asthma, Amenorrhea, Digestive problems, Anti-diabetic, Acute Dysentary.	**Contra-indication:** Hypersensitivity to the active substances or to any of the excipients of the madicinal products. **Side-effect:** Stomachache, Nausea, Exanthema, Erythema, Pruritus, Angioedema, Dyspnoea, Face Oedema.	New	American Botanical Council-Proprietary Botanican Product Pages-1-15. **Reference Product:** Monograph For Sinupret Syrup	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
27.	Aristopharma Ltd. (Herbal Division), Gachha, Gazipur Sadar, Gazipur.	Honey 10g, Triphala 400mg, Turmeric 10.5mg/100ml Oral Rinse Solution	Oral Rinse Solution	Natural Antiseptic Oral Rinse/Oral Mucositis, Oral Submucous Fibrosis, Pharyngitis and Other Oral Inflamatory Conditions.	**Contra-indication:** Not Recommended for children below 6 years. **Side-effect:** Honey, Triphala and Turmeric Oral Rinse is not known to have any side effects if taken as per the prescribed dosage.	New	Herbs and Natural Supplements Pages-553-559. **Reference Product:** Oro-T Oral Rinse	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
28.	Aristopharma Ltd. (Herbal Division), Gachha, Gazipur Sadar, Gazipur.	Calcium Carbonate (Derived from coral calcium)(DC Grade) In-house 1250 mg Eqv.to Calcium 500 mg + Dry Vitamin D3 Type 100 CWS (100000 IU/g) In-house 10 mg Eqv.to Vitamin D3 1000 IU + Vitamin K2 (Menaquinone-7) In-house 0.075 mg Tablet	Tablet	Dietary Supplement, Reduce Bone Fracture, Bone Loss (Osteoporosis), Certain Muscle Disease (Latent Tetany), Hypoparathyroidism	**Contra-indication:** This tablet is contraindicated in patients on a low sodium diet. **Side-effect:** This tablet may occur constipation, or stomach upset, nausea/vomiting, loss of appetite, unusual weight loss, mental/mood changes	New	PDR For Nutritional Supplements-2nd edition Calcium, Pages-109-116, Vitamin D3, Pages-669-681 Vitamin K, Pages-708-713 **Reference Product:** VIGANTOLVIT, Merk Selbstmedikation GmbH	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
29.	Aristopharma Ltd. (Herbal Division), Gachha, Gazipur Sadar, Gazipur.	Omega-3 Fatty Acids In-house 360 mg + Lutein & Zeaxanthin Extract Oil 20% In-house 16.65mg Eqv.to Lutein 3.33 mg & Zeaxanthin 0.666mg + Ascorbic Acid (Vitamin C) BP 166.66 mg + D-AlphaTocopherol Acetate (Vitamin E) In-house 98.165 mg Eqv.to D-Alpha Tocopherol 89.33 mg + Zinc Oxide BP 10.371mg Eqv.to Zinc 8.33 mg + Cupric Oxide Ph. Grade 0.501mg Eqv. to Copper 0.4 mg Capsule	Capsule	This preparation is indicated for eye disease. This is an advanced new antioxidant supplement formulated to provide nutritional support for the eye. Prevent oxidative stress in age related eye diseases. It is indicated for dry eye cataract and age-related macular degeneration.	**Contra-indication:** It is contraindicated in persons with a history of hypersensitivity to any of its ingredients. **Side-effect:** Upset Stomach, Headache, Unusual or Unpleasant Taste in Mouth	New	PDR For Nutritional Supplements-2nd edition, Omega-3 Fatty Acids-Pages-208-213, Leutin & Zeaxanthin, Pages-390, 395, Vitamin C, Pages-654-669. **Reference Product:** VITAEYES, Vitamin Health Inc. Eyewise Omega3, Lamberts Healthcare Ltd., UK.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
30.	Incepta Pharmaceuticals Ltd., Herbal and Nutricare Division. Dhamrai, Dhaka.	Damiana Extract (*Turnera diffusa*) In-House 200 mg Capsule	Capsule	Damiana extract can significantly suppress aromatase activity; producing an increase in free testosterone. Testosterone improves sexual activity, libido, and pleasure	**Contra-indication:** No health hazards or side effects are known in con‡jvunction with the proper administration of designated therapeutic dosages. **PRECAUTIONS AND ADVERSE DRUG REACTIONS:** When taken by mouth: Damiana is LIKELY SAFE when taken by mouth in amounts commonly found in foods. Damiana is POSSIBLY SAFE when taken by mouth in medicinal amounts. But there have been serious side effects when taken in very high doses. Convulsions and other symptoms similar to rabies or strychnine poisoning have been reported after taking 200 grams of damiana extract. Pregnancy and breastfeeding: There isn't enough reliable information to know if damiana is safe to use when pregnant or breastfeeding. Stay on the safe side and avoid use.	New	**Originator Product:** Damilib Capsule Bio search Life, Spain https://www.biosearchlife.es/en/exxentia/womens-health/damilib **Reference Book:** PDR for Herbal Medicine (4th Edition, Page: 244)	শুধুমাত্র রেজিস্টার্ড চিকিৎসকের ব্যবস্থাপত্র মোতাবেক বিক্রয় হবে এই শর্তে পদটি অনুমোদনের সুপারিশ করা যেতে পারে।	শুধুমাত্র রেজিস্টার্ড চিকিৎসকের ব্যবস্থাপত্র মোতাবেক বিক্রয় হবে এই শর্তে অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					Diabetes: Damiana might affect blood sugar levels in people with diabetes. Watch for signs of low blood sugar (hypoglycemia) and monitor your blood sugar carefully if you have diabetes and use Damiana. **Surgery**: Since Damiana seems to affect blood glucose levels, there is a concern that it might interfere with blood glucose control during and after surgery. Stop using Damiana at least 2 weeks before a scheduled surgery. **DRUG INTERACTIONS:** Damiana might decrease blood sugar. Diabetes medications are also used to lower blood sugar. Taking Damiana along with diabetes medications might cause your blood sugar to go too low. Monitor your blood sugar closely. The dose of your diabetes medication might need to be changed. Some medications used for diabetes include glimepiride (Amaryl), glyburide (Diabeta, Glynase PresTabs, Micronase), insulin, metformin (Glucophage), pioglitazone (Actos), rosiglitazone (Avandia), and others.				
31.	Incepta Pharmaceuticals Ltd., Herbal and Nutricare Division. Dhamrai, Dhaka.	Lycopene USP 25mg Tablet	Tablet	Indicated for particularly prostate cancer, and may confer some protection against cardiovascular disease.	**Contra-indication:** Avoid use in individuals with hypersensitivity to lycopene or any of its food sources, especially tomatoes. Tomato-based products are acidic and may irritate stomach ulcers. **PRECAUTIONS AND ADVERSE DRUG REACTIONS:** This medication contains lycopene. Do not take all-trans lycopene, psi-carotene, psi-psi-carotene, or solanrubin if you are allergic to lycopene or any ingredients contained in this drug.	New	**Herbal Reference Book:** PDR for Nutritional Supplements (2nd Edition, Page: 401-404) **Product Reference:** Lycopene- UK	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					Keep out of reach of children. In case of an overdose, get medical help or contact a Poison Control Center immediately. **DRUG INTERACTIONS:** If your doctor has directed you to use this medication, your doctor or pharmacist may already be aware of any possible drug interactions and may be monitoring you for them. Do not start, stop, or change the dosage of any medicine before checking with your doctor, health care provider or pharmacist first. Calcium-containing products: Lycopene decreases the bioavailability of calcium.				
32.	Incepta Pharmaceuticals Ltd., Herbal and Nutricare Division. Dhamrai, Dhaka.	Fenugreek Extract (*Trigonella foenum-graecum*) USP 375.0000mg Capsule	Capsule	• Heartburn • GERD • Use as part of the diet to help maintain a healthy blood sugar level.	**Contra-indication:** The drug should not be used during pregnancy. **PRECAUTIONS AND ADVERSE DRUG REACTIONS:** Health risks or side effects following the proper administration of designated therapeutic dosages are not recorded. Sensitization is possible through repeated external administration of the drug. **DRUG INTERACTIONS:** Fenugreek has hypoglycemic effect. There is a potential for the herb to interact with hypoglycemic drugs that are used to treat diabetes resulting in an exaggerated hypoglycemic effect.	New	**Herbal Reference Book:** PDR for Herbal Medicine (4th Edition, Page: 304) **Product Reference:** FenuLife-USA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
33.	Incepta Pharmaceuticals Ltd., Herbal and Nutricare Division. Dhamrai, Dhaka.	Fenugreek Seed Powder (*Trigonella foenum-graecum*) USP 200.0000mg + Fennel Seed Powder (*Foeniculum vulgare*) In-House 50.0000mg + Milk Thistle Seed Extract (*Silybum marianum*) USP 150.0000mg Capsule	Capsule	Used to stimulate lactation for healthy breastfeeding.	**Contra-indication:** The drug should not be used during pregnancy. **Precautions and Adverse Drug Reactions:** • Keep out of reach of children • Keep away from eyes.	New	**Herbal Reference Book:** PDR for Herbal Medicine (4th Edition, Page: 302-305, 516-519) **Product Reference:** Organic Lactation Support-USA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					DRUG INTERACTIONS: There are no interactions with other medications				
34.	Incepta Pharmaceuticals Ltd., Herbal and Nutricare Division. Dhamrai, Dhaka.	Proteoglycans In-House 300.0000mg + Acerola Cherry Extract (*Malpighia emarginata DC*) In-House 100.0000mg + Silica/Colloidal Silicon Dioxide USP-NF 30.0000mg + Horsetail Extract (*Equisetum arvense*) In-House 25.0000mg + D-biotin BP/Ph.Eur. 0.0900mg Tablet	Tablet	To help maintain a normal hair growth cycle, which helps to support normal healthy hair growth.	**Contra-indication:** Horsetail is contraindicated in patients who have edema due to impaired heart and kidney function. **PRECAUTIONS AND ADVERSE DRUG REACTIONS:** Should not be consumed by the patients who are allergic to fish **DRUG INTERACTIONS:** There are no interactions with other medications.	New	**Herbal Reference Book:** PDR for Nutritional Supplements (2nd Edition, Page: 84-89, 97-98, 155-156, 656-663) PDR for Herbal Medicine (4th Edition, Page: 409-410) **Product Reference:** Nourkrin Woman-UK	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
35.	Incepta Pharmaceuticals Ltd., Herbal and Nutricare Division. Dhamrai, Dhaka.	Proteoglycans In-House 300.0000mg + Acerola Cherry Extract (*Malpighia emarginata DC*) In-House 120.0000mg + Fenugreek Extract (*Trigonella foenum-graecum*) USP 45.0000mg + Silica/Colloidal Silicon Dioxide USP-NF 30.0000mg + Horsetail Extract (*Equisetum arvense*) In-House 25.0000mg + Cod Liver Oil Extract In-House 10.0000mg + D-biotin BP/Ph.Eur. 0.0900mg Tablet	Tablet	To help maintain a normal hair growth cycle, which helps to support normal healthy hair growth.	**Contra-indication:** Horsetail is contraindicated in patients who have edema due to impaired heart and kidney function. **PRECAUTIONS AND ADVERSE DRUG REACTIONS:** Should not be consumed by patients who are allergic to fish. **DRUG INTERACTIONS:** There are no interactions with other medications.	New	**Herbal Reference Book:** PDR for Nutritional Supplements (2nd Edition, Page: 84-89, 97-98, 155-156, 656-663) PDR for Herbal Medicine (4th Edition, Page: 409-410) **Product Reference:** Nourkrin Man- UK	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
36.	Incepta Pharmaceuticals Ltd., Herbal and Nutricare Division. Dhamrai, Dhaka.	Lactobacillus Helveticus Rosell-52 + Lactobacillus Rhamnosus Rosell-11 + Bifidobacterium Longum Rosell-175 + Saccharomyces Boulardii CNCM-1079 (1.25 x 10^9 CFU) Containing Blend INN	Sachet	Primarily used to treat diarrhea. Also effectively treats irritable bowel syndrome, lactose intolerance, Crohn's disease (inflammatory bowel disease), and bacterial overgrowth in the intestines.	**Contra-indication:** There are no known contraindications **PRECAUTIONS AND ADVERSE DRUG REACTIONS:** Before taking this medicine, you should let your doctor know if you have liver or kidney problems. Pregnant or	New	**Herbal Reference Book:** PDR for Nutritional Supplements (2nd Edition, Page: 517-522) **Product Reference:** Darolac Capsule-India	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
		2.0000gm/Sachet			breastfeeding women should also consult their doctor. • Keep out of reach of children • Keep away from eyes **DRUG INTERACTIONS:** Lactobacillus Helveticus Rosell-52+ Lactobacillus Rosell-11+ Bifidobacterium longum Rosell-175+ Saccharomyces Boulardii CNCM- 1079 Sachet 2 gm may interact with steroids (prednisone, dexamethasone, methylprednisolone), antibiotics, and immunosuppressants. Drug-Food Interaction: Avoid alcohol intake while using Lactobacillus Helveticus Rosell-52+ Lactobacillus Rosell-11+ Bifidobacterium longum Rosell-175+ Saccharomyces Boulardii CNCM- 1079 Sachet 2 gm				
37.	Incepta Pharmaceuticals Ltd., Herbal and Nutricare Division. Dhamrai, Dhaka.	D-Mannose INN/In-house 500mg + Cranberry Extract (*Vaccinium oxycoccos*) INN/In-house 200mg Tablet	Tablet	Get rid of those embarrassing urinary problems with simply Nutra D-Mannose + Cranberry dietary supplement that helps relieve from urinary pain and burning, increased frequency, and sensation of urgency.	**Contra-indication:** No information was found. **PRECAUTIONS AND ADVERSE DRUG REACTIONS:** • Read the label carefully before use • Store in a cool dry place away from direct sunlight • Keep out of reach of the children • Use under medical supervision • Do not exceed the recommended dose **DRUG INTERACTIONS:** No information was found.	New	**Herbal Reference Book:** PDR for Herbal Medicine (4th Edition, Page no: 20-21) Mosby's Drug Consult , Page no: 29 (Supplement section) Ala-Jaakkola *et al.* Nutrition Journal (2022) 21:18 **Product Reference:** D-Mannose + Cranberry- India.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
38.	Incepta Pharmaceuticals Ltd., Herbal and Nutricare Division. Dhamrai, Dhaka.	Salvia officinalis leaf extract (*Salvia officinalis*) In-house 100mg + D-Mannose In-house 140mg + Cranberry Extract (*Vaccinium oxycoccos*) In-house 72mg Tablet	Tablet	• Cleanse & protect urinary tract • Flush out toxins & bacteria. • Relieve pain & burning sensation • Reduce inflammation • Prevent UTI & recurrent UTI.	**Contra-indication:** Salvia officinalis preparations are contraindicated during pregnancy. **PRECAUTIONS AND ADVERSE DRUG**	New	**Herbal Reference Book:** PDR for Herbal Medicine (4th Edition, Page: 655) **Product Reference:** Chicnutrix Happee-Natural UTI Management- India	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					REACTIONS: No health hazards or side effects are known in con‡jvunction with the proper administration of designated therapeutic dosages. **DRUG INTERACTION:** No known interaction with other medicines.				
39.	Incepta Pharmaceuticals Ltd., Herbal and Nutricare Division. Dhamrai, Dhaka.	Tribulus Terrestris Extract (*Tribulus Terrestris*) In-house 750 mg Tablet	Tablet	Orally for the treatment of cough, headache, and mastitis. Also Supports reproductive function.	**Contra-indication:** in case of hypersensitivity or allergy to the plant. **PRECAUTIONS AND ADVERSE DRUG REACTIONS** Due to the possibility of phototoxic reactions, patients using Tribulus Terrestris should avoid excessive exposure to sunlight and use sunscreen with a high sun protection factor (>30) while taking the crude drug. **DRUG INTERACTIONS:** No information was found.	New	**Herbal Reference Book:** WHO monographs on selected medicinal plants (Volume 4, Page: 323-334) **Product Reference:** Tribulus Extract- California	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
40.	Incepta Pharmaceuticals Ltd., Herbal and Nutricare Division. Dhamrai, Dhaka.	Sennosides USP 15mg Tablet	Tablet	• Relieves occasional constipation (irregularity) • Generally, produces a bowel movement in 6-12 hours	**Contra-indication:** Hypersensitivity to senna or to any of the excipients. Concomitantly with other laxative agents. Senna Tablets should not be given to patients with symptoms of appendicitis, intestinal obstruction, stenosis, atony, inflammatory bowel disease (e.g. Crohn's disease, ulcerative colitis), abdominal pain of unknown origin, severe dehydration state with water and electrolyte depletion. Children under 12 years of age. **PRECAUTIONS AND ADVERSE DRUG REACTIONS** Patients should be advised to consult their doctor if senna is needed every day, or if	New	**Herbal Reference Book:** PDR for Herbal Medicine (4th Edition, Page: 684-687) **Product Reference:** Senokot- Barcelona.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					abdominal pain persists or worsens. Patients should be advised to consult their doctor if there are no bowel movements after three days. If senna is needed every day the cause of the constipation should be investigated. Long-term use of laxatives should be avoided. Senna should not be taken by patients suffering from fecal impaction and undiagnosed, acute, or persistent gastrointestinal complaints, e.g. abdominal pain, nausea, and vomiting unless advised by a doctor because these symptoms can be signs of potential or existing intestinal blockage (ileus). If stimulant laxatives are taken for longer than a brief period of treatment, this may lead to impaired function of the intestine and dependence on laxatives. Senna pod preparations should only be used if a therapeutic effect cannot be achieved by a change of diet or the administration of bulk-forming agents. Prolonged and excessive use may lead to diarrhea with excessive loss of water and electrolytes, particularly potassium; there is also the possibility of developing an atonic non-functioning colon. Intestinal loss of fluids may promote dehydration. Symptoms may include thirst and oliguria. Prolonged and excessive use may lead to				

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					fluid and electrolyte imbalance and hypokalaemia. Patients with kidney disorders should be aware of possible electrolyte imbalances. Laxatives do not help in long-term weight loss. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption should not take this medicine. **DRUG INTERACTIONS:** Hypokalaemia (resulting from long-term laxative abuse) potentiates the action of cardiac glycosides and interacts with antiarrhythmic medicinal products, with medicinal products, which induce reversion to sinus rhythm (e.g., quinidine) and with medicinal products inducing QT-prolongation. Concomitant use with other medicinal products inducing hypokalaemia (e.g., diuretics, adrenocorticosteroids, and licorice root) may enhance electrolyte imbalance.				
41.	Incepta Pharmaceuticals Ltd., Herbal and Nutricare Division. Dhamrai, Dhaka.	Sennosides USP 7.5 mg Tablet	Tablet	Naturally relieves the symptoms of constipation. Senna helps to gently stimulate the bowel muscles to help return the body to its natural rhythm. This usually begins to work within 8-12 hours.	**Contra-indication:** Hypersensitivity to senna or to any of the excipients. Concomitantly with other laxative agents. Senna Tablets should not be given to patients with symptoms of appendicitis, intestinal obstruction, stenosis, atony, inflammatory bowel disease (e.g., Crohn's disease, ulcerative colitis), abdominal pain of unknown origin, severe dehydration state with water and electrolyte depletion.	New	**Herbal Reference Book:** PDR for Herbal Medicine (4th Edition, Page: 684-687) **Product Reference:** Senokot- Barcelona.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					Children under 12 years of age. **<u>PRECAUTIONS AND ADVERSE DRUG REACTIONS</u>** Patients should be advised to consult their doctor if senna is needed every day, or if abdominal pain persists or worsens. Patients should be advised to consult their doctor if there are no bowel movements after three days. If senna is needed every day the cause of the constipation should be investigated. Long-term use of laxatives should be avoided. Senna should not be taken by patients suffering from fecal impaction and undiagnosed, acute or persistent gastrointestinal complaints, e.g. abdominal pain, nausea and vomiting, unless advised by a doctor, because these symptoms can be signs of potential or existing intestinal blockage (ileus). If stimulant laxatives are taken for longer than a brief period of treatment, this may lead to impaired function of the intestine and dependence on laxatives. Senna pod preparations should only be used if a therapeutic effect cannot be achieved by a change of diet or the administration of bulk-forming agents. Prolonged and excessive use may lead to diarrhea with excessive loss of water and electrolytes, particularly potassium; there is also the possibility of developing an atonic				

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					non-functioning colon. Intestinal loss of fluids may promote dehydration. Symptoms may include thirst and oliguria. Prolonged and excessive use may lead to fluid and electrolyte imbalance and hypokalaemia. Patients with kidney disorders should be aware of possible electrolyte imbalance. Laxatives do not help in long-term weight loss. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **DRUG INTERACTIONS:** Hypokalaemia (resulting from long-term laxative abuse) potentiates the action of cardiac glycosides and interacts with antiarrhythmic medicinal products, with medicinal products, which induce reversion to sinus rhythm (e.g., quinidine) and with medicinal products inducing QT-prolongation. Concomitant use with other medicinal products inducing hypokalaemia (e.g., diuretics, adrenocorticosteroids and licorice root) may enhance electrolyte imbalance				
42.	Incepta Pharmaceuticals Ltd., Herbal and Nutricare	Sennosides USP 0.15g/100ml (7.5mg/5ml) Syrup	Syrup	Sennoside is a laxative made with natural senna treated especially to yield a constant amount of active ingredient in each dose, to give	**Contra-indication:** Hypersensitivity to the active substance or to any of the excipients. Not to be used at the same time as other laxative agents. Cases of intestinal	New	**Herbal Reference Book:** PDR for Herbal Medicine (4th Edition, Page: 684-687) **Product Reference:** Senokot 7.5mg/5ml	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Division. Dhamrai, Dhaka.			predictable relief from occasional or non-persistent constipation.	obstructions and stenosis, atony, appendicitis, inflammatory colon diseases (e.g., Crohn's disease, ulcerative colitis), abdominal pain of unknown origin, severe dehydration state with water and electrolyte depletion. Children under 2 years of age. **PRECAUTIONS AND ADVERSE DRUG REACTIONS:** If there is no bowel movement after three days, a doctor should be consulted. If laxatives are needed every day or abdominal pain persists, a doctor should be consulted. If laxatives are needed every day the cause of the constipation should be investigated. Long-term use of laxatives should be avoided. Contains maltitol liquid. Patients with rare hereditary problems of fructose intolerance should not take this medicine. Each 5 ml of syrup can provide up to 3.2 kcal and this should be taken into account in patients with diabetes mellitus. Methyl and propyl parahydroxybenzoate may cause allergic reactions (possibly delayed). This medicine contains 6.9 mg of alcohol (ethanol) in each 5ml dose. The amount in each dose of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects. Do not exceed the stated dose. Patients taking cardiac glycosides, antiarrhythmic medicinal products, medicinal products inducing QT-prolongation, diuretics, adrenocorticosteroids, or licorice root have to consult a doctor before taking this product concomitantly.		Syrup- United Kingdom		

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					Like all laxatives, this product should not be taken by patients suffering from fecal impaction and undiagnosed, acute or persistent gastro-intestinal complaints, e.g., abdominal pain, nausea, and vomiting, unless advised by a doctor, because these symptoms can be signs of potential or existing intestinal blockage (ileus). If stimulant laxatives are taken for longer than a brief period of treatment, this may lead to impaired function of the intestine and dependence on laxatives. This product should only be used if a therapeutic effect cannot be achieved by a change of diet or the administration of bulk forming agents. Prolonged use may precipitate the onset of an atonic, non-functioning colon. Prolonged and excessive use may lead to fluid and electrolyte imbalance and hypokalaemia. Intestinal loss of fluids may promote dehydration. Symptoms may include thirst and oliguria. Patients with kidney disorders should be aware of possible electrolyte imbalances. When administering this product to incontinent adults, pads should be changed more frequently to prevent extended skin contact with feces. Laxatives do not help in long-term weight loss. **DRUG INTERACTIONS:** Hypokalaemia (resulting from long-term laxative abuse) potentiates the action of cardiac glycosides and interacts with antiarrhythmic medicinal products with				

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					medicinal products which induce reversion to sinus rhythm (e.g., quinidine) and with medicinal products inducing QT-prolongation. Concomitant use with other medicinal products including hypokalaemia (e.g. diuretics, adrenocorticosteroids and liquor ice root) may enhance electrolyte imbalance				
43.	Incepta Pharmaceuticals Ltd., Herbal and Nutricare Division. Dhamrai, Dhaka.	Wintergreen Oil (*Gaultheria fragrantissima*) BP/Ph. Eur. 10g + Camphor Oil (*Cinnamomum camphora*) BP/Ph. Eur. 5g + Mint Extract (*Mentha sp Satva)* BP/Ph. Eur. 22g + Oleoresin Capsicum (*Capsicum annum L*) USP 0.04g/100g Cream	Cream	Pain relief cream offers quick pain relief from knee and other joint pains & inflammation, stiffness, sprains, and sciatica.	**Contra-indication:** Camphor should not be used during pregnancy. **PRECAUTIONS AND ADVERSE DRUG REACTIONS:** Store all medicines out of sight and reach of children. **DRUG INTERACTIONS:** There are no interactions with other medications.	New	**Herbal Reference Book:** PDR for Herbal Medicine (4th Edition, Page: 143, 165-168, 580, 709, 820) **Product Reference:** Moov ortho- India.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
44.	Incepta Pharmaceuticals Ltd., Herbal and Nutricare Division. Dhamrai, Dhaka.	(Wintergreen Oil (*Gaultheria fragrantissima*) BP/Ph. Eur. 12g + Eucalyptus Oil (*Eucalyptus globulus*) USP 0.80g + Peppermint Oil (*Mentha piperita*) BP/Ph. Eur. 13g + Caraway Oil (*Trachyspermum ammi*) BP/Ph. Eur. 0.75g)/100g Ointment	Ointment	Relieves headaches & body aches. Protect against cold.	**Contra-indication:** There are no known contraindications. **PRECAUTIONS AND ADVERSE DRUG REACTIONS:** • Keep out of reach of children • Keep away from eyes. • Wash hands properly after applying. Store all medicines out of sight and reach of children. **DRUG INTERACTIONS:** There are no interactions with other medications.	New	**Herbal Reference Book:** PDR for Herbal Medicine (4th Edition, Page: 81, 148, 283, 580, 820) **Product Reference:** Zandu Balm- India.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
45.	Incepta Pharmaceuticals Ltd., Herbal and Nutricare Division. Dhamrai, Dhaka.	(Wintergreen Oil (*Gaultheria fragrantissima*) BP/Ph. Eur. 15g + Eucalyptus Oil (*Eucalyptus globulus*) USP 2g + Turpentine Oil (*Pinus palustris Mill*) BP/Ph. Eur. 3g + Mint Extract (*Mentha*	Cream	Pain reliever, Relieves headaches & body aches.	**Contra-indication:** There are no known contraindications **PRECAUTIONS AND ADVERSE DRUG REACTIONS:** • Keep out of reach of children	Not Introduce	**Herbal Reference Book:** PDR for Herbal Medicine (4th Edition, Page: 190, 283-286, 580-583, 674-677, 709, 820) **Product Reference:** Moov- India.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
		sp Satva) BP/Ph. Eur. 5g) /100g Cream			• Keep away from eyes. Store all medicines out of sight and reach of children. **DRUG INTERACTIONS:** There are no interactions with other medications.				
46.	Incepta Pharmaceuticals Ltd., Herbal and Nutricare Division. Dhamrai, Dhaka.	(Wintergreen Oil (*Gaultheria fragrantissima*) BP/Ph. Eur. 15g + Eucalyptus Oil (*Eucalyptus globulus*) USP 2g + Turpentine Oil (*Pinus palustris Mill*) BP/Ph. Eur. 3g + Cinnamon Oil (*Cinnamomum verum*) BP/Ph. Eur. 0.40g + Mint Extract (*Mentha sp Satva*) USP 5g) /100g Solution	Solution	Pain reliever, Relieves headaches & body aches.	**Contra-indication:** There are no known contraindications **PRECAUTIONS AND ADVERSE DRUG REACTIONS:** • Keep out of reach of children • Keep away from eyes. Store all medicines out of sight and reach of children. **DRUG INTERACTIONS:** There are no interactions with other medications.	Not Introduce	**Herbal Reference Book:** PDR for Herbal Medicine (4th Edition, Page: 190, 283-286, 580-583, 674-677, 709, 820) **Product Reference:** Moov- India.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
47.	Incepta Pharmaceuticals Ltd., Herbal and Nutricare Division. Dhamrai, Dhaka.	(Menthol USP 2.5g + Eucalyptus Oil (*Eucalyptus globulus*) USP 0.72g + Clove Oil (*Eugenia Caryophyllatus*) BP/Ph. Eur. 0.25g)/100g Solution	Solution	For the temporary relief of aches and pains of muscles and joints associated with backache, lumbago, strains, bruises, sprains, and arthritic or rheumatic pain, the pain of tendons and ligaments.	**Contra-indication:** Wound or skin that has been scratched **PRECAUTIONS AND ADVERSE DRUG REACTIONS:** For external use only. Do not apply to wounds or damaged skin. Do not inhale. Avoid contact with eyes and mucous membranes. Discontinue use if rash or irritation occurs. The application of external heat, such as an electric heating pad, may result in excessive skin irritation or skin burn. Do not bandage. Keep away from heat, sparks, and open flames. **DRUG INTERACTIONS:** Serious Interactions of eucalyptus include:	Not Introduce	**Herbal Reference Book:** PDR for Herbal Medicine (4th Edition, Page:195-196, 283-286, 580-583) **Product Reference:** Arthri-Plus Spray- Canada	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					• Astemizole • Cisapride • Dihydroergotamine • Dihydroergotamine Intranasal • Dronedarone • Ergotamine • Erythromycin Base • Erythromycin Ethylsuccinate • Erythromycin Lactobionate • Erythromycin Stearate • Everolimus • Lovastatin • Ranolazine • Sertindole • Silodosin • Simvastatin • Sirolimus • Terfenadine • Tolvaptan				
48.	Incepta Pharmaceuticals Ltd., Herbal and Nutricare Division. Dhamrai, Dhaka.	(Menthol USP 5g + Eucalyptus Oil (*Eucalyptus globulus*) USP 1.25g + Clove Oil (*Eugenia Caryophyllatus*) BP/Ph. Eur. 5g)/100g Cream	Cream	For the temporary relief of aches and pains of muscles and joints associated with backache, lumbago, strains, bruises, sprains, and arthritic or rheumatic pain, the pain of tendons and ligaments.	**Contra-indication:** Wound or skin that has been scratched **PRECAUTIONS AND ADVERSE DRUG REACTIONS:** For external use only. Do not apply to wounds or damaged skin. Do not inhale. Avoid contact with eyes and mucous membranes. Discontinue use if rash or irritation occurs. The application of external heat, such as an electric heating pad, may result in excessive skin irritation or skin burn. Do not bandage. Keep away from heat, sparks, and open flames. **DRUG INTERACTIONS:** Serious Interactions of eucalyptus include: • Astemizole	Not Introduce	**Herbal Reference Book:** PDR for Herbal Medicine (4th Edition, Page:195-196, 283-286, 580-583) **Product Reference:** Arthri-Plus Extra Strength Cream- Canada	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					• Cisapride • Dihydroergotamine • Dihydroergotamine Intranasal • Dronedarone • Ergotamine • Erythromycin Base • Erythromycin Ethylsuccinate • Erythromycin Lactobionate • Erythromycin Stearate • Everolimus • Lovastatin • Ranolazine • Sertindole • Silodosin • Simvastatin • Sirolimus • Terfenadine • Tolvaptan				
49.	Opsonin Herbal & Nutraceuticals Ltd. Bagura Road, Barishal.	*Boswellia Serrata* Extract (30% Boswelic acid) 100 mg + *Aegle Marmelos* dried fruit 100 mg Capsule	Capsule	➢ It helps to support lower respiratory tract health ➢ It helps to support lower respiratory tract health that includes the bronchial tubes and the lungs' health	**Contraindications:** Hypersensitivity towards the components or other closely related substances. **Do not take, if pregnant or nursing. For Children 12 or younger, it is not intended to promote healthy respiratory tract**. **Side Effects:** No side effects have been reported.	New	**Originator Product:** Alviolife Capsule, PLT Health Solution, 119 Headquarters Plaza, Morristown, N‡JV 07960 USA **Reference:** PDR for Herbal Medicine 4th Edition	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
50.	Opsonin Herbal & Nutraceuticals Ltd. Bagura Road, Barishal	Bacillus Clausii spores 2.0 billion/5.0 ml Oral Suspension	Oral Suspension	Bacillus clausii spores is used for managing the alterations of the intestinal bacterial flora. Bacillus clausii spores restores the equilibrium of the intestinal flora changed during diarrhea or in the course of thera-pies with antibiotics or chemo-therapy, contributing to correct the consequent dysvitaminosis (that is the imbalance of production and assimilation of the vitamins).	**Contraindications:** Hypersensitivity towards the components or other closely related substances. **Side Effects:** No side effects have been reported with the use of Enterogermina. However, it is important to communicate any undesirable effects.	Enterogermina Bacillus Clausii spore's sachet	**Originator Product:** Enterogermina (Bacillus Clausii spores) Oral Suspension, sanofi aventis **Reference:** MIMS Hong Kong	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
51.	Opsonin Herbal & Nutraceuticals Ltd. Bagura Road, Barishal	Onion (Allium cepa) Oil 50% + Black Seed Hair Oil 25% + Tocopherol Acetate (Vitamin E) 0.5% Oil	Oil	**» Healthy Growth & Shine**: Onion Black Seed oil enriched with essential nutrients to promote hair growth, averts hair fall, scalp infections and nourishes your follicles, increase the volume, shine and stronger hair. **» For All Hair Types:** HOLY NATURAL black seed oil use for textured, curly, or straight; thick, coarse, damaged or chemically treated hair or natural. » **Multi Benefits:** Onion Oil is Good Hair Growth promoter, improving of hair texture, Reduced Dryness of Hair, treated damaged and chemically hair, supports health hair, improving in dandruff controls, reduce hair loss, Improving hair long, lustrous, shiny hair. **» Onion Black Seed oil helps to:** Dry, damaged or chemically treated hair. Also suitable for men & women of all ages	**Contraindications:** There is no absolute contraindication. **Side Effects:** It is not a harmful side effect; onion can have a very strong smell.	New	**Originator Product:** Onion Black Seed Oil, India **Reference:** PDR for Herbal Medicine 4th Edition	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
52.	Opsonin Herbal & Nutraceuticals Ltd. Bagura Road, Barishal	Calcium (from Algas Calcareas) – 360 mg + Boron (as glycinate) 1.5 mg + Magnesium 175 mg + Vitamin C (as calcium ascorbate) 25 mg + Vitamin D3 (as Colecalciferol) – 800 IU + Vitamin K2 (as menaquinone-7) - 50 mcg Capsule	Capsule	Calcium & Vitamin-D deficiency Osteoporosis, Vitamin K deficiency Increase bone density	**Contraindications:** Hypersensitivity towards the components or other closely related substances. **Side Effects:** No side effects have been reported. However, in rare cases, mild gastric disorders may occur.	New	**Originator Product:** AlgaeCal Plus, USA **Reference:** PDR for Herbal Medicine 4th Edition	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
53.	Opsonin Herbal & Nutraceuticals Ltd. Bagura Road, Barishal	Boswellia dry extract (65% Boswellic Acid) API 40 mg + Coleus Forskohlii dry extract (Coleus Forskohlii root) 40 mg + Maca dry extract(Macamides and macaenes 0.6%) 30 mg + Saw Palmetto Extract (Serenoa repens) 80 mg + Soy concentrate IP (40% Isoflavones aglicones) 33.33 mg + Vitamin B6 (as pyridoxin HCl) 1.7 mg + Zinc gluconate 3.3 mg Tablet	Tablet	It is a supplement that prevents the excessive growth of the prostrate gland.	Contraindications: Capsules should not be taken in case of an allergic reaction to their components. The drug is contraindicated in persons who have not completely passed the period of puberty. The agent should not be taken with prostate adenoma, since there is a threat of stimulating the growth of the neoplasm. Capsules are not recommended for use in tumor, autoimmune, severe inflammatory diseases, as well as in the early period of postoperative recovery, with bleeding, diabetes mellitus, depletion of the body. **Side Effects:** No side effects have been reported.	New	**Originator Product:** Prostaffect, USA **Reference;** PDR for Herbal Medicine 4th Edition	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
54.	Opsonin Herbal & Nutraceuticals Ltd. Bagura Road, Barishal	Vitamin B6 (as pyridoxine HCl) 2.5 mg 250% + Zinc (from zinc picolinate) 7.5 mg + Copper (from copper gluconate) 0.50 mg + Saw Palmetto Berry (Providing minimum 10% liposterolic acids) 300 mg + l-glutamic acid 60 mg + glycine 10 mg + l-alanine 15 mg + Pumpkin Seed (cucurbita pepo) 25 mg + Pygeum Bark Extract (prunus africana; concentrated 30:1) (extract equivalent to 300 mg whole herb) 5 mg + Burdock	Capsule	It is intended to provide nutritive support for healthy prostate function in men. Nature's Life(R) Active Aminos is a proprietary free form blend of L-Glutamic Acid, L-Alanine and Glycine - the primary prostate proteins. Other herbs, including pumpkin seed and pygeum bark are traditionally used for men's health.	**Contraindications:** Saw palmetto is not indicated for advanced BPH with severe urinary retention. It should not be used without first ruling out prostate cancer. **Side Effects:** Rare case of GI disturbance has been reported. Ingestion on an empty stomach may cause nausea. Hypertension was reported in 3.1% taking saw palmetto extract.	New	**Originator Product:** Prostate 600+ ;Nature's Life, USA **Reference:** PDR for Herbal Medicine 4th Edition	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
		Root (arctium lappa) 2.5 mg + Cayenne Fruit (capsicum annuum var. annuum) 2.5 mg + Goldenseal Plant (hydrastis canadensis) 2.5 mg + Gravel Root (eupatorium purpureum) 2.5 mg + Juniper Berry (juniperus oxycedrus) 2.5 mg + Marshmallow Root (althaea officinalis) 2.5 mg + Parsley Leaf (petroselinum crispum) 2.5 mg + White Pond Lily Root (nymphaea odorata) 2.5 mg Capsule							
55.	Opsonin Herbal & Nutraceuticals Ltd. Bagura Road, Barishal	Docusate Sodium 50mg + Sennosides (Senna extract) 8.6 mg Tablet	Tablet	• Relieves occasional constipation (irregularity) • Generally produces a bowel movement in 6-12 hours	Contraindications: Contradindicated if patient have stomach pain, nausea, vomiting, change in bowel habit that continues over a period of 2 weeks. Do not use: If you are now taking mineral oil, unless directed by a doctor Laxative products for longer than 1 week unless directed by a doctor Side Effects: Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention. Incidence not known • Black, tarry stools • blood in the stools • nausea or vomiting • stomach pain	New	**Originator Product:** Senokot-S, Avrio Health L.P. is a wholly owned a subsidiary of Purdue Pharma L.P. USA **Book Reference:** PDR for Herbal Medicine 4th Edition, BNF (2020-2021)	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
56.	Opsonin Herbal & Nutraceuticals Ltd. Bagura Road, Barishal	Each 5 ml of syrup contains sennosides, as calcium salts, equivalent to 7.5 mg hydroxyanthracene glycosides, calculated as sennoside B.	Syrup	It is used to relieve occasional constipation in adults and children. This medicine is a laxative. It generally produces bowel movement in 6 to 12 hours.	Contraindications: Contradindicated if patient have stomach pain, nausea, vomiting, change in bowel habit that continues over a period of 2 weeks. Do not use: If you are now taking mineral oil, unless directed by a doctor Laxative products for longer than 1 week unless directed by a doctor **Side Effects:** Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention. Incidence not known • Black, tarry stools • blood in the stools • nausea or vomiting stomach pain	Senna extract Tablet	**Originator Product:** Senokot Syrup **Book Reference:** PDR for Herbal Medicine 4th Edition	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
57.	Opsonin Herbal & Nutraceuticals Ltd. Bagura Road, Barishal	[Ginger Root extract (Zingiber officinale) 5 mg + Fennel Seed extract (Foeniculum vulgare) 5 mg]/ 5 ml Syrup	Syrup	Relieves occasional discomfort from gas, colic, hiccups and general fussiness in infant.	**Contraindications:**Hypersensitivity towards the components or other closely related substances. **Side Effects:** It is probably safe, but there are safer alternatives. If you do give your infant, Chance of allergic reaction. Allergy symptoms can vary.	New	**Originator Product:** Gripe water, Mommy's Bliss (USA) **Book Reference:** PDR for Herbal Medicine 4th Edition	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
58.	Opsonin Herbal & Nutraceuticals Ltd. Bagura Road, Barishal	(Lactobacillus reuteri 1 billion CFU + Yeast Forlified Zinc sulphate 1.5 mg + Electrolytes (Sodium citrate 0.50 gm + Potassium chloride 0.20 gm + Sodium chloride 0.35 gm) + Glucose 3.75 gm)/Sachet	Sachet	Used as a dietary treatment in the treatment of electrolyte disorders and dehydration from mild to moderate diarrhea and / or vomiting, sweating from fever, or strenuous exercise etc.	**Contraindications:** The use of probiotics is not advised in patients at risk of opportunistic infections and in those with badly damaged GI tracts. **Side Effects:** No side effects have been reported.	New	**Originator Product:** BioGaia Protectis ORS, Sweden **Book Reference:** PDR for Herbal Medicine 4th Edition	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
59.	Opsonin Herbal & Nutraceuticals Ltd. Bagura Road, Barishal	Lactobacillus rhamnosus GG Ph. Gr 400 Billion + Vitamin D3 (Lichen extract) BP 160000 IU/100 ml Liquid	Liquid	Digestive Health and Healthy bone development	**Contraindications:** Hypersensitivity towards the components or other closely related substances. **Side Effects:** No side effects have been reported. However, In rare cases, mild gastric disorders may occur.	New	**Originator product:** Probiotic Drops, Mommy's Bliss (USA **Book Reference:** PDR for Herbal Medicine 4th Edition	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
60.	Opsonin Herbal & Nutraceuticals Ltd. Bagura Road, Barishal	Melatonin USP 2.5 mg/5ml Syrup	Syrup	assists with occasional sleeplessness and helps you fall asleep faster, stay asleep longer and wake up feeling rested. It is great tasting and an ideal alternative to taking pills before bed.	**Contraindications:** known hypersensitivity to a melatonin containing product. **Side Effects:** stomach discomfort, morning grogginess, feeling of a heavy head, depression, headache, lethargy, amnesia.	3mg Tablet (Pharmaceuticals)	**Originator product:** Natrol Liquid Melatonin, USA **https://www.natrol.com/products/melatonin-liquid-sleep-support-berry** **Book Reference:** PDR for Herbal Medicine 4th Edition	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
61.	Opsonin Herbal & Nutraceuticals Ltd. Bagura Road, Barishal	Saw palmetto extract 160 mg + Stinging nettle root (Urtica dioica) 120 mg dry extract Capsule	Capsule	Drugs used in benign prostatic hypertrophy.	**Contraindications:** Slight nausea, vomiting or diarrhea when taken while fasting. **Side Effects:** No side effects have been reported.	New	**Originator product:** Prostagutt forte, Germany https://www.arzneiprivat.de/product/prostagutt-duo-160-mg-120-mg-weichkapseln.931567.html?language_code=en **Book Reference:** The American Botanical Council (The ABC Clinical Guide to Herbs), Page 387	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
62.	Opsonin Herbal & Nutraceuticals Ltd. Bagura Road, Barishal	Tea Tree Medicated Gel Melaleuca Oil 200 mg/gm	Gel	It is indicated for the treatment to help reduce the occurrence of pimples, blackheads and the symptoms of acne.	**Contraindications:** Hypersensitivity towards the components or other closely related substances. **Side Effects:** No side effects have been reported.		**Originator product:** Tea Tree Medicated Gel, Thursday Plantation, Australia **https://thursdayplantation.com.au /products/tea-tree-medicated-gel-for-acne/**	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
							Book Reference: PDR for Herbal Medicine 4th Edition		
63.	Opsonin Herbal & Nutraceuticals Ltd. , Bagura Road, Barishal	5% Tea Tree oil Shampoo	Shampoo	Use in dandruff and reduce itching and flaking.	**Contraindications:** Hypersensitivity towards the components or other closely related substances. **Side Effects:** No side effects have been reported.		**Originator product:** Maple Holistics Tea Tree Shampoo, USA https://mapleholistics.com/ products/tea-tree-shampoo **Reference:** PDR for Herbal Medicine 4th Edition	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
64.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	*Epimedium Sagittatum* Extract (areal part) (10% Icariins) + Maca Root (Lepidium meyenii Root) + L-Arginine (as L-Arginine HCl) + Tongkat Ali Root Extract (Eurycoma longifolia Root Extract) + Tribulus Terrestris Fruit Extract (45% saponins) + Muira Puama Bark + Polypodium Vulgare Root + Panax Ginseng Extract (5% ginsenoside) + Black Pepper Extract (95% Piperine) Capsule *Epimedium Sagittatum* Extract (areal part) (10% Icariins) 500 mg + Maca Root (Lepidium meyenii Root) 125 mg + L-Arginine (as L-Arginine HCl)	Capsule	Boost Energy, Vitality & Performance Helps Improve Endurance & Stamina Supports Blood Flow & Circulation Enhance Libido & Sexual Health	**Contra-Indication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effects:** Well tolerated in recommended dose.	New	**Originator Product:** Horny Goat Weed Nutrachamps, USA **Book Reference:** **1.** American Botanical Council, **2.** USP DSC 2015: Volume-1, Page: 877, **3.** WHO Monographs on Selected Medicinal Plants vol.:4, P: 323, **4.** PDR for Herbal Medicine.4th Edition Page: 107, 384 & 592.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
		50 mg + Tongkat Ali Root Extract (Eurycoma longifolia Root Extract) 50 mg + Tribulus Terrestris Fruit Extract (45% saponins) 37.5 mg + Muira Puama Bark 10 mg+ Polypodium Vulgare Root 10 mg + Panax Ginseng Extract (5% ginsenoside) 10 mg+ Black Pepper Extract (95% Piperine) 2.5 mg							
65.	Square Pharmaceuticals Ltd., (Herba Division), BSCIC, Pabna	Vitamin C (Ascorbic Acid) + Vitamin E (d-alpha Tocopherol Succinate) + Folate (as Folic Acid) + Vitamin B 12 (as Methyl cobalamin) + Zinc (as Zinc Citrate) + Copper (as Copper Citrate) + Bilberry, European Fruit Extract 4:1 + Grape seed extract (95% Proanthocyanadins) + Lutein (from Marigold Flower Extract) + Zeaxanthin (from Marigold Flower Extract), Black Pepper extract (95% Piperine) Capsule Vitamin C (Ascorbic Acid) 125 mg + Vitamin E (d-alpha Tocopherol Succinate) 10 mg + Folate (as Folic Acid) 200 mcg+ Vitamin B 12 (as Methylcobalamin) 50 mcg+ Zinc (as Zinc Citrate) 12.5 mg + Copper (as Copper Citrate) 1 mg + Bilberry (European Fruit Extract 4:1) 25 mg+ Grape seed extract (95%	Capsule	Maintain Healthy Vision* Reduce Eye Strain* Improve Visual Processing Speed*	**Contra-indication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effects:** Well tolerated in recommended dose.	New	**Originator Product:** Physician's Choice Eye Health Capsule (Physician's Choice, USA) https://physicianschoice.com/products/eye-health-support **Book Reference:** **1.** PDR for Herbal Medicine, P: 78, 107, 405, 962, 980, 1008, 1013, 1021, **2.** USP Dietary Supplements Compendium 2015. P: 201,1038,1278	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
		Proanthocyanadins) 12.5 mg+ Lutein (from Marigold Flower Extract) 10 mg + Zeaxanthin (from Marigold Flower Extract) 2 mg, Black Pepper extract (95% Piperine) 2.5 mg							
66.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Vitamin C (Ascorbic Acid) + Vitamin E (d-alpha Tocopherol Succinate) + Zinc (as Zinc Citrate) + Copper (as Copper Citrate) + Zeaxanthin (from Marigold Flower Extract) + + Lutein (from Marigold Flower Extract) + Quercetin + Bilberry (Vaccinium myrtillus) Fruit extract + Green Tea (camellia sinensis) Leaf Extract Capsule Vitamin C (Ascorbic Acid) 250 mg + Vitamin E (d-alpha Tocopherol Succinate) 134 mg + Zinc (as Zinc Citrate) 12.5 mg + Copper (as Copper Citrate) 0.5 mg + Zeaxanthin (from Marigold Flower Extract) 2.5 mg (Meso zeaxanthin 0.625 mg) + Lutein (from Marigold Flower Extract) 12.5 mg + Quercetin 7mg + Bilberry (Vaccinium myrtillus) Fruit extract 15 mg + Green Tea (camellia sinensis) Leaf Extract 15 mg	Capsule	Supports Macular Health Helps reduce eye fatigue Improves fine details vision Preserves retinal health	**Contra-indication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effects:** Well tolerated in recommended dose.	New	**Originator Product:** Macutene Protect (Eye check, USA) **https://eyecheck.com/products/macutene%C2%AE-protect** **Book Reference:** 1. PDR for Herbal Medicines page no. 78, 414, 980, 1001, 1008, 1013, 1021, 2. USP Dietary Supplements Compendium, Vol-1, Page no. 201, 1038	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
67.	Square Pharmaceuticals Ltd., (Herba Division), BSCIC, Pabna	Vitamin D (as Cholecalciferol D-3) + Calcium (as Coral Calcium) + Magnesium (as Magnesium Oxide) Capsule Vitamin D (as Cholecalciferol D-3) 100 IU + Calcium (as Coral Calcium) 200 mg + Magnesium (as Magnesium Oxide) 100 mg	Capsule	Osteoporosis, Osteomalacia, Rickets, Tetany, Parathyroid disease etc.	**Contra-indication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effects:** Well tolerated in recommended dose.	New	**Originator Product:** GNC Coral Calcium https://www.gnc.com/calcium/553723.html **Book Reference:** USP Dietary Supplements Compendium 2015. Voulme-1, Page: 943, 1020, 1252	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
68.	Square Pharmaceuticals Ltd., (Herba Division), BSCIC, Pabna	Ubidecarenone (Coenzyme Q10) 50mg/5ml Syrup Ubidecarenone (Coenzyme Q10) 50mg/5ml	Syrup	Supports Heart and Vascular Health Beneficial for Statin users Essential for cellular Energy Production Powerful Antioxidant	**Contra-indication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effects:** Well tolerated in recommended dose.	New	**Originator Product:** Qunol Liquid CoQ10, USA https://www.qunol.com/products /qunol-liquid-coq10 **Book Reference:** PDR for Herbal Medicine, 4th Edition, Page: 958	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
69.	Square Pharmaceuticals Ltd., (Herba Division), BSCIC, Pabna	Vitamin D3 (Cholecalciferol) + Vitamin K2 (Menaquinone-7) SOFTGEL Capsule Vitamin D3 (Cholecalciferol) 4000 IU + Vitamin K2 (Menaquinone-7) 100 mcg	Soft gel Capsule	Maintenance of normal bones and teeth Helps in absorption of Calcium and Phosphorus Ensures healthy immune system	**Contra-indication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effects:** Well tolerated in recommended dose.	New	**Originator Product:** Howard & James (D3 & K2) (Howard & James, UK) **Book Reference:** BNF 84, P: 1179, USP, Dietary Supplement Compendium, Volume-2, Page: 154.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
70.	Square Pharmaceuticals Ltd., (Herba Division), BSCIC, Pabna	Dextrose (Monohydrate) 15gm/ Powder in Sachet	Powder in Sachet	Restores blood glucose in Hypoglycemia.	**Contra-indication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effects:** Well tolerated in recommended dose. In rare cases stomach upset, fever, confusion, a light-headed feeling may occur.	New	**Originator Product:** Advocate Glucose SOS (SOS Life Sciences, USA) https://glucosesos.com/glucose-sos-kiwi-strawberry/ **Book Reference:** BNF 84, Page: 1132	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
71.	Square Pharmaceuticals Ltd., (Herba Division), BSCIC, Pabna	Alpha Lipoic Acid 300mg Capsule	Capsule	Improves memory and cognitive function Ease symptoms of nerve damage and lower the risk of Diabetic Retinopathy Reduces insulin resistance and improves blood sugar control	**Contra-indication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effects:** Well tolerated in recommended dose. In rare cases stomach upset, fever, confusion, a light-headed feeling may occur.	New	**Originator Product:** Nutricost Alpha Lipoic Acid (Nutricost, USA) **https://www.amazon.com/Nutricost-Alpha-Lipoic-Acid-Capsules/dp/B01CKLMWYS?th=1** **Book Reference:** USP Dietary Supplements Compendium, Volume: 1, Page: 1233	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
72.	**Renata Limited (Herbal Division)** Kashor, Bhaluka, Mymensingh.	Echinacea Extract 10mg/1.5gm Powder Alu-Alu Sachet	Sachet	It is used to treat throat pain. It is useful in strengthening the immune system. It protects the mouth from bacterial and viral infections. It helps in maintaining oral hygiene and keeps bad breath at bay.	Contraindication: Nill Side-effects: Nill	New	**Book Reference:** ABC (The American Botanical Council) Guide of Herbs Page: 85	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
73.	**Renata Limited (Herbal Division)** Kashor, Bhaluka, Mymensingh	Andrographis extract USP 100mg and Siberian Ginseng extract 60mg Alu-Alu blister Capsule	Capsule	This medication is used as antiviral, antibacterial immunostimulant agent.	Contraindication: Nil Side-effects: Nil	New	**Book Reference:** USP DSC; Page: 874, PDR for herbal medicines. Page: 751	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
74.	Radiant Nutraceuticals Limited (Herbal Division)	Astragalus (Astragalus membranaceus) root extract 111.5 mg + Red sage (Salvia miltiorrhiza) root extract 22.3 mg + Milk peony (Paeonia lactiflora) root extract 22.3 mg + Sichuan lovage (Ligusticum chuanxiong) root extract 22.3 mg + Dong quai (Angelica sinensis) root extract 22.3 mg + Safflower (Carthamus tinctorius) flower extract 22.3 mg + Peach (Prunus persica) seed extract 22.3 mg + Thinleaf milkwort (Polygala tenuifolia) root extract 22.3 mg + Acori Tatarinowii (Acorus tatarinowii) root extract 22.3 mg	Capsule	• Ischemic stroke • Cranial brain in‡jvuries • Post-traumatic brain in‡jvury • Haemorrhagic Stroke • Spinal cord in‡jvuries • Cerebral ischemia • Post-stroke recovery • Dementia and cognitive impairment Alzheimer's disease	**Contraindications:** Contraindicated in patients with known hypersensitivity to Astragalus (Astragalus membranaceus), Red sage (Salvia miltiorrhiza), Milk peony (Paeonia lactiflora), Sichuan lovage (Ligusticum chuanxiong), Dong quai (Angelica sinensis), Safflower (Carthamus tinctorius), Peach (Prunus persica), Thin leaf milkwort (Polygala tenuifolia), Acori Tatarinowii (Acorus tatarinowii). **Side Effects/Toxicity:** The safety profile of this combination is well established. Clinical trials reported only rare cases of nausea, minor headaches, increased thirst, dry mouth and vomiting. In such cases, it is advised to halving the dose for a few days and progressively increase it. Published clinical trials have confirmed that this combination has no effect on blood thinning, hepatic functions, renal functions, blood pressure, cardiovascular parameters and other biological parameters.	New	**Product Reference:** NeuroAiD, Singapore **Book Reference:** Astragalus: PDR for Herbal Medicine, Fourth Edition, Page No.-54 Red sage: PDR for Herbal Medicine, Fourth Edition, Page No.-636 Milk peony: PDR for Herbal Medicine, Fourth Edition, Page No.-295 Sichuan lovage The ABC Clinical Guide to Herbs Page Dong quai: Mosby's Drug Consult, Page No.-36 Safflower: PDR for Herbal Medicine, Fourth Edition, Page No.-652 Long Peach wood: PDR for Herbal Medicine, Fourth Edition, Page No.-480 Thin leaf Milkwort: PDR for Herbal Medicine, Fourth Edition, Page No.-85 Acori Tatarinowii: The ABC Clinical Guide to Herbs Page No:-13	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
75.	Radiant Nutraceuticals Limited (Herbal Division)	Saccharomyces boulardii USP 125mg eqv. to 2.5 billion + Sucrose USP 2.7 gm + Sodium Chloride USP 0.52 gm + Tri-sodium citrate dehydrate USP 0.57 gm + Potassium chloride USP 0.3 gm + Zinc from Yeast (Saccharomyces cerevisiae) USP 4 mg	Sachet	• Acute infectious diarrhea of infants, children and adults • Antibiotic associated diarrhea • Persistent diarrhea • Irritable bowel syndrome • Traveler's diarrhea • Clostridium difficile colitis • H. pylori eradication therapy side-effects • Relapses in Crohn's disease • Enteral nutrition-related diarrhea • Dyspeptic complaints • Giardiasis • Loss of appetite • Lactose intolerance • Eczema, furuncles, acne	**Contraindications:** Contraindicated to the patient with known hypersensitivity to Saccharomyces boulardii, Glucose anhydrous, Sodium Chloride, Tri-sodium citrate dehydrate, Potassium chloride Yeast Zinc. Contraindications: Saccharomyces boulardii is contraindicated for use in patients with a central venous catheter placement. **Side Effects/Toxicity:** The intake of large quantities may cause gastritis. Allergic intolerance reactions are possible (itching, urticaria, exanthema, Quinck's disease). Migraine headaches can be triggered in susceptible patients.	Not Introduced	**Product Reference**: Prohydrate-Z, India **Book Reference:** Saccharomyces: PDR for Herbal Medicine, Fourth Edition, Page No.-118 The Complete German Commission E Monograph Sucrose: USP Dietary Supplements Compendium, Page No.- 902 Sodium Chloride: USP Dietary Supplements Compendium, Page No.- Potassium chloride: USP Dietary Supplements Compendium, Page No.- 1562 Sodium citrate: USP Dietary Supplements Compendium, Page No.- 3193 Zinc from Yeast (Saccharomyces cerevisiae): PDR for Herbal Medicine, Fourth Edition, Page No.-1021 USP Dietary Supplements Compendium, Page No.- 4692	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
76.	Radiant Nutraceuticals Limited (Herbal Division)	Undenatured Collagen II 40 mg+ Sodium Hyaluronate 50 mg + Boswellia serrata extract 100 mg	Capsule	• Osteoporosis • Osteoarthritis • Osteomalacia • Osteopenia • Rheumatoid arthritis • Bone and Joint heath	**Contraindications:** Contraindicated in patient with known hypersensitivity to Undenatured collagen II, Glucosamine, Hyaluronic acid & Boswellia serrata extract **Side Effects/Toxicity**: Generally, well tolerated in recommended dose. Occasionally constipation or stomach upset may occur.	New	**Product Reference:** Vylex, Malaysia **Book Reference:** Undenatured Collagen II: PDR for Herbal Medicine, Fourth Edition, Page No.-129 Hyaluronic acid: The Korean Pharmacopoeia, 10th Edition Page No:-1092 Boswellia serrata: WHO monographs on selected medicinal plants Volume 04 Page No.-48	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
77.	Radiant Nutraceuticals Limited (Herbal Division)	Tart cherry (Prunus cerasus) extract USP 500 mg + Turmeric (Curcuma longa) extract as Curcuminoids USP 100 mg + Boswellia serrata extract USP 100 mg	Tablet	• Gout • Chronic hyperuricemia • Arthritis • Exercise induced pain, muscle damage • Joint Inflammation and pain • Muscle soreness	**Contraindications:** Contraindicated to the patient with known hypersensitivity to Tart cherry, turmeric and boswellic acid. **Side Effects/Toxicity:** Generally, well tolerated in recommended dose.	New	**Product Reference:** Tart cherry Complete, USA **Book Reference:** Tart cherry: The ABC Clinical Guide to Herbs Page No.-6 Turmeric: Mosby's Drug Consult, Page No.-111 PDR for Herbal Medicine, Fourth Edition, Page No.-775 Boswellia serrata: WHO monographs on selected medicinal plants Volume 04, Page: 48	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
78.	Radiant Nutraceuticals Limited (Herbal Division)	Microencapsulated Iron 30 mg + Vitamin C from Corn Extract 60 mg + Folate from Yeast (Saccharomyces cerevisiae) 400 mcg + Vitamin B_{12} (Cobalamin) from Yeast (Saccharomyces cerevisiae) 2.5 mcg	Sachet	• Anemia • Boost immune system • Vitamin deficiency • Reproductive health • Boosts cognitive performance • Iron, folic acid, vitamin B-12 & vitamin-C deficiency, especially for Pregnant woman, Lactating mother, Woman with heavy menstrual bleeding, Geriatric patient • Generalized weakness due to vitamin and mineral deficiency	**Contraindications:** Contraindicated to the patient with known hypersensitivity to any of the elements in the combination or those with iron overloaded. **Side Effects/Toxicity:** Gastrointestinal irritations such as nausea, anorexia, vomiting, discomfort, constipation & diarrhea may occur.	New	**Product Reference:** Ferrolip Forte, Italy **Book Reference:** Microencapsulated Iron: PDR for Herbal Medicine, Fourth Edition, Page: 974 Vitamin C from Corn Extract PDR for Herbal Medicine, Fourth Edition, Page 1008 USP –Dietary Supplement Compendium Page:383 Folate from Yeast (Saccharomyces cerevisiae): PDR for Herbal Medicine, Fourth Edition, Page: 962 USP Dietary Supplements Compendium, Page: 2026 Vitamin B_{12} (Cobalamin) from Yeast (Saccharomyces cerevisiae) USP Dietary Supplements Compendium, Page: 137 Mosby's Drug Consult, Page: 116	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
79.	Radiant Nutraceuticals Limited (Herbal Division)	L-Glutathione USP 500mg	Tablet	• Skin health & beauty • Wrinkle associated with aging • Improve skin elasticity • Improve skin lightening • Promotes healthy liver function • Promotes a healthy immune system	**Contraindication:** Contraindicated to the patient with known hypersensitivity to L-Glutathione **Side Effects/Toxicity:** Well tolerated in recommended dose. Occasionally it can cause nausea, vomiting, and diarrhea or constipation. Rarely, it can cause rashes, fever, headache, drowsiness, low blood pressure.	New	**Product Reference:** Maxiliv, India **Book References:** L-Glutathione: USP –Dietary Supplement Compendium Page:4998	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
80.	Radiant Nutraceuticals Limited (Herbal Division)	Astaxanthin from Microalgae Haematococcus pluvialis extract 4 mg + d- alpha tocopherol (Vitamin E) 10 mg + Vitamin C from Corn Extract 60 mg	Capsule	• Antioxidant • Eye health • Strength and endurance & immune system • Oxidative stress • Internal beauty and skin improvement • Cardiovascular health • Brain and central nervous system health	**Contraindications:** Contraindicated to the patient with known hypersensitivity to Astaxanthin, Vitamin E & Vitamin C **Side Effects/Toxicity:** No reports have been found regarding this combination.	New	**Product Reference:** Astaxin, USA **Book Reference:** Astaxanthin from Microalgae Haematococcus pluvialis extract 4 mg: USP –Dietary Supplement Compendium Page:4735 Vitamin E: Mosby's Drug Consult, Page No.-121 PDR for Herbal Medicine, Fourth Edition, Page 1013 Vitamin C PDR for Herbal Medicine, Fourth Edition, Page 1008 USP –Dietary Supplement Compendium Page:383	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
81.	Radiant Nutraceuticals Limited (Herbal Division)	Carob (Ceratonia siliqua) extract (as d-chiro-inositol) 50 mg + Inositol from corn Phytin`s extract (as Myo-inositol) 2000 mg + Folic acid from Yeast (Saccharomyces cerevisiae)200 mcg	Sachet	• Polycystic ovary syndrome (PCOS) • Anovulation • Menstrual disorders such as amenorrhea • Hyperandrogenism complaints such as hirsutism, alopecia, acanthosis nigricans, acne • Ovarian hyperthecosis	**Contraindications:** Contraindicated to the patient with known hypersensitivity to Myo-inositol, D-chiro-inositol, Yeast (Saccharomyces cerevisiae) enriched Folate. **Side Effects/Toxicity:** Well tolerated in recommended dose.	New	**Product Reference:** Ovofolic, Canada **Book Reference:** Carob extract (as d-chiro-inositol): PDR for Herbal Medicine, Fourth Edition, Page 151 Inositol (as Myo-inositol): USP –Dietary Supplement Compendium Page: 2460 Yeast enriched Folate: PDR for Herbal Medicine, Fourth Edition, Page 962 USP –Dietary Supplement Compendium Page: 2026	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
82.	Radiant Nutraceuticals Limited (Herbal Division)	Chondroitin Sulfate 200 mg + Collagen type I 40 mg + L-arginine 500 mg + Sodium hyaluronate 30 mg + Vitamin C from Corn extract (Zea mays) 12.5 mg	Tablet	• Tendopathies • Tendonitis • Frozen shoulder • Plantar fasciitis • Achilles tendinopathy • Joint discomfort & stiffness	**Contraindications:** Contraindicated in patient with known hypersensitivity to Chondroitin Sulfate, Collagen type I, L-arginine, Sodium hyaluronate and Vitamin C **Side Effects/Toxicity:** Generally well-tolerated in the recommended dose.	New	**Product Reference**: Tendofit Forte, India **Book Reference:** Chondroitin Sulfate: Mosby's Drug Consult, Page No.-23 PDR for Herbal Medicine, Fourth Edition, Page 955 Collagen type I: PDR for Herbal Medicine, Fourth Edition, Page: 129 Mosby's Drug Consult, Page: 101	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
							L-arginine: USP –Dietary Supplement Compendium Page: 449 Hyaluronic acid: The Korean Pharmacopoeia 10th Edition Page 1092 Corn Extract (as Vitamin C) PDR for Herbal Medicine, Fourth Edition, Page 1008 USP –Dietary Supplement Compendium Page:383		
83.	Radiant Nutraceuticals Limited (Herbal Division)	Undenatured Collagen II 40 mg + Boswellia serrata extract 100 mg + Hyaluronic acid 50 mg + Vitamin C from Corn extract (Zea mays) 60 mg	Capsule	• Osteoporosis • Osteoarthritis • Osteomalacia • Osteopenia • Rheumatoid arthritis • Bone and Joint heath	**Contraindications:** Contraindicated in patient with known hypersensitivity to Undenatured collagen II, Glucosamine, Hyaluronic acid & Boswellia serrata extract. **Side Effects/Toxicity:** Generally, well tolerated in recommended dose. Occasionally constipation or stomach upset may occur.	New	**Product Reference:** Wonflex, India **Book Reference:** Undenatured Collagen II: PDR for Herbal Medicine, Fourth Edition, Page No.-129 Boswellia serrata: WHO monographs on selected medicinal plants Volume 04 Page No.-48 Hyaluronic acid: The Korean Pharmacopoeia 10th Edition Page 1092 Corn Extract (as Vitamin C) PDR for Herbal Medicine, Fourth Edition, Page 1008 USP –Dietary Supplement	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
							Compendium Page:383		
84.	Radiant Nutraceuticals Limited (Herbal Division)	Menaquinone-7 (as Vitamin K2) 45 mcg + Calcium carbonate from Red Algae (Rhodophyta) Extract 500 mg + Cholecalciferol from Lichen (Cryptothele) Extract 1000IU	Tablet	• Osteoporosis • Prevention of Vitamin K2, Calcium and Vitamin D deficiency • Heart health • Dental health	**Contraindications:** Contraindicated in patient with known hypersensitivity to Menaquinone-7 (Vitamin K2) or Red Algae Extract (Calcium) or Lichen Extract (Vitamin D3). **Side Effects/Toxicity:** Generally, well tolerated in recommended dose. Occasionally constipation or stomach upset may occur.	New	**Product Reference:** Menacal-7, USA **Book Reference:** Menaquinone-7: USP –Dietary Supplement Compendium, Page: 7096 Red Algae Extract (as Calcium carbonate): PDR for Herbal Medicine, Fourth Edition, Page: 948 USP –Dietary Supplement Compendium, Page: 1591 Cholecalciferol: Mosby's Drug Consult, Page: 118 USP –Dietary Supplement Compendium, Page: 1742	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
85.	Radiant Nutraceuticals Limited (Herbal Division)	Mucopolysaccharides (Chondroitin sulfate) 220 mg + Collagen Type I 40 mg + Vitamin C from Corn extract (Zea mays) 30 mg	Capsule	• Tendopathies • Tendonitis • Frozen shoulder • Plantar fasciitis • Achilles tendinopathy • Joint discomfort & stiffness	**Contraindications**: Contraindicated in patient with known hypersensitivity to Chondroitin Sulfate, Collagen type I, Vitamin C **Side Effects/Toxicity:** Generally well-tolerated in the recommended dose.	New	**Product Reference:** Tendoactive, Spain **Book Reference:** Chondroitin Sulfate: Mosby's Drug Consult, Page No.-23 PDR for Herbal Medicine, Fourth Edition, Page 955 Collagen type I: PDR for Herbal Medicine, Fourth Edition, Page: 129 Mosby's Drug Consult, Page: 101 Corn Extract (as Vitamin C) PDR for Herbal Medicine, Fourth Edition, Page: 1008 USP –Dietary Supplement Compendium, Page:383	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
86.	Radiant Nutraceuticals Limited (Herbal Division)	Ubidecarenone (Coenzyme Q10) USP 100mg + L-Carnitine USP 750 mg + Vitamin C from Amla Extract (Phyllanthus emblica) USP 20 mg + D-alpha Tocopherol USP 5mg + Zinc from Yeast (Saccharomyces cerevisiae) USP 5mg + Folic acid from Yeast (Saccharomyces cerevisiae) USP 50mcg + Selenium from Yeast (Saccharomyces cerevisiae)	Tablet	• Female infertility • Male Infertility	**Contraindications:** Contraindicated in patient with known hypersensitivity to ubidecarenone, l- carnitine, vitamin c, d-alpha tocopherol, zinc, folic acid, selenium, vitamin b12 **Side Effects/Toxicity:** Ubidecarenone seems to be safe and relatively well tolerated in recommended dose. Occasionally gastrointestinal discomfort, dizziness and skin rash may occur but these tend to with higher doses.	New	**Product Reference:** Fertifoid, India **Book Reference:** Ubidecarenone: PDR for Herbal Medicine, Fourth Edition, Page: 958 USP –Dietary Supplement Compendium, Page: 86 Mosby's Drug Consult,	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
		USP 20 mcg + Vitamin B12 (Cobalamin) from yeast (Saccharomyces cerevisiae) USP 0.5 mcg					Page: 25 L- Carnitine: USP –Dietary Supplement Compendium, Page: 71 Corn Extract (as Vitamin C): PDR for Herbal Medicine, Fourth Edition, Page: 1008 USP –Dietary Supplement Compendium, Page: 383 D-alpha Tocopherol: PDR for Herbal Medicine, Fourth Edition, Page: 1013 Mosby's Drug Consult, Page: 121 Yeast enriched Zinc: PDR for Herbal Medicine, Fourth Edition, Page: 1021 USP –Dietary Supplement Compendium, Page: 3501 Yeast enriched Folate: PDR for Herbal Medicine, Fourth Edition, Page: 962 USP –Dietary Supplement Compendium, Page: 2026 Selenium: Mosby's Drug Consult, Page: 99		

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
							USP –Dietary Supplement Compendium, Page: 3171 Yeast enriched Cobalamin: Mosby's Drug Consult, Page: 116		
87.	Radiant Nutraceuticals Limited (Herbal Division)	Biotin USP 5000mcg + D-Alpha Tocopherol 200IU + Vitamin C from Amla Extract (Phyllanthus emblica) 90mg	Tablet	• Hair loss • Brittle nails	**Contraindications:** Contraindicated to the patient with known hypersensitivity to Biotin, D-Alpha Tocopherol and Ascorbic acid. **Side Effects/Toxicity:** Generally well tolerated in recommended dose. Occasionally stomach upset may occur.	New	**Product Reference:** Hair Nirvana, USA **Book Reference:** Biotin: USP –Dietary Supplement Compendium, Page: 1530 d-alpha tocopherol: Mosby's Drug Consult, Page No.-121 PDR for Herbal Medicine, Fourth Edition, Page 1013 Corn Extract (as Vitamin C): PDR for Herbal Medicine, Fourth Edition, Page: 1008 USP –Dietary Supplement Compendium, Page: 383	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
88.	Radiant Nutraceuticals Limited (Herbal Division)	Tribulus terrestris Extract (saponins 60%) 66.67 mg + Panax ginseng extract (Ginsenosides 12%) 30 mg + N-Acetylcysteine 180 mg + L-Glutathione reduced 30 mg + L-Arginine 80 mg + L-Carnitine 30 mg + Ubidecarenone (Coenzyme Q10) 10 mg + Vitamin C from Amla Extract (Phyllanthus emblica)120 mg + D-alpha Tocopherol 24 mg + Zinc from Yeast (Saccharomyces cerevisiae) 10 mg + Selenium from Yeast (Saccharomyces cerevisiae) 20 mcg 55 mcg	Tablet	• Oligozoospermia • Teratozoospemia • Asthenozoospermia • Erectile dysfunction	**Contraindications**: Contraindicated to the patient with known hypersensitivity to those all ingredients. **Side Effects/Toxicity:** Well tolerated in recommended dose.	New	**Product Reference:** Semyn 100, Italy **Book Reference:** Tribulus terrestris: WHO monographs on selected medicinal plants Volume 04, Page: 323 Panax ginseng: The ABC Clinical Guide to Herbs Page No.-214 PDR for Herbal Medicine, Fourth Edition, Page: 346 N-Acetylcysteine: USP –Dietary Supplement Compendium Page: 726 L-Glutathione: USP –Dietary Supplement Compendium Page: 4998 L-Arginine: USP –Dietary Supplement Compendium Page: 449 L-Carnitine: USP –Dietary Supplement Compendium Page: 1401 Ubidecarenone: PDR for Herbal Medicine, Fourth Edition, Page: 958 Mosby's Drug Consult, Page: 25	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
							USP –Dietary Supplement Compendium, Page: 86 Corn Extract (as Vitamin C): PDR for Herbal Medicine, Fourth Edition, Page 1008 USP –Dietary Supplement Compendium Page:383 d-alpha tocopherol: Mosby's Drug Consult, Page No.-121 PDR for Herbal Medicine, Fourth Edition, Page 1013 Yeast enriched Zinc: PDR for Herbal Medicine, Fourth Edition, Page No.-1021 USP Dietary Supplements Compendium, Page No.- 4692 Selenium: Mosby's Drug Consult, Page: 99 USP –Dietary Supplement Compendium, Page: 3171		

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
89.	Radiant Nutraceuticals Limited (Herbal Division)	Biotin 5000 mcg + Alpha Lipoic Acid 50 mg + Keratin 10 mg	Tablet	Hair loss Brittle nails	Contraindications: Contraindicated to the patient with known hypersensitivity to Biotin, D-Alpha Tocopherol and Ascorbic acid. Side Effects/Toxicity: Generally, well tolerated in recommended dose. Occasionally stomach upset may occur.	New	**Product Reference:** Natures Truth Biotin Keratin, USA **Book Reference:** Biotin: USP –Dietary Supplement Compendium, Page: 1530 Alpha Lipoic Acid: PDR for Herbal Medicine, Fourth Edition, Page: 935	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
90.	Radiant Nutraceuticals Limited (Herbal Division)	Adhatoda vasica powder extract 13.60 gm + Piper longum powder extract 2.80 gm + Ocimum tenuiflorum powder extract 1.00 gm + Glycyrrhiza glabra powder extract 0.136 gm + Zingiber officinale powder extract 0.136 gm + Piper nigrum powder extract 0.136 gm + Terminalia chebula powder extract 0.136 gm + Syzygium aromaticum powder extract 0.136 gm + Cinnamomum zeylanicum powder extract 0.136 gm + Cinnamomum tamala powder extract 0.136 gm + Pistacia integerrima powder extract 0.136 gm + Myrica nagi powder extract 0.136 gm + Eletteria cardamomum powder extract 0.136 gm + Saussurea lappa powder extract 0.136 gm /100 ml	Syrup	• Dry imitable cough • Liquefies phlegm • Asthma, smoker's induced cough • Throat hoarseness	**Contraindications:** Contraindicated to the patient with known hypersensitive to Adhatoda vasica powder extract ,Piper longum powder extract , Ocimum tenuiflorum powder extract, Glycyrrhiza glabra powder extract, Zingiber officinale powder extract, Piper nigrum powder extract, Terminalia chebula powder extract, Syzygium aromaticum powder extract, Cinnamomum zeylanicum powder extract , Cinnamomum tamala powder extract , Pistacia integerrima powder extract, Myrica nagi powder extract , Eletteria cardamomum powder extract, Saussurea lappa powder extract . **Side Effects/Toxicity:** Generally, well tolerated & well tolerated. In the recommended doses side effect are rare.	New	**Product Reference:** Acme's Basok, Bangladesh **Reference Book:** Adhatoda: PDR for Herbal Medicine, Fourth Edition, Page 402 Piper longum: Indian herbal pharmacopoeia page 44 Ocimum tenuiflorum: The ABC Clinical Guide to Herbs Page No.-98 Glycyrrhiza glabra : The Complete German Commission E Monograph Zingiber officinale: PDR for Herbal Medicine, Fourth Edition, Page 339 Piper nigrum: PDR for Herbal Medicine, Fourth Edition, Page 103	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
							Terminalia chebula : PDR for Herbal Medicine, Fourth Edition, Page 772 Syzygium aromaticum: PDR for Herbal Medicine, Fourth Edition, Page 195 Cinnamomum zeylanicum : The ABC Clinical Guide to Herbs Page No.-95 Cinnamomum tamala: The ABC Clinical Guide to Herbs Page No.-95 Pistacia integerrima: PDR for Herbal Medicine, Fourth Edition, Page 508 Myrica nagi: PDR for Herbal Medicine, Fourth Edition, Page 705 Eletteria cardamomum: PDR for Herbal Medicine, Fourth Edition, Page 149 Saussurea lappa : PDR for Herbal Medicine, Fourth Edition, Page 1221		

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
91.	Radiant Nutraceuticals Limited (Herbal Division)	Cranberry extract (Vaccinium macrocarpon) 400mg + D-Mannose 1000 mg	Tablet	• Urinary tract infection (UTI) • Prevent Liver problems • Scurvy and in the preparation of wound dressings • Antioxidant activity	Contraindications: Contraindicated to the patient with known hypersensitivity to Cranberry & D-Mannose Side Effects/Toxicity: Well tolerated in recommended dose. Occasionally diarrhea or mild gastrointestinal upset may occur at high dose.	New	**Product Reference:** CranActin, USA **Book References:** Cranberry: The ABC clinical guide to herbs; p-76 D-mannose: USP	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
92.	Radiant Nutraceuticals Limited (Herbal Division)	Probiotic Blend/Powder of *Bifidobacterium animalis subsp. lactis* 100mg (eqv. to 1 billion viable strain)	Sachet	The Bifidobacterium, BB-12 strain has been associated with several health benefits- In babies and children: Digestive health: Associated with softer and more frequent bowel movements, and shorter and fewer episodes of loose stools and overall regularity. Excessive crying and fussing: Associated with significantly less excessive crying and fussing in babies. Daily sleep: Associated with additional daily sleep in babies with excessive crying and fussing and an improvement in the health-related quality of life of their parents/caregivers Respiratory health: Associated with fewer episodes of respiratory discomfort. Immune health: Associated with better immune system support. Skin health: Associated with fewer instances of red, dry, and scaly skin in babies.	Contraindications: A person who has hypersensitivity towards the components of the medicine or other closely related substances. Side Effects/Toxicity: B. lactis is likely safe. It's been used safely alone and together with other probiotics for up to one month. Some people might experience gas and bloating from probiotics, but B. lactis seems to be well-tolerated.	New	**Product Reference:** Acidolac Baby Poland, PROBX Denmark, Viva Nutriton USA, BioDrop Denmark, OptiBac Probiotics, USA **Book Reference:** PDR for Herbal Medicine, Fourth Edition, Page-997, 999	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
				In adults: Oral health: Associated with lower salivary levels of specific bacteria that contribute to poor oral health. Frequency of bowel movements: Associated with more regular bowel movements in adults and the elderly. Immune health: Associated with benefits for immune system function. Cholesterol levels: Associated with supporting healthy levels of cholesterol.					
93.	Drug International Ltd (Herbal Division) Monipur Bazar, Bokran, Gazipur	Probiotic Blended Powder Ph. Grade 5.0 gm (Contains Bifidobacteriumlongum 5 billion cfu (20 mg)/per sachet.	Sachet	It is used in the control of symptoms related to irritable bowel syndrome with a component of functional constipation, diarrhea or mixed as well as to reconstitute the intestinal flora in cases of antibiotic therapy, mild diarrhea or constipation. It has been especially helpful in improving constipation and flatulence in individuals with irritable bowel. It has also been used to combat constipation that accompanies weight loss diets.	**Contraindication:** It is contraindicated in those patients who are hypersensitive to any component of this product. **Side effects**: There is no data available.	New	**Book Reference:** a) PDR for Nutritional Supplements (2nd Edition), Page no. 237,328,517,518 b)https://www.1mg.com/otc/florachamp-sachet-orange-otc705822 **Products Reference:** **a) Product Name:** Probiotic Blend Powder **Company Name**: Abbott Healthcare Private Limited, India.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
94.	Drug International Ltd (Herbal Division) Monipur Bazar, Bokran, Gazipur	L. rhamnosus Lr-32 7.5 Billion , B. animalis ssp. lactis HN019 5.0 Billion, B. lactis BI-04 4.5 Billion, L. paracasei Lpc-37 4.0 Billion, L. plantarum Lp-115 3.7 Billion, L. casei Lc-11 1.5 Billion, S. thermophilus St-21 1.5 Billion, B. breve Bb-03 750 Million, B. longum BI-05 650 Million, L. plantarum CECT 7527 200 Million, L. plantarum CECT 7528 200 Million, L. plantarum CECT 7529 200 Million, B. infantis Bi-26 100 Million, L. delbrueckii ssp. bulgaricus Lb-87 100 Million, L. reuteri 1E1 100 Million.	Hard Capsule	The Probiotic may help enhance immune system function in the elderly, support digestive system health, maintain immune system health, support healthy bowel function, Help restore good gut flora.	**Contraindication**: This Capsule is contraindicated in those patients who are hypertensive to any component of this product. **Side effects**: This capsule generally well tolerated. No significant side effects have been observed in therapeutic dosage.	New	**Book Reference:** a) PDR for Nuritional Supplement. Page no: 517 b) PDR for Herbal Medicines 4th edition. Page no: 997-1001 c)https://www.lifespaceprobiotics.com/products/probiotic-for-60-years. **Products Reference:** **a) Product Name:** Probiotic for 60+ **Company Name:** Life space group,Australia.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
95.	Drug International Ltd (Herbal Division) Monipur Bazar, Bokran, Gazipur	Hydrolyzed Collagen PDR-HM 1000 mg, Biotin PDR-NS 0.50 mg, Vitamin C PDR-HM 15mg.	Soft Capsule	Hydrolyzed Collagen is useful in counteracting degenerative joint diseases. Biotin is used for healthy hair, skin and nails. Vitamin C is used as an antioxidant.	**Contraindication:** It is contraindicated in patients who exhibit hypersensitivity to any components of this medication. **Side effects:** This tablet generally well tolerated. No significant side effects have been observed in therapeutic dosage.	New	**Book Reference:** a) PDR-HM: Physician Desk Reference-for Herbal Medicines, 4th edition, Page no: 300-301. b) PDR-NS: Physician Desk Reference-for Nutritional Supplements, 2nd Edition, Page no: 84-89. c) PDR-HM: Physician Desk Reference-for Herbal Medicines, 4th edition, Page no: 1008-1012. d)https://www.amazon.com/Youtheory-Collagen-Advanced-Formula-	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
							Tablets/dp/B07CKCVJMB **Products Reference:** **a) Product Name:** Collagen+biotin **Company Name:** Youtheory, USA.		
96.	Drug International Ltd (Herbal Division) Monipur Bazar, Bokran, Gazipur	Coconut Oil (Organic Extra Virgin) PDR-HM.	Hair Oil	Coconut Oil externally used for Stop hair turning gray, moisturize hair and scalp. It is used to prevention from dandruff and Pediculosis. Coconut Oil also protecting hair from environmental damage. The Oil of Coconut has been used for healing wounds skin infection, inflammation.	**Contraindication:** It is contraindicated in those patients who are hypersensitive to any component of this product. **Side effects:** There is no data available.	New	**Reference :** Physician Desk Reference-for Herbal Medicines, 4th edition, Page: 209-210. b) USP-41 NF 36, Pages 5299 c)https://www.netmeds.com/health **Products Reference:** **a) Product Name:** Coconut OilExtra Virgin Company Name:Nature way,USA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
97.	Drug International Ltd (Herbal Division) Monipur Bazar, Bokran, Gazipur	Chamomile 370.50mg (standardized Chamomile extract with 100mg % essential oil and 3mg % Chamazulene), Peppermint 18.50mg (Peppermint Oil), Sage Oil 6.00mg, Anise 7.00mg (Anise Oil), Pine Needle Oil 1.00mg, Bergamot Oil 0.5mg, Eucalytol 5.00mg, Methyl Salicylate 1.00mg .	Oral Spray	It is indicated for inflammatory affections of the buccal and pharyngeal cavity, Parodontosis, Acute Gingivitis, Pain After tooth extraction and during second dentition, Mucosal irritation caused by dental plates, Tonsillary angina, Canker sores and Bad breath.	**Contraindication:** There is no data available. **Side effects:** There is no data available.	New	**Book Reference:** a) Physician Desk Reference-for Herbal Medicines, 4th edition, Page: 39-40, 293-296, 357-360, 624-625, 640-643, 717-719, 736-738, 905. b)https://www.amazon.com/Kamillosan-Spray-Bacteria-Throat-Tonsil/dp/B011443SIQ. **Products Reference:** a) Product Name: Kamillosan M **Company Name:** MEDA Interthai Pharmaceutical Manufacturing Ltd. Bangkok, Thailand. Manufactured Under License of MEDA Pharma GmbH &Co;KG, Bad Homburg, Germany. Marketed by A. Menarini(Thailand) Limited, Bangkok.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
98.	Drug International Ltd (Herbal Division) Monipur Bazar, Bokran, Gazipur	Glucosamine Sulfate (Crystalline) PDR-HM 1884 mg (eqv. to 1500mg of Glucosamine Sulfate) Sachet.	Sachet	It is indicated for all forms of degenerative osteoarticular disease, reduce joint pain (knee, ankle, shoulder, fingers), and reduce stiffness in joints.	**Contraindication:** There is no data available. **Side effects:** There is no data available.	New	**Book Reference:** a) Physician Desk Reference-for Herbal Medicines, 4th edition, Page: 967-970 b) PDR for Nutritional Supplements 2nd edition (PDR-NS): Page- 267-268. c) United States Pharmacopoeia. d)https://www.amazon.com/Viartril-S-Glucosamine-1500mg-Sachets-Supplement/dp/B01CJTQQE8. **Products Reference:** **a) Product Name:** Viartril-S **Company Name:** Manufactured by: Rottapharm Ltd, (Ireland), Marketing Authorization Holder: Mylan Philippines, Inc,	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
							Philippines.		
99.	Drug International Ltd (Herbal Division) Monipur Bazar, Bokran, Gazipur	Coconut oil (Organic Extra Virgin) 1000 mg	Soft Capsule	The oil of Coconut has been used for healing wounds and skin infections. Internally it is used for colds and inflammation of the throat and for tooth decay. Coconut oil is used for dysuria, coughs, bronchitis, and to stop hair from turning gray. It also used for healthy digestion, weight management, brain health and healthy cholesterol.	**Contraindication:** It is contraindicated in those patients who are hypersensitive to any component of this product. **Side effects:** There is no data available.	New	**Book Reference:** a) Physician Desk Reference-for Herbal Medicines, 4th edition, Page: 209-210 b)https://www.amazon.com/Coconut-Oil-Capsules-Softgels-Management/dp/B00T6UTILC?th=1 c) USP-41 NF 36, Pages 5299 d)https://www.thpherbal.com/en/product/23905-26860/cococap-1000 e)https://www.amazon.com/Organic-Capsules-Softgels-Supports-Cholesterol/dp/B00VAROBE8 **Products Reference:** **a) Product Name:** Cococap-1000 Soft Capsule (Thailand), Coconut Oil. **Company Name:** Manufactured by: Drug International Ltd (Herbal Division) We Export for Thailand (THP Brand), YounGlo Research, USA.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
100.	Drug International Ltd (Herbal Division) Monipur Bazar, Bokran, Gazipur	Thiamine (Viatmin B1) 50mg, Riboflavin (Vitamin B2) 50mg, Niacin as Niacinamide 50mg,Vitamin B6 (Pyridoxine Hydrochloride) 50mg,Folate as quatrefolic (Methyltetrahydrofolic acid) 680mcg,Vitamin B12 (Cyanocobalamin) 500mcg,Biotin 75mcg, Pantothenic Acid as (Calcium D Pantothenate) 50mg,Choline as Choline Bitartrate 19mg & Inositol 50mg.	Soft Capsule	This Capsule provides baseline nutrition for a variety of protocols. Builds metabolic reserve and protects against dietary deficiencies. Protects against Stress-Induced nutrient depletion. Supports healthy metabolism.	**Contraindication:** This Capsule is contraindicated in those patient who are hypersensitive to any component of this product. **Side effects:** No health hazards or side effects are known in con‡jvunction with the proper administration of designated therapeutic dosages.	New	**Book Reference:** PDR-NS.(PDR for Nutritional Supplements 2nd Edition)Page No: (136-138,225-234,441-444,443-435,479-482,547-552,609-614,634-643,644-653). **Products Reference:** https://www.orthomolecularproducts.com /product/methyl-b-complex. **Company name:** Orthomolecular products, USA	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
101.	Total Herbal & Nutraceuticals	Magnesium Oxide 400mg Tablet	Tablet	a) Ventricular arrhythmias, (b) Leg & muscle cramps (c) Nervousness, (d) Moderate anxiety (e) Prevent Diabetes patients of Insulin resistance and Hypomagnesaemia	**Contra-indication:** No contraindicated with other drugs. **Side Effect:** No side effect has been reported.	New	**Book Reference:** 1) United States Pharmacopeia- DSC-2015, Vol-1, Page No -1252-1255 **Reference Products:** Brand: Magox /Magnesium 400 mg, a) Akorn Consumer Health, USA. / b) Windmill Health Products- USA	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
102.	Total Herbal & Nutraceuticals	Magnesium Oxide 400mg + Vitamin B_6 25 mg Tablet	Tablet	(a) Nervousness, (b) entricular arrhythmias (c) Transient fatigue,(d) Mild sleep disorders; (e) Moderate anxiety, (f) Gastrointestinal cramps or palpitations ,(g) Muscle cramps, (h) Numbness	**Contra-indication:** No contraindicated with other drugs. **Side Effect:** No side effect has been reported.	New	**Products Reference:** Products Reference: Magnesium400mg & Vitamin B_6 25mg, Bluebonnet Nutrition Corporation, 12915 Dairy Ashford Road, Sugar Land Texas 77478, USA **Book Reference:** 1. USP-Dietary Supplement Compendium- DSC, Volume -1 Page No-1252-1255, 1348-1349.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
103.	Total Herbal & Nutraceuticals	Magnesium Oxide 400mg +Vitamin B_{13}.3.30mg + Vitamin B_6 4.20 mg + Vitamin B_{12}7.50 mcg + Vitamin $D_3$1500 IU+ Folic Acid 600 mcg Tablet	Tablet	(a) Muscle cramps & Numbness, (b) Ventricular arrhythmias Moderate anxiety, (c) Transient fatigue,(d) Mild sleep disorders; (e) Nervousness	**Contra-indication:** No contraindicated with other drugs. **Side Effect:** No side effect has been reported.	Introduce in DCC-251, Different strength	**Reference Products:** **Magnesium Plus, Hansa-pharm,** Hessenweg 10,48157 Münster, **Germany, Contact** Tel. +49 (0)251 1421.0 **Book Reference:** 1. USP-Dietary Supplement Compendium- DSC, Volume -1 Page No-1020-1023,1118-1119, 1053-1054,1252-1255, 1348-1349,1427-1428.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
104.	Total Herbal & Nutraceuticals	Magnesium Citrate 300 mg Tablet	Tablet	a) Ventricular arrhythmias, (b) Leg & muscle cramps (c) Nervousness, (d) Moderate anxiety (e) Prevent Diabetes patients of Insulin resistance and Hypomagnesaemia	**Contraindication:** No contraindicated with other drugs. **Side Effect:** No side effect has been reported.	New	**Products Reference:** Magnesium Citrate Tablet, https://www.bioactivenutrients.com/magnesium-citrate/ - USA **Book Reference:** A). USP-Dietary Supplement Compendium-2015 (DSC), Volume -1, Page No-1249-1250	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
105.	Total Herbal & Nutraceuticals	L-Arginine 1000 mg	Tablet	1) Supports arterial health 2) Helps maintain healthy tissue & bones 3) Supports already-healthy blood pressure levels May help maintain a healthy immune system	**Contra-indication:** It can cause side effects such as **dry mouth, nausea, vomiting, and diarrhea**. **Side Effect:** No side effect has been reported.	New	**Pharmacopeia Reference:** USP-Dietary Supplement Compendium –USP-DSC, Page no: 878-879 **Reference products:** L-Arginine 1000mg Capsule. Nature's Bounty, USA, L-Arginine 1000mng Capsule. GNC, USA.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
106.	Total Herbal & Nutraceuticals	β-glucan (Cauliflower mushroom extract) 500 mg	Capsule	1) Boost Your Immune System 2) Healthy Circulating Support as treat high lipids. 3) Healthy Heart Support 4) Digestive Support a)	**Contraindicated:** Excess Dosage May cause stomach problems, including nausea, vomiting **Side Effect:** beta-glucan is generally considered safe, there's some concern that it may lower blood sugar.	New	**Products Reference:** Beta Glucan, Zein Pharma, Germany, https://www.zeinpharma.com/Products/ **Book Reference** . USP- Dietary supplement Compendium, Page 910—913	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
107.	Total Herbal & Nutraceuticals	BCAA 1000 mg capsule (L Leucine 500 mg +L Isoleucine 250 mg + L Valine 250 mg)	Capsule	1) Supports detoxification of ammonia in the brain and skeletal muscles. 2) Treats and prevents hepatic encephalopathy. 3) Improves nutritional status and prevents hepatic cachexia. Improves quality of life	**Contraindication:** In rare cases, branched-chain amino acids may cause stomach problems, including nausea, vomiting, diarrhoea, and stomach bloating. **Side Effect:** No side effect has been reported.	New	**Products Reference:** 16. Products Reference: Optimum Nutrition, 3500 Lacey Road, Suite 1200 Downers Grove, IL 60515, 1-800-705-5226. **Book Reference:** Pharmacopeia Reference: USP-Dietary Supplement Compendium, Page no: 1226,1215-1216,1456-1457	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
108.	Total Herbal & Nutraceuticals	BCAA 1000 mg capsule (L Leucine 500 mg +L Isoleucine 250 mg + L Valine 250 mg)	Powder	1) Supports detoxification of ammonia in the brain and skeletal muscles. 2) Treats and prevents hepatic encephalopathy. 3) Improves nutritional status and prevents hepatic cachexia. 1) 4) Improves quality of life	**Contraindication:** In rare cases, branched-chain amino acids may cause stomach problems, including nausea, vomiting, diarrhoea, and stomach bloating. **Side Effect:** No side effect has been reported.	New	**Products Reference:** 16. Products Referance: Optimum Nutrition, 3500 Lacey Road, Suite 1200 Downers Grove, IL 60515, 1-800-705-5226. **Book Reference:** Pharmacopeia Reference: USP-Dietary Supplement Compendium, Page no: 1226,1215-1216,1456-1457	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
109.	Total Herbal & Nutraceuticals	Hyaluronic Acid 3% Serum	Serum	1) Dry skin, 2) Fine lines, wrinkles 3) Uneven skin tone 4) Oily skin, 5) Enlarged pores 6) Age spots,	**Contraindicating:** In some people those have sensitivity allergic reactions **Side Effect:** No side effect has been reported.	New	**Products Reference:** QRxLabs Hydrolific Serum, USA www.qrxlabs.com, **Book Reference:** I. Korean Pharmacopeia, Tenth Edition, Page 1092-1095	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
110.	Total Herbal & Nutraceuticals	Saw Palmetto Extract 320mg +Lycopane 10mg + Pumpkin Extract 100mg + Pygeum Africanum Extact 100 mg +Stinging Nettle Extract 100 mg + Vitamin D3 400 IU + Vitamin E 50 IU + Folate 133 mcg +Vitamin B12 17 mcg + Calcium 135mg + Magnesium 40 mg +Zinc 9.4 mg + Selenium 63 mcg	Tablet	1) Benign Prostatic hyperplasia 2) Frequent urination 3) Support normal prostate function 4) Healthy urinary flow.	**Contraindication:** No contraindicated with other drugs. **Side Effect:** No side effect has been reported.	New	**Products Reference**: Brand Name: Urozonic Tablet, Manufactured by: Vitanergy, Canada. **Book Reference**: 1) British Herbal Pharmacopeia 1996, Page no: 166-167, 143-144,155-156 1) United State Pharmacopeia-DSC-, Page no:1020-1021,1118-1119,1239-1240,1462-1463,1052-1053, 943-944, 1252-1253,1718-1719.943-944.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
111.	Total Herbal & Nutraceuticals	Bromelain (providing GDU) 100 mg + Lipase 100mg+ Protease 100mg + Amylase 100mg + Betaine hydrochloride 75mg + Papain (providing protease) 50mg + Lactase 10mg	Capsule	Digestive enzyme complex for 1) Heartburn 2) Irritable Bowel Syndrome (IBS) 3) Chron's disease 4) Celiac's disease 5) Ulcerative colitis	**Contraindicating:** DO NOT TAKE IF PEPTIC ULCERS ARE PRESENT OR SUSPECTED. Do not use if there is a hiatus hernia or any inflammation of the digestive tract. **Side Effect:** No side effect has been reported.	New	**Reference Products: CYTO-ZYME,** Cytoplan Ltd. Unit 8, Hanley Workshops, Hanley Swan, Worcestershire, WR8 0DX, **UK** https://www.cytoplan.co.uk/digestive-enzyme-supplement-cyto-zyme **Book Reference:** United States Pharmacopeia-USP-DSC, Page no-1018-1019, 1315-1319, 1996-1997.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
112.	Total Herbal & Nutraceuticals	N-acetyl-L-cysteine (NAC) 600 mg capsule	Capsule	1) Supports immune, bronchial & respiratory health 2) Encourages liver health & function 3) Support immune health 4) Anxiety and depression Neuroprotection	**Contra-indication:** It can cause side effects such as **dry mouth, nausea, vomiting, and diarrhea**. It has an unpleasant odor that some people find hard to tolerate. **Side Effect:** No side effect has been reported.	New	**Products Reference:** Products Name: NAC Lamberts HealthCare Ltd, **UK**, **Book Reference** USP-Dietary Supplement Compendium, Page no: 854.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
113.	Total Herbal & Nutraceuticals	Alpha Lipoic Acid 600 mg+ Chromium as Picolinate 100 mcg + Zinc 10 mg + Selenium 50 mcg + Vitamin E 15 mg + Vitamin B5 9 mg + Vitamin B6 3 mg + Vitamin B1 2 mg + Vitamin H Biotin 100 mcg **Capsule**	Tablet	1) Neurotropic 2) Anti-Inflammatory 3) Antioxidant 4) Altered Nervous Tropism 1) Oxidative Stress.	**Contraindication:** Women who are pregnant or who could become pregnant should not use this supplement. **Side Effect:** No side effect has been reported	New	**Products Reference:** Brand Name: **Nevralip,** RIVER PHARMA s.r.l. Viale Stazione n. 6 | 26863 Orio Litta (LO) – Italy **Book Reference: -** United States Pharmacopeia- DSC-2015, Page No. Page No: 1225-1226.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
114.	Total Herbal & Nutraceuticals	Maca (Root) 100 mcg + Withania Sombifera (Root) 50 mg + Pannax Ginseng Root 50 mg + Mucuna Puriens Extract (Seed) 50 mg + d-Ribose 50 mg + CoQ10 50 mg + L-lutathione Reduced 50 mg + Vitamin C 500 mg + Riboflavin15 mg + Niacin 25 mg + Vitamin B12 100 mcg **Capsule**	Capsule	Sperm Count Booster for Men: 2) Increase sperm count for male 3) Increase sperm mobility for male 4) Support overall productivity for male	**Contraindication:** No interactions have been reported. Safe, non-prescription formula **Side Effect:** No side effect has been reported.	New	**Products Reference:** Brand : **Count Boost for Men** Fairhaven Health, LLC 1410 11th St.Bellingham, WA 98225, USA. **Book Reference:** United States Pharmacopeia- DSC-2015, Page No, Vol-2- Page: 139-144, 19-22. USP-DSC-Vol-1 Page: 881-883, 882-806, 1445-1447, 1174, 880, 1359, 1306, 1052.	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
115.	Total Herbal & Nutraceuticals	Red Clover Leaf 4:1 extract 225 mg + PABA200 mg + Eleuthero Root 5:1 extract 125 mg + Chaste Tree Fruit 4:1 extract 40 mg + Ginkgo Leaf Extract 30 mg + Vitamin A 4000 IU + Vitamin C 85mg + Vitamin D3 400 IU + Vitamin E 100 IU + Thiamin 1.5mg + Riboflavin 1.7 mg + Niacin 20 mg + Vitamin B6 2 mg + Folic Acid 600 mg + Vitamin B12 6	Capsule	Fertility support for Women 1) Help to women conceive naturally, an effective alternative to invasive /Expensive infertility treatment. 2) Provides optimal nutritional support for trying to conceive women. 3) Particularly helpful of those with irregular cycles for conditions such as PCOS	**Contraindication:** No interactions have been reported. Safe, non-prescription formula **Side Effect:** No side effect has been reported.	New	**Products Reference:** FertilAid for Women Fairhaven Health, LLC 1410 11th St.Bellingham, WA 98225, USA. **Book Reference:** United States Pharmacopeia-DSC-2015, Page No: 1350-1353, 2461, 1085,1013,1156,1460,879,1020,1462,1427,135,1305,1348,958,1052,966,1215,1214,1252,1252,1248,1715,1398,2470,10	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
		mcg + Pantothenic Acid 10 mg + Iron 18 mg + Iodine 245 mg +Magnesium: as magnesium oxide 320 mg + as magnesium Chloride 75 mg + Zinc 15 mg + Selenium 70 mcg + Copper 2 mg **Capsule**					38.		
116.	Total Herbal & Nutraceuticals	L-Carnitine 350.00 mg, + Maca 300.00 mg + Grape Seed Extract 100.00 mg +Asian Ginseng 100.00 Mg + Coq10 50.00 Mg+ Vitamine A 5000.00 IU + Vitamin C 250.00 mg + Vitamin D3 400.00 IU + Vitamin E 150.00 IU + Vitamin K 80.00 mcg + Thiamin Hcl 1.50 mg + Riboflavin 1.70 mg + Vitamin B6 2.00 mg + Folic Acid 500.00 mcg + Vitamin B12 25.00 mcg + Pantothenic Acid 10.00 mg + iodine 150.00 mcg +Zinc 30.00 mg + Selenium 100.00 Mg + Copper 2.00 Mg + Manganese 2.00mg + Chromium 120.0 0 Mcg **Capsule**	Capsule	Fertility support for Men 1) Improve overall male reproductive Health 2) Sperm parameters such Increase Sperm Count 3) Increase Sperm motility (movement) and morphology (shape) 4) Infertility formulation support for men	**Contraindication:** No interactions have been reported. Safe, as non-prescription formula **Side Effect:** No side effect has been reported.	New	**Products Reference:** Brand: **FertilAid for Men** 1. Fairhaven Health, LLC 1410 11th St.Bellingham, WA 98225, USA. **Book Reference:** United States Pharmacopeia- DSC-2015, Page No. Page No: 1226-1227,139-146, 1183-1185, 889-890, 1445-1446, 906-907, 879-880, 1497-1503, 1462-1463, 1268 ,1427-1428, 1359-1360, 1348-1349, 1643-1644, 1052-1053, 967-968, 1214, 1715-1717, 1398-1399, 1038-1039,1262-1263,1031-1032.	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
117.	Total Herbal & Nutraceuticals	Myo Inositol 2000 mg + D Chiro Inositol 50mg + L Methyl Folate 1000 mcg+ Vitamin D31000 IU Sachet	Powder Sachet	1) Polycystic ovary syndrome (PCOS) 2) Women Infertility. 3) Premenstrual syndrome (PMS) 4) Menopausal complaints	**Contraindication:** The drug is contraindicated in pregnancy and in nursing mothers. **Side Effect:** No side effect has been reported.	New	**Products Reference:** Lactonova, #81-3, IDA Mallapur, Hyderabad, Telangana 500076, India **Book Reference:** 1) USP Dietary Supplements Compendium-2015, Page no-2068-2067, 958, 1118, 1020-1021.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
							2) PDR Herbal Medicine- Herbal Monograph, Page No: 151-152.		
118.	Total Herbal & Nutraceuticals	Hops Extract (Flower) Extract 200 mg + Tribulus Terriestories (20% Saponin) Extract150 mg + Mucina Puriens (Seed 25% L-dopa) Extract 125 mg +Ginkgo Biloba Extract 24:6 Extract125 mg + Epimedium Extract 100 mg + Niacin (as Niacinamide) Extract 20 mg + Cyanee (Piper) Extract 30 mg +DHEA Extract 25 mg +Melatonin Extract 5 mg	Tablet	1) To increase the body's natural energy levels for women 2) Alleviates vaginal dryness. 3) Increases blood flow to the by dilating the blood vessels. 4) To increase blood flow throughout the body **Increases pleasure & stimulation for women**	**Contraindication:** Women who are pregnant or who could become pregnant should not use this supplement. **Side Effect:** No side effect has been reported	New	**Products Reference**: Hersolution tablet. **Hersolution Address**, 100 Fidelitone Way, Elizabethton, TN, 37643, United States of America. Ameriaca. https://hersolution.pro/ingredients.html **Book Reference** United States Pharmacopeia- DSC-Page-927,1156-11159, 1266, 1305-1306, Indian Herbal Pharmacopeia- IP-2018, Page: 3790-3791, 3815-3816, Chinese Pharmacopeia -176-178, PDR Herbal Medicine, Fourth Edition, Page-400-401,817	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
119.	Total Herbal & Nutraceuticals	S Acetyl Glutathione 100 mg Capsule	Capsule	a) Powerful intracellular antioxidant. b) Promotes liver health a. c) Orally bioavailble glutathione	**Contraindication:** S-Acetyl L-Glutathione is very well tolerated when taken at the recommended dosage and adverse side effects are very rarely reported. **Side Effect:** No side effect has been reported	New	**Book Reference:** USP-Dietary Supplement Compendium, Page no: 1174-1175. **Reference Products**: Products Reference: Jorrow Formula, USA and New Root Herbal, USA,	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
120.	Total Herbal & Nutraceuticals	S-Adenosylmethionine (SAMe) 400 mg Tablet	Capsule	a) Osteoarthritis b) Fibromyalgia c) Liver Disease d) Depression	**Contraindication:** Large doses of SAMe may cause mania (abnormally elevated mood). Start at a low dose and gradually increase it; do not exceed recommended doses. Pregnant and breastfeeding women should not take SAMe **Side Effect:** No side effect has been reported	New	**Products Reference**: General Nutrition Company-GNC, USA - S-Adenosylmethionine 400 mg Capsule **Book Reference:** USP-Dietary Supplement Compendium, Page no: 1375-1376.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
121.	Total Herbal & Nutraceuticals	Chicory root (inulin) 500 mg powder	Capsule	a) Improves and stabilizes the gut flora composition b) Functional disturbance of the bowel transgression c) Constipation & Dysbacteriosis and Facilitates digestion d) Normalizes the carbohydrate and lipid metabolism f) Reduces the body weight, feeling of hunger and appetite g) Supporting bowel health kids & adult.	**Contraindication:** Those who are allergic should not take. Additionally, and very rarely people with a food allergy to inulin. **Side Effect:** No side effect has been reported	New	**Products Reference**: Inulin Pure Powder, Now Health , USA **Book Reference:** PDR for Herbal Medicine-4th Edition, Page no: 181-182.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
122.	Total Herbal & Nutraceuticals	Chicory root (inulin) 3 gram powder	Powder	a) Improves and stabilizes the gut flora composition b)Functional disturbance of the bowel transgression c) Constipation & Dysbacteriosis and Facilitates digestion d) Normalizes the carbohydrate and lipid metabolism f) Reduces the body weight, feeling of hunger and appetite g) Supporting bowel health kids & adult.	**Contraindication:** Those who are allergic should not take. Additionally and very rarely people with a food allergy to inulin. **Side Effect:** No side effect has been reported	New	**Products Reference**: Inulin Pure Powder, Now Health , USA **Book Reference:** PDR for Herbal Medicine-4th Edition, Page no: 181-182.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
123.	Total Herbal & Nutraceuticals	Diosmin 450 mg + Hosperidine 50 mg+ Horse Chestnut Extract 200 mg Tablet	Tablet	a) Acute & Chronic hemorrhoidal disease. b) Organic and functional chronic venous insufficiency of the c) Lower limbs with the following symptoms: heavy legs, pain, **d) I**mproves vascular tone, e) Supports lymphatic drainage of the legs and strengthens vascular structures	**Contraindication:** Proper data on contraindication is not available. If the hemorrhoidal symptoms do not disappear within 15 days, patient should ask doctor for advice **Side Effect:** No side effect has been reported		**Products Reference**: Tablet Hespidin, **Walmark, a.s.** Czech Republic **Book Reference** USP-Dietary Supplement Compendium- DSC, Volume -1 Page No-1058-1059, 1209-1213	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
124.	Total Herbal & Nutraceuticals	Calcium 600 mg + Magnesium 150 mg + Zinc 5 mg + Vitamin D3 25 mcg + Copper 250mcg+Manganese 0.25 mg + Selenium 27.5 mcg+ Boron 1 mg Tablet	Tablet	Helps to improve and maintenance of normal bones and healty joints, Oesteoarthritis, Osteomalacia, normalise muscle function	**Interactions with other drugs:** No interactions have been reported **Side Effect:** No side effect has been reported	New	**Products Reference**: Calcicum D_3 **Vitabiotics Ltd.** 1 Apsley Way, London, NW2 7HF, United Kingdom, https://www.vitabiotics.com/pages/contact-us. **Book Reference:** USP Dietary Supplement Compendium - 2015, Page-1020-1021, 946-947, 947-948, 1717- 1718, 1038-1039, 1261-1262, 102-103, 2430-2431	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
125.	Total Herbal & Nutraceuticals	Myo Inositol 1000 mg +D-Chiro Inositol 50 mg +L Methyl Folate 400 mcg + Cholecalciferol 1000 IU+ Melatonin 3 mg + Vitamin B_{12}	Tablet	1) Polycystic ovary syndrome (PCOS) 2) Women Infertility. 3) Premenstrual syndrome (PMS) 4) Menopausal complaints	**Interactions with other drugs:** No interactions have been reported **Side Effect:** No side effect has been reported	New	**Products Reference**: **Pisotop Tablet,** Orion Life Science, Block No.815/2, Plot 3/1/A, Opp.Kan Alloys, Nr. Gajanand Food, At. Santej, Dist.Gandhinagar, Gujarat. Ph+91- 63 593 98921/22/23, Email: info@orionlifes.com **Book Reference:** 1) USP Dietary supplements Compendium-2015, Page no-2068-2067, 1266-1267, 1118-1119, 1020-1021, 1052-1053. 2) PDR Herbal Medicine- Herbal Monograph, Page No: 151-152.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
126.	Total Herbal & Nutraceuticals	Mastic Gum Powder 100 mg + Slippery Elm 100mg +Zinc 8mg + Zinc L Carnosine Complex 37.50 + Calcium 70 mg	Tablet	a) Reducing stomach pain and heartburn b) Reducing Helicobacter pylori bacteria in the gut c) Heal inflammatory bowel disease (IBD) symptoms d) Heal stomach ulcers & liver health e) Lower cholesterol and blood glucose levels	**Interactions with other drugs:** No interactions have been reported **Side Effect:** No side effect has been reported	New	**Products Reference**: Tablet Ulcertol, Now Corporation.244 Knollood Drive. Bloomingdale, IL 60108, USA. Telephone: 888-669-3663 **Book Reference:** 1) PDR for Herbal Medicine, Fourth Edition, Page no: 508, 697. 2) Dietary Supplement Compendium, Volume-1, Page:943-944, 1717	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
127.	Total Herbal & Nutraceuticals	Mastic Gum 150 mg + Licorice Powder Extract 4:1 100 mg +Aniseed100mg + Fennel Powder Extract 6:1 25mg	Capsule	a) Reducing stomach pain and heartburn b) Reducing Helicobacter pylori bacteria in the gut c) Heal inflammatory bowel disease (IBD) symptoms d) Heal stomach ulcers & liver health e) Lower cholesterol and blood glucose levels	**Interactions with other drugs:** No interactions have been reported **Side Effect:** No side effect has been reported	New	**Products Reference**: *Mastic Gum Plus*, *Bionutri,* 1 Beech Rd, Bournville, Birmingham, B30 1LL, *UK* **Book Reference:** PDR for Herbal Medicine, Fourth Edition, Page no: 508,469-474,35-36,302-303	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
128.	Total Herbal & Nutraceuticals	Mastic Gum 500mg Capsule	Capsule	a) Reducing stomach pain and heartburn b) Reducing Helicobacter pylori bacteria in the gut c) Heal inflammatory bowel disease (IBD) symptoms d) Lower cholesterol and blood glucose levels	**Interactions with other drugs:** No interactions have been reported **Side Effect:** No side effect has been reported	New	**Products Reference**: Products Reference: Mastic Gum , Jarrow Formulas, USA **Book Reference:** PDR for Herbal Medicine, Page no: 508	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
				e) Heal stomach ulcers f) Helps liver health g) Help allergic asthma symptoms					
129.	Total Herbal & Nutraceuticals	Carnosine 500mg Capsule	Capsule	a) Supports muscle b) Supports bone health function. c) Supports heart health. d) Contributes to overall systemic protection	**Interactions with other drugs:** No interactions have been reported **Side Effect:** No side effect has been reported	New	**Products Reference**: L Carnosine 500mg Capsule, NOW Food, USA **Book Reference:**USP-Dietary Supplement Compendium, Page no: 1202.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
130.	Total Herbal & Nutraceuticals	Bromelain(providing GDU)100 mg + Lipase100 mg + Protease100 mg + Amylase100 mg + Betaine hydrochloride 75 mg + Papain (providing protease) 50 mg+ Lactase10 mg	Capsule	a)Digestive enzyme complex b) Heartburn c) Irritable Bowel Syndrome (IBS) 4) Chron's disease 5) Celiac's disease 6) Ulcerative colitis	**Interactions with other drugs:** This product is not recommended for children under 12 years old, pregnant or lactating women. **Side Effect:** No side effect has been reported	New	**Products Reference**: **CYTO-ZYME,** Cytoplan Ltd, Unit 8, Hanley Workshops, Hanley Swan, Worcestershire, WR8 0DX, UK.https://www.cytoplan.co.uk/digestive-enzyme-supplement-cyto-zyme **Book Reference:** 1) USP-Dietary Supplement Compendium, Page no-1225-1226,1318-1319,1996-1997, 1315-1317, 2) PDR for Herbal Medicine- Fourth Edition, Page-593-594	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
131.	Total Herbal & Nutraceuticals	Tea tree oil 1%+ White Willow Bark Extract (Salicylic Acid) 2% Soap	Soap	a) Iching, b)Anti Acne, c) Scabies	**Interactions with other drugs:** No interactions have been reported **Side Effect:** No side effect has been reported	New	**Products Reference**: MARS Medi Soap, 54/B/2 Changodar Ind. Estate, Changodar,Ahmedabad-382213, Gujarat, India **Book Reference:** British Pharmacopeia-BP2016- 796-797 1) Who Monograph- Volume-1, Page no172-178	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
132.	Total Herbal & Nutraceuticals	L-Carnitine (Base) 50 mg +L-Arginine(HCL) 150 mg + Omega-3 Fatty acids 100 mg + Asparagus racemosus extract 150 mg + N-Acetyl Cysteine 75 mg + Myo-Inositol 100 mg + L-Methyl Folate (10% Overage) 100 mcg + Withania Somnifera extract 50 mg eqv.to5.2 mg + Dehydroepiandrosteron (DHEA) 100 mcg eqv to. 0.264 mg + CoQ10 100 mcg (5% Overage) 0.88 mg + Zinc 28 mg + Folic Acid 200 mcg (50% Overage) 0.30 mg + Selenium 100 mcg (10% Overage) 0.264 mg Tablet	Tablet	1) Helps to improve Oligospermia, Asthenospermia, Teratozoospermia, 2) Motility of sperms Kinetic features of semen and to stimulate reproductive organs	**Contraindication:** Not reported. **Side effects:** This combination product is not known to have any side effects if taken as per the prescribed dosage by your physician.	New	**Products Reference:** *Brand Name: PROSPERM TABLET,* **Unijules Life Sciences Ltd.,** Survey No. 338(P-38), Next to MIDC Industrial Area, Kalmeshwar, Dist: Nagpur-441501,(M.S) India **Book Reference:** Indian Pharmacopoeia, IP 2018, Page no-3743-3744, 3790-3791, 3815-3816, United States Pharmacopeia-DSC-Page102,855,876,1226, 1445,1715.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
133.	Total Herbal & Nutraceuticals	Myo-Inositol 1000 mg + D-Chiro Inositol 10 mg + L-Arginine 100 mg + N-Acetyl Cysteine 50 mg + Zinc (as Zinc Sulphate Monohydrate) 42 mg + L-Methyl Folate (10% Overages) 0.11 mg +Vitamin D3 400 IU (30% Overage) 5.2 mg + Selenium 100 mcg (10%	Tablet	1) Useful in an ovary disorders known as Poly Cystic Ovarian Syndrome (PCOS). 2) Symptoms like Hirsutism, Acne, Alopecia, Insulin resistance and Infertility **1.**	**Contra Indication:** None reported. **Side effects:** This combination product is not known to have any side effects if taken as per the prescribed dosage by your physician.	New	**Products Reference: Brand Name: ZYGOTEX TABLET,** Unijules Life Sciences Ltd., Survey No. 338(P-38), Next to MIDC Industrial Area, Kalmeshwar, Dist: Nagpur- 441501, (M.S) India. **Book Reference:** United States	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
		Overages) 0.264 mg + Chromium 100 mcg (10% Overages) 0.88 mg Tablet					Pharmacopeia –DSC- Page-2068-2069, 876-879, 854, 1715-1718, 958, 1020-1021, 102, 1031-1032. PDR Herbal Medicine, Fourth Edition, Page no-151		
134.	Total Herbal & Nutraceuticals	Mucuna pruriens extract 200 mg + Tribulus terrestris extract 200 mg +L-Carnitine 75 mg + L-Arginine 100 mg + N-Acetyl Cysteine 50 mg + Withania Somnifera extract 50 mg + Vitamin C 30 mg + Co enzyme Q10 25 mg + Zinc (as Zinc Sulphate Monohydrate) 28 mg + Selenium 10 0.264 mg	Tablet	1) Helps to improve Oligospermia, Asthenospermia, Teratozoospermia, motility of sperms and 6) Kinetic features of semen and to stimulate reproductive organs	**Contra Indication:** None reported. **Side effects:** This combination product is not known to have any side effects if taken as per the prescribed dosage by your physician.	New	**Products Reference: Brand Name: PROSPERM TABLET,** Unijules Life Sciences Ltd., Survey No. 338(P-38), Next to MIDC Industrial Area, Kalmeshwar, Dist: Nagpur- 441501, (M.S) India. **Book Reference:** Indian Pharmacopoeia, IP 2018, Page no-3743-3744, 3790-3791, 3815-3816, United States Pharmacopeia- DSC- Page-102, 854, 879-880,885-886, 877-878, 1226-1229, 1446-1448, 1721-1722.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
135.	Total Herbal & Nutraceuticals	L Carnitine (Acetyl-L-carnitine) 500 mg	Capsule	a) Promotes healthy body composition by helping to convert fat into energy b) Boosts physical and mental energy c) Enhances overall well-being by lessening fatigue d) Improves athletic performance and speeds muscle recovery after exercise 1. e) Reduces the risk of cardiovascular disease	**Contra Indication:** ALC is considered safe at these dosages and without incidence of significant side effects. **Side effects:** This combination product is not known to have any side effects if taken as per the prescribed dosage by your physician.	New	**Products Reference: L Carnitine 500mg Capsule**, Nature's Bounty, ATTN: Consumer Affairs, 110 Orville Dr. Bohemia, NY 11716, USA **Book Reference:** USP-Dietary Supplement Compendium, Page no: 1226-1229	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
136.	Total Herbal & Nutraceuticals	L Glutamine 500 mg	Capsule		**Contra Indication:** None reported. **Side effects:** This combination product is not known to have any side effects if taken as per the prescribed dosage by your physician.	New	**Products Reference: L Glutamine 500mg Capsule**, Nature's Bounty, ATTN: Consumer Affairs, 110 Orville Dr. Bohemia, NY 11716, USA **Book Reference:** USP-Dietary Supplement Compendium, Page no: 1226-1229	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
137.	Total Herbal & Nutraceuticals	Lichen Extract (as Vitamin D3) 5000 IU drop/30ml	Drop	1) Osteomalacia **(**3) Vitamin D Deficiency (3) Rickets (4) Strong bone & Teeth.	**Contra Indication:** None reported. **Side effects:** This combination product is not known to have any side effects if taken as per the prescribed dosage by your physician.	New	**Products Reference:** (a) **Bidro ApS, (**Nordics Naturals) Midskovvej 58, DK-5370 Mesinge, Denmark. (b) Bluebonnet Nutrition Corp, 12915 Dairy Ashford, Sugar Land, TX 77478, 281-240-3332 **Book Reference:**USP-Dietary Supplement Compendium- DSC, Volume -1, Page no: 1020-1023.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
138.	Total Herbal & Nutraceuticals	Tongat Ali 500mg Capsule	Capsule	a) Increase Energy. b) Increase metabolism. c) Enhance Endurance d) Stimulate Muscle e) Increase male fertility.	**Contra Indication:** None reported. **Side effects:** This combination product is not known to have any side effects if taken as per the prescribed dosage by your physician.	New	**Products Reference:** Tongat Ali 500mg, Aadway sdn bhd, Malaysia. **Book Reference:** Thai Herbal Pharmacopeai, Page no: 535-543	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
139.	Total Herbal & Nutraceuticals	Evening Primrose Oil (GLA 10%) 500mg + Vitamin E 50mg	Capsule	1) Premenstrual Syndrome (PMS) 2) Mastalgia 3) Breast Engorgement 4) Rheumatoid arthritis 5) Diabetes Neuropathy	**Contra Indication:** None reported. **Side effects:** This combination product is not known to have any side effects if taken as per the prescribed dosage by your physician.	New	**Products Reference:** HealthAid Limited, UK. **Product Name:** Evening Primrose Oil 500mg. **Book Reference:** USP-Dietary supplements Compendium 2015- DSC. Page No: 1095, 1462-1464	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
140.	Total Herbal & Nutraceuticals	Polygonum cuspidatum/ Japanes knotweed extact (Resveratrol) 500 mg Capsule	Capsule	a) Promote neurological functions b) Support cardiovascular health and Cholesterol control c) Help to prevent tumor d) Weight control e) Glycemic index control	**Contra Indication:** None reported. **Side effects:** This combination product is not known to have any side effects if taken as per the prescribed dosage by your physician.	New	**Products Reference:** Resveratrol. EF. BioPro, Inc, California, USA. **Book Reference:** PDR for Herbal Medicine, Fourth Edition, Page no: 448-449	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
141.	Total Herbal & Nutraceuticals	Coffee Extract (as Caffeine) 5.00 % + Saw Palmetto 3.00 % + Ketoconazole 1.00 % + Wheat Protein 3.00 % + Biotin 0.25 % + Peppermint 1.00 % + Provitamin B5 3.00 %	Shampoo	1) Stimulate Hair & Skin Health. 2) DHT Blocker. 3) Promote Hair & Skin Growth. 4) Improve Hair Shine & Volume.	**Contra Indication:** None reported. **Side effects:** This combination product is not known to have any side effects	New	**Products Reference:** Sent from Earth; USA. **Product Name:** Caffeine & Saw Palmetto Biotin Peppermint Shampoo **Book Reference:** 1. USP-DSC-2015, Page: 1383-1385, 1704-1706, 915-917, 1864-1865, 1318. 2.PDR for Herbal Medicines (2000); Pages: 202-204. 3. BP 2020; Pages: 53-54	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
142.	UniMed UniHealth Pharmaceuticals (Herbal Division) B.K.Bari, Gazipur	Aloe Vera Gel 10% + D-Alpha Tocopherol (Vitamin E) 0.50% Each 100 g lotion contains Aloe-Vera 10.000g + D-Alpha Tocopherol (Vitamin E) 0.500 g	Liquid/ Lotion	It has Moisturizing effect & Hydrates skin # Acne, Rash, Minor Skin Eruption, Sunburn, Minor cut, wounds & Skin Allergies	Contra-Indication: It is contraindicated in case of known allergy to plant Side effect: Not Known	New (Recipe of Aloe-Vera gel 99% ,Aloe-vera gel with Tea tree oil has approved in DCC – 252)	**Products Reference:** Aloe- Vera & Vitamin E lotion NMF; manufactured by Palsons Derma Pvt. Ltd, India **Book Reference:** a) PDR for Herbal Medicine , 4th Edition; Page:19-26 b) WHO monographs on selected medicinal plants. Volume-I; Page :43-48 c) Dietary Supplement Compendium-2015; Page:1462	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
143.	UniMed UniHealth Pharmaceuticals (Herbal Division) B.K.Bari, Gazipur	Birch bark extract gel (Each 1g gel contains Birch bark extract 0.100 g)	Semisolid/ Gel	Treatment of partial thickness wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in patients 6 months and older	Contra-Indication : Not to be used during pregnancy Side effect: Not Known	New (Birch bark ointment /gel has enlisted on Bangladesh National Ayurvedic Formulary – 2nd Edition (2011): Single Drugs, Birch (*betula species*)	**Products Reference:** Filsuvez Gel; manufactured by Amryt Pharmaceuticals DAC., , Ireland **Book Reference:** a)Insert / Leaflet of inventor brand : Filsuvez Gel b)Summary of Product characteristic	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Page: 829-830)	from electronic medicines compendium (emc) c)An overview of Filsuvez gel and why it is authorized in the EU by European Medicine Agency (EMA) d).PDR for Herbal Medicine , 4th Edition; Page: 82-83 e)Photocopyof Bangladesh National Ayurvedic Formulary – 2nd Edition (2011): Single Drugs, Birch (*betula species*) Page:829-830		
144.	UniMed UniHealth Pharmaceuticals (Herbal Division) B.K.Bari, Gazipur	Myo-inositol 500.00 mg + D-Chiroinositol 12.50 mg capsule Each capsule contains Myo-inositol 500.00 mg +D-Chiroinositol 12.50 mg	Capsule	● Polycystic ovary syndrome (PCOS) ●Anovulation ●Menstrual disorders such as amenorrhea ●Hyperandrogenism complaints such as hirsutism, alopecia, acanthosis nigricans, acne ●Ovarian hyperthecosis	Contra-Indication : Contraindicated in patient with known hypersensitivity to any ingredient Side effect: Not Known	New (Recipe of D-chiro Inositol 500 mg capsule has been approved DGDA under Herbal Medicine Manufacturing Licence available product in Bangladesh market –Femisitol 500 mg capsule)	**Products Reference:** Omnibiotics- Myo inositol Plus ™ (with D-chiro inositol) Manufacture by OMNIBIOTICS, USA. **Book Reference:** a) PDR for Herbal Medicine, 4nd edition. Page :151-152 b) USP Dietary supplements Compendium-2015, Page no :2068 c) PDR for Nutritional supplement, 2nd edition, Page No.433	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
145.	UniMed UniHealth Pharmaceuticals (Herbal Division) B.K.Bari, Gazipur	Folate (As l-5-methyltetrahydrofolate /6s-5-methyltetrahydrofolate) 400 mcg capsule Each capsule contains Folate (As l-5-methyltetrahydrofolate /6s-5-methyltetrahydrofolate) 400 mcg	Capsule	Folate is indicated in the following conditions: • During pregnancy and lactation. • For pregnant women to prevent neural tube defect in babies. • As a dietary supplement in adults and older people. • To prevent risk of spontaneous abortions. • In postmenopausal women to normalize homocysteine, contributing to helping hot flashes, cardiovascular and bone health of aging women.	Contra-Indication : It is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients. Side effect: Folate is generally well-tolerated. Gastrointestinal disturbances and hypersensitivity reactions have been reported rarely	New	**Products Reference:** a) Folate (Quatrefolic® is registered trade mark of Gnosis, S.P.A. Italy) 400 µg capsules , Manufactured by Zein Pharma, Germany. a) Folineo (Quatrefolic® is registered trade mark of Gnosis, S.P.A. Italy,) Manufactured for: Martin Dow Marker Ltd, Manufactured by Novamed Healthcare (Pvt.) Ltd., 28-KM Ferozepur Road, Lahore, Pakistan.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
				• Folate deficiency caused by some medicines (e.g. those used to treat epilepsy such as phenytoin, phenobarbital and primidone) • Folate deficiency caused by long-term red blood cell damage or kidney dialysis. • In Depression, Cognitive impairment, Dementia and Alzheimer's disease			**Book Reference:** a) PDR for Nutritional Supplements, 2nd edition. Page :225-237 b) Quatrefolic (6S)-5-Methyltetrahydrofolic acid, Glucosamine Salt) from Gnosis Bioresearch S.r., Italy		
146.	UniMed UniHealth Pharmaceuticals (Herbal Division) B.K.Bari, Gazipur	S-adenosyl-L-methionine 200 mg Tablet Each Tablet contains Ademetionine 1,4 butanedisulfonate (As S-adenosyl-L-methionine) 200 mg	Tablet	For Adult : Supporting healthy liver function, reduce of tiredness and fatigue ; Providing general liver tonic; Supporting healthy mood balance	Contra-Indication : If the patient is sensitive or allergic to the active substance or to any of the inactive ingredients, do not use this product Side effect: Ademetionine can sometimes cause nausea, abdominal pain, vomiting, diarrhea, flatulence, dizziness and headache	New	**Products Reference:** Hepatral 200 mg / 400 mg Tablet, Manufacturer by Abbott **Book Reference:** a) PDR for Herbal Medicine, 4nd edition. Page: 1003-1006 b) PDR for Nutritional Supplements-2nd edition, Page :557-561 c) Full Prescribing Information-Heptral 200 mg/400 mg d) Documents of Adonat-S-Adenosyl methionine from Gnosis.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
147.	UniMed UniHealth Pharmaceuticals (Herbal Division) B.K.Bari, Gazipur	S-adenosyl-L-methionine 400 mg Tablet Each Tablet contains Ademetionine 1,4 butanedisulfonate (As S-adenosyl-L-methionine) 400 mg	Tablet	For Adult : Supporting healthy liver function, reduce of tiredness and fatigue ; Providing general liver tonic; Supporting healthy mood balance	Contra-Indication: If the patient is sensitive or allergic to the active substance or to any of the inactive ingredients, do not use this product Side effect: Ademetionine can sometimes cause nausea, abdominal pain, vomiting, diarrhea, flatulence, dizziness and headache	New	**Products Reference:** Hepatral 200 mg / 400 mg Tablet, Manufacturer by Abbott **Book Reference:** a) PDR for Herbal Medicine, 4nd edition. Page: 1003-1006 b) PDR for Nutritional Supplements-2nd edition, Page :557-561 c) Full Prescribing Information-Heptral 200 mg/400 mg d) Documents of Adonat-S-Adenosyl methionine from Gnosis.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
148.	UniMed UniHealth Pharmaceuticals (Herbal Division) B.K.Bari, Gazipur	White Kidney Bean Extract 100 mg Capsule Each capsule contains White Kidney Bean Extract (BEANBLOCK® is triple standardized.) 100 mg	Capsule	# Promote Healthy Body Weight # Aid your body in stocking fewer Carb Calories # Reduce the enzymatic digestion of dietary starches	Contra-Indication : Not Known Side effect: White bean extract is considered safe if taken as prescribed. It is not intended for long-term or ongoing use. White bean extract may trigger minor side effects in some, including nausea, bloating, gas, and diarrhea.[3]People allergic to beans should avoid white bean extracts. White bean extract should not be used in children due to the lack of relevant research. If you're looking to manage your weight or that of your children, the National Institutes of Health suggest following a plan that pairs a balanced diet with regular exercise. If you're still considering using white bean extract, be sure to talk with your healthcare provider first to discuss whether it's appropriate for you	New	**Products Reference:** Bean Block 100 mg Capsule ,Fargon , Johannesburg, South Africa **Book Reference:** a) PDR for Herbal Medicine, 4th edition. Page:69 b) Brochure of Bean Block 100 mg Capsule ,Fargon , Johannesburg, South Africa c) Brochure of Bean Block (White Kidney Bean Extract), Indena, Italy d) Minutes of DCC-251; (Annex-: G Products for Locally Manufacture (Herbal), Page:11-15).	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
149.	Alien Pharma (Herbal)	Lichen Extract (as vitamin D3) 200 IU Natto Extract (as Vitamin K2) (Vitamin K2 from Natto Extract) 15 µg	Pediatric Drop	1) Support immune system, 2) Support bone health, 3) Protect cardiovascular health, 4) Bone mineralization, 5) Regulates normal blood clotting.	No interactions were found with K2 and Vitamin D3. However, this does not necessarily mean no interactions exist.	New	**Book Ref.:** 1) USP-DSC, Vol -1 Page No- Page no: 1020-1023, 1268-1270. **Products Ref**.: Vitamin D3 200 I.U. + K2 15 µg Family Drops, Zein Pharma, Germany.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
150.	Alien Pharma (Herbal)	Horny Goat Weed Extract (Epimedium aerial parts) 50.00 mg Maca P.E. (Lepidium meyenii) 125.00 mg Mucuna Pruriens Extract 15.00 mg Polypodium Vulgare Extract (Common Polypody) 10.00 mg Tongkat Ali Root Powder Extract (Eurycoma Logifolia) 50.00 mg Saw Palmetto Powder Extract (Serenoa repens) 50.00 mg Muira Puama Root Powder Extract (Ptychopetalum olacoides) 10.00 mg Arginine (L-Arginine HCl) 10.00 mg Panax Ginseng Powder Extract (Asian Ginseng) 10.00 mg	Tablet	a) Lack of stamina. b) Improving blood circulatory function. c) Hormonal imbalances. d) Manifested as impotence and seminal emission.	There have been no reports of significant drug interactions	New	**Book Ref.:** 1) USP-DSC, Vol -1 Page No- 876-877. 2) USP-DSC, Vol -2 Page No- 139-141. 3) Chinese Pharmacopoeia Vol - 1 - 2015, Pages: 177-178, 182-183. 4) PDR for Herbal Medicines (2000) Pages: 230-231, 346-351, 454-455, 531-532, 664-666. **Products Ref.:** a) Arazo Nutrition, USA. Product Name: Horny Goat Weed Proprietary Blend.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
151.	Alien Pharma (Herbal)	Coal Tar Oil (Pine Tar Oil) 1.00% Willow Bark Extract (as Salicylic Acid) 3.00%	Shampoo	1) Psoriasis, 2) Seborrheic dermatitis, 3) Dandruff other skin disorders.	No monograph available at this time.	New	**Book Ref.:** 1) BP 2016; Page no.: 991, 796-797, 2) PDR FOR HERBAL MEDICINES Pages: 807-809. **Products Ref**.: Salve Pharmaceuticals Pvt. Ltd, India. Product Name: Cosalic Coaltar & Salicylic Acid Shampoo.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
152.	Alien Pharma (Herbal)	Myo-inositol (Inositol) 1000.00 mg Co enzyme Q10 (Ubiquinol) 10.00 mg L-Carnitine (Levocarnitine) 50.00 mg Melatonin 500.00 mcg L-Methyl Folate 200.00 mcg Lichen Extract (as vitamin D3) 50.00 IU	Tablet	1) Polycystic ovary syndrome (PCOS), 2) Women Infertility, 3) Premenstrual syndrome (PMS), 4) Menopausal complaints, 5) Support egg quality.	The drug is contraindicated in pregnancy and in nursing Mothers.	New	**Book Ref.:** a) USP-DSC, 2015, Pages-2068-2069, 1445-1446, 1226-1228, 60-61, 1020-1021, 1266-1267, b) USP VOLUME-4-(2017) 40 NF 35, Pages-7094-7095. **Products Ref**.: Asfar Healthcare, Kasur Lahore Road, Pakistan. Product Name: OVA-Booster.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
153.	Alien Pharma (Herbal)	Elderberry Fruit Extract (Sambucus Nigra) 50.00 mg Vitamin C (Ascorbic Acid) 1000.00 mg Lichen Extract (as vitamin D3) 2000 IU Zinc 10.00 mg	Effervescent Tablet	a) Fight against cold and flu and help soothe respiratory problems such as coughing and throat irritation, b) Support & strengthen the immune system, c) Protect cells against oxidative stress, d) Remove the feeling of fatigue and weariness & e) Develop bone and joint health.	There have been no reports of significant drug interactions with antibiotics or antidepressants.	New	**Book Ref.:** a) USP-DSC, 2015, Pages: No- 879-880, 1020-1023, b) PDR for Herbal Medicines; Pages: 287-289, 1021-1024 **Products Ref**.: maspex GMW Sp z o.o., Poland. Product Name: Dr. Vitt Imun Max 20.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
154.	Alien Pharma (Herbal)	Biotin 130.00 mg Vitamin C (Ascorbic Acid) 500.00 mg Vitamin B1- 10.40 mg Zinc 10.00 mg Vitamin B2 13.60 mg Niacin (Vitamin B3) 45.30 mg Vitamin B6 7.10 mg L-Methyl Folate 7.10 mg Vitamin B12 8.60 mg Pantothenic Acid 22.70 mg Magnesium 190.00 mg	Effervescent Tablet	a) Fight against cold and flu and help soothe respiratory problems such as coughing and throat irritation, b) Support & strengthen the immune system, c) Protect cells against oxidative stress & d) Remove the feeling of fatigue and weariness.	There have been no reports of significant drug interactions with antibiotics or antidepressants.	New	**Book Ref.:** a) USP- DSC-2015, Pages: No- 879-880, 1427-1428, 1359-1360, 1305-1307, 1347-1349, 60-61, 1052-1053, 915-917, 1318, 1252-1253; b) PDR for Herbal Medicines - 2010; Pages: 1021-1024. **Products Ref**.: a) Valpak, EU. Product Name: Valpak Effervescent Energy Release Vitamin B+C.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
155.	Alien Pharma (Herbal)	Raspberry Leaf Extract (Rubus idaeus) 150.0 mg Licorice Root Extract (Glycyrrhiza glabra) 121.0 mg Damiana Leaf Extract (Turnera diffusa) 115.0 mg Valerian Root Extract (Valeriana officinalis) 100.0 mg Ginkgo Biloba Extract 111.0 mg Vitamin B12 (Saccharomyces cerevisiae PE.) 111.0 mg Citrus limon PE (as ascorbic acid) 112.0 mg	Tablet	a) Promotes hormonal balance for Females, b) Enhances Vaginal lubrication, c) Supports balance in the female reproductive system & d) Heightened physical and mental arousal.	The drug is contraindicated during pregnancy	New	**Book Ref.:** a) PDR for Herbal Medicines (2000) Pages: 244, 469-472, 630-631, 783-785; b) The ABC Clinical guide to herbs Pages: 185-192; c) USP-DSC-Vol-1-2015; Pages: 1052-1053, 879-880. **Products Ref**.: Infinity Made in USA. Products Name: Lipstick Female Sexual Enhancement Red Pill.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
156.	Alien Pharma (Herbal)	Coal Tar Oil (Pine Tar Oil) 6.00% Willow Bark Extract (as Salicylic Acid) 3.00%	Ointment	1) Psoriasis, 2) Seborrheic dermatitis, 3) Dandruff other skin disorders.	No monograph available at this time.	New	**Book Ref.:** 1) BP 2016; Page no.: 991, 796-797, 2) PDR FOR HERBAL MEDICINES Pages: 807-809. **Products Ref**.: Salve Pharmaceuticals Pvt. Ltd, India. Product Name: Cosalic Coaltar & Salicylic Acid Ointment.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
157.	Alien Pharma (Herbal)	Selenium Sulfide (Selenium disulfide) 2.25%	Shampoo	a) Treatment of tinea versicolor, b) Seborrheic dermatitis of the scalp, c) Treatment of dandruff.	Oiliness or dryness of hair and scalp.	New	**Book Ref.:** USP VOLUME 3-(2017)-USP 40 NF 35, Page: 6140. **Products Ref**.: Method Pharmaceuticals, LLC; USA. Product Name: Selenium Sulfide 2.25% Shampoo.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
158.	Alien Pharma (Herbal)	Moringa Leaf Powder (Moringa Oleifera) 250.00 mg Wheat Grass Powder (Triticum aestivum) 100.00 mg Spirulina Powder (Arthrospira platensis) 75.00 mg Barley Grass Powder (Hordeum distichon) 75.00 mg	Tablet	1) Immunity Booster, 2) Regulates Blood Pressure, 3) Effective Against Anemia, 4) Lowers Blood Sugar Level, 5) Good for Heart & 6) Improves Brain Function.	Natural multivitamin, no interaction has been reported	New	**Book Ref.:** a) USP-DSC-2015. Page No: 2181-2184; b) PDR For Herbal Medicine – 2000, Pages: 63, 67-68, 799-800. **Products Ref**.: a) Everest Pharma, India. Product Name: Organic Supergreens.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
159.	Alien Pharma (Herbal)	L-Carnitine (as Tartrate) 116.60 mg Maca Root Extract 100.00 mg Asian Ginseng Extract 33.30 mg Coenzyme Q10 16.60 mg Vitamin A (as Beta Carotene) 1666.00 IU Vitamin C (as Ascorbic Acid) 83.30 mg Vitamin E (as D-Alpha Tocopherol) 50.00 IU L-Methyl Folate 166.00 mcg Vitamin B12 (as Methylcarbylamine) 8.50 mcg Zinc (as Zinc Gluconate) 10.00 mg DHA (Docosahexaenoic acid) 3.30 mg L-Arginine 8.50 mcg Lichen Extract (as vitamin D3) 133.00 IU	Capsule	1) Improve overall male reproductive Health. 2) Sperm parameters such as Increase Sperm Count. 3) Increase Sperm motility (movement) and morphology (shape).	Headaches & Male-pattern baldness may occur.	New	**Book Ref.:** a) USP-DSC-2015. Page No: 1226-1228, 139-141, 862-864, 1445-1446, 906-907, 876-877, 879-880, 1462-1464, 1052-1053, 1715-1717, 60-61, 1020-1023, 1041-1043. **Products Ref**.: a) Fairhaven Health, LLC, USA. Product Name: FertilAid for men.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
160.	Alien Pharma (Herbal)	Licorice 2.00% Kojic Acid 2.00% Alpha Arbutin 1.00% Niacinamide (as niacin) 3.00% Rice Water 5.00%	Liquid Serum	a) Anti-ageing effects, b) Lightens dark spots & decreases the appearance of scars, c) Treats melasma, d) Blocking tyrosine e) Recurrence of skin discoloration even after a sunburn	Itching, redness or skin irritation may occur.	New	**Book Ref.:** a) USP-DSC-2015. Page No: 1305-1307. b) PDR for Herbal Medicines (2000); Pages: 469-472, 893. c) EP-7.0; Pages: 388. **Products Ref**.: Nutriley Healthcare Private Limited., India. Product Name: Kojic Acid Face Serum	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
161.	Alien Pharma (Herbal)	Bromelain (Pineapple Extract) 250.00 mg Papain 125.00 mg Pancreatin 5X 100.00 mg Amylase (Pancrelipase) 12500 Units Lipase 1000 Unites Protease 12500 Unites Chymotrypsin 100 Unites Trypsin 75.00 mg	Tablet	1) Loss of appetite 2) Gastrointestinal ailments 3) Supports Digestive and Intestinal Health 4) Gastric and pancreatic proteases 5) Gastric symptoms and Stomach disorders.	No interaction has been reported but do not exceed the recommended dose.	New	**Book Ref.:** a) USP- DSC - 2015. Page No: 1318-1319, 1315-1317, 14381439. b) USP 43 NF 38 2020; Pages: 3382-3384, 993-994 c) PDR for Herbal Medicines (2000).pdf; Pages: 593-594. **Products Ref**.: Wonder Labs, USA. Product Name: Proteolytic Enzymes	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
162.	Alien Pharma (Herbal)	Magnesium Chloride (Elemental Magnesium) 50.00 mg/ml	Oil	a) Foot soaks, b) Leg cramps, c) Migraines, d) Nerves, e) Muscle stiffness disease	Possible reaction if allergic to shellfish	New	**Book Ref.:** a) USP- DSC - 2015. Page No-1248-1249. **Products Ref**.: Health and Wisdom Ltd, USA. Product Name: Topical Magnesium Oil.	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
163.	Alien Pharma (Herbal)	Zinc (as Zinc Gluconate) 25.00 mg	Tablet	a) Enhance immune function, b) Skin health, c) Eyes health, and d) Healthy heart.	None reported	New	**Book Ref.:** a) USP- DSC - 2015. Page No-1715-1717. **Products Ref**.: Puritan's Pride Inc. USA. Products Name: Zinc (Zinc Gluconate) 25mg.	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
164.	Alien Pharma (Herbal)	Ketoconazole 2.00 % ZPTO 1.00 %	Soap/Bar	a) Anti-fungal b) Anti-Bacterial.	Before using ketoconazole, tell your doctor or pharmacist if you are allergic to it.	New	**Book Ref.:** a) BP 2020- Volume-2; Pages: 53-54. b) EP 7.0; Pages: 1443-1445. **Products Ref**.: NRN International, Gujarat, India. Brand Name: KETO-N SOAP.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
165.	Alien Pharma (Herbal)	Tea Tree Oil (Melaleuca alternifolia) 5.00% Benzoyl Peroxide 5.00%	Gel	a) Acne, b) Bromidrosis & Tinea pedis, c) Mycotic onychia (onychomycosis), d) Furunculosis, e) Anti-inflammatory & Antimicrobial properties.	No monograph is available at this time. Do not use it on broken skin.	New	**Book Ref.:** a) WHO monographs on Selected Medicinal Plants -Vol -2; Pages- 172-178. b) EP 7.0; Pages: 1468-1469. **Products Ref**.: DDF Consultants Pvt. Ltd., India. Product Name: Benzoyl Peroxide Gel 5% with Tea Tree Oil	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
166.	Alien Pharma (Herbal)	Willow Bark Extract (as Salicylic Acid) 2.00%	Face Wash	a) Acne Clearing, b) Blemish-Prone Skin, c) Oil Free, d) Anti-inflammatory properties.	It may also remove too much oil, resulting in dryness and potential irritation.	New	**Book Ref.:** a) PDR for Herbal Medicines (2000); Pages: 807-809. **Products Ref**.: Pierre Fabre Dermo-Cosmetique Inc. New Jersey, USA. Product Name: GLYTONE Acne Clearing Cleanser.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
167.	Alien Pharma (Herbal)	L-Alanine 85.00 mg L-Arginine 97.00 mg L-Aspartic Acid 56.00 mg L-Glutamic Acid 112.00 mg L-Glycine 206.00 mg L-Histidine 14.00 mg L-Isoleucine 14.00 mg L-Leucine 32.00 mg L-Lysine 35.33 mg L-Methionine 9.00 mg L-Phenylalanine 23.00 mg L-Proline 138.00 mg L-Serine 35.00 mg	Tablet	1) Boost immunity. 2) Produce ATP. 3) Grow and repair body tissue. 4) Helps Protein synthesis and nutrient absorption. 5) Make hormones and brain chemicals (neurotransmitters).	No data available	New	**Book Ref.:** a) USP- DSC-2015. Page No: 876-877, 858-859, 891-892, 1172-1173, 1176-1177, 1202-1203, 1215-1216, 1226, 1244-1246, 1277, 1322-1323, 1339, 1404-1405, 1431-1432, 1445, 1456-1457 **Products Ref**.: a) Horbäach, LLC, USA. Product Name: Amino Acid Complex.	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
		L-Threonine 19.00 mg L-Tyrosine 7.00 mg L-Valine 23.00 mg L-Hydroxylysine 4.00 mg L-Hydroxyproline 111.00 mg							
168.	Alien Pharma (Herbal)	Myo-inositol (Inositol) 1100.00 mg D-Chiro Inositol (Carob Extract) 27.60 mg Melatonin 3.00 mg L-Methyl Folate 200.00 mcg Lichen Extract (as vitamin D3) 400.00 IU	Tablet	1) Polycystic ovary syndrome (PCOS) 2) Women Infertility. 3) Premenstrual syndrome (PMS). 4) Menopausal complaints. 5) Support egg quality	The drug is contraindicated in pregnancy and in nursing Mothers.	New	**Book Ref.:** a) USP- DSC-2015. Pages- 2068-2069, 60-61, 1020-1021, 1266-1267; b) USP VOLUME-4-(2017) 40 NF 35, Pages- 7094-7095; c) PDR for Herbal Medicines 2000; Pages: 151-152. **Products Ref**.: Adorefem Pharmaceutical Company Ltd, India. Product Name: Swapcod Tablet.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
169.	Alien Pharma (Herbal)	Myo-inositol (Inositol) 1100.00 mg D-Chiro Inositol (Carob Extract) 27.60 mg Melatonin 1.50 mg L-Methyl Folate 200.00 mcg Lichen Extract (as vitamin D3) 400.00 IU	Sachet	1) Polycystic ovary syndrome (PCOS) 2) Women Infertility. 3) Premenstrual syndrome (PMS). 4) Menopausal complaints. 5) Support egg quality	The drug is contraindicated in pregnancy and in nursing Mothers.	New	**Book Ref.:** a) USP- DSC-2015. Pages- 2068-2069, 60-61, 1020-1021, 1266-1267; b) USP VOLUME-4-(2017) 40 NF 35, Pages- 7094-7095; c) PDR for Herbal Medicines 2000; Pages: 151-152. **Products Ref**.: Gladfem Gynec And Profertiliy Care, India. Product Name: Myozoc Forte Sachet.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
170.	Alien Pharma (Herbal)	Selenium Sulfide 2.5%	Lotion	a) Treatment of tinea versicolor, b) Seborrheic dermatitis of the scalp, c) Treatment of dandruff.	Scalp irritation and Skin Irritation may ocer.	New	**Book Ref.:** USP Vol. 3-(2017)-40 NF 35, Page: 6140. **Products Ref**.: 1) Morton Grove Pharmaceuticals, USA. Product Name: Selenium Sulfide Lotion, 2.5%; 2) Perrigo, Bronnx, New York, USA. Product Name: Selenium Sulfide Lotion 2.5%.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
171.	Alien Pharma (Herbal)	Lichen Ext. (as vitamin D3) 200 IU Calcium (Calcium Carbonate) 333.00 mg Almond Extract (as Magnesium) 134.00 mg Zinc (as Zinc Gluconate) 8.50 mg	Tablet	1) Promote strong bones and a relaxed, calm mood. 2) Important for the contraction and relaxation of muscles. 3) Cardiac muscle and normalize the muscle tone of blood vessels. 4) Helps to maintain immunity.	No interaction has been reported but do not exceed the recommended dose.	New	**Book Ref.:** USP-DSC-2015; Page No: 1020-1023, 943-947, 1252-1253, 1715-1717. **Products Ref**.: Nature's Bounty, USA. Product Name: Calcium Magnesium Zinc with Vitamin D3	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
172.	Alien Pharma (Herbal)	Biotin 3350.00 mcg L-Methyl Folate 350.00 mcg Collagen 333.00 mg Saw Palmetto 83.00 mg Onion Extract (as Keratin) 166.00 mg	Capsule	1) Stimulate Hair, Nails & Skin Health. 2) DHT Blocker. 3) Promote Hair, Nail & Skin Growth. 4) Improve Hair Shine & Volume.	No interactions have been reported.	New	**Book Ref.:** a) USP-DSC 2015- DSC. Pages: 915-917, 1383-1385, 60-61; b) USP VOL. 1-(2017)- USP 40 NF 35; Pages: 185-190; c) PDR for Herbal Medicines (2000); Pages: 557-558. **Products Ref**.: Clean Nutraceuticals, USA. Product Name: One Bottle of Multimane.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
173.	Alien Pharma (Herbal)	Coffee Ext. (as Caffeine) 5.00 % Saw Palmetto 3.00 % Ketoconazole 1.00 % Wheat Protein 3.00 % Biotin 0.25 % Peppermint 1.00 % Provitamin B5 3.00 %	Shampoo	1) Stimulate Hair & Skin Health. 2) DHT Blocker. 3) Promote Hair & Skin Growth. 4) Improve Hair Shine & Volume.	No interactions have been reported.	New	**Book Ref.:** a) USP-DSC-2015, Page: 1383-1385, 1704-1706, 915-917, 1864-1865, 1318; b) PDR for Herbal Medicines (2000); Pages: 202-204; c) BP 2020; Pages: 53-54. **Products Ref**.: Sent From Earth; USA. Product Name: Caffeine & Saw Palmetto Biotin Peppermint Shampoo.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
174.	Alien Pharma (Herbal)	Evening Primrose Oil PE 500.00 mg Vitamin E (15 IU)10.00 mg Gamma Linolenic Acid (Black Currant Extract) 50.00 mg	Capsule	1) Premenstrual Syndrome (PMS) 2) Mastalgia 3) Breast Engorgement 4) Rheumatoid arthritis 5) Diabetes Neuropathy	No interactions have been reported.	New	**Book Ref.:** a) USP-DSC-2015, Page: 1095, 1462-1464; b) PDR for Herbal Medicines (2000), Pages: 94-96. **Products Ref**.: HealthAid Limited, UK. Product Name: Evening Primrose Oil 500mg.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
175.	Alien Pharma (Herbal)	Lactobacillus reuteri 15 billion Lactobacillus rhamnosus 5 billion Lactobacillus paracasei 15 billion Lactobacillus casei 5 billion Lactobacillus fermentum 10 billion Lactobacillus lactis 10 billion	Liquid Drop	1) Support immune system, 2) Flu and flu-like symptom, 3) Digestive issues, 4) Allergies, 5) Mental health problems & 6) Lactose intolerance.	Do not get at this time	New	**Book Ref.:** a) PDR for Herbal Medicines (2000), Pages: 996-1001. **Products Ref**.: Fu-E Lifesciences Co, Ltd, Taiwan. Product Name: Super Kides.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
176.	Alien Pharma (Herbal)	Retinol (as Vitamin A) 0.30% Niacinamide (as niacin) 3.00% Hyaluronic Acid 0.25%	Liquid Serum	a) Anti-ageing effects, b) Lightens dark spots & decreases the appearance of scars, c) Treats melasma, d) Deep wrinkles e) Premature sun damage.	Itching, redness or skin irritation may occur.	New	**Book Ref.:** a) USP-DSC-2015; Pages-906-907, 1305-1307, 2164-2166. **Products Ref**.: Standard Skin & Beauty, South Africa. Product Name: 0.3% Retinol with Niacinamide & Hyaluronic Acid.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
177.	Alien Pharma (Herbal)	Retinol (as Vitamin A) 1.00% Niacinamide (as niacin) 3.00%	Liquid Serum	a) Anti-ageing effects, b) Lightens dark spots & decreases the appearance of scars, c) Treats melasma, d) Deep wrinkles e) Premature sun damage.	Itching, redness or skin irritation may occur.	New	**Book Ref.:** a) USP-DSC-2015; Pages-906-907, 1305-1307. **Products Ref**.: La Roche Posay Dermatological Laboratory, France. Product Name: RETINOL B3 ANTI-AGING FACE SERUM.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
178.	Alien Pharma (Herbal)	Nicotinamide 5.00% Vitamin B3 4.00% Allium Cepa (Onion Ext.) 10.00%	Scar Gel	a) Reduces stretch marks, b) Dissolves deep scar tissues, c) Anti-ageing effects, d) Lightens dark spots & decreases the appearance of scars, e) Provides moisturization to the skin.	Itching, redness or skin irritation may occur.	New	**Book Ref.:** a) USP-DSC-2015; Pages-1305-1307; b) PDR for Herbal Medicines (2000); Pages: 557-558. **Products Ref**.: Fixderma Cosmetic Laboratories Inc., USA. Product Name: Fixderma Scar Gel.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
179.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal Division)	Organic Fenugreek Seed Powder 300mg + Organic Milk Thistle Seed Extract (80%) (Silymarin) 150mg + Organic Fennel Seed Powder 50mg.	**Capsule**	Promote lactation for Breastfeeding	**Contraindication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effect:** Well tolerated in recommended dose.	New	1. PDR For Herbal Medicine, 4th Edition. Page No.: 319, 578, 317. **Reference Product:** Organic Lactation Support, Pure Mom by PURE CO, USA.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
180.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal Division)	Grape Seed Extract (Vitis Vinifera seed) 100mg + Olive Leaf Extract (Olea europaea; leaf) 100mg + Garlic Extract (Allium sativum, root) 100mg + Hawthorn Leaf Extract (Crataegus pinnatifida; leaf) 100mg	**Capsule**	➢ Improves cardiovascular health ➢ Promotes relaxation ➢ Helps manage stress	**Contraindication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effect:** Well tolerated in recommended dose.	New	PDR For Herbal Medicine, 4th Edition. Page No.: 405, 617, 345, 279. **Reference Product:** Herbal-BP Natural Cardiovascular Suppo rt, **Manufactured by:** Daily Nutra, USA.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
181.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal Division)	Organic Milk Thistle 5:1 Concentrated Extract 400mg (Silybum marianum; whole plant) + Organic Dandelion Root 75mg (Taraxacum officinale) + Organic Black Pepper Powder 5 mg	**Capsule**	➢ Supports Healthy Liver Function ➢ Restores Antioxidant Levels and Helps Reduce Inflammation 3. Enhanced Bioavailability	**Contraindication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effect:** Well tolerated in recommended dose.	New	PDR For Herbal Medicine, 4th Edition. Page No.: 578, 251, 107. **Reference Product:** Organic Milk Thistle & Dandelion Capsule **Manufactured by:** Holistic Labs Ltd. 1971 E. Beltline NE, Suite 106-719 Grand Rapids, MI 49525 (312) 324-0024, USA.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
182.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal Division)	Proprietary Herbal Blend (Horsetail (Equisetum arvense) (herb), Stinging Nettle (Urtica dioica) (leaf), Garlic (Allium satibum) (bulb) and Celery (Apium graveolens) (Seeds) 400mg	**Capsule**	➢ Helps Improve Joint Mobility ➢ Helps Improve Joint Flexibility **5.** Promotes Joint Comfort	**Contraindication:** No Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effect:** Generally well tolerated in recommended dose.	New	PDR For Herbal Medicine, 4th Edition. Page No.: 458, 792, 345, 182. **Reference Product:** Reuma-Art X Strength **Manufactured by:** Full Life Natural Health Products, Hollywood, FL 33020, USA.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
183.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal Division)	Chaste Tree Berry (Vitex agnus-castus) Powder 450mg + Ginger Extract 4:1 (Zingiber officinale) 50mg	**Capsule**	➢ Promotes Mood & Well Being ➢ Supports Healthy Menstrual Cycle ➢ Naturally Balances Your Hormones **6.** Supports Ovarian and Reproductive Health	**Contraindication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effect:** Well tolerated in recommended dose.	New	PDR For Herbal Medicine, 4th Edition, Page: 185, 365 **Reference Product:** VITEX (Chasteberry) With Ginger Capsule **Manufactured by:** Intimate Rose, North Kansas City, USA.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
184.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal Division)	Probiotic Blend 29 mg (2.5 billion CFUs) (Lactobacillus rhamnosus GG (LGG) + Bifidobacterium animalis subsp. lactis (BB-12) + Vitamin D (as cholecalciferol) 10 mcg (400 IU)	**Baby Drop**	➢ Promotes the development of Healthy Digestive ➢ Immune Systems ➢ Vitamin D to help build strong bones 4.	**Contraindication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effect:** Well tolerated in recommended dose.	New	PDR For Herbal Medicine, 4th Edition, Page: 996-998. BNF, Page: 1145 **Reference Product:** Culturelle Baby Grow + Thrive (Probiotic + Vitamin D) Drop **Manufactured by:** Culturelle I-Health, Inc. 55 Sabithe Drive Cromwel CT 06416, USA.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
185.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal Division)	Coenzyme Q10 100 mg + Vitamin E powder (as dl-alpha-tocopheryl acetate) 68 mg	**Capsule**	➢ Enhance Immunity ➢ Skin aging ➢ Cardiovascular Disease ➢ Male Infertility ➢ Alzheimer's Disease ➢ Diabetes ➢ Cataracts ➢ Asthma and Rheumatoid Arthritis ➢ Premenstrual Syndrome ➢ Muscle Cramps ➢ Supports Heart & Vascular Health ➢ Promotes Healthy Pressure Levels 4) Essential For Energy Production	**Contraindication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effect:** Well tolerated in recommended dose.	New	PDR For Herbal Medicine, 4th Edition, Page: 958, 1013 **Reference Product:** Qunol Ultra CoQ10 100mg Capsule **Company Name :** Quten Research Institute, LLC, USA.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
186.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal Division)	Vitamin D (Cholecalciferol) 10 mcg (400 IU)	**Baby Drop**	➢ Prevent bone loss and fracture • Improve bone density	**Side effect & Contraindication:** Vitamin D at normal doses usually has no side effects. If you have any unusual effects, contact your doctor or pharmacist promptly	New	PDR for Nutritional Supplements, Page: 498-505 BNF, Page: 1145 **Reference Product:** Baby D drops Liquid Vitamin D_3 **Manufactured by:** Ddrops, Canada.	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
187.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal Division)	Vitamin C 6.0%+ Turmeric Root 0.2%+ Salicylic Acid 2.0%	**Skin Care Spray**	➢ Brightens, illuminates and helps even out the look of your skin tone ➢ Super-hydrates while providing a fresh glow ➢ Reduces the appearance of dark spots and uneven skin tone ➢ Help reduce the appearance of wrinkles, improve skin tone and brighten the complexion ▪	**Contraindication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effect:** Well tolerated in recommended dose.	New	PDR for Herbal Medicine 4th Edition. Page: 864 British National Formulary (BNF), Page: 1143, 1353 **Reference Product:** Revel Beauty Bright & Tight Serum **Manufactured by:** REVEL BEAUTY, China.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
188.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal Division)	Magnesium 120mg + Glucosamine HCL 500mg + Boswellia serrata Extract (resin) 30mg	**Tablet**	➢ Soothes Joints ➢ Supports Joint Function ➢ Helps with Occasional Joint Stiffness	**Contraindication:** No Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effect:** Generally well tolerated in recommended dose.	New	PDR for Herbal Medicine, 4th Edition, Page: 985, 967, 337. **Reference Product:** Osteo Bi-Flex Joint Health Tablet **Manufactured by:** Rexall Sundown, Inc. USA.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
189.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal	Organic Rosemary (Rosmarinus officinalis) 3% + Organic Saw Palmetto (Serenoa repens) 2% + Organic Stinging Nettle (Urtica dioica) 2% + Organic Burdock (Arctium lappa) 1% + Organic Horsetail (Equisetum arvense) 4% + Organic Sweet Basil	**Shampoo**	➢ Prevent hair loss ➢ Promote new healthy hair growth ➢ Softens hair, nourishes the hair-shaft, and rejuvenates hair follicles. ➢ Helps relieve scalp irritation ➢ Improve scalp conditions ➢ Getting rid of scalp itching,	**Contraindication:** No Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effect:** No known side effects.	New	PDR For Herbal Medicine, 4th Edition, Page: 709, 725, 792, 136, 458, 68, 19 **Reference Product:** Larritelle Organic Herbal Magic Shampoo ***Manufactured by:*** *Larritelle, 6747 ODESSA AVE. # 205 VAN NUYS, CA*	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Division)	(Ocimum basilicum) 2% + Organic Aloe Vera (Aloe barbadensis) 5%		redness and dandruff ➢ Improving hair strength, shine and body • Helps to treat scalp conditions such as dandruff and seborrhea			*91406, USA.*		
190.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal Division)	Biotin 10000 mcg	**Capsule**	➢ For healthy hair, skin and nails ➢ Aids in the body's energy and metabolic processes • Eczema & dermatitis	**Contraindication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effect:** Well tolerated in recommended dose.	New	PDR For Nutritional Supplement, Page: 50 Japanese Pharmacopeia Page: 510 **Reference Product:** Biotin 10000 mcg Capsules **Manufactured by:** Nutricost, USA.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
191.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal Division)	(Lactobacillus rhamnosus 4 billion, Lactobacillus reuteri 2 billion, Lactobacillus acidophilus 4 billion, Lactobacillus plantarum 4 billion, Lactobacillus crispatus 2 billion, Lactobacillus fermentum 4 billion, Lactobacillus gasseri 2 billion, Lactobacillus paracasei 2 billion, Lactobacillus helveticus 2 billion, Lactobacillus casei 4 billion, Bifidobacterium longum 4 billion, Bifidobacterium bifidum 4 billion, Bifidobacterium infantis 4 billion, Bifidobacterium lactis 2 billion, Bifidobacterium breve 4 billion, Bifidobacterium adolescentis 2 billion, Organic Cranberry Extract 50 mg) Probiotic Composite Blend 50 billion	**Capsule**	➢ Promote digestive and immune health ➢ Maintain Vaginal & Urinary Health ➢ Ease occasional bloating, constipation & Digestive discomfort ➢ Improved mood and anxiety relief ➢ Stronger bones, muscles & strength ➢ Proper nerve function and better memory ➢ Relaxation & restful sleep	**Contraindication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effect:** Generally Well tolerated in recommended dose.	New	PDR for Herbal Medicine 4th edition, Page: 996, 238 **Reference Product:** Women's Probiotics, USA.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
192.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal Division)	Extract of Turmeric 0.50 % + Oils of orange peel 0.50 % + Lemon Grass 0.30 % + Oregano 3.5 % + Golden Seal 4.0 %	**Tooth-Paste**	Protect teeth and gums Cleans the bad breath Tooth decay Periodontitis Reduce plaque and inflammation ➢	**Contraindication:** No known contraindications. **Side effect:** No know side effect.	New	Physician Desk Reference-for Herbal Medicines, 4th edition, Page no: 864, 90, 515, 621, 395 **Reference Product:** Black Seed Toothpaste, USA.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
193.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal Division)	Camellia Sinesis leaf extract 5%+ Salvia miltorrhiza extract 0.5%+ Hamamelis virginiana extract 4%+ Glycyrrhiza Uralensis root Extract 4.5%+ Scutellaria Baicalensis extract 3%+ Aloe Barbodensis leaf extract 3.04%+ Lonicera japonica flower extract 0.5%	**Cream**	➢ Improve sensitive skin, Sooth and repair ➢ Acne Removal ➢ Oil Control & Moisturizing ➢ Remove Acne marks ➢ Blackhead Removal ➢ Anti-bacterial and Anti-inflammatory	**Contraindication:** Safe, No Interaction. **Side effect:** Do not get any side effects.	New	PDR for Herbal Medicine 4th Edition. Page:414, 698, 906, 522, 739, 19, 446 **Reference Product :** Herbal Acne Treatment Cream, UK.	আবেদন না মঞ্জুর করার সুপারিশ করা যেতে পারে।	আবেদন না মঞ্জুর করা হলো।
194.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal Division)	Folate 1,700 mcg (1,000 mcg folic acid)	**Capsule**	➢ Prevention of neural tube defects in pregnancy ➢ Treatment of megaloblastic anemias caused by folic acid deficiency ➢ Treatment of folic acid deficiency caused by oral contraceptive or anticonvulsant therapy	**Contraindication:** Folic acid is contraindicated for use in patients with folic acid hypersensitivity. **Side effect:** No side effect in recommended dose.	New	PDR for Herbal Medicine 4th Edition. (Page No. 962-966)**Reference Product:** Premium Quality Kidney Support Capsules **Reference Product:** Folic Acid Capsules **Manufactured by:** Nutricost, Vineyard, UT 84057, USA. .	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
195.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal	Beet Root Extract (Beta vulgaris) 500 mg **Capsule**	**Capsule**	➢ Lower Blood Pressure ➢ Improved Brain Function ➢ Improved Athletic Performance ➢ Reduced Inflammation & Joint Pain ➢ Supports Healthy Digestion ➢ Supports Healthy Circulation ➢ Supports Healthy Immunity	**Contraindication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effect:** Generally Well tolerated in recommended dose.	New	PDR For Herbal Medicine, 4th Edition, Page: 70 **Reference Product:** Beet Root Extract 500mg Capsule **Manufactured by:** Puritan's Pride, USA.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

Sl	Name of the Manufacturer	Generic Name with Strength	Dosage Form	Indication and Usage	Contra-indication & Side effect	Status (New Molecule / Existing)	Herbal Reference Book & Product Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Division)								
196.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal Division)	Elderberry Extract 4 : 1 (Sambucus nigra fruit) 300mg + Organic Elderberry Fruit Powder (Sambucus nigra) 200mg	**Capsule**	➢ Supports your body's natural resistance with immune-boosting properties. ➢ High in flavonoids help prevent free radicals from damaging your cells. ➢ Promotes a natural boost in your skin health with high Vit A and antioxidants.	**Contraindication:** No contraindications to elderberry have been identified. **Side effect:** No side effect in recommended doses.	New	PDR For Herbal Medicine, 2nd Edition, Page: 287-289. **Reference Product:** Black Elderberry Capsules **Manufactured by:** Herbal Roots Supplements, USA.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
197.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal Division)	Ubiquinol 250 mg **Capsule**	**Capsule**	➢ Antioxidant Support for Mitochondrial Health ➢ Energy Production ➢ Cardiovascular Function	**Contraindication:** People with chronic diseases such as heart failure, kidney or liver problems, or diabetes should be wary of using this product. **Side effect:** Nausea, loss of appetite, upset stomach, or diarrhea may rarely occur.	New	PDR For Herbal Medicine, 4th Edition, Page: 958-961. **Reference Product:** Ubiquinol 250mg Capsule **Manufactured by:** Jarrow Formulas, USA.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।
198.	Bexter Herbal & Nutraceuticals Matidali 2nd Bypass Road, Manikchock, Bogura. (Herbal Division)	Bitter Melon (Momordica charantia) 500mg	**Capsule**	➢ Blood Sugar Support ➢ Digestive Health Aid ➢ Healthy Blood Glucose Level Management ➢ Hormone Balance Support	**Contraindication:** No contraindications to elderberry have been identified. **Side effect:** No side effect in recommended doses.	New	PDR For Herbal Medicine, 4th Edition, Page: 88 **Reference Product:** Bitter Melon 500mg Capsule **Manufactured by:** SWANSON, USA.	অনুমোদনের সুপারিশ করা যেতে পারে।	অনুমোদন করা হলো।

বিবিধ আলোচনাঃ

১। মেসার্স স্কয়ার ফার্মাসিউটিক্যালস্ লিমিটেড (হার্বাল ডিভিশন) নামীয় প্রতিষ্ঠানটি ঔষধ নিয়ন্ত্রণ কমিটির ১৬ এপ্রিল ২০১৮ এ অনুষ্ঠিত ২৪৯ তম সভায় অনুমোদিত রেজিস্ট্রেশন গ্রহণপূর্বক **"ইউরিপাম সফটজেল ক্যাপসুল"** নামে ঔষধটি বাজারজাত করছে। প্রোডাক্ট এর রেফারেন্স: GNC Men's Ultra Saw Palmetto Formula (web link: https://www.gnc.com/saw-palmetto/062431.html)

ঔষধটির জেনেরিক নাম ঃ (Saw palmetto 160 mg + Korean ginseng 3.3 mg + Pygeum bark 1.7 mg +Zinc Sulphate 33.10 mg + Copper Gluconate 2mg) Capsule

উল্লেখ্য ঔষধটি বাজারজাত করণ শুরুর ১.৫-২ বছর পর Satbility Chamber হতে নমুনা সংগ্রহ করে আমরা দেখতে পাই যে, এটি ব্লিস্টার প্যাকের ভিতরে আকারে কিছুটা সংকুচিত হয়ে যায়। যা নিয়ে আমাদের ফর্মুলেশন ডেভেলপমেন্ট ডিপার্টমেন্ট সমস্যাটির সমাধানের জন্য কাজ শুরু করে। পরবর্তীতে তারা দেখতে পায় যে, রেসিপি তে ব্যবহৃত Zinc Sulphate Monohydrate এর পরিবর্তে Zinc Oxide ব্যবহার করলে এবং Copper Gluconate এর পরিমাণের সাথে 40% overage সংযোজন করলে এই ঔষধটির ফর্মুলেশনে উপরে উল্লেখিত সমস্যাটি সমাধানের পাশাপাশি এর স্ট্যাবিলিটিও বৃদ্ধি পায়।

ফর্মুলেশনে আবেদনকৃত পরিবর্তন নিম্নরূপঃ

Name of the Active Ingredients	Existing Formula (qty./Cap)	Proposed Formula (qty./Cap)
Saw Palmetto	160.00 mg	160.00 mg
Pygeum Bark	1.70 mg	1.70 mg
Korean Ginseng	3.30 mg	3.30 mg
Zinc Sulphate Monohydrate	33.10 mg	Nil
Zinc Oxide	Nil	15.00
Copper Gluconate	2.00 mg	2.00 mg (With 40% overage)

ফর্মুলেশনে আবেদনকৃত মূল উপাদান সমূহের পরিমাণগত পরিবর্তনের যৌক্তিকতা:

১. আবেদনে উল্লেখিত Zinc Sulphate Monohydrate এবং Zinc Oxide উভয়েই elemental Zinc নিশ্চিত করে যা Pharmacologically active Zinc এর স্ট্যাবল এবং ইউনিফরম dispersion নিশ্চিত করে।

২. পরিবর্তিত ফর্মুলেশনে 33.1 mg of Zinc Sulphate Monohydrate (যা 12 mg elemental Zinc নিশ্চিত করে) এর পরিবর্তে 15.0 mg Zinc Oxide (যা 12 mg elemental Zinc নিশ্চিত করে) ব্যবহার করা হয়েছে।

৩. পরিবর্তিত ফর্মুলেশনে Copper Gluconate এর পরিমান 2.00 mg এর সাথে 40% overage সংযোজন করা হয়েছে যা জিলাটিন অংশে যুক্ত থাকে। যেহেতু এটি সফটজেল ক্যাপসুল এবং জিলাটিন অংশের process loss সাধারণত ৪০%, সেহেতু Copper Gluconate এর পরিমান ৪০% বৃদ্ধি করা হয়েছে। এতে আরও স্ট্যাবল ফর্মুলেশন নিশ্চিত হয়।

এমতাবস্থায়, ঔষধটির সক্রিয় উপাদানে Zinc Sulphate Monohydrate এর পরিবর্তে Zinc Oxide ব্যবহার করলে এবং Copper Gluconate এর পরিমাণের সাথে 40% overage সংযোজন অনুমোদনের বিষয়ে সভায় উপস্থাপন করা হলো।

টেকনিক্যাল সাব কমিটির সুপারিশঃ মেসার্স স্কয়ার ফার্মাসিউটিক্যালস্ লিমিটেড (হার্বাল ডিভিশন) নামীয় প্রতিষ্ঠানটির "ইউরিপাম সফটজেল ক্যাপসুল" নামীয় ক্যাপসুলটির সক্রিয় উপাদানের সংশোধিত ফর্মুলেশন অনুমোদন করা যেতে পারে।

ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্তঃ মেসার্স স্কয়ার ফার্মাসিউটিক্যালস্ লিমিটেড (হার্বাল ডিভিশন) নামীয় প্রতিষ্ঠানটির "ইউরিপাম সফটজেল ক্যাপসুল" নামীয় ক্যাপসুলটির সক্রিয় উপাদানের সংশোধিত ফর্মুলেশন অনুমোদন করা হলো।