ঔষধ নিয়ন্ত্রণ কমিটির ২০ মার্চ, ২০২২ তারিখে অনুষ্ঠিত ২৫৩ তম সভার কার্যবিবরণী

স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়ের স্বাস্থ্য সেবা বিভাগের সিনিয়র সচিব জনাব লোকমান হোসেন মিয়া মহোদয়- এর সভাপতিত্বে ঔষধ নিয়ন্ত্রণ কমিটির ২৫৩ তম সভা বিগত ২০ মার্চ ২০২২ তারিখ বিকাল ০৩:০০ ঘটিকায় স্বাস্থ্য সেবা বিভাগ, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়ের সভা কক্ষে অনুষ্ঠিত হয়।

সভায় কমিটির নিম্নবর্ণিত সদস্যগণ উপস্থিত ছিলেন (জেষ্ঠ্যতার ক্রমানুসারে নয়) ঃ

১. মেজর জেনারেল মোহাম্মদ ইউসুফ, মহাপরিচালক, ঔষধ প্রশাসন অধিদপ্তর।
২. জনাব মোঃ এনামুল হক, অতিরিক্ত সচিব, স্বাস্থ্য সেবা বিভাগ, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়, বাংলাদেশ সচিবালয়, ঢাকা।
৩. অধ্যাপক ডাঃ মোঃ ইসমাইল খান, উপাচার্য, চট্টগ্রাম মেডিকেল বিশ্ববিদ্যালয়, চট্টগ্রাম।
৪. ব্রিঃ জেঃ মোঃ কুদরত-ই-ইলাহী, উপদেষ্টা চিকিৎসা বিশেষজ্ঞ এবং মেডিক্যাল অনকোলজিস্ট, সি এম এইচ, ঢাকা।
৫. অধ্যাপক সীতেশ চন্দ্র বাছার, ডীন, ফার্মেসী অনুষদ, ঢাকা বিশ্ববিদ্যালয়।
৬. অধ্যাপক ড. এস. এম. আবদুর রহমান, চেয়ারম্যান, ক্লিনিক্যাল ফার্মেসী ও ফার্মাকোলজি, ঢাকা বিশ্ববিদ্যালয়।
৭. জনাব মোঃ মোস্তাফিজুর রহমান, পরিচালক (চঃদাঃ) (প্রশাসন), ঔষধ প্রশাসন অধিদপ্তর।
৮. ডা. দেবাশীষ দাশ, পরিচালক (প্রশাসন), প্রাণিসম্পদ অধিদপ্তর।
৯. প্রফেসর ডা. আহমেদুল কবির, ADG (Admin), স্বাস্থ্য অধিদপ্তর।
১০. অধ্যাপক ডাঃ জাকির হোসাইন গালিব, চর্ম ও যৌন রোগ বিভাগ, স্যার সলিমুল্লাহ্ মেডিকেল কলেজ, ঢাকা।
১১. ডাঃ আফরোজা কুতুবী, অধ্যাপক, গাইনি বিভাগ, স্যার সলিমুল্লাহ্ মেডিকেল কলেজ, মিটফোর্ড হাসপাতাল, ঢাকা।
১২. ডাঃ মোঃ টিটো মিঞা, প্রিন্সিপাল, ঢাকা মেডিকেল কলেজ, ঢাকা।
১৩. ডাঃ জামাল উদ্দিন চৌধুরী, কেন্দ্রীয় কমিটি সদস্য, বাংলাদেশ মেডিকেল এসোসিয়েশন।
১৪. জনাব মোঃ রিয়াজুল হক, সদস্য, বাংলাদেশ ইম্পোর্টার্স এসোসিয়েশন।
১৫. জনাব মুহাম্মদ মাহবুবুল হক, সচিব, বাংলাদেশ ফার্মেসী কাউন্সিল।
১৬. জনাব তানভীর আহমেদ, সহকারী পরিচালক, ঔষধ প্রশাসন অধিদপ্তর।
১৭. জনাব এস, এম, সাবরীনা ইয়াছমিন, সহকারী পরিচালক, ঔষধ প্রশাসন অধিদপ্তর।

পর্যবেক্ষক (জেষ্ঠ্যতার ক্রমানুসারে নয়) ঃ

১. জনাব রাব্বুর রেজা, বিশেষজ্ঞ প্রতিনিধি, বাংলাদেশ ঔষধ শিল্প সমিতি এবং সিওও, মেসার্স বেক্সিমকো ফার্মাসিউটিক্যালস লিঃ।
২. জনাব আব্দুল মুক্তাদির, বিশেষজ্ঞ প্রতিনিধি, বাংলাদেশ ঔষধ শিল্প সমিতি এবং ব্যবস্থাপনা পরিচালক, মেসার্স ইনসেপ্টা ফার্মাসিউটিক্যালস লিঃ।
৩. জনাব মোঃ আবদুর রাজ্জাক, বাংলাদেশ ঔষধ শিল্প সমিতি কর্তৃক মনোনীত মেডিকেল ডিভাইস বিশেষজ্ঞ এবং ব্যবস্থাপনা পরিচালক, জেএমআই সিরিঞ্জেস এন্ড মেডিকেল ডিভাইসেস লিঃ, কুমিল্লা ।
৪. জনাব আ খ মাহবুবুর রহমান সাকী, প্রতিনিধি (ইউনানী) বাংলাদেশ ইউনানী ও আয়ুর্বেদিক বোর্ড।
৫. কবিরাজ শ্রীকৃষ্ণকান্ত রায়, বিশেষজ্ঞ প্রতিনিধি, বাংলাদেশ ইউনানী ও আয়ুর্বেদিক বোর্ড ঢাকা।

সভায় আলোচ্য বিষয়সমূহ :

১. ঔষধ নিয়ন্ত্রণ কমিটির ১৮ ফেব্রুয়ারী, ২০২১ তারিখে অনুষ্ঠিত ২৫২ তম সভার কার্যবিবরণী নিশ্চিতকরণ প্রসঙ্গে ।
২. স্থানীয়ভাবে উৎপাদনের জন্য ৪১২ টি হিউম্যান ঔষধের আবেদনের বিষয়ে সিদ্ধান্ত গ্রহণ।
৩. আমদানীর জন্য ৩৯ টি হিউম্যান ঔষধের আবেদনের বিষয়ে সিদ্ধান্ত গ্রহণ।
৪. স্থানীয়ভাবে উৎপাদনের জন্য ০১ টি হিউম্যান ভ্যাক্সিনের এবং আমদানির লক্ষ্যে ০৩ টি হিউম্যান ভ্যাক্সিনের আবেদনের বিষয়ে সিদ্ধান্ত গ্রহণ।
৫. স্থানীয়ভাবে উৎপাদনের জন্য ৩৩ টি ভেটেরিনারি ঔষধের আবেদনের বিষয়ে সিদ্ধান্ত গ্রহণ।
৬. স্থানীয়ভাবে উৎপাদনের জন্য ১২ টি ভেটেরিনারী ভ্যাক্সিনের আবেদনের বিষয়ে সিদ্ধান্ত গ্রহণ।
৭. আমদানীর জন্য ৯৬ টি ভেটেরিনারি ঔষধের আবেদনের বিষয়ে সিদ্ধান্ত গ্রহণ।
৮. আমদানীর জন্য ১৮ টি একোয়াকালচার প্রডাক্টের বিষয়ে সিদ্ধান্ত গ্রহণ।
৯. স্থানীয়ভাবে উৎপাদনের জন্য ১৫৮ টি হারবাল ঔষধের আবেদনের বিষয়ে সিদ্ধান্ত গ্রহণ।
১০. বিবিধ আলোচনা।

সভার আলোচনা ও সিদ্ধান্ত ঃ

সভাপতি মহোদয় উপস্থিত সকলকে স্বাগত জানিয়ে সভার কার্যক্রম শুরু করেন। তিনি ঔষধ প্রশাসন অধিদপ্তরের মহাপরিচালক মেজর জেনারেল মোহাম্মদ ইউসুফকে সভার আলোচ্যসূচী উপস্থাপনের জন্য অনুরোধ করেন। তিনি সভার আলোচ্যসূচী উপস্থাপন করেন।

তিনি উল্লেখ করেন যে, ইতোমধ্যে ড্রাগ কন্ট্রোল কমিটির ২৫৩ তম সভায় উপস্থাপনের লক্ষ্যে নিম্নবর্ণিত মোট ০৩ টি টেকনিক্যাল সাব কমিটির সভা অনুষ্ঠিত হয়েছে।

- ডিসিসি এর টেকনিক্যাল সাব কমিটির (হিউম্যান মেডিসিন ও ভ্যাক্সিন) সভা ০২ টিঃ ২৪/১০/২০২১ ও ১৪/১২/২০২১ তারিখে অনুষ্ঠিত হয়।
- হার্বাল এডভাইজরি কমিটির (ডিসিসি এর টেকনিক্যাল সাব কমিটি) সভা ০১ টিঃ ২৮/১২/২০২১ তারিখে অনুষ্ঠিত হয়।

ড্রাগ কন্ট্রোল কমিটির ২৫২ তম সভার কার্যবিবরণী নিশ্চিতকরণঃ

তিনি প্রথমেই ড্রাগ কন্ট্রোল কমিটির ২৫২ তম সভার কার্যবিবরণী নিশ্চিতকরণ সংক্রান্ত বিষয়াদি উপস্থাপন করেন। সভায় নিম্নবর্ণিত সিদ্ধান্ত সহকারে ড্রাগ কন্ট্রোল কমিটির ২৫২ তম সভার কার্যবিবরণী নিশ্চিত করা হয়।

(ক) নিম্নবর্ণিত দুইটি পদের বিষয়ে সাইক্রিয়াটিস্ট এর মতামত গ্রহণের জন্য পুনরায় পত্র প্রেরণের সিদ্ধান্ত গৃহীত হয়।

পদসমূহঃ

(a) Pitolisant hydrochloride equivalent to Pitolisant 4.45 mg Tablet,

(b) Pitolisant hydrochloride equivalent to Pitolisant 17.8 mg Tablet

(খ) নিম্নবর্ণিত পদের বিষয়ে ইউরোলজিস্ট এর মতামত গ্রহণের জন্য পুনরায় পত্র প্রেরণের সিদ্ধান্ত গৃহীত হয়।

পদটিঃ

(a) Tiopronin 100 mg delayed release tablet

(গ) MUPS হিসেবে প্রয়োজনীয় রেফারেন্স না থাকায় Rabeprazole Sodium Delayed release Pellets 15% w/w (Mups) Ph. Grade 133.333 mg (Eq. to 20 mg of Rabeprazole Sodium , MUPS Tablet টি ড্রাগ কন্ট্রোল কমিটির ২৫২ তম সভায় বাতিল করা হয়। মেসার্স বীকন ফার্মাসিউটিক্যালস পদটি বহাল রাখার বিষয়ে আপিল করে, যা এখনও নিষ্পন্ন হয়নি। এতদ্ববিষয়ে আপিলের সিদ্ধান্ত চূড়ান্ত হিসেবে বিবেচিত হবে।

(ঘ) বর্তমান বিশ্বে প্রায় 1.27 million মানুষ Antimicrobial Resistant (AMR) এর কারণে মারা যাচ্ছে। এ অবস্থা চলতে থাকলে ২০৫০ সালে প্রতি বছর মারা যাবে প্রায় ১ কোটি মানুষ। Antimicrobial Resistant (AMR) এর বিষয়টিকে বিবেচনায় নিয়ে ড্রাগ কন্ট্রোল কমিটির ২৫২ তম সভায় এন্টিবায়োটিকগুলোকে সহজে চেনার জন্য আইডেন্টিফিকেশন মার্ক প্রণয়নের বিষয়ে ঔষধ প্রশাসন অধিদপ্তর এবং ঔষধ শিল্প সমিতিকে আলোচনার মাধ্যমে সিদ্ধান্ত গ্রহণের নির্দেশনা প্রদান করা হয়।

ঔষধ প্রশাসন অধিদপ্তর হতে ফার্মেসী রিটেইলারদের মধ্যে Antimicrobial Resistant (AMR) এর বিষয়ে সচেতনতার স্তর যাচাইয়ের লক্ষ্যে বাংলাদেশের ০৮ টি বিভাগে ৪২৭ জন ফার্মেসী রিটেইলারদের উপর একটি সার্ভে করা হয়। যেখান থেকে দেখা গেছে ৬৭.৩% ফার্মেসী রিটেইলার এন্টিমাইক্রোবিয়াল মেডিসিন চেনেন না এবং তারা সহজেই এন্টিবায়োটিকগুলো সনাক্ত করতে পারেন না। প্রস্তাবিত ঔষধ আইনে প্রেসক্রিপশন ছাড়া এন্টিবায়োটিক বিক্রয়ে শাস্তির বিধান রাখা হয়েছে। কিন্তু এই ফার্মেসী রিটেইলাররা যেন সহজেই এন্টিবায়োটিকগুলো সনাক্ত করতে পারেন সে ব্যবস্থা রাখাও প্রয়োজন।

যে কারণে ঔষধ প্রশাসন অধিদপ্তর হতে আর একটি Key Informant Interview ১৪ জন ব্যক্তির নেওয়া হয়। উক্ত Key Informant Interview এ অনেকগুলো আইডেন্টিফিকেশন মার্কসহ এন্টিবায়োটিকের প্রাইমারী ও সেকেন্ডারী প্যাকেজিং মাটেরিয়াল এর ডিজাইন উপস্থাপন করা হয় এবং এর উপর তাঁদের মতামত প্রদানে জন্য বলা হয় এবং তাঁরা যে সমস্ত প্যাকেজিং মাটেরিয়াল এর ডিজাইন ইফেক্টিভ বলে মতামত

দেন সেগুলো ৩০ জানুয়ারী, ২০২২ এ ঔষধ প্রশাসন অধিদপ্তর ও বাংলাদেশ ঔষধ শিল্প সমিতির মাধ্যে এতদ্ব বিষয়ে অনুষ্ঠিত সভায় উপস্থাপন করা হয়।

উক্ত সভায় নিম্নোক্ত আইডেন্টিফিকেশন মার্কসহ এন্টিবায়োটিকের প্রাইমারী ও সেকেন্ডারী প্যাকেজিং মাটেরিয়াল এর বিষয়ে নিম্নোক্ত সুপারিশ করা হয়ঃ

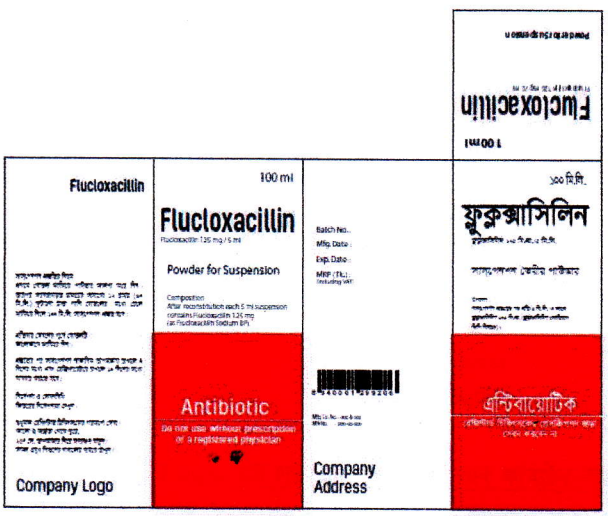
"এন্টিবায়োটিক এর কার্টনের একপাশে লাল আইডেন্টিফিকেশন মার্ক এর উপর বাংলায় "এন্টিবায়োটিক" এবং "নিবন্ধিত চিকিৎসকের প্রেসক্রিপশন ছাড়া ব্যবহার করবেন না" লিখা থাকবে এবং কার্টনের অপর পাশে লাল আইডেন্টিফিকেশন মার্ক এর উপর ইংরেজীতে লিখা থাকবে "Antibiotic" এবং " Do not use without prescription of registered physician". প্রাইমারী প্যাকেজিং (স্ট্রিপ, ব্লিস্টার) এর দুই পাশে লাল আইডেন্টিফিকেশন মার্ক এর উপর বাংলায় "এন্টিবায়োটিক" এবং ইংরেজীতে "Antibiotic" লিখা থাকবে।
এই সিদ্ধান্ত বাস্তবায়নের জন্য এন্টিবায়োটিক উৎপাদনকারী প্রতিষ্ঠানসমূহকে ০৬ মাস সময় দেওয়া হবে। তবে যারা এন্টিবায়োটিক জাতীয় পদের রেজিস্ট্রেশনের জন্য নতুন আবেদন করবেন, তারা মোড়ক সামগ্রী অনুমোদনের সময় উক্ত নির্দেশনা মোতাবেক মোড়ক সামগ্রী দাখিল করবেন।"

সিনিয়র সচিব, স্বাস্থ্য সেবা বিভাগ, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয় বলেন, এটি নিঃসন্দেহে একটি যুগান্তকারী পদক্ষেপ এবং এ জন্য তিনি ঔষধ প্রশাসন অধিদপ্তর এবং ঔষধ শিল্প সমিতিকে সাধুবাদ জানান। তিনি পরবর্তীতে Antimicrobial Resistance নিয়ে সারাদেশব্যপি জনসচেতনতা বৃদ্ধিতে awareness program করার এবং প্রিন্ট ও ইলেকট্রনিক মিডিয়ার মাধ্যমে বিষয়টি প্রচারের জন্য ঔষধ প্রশাসন অধিদপ্তরকে নির্দেশনা প্রদান করেন। সভায় সর্বসম্মতিক্রমে নিম্নোক্ত সিদ্ধান্ত গৃহীত হয়।

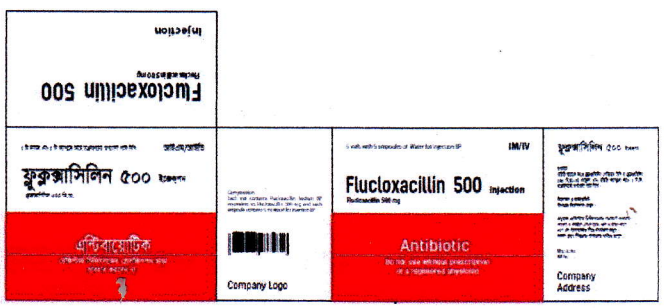
ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্তঃ

"এন্টিবায়োটিক এর কার্টনের একপাশে লাল আইডেন্টিফিকেশন মার্ক এর উপর বাংলায় "এন্টিবায়োটিক" এবং "নিবন্ধিত চিকিৎসকের প্রেসক্রিপশন ছাড়া ব্যবহার করবেন না" লিখা থাকবে এবং কার্টনের অপর পাশে লাল আইডেন্টিফিকেশন মার্ক এর উপর ইংরেজীতে লিখা থাকবে "Antibiotic" এবং " Do not use without prescription of registered physician". প্রাইমারী প্যাকেজিং (স্ট্রিপ, ব্লিস্টার) এর দুই পাশে লাল আইডেন্টিফিকেশন মার্ক এর উপর বাংলায় "এন্টিবায়োটিক" এবং ইংরেজীতে "Antibiotic" লিখা থাকবে।
এই সিদ্ধান্ত বাস্তবায়নের জন্য এন্টিবায়োটিক উৎপাদনকারী প্রতিষ্ঠানসমূহকে ০৬ মাস সময় দেওয়া হবে। তবে যারা এন্টিবায়োটিক জাতীয় পদের রেজিস্ট্রেশনের জন্য নতুন আবেদন করবেন, তারা মোড়ক সামগ্রী অনুমোদনের সময় উক্ত নির্দেশনা মোতাবেক মোড়ক সামগ্রী দাখিল করবেন।"

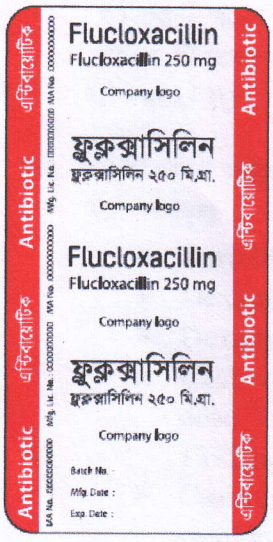
Text for Inner Carton of powder for Suspension



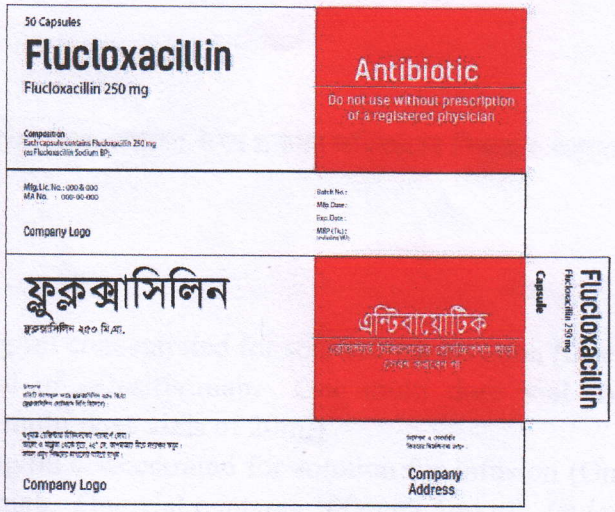
Text for Inner Carton of Injection



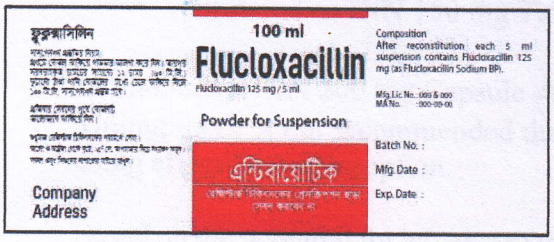
Text for Printed Foil of Tablet/Capsule



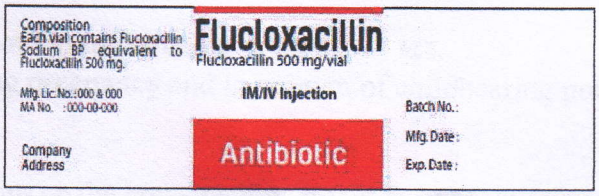
Text for Inner Carton of Tablet/Capsule



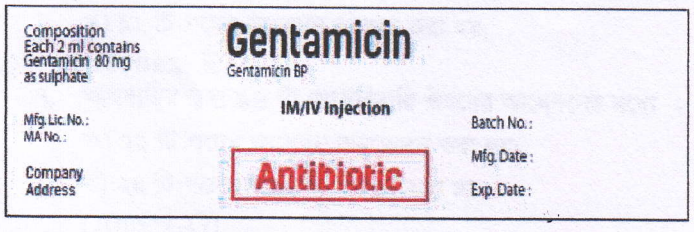
Text for Label of powder for Suspension



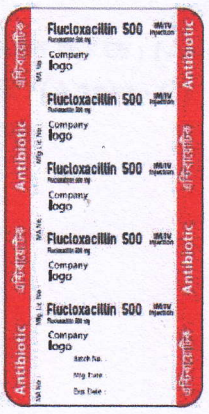
Text for Label of Vial/ ampoule



Text for Ceramic Printing in Ampoule



Text for Printed Foil of Injection



ড্রাগ কন্ট্রোল কমিটির ২৫৩তম সভায় টেকনিক্যাল সাব কমিটির সভাসমূহের সুপারিশসমূহের বিষয়ে সিদ্ধান্ত ঃ

১. স্থানীয়ভাবে উৎপাদনের জন্য ৪১২ টি হিউম্যান ঔষধের আবেদনের মধ্যে -

ক) ১৮৯ টি পদের আবেদন অনুমোদন করা হয়;

খ) ২২৩ টি পদের আবেদন নামঞ্জুর করা হয়;

গ) Griseofulvin USP ultramicrosize 250 mg Tablet এর আবেদন নামঞ্জুরের সিদ্ধান্ত গৃহীত হয়। কারণ বিভিন্ন ডোজেস ফরম বাজারে সরবরাহ থাকার কারণে Anti Microbial Resistance বৃদ্ধির সম্ভবনা রয়েছে।

(Annex- A)

২. আমদানীর জন্য ৩৯ টি হিউম্যান ঔষধের আবেদনের মধ্যে-

ক) ৩৩ টি পদের আবেদন অনুমোদন করা হয়;

খ) ০৬ টি পদের আবেদন নামঞ্জুর করা হয়;

(Annex- B)

৩. ০৭ টি পদের অনুকূলে **Emergency Use Authorization** প্রদানের ঔষধ প্রশাসন অধিদপ্তরের সিদ্ধান্তকে অনুমোদন করা হয়। পদসমূহঃ

- Baricitinib 4mg Tablet,
- Dexamethasone 6mg Tablet,
- Dexamethasone 6mg/ml inj,
- Casirivimab and Imdevimab 120mg/ml concentrated for solution for infusion (One multi dose vial contains 1332mg/11.1ml of Casirivimab, One multi dose vial contains 1332mg/11.1ml of Imdevimab (2 multi dose vials of 20ml)
- Casirivimab and Imdevimab 120mg/ml concentrated for solution for infusion (One vial contains 300mg/2.5ml of Casirivimab, One vial contains 300mg/2.5ml of Imdevimab (2 vials of 6ml)
- Molnupiravir INN 200 mg Capsule.
- Nirmatrelvir INN 150 mg Tablet এবং Ritonavir 100 mg Tablet এর কো- প্যাক।

Molnupiravir INN 200 mg Capsule এর patient information এ উল্লেখ করতে হবে,
Molnupiravir is not recommended during pregnancy and in women of childbearing potential not using effective contraception.

Based on the potential for adverse reactions on the breastfeeding infant from Molnupiravir, breast-feeding should be interrupted during treatment and for 4 days after the last dose of Molnupiravir.
(Annex- D)

৪. স্থানীয়ভাবে উৎপাদনের জন্য ১ টি হিউম্যান ভ্যাক্সিনের আবেদন অনুমোদন করা হয়। **(Annex- C)**

৫. আমদানীর জন্য ৩ টি হিউম্যান ভ্যাক্সিনের আবেদন অনুমোদন করা হয়। **(Annex- C)**

৬. স্থানীয়ভাবে উৎপাদনের জন্য ৩৩ টি ভেটেরিনারি ঔষধের আবেদনের মধ্যে -

ক) ২১ টি পদের আবেদন অনুমোদন করা হয়;

খ) ১২ টি পদের আবেদন নামঞ্জুর করা হয়;

(Annex- E)

৭. আমদানীর জন্য ৯৬ টি ভেটেরিনারি ঔষধের আবেদনের মধ্যে -

ক) ৭২ টি পদের আবেদন অনুমোদন করা হয়;

খ) ২৪ টি পদের আবেদন নামঞ্জুর করা হয়;

(Annex-G)

৮. স্থানীয়ভাবে উৎপাদনের জন্য আবেদিত নতুন ১২ টি ভেটেরিনারী ভ্যাক্সিন এর মধ্যে ০৬টি ভ্যাক্সিনের ফিল্ড ট্রায়াল রিপোর্ট দাখিল করায় উক্ত ০৬টি এ্যানিমেল ভ্যাক্সিন শর্ত ব্যতীত এবং বাকী ০৬টি ভ্যাক্সিনের আবেদন শর্তসাপেক্ষে মঞ্জুর করা হয়। (Annex-G)

৯. ভেটেরিনারী ঔষধের আবেদনের বিষয়ে প্রাণী সম্পদ অধিদপ্তরের নিকট কোন মতামত চাওয়া হলে মতামতসমূহ লিখিতভাবে উক্ত বিষয়ে প্রাণী সম্পদ অধিদপ্তরে অনুষ্ঠিত সভার কার্যবিবরণীসহ ট্যাকনিক্যাল সাব কমিটিতে প্রেরণ করতে হবে।

১০. আমদানীর জন্য ১৮ টি নতুন একোয়াকালচার প্রোডাক্ট এর আবেদন স্থগিত রাখা হয়। এই প্রডাক্টগুলো মূল্যায়নের লক্ষ্যে একটি কমিটিও গঠণ করা হয়েছে। উক্ত কমিটির মতামতের প্রেক্ষিতে পরবর্তীতে এই ১৮ টি একোয়াকালচার প্রোডাক্ট এর বিষয়ে সিদ্ধান্ত গ্রহণ করা হবে। (Annex-H)

১১. ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটি ও ড্রাগ কন্ট্রোল কমিটিতে ডিপার্টমেন্ট অব ফিশারিজ হতে প্রতিনিধি অন্তর্ভূক্তকরণের সিদ্ধান্ত গৃহীত হয়।

১২. পরিবেশ, বন ও জলবায়ু পরিবর্তন মন্ত্রণালয়ের ইদ্যোগে ০৮ ফেব্রুয়ারী, ২০২১ তারিখে মহাবিপন্ন শকুন রক্ষার্থে ক্ষতিকর ভেটেরিনারী ঔষধ কিটোপ্রোফেন উৎপাদন বন্ধকরণের জন্য মন্ত্রী পরিষদ বিভাগ হতে নির্দেশনা প্রদান করা হয়। যার পরিপ্রেক্ষিতে স্বাস্থ্য সেবা বিভাগ, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়ের স্মারক নং-৪৫.০০.০০০০.১৮২.৯৯.০০১.২০.২৮৪, তারিখঃ ২৫ নভেম্বর, ২০২১ মোতাবেক মহাবিপন্ন শকুন রক্ষার্থে ক্ষতিকর ভেটেরিনারী ঔষধ কিটো প্রোফেন উৎপাদন বন্ধকরণের নিমিত্তে প্রয়োজনীয় ব্যবস্থা গ্রহণের জন্য নির্দেশনা প্রদান করা হয়।
ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সভার সুপারিশ ঃ মহাবিপন্ন শকুন রক্ষার্থে ক্ষতিকর ভেটেরিনারী ঔষধ কিটোপ্রোফেন বাতিলের সুপারিশ করা হয়।

ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত ঃ মহাবিপন্ন শকুন রক্ষার্থে ক্ষতিকর ভেটেরিনারী ঔষধ কিটোপ্রোফেন বাতিলের সিদ্ধান্ত গৃহীত হয়।

১৩. প্রাণি চিকিৎসায় Colistin জাতীয় ঔষধের সকল ডোসেজ ফরম (Oral solution & Injectable Form) বাতিলের বিষয়ে প্রাণিসম্পদ অধিদপ্তরের মতামত চেয়ে পত্র প্রেরণ করা হয়। যার পরিপ্রেক্ষিতে প্রাণীসম্পদ অধিদপ্তর হতে প্রাণি চিকিৎসায় Colistin জাতীয় ঔষধের সকল ডোসেজ ফরম (Oral solution & Injectable Form) বাতিলের সুপারিশ করা হয়। ড্রাগ কন্ট্রোল কমিটির ২৫৩ তম সভায় প্রাণি চিকিৎসায় Colistin জাতীয় ঔষধের সকল ডোসেজ ফরম (Oral solution & Injectable Form) বাতিল করা হয়।

১৪. **স্থানীয়ভাবে উৎপাদনের জন্য ১৫৮ টি হারবাল ঔষধের আবেদনের মধ্যে -**

ক) ৭৬ টি পদের আবেদন অনুমোদন করা হয়;
খ) ৮১ টি পদের আবেদন নামঞ্জুর করা হয়;
গ) ০১ টি পদ (Astaxanthin powder 5% 40 mg) কার্ডিওলজিস্ট এর মতামত গ্রহণের সিদ্ধান্ত গৃহীত হয়।
(Annex- G)

১৫. হার্বাল ঔষধের শ্রেণিগত (Generic) নামের ক্ষেত্রে বৈজ্ঞানিক নাম উল্লেখ করার সিদ্ধান্ত গৃহীত হয়।

১৬. হার্বাল ঔষধ অনুমোদনের জন্য ২১তম রেফারেন্স বুক হিসাবে European Medicine Agency এর ফার্মাকোপিয়া অন্তর্ভূক্ত করা হয়।

১৭. ড্রাগ কন্ট্রোল কমিটির ২৫০ তম সভার সিদ্ধান্ত মোতাবেক দেশে উৎপাদনের ক্ষেত্রে কোন ঔষধের রেজিস্ট্রেশন মূল্যায়নের লক্ষ্যে রেফারেন্স হিসেবে USFDA, UKMHRA, EMA এবং BNF-এ অন্তর্ভুক্তির রেফারেন্স বিবেচনা করা হয়। ড্রাগ কন্ট্রোল কমিটির ২৫৩ তম সভায় উক্ত রেফারেন্সগুলোর সাথে PMDA (Japan) এবং TGA (Australia) এর রেফারেন্সকে বিবেচনা করার সিদ্ধান্ত গৃহীত হয়।

১৮. টোটিসেল লিঃ নামীয় প্রতিষ্ঠানটি Human Umbilical Cord Mesenchymal Stem/Stromal Cells নামীয় পদটির অনুমোদনের জন্য আবেদন করেছে। এ ধরনের স্টেম সেল প্রোডাক্ট বাংলাদেশে নতুন। পদটি ড্রাগ কন্ট্রোল কমিটি কর্তৃক অনুমোদিত নয় বিধায় ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির মতামত প্রয়োজন ছিল। প্রতিষ্ঠানটি ১৪ ডিসেম্বর, ২০২১ তারিখে অনুষ্ঠিত টেকনিক্যাল সাব কমিটির মতামতের পর আবেদন করে, যেহেতু ২০ মার্চ, ২০২২ এ ড্রাগ কন্ট্রোল কমিটির সভা অনুষ্ঠিত হয়, এ জন্য পদটির বিষয়ে ই-মেইলে মতামত প্রদানের জন্য ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সম্মানিত সদস্যদের পত্র প্রেরণ করা হয়। ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির ০৮ জন সদস্য প্রডাক্টটি অনুমোদনের বিষয়ে সুপারিশ করেন।

ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত:

নিম্নোক্ত সদস্যদের সমন্বয়ে একটি পরিদর্শক দল গঠণের সিদ্ধান্ত গৃহীত হয়।

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

উক্ত সদস্যগণ টোটিসেল লিঃ নামীয় প্রতিষ্ঠানটির উৎপাদন ফ্যাসিলিটিজ পরিদর্শন করতঃ মতামত প্রদান করবেন, যা পরবর্তী ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সভায় উপস্থাপন করা হবে।

১৯. ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সভা প্রতি মাসে ০১ বার করে এবং প্রতি ০৩ মাস অন্তর অন্তর ড্রাগ কন্ট্রোল কমিটির সভা অনুষ্ঠিত হওয়ার সিদ্ধান্ত গৃহীত হয়।

২০. বিবিধ আলোচনা। **(Annex- D)**

২১. ভেটেরিনারি ঔষধ সম্পর্কিত বিবিধ আলোচনা। **(Annex- I)**

অন্য কোন আলোচ্য বিষয় না থাকায় সভাপতি মহোদয় উপস্থিত সকলকে ধন্যবাদ জ্ঞাপন করে সভার সমাপ্তি ঘোষণা করেন।

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

লোকমান হোসেন মিয়া
সিনিয়র সচিব, স্বাস্থ্য সেবা বিভাগ
স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়
ও
সভাপতি
ঔষধ নিয়ন্ত্রণ কমিটি

Annex-A: Proposed Product for locally manufacture (Human)

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
1.	Beximco Pharmaceuticals Ltd. Ziska Pharmaceuticals Ltd. Opsonin Pharma Limited, Rupatali, Barishal. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna General Pharmaceutical Ltd., Gazipur Popular Pharmaceuticals Ltd., Tongi, Gazipur Beacon Pharmaceuticals Limited Healthcare Pharmaceuticals Ltd. Eskayef Pharmaceuticals	Empagliflozin 10 mg + Linagliptin 5 mg Tablet	Empagliflozin INN 10 mg + Linagliptin INN 5 mg	Therapeutic Class: Antidiabetic Therapeutic Code:015	It is a combination of empagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor and linagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. **Limitations of Use** • Not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients • Has not been studied in patients with a history of pancreatitis • Not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m	Contra-indication: • Patients on dialysis • Hypersensitivity to empagliflozin, linagliptin, or any of the excipients in this combination. Side-effects: The most common side effects are • urinary tract infection • stuffy or runny nose and sore throat • upper respiratory tract infection Warnings and Precautions: Pancreatitis: There have been postmarketing reports of acute pancreatitis, including fatal pancreatitis. If pancreatitis is suspected, promptly discontinue combination. • Heart Failure: Heart failure has been observed with two other members of the DPP-4 inhibitor class. Consider risks and benefits of Combination in patients who have known risk factors for heart failure. Monitor for signs and symptoms.	Empagliflozin 10mg and 25mg Tablet, Linagliptin 5 mg Tablet	USFDA ডিসিসি-২৫২ তম সভায় উক্ত পদটি ডিসিসি-২৫৩ তম সভায় উপস্থাপনের সিদ্ধান্ত প্রদান করা হয়েছিল। আমদানির জন্যও আবেদন করা হয়েছে। SI: 32	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদনকারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Limited, Tongi, Gazipur. NIPRO JMI Pharma Ltd, Rajandrapur, Chaddagram, Cumilla The ACME Laboratories Ltd. Dhamrai, Dhaka Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Delta Pharma Ltd. Pharmacil Limited.									
2.	Beximco Pharmaceuticals Ltd. Ziska Pharmaceuticals Ltd. Opsonin Pharma Limited, Rupatali, Barishal. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Empagliflozin 25 mg + Linagliptin 5 mg Tablet	Empagliflozin INN 25 mg + Linagliptin INN 5 mg	Therapeutic Class: Antidiabetic Therapeutic Code:015	It is a combination of empagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor and linagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. **Limitations of Use** • Not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic	Contra-indication: • Patients on dialysis • Hypersensitivity to empagliflozin, linagliptin, or any of the excipients in this combination. Side-effects: The most common side effects are • urinary tract infection • stuffy or runny nose and sore throat • upper respiratory tract infection Warnings and Precautions: Pancreatitis: There have been postmarketing reports of acute pancreatitis, including fatal pancreatitis. If pancreatitis is suspected, promptly discontinue	Empagliflozin 10mg and 25mg Tablet, Linagliptin 5 mg Tablet	USFDA ডিসিসি-২৫২ তম সভায় উক্ত পদটি ডিসিসি-২৫৩ তম সভায় উপস্থাপনের সিদ্ধান্ত প্রদান করা হয়েছিল। আমদানির জন্যও আবেদন করা হয়েছে। SI: 33	**অনুমোদনের সুপারিশ করা হয়।**	**অনুমোদন করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	General Pharmaceutical Ltd., Gazipur Beacon Pharmaceuticals Limited Healthcare Pharmaceuticals Ltd Eskayef Pharmaceuticals Limited, Tongi, Gazipur. NIPRO JMI Pharma Ltd, Rajandrapur, Chaddagram, Cumilla The ACME Laboratories Ltd. Dhamrai, Dhaka Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka **Delta Pharma Ltd.** **Pharmacil**				ketoacidosis in these patients • Has not been studied in patients with a history of pancreatitis • Not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m	combination. • Heart Failure: Heart failure has been observed with two other members of the DPP-4 inhibitor class. Consider risks and benefits of Combination in patients who have known risk factors for heart failure. Monitor for signs and symptoms.				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Limited. Popular Pharmaceuticals Ltd., Tongi, Bangladesh									
3.	Beximco Pharmaceuticals Ltd.	Benidipine Hydrochloride 4 mg Tablet	Benidipine Hydrochloride INN 4 mg	Therapeutic Class: Antihypertensive Therapeutic Code:022	It is a potent and long-lasting drug indicated for the treatment of cardiovascular diseases such as hypertension, renoparenchymal hypertension and angina pectoris	Contrindication: • Hypersensitivity to the dihydropyridine Ca2+ channel blockers. • Pregnancy and lactation Side-effects: • Headache • Dizziness • Constipation • Skin rash • Decreased blood pressure • Nausea • Lightheadedness • Palpitations • Edema Warning & Precautions: • It may cause dizziness or lightheadedness, do not drive a car or operate machinery while taking this medication. • Avoid abrupt withdrawal.	New	রেফারেন্স নাই। Japan	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						• Monitor liver function regularly while taking this medication.				
4.	Beximco Pharmaceuticals Ltd.	Benidipine Hydrochloride 8 mg Tablet	Benidipine Hydrochloride INN 8 mg	Therapeutic Class: Antihypertensive Therapeutic Code:022	It is a potent and long-lasting drug indicated for the treatment of cardiovascular diseases such as hypertension, renoparenchymal hypertension and angina pectoris	Contrindication: • Hypersensitivity to the dihydropyridine Ca2+ channel blockers. • Pregnancy and lactation Side-effects: • Headache • Dizziness • Constipation • Skin rash • Decreased blood pressure • Nausea • Lightheadedness • Palpitations • Edema Warning & Precautions: • It may cause dizziness or lightheadedness, do not drive a car or operate machinery while taking this medication. • Avoid abrupt withdrawal. • Monitor liver function regularly while taking this medication.	New	রেফারেন্স নাই। Japan	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**
5.	Beximco Pharmaceuticals Ltd. Beacon Pharmaceuticals	Amlodipine 5 mg + Olmesartan 20 mg + Hydrochlorothiazide 12.5 mg Tablet	Amlodipine Besilate BP 5 mg + Olmesartan Medoxomil BP 20 mg + Hydrochlorothiazid	Therapeutic Class: Antihypertensive Therapeutic Code:022	It is a combination of olmesartan medoxomil, an angiotensin II receptor blocker, amlodipine, a dihydropyridine calcium channel blocker, and hydrochlorothiazide, a thiazide diuretic, indicated for the treatment of	Warning: Fetal Toxicity Contra-indication: • Anuria: Hypersensitivity to sulfonamide-derived drugs. • Do not co-administer aliskiren with Tribenzor in patients with diabetes	Amlodipine 5 mg + Olmesartan 20 mg combination tablet and	USFDA	**প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Limited		e BP 12.5 mg		hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Limitations of Use: It is not indicated for initial therapy.	Side-effect: The most common Side-effects of amlodipine, Olmesartan and Hydrochlorothiazide combination tablets used to treat people with high blood pressure include dizziness, swelling (edema) of the ankles, feet, and hands, headache, tiredness, stuffy or runny nose and sore throat, muscle twitching (spasms), nausea. Warning & Precautions: • Hypotension: Correct volume or salt depletion prior to administration. • Monitor renal function and potassium in susceptible patients • Increased angina or myocardial infarction with calcium channel blockers may occur upon dosage initiation or increase.	Olmesartan 20 mg + Hydrochlorothiazide 12.5 mg combination tablet available.			
6.	Beximco Pharmaceuticals Ltd.	Amlodipine 5 mg + Olmesartan 40 mg + Hydrochlorothiazide 12.5 mg Tablet	Amlodipine Besilate BP 5 mg + Olmesartan Medoxomil BP 40 mg + Hydrochlorothiazide BP 12.5 mg	Therapeutic Class: Antihypertensive Therapeutic Code:022	It is a combination of olmesartan medoxomil, an angiotensin II receptor blocker, amlodipine, a dihydropyridine calcium channel blocker, and hydrochlorothiazide, a thiazide diuretic, 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. Limitations of Use: It is not indicated for initial therapy.	Warning: Fetal Toxicity Contra-indication: • Anuria: Hypersensitivity to sulfonamide-derived drugs. • Do not co-administer aliskiren with Tribenzor in patients with diabetes Side-effect: The most common Side-effects of amlodipine, Olmesartan and Hydrochlorothiazide combination tablets used to treat people with high blood pressure include dizziness, swelling (edema) of the ankles, feet, and hands, headache, tiredness, stuffy or runny nose and sore throat, muscle twitching (spasms), nausea. Warning & Precautions: • Hypotension: Correct volume or salt depletion	Amlodipine 5 mg + Olmesartan 40 mg combination tablet and Olmesartan 40 mg + Hydrochlorothiazide 12.5 mg combination tablet available.	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						prior to administration. • Monitor renal function and potassium in susceptible patients • Increased angina or myocardial infarction with calcium channel blockers may occur upon dosage initiation or increase.				
7.	Beximco Pharmaceuticals Ltd.	Amlodipine 5 mg + Olmesartan 40 mg + Hydrochlorothiazide 25 mg Tablet	Amlodipine Besilate BP 5 mg + Olmesartan Medoxomil BP 40 mg + Hydrochlorothiazide BP 25 mg	Therapeutic Class: Antihypertensive Therapeutic Code:022	It is a combination of olmesartan medoxomil, an angiotensin II receptor blocker, amlodipine, a dihydropyridine calcium channel blocker, and hydrochlorothiazide, a thiazide diuretic, 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. Limitations of Use: It is not indicated for initial therapy.	Warning: Fetal Toxicity Contra-indication: • Anuria: Hypersensitivity to sulfonamide-derived drugs. • Do not co-administer aliskiren with Tribenzor in patients with diabetes Side-effect: The most common Side-effects of amlodipine, Olmesartan and Hydrochlorothiazide combination tablets used to treat people with high blood pressure include dizziness, swelling (edema) of the ankles, feet, and hands, headache, tiredness, stuffy or runny nose and sore throat, muscle twitching (spasms), nausea. Warning & Precautions: • Hypotension: Correct volume or salt depletion prior to administration. • Monitor renal function and potassium in susceptible patients • Increased angina or myocardial infarction with calcium channel blockers may occur upon dosage initiation or increase.	Amlodipine 5 mg + Olmesartan 40 mg combination tablet and Olmesartan 40 mg + Hydrochlorothiazide 12.5 mg combination tablet available.	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
8.	Beximco Pharmaceuticals Ltd. Beacon Pharmaceuticals	Atorvastatin 10 mg + Ezetimibe 10 mg Tablet	Atorvastatin calcium USP eq. to Atorvastatin 10 mg + Ezetimibe USP 10 mg	Therapeutic Class: Lipid Lowering Therapeutic Code:061	It contains a cholesterol absorption inhibitor and an HMG-CoA reductase inhibitor (statin), is indicated as adjunctive therapy to diet to: • reduce elevated total-C, LDL-C, Apo B, TG, and non-HDL-C, and to	Contra-indication: Active liver disease or unexplained persistent elevations of hepatic transaminase levels. • Hypersensitivity to any component of the combination • Women who are pregnant or may become	Atorvastatin 10 mg & 20 mg Tablet Ezetimibe 10mg tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Limited **Navana Pharmaceuticals Limited** **Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna** The ACME Laboratories Ltd. Dhamrai, Dhaka Delta Pharma Ltd.				increase HDL-C in patients with primary (heterozygous familial and non-familial) hyperlipidemia or mixed hyperlipidemia. • reduce elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH), as an adjunct to other lipidlowering treatments. Limitations of Use: • No incremental benefit of this combination on cardiovascular morbidity and mortality over and above that demonstrated for atorvastatin has been established. It has not been studied in Fredrickson Type I, III, IV, and V dyslipidemias.	pregnant. • Nursing mothers. Side-effects: Common adverse reactions (incidence ≥2% and greater than placebo) are: increased ALT, increased AST, and musculoskeletal pain. Warning & Precautions: Patients should be advised to report promptly any unexplained and/or persistent muscle pain, tenderness, or weakness. •Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): • Liver enzyme abnormalities				
9.	Beximco Pharmaceuticals Ltd. Beacon Pharmaceuticals Limited Navana Pharmaceuticals Limited Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna The ACME	Atorvastatin 20 mg + Ezetimibe 10 mg Tablet	Atorvastatin calcium USP eq. to Atorvastatin 20 mg + Ezetimibe USP 10 mg	Therapeutic Class: Lipid Lowering Therapeutic Code:061	It contains a cholesterol absorption inhibitor and an HMG-CoA reductase inhibitor (statin), is indicated as adjunctive therapy to diet to: • reduce elevated total-C, LDL-C, Apo B, TG, and non-HDL-C, and to increase HDL-C in patients with primary (heterozygous familial and non-familial) hyperlipidemia or mixed hyperlipidemia. • reduce elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH), as an adjunct to other lipidlowering treatments. Limitations of Use: • No incremental benefit of this	Contra-indication: Active liver disease or unexplained persistent elevations of hepatic transaminase levels. • Hypersensitivity to any component of the combination • Women who are pregnant or may become pregnant. • Nursing mothers. Side-effects: Common adverse reactions (incidence ≥2% and greater than placebo) are: increased ALT, increased AST, and musculoskeletal pain. Warning & Precautions: Patients should be advised to report promptly any unexplained and/or persistent muscle pain, tenderness, or	Atorvastatin 10 mg & 20 mg Tablet Ezetimibe 10mg tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Laboratories Ltd. Dhamrai, Dhaka Delta Pharma Ltd.				combination on cardiovascular morbidity and mortality over and above that demonstrated for atorvastatin has been established. It has not been studied in Fredrickson Type I, III, IV, and V dyslipidemias.	weakness. •Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): • Liver enzyme abnormalities				
10.	Beximco Pharmaceuticals Ltd. Ziska Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna General Pharmaceutical Ltd., Gazipur Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirganj, Narayanganj-1431 Drug International Ltd (Unit-3) 31/1,Satrong,	Rosuvastatin 5 mg + Ezetimibe 10 mg Tablet	Rosuvastatin Calcium BP eq. to Rosuvastatin 5 mg + Ezetimibe USP 10 mg	Therapeutic Class: Lipid Lowering Therapeutic Code:061	It is a combination of rosuvastatin, an HMG CoA-reductase inhibitor (statin), and ezetimibe, a dietary cholesterol absorption inhibitor, indicated in adults: • As an adjunct to diet in patients with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDLC). • Alone or as an adjuct to other LDL-C lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.	Contraindication: Active liver failure or decompensated cirrhosis • Hypersensitivity to any component of combination Side-effects: The most common side effects of ROSZET include: headache, nausea, muscle aches and pains, weakness, constipation, common cold and flu, diarrhea, dizziness, joint pain, stomach pain, runny nose and sore throat, tiredness, pain (back, hands, legs) Warning & Precautions: •Myopathy and Rhabdomyolysis: Risk factors include age 65 years or greater, uncontrolled hypothyroidism, renal impairment, concomitant use with certain other drugs, and higher combination dosage. Instruct patients to promptly report unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever.	Rosuvastatin 5mg, 10 mg & 20 mg Tablet Ezetimibe 10mg tablet	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Tongi I/A, Gazipur. Organic Health Care Ltd. Gilarchala, 7 Kewa Mouza, Sreepur, Gazipur Navana Pharmaceuticals Limited Healthcare Pharmaceuticals Ltd Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Silva Pharmaceuticals Ltd. Delta Pharma Ltd. The ACME Laboratories Ltd. Dhamrai, Dhaka DBL Pharmaceuticals Ltd. Surabari,									

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Kashimpur, Gazipur Beacon Pharmaceuticals Limited **Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka**									
11.	Beximco Pharmaceuticals Ltd. Ziska Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Organic Health Care Ltd. Gilarchala, 7 Kewa Mouza, Sreepur, Gazipur General Pharmaceutical Ltd., Gazipur	Rosuvastatin 10 mg + Ezetimibe 10 mg Tablet	Rosuvastatin Calcium BP eq. to Rosuvastatin 10 mg + Ezetimibe USP 10 mg	Therapeutic Class: Lipid Lowering Therapeutic Code:061	It is a combination of rosuvastatin, an HMG CoA-reductase inhibitor (statin), and ezetimibe, a dietary cholesterol absorption inhibitor, indicated in adults: • As an adjunct to diet in patients with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDLC). • Alone or as an adjuct to other LDL-C lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.	Contraindication: Active liver failure or decompensated cirrhosis • Hypersensitivity to any component of combination Side-effects: The most common side effects of ROSZET include: headache, nausea, muscle aches and pains, weakness, constipation, common cold and flu, diarrhea, dizziness, joint pain, stomach pain, runny nose and sore throat, tiredness, pain (back, hands, legs) Warning & Precautions: •Myopathy and Rhabdomyolysis: Risk factors include age 65 years or greater, uncontrolled hypothyroidism, renal impairment, concomitant use with certain other drugs, and higher combination dosage. Instruct patients to promptly report unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever.	Rosuvastatin 5mg, 10 mg & 20 mg Tablet Ezetimibe 10mg tablet	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirganj, Narayanganj-1431 Drug International Ltd (Unit-3) 31/1,Satrong, Tongi I/A, Gazipur. Navana Pharmaceuticals Limited Healthcare Pharmaceuticals Ltd Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Silva Pharmaceuticals Ltd. Delta Pharma Ltd. The ACME									

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Laboratories Ltd. Dhamrai, Dhaka DBL Pharmaceuticals Ltd. Surabari, Kashimpur, Gazipur Beacon Pharmaceuticals Limited **Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka**									
12.	Beximco Pharmaceuticals Ltd. Ziska Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna General Pharmaceutical Ltd., Gazipur	Rosuvastatin 20 mg + Ezetimibe 10 mg Tablet	Rosuvastatin Calcium BP eq. to Rosuvastatin 20 mg + Ezetimibe USP 10 mg	Therapeutic Class: Lipid Lowering Therapeutic Code:061	It is a combination of rosuvastatin, an HMG CoA-reductase inhibitor (statin), and ezetimibe, a dietary cholesterol absorption inhibitor, indicated in adults: • As an adjunct to diet in patients with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDLC). • Alone or as an adjuct to other LDL-C lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.	Contraindication: Active liver failure or decompensated cirrhosis • Hypersensitivity to any component of combination Side-effects: The most common side effects of ROSZET include: headache, nausea, muscle aches and pains, weakness, constipation, common cold and flu, diarrhea, dizziness, joint pain, stomach pain, runny nose and sore throat, tiredness, pain (back, hands, legs) Warning & Precautions: •Myopathy and Rhabdomyolysis: Risk factors include age 65 years or greater, uncontrolled hypothyroidism, renal impairment, concomitant use with certain other drugs, and higher combination dosage. Instruct patients to promptly report unexplained muscle pain, tenderness, or weakness, particularly if accompanied	Rosuvastatin 5mg, 10 mg & 20 mg Tablet Ezetimibe 10mg tablet	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Organic Health Care Ltd. Gilarchala, 7 Kewa Mouza, Sreepur, Gazipur Navana Pharmaceuticals Limited Healthcare Pharmaceuticals Ltd Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Silva Pharmaceuticals Ltd. Delta Pharma Ltd. The ACME Laboratories Ltd. Dhamrai, Dhaka Beacon Pharmaceuticals Limited					by malaise or fever.				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
13.	Ziska Pharmaceuticals Ltd. General Pharmaceutical Ltd., Gazipur Navana Pharmaceuticals Limited Healthcare Pharmaceuticals Ltd Delta Pharma Ltd.	Rosuvastatin 40 mg + Ezetimibe 10 mg Tablet	Rosuvastatin BP 40 mg + Ezetimibe USP 10 mg	Therapeutic Class: Lipid Lowering Therapeutic Code:061	It is a combination of rosuvastatin, an HMG CoA-reductase inhibitor (statin), and ezetimibe, a dietary cholesterol absorption inhibitor, indicated in adults: • As an adjunct to diet in patients with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDLC). • Alone or as an adjuct to other LDL-C lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.	Contraindication: Active liver failure or decompensated cirrhosis • Hypersensitivity to any component of combination Side-effects: The most common side effects of ROSZET include: headache, nausea, muscle aches and pains, weakness, constipation, common cold and flu, diarrhea, dizziness, joint pain, stomach pain, runny nose and sore throat, tiredness, pain (back, hands, legs) Warning & Precautions: •Myopathy and Rhabdomyolysis: Risk factors include age 65 years or greater, uncontrolled hypothyroidism, renal impairment, concomitant use with certain other drugs, and higher combination dosage. Instruct patients to promptly report unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever.	Rosuvastatin 5mg, 10 mg & 20 mg Tablet Ezetimibe 10mg tablet	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
14.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Ziska Pharmaceuticals Ltd. Opsonin Pharma Limited, Rupatali, Barishal.	Vericiguat 2.5 mg Tablet	Vericiguat INN 2.5 mg	Therapeutic Class: Antihypertensive Therapeutic Code:022	Vericiguat is a soluble guanylate cyclase (sGC) stimulator, indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%	Warning: Embryo-Fetal Toxicity Contraindication: • Patients with concomitant use of other soluble guanylate cyclase (sGC) stimulators, pregnancy. Side-effects: Hypotension and anemia. Warnings and Precautions: Embryo-Fetal Toxicity	New	USFDA	অনুমোদনের সুপারিশ করা হয়। পদটির **PIL** এ **Black box Warning** হিসেবে **Embryo-Fetal Toxicity** উল্লেখ করতে হবে।	অনুমোদন করা হয়। পদটির **PIL** এ **Black box Warning** হিসেবে **Embryo-Fetal Toxicity** উল্লেখ করতে হবে।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	General Pharmaceutical Ltd., Gazipur Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirganj, Narayanganj-1431 Drug International Ltd (Unit-3) 31/1,Satrong, Tongi I/A, Gazipur. Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Navana Pharmaceuticals Limited Healthcare Pharmaceuticals Ltd Eskayef Pharmaceuticals Limited, Tongi, Gazipur.									

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur UniMed UniHealth Phr. Ltd. B.k Bari, Gazipur Sadar, Gazipur The ACME Laboratories Ltd. Dhamrai, Dhaka Beacon Pharmaceuticals Limited Team Pharmaceuticals Ltd. BSCIC, Rajshahi The IBN SINA Pharmaceutical									

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Industries Ltd.									
15.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Ziska Pharmaceuticals Ltd. Beacon Pharmaceuticals Limited Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Opsonin Pharma Limited, Rupatali, Barishal. General Pharmaceutical Ltd., Gazipur Orion Pharma Ltd.	Vericiguat 5 mg Tablet	Vericiguat INN 5 mg	Therapeutic Class: Antihypertensive Therapeutic Code:022	Vericiguat is a soluble guanylate cyclase (sGC) stimulator, indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%	Warning: Embryo-Fetal Toxicity Contraindication: • Patients with concomitant use of other soluble guanylate cyclase (sGC) stimulators, pregnancy. Side-effects: Hypotension and anemia. Warnings and Precautions: Embryo-Fetal Toxicity	New	USFDA	অনুমোদনের সুপারিশ করা হয়। পদটির **PIL** এ **Black box Warning** হিসেবে **Embryo-Fetal Toxicity** উল্লেখ করতে হবে।	অনুমোদন করা হয়। পদটির **PIL** এ **Black box Warning** হিসেবে **Embryo-Fetal Toxicity** উল্লেখ করতে হবে।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	D/28/2, Sumilpara, Siddhirganj, Narayanganj-1431 Drug International Ltd (Unit-3) 31/1,Satrong, Tongi I/A, Gazipur. Navana Pharmaceuticals Limited Healthcare Pharmaceuticals Ltd Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj Pharmasia Limited Gojariapara, Bhawal Mirzapur,									

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Gazipur Sadar, Gazipur UniMed UniHealth Phr. Ltd. B.k Bari, Gazipur Sadar, Gazipur The ACME Laboratories Ltd. Dhamrai, Dhaka Team Pharmaceuticals Ltd. BSCIC, Rajshahi The IBN SINA Pharmaceutical Industries Ltd.									
16.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Ziska Pharmaceuticals Ltd. Beacon Pharmaceuticals Limited	Vericiguat 10 mg Tablet	Vericiguat INN 10 mg	Therapeutic Class: Antihypertensive Therapeutic Code:022	Vericiguat is a soluble guanylate cyclase (sGC) stimulator, indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%	Warning: Embryo-Fetal Toxicity Contraindication: • Patients with concomitant use of other soluble guanylate cyclase (sGC) stimulators, pregnancy. Side-effects: Hypotension and anemia. Warnings and Precautions: Embryo-Fetal Toxicity	New	USFDA	অনুমোদনের সুপারিশ করা হয়। পদটির **PIL** এ **Black box Warning** হিসেবে **Embryo-Fetal Toxicity** উল্লেখ করতে হবে।	অনুমোদন করা হয়। পদটির **PIL** এ **Black box Warning** হিসেবে **Embryo-Fetal Toxicity** উল্লেখ করতে হবে।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Opsonin Pharma Limited, Rupatali, Barishal. General Pharmaceutical Ltd., Gazipur Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirganj, Narayanganj-1431 Drug International Ltd (Unit-3) 31/1,Satrong, Tongi I/A, Gazipur. Navana Pharmaceuticals Limited Healthcare Pharmaceuticals Ltd Eskayef Pharmaceuticals Limited, Tongi, Gazipur.									

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur UniMed UniHealth Phr. Ltd. B.k Bari, Gazipur Sadar, Gazipur The ACME Laboratories Ltd. Dhamrai, Dhaka Team Pharmaceuticals Ltd. BSCIC, Rajshahi The IBN SINA Pharmaceutical Industries Ltd.									

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
17.	Beximco Pharmaceuticals Ltd. Navana Pharmaceuticals Limited The ACME Laboratories Ltd. Dhamrai, Dhaka	Roxadustat 70.00mg Tablet	Roxadustat INN 70.00mg	Therapeutic Class: Vitamins and Combination Therapeutic Code:078	In the treatment of anaemia in patients with dialysis dependent chronic kidney disease (DD-CKD) and non-dialysis dependent chronic kidney disease (NDD-CKD)	Contraindications: Hypersensitivity to the active substances or to any of the excipients Side-effects: Roxadustat was associated with higher rates of hyperkalemia and respiratory infections. Warnings and Precautions: Roxadustat therapy may cause serious thromboembolism including cerebral infarction, myocardial infarction, and pulmonary embolism, with a possible fatal outcome. Roxadustat therapy should be preceded by the assessment of risks of thromboembolism, such as current or past history of cerebral infarction, myocardial infarction, and pulmonary embolism, based on which whether to use Roxadustat be carefully determined. During Roxadustat therapy, patient condition should be closely monitored for any signs or symptoms suggestive of thromboembolism. Patients should be instructed to visit a medical institution immediately in case of such symptoms.	New	EMA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
18.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Popular Pharmaceuticals Ltd., Tongi,	Pregabalin 82.5 mg Extended release tablet.	Pregabalin EP 82.5 mg	Therapeutic Class: Drug used in Epilepsy Therapeutic Code: 025	It is indicated for the management of: • Neuropathic pain associated with diabetic peripheral neuropathy (DPN) • Postherpetic neuralgia (PHN).	Contraindications: Hypersensitivity to the active substance or to any of the excipients. Side-effects : Dizziness, somnolence, headache, nasopharyngitis, inextended releaseeased appetite, euphoria, confusion, sedation, insomnia, visual disturbances, disorientation, deextended releaseeased libido, irritability, ataxia, attention disturbances, impaired coordination and memory, tremor, dysarthria, paraesthesia, hypoaesthesia, dry mouth, GI upset, erectile dysfunction, fatigue, oedema and weight gain. Warning & precautions: Angioedema, Peripheral Edema, Dizziness and	Pregabalin 330 mg Extended release tablet. Capsule: 25mg,50mg, 75mg, 100mg, 150mg	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Gazipur Navana Pharmaceuticals Limited Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj. NIPRO JMI Pharma Ltd, Rajandrapur, Chaddagram, Cumilla Ziska Pharmaceuticals Ltd. Renata Limited Mirpur, Dhaka **The ACME Laboratories Ltd. Dhamrai, Dhaka**					Somnolence, Increased seizure frequency may occur in patients with seizure disorders.				
19.	Beximco Pharmaceuticals Ltd. Square	Pregabalin 165 mg Extended release tablet.	Pregabalin EP 165 mg	Therapeutic Class: Drug used in Epilepsy Therapeutic	It is indicated for the management of: • Neuropathic pain associated with diabetic peripheral neuropathy (DPN) • Postherpetic neuralgia (PHN).	Contraindications: Hypersensitivity to the active substance or to any of the excipients. Side-effects : Dizziness, somnolence, headache, nasopharyngitis, inextended releaseeased appetite, euphoria, confusion, sedation, insomnia,	Pregabalin 330 mg Extended release tablet. 25mg,50mg,	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Popular Pharmaceuticals Ltd., Tongi, Gazipur Navana Pharmaceuticals Limited Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj. NIPRO JMI Pharma Ltd, Rajandrapur, Chaddagram, Cumilla Renata Limited Mirpur, Dhaka The ACME Laboratories Ltd. Dhamrai, Dhaka			Code: 025		visual disturbances, disorientation, deextended releaseeased libido, irritability, ataxia, attention disturbances, impaired coordination and memory, tremor, dysarthria, paraesthesia, hypoaesthesia, dry mouth, GI upset, erectile dysfunction, fatigue, oedema and weight gain. Warning & precautions: Angioedema, Peripheral Edema, Dizziness and Somnolence, Increased seizure frequency may occur in patients with seizure disorders.	75mg, 100mg, 150mg, 300mg Capsule			

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
20.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur General Pharmaceutical Ltd., Gazipur Eskayef Pharmaceuticals Limited, Tongi, Gazipur. NIPRO JMI Pharma Ltd, Rajandrapur, Chaddagram, Cumilla The ACME Laboratories Ltd. Dhamrai, Dhaka	Empagliflozin 5 mg + Metformin Hydrochloride 1000 mg Tablet	Empagliflozin INN 5 mg + Metformin Hydrochloride BP/EP 1000 mg	Therapeutic Class: 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	Warning: Risk Of Lactic Acidosis Contraindication: Renal Impairment, ESRD, or on dialysis •Metabolic acidosis, including diabetic ketoacidosis, History of serious hypersensitivity reaction to empagliflozin or metformin Side-effects: Stuffy or runny nose and sore throat Warning & precautions: Lactic acidosis, Hypotension, Ketoacidosis, Impairment in renal function, Genital mycotic infections, Urinary tract infections	Empagliflozin 5mg + Metformin Hydrochloride 500 mg tablet	USFDA ডিসিসি-২৫১ তম সভায় টেকনিক্যাল সাব কমিটির সভায় পদটি উপস্থাপনের সিদ্ধান্ত প্রদান করা হয়।	**প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।**
21.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir,	Empagliflozin 12.5 mg + Metformin Hydrochloride 500 mg Tablet	Empagliflozin INN 12.5 mg + Metformin Hydrochloride BP/EP 500 mg Tablet	Therapeutic Class: 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	Warning: Risk Of Lactic Acidosis Contraindication: Renal Impairment, ESRD, or on dialysis •Metabolic acidosis, including diabetic ketoacidosis, History of serious hypersensitivity reaction to empagliflozin or metformin Side-effects:	Empagliflozin 5mg + Metformin Hydrochloride 500 mg tablet	USFDA	**প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Gazipur General Pharmaceutical Ltd., Gazipur Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Renata Limited Mirpur, Dhaka The ACME Laboratories Ltd. Dhamrai, Dhaka				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	Stuffy or runny nose and sore throat Warning & precautions: Lactic acidosis, Hypotension, Ketoacidosis, Impairment in renal function, Genital mycotic infections, Urinary tract infections				
22.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur General Pharmaceutical Ltd., Gazipur Eskayef Pharmaceuticals Limited, Tongi,	Empagliflozin 12.5mg + Metformin Hydrochloride 1000mg Tablet	Empagliflozin INN 12.5mg + Metformin Hydrochloride BP 1000mg	Therapeutic Class: 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	Warning: Risk Of Lactic Acidosis Contraindication: Renal Impairment, ESRD, or on dialysis •Metabolic acidosis, including diabetic ketoacidosis, History of serious hypersensitivity reaction to empagliflozin or metformin Side-effects: Stuffy or runny nose and sore throat Warning & precautions: Lactic acidosis, Hypotension, Ketoacidosis, Impairment in renal function, Genital mycotic infections, Urinary tract infections	Empagliflozin 5mg + Metformin Hydrochloride 500 mg tablet	USFDA ডিসিসি-২৫১ তম সভায় টেকনিক্যাল সাব কমিটির সভায় পদটি উপস্থাপনের সিদ্ধান্ত প্রদান করা হয়।	**প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Gazipur. The ACME Laboratories Ltd. Dhamrai, Dhaka									
23.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Cholecalciferol 400 IU/ ml Oral Solution	Cholecalciferol BP 400 IU/ ml	Therapeutic Class: Vitamins and Combination Therapeutic Code:078	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 hypercalcaemia. It is also contraindicated in patients with known hypersensitivity to Cholecalciferol (or medicines of the same class) and any of the constituent excipients. 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.	New	রেফারেন্স নাই। TGA, Australia	**প্রয়োজনীয় রেফারেন্স নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স নেই বিধায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
24.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna **Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka** The ACME Laboratories Ltd. Dhamrai, Dhaka	Cholecalciferol 2000 IU/ ml Oral Solution	Cholecalciferol BP 2000 IU/ ml	Therapeutic Class: Vitamins and Combination Therapeutic Code:078	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 hypercalcaemia. It is also contraindicated in patients with known hypersensitivity to Cholecalciferol (or medicines of the same class) and any of the constituent excipients. 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.	New	BNF-81	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
25.	Beximco Pharmaceuticals Ltd. Ziska Pharmaceuticals Ltd.	Ertugliflozin 5 mg Tablet	Ertugliflozin L-Pyroglutamic Acid INN 6.480mg eq. to Ertugliflozin 5 mg	Therapeutic Class: Antidiabetic Therapeutic Code:015	It 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. Limitations of Use: Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.	Contraindiacation: Severe renal impairment, end-stage renal disease, or dialysis, History of serious hypersensitivity reaction to Ertugliflozin. Side-effect: The most common adverse reactions associated with Ertugliflozin (incidence ≥ 5%) were female genital	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Navana Pharmaceuticals Limited					mycotic infections. Warning and Precautions: Hypotension, Ketoacidosis, Acute Kidney Injury and Impairment in Renal Function, Urosepsis and Pyelonephritis, Lower Limb Amputation, Hypoglycemia, Genital Mycotic Infections.				
26.	Beximco Pharmaceuticals Ltd. Ziska Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Navana Pharmaceuticals Limited	Ertugliflozin 15 mg Tablet	Ertugliflozin L-Pyroglutamic Acid INN 19.440mg eq. to Ertugliflozin 15 mg	Therapeutic Class: Antidiabetic Therapeutic Code:015	It 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. Limitations of Use: Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.	Contraindiacation: Severe renal impairment, end-stage renal disease, or dialysis, History of serious hypersensitivity reaction to Ertugliflozin. Side-effect: The most common adverse reactions associated with Ertugliflozin (incidence ≥ 5%) were female genital mycotic infections. Warning and Precautions: Hypotension, Ketoacidosis, Acute Kidney Injury and Impairment in Renal Function, Urosepsis and Pyelonephritis, Lower Limb Amputation, Hypoglycemia, Genital Mycotic Infections.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
27.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Ertugliflozin 5 mg + Sitagliptin 100 mg Tablet	Ertugliflozin L-Pyroglutamic Acid INN eq. to Ertugliflozin 5 mg + Sitagliptin Phosphate monohydrate BP/USP eqv. to Sitagliptin 100 mg	Therapeutic Class: Antidiabetic Therapeutic Code:015	It is a combination of ertugliflozin, a sodium glucose cotransporter 2 (SGLT2) inhibitor, and sitagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both ertugliflozin and sitagliptin is appropriate.	Contraindiaction: • Severe renal impairment, end stage renal disease, or dialysis. • History of a serious hypersensitivity reaction to sitagliptin, such as anaphylaxis or angioedema. • History of serious hypersensitivity reaction to ertugliflozin Side-effect: Most common adverse reactions associated with	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					Limitations of Use: • Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. • Has not been studied in patients with a history of pancreatitis.	ertugliflozin: Vaginal yeast infections and yeast infections of the penis. Most common adverse reactions associated with sitagliptin: upper respiratory tract infection, nasopharyngitis and headache. Warning and Precautions: Pancreatitis, Hypotension, Ketoacidosis, Acute Kidney Injury and Impairment in Renal Function, Urosepsis and Pyelonephritis, Lower Limb Amputation, Hypoglycemia, Genital Mycotic Infections.				
28.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Ertugliflozin 15 mg + Sitagliptin 100 mg tablet	Ertugliflozin L-Pyroglutamic Acid INN eq. to Ertugliflozin 15 mg + Sitagliptin Phosphate monohydrate BP/USP eq to Sitagliptin 100 mg	Therapeutic Class: Antidiabetic Therapeutic Code:015	It is a combination of ertugliflozin, a sodium glucose cotransporter 2 (SGLT2) inhibitor, and sitagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both ertugliflozin and sitagliptin is appropriate. Limitations of Use: • Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. • Has not been studied in patients with a history of pancreatitis.	Contraindiaction: • Severe renal impairment, end stage renal disease, or dialysis. • History of a serious hypersensitivity reaction to sitagliptin, such as anaphylaxis or angioedema. • History of serious hypersensitivity reaction to ertugliflozin Side-effect: Most common adverse reactions associated with ertugliflozin: Vaginal yeast infections and yeast infections of the penis. Most common adverse reactions associated with sitagliptin: upper respiratory tract infection, nasopharyngitis and headache. Warning and Precautions: Pancreatitis, Hypotension, Ketoacidosis, Acute Kidney Injury and Impairment in Renal Function, Urosepsis and Pyelonephritis, Lower Limb Amputation, Hypoglycemia, Genital Mycotic Infections.	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
29.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka NIPRO JMI Pharma Ltd, Rajandrapur, Chaddagram, Cumilla	Empagliflozin 5 mg + Metformin Hydrochloride 1000 mg Extended Release Tablet	Empagliflozin INN 5 mg + Metformin Hydrochloride BP/EP 1000 mg	Therapeutic Class: 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	Warning: Risk Of Lactic Acidosis Contraindication: Renal Impairment, ESRD, or on dialysis •Metabolic acidosis, including diabetic ketoacidosis, History of serious hypersensitivity reaction to empagliflozin or metformin Side-effects: Stuffy or runny nose and sore throat Warning & precautions: Lactic acidosis, Hypotension, Ketoacidosis, Impairment in renal function, Genital mycotic infections, Urinary tract infections	Empagliflozin 5mg + Metformin Hydrochloride 500 mg tablet	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
30.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Empagliflozin 10 mg + Metformin Hydrochloride 1000 mg Extended Release Tablet	Empagliflozin INN 10 mg + Metformin Hydrochloride BP/EP 1000 mg	Therapeutic Class: 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	Warning: Risk Of Lactic Acidosis Contraindication: Renal Impairment, ESRD, or on dialysis •Metabolic acidosis, including diabetic ketoacidosis, History of serious hypersensitivity reaction to empagliflozin or metformin Side-effects: Stuffy or runny nose and sore throat Warning & precautions: Lactic acidosis, Hypotension, Ketoacidosis, Impairment in renal function, Genital mycotic infections, Urinary tract infections	Empagliflozin 5mg + Metformin Hydrochloride 500 mg tablet	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	NIPRO JMI Pharma Ltd, Rajandrapur, Chaddagram, Cumilla				mellitus or diabetic ketoacidosis					
31.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka NIPRO JMI Pharma Ltd, Rajandrapur, Chaddagram, Cumilla	Empagliflozin 12.5 mg + Metformin Hydrochloride 1000 mg Extended Release Tablet	Empagliflozin INN 12.5 mg + Metformin Hydrochloride BP/EP 1000 mg	Therapeutic Class: 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	Warning: Risk Of Lactic Acidosis Contraindication: Renal Impairment, ESRD, or on dialysis •Metabolic acidosis, including diabetic ketoacidosis, History of serious hypersensitivity reaction to empagliflozin or metformin Side-effects: Stuffy or runny nose and sore throat Warning & precautions: Lactic acidosis, Hypotension, Ketoacidosis, Impairment in renal function, Genital mycotic infections, Urinary tract infections	Empagliflozin 5mg + Metformin Hydrochloride 500 mg tablet	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
32.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Empagliflozin 25 mg + Metformin Hydrochloride 1000 mg Extended Release Tablet	Empagliflozin INN 25 mg + Metformin Hydrochloride BP/EP 1000 mg	Therapeutic Class: 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	Warning: Risk Of Lactic Acidosis Contraindication: Renal Impairment, ESRD, or on dialysis •Metabolic acidosis, including diabetic ketoacidosis, History of serious hypersensitivity reaction to empagliflozin or metformin Side-effects: Stuffy or runny nose and sore throat	Empagliflozin 5mg + Metformin Hydrochloride 500 mg tablet	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka				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	Warning & precautions: Lactic acidosis, Hypotension, Ketoacidosis, Impairment in renal function, Genital mycotic infections, Urinary tract infections				
33.	Beximco Pharmaceuticals Ltd. Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Insulin Glargine Ph.Eur. 3.640mg (eqv. to 100 units of Insulin Glargin + Lixisenatide 0.033mg / mL.	Insulin Glargine Ph.Eur. 3.640mg (eqv. to 100 units of Insulin Glargin + Lixisenatide 0.033mg / mL.	Therapeutic Class: Antidiabetic Therapeutic Code:015	It is a combination of a long-acting human insulin analog with 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 inadequately controlled on basal insulin (less than 60 units daily) or lixisenatide. Limitations of Use: • Has not been studied in patients with a history of unexplained pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis. • Not recommended for use in combination with any other product containing lixisenatide or another GLP-1 receptor agonist. • Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis. • Not recommended for use in patients with gastroparesis. • Has not been studied in combination with prandial insulin.	Contraindications: • During episodes of hypoglycemia. • In patients with hypersensitivity to INSULIN GLARGINE & LIXISENATIDE COMBINATION, either of the active drug substances (insulin glargine or lixisenatide), or any of its excipients. Hypersensitivity reactions including anaphylaxis have occurred with both lixisenatide and insulin glargine. Side- effects: Low blood sugar (hypoglycemia) , nausea, stuffy or runny nose and sore throat,diarrhea, upper respiratory tract infection, headache etc. Warning and Precautions: Anaphylaxis and Serious Hypersensitivity Reactions: In clinical trials of lixisenatide, a component of INSULIN GLARGINE & LIXISENATIDE COMBINATION, there have been cases of anaphylaxis (frequency of 0.1% or 10 cases per 10,000 patient-years) and other serious hypersensitivity reactions including angioedema. Severe, life-threatening, generalized allergic reactions, including anaphylaxis, generalized skin reactions, angioedema, bronchospasm, hypotension, and shock can occur with insulins, including insulin glargine, a component of INSULIN GLARGINE & LIXISENATIDE COMBINATION. Inform and closely monitor patients with a history of anaphylaxis or	Insulin Glargine 100 units	USFDA	পদটির জন্য দেশে **non inferiority trial** করতে হবে, এই শর্তে অনুমোদনের সুপারিশ করা হয়।	পদটির জন্য দেশে **non inferiority trial** করতে হবে, এই শর্তে অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						angioedema with another GLP-1 receptor agonist for allergic reactions, because it is unknown whether such patients will be predisposed to anaphylaxis with lixisenatide. INSULIN GLARGINE & LIXISENATIDE COMBINATION is contraindicated in patients with known hypersensitivity to lixisenatide or insulin glargine. If a hypersensitivity reaction occurs, the patient should discontinue INSULIN GLARGINE & LIXISENATIDE COMBINATION and promptly seek medical attention. Never Share a Pen Between Patients INSULIN GLARGINE & LIXISENATIDE COMBINATION prefilled pens must never be shared between patients, even if the needle is changed. Sharing of the pen poses a risk for transmission of blood-borne pathogens. Pancreatitis Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been reported postmarketing in patients treated with GLP-1 receptor agonists. In clinical trials of lixisenatide, a component of INSULIN GLARGINE & LIXISENATIDE COMBINATION, there were 21 cases of pancreatitis among lixisenatide-treated patients and 14 cases in comparator-treated patients (incidence rate of 21 vs 17 per 10,000 patient-years). Lixisenatide cases were reported as acute pancreatitis (n=3), pancreatitis (n=12), chronic pancreatitis (n=5), and edematous pancreatitis (n=1). Some patients had risk factors for pancreatitis, such as a history of cholelithiasis or alcohol abuse. After initiation of INSULIN GLARGINE & LIXISENATIDE COMBINATION, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, promptly				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						discontinue INSULIN GLARGINE & LIXISENATIDE COMBINATION and initiate appropriate management. If pancreatitis is confirmed, restarting INSULIN GLARGINE & LIXISENATIDE COMBINATION is not recommended. Consider antidiabetic therapies other than INSULIN GLARGINE & LIXISENATIDE COMBINATION in patients with a history of pancreatitis.				
34.	Beximco Pharmaceuticals Ltd.	Semaglutide 0.5 mg / 0.5 ml pre-filled syringe	Semaglutide INN 0.5 mg / 0.5 ml	Therapeutic Class: Antidiabetic Therapeutic Code:015	Semaglutide is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: •30 kg/m2 or greater (obesity) or •27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)	Warning: Risk Of Thyroid C-Cell Tumors Contraindications: •A personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). •A prior serious hypersensitivity reaction to semaglutide or to any of the excipients in SEMAGLUTIDE. Serious hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with semaglutide. Side-effects Nausea, stomach, (abdomen) pain, dizziness, stomach flu, diarrhea, headache, feeling bloated, heartburn, vomiting tiredness (fatigue), belching, constipation, upset stomach and gas. Warning and Precautions: Pancreatitis, Diabetic Retinopathy Complications, Thyroid C-cell Tumors, Hypoglycemia, Heart Rate Increase, Hypersensitivity Reactions.	Semaglutide 1.34mg/ml Pre-filled Pen for Injection and Semaglutide 3, 7 & 14mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
35.	Beximco Pharmaceuticals Ltd.	Semaglutide 0.25 mg / 0.5 ml pre-filled syringe	Semaglutide INN 0.25 mg / 0.5 ml	Therapeutic Class: Antidiabetic Therapeutic Code:015	Semaglutide is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:	Warning: Risk Of Thyroid C-Cell Tumors Contraindications: •A personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). •A prior serious hypersensitivity reaction to	Semaglutide 1.34mg/ml Pre-filled Pen for Injection and Semaglutide 3, 7 & 14mg	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					•30 kg/m2 or greater (obesity) or •27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)	semaglutide or to any of the excipients in SEMAGLUTIDE. Serious hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with semaglutide. Side-effects Nausea, stomach, (abdomen) pain, dizziness, stomach flu, diarrhea, headache, feeling bloated, heartburn, vomiting tiredness (fatigue), belching, constipation, upset stomach and gas. Warning and Precautions: Pancreatitis, Diabetic Retinopathy Complications, Thyroid C-cell Tumors, Hypoglycemia, Heart Rate Increase, Hypersensitivity Reactions.	Tablet			
36.	Beximco Pharmaceuticals Ltd.	Semaglutide 1 mg / 0.5 ml pre-filled syringe	Semaglutide INN 1 mg / 0.5 ml	Therapeutic Class: Antidiabetic Therapeutic Code:015	Semaglutide is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: •30 kg/m2 or greater (obesity) or •27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)	Warning: Risk Of Thyroid C-Cell Tumors Contraindications: •A personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). •A prior serious hypersensitivity reaction to semaglutide or to any of the excipients in SEMAGLUTIDE. Serious hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with semaglutide. Side-effects Nausea, stomach, (abdomen) pain, dizziness, stomach flu, diarrhea, headache, feeling bloated, heartburn, vomiting tiredness (fatigue), belching, constipation, upset stomach and gas. Warning and Precautions: Pancreatitis, Diabetic Retinopathy Complications, Thyroid C-cell Tumors, Hypoglycemia, Heart Rate Increase, Hypersensitivity Reactions.	Semaglutide 1.34mg/ml Pre-filled Pen for Injection and Semaglutide 3, 7 & 14mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
37.	Beximco Pharmaceuticals Ltd.	Semaglutide 1.7 mg / 0.75 ml pre-filled syringe	Semaglutide INN 1.7 mg / 0.75 ml	Therapeutic Class: Antidiabetic Therapeutic Code:015	Semaglutide is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: •30 kg/m2 or greater (obesity) or •27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)	Warning: Risk Of Thyroid C-Cell Tumors Contraindications: •A personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). •A prior serious hypersensitivity reaction to semaglutide or to any of the excipients in SEMAGLUTIDE. Serious hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with semaglutide. Side-effects Nausea, stomach, (abdomen) pain, dizziness, stomach flu, diarrhea, headache, feeling bloated, heartburn, vomiting tiredness (fatigue), belching, constipation, upset stomach and gas. Warning and Precautions: Pancreatitis, Diabetic Retinopathy Complications, Thyroid C-cell Tumors, Hypoglycemia, Heart Rate Increase, Hypersensitivity Reactions.	Semaglutide 1.34mg/ml Pre-filled Pen for Injection and Semaglutide 3, 7 & 14mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
38.	Beximco Pharmaceuticals Ltd.	Semaglutide 2.4 mg / 0.75 ml pre-filled syringe	Semaglutide INN 2.4 mg / 0.75 ml	Therapeutic Class: Antidiabetic Therapeutic Code:015	Semaglutide is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: •30 kg/m2 or greater (obesity) or •27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)	Warning: Risk Of Thyroid C-Cell Tumors Contraindications: •A personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). •A prior serious hypersensitivity reaction to semaglutide or to any of the excipients in SEMAGLUTIDE. Serious hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with semaglutide. Side-effects Nausea, stomach, (abdomen) pain, dizziness, stomach flu, diarrhea, headache, feeling bloated,	Semaglutide 1.34mg/ml Pre-filled Pen for Injection and Semaglutide 3, 7 & 14mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						heartburn, vomiting tiredness (fatigue), belching, constipation, upset stomach and gas. Warning and Precautions: Pancreatitis, Diabetic Retinopathy Complications, Thyroid C-cell Tumors, Hypoglycemia, Heart Rate Increase, Hypersensitivity Reactions.				
39.	Beximco Pharmaceuticals Ltd. Ziska Pharmaceuticals Ltd. Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirganj, Narayanganj-1431 General Pharmaceutical Ltd., Gazipur Navana Pharmaceuticals Limited Beacon Pharmaceuticals Limited Healthcare Pharmaceuticals	Finerenone 10 mg Tablet	Finerenone INN 10 mg	Therapeutic Class: Antidiabetes Therapeutic Code:015	Kerendia is a non-steroidal mineralocorticoid receptor antagonist (MRA) indicated to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D)	Contraindications: Concomitant use with strong CYP3A4 inhibitors, Patients with adrenal insufficiency Side effect: Adverse reactions occurring in ≥ 1% of patients on Kerendia and more frequently than placebo are hyperkalemia, hypotension, and hyponatremia Warning & Precautions: Hyperkalemia. Patients with decreased kidney function and higher baseline potassium levels are at increased risk. Monitor serum potassium levels and adjust dose as needed	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Ltd EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagnj, BANGLADESH Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj. The ACME Laboratories Ltd. Dhamrai, Dhaka Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka The IBN SINA Pharmaceutical Industries Ltd.									
40.	Beximco Pharmaceuticals Ltd. Ziska Pharmaceuticals Ltd.	Finerenone 20 mg Tablet	Finerenone INN 20 mg	Therapeutic Class: Antidiabetes Therapeutic Code:015	Kerendia is a non-steroidal mineralocorticoid receptor antagonist (MRA) indicated to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease	Contraindications: Concomitant use with strong CYP3A4 inhibitors, Patients with adrenal insufficiency Side effect: Adverse reactions occurring in ≥ 1% of patients on Kerendia and more frequently than placebo are hyperkalemia, hypotension, and hyponatremia	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirganj, Narayanganj-1431 Navana Pharmaceuticals Limited General Pharmaceutical Ltd., Gazipur Beacon Pharmaceuticals Limited Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj. The ACME Laboratories Ltd. Dhamrai, Dhaka Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka The IBN SINA Pharmaceutical				(CKD) associated with type 2 diabetes (T2D)	Warning & Precautions: Hyperkalemia. Patients with decreased kidney function and higher baseline potassium levels are at increased risk. Monitor serum potassium levels and adjust dose as needed				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Industries Ltd.									
41.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Paracetamol 160 mg / 5 ml syrup	Paracetamol BP 160 mg / 5 ml	Therapeutic Class: Analgesics and Antipyretics Therapeutic Code : 006	Paracetamol is indicated for the treatment of fever and mild to moderate pain. It can be used in many conditions including headache, toothache, earache, sore throat, colds and influenza, general aches and pains and post-immunization fever	Contraindication: Hypersensitivity to paracetamol or any of the other ingredients. Side effects: Thrombocytopenia, Agranulocylosis These are not necessarily causally related to paracetamol Anaphylaxis, Cutaneous hypersensitivity reactions including skin rashes, angiodema and Stevens Johnson syndrome/toxic epidermal necrolysis Warning and Precautions: Care is advised in the administration of Paracetamol to patients with severe hepatic or renal dysfunction. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. It should not be given with any other paracetamol containing products. Immediate medical advice should be sought in the event of an overdose, even if the child seems well. Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed, serious liver damage. For oral use only. Keep out of the reach and sight of children	Paracetamol BP 120 mg/5 ml syrup.	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
42.	Ziska Pharmaceuticals Ltd. Beacon Pharmaceuticals Limited Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj. Delta Pharma Ltd. The ACME Laboratories Ltd. Dhamrai, Dhaka Navana Pharmaceuticals Limited Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Filgotinib 100mg Tablet	Filgotinib Maleate INN 127.280 mg eqv.to Filgotinib 100mg	Therapeutic Class: Immune-suppressant Therapeutic Code : 058	Filgotinib is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Filgotinib may be used as monotherapy or in combination with methotrexate (MTX).	Contraindications: • Hypersensitivity to the active substance or to any of the excipients, • Active tuberculosis (TB) or active serious infections, • Pregnancy Side effects: The most frequently reported adverse reactions are nausea (3.5%), upper respiratory tract infection (URTI, 3.3%), urinary tract infection (UTI, 1.7%) and dizziness (1.2%). Warning & Precaution: • Immunosuppressive medicinal products: Combination of filgotinib with other potent immunosuppressants such as azathioprine, ciclosporin, tacrolimus, biologic DMARDs (bDMARDs) or other Janus kinase (JAK) inhibitors is not recommended as a risk of additive immunosuppression cannot be excluded.	New	EMA, UKMHRA & BNF 81	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
43.	Ziska Pharmaceuticals Ltd. Beacon Pharmaceuticals Limited	Filgotinib 200mg Tablet	Filgotinib Maleate INN 254.560 mg eqv.to Filgotinib 200mg	Therapeutic Class: Immune-suppressant Therapeutic Code : 058	Filgotinib is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Filgotinib may be used as monotherapy or in	Contraindications: • Hypersensitivity to the active substance or to any of the excipients, • Active tuberculosis (TB) or active serious infections, • Pregnancy Side effects: The most frequently reported adverse reactions are nausea (3.5%), upper respiratory tract infection (URTI, 3.3%), urinary tract infection (UTI, 1.7%) and dizziness (1.2%).	New	UKMHRA, BNF 81	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj. Delta Pharma Ltd. The ACME Laboratories Ltd. Dhamrai, Dhaka Navana Pharmaceuticals Limited Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka				combination with methotrexate (MTX).	Warning & Precaution: • Immunosuppressive medicinal products: Combination of filgotinib with other potent immunosuppressants such as azathioprine, ciclosporin, tacrolimus, biologic DMARDs (bDMARDs) or other Janus kinase (JAK) inhibitors is not recommended as a risk of additive immunosuppression cannot be excluded.				
44.	Ziska Pharmaceuticals Ltd. Renata Limited Mirpur, Dhaka The ACME Laboratories Ltd. Dhamrai, Dhaka Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Estetrol 14.2 mg & Drospirenone 3 mg Tablet	Estetrol INN 14.2 mg & Drospirenone INN 3 mg	Therapeutic Class: Oral contraceptive Therapeutic Code : 039	It is a combination of drospirenone, a progestin, and estetrol, an estrogen, indicated for use by females of reproductive potential to prevent pregnancy. Limitations of Use: This combination may be less effective in females with a BMI ≥ 30 kg/m2. In females with BMI ≥ 30 kg/m2, decreasing effectiveness may be associated with increasing BMI	Warning: Cigarette Smoking And Serious Contraindications: A high risk of arterial or venous thrombotic diseases • Current or history of a hormonally-sensitive malignancy (e.g., breast cancer) • Hepatic adenoma, hepatocellular carcinoma, acute hepatitis or decompensated cirrhosis • Co-administration with hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir • Abnormal uterine bleeding that has an undiagnosed etiology • Renal impairment • Adrenal insufficiency Warning & Precaution: Thromboembolic Disorders and Other Vascular Problems, Hyperkalemia, Hypertension, Migraine,	Drospirenone 3mg+ Ethinylestradiol 0.030mg Tablet Drospirenone BP 0.5mg + Estradiol BP 1.0mg Tablet Drospirenone BP 2mg + Estradiol BP 1.0mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka Nuvista Pharma Ltd.					Hormonally-Sensitive Malignancy, Liver Disease, Glucose Tolerance and Hypertriglyceridemia, Gallbladder Disease and Cholestasis, Bleeding Irregularities and Amenorrhea Side effects: Irregular vaginal bleeding (including absence of period), pain with your periods, mood changes, acne, headache, weight gain, breast tenderness, pain, and discomfort, decreased sex drive	Drospirenone BP 0.25mg + Estradiol BP			
45.	Ziska Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Navana Pharmaceuticals Limited Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj.	Flibanserin 100 mg tablet	Flibanserin INN 100 mg tablet	Therapeutic Class: Other Classification Therapeutic Code:075	It is indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to: • A co-existing medical or psychiatric condition, • Problems within the relationship, or • The effects of a medication or other drug substance. Limitations of Use: It is not indicated for the treatment of HSDD in postmenopausal women or in men. It is not indicated to enhance sexual performance.	Warning: Hypotension And Syncope In Certain Settings Contraindications: Alcohol, Moderate or strong cytochrome P450 3A4 (CYP3A4) inhibitors, Hepatic impairment Side effects: Most common adverse reactions (incidence ≥2%) are dizziness, somnolence, nausea, fatigue, insomnia, and dry mouth. Warning & Precaution: Hypotension and Syncope with Flibanserin Alone, Central Nervous System (CNS) Depression (e.g., Somnolence, Sedation).	New	USFDA	অনুমোদনের সুপারিশ করা হয়। **PIL এ উল্লেখ করতে হবে** **It is not indicated for the treatment of HSDD in postmenopausal women or in men.**	অনুমোদন করা হয়। **PIL এ উল্লেখ করতে হবে** **It is not indicated for the treatment of HSDD in postmenopausal women or in men.**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur The ACME Laboratories Ltd. Dhamrai, Dhaka									
46.	Ziska Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Navana Pharmaceuticals Limited Renata Limited Mirpur, Dhaka	Sotagliflozin 200 mg Tablet	Sotagliflozin INN 200 mg	Therapeutic Class: Antidiabetic Therapeutic Code:015	Sotagliflozin is indicated as an adjunct to insulin therapy to improve glycaemic control in adults with type 1 diabetes mellitus with a Body Mass Index (BMI) ≥ 27 kg/m2, who have failed to achieve adequate glycaemic control despite optimal insulin therapy.	Contraindications: Contraindications: Hypersensitivity to the active substance or to any of the excipients listed below: Tablet core • Microcrystalline cellulose (E460i), • Croscarmellose sodium, • Colloidal anhydrous silica, • Colloidal anhydrous silica, • Magnesium stearate, • Talc, • Film-coating, • Poly (vinyl alcohol), • Macrogol, • Titanium dioxide (E171), • Talc Indigo carmine aluminum lake (E132). Printing ink • Shellac, • Iron oxide black (E172), • Propylene glycol Warning & Precaution: • Diabetic ketoacidosis	New	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
47.	Ziska Pharmaceuticals Ltd.	Tofacitinib INN 1 mg/ml oral solution	Tofacitinib INN 1mg/ml	Therapeutic Class: Immune-suppressant Therapeutic Code : 058	Rheumatoid Arthritis, Psoriatic Arthritis, Ulcerative Colitis, Polyarticular Course Juvenile Idiopathic Arthritis	Warning: Serious Infections, Mortality, Malignancy And Thrombosis Contraindications: None Side effects: Most common adverse reactions are: • Rheumatoid and Psoriatic Arthritis: upper respiratory tract infection, nasopharyngitis, diarrhea, and headache. • Ulcerative Colitis: nasopharyngitis, elevated cholesterol levels, headache, upper respiratory tract infection, increased blood creatine phosphokinase, rash, diarrhea, and herpes zoster. • Polyarticular Course Juvenile Idiopathic Arthritis: upper respiratory tract infections (common cold, sinus infections), nasal congestion, sore throat, and runny nose (nasopharyngitis), headache, fever, nausea, vomiting. Warning & Precaution: Acetaminophen liver damage warning: Serious Infections: Avoid use of Tofacitinib Oral Solution during an active serious infection, including localized infections. Thrombosis, including pulmonary, deep venous and arterial, some fatal, Gastrointestinal Perforations, Laboratory Monitoring, Immunizations	New (Tofacitinib 5 mg & 11 XR Tablet is available)	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
48.	Ziska Pharmaceuticals Ltd.	Naltrexone HCl 8 mg and Bupropion HCl 90 mg Tablet	Naltrexone HCl USP 8 mg and Bupropion HCl USP 90 mg	Therapeutic Class: Opioid Antagonists Therapeutic	Indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: • 30 kg/m2 or greater (obese)	Contraindications: Uncontrolled hypertension • Seizure disorders, anorexia nervosa or bulimia, or undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs • Use of other	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
				Code : 066	or • 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia). Limitations of Use: • The effect of naltrexone HCl and bupropion HCl on cardiovascular morbidity and mortality has not been established. • The safety and effectiveness of naltrexone HCl and bupropion HCl in combination with other products intended for weight loss, including prescription and over-the-counter drugs, and herbal preparations, have not been established.	bupropion-containing products • Chronic opioid use • During or within 14 days of taking monoamine oxidase inhibitors (MAOI), • Pregnancy Side effects: Most common adverse reactions (greater than or equal to 5%): nausea, constipation, headache, vomiting, dizziness, insomnia, dry mouth and diarrhea. Warning & Precaution: Suicidal Behavior and Ideation: Monitor for depression or suicidal thoughts. Discontinue Naltrexone HCl and Bupropion HCl if symptoms develop. • Risk of seizure may be minimized by adhering to the recommended dosing schedule and avoiding coadministration with high-fat meal. • Increase in Blood Pressure and Heart Rate: Monitor blood pressure and heart rate in all patients, especially those with cardiac or cerebrovascular disease. • Hepatotoxicity: Cases of hepatitis and clinically significant liver dysfunction observed with naltrexone exposure. • Angle-closure glaucoma: Angle-closure glaucoma has occurred in patients with untreated anatomically narrow angles treated with antidepressants. • Use of Antidiabetic Medications: Weight loss may cause hypoglycemia. Monitor blood glucose.				
49.	Ziska Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Ertugliflozin 2.5 mg + Metformin HCL 500 mg Tablet	Ertugliflozin INN 2.5 mg + Metformin HCL BP 500 mg	Therapeutic Class: Antidiabetic Therapeutic Code:015	It is a combination of ertugliflozin, a sodium glucose cotransporter 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 ertugliflozin or metformin, or in patients	Warning: Lactic Acidosis Contraindications: • Severe renal impairment, end stage renal disease, or dialysis. • Metabolic acidosis, including diabetic ketoacidosis. • History of serious hypersensitivity reaction to ertugliflozin or metformin.	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					who are already treated with both ertugliflozin and metformin.	Side effects: The most common adverse reactions associated with ertugliflozin (incidence ≥5%) were female genital mycotic infections. • Most common adverse reactions associated with metformin (incidence ≥5%): diarrhea, nausea, vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache. Warning & Precaution: Lactic Acidosis, Hypotension, Ketoacidosis, Acute Kidney Injury and Impairment in Renal Function, Urosepsis and Pyelonephritis, Lower Limb Amputation, Hypoglycemia, Genital Mycotic Infections, Increased LDL-C				
50.	Ziska Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Ertugliflozin 2.5 mg + Metformin HCL 1000 mg Tablet	Ertugliflozin INN 2.5 mg + Metformin HCL BP 1000 mg	Therapeutic Class: Antidiabetic Therapeutic Code:015	It is a combination of ertugliflozin, a sodium glucose cotransporter 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 ertugliflozin or metformin, or in patients who are already treated with both ertugliflozin and metformin.	Warning: Lactic Acidosis Contraindications: • Severe renal impairment, end stage renal disease, or dialysis. • Metabolic acidosis, including diabetic ketoacidosis. • History of serious hypersensitivity reaction to ertugliflozin or metformin. Side effects: The most common adverse reactions associated with ertugliflozin (incidence ≥5%) were female genital mycotic infections. • Most common adverse reactions associated with metformin (incidence ≥5%): diarrhea, nausea, vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache. Warning & Precaution: Lactic Acidosis, Hypotension, Ketoacidosis, Acute Kidney Injury and Impairment in Renal Function, Urosepsis and Pyelonephritis, Lower Limb Amputation, Hypoglycemia, Genital Mycotic	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Infections, Increased LDL-C				
51.	Ziska Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Ertugliflozin 7.5 mg + Metformin HCL 500 mg Tablet	Ertugliflozin INN 5.5 mg + Metformin HCL BP 500 mg	Therapeutic Class: Antidiabetic Therapeutic Code:015	It is a combination of ertugliflozin, a sodium glucose cotransporter 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 ertugliflozin or metformin, or in patients who are already treated with both ertugliflozin and metformin.	Warning: Lactic Acidosis Contraindications: • Severe renal impairment, end stage renal disease, or dialysis. • Metabolic acidosis, including diabetic ketoacidosis. • History of serious hypersensitivity reaction to ertugliflozin or metformin. Side effects: The most common adverse reactions associated with ertugliflozin (incidence ≥5%) were female genital mycotic infections. • Most common adverse reactions associated with metformin (incidence ≥5%): diarrhea, nausea, vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache. Warning & Precaution: Lactic Acidosis, Hypotension, Ketoacidosis, Acute Kidney Injury and Impairment in Renal Function, Urosepsis and Pyelonephritis, Lower Limb Amputation, Hypoglycemia, Genital Mycotic Infections, Increased LDL-C	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
52.	Ziska Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Ertugliflozin 7.5 mg + Metformin HCL 1000 mg Tablet	Ertugliflozin INN 7.5 mg + Metformin HCL BP 1000 mg	Therapeutic Class: Antidiabetic Therapeutic Code:015	It is a combination of ertugliflozin, a sodium glucose cotransporter 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	Warning: Lactic Acidosis Contraindications: • Severe renal impairment, end stage renal disease, or dialysis. • Metabolic acidosis, including diabetic ketoacidosis. • History of serious hypersensitivity reaction to ertugliflozin or metformin.	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					ertugliflozin or metformin, or in patients who are already treated with both ertugliflozin and metformin.	Side effects: The most common adverse reactions associated with ertugliflozin (incidence ≥5%) were female genital mycotic infections. • Most common adverse reactions associated with metformin (incidence ≥5%): diarrhea, nausea, vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache. Warning & Precaution: Lactic Acidosis, Hypotension, Ketoacidosis, Acute Kidney Injury and Impairment in Renal Function, Urosepsis and Pyelonephritis, Lower Limb Amputation, Hypoglycemia, Genital Mycotic Infections, Increased LDL-C				
53.	Ziska Pharmaceuticals Ltd Beacon Pharmaceuticals Limited. Eskayef Pharmaceuticals Limited, Tongi, Gazipur. The IBN SINA Pharmaceutical Industries Ltd.	Trilaciclib 300.00mg/Vial as Lyophilized Powder.	Trilaciclib Dihydrochloride INN 349.00mg eqv. to Trilaciclib 300.00mg/Vial	Therapeutic Class: Anticancer Therapeutic Code:010	It is indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan containing regimen for extensive-stage small cell lung cancer (ES-SCLC).	Contraindications: It is contraindicated in patients with a history of serious hypersensitivity reactions to Trilaciclib. Reactions have included anaphylaxis. Side effects: Fatigue, hypocalcemia, hypokalemia, hypophosphatemia, aspartate aminotransferase increased, headache, and pneumonia. Warning & Precaution: Injection-Site Reactions, Including Phlebitis and Thrombophlebitis, Acute Drug Hypersensitivity Reactions, Interstitial Lung Disease (ILD)/Pneumonitis, Interrupt and evaluate patients with new or worsening symptoms suspected to be due to ILD/pneumonitis, Embryo-Fetal Toxicity	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
54.	Ziska Pharmaceuticals Ltd. Eskayef Pharmaceuticals.	Clobetasol Propionate 0.05% & Salicylic Acid 6% ointment	Clobetasol Propionate BP 0.05% & Salicylic Acid BP 6%	Topical corticosteroids	For the relief of the inflammatory manifestations of hyperkeratotic and dry corticosteroid-responsive dermatoses such as : psoriasis, chronic atopic dermatitis, neurodermatitis (lichen simplex chronicus), lichen planus, eczema (including nummular eczema, hand eczema, eczematous dermatitis), dyshidrosis (pompholyx), seborrheic dermatitis of the scalp, ichthyosis vulgaris and other ichthyotic conditions	Contraindications: The ointment is not meant for children less than 12 years if age. This drug is contraindicated in patients who are under treatment for Ulcerative conditions, Rosacea, Pruritus, and acute infections. Also, the usage of the drug should be discontinued if hypersensitivity to any of its ingredients is noted. Side effects: The most common adverse reactions associated with this combination Redness, rash or itching affecting the normal skin around the wart, Hives Warning & Precaution: • Are allergic to Clobetasol propionate and salicylic acid or to any of the other ingredients. • Have poor blood circulation the wart or skin surrounding it is inflamed or broken. • Have moles, birthmarks, unusual warts with hair growth. • Have any type of skin infection.	New	রেফারেন্স নাই ডিসিসি-২৫১ তম সভায় পদটি পোস্ট অ্যাপ্রুভালের জন্য উপস্থাপন করা হয়। পদটি এসকেএইফ এর অনুকূলে রেজিস্ট্রেশন ছিল কিন্তু ডিসিসি-২৪৩ ও ২৫০ এ নামঞ্জুর করা হয়। এ বিষয়ে ডিজিডিএকে অনুসন্ধান করতে বলা হয়। ডিজিডিএ পরবর্তীতে এসকেএইফ এর অনুকূলে রেজিস্ট্রেশন বাতিল করে। পদটি পরবর্তী ডিসিসি এর টেকনিক্যাল সাব কমিটিতে উপস্থাপন করার সিদ্ধান্ত গৃহীত হয়। যে কারণে এই সভায় উপস্থান করা হয়েছে।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
55.	Ziska Pharmaceuticals Ltd.	Ascorbic acid 60 mg, folic acid 5 mg, biotin 300 mcg, thiamine hydrochloride 1.5 mg, riboflavin 1.5 mg, niacinamide 20 mg, pyridoxine hydrochloride 50 mg, cyanocobalamin 1 mg, and calcium pantothenate 10 mg Tablet	Ascorbic acid BP 60 mg, folic acid BP 5 mg, biotin USP 300 mcg, thiamine hydrochloride USP 1.5 mg, riboflavin BP 1.5 mg, niacinamide BP 20 mg, pyridoxine hydrochloride BP 50 mg, cyanocobalamin BP 1 mg, and	Therapeutic Class: Vitamins and Combinations Therapeutic Code:078	It is a prescription multi-vitamin supplement that can be taken to improve nutritional status in conditions requiring dietary supplementation. It can also be used for the dietary management of individuals with distinct nutritional needs under a physician or healthcare provider's supervision for end stage failure, dialysis, hyper-homocysteinemia or inadequate dietary vitamin intake.	Contraindications: This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. Side effects: Allergic sensitization has been reported following both oral and parenteral administration of folic acid. Paresthesia and somnolence have been reported with the use of pyridoxine hydrochloride. Mild transient diarrhea, polycythemia vera, peripheral vascular thrombosis,	New	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
			calcium pantothenate USP 10 mg Tablet			itching transitory exanthema and feeling of swelling of the entire body has been associated with the use of cyanocobalamin. Warning & Precaution: This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.				
56.	Opsonin Pharma Limited, Rupatali, Barishal.	Multivitamin with L-Lysine Syrup	Ascorbic Acid 300 mg + Calcium Pantothenate BP 43.472 mg + Cyanocobalamin BP 18 mcg + L-Lysine Hydrochloride USP 2.498 gm + Nicotinamide BP 120 mg + Pyridoxine Hydrochloride BP 10 mg + Riboflavin Sodium Phosphate BP 10 mg + Thiamine Hydrochloride BP 10 mg + Vitamin A BP 20000 IU + Vitamin D3 4000 IU + dl-Alpha Tocopheryl Acetate Oily Form (Vitamin E) USP 100 mg	Therapeutic Class: Vitamins and Combinations Therapeutic Code:078	Promotes muscle growth, weight gain and calcium retention; Helps to enhance body height and weight gain; Ensures good eye sight; Necessary for the normal process in protein, fat carbohydrate metabolism; For RBC formation and correct functioning of nervous system & proper food assimilation and For proper cell functioning and protect body cell from free radical.	Contraindications: The products are contraindicated in patients with a known hypersensitivity to any of the ingredients of the products. Side effects: Generally well tolerated. Precautions & warnings: Dermatological disorder, GI upset. Vitamin E has been reported to increase blood-clotting time in patients receiving oral anticoagulants.	New	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
57.	The ACME Laboratories Ltd. Dhamrai, Dhaka Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Trelagliptin 50 mg Tablet	Trelagliptin Succinate INN 66.50mg eqv. to Trelagliptin 50 mg Tablet	Therapeutic Class: 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	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
58.	Opsonin Pharma Limited, Rupatali, Barishal	Clocortolone Pivalate 0.1% Cream	Clocortolone Pivalate USP 0.1%	Therapeutic Class: Skin and Mucous membrane preparations Therapeutic Code:071	Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.	Contraindications: None Side effects: Many people have no side effects or only have minor side effects. Few side effects are: Burning, Skin scabbing and crusting, Dry skin, Itching, Flaking, Oozing, Pain, Redness, Skin sores, Sinus pain etc. Precautions & warnings: Local inflammatory reactions, Photosensitivity: Due to the potential for increased sensitivity to sunlight, avoid or minimize sunlight exposure (including sunlamps or other artificial sunlight exposure) during treatment, Systemic reactions: Flu-like symptoms (arthralgias, chills, fatigue, fever, malaise, myalgias, nausea, rigors) may accompany or precede local inflammatory reactions; may require treatment interruption,	New	**USFDA**	**অনুমোদনের সুপারিশ করা হয়।**	**অনুমোদন করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Autoimmune disorders: Safety and efficacy in immunosuppressed patients have not been established, Basal cell carcinoma: Use should be limited to superficial carcinomas with a maximum diameter of 2 cm, Not intended for oral, nasal, intravaginal, or ophthalmic use. Administration is not recommended until tissue is healed from any previous drug or surgical treatment.				
59.	Opsonin Pharma Limited, Rupatali, Barishal Ziska Pharmaceuticals Ltd.	Griseofulvin ultramicrosize 125 mg Tablet	Griseofulvin USP ultramicrosize 125 mg	Therapeutic Class: Antifungal Therapeutic Code:020	Indicated for the treatment of tinea infections (tinea corporis, tinea pedis, tinea cruris, tinea barbae, tinea capitis and tinea unguium etc.)	Contraindication: This drug is contraindicated in patients with porphyria or hepatocellular failure and in individuals with a history of hypersensitivity to griseofulvin. Side-effects: Side effects reported occasionally are oral thrush, nausea, vomiting, epigastric distress, diarrhea, headache, fatigue, dizziness, insomnia, mental confusion, and impairment of performance of routine activities. Proteinuria and leukopenia have been reported rarely. Precautions & Warnings: Patients on prolonged therapy with any potent medication should be under close observation. Periodic monitoring of organ system function, including renal, hepatic and hematopoietic, should be done. Since griseofulvin is derived from species of Penicillium, the possibility of cross sensitivity with penicillin exists; however, known penicillin-sensitive patients have been treated without difficulty. Since a photosensitivity reaction is occasionally associated with griseofulvin therapy, patients should be warned to avoid exposure to intense natural or artificial sunlight. Lupus erythematosus or lupus-like syndromes have been	Griseofulvin 500 mg Tablet Griseofulvin 125 mg/5ml suspension	**USFDA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদনের সুপারিশ করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						reported in patients receiving griseofulvin. Griseofulvin decreases the activity of warfarin-type anticoagulants so that patients receiving these drugs concomitantly may require dosage adjustment of the anticoagulant during and after griseofulvin therapy. Barbiturates usually depress griseofulvin activity and concomitant administration may require a dosage adjustment of the antifungal agent. There have been reports in the literature of possible interactions between griseofulvin and oral contraceptives. The effect of alcohol may be potentiated by griseofulvin, producing such effects as tachycardia and flush. Prophylactic Usage – Safety and efficacy of griseofulvin for prophylaxis of fungal infections have not been established.				
60.	Opsonin Pharma Limited, Rupatali, Barishal Ziska Pharmaceuticals Ltd.	Griseofulvin ultramicrosize 250 mg Tablet	Griseofulvin USP ultramicrosize 250 mg	Therapeutic Class: Antifungal Therapeutic Code:020	Indicated for the treatment of tinea infections (tinea corporis, tinea pedis, tinea cruris, tinea barbae, tinea capitis and tinea unguium etc.)	Contraindication: This drug is contraindicated in patients with porphyria or hepatocellular failure and in individuals with a history of hypersensitivity to griseofulvin. Side-effects: Side effects reported occasionally are oral thrush, nausea, vomiting, epigastric distress, diarrhea, headache, fatigue, dizziness, insomnia, mental confusion, and impairment of performance of routine activities. Proteinuria and leukopenia have been reported rarely. Precautions & Warnings: Patients on prolonged therapy with any potent medication should be under close observation. Periodic monitoring of organ system function, including renal, hepatic and hematopoietic, should be done. Since griseofulvin is derived from species of Penicillium, the possibility of cross sensitivity with penicillin exists; however, known penicillin-	Griseofulvin 500 mg Tablet Griseofulvin 125 mg/5ml suspension	USFDA	অনুমোদনের সুপারিশ করা হয়।	নামঞ্জুর করা হয়। কারণ বিভিন্ন ডোজেস ফরম বাজারে সরবরাহ থাকার কারণে Anti Microbial Resistance বৃদ্ধির সম্ভবনা রয়েছে।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						sensitive patients have been treated without difficulty. Since a photosensitivity reaction is occasionally associated with griseofulvin therapy, patients should be warned to avoid exposure to intense natural or artificial sunlight. Lupus erythematosus or lupus-like syndromes have been reported in patients receiving griseofulvin. Griseofulvin decreases the activity of warfarin-type anticoagulants so that patients receiving these drugs concomitantly may require dosage adjustment of the anticoagulant during and after griseofulvin therapy. Barbiturates usually depress griseofulvin activity and concomitant administration may require a dosage adjustment of the antifungal agent. There have been reports in the literature of possible interactions between griseofulvin and oral contraceptives. The effect of alcohol may be potentiated by griseofulvin, producing such effects as tachycardia and flush. Prophylactic Usage – Safety and efficacy of griseofulvin for prophylaxis of fungal infections have not been established.				
61.	Opsonin Pharma Limited, Rupatali, Barishal. Navana Pharmaceuticals Limited Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Olanzapine 10 mg + Samidorphan 10 mg Tablet	Olanzapine USP 10 mg + Samidorphan INN 10 mg	Therapeutic Class: Antipsychotic Therapeutic Code:028	It is a combination of olanzapine, an atypical antipsychotic, and samidorphan, an opioid antagonist, indicated for the treatment of: • Schizophrenia in adults • Bipolar I disorder in adults o Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate o Maintenance monotherapy treatmen	Warning: Increased Mortality In Elderly Patients With Dementia-Related Psychosis Contraindications: Patients using opioids. • Patients undergoing acute opioid withdrawal. • If administered with lithium or valproate, refer to the lithium or valproate Prescribing Information for the contraindications for those products Side effects: •Dry mouth, weight gain, increased appetite, dizziness, back pain, constipation, problems speaking, mouth watering, memory problems, numbness and tingling in your arm and legs	Olanzapine 5 mg & 10 mg Tablet (Opsonin Pharma) Olanap 5 mg & 10 mg Tablet (Incepta Pharma)	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Precautions & warnings: Cerebrovascular Adverse Reactions in Elderly Patients with Dementia Related Psychosis: Increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack, including fatalities). • Precipitation of Opioid Withdrawal in Patients Who are Dependent on Opioids: can precipitate opioid withdrawal in patients who are dependent on opioids. Prior to initiating it, there should be at least a 7-day opioid-free interval from the last use of short-acting opioids, and at least a 14-day opioid-free interval from the last use of long-acting opioids to avoid precipitation of opioid withdrawal. • Vulnerability to Life-Threatening Opioid Overdose: o Risk of Opioid Overdose from Attempts to Overcome LYBALVI Opioid Blockade: Attempts to overcome opioid blockade with high or repeated doses of opioids may lead to fatal opioid intoxication, particularly if the therapy is interrupted or discontinued. o Risk of Resuming Opioids in Patients with Prior Opioid Use: Patients with a history of chronic opioid use prior to treatment may have decreased opioid tolerance if the therapy is interrupted or discontinued. • Neuroleptic Malignant Syndrome: Manage with immediate discontinuation and close monitoring. • Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): Discontinue if DRESS is suspected. • Metabolic Changes: Monitor for hyperglycemia/diabetes mellitus, dyslipidemia, and weight gain. • Tardive Dyskinesia: Discontinue if clinically appropriate. • Orthostatic Hypotension and Syncope: Monitor				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						heart rate and blood pressure and warn patients with known cardiovascular or cerebrovascular disease, and risk of dehydration or syncope. • Leukopenia, Neutropenia, and Agranulocytosis: Perform complete blood counts in patients with a history of a clinically significant low white blood cell (WBC) count. Consider discontinuation if clinically significant decline in WBC in the absence of other causative factors. • Seizures: Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold. • Potential for Cognitive and Motor Impairment: Use caution when operating machinery. • Anticholinergic (Antimuscarinic) Effects: Use with caution with other anticholinergic drugs and in patients with urinary retention, prostatic hypertrophy, constipation, paralytic ileus or related conditions. • Hyperprolactinemia: May elevate prolactin levels.				
62.	Opsonin Pharma Limited, Rupatali, Barishal. Navana Pharmaceuticals Limited	Olanzapine 15 mg + Samidorphan 10 mg Tablet	Olanzapine USP 15 mg + Samidorphan INN 10 mg	Therapeutic Class: Antipsychotic Therapeutic Code:028	It is a combination of olanzapine, an atypical antipsychotic, and samidorphan, an opioid antagonist, indicated for the treatment of: • Schizophrenia in adults • Bipolar I disorder in adults o Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate o Maintenance monotherapy treatmen	Warning: Increased Mortality In Elderly Patients With Dementia-Related Psychosis Contraindications: Patients using opioids. • Patients undergoing acute opioid withdrawal. • If administered with lithium or valproate, refer to the lithium or valproate Prescribing Information for the contraindications for those products Side effects: •Dry mouth, weight gain, increased appetite, dizziness, back pain, constipation, problems speaking, mouth watering, memory problems, numbness and tingling in your arm and legs	Olanzapine 5 mg & 10 mg Tablet (Opsonin Pharma) Olanap 5 mg & 10 mg Tablet (Incepta Pharma)	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Precautions & warnings: Cerebrovascular Adverse Reactions in Elderly Patients with Dementia Related Psychosis: Increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack, including fatalities). • Precipitation of Opioid Withdrawal in Patients Who are Dependent on Opioids: can precipitate opioid withdrawal in patients who are dependent on opioids. Prior to initiating it, there should be at least a 7-day opioid-free interval from the last use of short-acting opioids, and at least a 14-day opioid-free interval from the last use of long-acting opioids to avoid precipitation of opioid withdrawal. • Vulnerability to Life-Threatening Opioid Overdose: o Risk of Opioid Overdose from Attempts to Overcome LYBALVI Opioid Blockade: Attempts to overcome opioid blockade with high or repeated doses of opioids may lead to fatal opioid intoxication, particularly if the therapy is interrupted or discontinued. o Risk of Resuming Opioids in Patients with Prior Opioid Use: Patients with a history of chronic opioid use prior to treatment may have decreased opioid tolerance if the therapy is interrupted or discontinued. • Neuroleptic Malignant Syndrome: Manage with immediate discontinuation and close monitoring. • Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): Discontinue if DRESS is suspected. • Metabolic Changes: Monitor for hyperglycemia/diabetes mellitus, dyslipidemia, and weight gain. • Tardive Dyskinesia: Discontinue if clinically appropriate. • Orthostatic Hypotension and Syncope: Monitor				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						heart rate and blood pressure and warn patients with known cardiovascular or cerebrovascular disease, and risk of dehydration or syncope. • Leukopenia, Neutropenia, and Agranulocytosis: Perform complete blood counts in patients with a history of a clinically significant low white blood cell (WBC) count. Consider discontinuation if clinically significant decline in WBC in the absence of other causative factors. • Seizures: Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold. • Potential for Cognitive and Motor Impairment: Use caution when operating machinery. • Anticholinergic (Antimuscarinic) Effects: Use with caution with other anticholinergic drugs and in patients with urinary retention, prostatic hypertrophy, constipation, paralytic ileus or related conditions. • Hyperprolactinemia: May elevate prolactin levels.				
63.	Opsonin Pharma Limited, Rupatali, Barishal. Navana Pharmaceuticals Limited	Olanzapine 20 mg + Samidorphan 10 mg Tablet	Olanzapine USP 20 mg + Samidorphan INN 10 mg	Therapeutic Class: Antipsychotic Therapeutic Code:028	It is a combination of olanzapine, an atypical antipsychotic, and samidorphan, an opioid antagonist, indicated for the treatment of: • Schizophrenia in adults • Bipolar I disorder in adults o Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate o Maintenance monotherapy treatmen	Warning: Increased Mortality In Elderly Patients With Dementia-Related Psychosis Contraindications: Patients using opioids. • Patients undergoing acute opioid withdrawal. • If administered with lithium or valproate, refer to the lithium or valproate Prescribing Information for the contraindications for those products Side effects: •Dry mouth, weight gain, increased appetite, dizziness, back pain, constipation, problems speaking, mouth watering, memory problems, numbness and tingling in your arm and legs	Olanzapine 5 mg & 10 mg Tablet (Opsonin Pharma) Olanap 5 mg & 10 mg Tablet (Incepta Pharma)	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Precautions & warnings: Cerebrovascular Adverse Reactions in Elderly Patients with Dementia Related Psychosis: Increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack, including fatalities). • Precipitation of Opioid Withdrawal in Patients Who are Dependent on Opioids: can precipitate opioid withdrawal in patients who are dependent on opioids. Prior to initiating it, there should be at least a 7-day opioid-free interval from the last use of short-acting opioids, and at least a 14-day opioid-free interval from the last use of long-acting opioids to avoid precipitation of opioid withdrawal. • Vulnerability to Life-Threatening Opioid Overdose: o Risk of Opioid Overdose from Attempts to Overcome LYBALVI Opioid Blockade: Attempts to overcome opioid blockade with high or repeated doses of opioids may lead to fatal opioid intoxication, particularly if the therapy is interrupted or discontinued. o Risk of Resuming Opioids in Patients with Prior Opioid Use: Patients with a history of chronic opioid use prior to treatment may have decreased opioid tolerance if the therapy is interrupted or discontinued. • Neuroleptic Malignant Syndrome: Manage with immediate discontinuation and close monitoring. • Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): Discontinue if DRESS is suspected. • Metabolic Changes: Monitor for hyperglycemia/diabetes mellitus, dyslipidemia, and weight gain. • Tardive Dyskinesia: Discontinue if clinically appropriate. • Orthostatic Hypotension and Syncope: Monitor				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						heart rate and blood pressure and warn patients with known cardiovascular or cerebrovascular disease, and risk of dehydration or syncope. • Leukopenia, Neutropenia, and Agranulocytosis: Perform complete blood counts in patients with a history of a clinically significant low white blood cell (WBC) count. Consider discontinuation if clinically significant decline in WBC in the absence of other causative factors. • Seizures: Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold. • Potential for Cognitive and Motor Impairment: Use caution when operating machinery. • Anticholinergic (Antimuscarinic) Effects: Use with caution with other anticholinergic drugs and in patients with urinary retention, prostatic hypertrophy, constipation, paralytic ileus or related conditions. • Hyperprolactinemia: May elevate prolactin levels.				
64.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Tirzepatide	Tirzepatide 10 mg prefilled Injection	Therapeutic Class: 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	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
65.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Betamethasone betamethasone sodium phosphate 3mg+Betamethasone Acetate BP 3 mg/ml Injection	Betamethasone sodium phosphate 3mg+Betamethasone Acetate BP 3 mg/ml Injection	Therapeutic Class: Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic Code:044	When oral therapy is not feasible, the intramuscular use of BETAMETHASONE SODIUM PHOSPHATE AND BETAMETHASONE ACETATE Injectable Suspension is indicated as follows: Allergic States Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in asthma, atopicdermatitis, contact dermatitis, drug hypersensitivity reactions, perennial or seasonal allergic rhinitis, serum sickness, transfusion reactions. Dermatologic Diseases Bullousdermatitis herpetiformis, exfoliative erythroderma, mycosis fungoides, pemphigus, severe erythema multiforme (Stevens-Johnson syndrome). Endocrine Disorders Congenital adrenal hyperplasia, hypercalcemia associated with cancer, nonsuppurative thyroiditis. Hydrocortisone or cortisone is the drug of choice in primary or secondary adrenocortical insufficiency. Synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy mineralocorticoid supplementation is of particular importance. Gastrointestinal Diseases To tide the patient over a critical period of the disease in regional enteritis and ulcerative colitis. Hematologic Disorders Acquired (autoimmune) hemolytic anemia, Diamond-Blackfan anemia, pure red cell aplasia, selected cases of secondary	Contraindication: BETAMETHASONE SODIUM PHOSPHATE AND BETAMETHASONE ACETATE Injectable Suspension is contraindicated in patients who are hypersensitive to any components of this product. Intramuscular corticosteroid preparations are contraindicated for idiopathic thrombocytopenic purpura. Side-effects: Cardiovascular Bradycardia, cardiac arrest, cardiac arrhythmias, cardiac enlargement, circulatory collapse, congestive heart failure, fat embolism, hypertension, hypertrophic cardiomyopathy in premature infants, myocardial rupture following recent myocardial infarction, pulmonary edema, syncope, tachycardia, thromboembolism, thrombophlebitis, vasculitis. Dermatologic Acne, allergic dermatitis, cutaneous and subcutaneous atrophy, dry scaly skin, ecchymoses and petechiae, edema, erythema, hyperpigmentation, hypopigmentation, impaired wound healing, increased sweating, rash, sterile abscess, striae, suppressed reactions to skin tests, thin fragile skin, thinning scalp hair, urticaria. Endocrine Decreased carbohydrate and glucose tolerance, development of cushingoid state, glucosuria, hirsutism, hypertrichosis, increased requirements for insulin or oral hypoglycemic adrenocortical and pituitary unresponsiveness (particularly in times of stress, as in trauma, surgery, or illness), suppression of growth in pediatric patients. Fluid And Electrolyte Disturbances Congestive heart failure in susceptible patients, fluid retention, hypokalemic alkalosis, potassium loss, sodium retention. Gastrointestinal	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					thrombocytopenia. Miscellaneous Trichinosis with neurologic or myocardial involvement, tuberculous meningitis with subarachnoid block or impending block when used with appropriate antituberculous chemotherapy. Neoplastic Diseases For palliative management of leukemias and lymphomas. Nervous System Acute exacerbations of multiple sclerosis; cerebral edema associated with primary or metastatic brain tumor or craniotomy. Ophthalmic Diseases Sympathetic ophthalmia, temporal arteritis, uveitis and ocular inflammatory conditions unresponsive to topical corticosteroids. Renal Diseases To induce diuresis or remission of proteinuria in idiopathic nephritic syndrome or that due to lupus erythemato	Abdominal distention, bowel/bladder dysfunction (after intrathecal administration), elevation in serum liver enzyme levels (usually reversible upon discontinuation), hepatomegaly, increased appetite, nausea, pancreatitis, peptic ulcer with possible perforation and hemorrhage, perforation of the small and large intestine (particularly in patients with inflammatory bowel disease), ulcerative esophagitis. Metabolic Negative nitrogen balance due to protein catabolism. Musculoskeletal Aseptic necrosis of femoral and humeral heads, calcinosis (following intra-articular or intralesional use), Charcot-like arthropathy, loss of muscle mass, muscle weakness, osteoporosis, pathologic fracture of long bones, postinjection flare (following intra-articular use), steroidmyopathy, tendon rupture, vertebral compression fractures. Warnings and Precautions: General This product, like many other steroid formulations, is sensitive to heat. Therefore, it should not be autoclaved when it is desirable to sterilize the exterior of the vial. The lowest possible dose of corticosteroid should be used to control the condition under treatment. When reduction in dosage is possible, the reduction should be gradual. Since complications of treatment with glucocorticoids are dependent on the size of the dose and the duration of treatment, a risk/benefit decision must be made in each individual case as to dose and duration of treatment and as to whether daily or intermittent therapy should be used. Kaposi's sarcoma has been reported to occur in patients receiving corticosteroid therapy, most often for chronic				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						conditions. Discontinuation of corticosteroids may result in clinical improvement. Cardio-renal As sodium retentionwith resultant edema and potassium loss may occur in patients receiving corticosteroids, these agents should be used with caution in patients with congestive heart failure, hypertension, or renal insufficiency. Endocrine Drug-induced secondary adrenocortical insufficiency may be minimized by gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy. Therefore, in any situation of stress occurring during that period, naturally occurring glucocorticoids (hydrocortisone cortisone), which also have salt-retaining properties, rather than betamethasone, are the appropriate choices as replacement therapy in adrenocortical deficiency states. Gastrointestinal Steroids should be used with caution in active or latent peptic ulcers, diverticulitis, fresh intestinal anastomoses, and nonspecific ulcerative colitis, since they may increase the risk of a perforation. Signs of peritoneal irritation following gastrointestinal perforation in patients receiving corticosteroids may be minimal or absent. There is an enhanced effect of corticosteroids in patients with cirrhosis.				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
66.	Opsonin Pharma Limited, Rupatali, Barishal.	Pantoprazole Sodium 40 mg delayed-release oral granules for suspension	Pantoprazole Sodium USP 40 mg	Therapeutic Class: Proton Pump inhibitor Therapeutic Code:067	It is a proton pump inhibitor (PPI) indicated for the following: • Short-Term Treatment of Erosive Esophagitis Associated with Gastroesophageal Reflux Disease (GERD) • Maintenance of Healing of Erosive Esophagitis • Pathological Hypersecretory Conditions Including Zollinger-Ellison (ZE) Syndrome	Contradiction: • known hypersensitivity to any component of the formulation or to substituted benzimidazoles • Patients receiving rilpivirine-containing products Side effects: Most common adverse reactions are: • For adult use (>2%): headache, diarrhea, nausea, abdominal pain, vomiting, flatulence, dizziness, and arthralgia • For pediatric use (>4%): URI, headache, fever, diarrhea, vomiting, rash, and abdominal pain. Warnings & Precautions: • Gastric Malignancy: In adults, symptomatic response does not preclude presence of gastric malignancy. Consider additional follow-up and diagnostic testing. • Acute Tubulointerstitial Nephritis: Discontinue treatment and evaluate patients. • Clostridium difficile-Associated Diarrhea: PPI therapy may be associated with increased risk of Clostridium difficile-associated diarrhea. • Bone Fracture: Long-term and multiple daily dose PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist or spine. • Cutaneous and Systemic Lupus Erythematosus: Mostly cutaneous; new onset or exacerbation of existing disease; discontinue PROTONIX and refer to specialist for evaluation. • Cyanocobalamin (Vitamin B-12) Deficiency: Daily long-term use (e.g., longer than 3 years) may lead to malabsorption or a deficiency of cyanocobalamin. • Hypomagnesemia: Reported rarely with prolonged treatment with PPIs.	Pantoprazole 20 mg & 40 mg Tablet, 40 mg IV injection	**USFDA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						• Fundic Gland Polyps: Risk increases with long-term use, especially beyond one year. Use the shortest duration of therapy.				
67.	Opsonin Pharma Limited, Rupatali, Barishal.	Rabeprazole Sodium 20 mg Injection	Rabeprazole Sodium BP 20 mg	Therapeutic Class: Proton Pump inhibitor Therapeutic Code:067	Short-term treatment of gastric and duodenal ulcers, gastro-oesophageal reflux disease (GERD), and as an alternative to oral therapy in patients who are unable to take oral proton-pump inhibitor (PPI).	Contraindications: contraindicated in patients with a known hypersensitivity to rabeprazole, substituted benzimidazoles or to any component of the formulation. Side effects: Common side effects include headaches, diarrhoea, feeling or being sick, constipation, stomach pain or wind. Precautions & warnings: This product may contain inactive ingredients, which can cause allergic reactions or other problems. Proton pump inhibitors (such as rabeprazole) may increase the risk of bone fractures, especially with longer use, higher doses, and in older adults. It is unknown if this medication passes into breast milk. However, similar drugs pass into breast milk. The effects on a nursing infant are unknown.	Rabeprazole 20 mg Tab, 20 mg Capsule, 10 mg capsule	রেফারেন্স নাই।	**প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।**
68.	Opsonin Pharma Limited, Rupatali, Barishal. Nuvista Pharma Ltd. Navana Pharmaceuticals Limited	Tirbanibulin 1% ointment	Tirbanibulin INN 1%	Therapeutic Class: Skin and Mucous membrane preparation Therapeutic Code: 071	Tirbanibulin is a microtubule inhibitor indicated for the topical treatment of actinic keratosis of the face or scalp	Contraindications: None Side effects: Most common adverse reactions (incidence ≥2%) are local skin reactions, application site pruritus, and application site pain. Precautions & warnings: • May cause eye irritation upon ocular exposure. Avoid transfer of the drug into the eyes and to the periocular area. If accidental exposure occurs, flush eyes with water and seek medical care. • Local skin reactions can occur including severe reactions (e.g., vesiculation/pustulation,erosion/ulceration) in the	New	USFDA	**অনুমোদনের সুপারিশ করা হয়।**	**অনুমোদন করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						treated area. Avoid use until skin is healed from any previous drug or surgical treatment.				
69.	Opsonin Pharma Limited, Rupatali, Barishal. Navana Pharmaceuticals Limited	Vancomycin 250 mg Capsule	Vancomycin USP 250 mg	Therapeutic Class: Anti-infective Therapeutic Code: 023	Vancomycin is a glycopeptide antibacterial indicated in adult and pediatric patients (less than 18 years of age) for the treatment of: • Clostridioides difficile-associated diarrhea • Enterocolitis caused by Staphylococcus aureus (including methicillinresistant strains)	Contraindications: Hypersensitivity to vancomycin. Side effects: The most common adverse reactions (≥ 10%) were nausea (17%), abdominal pain (15%), and hypokalemia (13%). Precautions & warnings: • Vancomycin must be given orally for treatment of staphylococcal enterocolitis and C difficile-associated diarrhea. Orally administered Vancomycin is not effective for other types of infections. • Clinically significant serum concentrations have been reported in some patients who have taken multiple oral doses of Vancomycin for active C. difficile-associated diarrhea. Monitoring of serum concentrations may be appropriate in some instances. • Nephrotoxicity has occurred following oral Vancomycin 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. Assessment of auditory function may be appropriate in some instances. • Severe Dermatologic Reactions: Discontinue Vancomycin at the first appearance of skin rashes, mucosal lesions, or blisters. • Prescribing Vancomycin 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.	Vancomycin 1 gm Injection, Vancomycin 500 mg Injection	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
70.	Opsonin Pharma Limited, Rupatali, Barishal. Navana Pharmaceuticals Limited	Vancomycin 3.75 gm Oral Solution	Vancomycin USP 3.75 gm	Therapeutic Class: Anti-infective Therapeutic Code: 023	Vancomycin is a glycopeptide antibacterial indicated in adult and pediatric patients (less than 18 years of age) for the treatment of: • Clostridioides difficile-associated diarrhea • Enterocolitis caused by Staphylococcus aureus (including methicillinresistant strains) Limitations of Use: Orally administered vancomycin hydrochloride is not effective for treatment of 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%). Precautions & warnings: • Vancomycin must be given orally for treatment of staphylococcal enterocolitis and C difficile-associated diarrhea. Orally administered Vancomycin is not effective for other types of infections. • Clinically significant serum concentrations have been reported in some patients who have taken multiple oral doses of Vancomycin for active C. difficile-associated diarrhea. Monitoring of serum concentrations may be appropriate in some instances. • Nephrotoxicity has occurred following oral Vancomycin 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. Assessment of auditory function may be appropriate in some instances. • Severe Dermatologic Reactions: Discontinue Vancomycin at the first appearance of skin rashes, mucosal lesions, or blisters. • Prescribing Vancomycin 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.	Vancomycin 1 gm Injection, Vancomycin 500 mg Injection	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
71.	Opsonin Pharma Limited, Rupatali, Barishal. Navana	Vancomycin 7.50 gm Oral Solution	Vancomycin USP 7.50 gm	Therapeutic Class: Anti-infective Therapeutic Code: 023	Vancomycin is a glycopeptide antibacterial indicated in adult and pediatric patients (less than 18 years of age) for the treatment of: • Clostridioides difficile-associated	Contraindications: Hypersensitivity to vancomycin. Side effects: The most common adverse reactions (≥ 10%) were nausea (17%), abdominal pain (15%), and hypokalemia (13%). Precautions & warnings: • Vancomycin must be given orally for treatment of	Vancomycin 1 gm Injection, Vancomycin 500 mg Injection	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Pharmaceuticals Limited				diarrhea • Enterocolitis caused by Staphylococcus aureus (including methicillinresistant strains) Limitations of Use: Orally administered vancomycin hydrochloride is not effective for treatment of other types of infections	staphylococcal enterocolitis and C difficile-associated diarrhea. Orally administered Vancomycin is not effective for other types of infections. • Clinically significant serum concentrations have been reported in some patients who have taken multiple oral doses of Vancomycin for active C. difficile-associated diarrhea. Monitoring of serum concentrations may be appropriate in some instances. • Nephrotoxicity has occurred following oral Vancomycin 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. Assessment of auditory function may be appropriate in some instances. • Severe Dermatologic Reactions: Discontinue Vancomycin at the first appearance of skin rashes, mucosal lesions, or blisters. • Prescribing Vancomycin 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.				
72.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Navana Pharmaceuticals Limited Incepta	Plecanatide 3mg Tablet	Plecanatide INN 3mg	Therapeutic Class: Laxatives Therapeutic code: 060	Indicated in adults for treatment of chronic idiopathic constipation	Warning: Risk Of Serious Dehydration In Pediatric Patients Contra-indication: Patients less than 6 years of age due to the risk of serious dehydration. Patients with known or suspected mechanical gastrointestinal obstruction Side effect: Most common adverse reaction (≥2%) is diarrhea	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka									
73.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Healthcare Pharmaceuticals Ltd Navana Pharmaceuticals Limited	Calcium 1000mg + Cholecalciferol (Vit-D3) 880IU Effervescent Tablet	Calcium Carbonate (Coral Source) BP 2500mg (eqv 1000mg Calcium) + Dry Vitamin D3 Ph. Grade 8.8mg eqv. to Cholecalciferol (Vit-D3) 880IU	Therapeutic Class: Metals, Salts, Minerals and Calcium Preparations Therapeutic Code: 062	It is indicated: - for the prevention and treatment of vitamin D and calcium deficiency in the elderly - as vitamin D and calcium supplement as an adjunct to specific osteoporosis treatment of patients who are at risk of vitamin D and calcium deficiency.	Contraindications: - Hypersensitivity to the active substances or to any of the excipients - Hypercalciuria and hypercalcaemia and diseases and/or conditions, which lead to hypercalcaemia and/or hypercalciuria (e.g. myeloma, bone metastases, primary hyperparathyroidism, prolonged immobilisation accompanied by hypercalciuria and/or hypercalcaemia). - Nephrolithiasis - Nephrocalcinosis - Hypervitaminosis D - Severe renal impairment Side effects: Immune system disorders Not known (cannot be estimated from the available data): Hypersensitivity reactions such as angioedema or laryngeal oedema. Metabolism and nutrition disorders Uncommon: Hypercalcaemia, hypercalciuria. Gastrointestinal disorders Rare: Nausea, diarrhoea, abdominal pain, constipation, flatulence, abdominal distension. Skin and subcutaneous tissue disorders Rare: Rash, pruritus, urticaria.	Calcium 500 mg + Vitamin D 200 IU Tablet, Calcium 600 mg + Vitamin D 400 IU Tablet	UKMHRA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
74.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Eskayef	Deflazacort 18 mg Tablet	Deflazacort INN 18mg	Therapeutic Class: Steroidal Anti inflammatory Therapeutic Code: 072	Asthma and other airway Diseases, Rheumatoid arthritis, juvenile chronic arthritis, pemphigus, uveitis, nephritic, syndrome,Immune suppression in transplantation, anaphylaxis, severe,hypersensitivity reactions, dermatomyositis, mixed	Contraindications: Systemic infection; live virus vaccines in those receiving immunosuppressive doses. Side Effects: GI disturbances, musculoskeletal, endocrine, neuropsychiatric, ophthalmic, fluid and electrolyte	6mg, 24mg Tablet & 120mg/100ml Suspention	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Pharmaceuticals Ltd.				connective, tissue disease, polyarteritis nodosa, bullous pemphigoid, ulcerative colitis, optic neuritis, autoimmune haemolytic anaemia, idiopathic, thrombocytopenic, purpura, acute and lymphatic leukaemia, malignant lymphoma.	disturbances; susceptible to infection, impaired healing, hypersensitivity, skin atrophy, striae, telangiectasia, acne, myocardial rupture following recent MI, thromboembolism.				
75.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Ziska Pharmaceuticals Ltd. Organic Health Care Ltd. Gilarchala, 7 Kewa Mouza, Sreepur, Gazipur Opsonin Pharma Limited, Rupatali, Barishal General Pharmaceutical Ltd., Gazipur Drug International Ltd (Unit-3) 31/1,Satrong, Tongi I/A, Gazipur	Ibrexafungerp 150 mg Tablet	Ibrexafungerp Citrate INN 189.50mg eqv. to Ibrexafungerb 150mg	Therapeutic Class: **Anti-Fungal Agent** Therapeutic code: 020	It is a triterpenoid antifungal indicated for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (VVC).	Warnings and Precautions: Risk of Fetal Toxicity: May cause fetal harm based on animal studies. Advise females of reproductive potential to use effective contraception during treatment. Contraindications: Pregnancy, Hypersensitivity to ibrexafungerp. Side effects: Most common adverse reaction (>5%) in clinical trials were hot flushes, headache, fatigue, metrorrhagia.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Navana Pharmaceuticals Limited Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Nuvista Pharma Ltd. Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur The ACME Laboratories Ltd. Dhamrai, Dhaka DBL Pharmaceuticals Ltd. Surabari, Kashimpur, Gazipur The IBN SINA Pharmaceutical Industries Ltd. Incepta Pharmaceutic									

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	als Ltd.;Zirabo, Savar, Dhaka									
76.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Calcium L-5 Methyltetrahydrofolate 1 mg Tablet	Calcium L-5 Methyltetrahydrofolate USP 1 mg Tablet	Therapeutic Class: Vitamins and Combinations Therapeutic Code: 078	Folic acid is the man-made form of folate. Folate is a B-vitamin naturally found in some foods. It is needed to form healthy cells, especially red blood cells. Folic acid supplements may come in different forms (such as L-methylfolate, levomefolate, methyltetrahydrofolate). They are used to treat or prevent low folate levels. Low folate levels can lead to certain types of anemia. Conditions that can cause low folate levels include poor diet, pregnancy, alcoholism, liver disease, certain stomach/intestinal problems, kidney dialysis, among others. Women of childbearing age should receive adequate amounts of folic acid either through their diet or supplements to prevent infant spinal cord birth defects.	Contraindications: This product is contraindicated in patients with a known hypersensitivity to pregabalin or any of it's component. Side effect: It does not typically cause side effects.	New	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**
77.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur General Pharmaceutical Ltd., Gazipur	Vonoprazan 10mg Film Coated Tablet	Vonoprazan Fumarate INN 13.36mg eqv. to Vonoprazan 10mg Film Coated Tablet	Therapeutic Class: Proton Pump inhibitor Therapeutic code: 067	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	রেফারেন্স নাই। JP	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Ziska Pharmaceuticals Ltd. Aristopharma Ltd. Gachha, Gazipur Sadar, Gazipur. Renata Limited Mirpur, Dhaka The ACME Laboratories Ltd. Dhamrai, Dhaka Organic Health Care Ltd. Gilarchala, 7 Kewa Mouza, Sreepur, Gazipur Healthcare Pharmaceuticals Ltd									
78.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur General	Vonoprazan 20mg Film Coated Tablet	Vonoprazan Fumarate INN 26.72mg eqv. to Vonoprazan 20mg Film Coated Tablet	Therapeutic Class: Proton Pump inhibitor Therapeutic code: 067	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-	Contraindications: Hypersensitivity to the active substance or to any of the excipients. Vonoprazan tablets should not be co-administered with Atazanavir & Rilpivirine Side-effects:	New	রেফারেন্স নাই। JP	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Pharmaceutical Ltd., Gazipur Healthcare Pharmaceuticals Ltd Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Ziska Pharmaceuticals Ltd. M/s. Aristopharma Ltd. Gachha, Gazipur Sadar, Gazipur. Renata Limited Mirpur, Dhaka The ACME Laboratories Ltd. Dhamrai, Dhaka				steroidal anti-inflammatory drug administration. Adjunct therapy to Helicobacter pylori eradication.	The most common adverse reaction was constipation, diarrhoea, skin rash & nausea.				
79.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Opsonin Pharma Limited, Rupatali, Barishal.	Linaclotide 290mcg Capsule	Linaclotide pellets Ph. Grade 322.222mg eqv. to Linaclotide INN 290mcg Capsule	Therapeutic Class: Laxatives Therapeutic code: 060	Linaclotide is a guanylate cyclase-C agonist indicated in adults for treatment of: 1. Irritable bowel syndrome with constipation. (IBS-C) 2. Chronic idiopathic constipation. (CIC)	Warning: Pediatric Risk Contraindication: • Pediatric patients up to 6 years of age • Patients with known or suspected mechanical gastrointestinal obstruction Side Effects: Diarrhoea, dizziness, gastrointestinal discomfort,	New	USFDA, EMA, BNF	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Healthcare Pharmaceuticals Ltd. Nuvista Pharma Ltd. Navana Pharmaceuticals Limited					Uncommon Appetite decreased, dehydration, haemorrhage, hypokalaemia, nausea. postural, hypotension. vomiting, Frequency not known Rash				
80.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Navana Pharmaceuticals Limited Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Loperamide Hydrochloride 2mg + Simethicone 125 mg Tablet	Loperamide Hydrochloride USP 2mg + Simethicone DC Grade 100 Ph. Grade 208.333 mg (Equivalent to 125 mg Simethicone USP) Tablet	Therapeutic Class: Antidiarrhoeal Agents Therapeutic code: 016	It is indicated fr the treatment of acute diarrhea in adults and adolescents over 12 years when acute diarrhea is associated with gas-related abdominal discomfort including bloating, cramping or flatulence.	Contraindication: Active ulcerative colitis, antibioticassociated colitis, bacterial enterocolitis, conditions where abdominal distension develops. Side Effects: Common: Gastrointestinal disorders, headache. nausea Uncommon: Dizziness, drowsiness, dry mouth, gastrointestinal discomfort, skin reactions. vomiting Rare or very rare Angioedema, consciousness impaired, coordination abnormal, fatigue, miosis, muscle tone increased.	Loperamide 2 mg Capsule Simethicone 40 mg Chewable Tablet	USFDA, MHRA, BNF	**অনুমোদনের সুপারিশ করা হয়।**	**অনুমোদন করা হয়।**
81.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria,	Ilaaprazole 10 mg Tablet	Ilaaprazole INN 10 mg	Therapeutic Class: Proton Pump inhibitor Therapeutic code: 067	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	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
82.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj.	Carragelose 120mg/100ml Nasal Spray	Carragelose INN 120mg/100ml	Therapeutic Class: Ear and Nose Preparation Therapeutic code: 050	• Protects from common cold viruses. • Shorten the duration and severity of common cold/flu like symptoms. • Reduces chances of relapse of cold & flu-like symptoms.	Side-effects: There is no known adverse or side effects observed. Precautions & warning: No known side effects observed. Use only as directed. The use of this dispenser by more than one person may spread infection.	New	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
83.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria,	Sodium Chloride 0.9gm + Elemental Iodine 0.002gm/100ml Nasal Spray	Sodium Chloride BP 0.9gm + Elemental Iodine (as Iodine V which is a complex of Elemental Iodine and Fulvic acid) Ph. Grade 0.002gm/100ml	Therapeutic Class: Ear and Nose Preparation Therapeutic code: 050	It is indicated for the treatment of Antiseptic, Antiviral, Nasal decongestant, for cleaning the nasal cavity and the removal of the unpleasant mucus, For nasal irrigation	Side-effects: There is no known adverse or side effects observed. Precautions & warning: No known side effects observed. Use only as directed. The use of this dispenser by more than one person may spread infection.	New	USFDA- OTC	অনুমোদনের সুপারিশ করা হয়। তবে পদটি **Antiviral** হিসেবে ব্যবহার উল্লেখ করা যাবে না।	অনুমোদন করা হয়। তবে পদটি **Antiviral** হিসেবে ব্যবহার উল্লেখ করা যাবে না।
84.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria,	Iodinated Povidone (PVP-Iodine) 0.6gm/100ml Oro-Nasal Spray	Iodinated Povidone (PVP-Iodine) BP 0.6gm/100ml	Therapeutic Class: Ear and Nose Preparation Therapeutic code: 050	It is indicated for the treatment of Antiseptic, Antiviral and antimicrobial.	Side-effects: There is no known adverse or side effects observed. Precautions & warning: No known side effects observed. Use only as directed. The use of this dispenser by more than one person may spread infection.	New	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
85.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur The Acme Laboratories ltd. Dhamrai Dhaka	Cefixime 50mg + Clavulanic Acid 31.25mg Tablet	Cefixime Trihydrate USP 55.95 mg eqv. to Cefixime 50 mg + Diluted Potassium Clavulanate BP 78.125 mg eqv. to Clavulanic Acid 31.25 mg	Therapeutic Class: Anti-infective Therapeutic code: 023	Cefixime-Clavulanic Acid should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Cefixime-Clavulanic Acid is indicated for the treatment of – 1) Uncomplicated Urinary Tract Infections. 2) Otitis Media. 3) Pharyngitis and Tonsillitis. 4) Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis. 5) Uncomplicated gonorrhea etc.	Contraindications: Cefixime is contraindicated in patients with known allergy to the Cephalosporin class of antibiotics. Clavulanic Acid does not inactivate all β-Lactamases. Most chromosomally mediated β-Lactamases,e.g. the enzyme produced by pseudomonas aeruginosa, are resistant to its action. Other organism have different mechanisms of acquired resistance to β-Lactam antibiotics, against which clavulanic acid is ineffective. Side effects: Cefixime-Clavulanic Acid are diarrhea and stool changes. Events like nausea/vomiting, transient elevation in liver transaminases, alkaline phosphatase and jaundice can also occur. Thrombocytosis, thrombocytopenia, leucopenia, hypereosinophilia, neutropenia and agranulocytosis may also occur. Other adverse events that may occur are abdominal pain, abdominal cramps, flatulence, indigestion, headache, vaginitis, vulvar itch, rash, hives, itch, dysuria, chills, chest pain, shortness of breath, mouth ulcers, swollen tongue, sleepiness, thirst, anorexia.	Cefixime 100 mg, 200mg & 400mg Capsule Cefixime 200mg/5ml Powder For Suspension Cefixime 2.5gm/100 ml Paediatric Drop	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**
86.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur The Acme Laboratories ltd. Dhamrai Dhaka	Cefixime 100mg + Clavulanic Acid 62.5mg Tablet	Cefixime Trihydrate USP 111.9 mg eqv. to Cefixime 100 mg + Diluted Potassium Clavulanate BP 156.25 mg eqv. to Clavulanic Acid 62.50 mg	Therapeutic Class: Anti-infective Therapeutic code: 023	Cefixime-Clavulanic Acid should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Cefixime-Clavulanic Acid is indicated for the treatment of – 1) Uncomplicated Urinary Tract Infections. 2) Otitis Media. 3) Pharyngitis and Tonsillitis. 4) Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis. 5) Uncomplicated gonorrhea etc.	Contraindications: Cefixime is contraindicated in patients with known allergy to the Cephalosporin class of antibiotics. Clavulanic Acid does not inactivate all β-Lactamases. Most chromosomally mediated β-Lactamases,e.g. the enzyme produced by pseudomonas aeruginosa, are resistant to its action. Other organism have different mechanisms of acquired resistance to β-Lactam antibiotics, against which clavulanic acid is ineffective. Side effects: Cefixime-Clavulanic Acid are diarrhea and stool changes. Events like nausea/vomiting, transient elevation in liver transaminases, alkaline phosphatase and jaundice can also occur. Thrombocytosis, thrombocytopenia, leucopenia, hypereosinophilia, neutropenia and	Cefixime 100 mg, 200mg & 400mg Capsule Cefixime 200mg/5ml Powder For Suspension Cefixime 2.5gm/100 ml Paediatric Drop	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						agranulocytosis may also occur. Other adverse events that may occur are abdominal pain, abdominal cramps, flatulence, indigestion, headache, vaginitis, vulvar itch, rash, hives, itch, dysuria, chills, chest pain, shortness of breath, mouth ulcers, swollen tongue, sleepiness, thirst, anorexia.				
87.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur The Acme Laboratories ltd. Dhamrai Dhaka	Cefixime 200mg + Clavulanic Acid 125mg Tablet	Cefixime Trihydrate USP 223.8mg eqv. to Cefixime 200 mg + Diluted Potassium Clavulanate BP 312.5 mg eqv. to Clavulanic Acid 125 mg	Therapeutic Class: Anti-infective Therapeutic code: 023	Cefixime-Clavulanic Acid should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Cefixime-Clavulanic Acid is indicated for the treatment of – 1) Uncomplicated Urinary Tract Infections. 2) Otitis Media. 3) Pharyngitis and Tonsillitis. 4) Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis. 5) Uncomplicated gonorrhea etc.	Contraindications: Cefixime is contraindicated in patients with known allergy to the Cephalosporin class of antibiotics. Clavulanic Acid does not inactivate all β-Lactamases. Most chromosomally mediated β-Lactamases,e.g. the enzyme produced by pseudomonas aeruginosa, are resistant to its action. Other organism have different mechanisms of acquired resistance to β-Lactam antibiotics, against which clavulanic acid is ineffective. Side effects: Cefixime-Clavulanic Acid are diarrhea and stool changes. Events like nausea/vomiting, transient elevation in liver transaminases, alkaline phosphatase and jaundice can also occur. Thrombocytosis, thrombocytopenia, leucopenia, hypereosinophilia, neutropenia and agranulocytosis may also occur. Other adverse events that may occur are abdominal pain, abdominal cramps, flatulence, indigestion, headache, vaginitis, vulvar itch, rash, hives, itch, dysuria, chills, chest pain, shortness of breath, mouth ulcers, swollen tongue, sleepiness, thirst, anorexia.	Cefixime 100 mg, 200mg & 400mg Capsule Cefixime 200mg/5ml Powder For Suspension Cefixime 2.5gm/100 ml Paediatric Drop	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
88.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Naproxen 750 mg CR Tablet	Naproxen USP 750 mg	Therapeutic Class: NSAID Therapeutic code: 064	It is a nonsteroidal anti-inflammatory drug indicated for the treatment of: • rheumatoid arthritis (RA) • osteoarthritis (OA) • ankylosing spondylitis (AS) • tendinitis, bursitis • acute gout	Warning: Risk Of Serious Cardiovascular And Gastrointestinal Events Side Effects: The most frequent adverse events were headache (15%), followed by dyspepsia (14%), and flu syndrome (10%) Contraindication:	Existing: Naproxen 250 mg Naproxen 500 mg	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					• primary dysmenorrhea (PD) • the relief of mild to moderate pain	Known hypersensitivity to naproxen or any components of the drug product • History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs • In the setting of CABG surgery				
89.	General Pharmaceutical Ltd., Gazipur Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Ibuprofen BP 800 mg + Famotidine USP 26.6 mg Tablet	Ibuprofen BP 800 mg + Famotidine USP 26.6 mg	Therapeutic Class: Drug used in Non-steroidal anti intiinflamatory Therapeutic Code: 064	Ibuprofen & Famotidine is a combination of the NSAID ibuprofen and the histamine H2-receptor antagonist famotidine, is indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers, which in the clinical trials was defined as a gastric and/or duodenal ulcer, in patients who are taking ibuprofen for those indications. The clinical trials primarily enrolled patients less than 65 years of age without a prior history of gastrointestinal ulcer. Controlled trials do not extend beyond 6 months	Contraindications: • Pre-existing asthma, urticaria, or allergic reactions after taking aspirin or other NSAIDs • Use during the perioperative period in the setting of coronary artery bypass graft surgery • Starting at 30 weeks gestation, Ibuprofen & Famotidine should not be used by pregnant women as premature closure of the ductus arteriosus in the fetus may occur. • Known hypersensitivity to other H2-receptor antagonists Warnings And Precautions • Hypertension: Hypertension can occur with NSAID treatment; monitor blood pressure closely during treatment with Ibuprofen & Famotidine. • Congestive heart failure and edema: Fluid retention and edema can occur with NSAID treatment; use Ibuprofen & Famotidine with caution in patients with fluid retention or heart failure. • Active Bleeding: Active and clinically significant bleeding from any source can occur; discontinue Ibuprofen & Famotidine if active bleeding occurs • Renal Injury: Long-term administration of NSAIDs can result in renal papillary necrosis and other renal injury; use Ibuprofen & Famotidine with caution in patients at risk (e.g., the elderly, those with renal impairment, heart failure, liver impairment, and those taking diuretics or ACE inhibitors). • Anaphylaxis: Anaphylaxis may occur in patients with the aspirin triad or in patients without prior	Ibuprofen 200mg, 300mg 400mg Tab. 100mg/5ml Susp. & Famotidine 20mg, 40mg Tab., 40mg/5ml PFS	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						exposure to Ibuprofen & Famotidine; discontinue Ibuprofen & Famotidine immediately if an anaphylactoid reaction occurs. • Serious skin reactions: Includes exfoliative dermatitis, Stevens-Johnson Syndrome, and toxic epidermal necrolysis, which can be fatal; discontinue Ibuprofen & Famotidine if rash or other signs of local skin reaction occur. • Hepatic Injury: Hepatic injury ranging from transaminase elevations to liver failure can occur; discontinue Ibuprofen & Famotidine immediately if abnormal liver tests persist or worsen, if clinical signs and symptoms of liver disease develop or if systemic manifestations occur. Side Effects: Most common adverse reactions (≥1% and greater than ibuprofen alone) are nausea, diarrhea, constipation, upper abdominal pain, and headache				
90.	Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirganj, Narayanganj-1431 Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj.	Viloxazine 100 mg Capsule	Viloxazine INN 100 mg Capsule	Therapeutic Class: Antidepressants Therapeutic Code: 014	Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.	Warning: Suicidal Thoughts And Behaviors Contraindication: Concomitant administration of monoamine oxidase inhibitors (MAOI), or dosing within 14 days after discontinuing an MAOI Concomitant administration of sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range. Side effects: • Suicidal Thoughts and Behaviors • Blood Pressure and Heart Rate Increases • Activation of Mania or Hypomania • Somnolence and Fatigue	New	USFDA	অনুমোদনের সুপারিশ করা হয়। তবে **packaging material** এর সঙ্গে **parental guidance booklet** প্রদান করতে হবে।	অনুমোদন করা হয়। তবে **packaging material** এর সঙ্গে **parental guidance booklet** প্রদান করতে হবে।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
91.	Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirganj, Narayanganj-1431 Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj.	Viloxazine 150 mg Capsule	Viloxazine INN 150 mg Capsule	Therapeutic Class: Antidepressants Therapeutic Code: 014	Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.	Warning: Suicidal Thoughts And Behaviors Contraindication: Concomitant administration of monoamine oxidase inhibitors (MAOI), or dosing within 14 days after discontinuing an MAOI Concomitant administration of sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range. Side effects: • Suicidal Thoughts and Behaviors • Blood Pressure and Heart Rate Increases • Activation of Mania or Hypomania • Somnolence and Fatigue	New	USFDA	অনুমোদনের সুপারিশ করা হয়। তবে **packaging material** এর সঙ্গে **parental guidance booklet** প্রদান করতে হবে।	অনুমোদন করা হয়। তবে **packaging material** এর সঙ্গে **parental guidance booklet** প্রদান করতে হবে।
92.	Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirganj, Narayanganj-1431 Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj.	Viloxazine 200 mg Capsule	Viloxazine INN 200 mg Capsule	Therapeutic Class: Antidepressants Therapeutic Code: 014	Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.	Warning: Suicidal Thoughts And Behaviors Contraindication: Concomitant administration of monoamine oxidase inhibitors (MAOI), or dosing within 14 days after discontinuing an MAOI Concomitant administration of sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range. Side effects: • Suicidal Thoughts and Behaviors • Blood Pressure and Heart Rate Increases • Activation of Mania or Hypomania • Somnolence and Fatigue	New	USFDA	অনুমোদনের সুপারিশ করা হয়। তবে **packaging material** এর সঙ্গে **parental guidance booklet** প্রদান করতে হবে।	অনুমোদন করা হয়। তবে **packaging material** এর সঙ্গে **parental guidance booklet** প্রদান করতে হবে।
93.	Drug International Ltd (Unit-3) 31/1,Satrong, Tongi I/A, Gazipur.	Berotralstat 110 mg Capsule	Berotralstat Dihydrochloride INN 124.2 mg (Eqv. to 110 mg Berotralstat)	Coronary Vasodilator	It is indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years of age and older.	Contraindications: It is contraindication in patients who have hypersensitivity to Berotralstat or any excipiant of the formulation. Warning and Precautions: An increase in QT prolongation can occur at dosages higher than the recommended 150 mg once daily dosage. Additional doses or doses of Berotralstat higher	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						than 150 mg once daily are not recommended. Side effects Most common adverse reactions (≥10%) are abdominal pain, vomiting, diarrhea, back pain, and gastroesophageal reflux disease.				
94.	Drug International Ltd (Unit-3) 31/1,Satrong, Tongi I/A, Gazipur.	Berotralstat 150 mg Capsule	Berotralstat Dihydrochloride INN 169.4 mg (Eqv. to 150 mg Berotralstat)	Coronary Vasodilator	It is indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years of age and older.	Contraindications: It is contraindication in patients who have hypersensitivity to Berotralstat or any excipiant of the formulation. Warning and Precautions: An increase in QT prolongation can occur at dosages higher than the recommended 150 mg once daily dosage. Additional doses or doses of Berotralstat higher than 150 mg once daily are not recommended. Side effects Most common adverse reactions (≥10%) are abdominal pain, vomiting, diarrhea, back pain, and gastroesophageal reflux disease.	New	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
95.	Drug International Ltd (Unit-3) 31/1,Satrong, Tongi I/A, Gazipur.	Medroxyprogesterone Acetate Tablet.	Medroxyprogesterone Acetate BP 5.00mg	Therapeutic Class: Hormone Therapeutic Code: 056	It is indicated for the treatment of secondary amenorrhea and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as fibroids or uterine cancer. They are also indicated for use in the prevention of endometrial hyperplasia in nonhysterectomized postmenopausal women who are receiving daily oral conjugated estrogens 0.625 mg tablets.	Contraindications: It is contraindicated in patients with Thromboembolic disorders; cerebral apoplexy; severe hepatic dysfunction; undiagnosed vaginal bleeding, incomplete abortion, hormone-dependent carcinoma; pregnancy. Precaution: Caution should be exercised when it is using in patients with depression, DM, epilepsy, asthma, migraine, hypertension, renal or cardiac dysfunction. Monitor patient closely for loss of vision, proptosis, diplopia and thromboembolic disorders. Warning: As per precaution. Side effects: Side effects are- Depression, fluid retention. Fatigue, insomnia, dizziness, headache, nausea; breast tenderness; wt gain/loss, anorexia; cholestatic jaundice; pain at Inj site.	Medroxyprogesterone Acetate 10 mg Tablet	UKMHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
96.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Sotorasib INN 120 mg Capsule	Sotorasib INN 120.00 mg	Therapeutic Class: Anticancer Therapeutic Code: 010	Sotorasib is 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.	Contraindication: It is contraindicated in patients with hypersensitivity to Sotorasib or any component of the product. Precaution: Caution should be exercised when using Sotorasib in patients with Hepatotoxicity, Interstitial Lung Disease (ILD)/Pneumonitis, Embryo-Fetal Toxicity. Warning: Included as part of the "Precaution" Section. Side effects: The most common side effects are Hepatotoxicity, Interstitial Lung Disease (ILD) /Pneumonitis.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
97.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur. Beacon Pharmaceuticals Limited The ACME Laboratories Ltd. Dhamrai, Dhaka	Tepotinib 225mg Tablet.	Tepotinib Hydrochloride Hydrate INN 250mg eqv.to Tepotinib 225mg	Therapeutic Class: Anticancer Therapeutic Code: 010	It is a kinase inhibitor indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymalepithelial transition (MET) exon 14 skipping alterations. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.	Contraindications: None Side effect: Most common adverse reactions (≥ 20%) were edema, fatigue, nausea, diarrhea, musculoskeletal pain, and dyspnea. The most common Grade 3 to 4 laboratory abnormalities (≥ 2%) were decreased lymphocytes, decreased albumin, decreased sodium, increased gamma-glutamyltransferase, increased amylase, increased ALT, increased AST, and decreased hemoglobin. Warning & Precautions: Interstitial Lung Disease (ILD)/Pneumonitis: Immediately withhold TEPMETKO in patients with suspected ILD/pneumonitis. Permanently discontinue TEPMETKO in patients diagnosed with ILD/pneumonitis of any severity. • Hepatotoxicity: Monitor liver function tests. Withhold, dose reduce, or permanently discontinue TEPMETKO based on severity.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						• Embryo-fetal toxicity: TEPMETKO can cause fetal harm. Advise of potential risk to a fetus and use of effective contraception				
98.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur. Beacon Pharmaceuticals Limited	Tivozanib 0.89mg Capsule.	Tivozanib Hydrochloride INN 1.0mg eqv.to Tivozanib 0.89mg	Therapeutic Class: Anticancer Therapeutic Code: 010	It is a kinase inhibitor indicated for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies	Contraindications: None Side effect: The most common (≥20%) adverse reactions were fatigue, hypertension, diarrhea, decreased appetite, nausea, dysphonia, hypothyroidism, cough, and stomatitis, and the most common Grade 3 or 4 laboratory abnormalities (≥5%) were sodium decreased, lipase increased, and phosphate decreased. Warning & Precautions: Hypertension and Hypertensive Crisis: Control blood pressure prior to initiating FOTIVDA. Monitor for hypertension and treat as needed. For persistent hypertension despite use of anti-hypertensive medications, reduce the FOTIVDA dose. • Cardiac Failure: Monitor for signs or symptoms of cardiac failure throughout treatment with FOTIVDA. • Cardiac Ischemia and Arterial Thromboembolic Events: Closely monitor patients who are at increased risk for these events. Permanently discontinue FOTIVDA for severe arterial thromboembolic events, such as myocardial infarction and stroke. • Hemorrhagic Events: Closely monitor patients who are at risk for or who have a history of bleeding. • Proteinuria: Monitor throughout treatment with FOTIVDA. For moderate to severe proteinuria, reduce the dose or temporarily interrupt treatment with FOTIVDA. • Thyroid Dysfunction: Monitor before initiation and		USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						throughout treatment with FOTIVDA. • Risk of Impaired Wound Healing: Withhold FOTIVDA for at least 24 days before elective surgery. Do not administer for at least 2 weeks following major surgery and adequate wound healing. The safety of resumption of FOTIVDA after resolution of wound healing complications has not been established • Reversible Posterior Leukoencephalopathy Syndrome (RPLS): Discontinue FOTIVDA if signs or symptoms of RPLS occur. • Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception. • Allergic Reactions to Tartrazine: The 0.89 mg capsule of FOTIVDA contains FD&C Yellow No.5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible patients				
99.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur. Beacon Pharmaceuticals Limited	Tivozanib 1.34mg Capsule.	Tivozanib Hydrochloride INN 1.5mg eqv.to Tivozanib 1.34mg	Therapeutic Class: Anticancer Therapeutic Code: 010	FOTIVDA is a kinase inhibitor indicated for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies	Contraindications: None Side effect: The most common (≥20%) adverse reactions were fatigue, hypertension, diarrhea, decreased appetite, nausea, dysphonia, hypothyroidism, cough, and stomatitis, and the most common Grade 3 or 4 laboratory abnormalities (≥5%) were sodium decreased, lipase increased, and phosphate decreased. Warning & Precautions: Hypertension and Hypertensive Crisis: Control blood pressure prior to initiating FOTIVDA. Monitor for hypertension and treat as needed. For persistent hypertension despite use of anti-hypertensive medications, reduce the FOTIVDA dose. • Cardiac Failure: Monitor for signs or symptoms of cardiac failure throughout treatment with FOTIVDA. • Cardiac Ischemia and Arterial Thromboembolic		USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Events: Closely monitor patients who are at increased risk for these events. Permanently discontinue FOTIVDA for severe arterial thromboembolic events, such as myocardial infarction and stroke. • Hemorrhagic Events: Closely monitor patients who are at risk for or who have a history of bleeding. • Proteinuria: Monitor throughout treatment with FOTIVDA. For moderate to severe proteinuria, reduce the dose or temporarily interrupt treatment with FOTIVDA. • Thyroid Dysfunction: Monitor before initiation and throughout treatment with FOTIVDA. • Risk of Impaired Wound Healing: Withhold FOTIVDA for at least 24 days before elective surgery. Do not administer for at least 2 weeks following major surgery and adequate wound healing. The safety of resumption of FOTIVDA after resolution of wound healing complications has not been established • Reversible Posterior Leukoencephalopathy Syndrome (RPLS): Discontinue FOTIVDA if signs or symptoms of RPLS occur. • Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception. • Allergic Reactions to Tartrazine: The 0.89 mg capsule of FOTIVDA contains FD&C Yellow No.5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible patients				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
100.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Viloxazine 100 mg extended-release capsule	Viloxazine Hcl INN 115mg eqv to viloxazine 100 mg	Therapeutic Class: Antipsychotic Therapeutic Code: 028	Viloxazine is indicated for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.	Warning: Suicidal Thoughts And Behaviors Contraindication: Viloxazine is contraindicated in patients: receiving concomitant treatment withmonoamine oxidase inhibitors (MAOI), or within 14 days following discontinuing an MAOI, because of an increased risk of hypertensive crisis. receiving concomitant administration of sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range. Side-effects: Most commonly observed adverse reactions (≥5% and at least twice the rate of placebo) were: somnolence, decreased appetite, fatigue, nausea, vomiting, insomnia, and irritability Warnings and Precautions: • Blood Pressure and Heart Rate Increases: Assess heart rate and blood pressure prior to initiating treatment, following increases in dosage, and periodically while on therapy • Activation of Mania or Hypomania: Screen patients for bipolar disorder • Somnolence and Fatigue: Advise patients to use caution when driving or operating hazardous machinery due to potential somnolence (including sedation and lethargy) and fatigue	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
101.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Dried Ferrous Sulphate BP 325mg eqv.to 105mg Elemental Iron + Ascorbic Acid (VitaminC) BP 500mg Tablet	Dried Ferrous Sulphate BP 325mg eqv.to 105mg Elemental Iron + Ascorbic Acid (VitaminC) BP 500mg	078	Preventing and treating iron deficiency anaemia in people who also have a vitamin C deficiency	Contraindication: People with anaemia due to vitamin B12 deficiency (pernicious anaemia).People with anaemia due to folic acid deficiency. Genetic disease resulting in too much iron storage in the tissues (haemochromatosis). People with a disorder that affects storage of iron	New	BNF	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						in the body (haemosiderosis). People with a condition where there is sudden loss of haemoglobin (oxygen carrying protein in the blood) in the urine at night (paroxysmal nocturnal haemoglobinuria). People with other disorders involving haemoglobin, such as sickle cell anaemia or thalassaemia. People receiving repeated blood transfusions. Side-effects: Medicines and their possible side effects can affect individual people in different ways. The following are some of the side effects that are known to be associated with this medicine. Just because a side effect is stated here, it does not mean that all people using this medicine will experience that or any side effect. Abdominal pain. Constipation. Diarrhoea. Nausea and vomiting. Loss of appetite. Warnings and Precautions: This medicine may discolour the stools black or darker than usual. This is normal and not harmful. This medicine contains iron and so should be kept well out of the sight and reach of children, as iron overdose can be fatal in children. This medicine may give a false negative result with the clinistix test for the presence of sugar in the urine.				
102.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Ulinastatin 100000 IU Lyophilized Injection	Ulinastatin INN 2222.2222 mg/Vialeqv. to ulinastatin 100000IU	Therapeutic Class: Anti-infective Therapeutic Code: 023	Use in sepsis .Ulinastatin is an effective agent for immune modulation to prevent organ dysfunction and promote homeostasis	Contraindication: Hypersensitivity to the drug. Side-effects: Rare cases of rash, itching and pain at the site of injection. Rare cases of allergy. Rare cases of elevation of SCOT and SGPT.	New	রেফারেন্স নাই। JP	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Rare cases of nausea, vomiting and diarrhea. Warnings and Precautions: Not to be used for patients who are hypersensitive. Not to used in lactating women. Ulinastatin should be administered with caution if patient has history of allergy. Ulinastatincan not replace the traditional therapeutic methods (transfusion, oxygen therapy and antibiotics) for shocks.				
103.	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka UniMed UniHealth Phr. Ltd. B.k Bari, Gazipur Sadar, Gazipur Navana Pharmaceuticals Limited	Benzalkonium chloride 1mg per 1 gm, Chlorhexidine hydrochloride 1mg per 1gm, Isopropyl myristate 100mg per 1gm, Liquid paraffin 100mg per 1gm Cream	Benzalkonium chloride USP 0.1gm + Chlorhexidine Hydrochloride (Chlorhexidine Dihydrochloride) BP 0.1g + Isopropyl Myristate BP 10gm + Liquid paraffin BP 10gm/100gm	Therapeutic Class: Skin and Mucous Membrane Preparations Therapeutic Code: 071	An antimicrobial emollient cream for the management of dry and pruritic skin conditions, especially eczema and dermatitis. The cream is suitable for direct application, and for use as a soap substitute.	Contraindication Do not use in cases of known sensitivity (especially generalised allergic reaction) to any of the ingredients Side-effects: Like all medicines, Benzalkonium chloride + chlorhexidine dihydrochloride + isopropyl myristate + liquid paraffin Cream can cause side effects, although not everybody gets them. If you experience any of the following reactions stop using Benzalkonium chloride + chlorhexidine dihydrochloride + isopropyl myristate + liquid paraffin Cream and get urgent medical help: swelling of the face, lips, tongue or throat; a sudden uncharacteristic red itchy skin rash (hives) away from the site of application; wheezing or breathing difficulty; feeling faint or dizzy; a strange metallic taste in the mouth; or collapse. You may be having a serious allergic reaction. Warning & Precaution:	New	BNF-81 Page No: 1270	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Avoid contact with the eyes. Local skin reactions (e.g. contact dermatitis) to any of the ingredients are rare but possible in sensitive people. There are literature reports of chlorhexidine compounds inducing hypersensitivity, including anaphylactic shock. The prevalence of this is not known, but is likely to be very rare. Benzalkonium chloride + chlorhexidine dihydrochloride + isopropyl myristate + liquid paraffin Cream should not be administered to anyone with a possible history of allergic reaction to a chlorhexidine compound Benzalkonium chloride + chlorhexidine dihydrochloride + isopropyl myristate + liquid paraffin Cream contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).				
104.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Phenylephrine HCl 10 mg tablet	Phenylephrine Hcl BP 10 mg	Therapeutic Class: Ear and Nose Preparations Therapeutic Code: 050	Nasal congestion, Hypotensive states, Paroxysmal supraventricular tachycardia ।Mydriasis, Conjunctival decongestant.	Contraindication: Hypertension Ventricular Tachycardia Side-effects: Anxiety reflex bradycardia tachycardia arrhythmias headache cold extremities/gangrene, hypertension, nausea, vomiting, sweating, weakness, fear ।restlessness, insomnia, confusion, irritability, psychotic states, dyspnoea, anorexia ।palpitations, extravasation causing tissue necrosis and sloughing, mydriasis, difficulty in micturition and urinary retention, piloerection, increased salivation, hyperglycaemia, lactic acidosis Ophthalmic solutions may liberate pigment granules from the iris, corneal clouding/damage.	New	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Potentially Fatal' Increase in cardiac contractility, which may lead to angina or cardiac arrest; severe hypertension leading to cerebral haemorrhage or pulmonary oedema. Warning &Precaution: Severe hyperthyroidism,severeishchaemic heart disease,DM prostatic hyperplashiaadvancedarterioscelerosis.				
105.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Oteseconazole 150 mg Capsule	Oteseconazole INN 150 mg	Therapeutic Class: Antifungl 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	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
106.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Beacon Pharmaceuticals Limited	Aducanumab 100mg/ml (ready to fill sterile bulk) eqv.to 170mg/1.7 ml Vial Aducanumab Solution for Infusion	Aducanumab 100mg/ml (ready to fill sterile bulk)In-house 1.7ml/Vial eqv.to 170mg/Vial Aducanumab	Therapeutic Class: Other Classification Therapeutic Code: 075	It is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with Aducanumab. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).	Contraindication: No data available Side-effects: Headache, Dizziness Warnings and Precautions: • Amyloid Related Imaging Abnormalities (ARIA): Enhanced clinical vigilance for ARIA is recommended during the first 8 doses of treatment with ADUHELM, particularly during titration. If a patient experiences symptoms which could be suggestive of ARIA, clinical evaluation should be performed, including MRI testing if indicated. • Hypersensitivity Reactions: Angioedema and urticaria have occurred. If a hypersensitivity reaction occurs, promptly discontinue the infusion of ADUHELM and initiate appropriate therapy.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
107.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Aducanumab 100mg/ml (ready to fill sterile bulk) eqv.to 300mg/3 ml Vial Aducanumab Solution for Infusion	Aducanumab 100mg/ml (ready to fill sterile bulk) eqv.to 300mg/3 ml Vial Aducanumab	Therapeutic Class: Other Classification Therapeutic Code: 075	It is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with Aducanumab. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).	Contraindication: No data available Side-effects: Headache, Dizziness Warnings and Precautions: • Amyloid Related Imaging Abnormalities (ARIA): Enhanced clinical vigilance for ARIA is recommended during the first 8 doses of treatment with ADUHELM, particularly during titration. If a patient experiences symptoms which could be suggestive of ARIA, clinical evaluation should be performed, including MRI testing if indicated. • Hypersensitivity Reactions: Angioedema and urticaria have occurred. If a hypersensitivity reaction occurs, promptly discontinue the infusion of ADUHELM and initiate appropriate therapy.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
108.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	N-Acetyl carnosine 1.0%, Glycerin 1.0%, CMC 0.3%. Ophthalmic solution	N-Acetyl carnosine INN 1g +Glycerin BP 1g+Carboxymethyl cellulose USP 0.3g/100ml	Therapeutic Class: Ear and Nose Preparations Therapeutic Code: 050	N-Acetyl carnosine, Glycerin, CMC is used for the treatment of dry eye, macular degeneration and cataract.	Contraindication: Contraindicated to personas having a known allergy to any of the ingredients in this medicine. Side-effects: Use of this medicine may cause application site reactions such as burning sensation, itching, irritation, and redness. However, these are usually temporary and resolve by themselves. Warnings and Precautions: It is advised not to drive or operate heavy machinery immediately after using this medicine as it may cause temporary blurring of vision and may affect your ability to drive.	New	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
109.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Dasiglucagon 0.6 mg injection	Dasiglucagon HCl INN 0.63mg/0.6ml eqv. to 0.6 mg Dasiglucagon	Therapeutic Class: Antidiabetic Therapeutic Code: 015	It is an antihypoglycemic agent indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged 6 years and above.	Contraindication Pheochromocytoma, Insulinoma Side-effects: Dasiglucagon and Glucagon were observed to be safe and well-tolerated in the trial, with no injection site reactions observed with dasiglucagon. Nausea and vomiting were the most frequent side effects observed,predominantly at the higher dose-levels, with both dasiglucagon and Glucagon Warning& Precaution: Substantial Increase in Blood Pressure in Patients with Pheochromocytoma, Hypoglycemia in Patients with Insulinoma, Hypersensitivity and Allergic Reactions, Lack of Efficacy in Patients with Decreased Hepatic Glycogen	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
110.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Solithromycin 400 mg capsule	Solithromycin INN 400mg	Therapeutic Class: Anti-infective Therapeutic Code: 023	Solithromycin is used for the treatment of community-acquired bacterial pneumonia (CABP) caused by Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis, methicillin-susceptible Staphylococcus aureus, Legionella pneumophila and Mycoplasma pneumoniae.	Contraindication: No data available Side-effects: In the pooled phase 3 trials, 58 (6.8%) patients in the Solithromycin arm and 50 (5.8%) patients in the Moxifloxacin arm experienced serious adverse events (SAEs). In CE01-300, 1.4% (6/432) and 2.1% (9/424) of patients and 1.4% (6/426) and 2.8% (12/432) of patients in CE01-301 in the Moxifloxacin and Solithromycin arms, respectively were reported to have adverse events indicative of worsening bacterial pneumonia and its complications when the PTS (empyema/infectious pleural effusion, lung abscess, pneumonia/lobar pneumonia, respiratory tract infection and septic shock/sepsis) were combined. Cardiac SAEs were slightly higher in both arms of CE01-301 compared to both arms of CE01-300, but comparable between treatment groups. One individual in the Moxifloxacin arm	New	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						had an SAE of hepatorenal syndrome, but no other liver-related SAEs were noted in either arm. Two patients in the Solithromycin arm had cerebrovascular accidents. Anaphylaxis occurred in one patient in each treatment arm, and there was one episode of urticaria in the Solithromycin arm. Warnings and Precautions: No data available				
111.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Tirzepatide	Tirzepatide 5 mg prefilled Injection	Therapeutic Class: Antidiabetic 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	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**
112.	The ACME Laboratories Ltd. Dhamrai, Dhaka Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Trelagliptin	Trelagliptin Succinate INN 133mg eqv. to Trelagliptin 100 mg Tablet	Therapeutic Class: 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).	NEW	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Warning & Precautions: Patients with mild, moderate, or severe renal impairment and patients with end-stage renal failure.				
113.	Organic Health Care Ltd. Gilarchala, 7 Kewa Mouza, Sreepur, Gazipur	Brincidofovir 100 mg Tablet	Brincidofovir 100 mg	Therapeutic Class: Antiviral Therapeutic Code: 032	It is an orthopoxvirus nucleotide analog DNA polymerase inhibitor and is indicated for the treatment of human smallpox disease in adult and pediatric patients, including neonates.	Warning: Increased Risk For Mortality When Used For Longer Duration Contraindication: None Side-effects: Liver problems, Diarrhea, Nausea, Stomach Pain, Vomiting Warning and Precautions: Increased Risk for Mortality When Used for Longer Duration, Elevations in Hepatic Transaminases and Bilirubin, Diarrhea and Other Gastrointestinal Adverse Events, Embryo-fetal Toxicity, Carcinogenicity, Male Infertility	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
114.	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Renata Limited Mirpur, Dhaka Nuvista Pharma Ltd. The ACME Laboratories Ltd. Dhamrai, Dhaka	Relugolix 40mg, Estradiol 1mg & Norethidrone acetate 0.5mg Tablet	Relugolix INN 40mg + Estradiol Hemihydrate BP/Ph.Eur.1.033mg eqv.to 1mg Estradiol+ Norethidrone AcetateBP/Ph.Eur. 0.5mg	Therapeutic Class: Hormone Therapeutic Code: 056	Relugolix+estradiol+norethidrone acetate is a combination of relugolix, a gonadotropin-releasing hormone (GnRH) receptor antagonist, estradiol, an estrogen, and norethindrone acetate, a progestin, indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women	Warning: Thromboembolic Disorders And Vascular Events Contraindication Menstrual abnormalities, Hot flashes, Excessive sweating, Headache, Decreased bone mineral density Side-effects: Most common adverse reaction (>5%) in clinical trials were hot flushes, menstrual abnormalities, excessive sweating, headache and decreased bone mineral density. Warning & Precaution: Thromboembolic Disorders and Vascular Events, Bone Loss, Depression, Mood Disorders, and Suicidal Ideation, Hepatic Impairment and Transaminase Elevation, Elevated Blood Pressure, Change in Menstrual Bleeding Pattern and Reduced Ability to Recognize Pregnancy, Risk of	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna					Early Pregnancy Loss, Uterine Fibroid Prolapse or Expulsion, Hypersensitivity Reactions				
115.	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka	Astaxanthin Oleoresin 5% 80mg + Ascorbic Acid (Vitamin C) 66mg + Alpha Tocopheryl Acetate (Vitamin E) 15mg Capsule	Astaxanthin Oleoresin INN 5% 80mg + Ascorbic Acid (Vitamin C) BP/Ph.Eur66mg + Alpha Tocopheryl Acetate (Vitamin E) BP/Ph.Eur15mg	Therapeutic Class: Vitamins and Combinations Therapeutic Code: 078	It is indicated for improvement of muscle function and endurance. Daily intake of this effective formulation contributes to the maintenance of normal heart, muscle and bone health. As a food supplement combination of antioxidants and fish oil to improve health and vitality.	Contraindication Contraindicated for those with known allergies to Astaxanthin or any other component of the product. Side-effects: No clear data found Warning & Precaution: No data available	New	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
116.	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka	Astaxanthin Oleoresin 5% 40mg + Ascorbic Acid (Vitamin C) 41.30mg +Vitamin D3 (1M IU/GM) 20.80mg + Alpha Tocopheryl Acetate (Vitamin E) 9.85mg Capsule	Astaxanthin Oleoresin 5% INN 40mg + Ascorbic Acid (Vitamin C)BP/Ph. Eur 41.30mg +Vitamin D3 (1M IU/GM) BP/Ph. Eur 20.80mg + Alpha Tocopheryl Acetate (Vitamin E) BP/Ph. Eur 9.85mg	Therapeutic Class: Vitamins and Combinations Therapeutic Code: 078	It is indicated for improvement of muscle function and endurance. Daily intake of this effective formulation contributes to the maintenance of normal heart, muscle and bone health. As a food supplement combination of antioxidants and fish oil to improve health and vitality.	Contraindication Contraindicated for those with known allergies to Astaxanthin or any other component of the product. Side-effects: No clear data found Warning & Precaution: No data available	New	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
117.	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka	Conjugated estrogen 0.625mg/1gm cream	Conjugated Estrogens USP 0.0625gm/100gm	Therapeutic Class: Hormone Therapeutic Code: 056	Conjugated estrogen vaginal cream (conjugated estrogens) Vaginal Cream is a mixture of estrogens indicated for- • Treatment of Atrophic Vaginitis and Kraurosis Vulvae • Treatment of Moderate to Severe Dyspareunia, a Symptom of Vulvar and Vaginal Atrophy, due to Menopause	Warning: Endometrial Cancer, Cardiovascular Disorders, Breast Cancer And Probable Dementia Contraindication Central nervous system stimulation(i.eirritability, restlessness, jitteriness),cardiovascularUndiagnosed abnormal genital bleedingKnown, suspected, or history of breast cancerKnown or suspected estrogen-dependent neoplasiaActive DVT, PE, or a history of these conditions Side-effects: In a prospective, randomized, placebo-controlled, double-blind study, the most common adverse reactions 2 percent are headache, pelvic pain, vasodilation, breast pain, leucorrhea, metrorrhagia, vaginitis, vulvovaginal disorder. Warning & Precaution: Estrogens increase the risk of gallbladder diseaseDiscontinue estrogen if severe hypercalcemia, loss of vision, severe hypertriglyceridemia or cholestatic jaundice occurs Monitor thyroid function in women on thyroid replacement therapy.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
118.	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka	Sucralfate (25% w/w) gel	Sucralfate USP 25gm/100 gm	Therapeutic Class: Skin and Mucous Membrane Preparations Therapeutic Code: 071	Sucralfate 25% for dermal use which may be used in a wide variety of incidents and indications: Acute wounds: -Trauma -Minor injuries -Surgical wounds-scars -Burns	Contraindication No side effects or adverse events such as allergies, increased pain etc. nor any other contraindications have been described in association with Sucralfate 25% Gel application. Side-effects: Gastrointestinal: Diarrhoea,Nausea,vomitting	New	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Skin: Itching & rash Central nervous system: Dizziness, sleeplessness. Warning & Precaution: In the event of any adverse events (increased pain, reddening etc.), discontinue treatment and contact your attending physician. Keep away from children. Do not take internally. Do not use after the expiration date marked on the tube.				
119.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Bisoprolol fumarate + Cilnidipine	Bisoprolol Fumarate USP 2.5 mg + Cilnidipine INN 5 mg Tablet	Therapeutic Class: Antihypertensive Therapeutic Code: 022	Hypertension	Contra-indications: The Combination of Bisoprolol fumarate andCilnidipine is not recommended for use if youhave a history of allergy to Cilnidipine or any other component of this medicine. Side Effects: Sleepiness, Headache,Ankle swelling,Flushing ,Slow heart rate,Tiredness,Palpitations,Nausea,Edema (swelling),Constipation,Cold extremities Warning & Precautions: This medicine is not recommended for use in pregnant & breastfeeding women unless absolutely necessary. This medicine should be used with caution in patients suffering from heart diseases due to the increased risk of cardiac failure.	NEW	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**
120.	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka	Omega-3 Fatty Acids 330mg + Docosahexaenoic Acid (DHA) 260mg + Eicosapentaenoic Acid (EPA) 40mg + a-Linolenic Acid (ALA) 30mg + Linoleic Acid 30mg + Vitamin C (as Ester-C®*) 25mg +	Omega-3 Fatty Acids BP/Ph. Eur 330mg + Docosahexaenoic Acid (DHA) BP/Ph. Eur 260mg + Eicosapentaenoic Acid (EPA)BP/Ph. Eur 40mg + a-Linolenic Acid (ALA) BP/Ph. Eur 30mg + Linoleic	Therapeutic Class: Water for Injection, Electrolytes, Blood Volume Restorers and Caloric Agents Therapeutic Code: 079	Multivitamin/multimineral fatty acid dietary supplement indicated for use in improving the nutritional status of omen throughout pregnancy and in the postnatal period for both lactating and nonlactating mothers.	Contraindication This is contraindicated in patients with a known hypersensitivity to any of the ingredients. Side-effects: Allergic sensitization has been reported following both oral and parenteral administration of folic acid Warning & Precaution: Pediatric Use: Safety and effectiveness in pediatric patients have not been established. Geriatric Use: Clinical studies on this product have	New	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
		Vitamin D3 (Cholecalciferol) 0.00043mg eqv.to Vitamin D3 170IU+ Vitamin E (dl-alpha-tocopheryl acetate) 30mg eqv.to Vitamin E 30 IU + Folic Acid 1mg + Vitamin B6 (pyridoxinehydrochloride) 25mg + Calcium 150mg +Carbonyl Iron (elemental iron) 20mg +SumalateTM † (elemental iron) 7mg Capsule	Acid BP/Ph. Eur 30mg + Vitamin C (as Ester-C®*) BP/Ph. Eur 25mg + Vitamin D3 (Cholecalciferol) BP/Ph. Eur 0.00043mg eqv.to Vitamin D3 170IU+ Vitamin E (dl-alpha-tocopheryl acetate) BP/Ph. Eur 30mg eqv.to Vitamin E 30 IU + Folic Acid USP 1mg + Vitamin B6 (pyridoxinehydrochloride) BP/Ph. Eur 25mg + Calcium BP/Ph. Eur 150mg +Carbonyl Iron (elemental iron) In-house 20mg +SumalateTM † (elemental iron) In-house 7mg			not been performed to determine whether elderly subjects respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.				
121.	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka	5 Fluorouracil 0.5g/100g+Salicylic acid 10g/100g Topical solution	5 Fluorouracil USP 0.5g/100 g+Salicylic acid BP/PhEur 10g/100g	Therapeutic Class: Antiprotozoal Therapeutic Code: 027	Common warts, flat juvenile warts, plantar warts.	Contraindication Verrumal should not be used in the lactation period, in pregnant women or in women in whom pregnancy cannot be reliably excluded. Furthermore, it should not be used in persons hypersensitive to the preparation. Verrumal should not be used in babies. Verrumal is not intended for use on large skin areas (skin area larger than 25 cm2). Verrumal may not come into contact with the eyes	New	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						or mucous membranes. Side-effects: Occasional burning, particularly after application. Erosive cutaneous reactions in rare cases. Marked burning may necessitate discontinuation of therapy in very isolated cases. Owing to the intensive softening effect on the horny layer, whitish discoloration and desquamation of the skin can occur particularly in the vicinity of the warts. Warning & Precaution: No data available				
122.	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka The ACME Laboratories Ltd. Dhamrai, Dhaka	Dinoprostone 0.5mg/3gm Cervical gel	Dinoprostone BP/Ph Eur 0.5mg/3 gm	Therapeutic Class: Hormone Therapeutic Code: 056	Dinoprostone gel is indicated for ripening an unfavorable cervix in pregnant women at or near term with a medical or obstetrical need for labor induction.	Contraindication Dinoprostone gel is indicated for ripening an unfavorable cervix in pregnant women at or near term with a medical or obstetrical need for labor induction. Side-effects: Dinoprostone gel is indicated for ripening an unfavorable cervix in pregnant women at or near term with a medical or obstetrical need for labor induction. Dinoprostone gel is indicated for ripening an unfavorable cervix in pregnant women at or near term with a medical or obstetrical need for labor induction. Warning & Precaution: No data Available	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
123.	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka Advanced	Tretinoin 0.1gm + Benzoyl Peroxide 3g/100gm Cream	Tretinoin BP/Ph Eur 0.1gm + Hydrous Benzoyl Peroxide BP/Ph Eur 4.2857gm (eqv.to 3gBenzoyl	Therapeutic Class: Skin and Mucous Membrane Preparations Therapeutic Code: 071	It is a combination of tretinoin, a retinoid, and benzoyl peroxide indicated for the topical treatment of acne vulgaris in adults and	Contraindication Do not administer to patients with known hypersensitivity to this product Side-effects: >10%Erythema, mild (33%) Pigmentation, mild (27.3%)	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj. The ACME Laboratories Ltd. Dhamrai, Dhaka		Peroxide)/100gm		pediatric patients 9 years of age and older.	Dryness, mild (22.3%) Scaling, mild (16.4%)Itching, mild (11.1%) Application site pain (10.6%) 1-10%Erythema, moderate (6.9%) Pigmentation, moderate (6.3%) Burning, mild (5.9%) Stinging, mild (5.3%) Dryness, moderate (5.3%) Warning & Precaution: Hypersensitivity, Skin Irritation, Photosensitivity				
124.	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka	Sucralfate 7gm +Mupirocin 2gm/100gm Ointment	Sucralfate USP 7gm +Mupirocin BP/Ph.Eur 2gm/100gm	Therapeutic Class: Anti-infective Therapeutic Code: 023	This medication is an antibiotic, prescribed for impetigo. It works by stopping the production of essential proteins needed for bacterial surveillance. It is not effective against fungal or viral infections	Contraindication Do not administer to patients with known hypersensitivity to this product Side-effects: Burning, stinging, pain, itching and rash. Warning & Precaution: If you have an allergy to mupirocin or any other part of this drug. Tell your doctor if you are allergic to any drugs. Make sure to tell about the allergy and what signs you had. This includes telling about rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.	New	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
125.	Incepta Pharmaceuticals Ltd.; Dhamrai Unit, Dhaka	Leuprolide Mesylate 42mg ready to use Subcutaneous depot injection	Leuprolide Mesylate INN45.3mg/Syringe eqv. to 42mg/Syringe Leuprolide Pre-Filled Syringe Injection	Therapeutic Class: Anticancer Therapeutic Code: 010	It is a gonadotropin-releasing hormone (GnRH) agonist indicated for the treatment of adult patients with advanced prostate cancer	Contraindication It is contraindicated in patients known to be hypersensitive to GnRH, GnRH agonist analogs, or any of the excipients in it . Anaphylactic reactions to GnRH agonist analogs have been reported in the medical literature Side-effects: hot flushes,, high blood pressure (hypertension), injection site reactions (pain, redness, injection site bleeding, a lump, numbness and tingling, itching,	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						and warmth), upper respiratory tract infections, musculoskeletal pain, fatigue, pain in extremities, joint pain. Warning & Precaution: Tumor Flare, Hyperglycemia and Diabetes, Cardiovascular Diseases, QT/QTc Prolongation, Convulsions, Embryo-Fetal Toxicity				
126.	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka	Metronidazole 1gm +Sucralfate 7gm +Povidone Iodine 5gm/100mg Ointment	Metronidazole BP/Ph.Eur1gm +Sucralfate USP 7gm +Povidone Iodine BP/Ph.Eur5gm/100 mg	Therapeutic Class: Anti-infective Therapeutic Code: 023	used to treat skin infections	Contraindication Do not administer to patients with known hypersensitivity to this product Side-effects: Burning, stinging, pain, itching and rash. Warning & Precaution: Before using Povidone Iodine / Metronidazole, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.).	New	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
127.	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka	Amino Acids 5% IV Infusion L-Isoleucine USP 1.76g + L-Cystine BP/Ph.Eur 0.05g + L-Tyrosine USP 0.125g + L-Aspartic Acid USP 1.25g + L-Leucine USP 2.45g + L-Phenylalanine USP 2.665g + L-Glutamic Acid BP/Ph.Eur 0.375g + L-Tryptophan USP	Amino Acids 5% IV Infusion L-Isoleucine USP 1.76g + L-Cystine BP/Ph.Eur 0.05g + L-Tyrosine USP 0.125g + L-Aspartic Acid USP 1.25g + L-Leucine USP 2.45g + L-Phenylalanine USP 2.665g + L-Glutamic Acid BP/Ph.Eur 0.375g	Therapeutic Class: Electrolytes Therapeutic Code: 079	It acts as building blocking agent for the development of meat production. It also uses to increase egg & milk production. For use as a supplemental source of dextrose, electrolytes, vitamins and amino acid in all animals. Supporting therapy on the operation & after operation, convalescing, dehydration, weakness, vomiting, diarrhea, imbalance of electrolytes, ketosis, anaphylaxis, acidosis and hypoproteinemia.	Contraindication contraindicated in patients with inborn errors of amino acids metabolism, irreversible liver damage and severe uremia when dialysis facilities are not available. Side-effects: Amino acid is usually well tolerated. Nausea Occurs rarely. Vomiting, flushing and sweating have been observed during infusion of Amino acid at rates exceeding the recommended maximal rare. Transient increases liver test during intravenous nutrition have been reported. The reasons are at present unclear. The underlying disease and the components and their amount in	Existing	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
		0.45g + L-Methionine USP 1.125g + L-Histidine Hydrochloride Monohydrate BP/Ph.Eur 1.25g + L-Serine USP 0.5g + L-Valine USP 1.8g + L-Threonine USP 1.25g + L-Lysine Hydrochloride USP 2.15g + L-Arginine Hydrochloride USP 2.5g + L-Alanine USP 1g + Glycine BP/Ph.Eur 3.8g + L-Proline USP 0.5g/500ml	+ L-Tryptophan USP 0.45g + L-Methionine USP 1.125g + L-Histidine Hydrochloride Monohydrate BP/Ph.Eur 1.25g + L-Serine USP 0.5g + L-Valine USP 1.8g + L-Threonine USP 1.25g + L-Lysine Hydrochloride USP 2.15g + L-Arginine Hydrochloride USP 2.5g + L-Alanine USP 1g + Glycine BP/Ph.Eur 3.8g + L-Proline USP 0.5g/500ml			the intravenous feeding regimens have been suggested. Hypersensitivity reactions have been reported. As with all hypertonic infusion solution, thrombophlebitis may occur when peripheral veins are used. The Incidence may be reduced by the simultaneous infusion of 10% fat emulsion. If given to severely ill, premature infants, hyperphenylalaninemia may occur Warning & Precaution: No data available				
128.	Popular Pharmaceuticals Ltd., Tongi, Bangladesh	Phenylephrine Hydrochloride 0.1mg/mL IV Injection	Phenylephrine Hydrochloride 0.1mg/mL solution (5mL)	Therapeutic Class: Anaesthetics (General) Therapeutic Code: 004	The treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia.	Contraindications-None. Warnings & Precautions: Exacerbation of Angina, Heart Failure, or Pulmonary Arterial Hypertension. Peripheral and Visceral Ischemia. Skin and Subcutaneous Necrosis. Bradycardia. Renal Toxicity. Risk of Augmented Pressor Affect in Patients with Autonomic Dysfunction. Pressor Effect with Concomitant Oxytocic Drugs. Side Effects: Most common adverse reactions during treatment: nausea, vomiting, and headache.	New 10 mg/ml Injection	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
129.	Popular Pharmaceuticals Ltd., Tongi, Bangladesh Navana Pharmaceuticals Limited Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Lornoxicam 4 mg Tablet	Lornoxicam INN 4 mg	Therapeutic Class: Analgesics and Antipyretics Therapeutic Code: 006	Short term treatment of moderate pain such as pain after dental surgery, Treatment of pain associated with acute lumbo-sciatica, Symptomatic treatment of pain and inflammation in osteoarthritis and 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 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	New Molecule	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						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; • Someone suffer from SLE (lupus erythematosus, a rare immunological)				
130.	Popular Pharmaceuticals Ltd., Gazipur	Gliclazide 80 mg + Metformin 500 mg Tablet	Gliclazide 80 mg + Metformin 500 mg	Therapeutic Class: Antidiabetic Therapeutic Code: 015	Non insulin-dependent diabetes (type 2) in adults when dietary measures, physical exercise and weight loss alone are not sufficient to control blood glucose.	• Contraindication: Insulin-dependent diabetes mellitus, renal or hepatic failure,alcoholism, NIDDM complicated by severe ketosis and acidosis, diabetic precoma and coma, patients undergoing surgery, after severe trauma or during infections, chronic obstructive pulmonary disease, coronary heart disease, cardiac failure, peripheral vascular disease, pregnancy, known hypersensitivity to any of the ingredients. • Side effects: Gastrointestinal disturbances: Nausea, diarrhoea, gastric pain, constipation, vomiting, metallic taste in mouth. These reactions are generally dose related and disappear when the dose is reduced.	New Molecule Gliclazide 30mg, 60mg, 80mg Tablet	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Dermatological effects: Rash, puritus, urticaria, erythema and flushing. Miscellaneous: Headache and dizziness. Hypoglycaemia: Gliclazide appears to be associated with a low incidence of hypoglycaemia. Gliclazide may have the potiential to produce adverse cardiovascular effects; however Gliclazide has been established agent for the treatment of type 2 diabetes for a number of years without adverse cardiovascular effects. • Warning: Hypoglycaemia may occur if the patient's dietary intake is reduced or after accidental or deliberate overdose or after severe exercise, trauma and stress. Hypoglycaemic symptoms can be reduced by prescribing a diabetic meal plan. Immediate intervention should be done if signs and symptoms of hypoglycaemia occur. • Precautions: Adjust dose of combination according to blood and urinary glucose levels during the first few months. However, there have been few reports of lactic acidosis in patients of renal or liver disease.				
131.	Popular Pharmaceuticals Ltd., Gazipur	Voriconazole 100 mg Tablet	Voriconazole 100 mg	Therapeutic Class: Antifungal And Code: 020	-Treatment of invasive aspergillosis. -Treatment of candidaemia in non-neutropenic patients. -Treatment of fluconazole-resistant serious invasive Candida infections (including *C. krusei*). -Treatment of serious fungal infections caused by *Scedosporium spp.* and *Fusarium spp.*	Contraindications : Voriconazole is contraindicated in patients with known hypersensitivity to the drug or other azoles. Side effects : Most common adverse reactions: visual disturbances, fever, nausea, rash, vomiting, chills, headache, liver function test abnormal, tachycardia, hallucinations. Warnings :	New Molecule 50 mg, 200 mg Tablet, 200 mg/vial Injection 4 gm/100 ml Powder For Suspension	**BNF 81** Page no. 638-639	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Squamous cell carcinoma of the skin (SCC) has been reported in relation with long-term Voriconazole treatment. Precautions : Long term exposure (treatment or prophylaxis) greater than 180 days (6 months) requires careful assessment of the benefit-risk balance and physicians should therefore consider the need to limit the exposure to Voriconazole.				
132.	Navana Pharmaceuticals Limited	Alprostadil 2 mg/gm Cream	Alprostadil USP 2 mg/g	Therapeutic Class: Drug used for erectile dysfunction Therapeutic Code: 043	It is used to treat erectile dysfunction (ED) in men 18 years of age or older.	Contraindications: It should not be used in patients with any of the following: - Underlying disorders such as orthostatic hypotension, myocardial infarction and syncope. - Known hypersensitivity to alprostadil or any of the ingredients in it. - Conditions that might predispose them to priapism, such as sickle cell anaemia or trait, thrombocythemia, polycythemia or multiple myeloma or, leukaemia. - Abnormal penile anatomy such as severe hypospadias, in patients with anatomical deformation of the penis, such as curvature, and in patients with urethritis and balanitis (inflammation/infection of the glans of the penis). - Prone to venous thrombosis or who have a hyperviscosity syndrome and are therefore at increased risk of priapism (rigid erection lasting 4 or more hours). - It should not be used in patients for whom sexual activity is inadvisable as in men with unstable cardiovascular or unstable cerebrovascular conditions. - It should not be used for sexual intercourse with a woman with child-bearing potential unless the couple uses a condom barrier.	New	UKMHRA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Side Effects: Patient: − mild to moderate local aching, burning or pain and redness of the penis, − rash, − genital pruritus, − penile oedema − inflammation of the glans penis (balanitis) − penile tingling, throbbing numbness, burning. Patient's partner: - Mild vaginal burning or itching, vaginitis This effect may be due to the drug or to the act of vaginal penetration. Using a waterbased lubricant can help to make vaginal penetration easier. Warnings and precautions: Talk to your doctor or pharmacist before using it if you have a history of the following local effects that have been observed with the use of it: - Prolonged erections lasting >4 hours (priapism) - Symptomatic hypotension (dizziness) - Hepatic and/or renal insufficiency, a lowered dose due to impaired metabolism may be required - Fainting A condom should be used in the following situations: - Your partner is pregnant or breastfeeding - Your partner is of childbearing potential - To prevent sexually transmitted diseases - During oral sex and anal sex Only latex condoms have been studied. It is not known if condoms made of other materials may be damaged.				
133.	Navana Pharmaceuticals Limited	Phenylephrine HCl 1% Nasal Spray	Phenylephrine HCl INN 1% Nasal Spray	Therapeutic Class: Antihistamine Therapeutic Code: 021	Temporarily relieves nasal congestion due to: common cold hay fever upper respiratory allergies.	Contraindications: Cardiac disease (hypertension, HR, palpitations) Nonselective MAO inhibitors: Risk of hypertensive reaction Side Effects: • difficulty in breathing, swelling of the face, neck, tongue or throat (these are signs of a severe allergic reaction). If you experience any of the following symptoms, or have any other unusual symptoms or concerns with your medicine, stop taking it and talk to your pharmacist or doctor: •	New	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						fast heart rate, changes in heart rhythm, palpitations (feeling your Heartbeat), high blood pressure • feeling sick, vomiting • headache • men may have difficulty passing urine. Warning and precautions: Heart disease, diabetes, thyroid disease, high blood pressure & trouble urinating due to an enlarged prostate gland.				
134.	Navana Pharmaceuticals Limited	Diethylamine Salicylate 10% Cream	Diethylamine Salicylate INN 10% Cream	Therapeutic Class: Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic Code: 064	For symptomatic relief of rheumatic and minor musculo-skeletal conditions including lumbago, fibrositis, sciatica, bruises and strains.	Contraindications: Hypersensitivity to the active substances or to any of the excipients. It should not be used if the surface of the skin is broken. It contains terpene derivatives (ie camphor) as excipients, which can lower the epileptogenic threshold and, at excessive doses, lead to neurological accidents such as convulsions in infants and children. Therefore, Algesal should not be used by children who have a history of convulsions. Hypersensitivity to aspirin or other non-steroidal anti-inflammatory drugs (including when taken by mouth) especially where associated with a history of asthma. Side Effects: Temporary skin reactions (redness, burning sensation and rashes) may occur. Warnings and precautions: Consult your doctor before use if you are pregnant, breastfeeding, asthmatic or on any other medicines. For external use only. Not to be used on broken skin. Avoid contact with eyes and sensitive areas of the skin. Always try on a small area first. Always use sparingly. Some people may experience discomfort, particularly those with sensitive skin or if used in hot weather/after a hot bath. Temporary skin redness/burning sensation may occur. Discontinue use if excessive irritation or unwanted effects occur. Not to be used on children under 6	New	UKMHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						years of age. If symptoms persist consult your doctor. Keep all medicines out of the sight and reach of children. Instruct patients not to smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it. Excipient warnings: This medicine contains fragrance with d-limonene and linalool, which may cause allergic reactions.				
135.	Navana Pharmaceuticals Limited	Fluocortolone Pivalate 0.918 mg/g + Fluocortolone Hexanoate 0.945 mg/g + Cinchocaine Hydrochloride 5 mg/g Ointment	Fluocortolone Pivalate INN 0.918 mg/g + Fluocortolone Hexanoate INN 0.945 mg/g + Cinchocaine Hydrochloride INN 5 mg/g	Therapeutic Class: Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic Code: 064	Haemorrhoids, pruritus ani.	Contraindications: Tuberculous or syphilitic processes in the area to be treated; virus diseases (e. g. vaccinia, chickenpox); hypersensitivity to individual components. Side Effects: It is applied for long periods of time (more than 4 weeks), local concomitant symptoms, such as atrophy of the skin cannot be excluded. Allergic skin reactions may occur in rare cases. Warning and precautions: Additional specific therapy is required in fungal infections. Inadvertent contact of the preparation with the eyes should be avoided. Careful hand washing after use is recommended. Prolonged use (more than 4 weeks) may lead to local concomitant symptoms, such as atrophy of the skin.	New	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**
136.	Navana Pharmaceuticals Limited The ACME Laboratories Ltd. Dhamrai, Dhaka	Zileuton 600 mg ER Tablet	Zileuton INN 600 mg	Therapeutic Class: Drug used in Bronchial Asthma,Chronic obstructive pulmonary	It is a leukotriene synthesis inhibitor indicated for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older. Do not use it to treat an acute asthma attack	Contraindications: • Active liver disease or persistent hepatic function enzyme elevations ≥3 times the upper limit of normal. • History of allergic reaction to zileuton or any of the ingredients of it.	New	USFDA	**অনুমোদনের সুপারিশ করা হয়।**	**অনুমোদন করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
				disease(COPD) Therapeutic Code: 044		Side Effects: Most common adverse reactions (≥5%) included: sinusitis, nausea, and pharyngolaryngeal pain. Warning and precaution: Hepatotoxicity: Elevations of one or more hepatic function enzymes and bilirubin may occur with it. Assess hepatic function enzymes prior to initiation of it, monthly for the first 3 months, every 2-3 months for the remainder of the first year, and periodically thereafter. Use it with caution in patients who consume substantial quantities of alcohol and/or have a history of liver disease. Neuropsychiatric Events: Neuropsychiatric events, including sleep disorders and behavior changes, may occur with it. Instruct patients to be alert for neuropsychiatric events. Evaluate the risks and benefits of continuing treatment with it if such events occur.				
137.	Navana Pharmaceuticals Limited	Hydrogel (Modified CMC 2.3% & Propylene Glycol 20%) Gel	Hydrogel (Modified CMC INN 2.3% & Propylene Glycol INN 20%)	Therapeutic Class: Skin and Mucous Membrane Preparations Therapeutic Code: 071	It is indicated for the removal of non-viable tissue from shallow, undermined and deep wounds. • Pressure ulcers • Leg ulcers • Diabetic foot ulcers • Malignant wounds • Burns • Surgical wounds • Scalds, lacerations, grazes , excoriated skin • Amputation sites • Granulating cavity wounds • Radiation burns.	Contraindications: Do not use for moderate to heavily exudating wounds. Warning and precautions: • Known sensitivity to it or any of its ingredients (Propylene glycol) • It should be used with care in the vicinity of the eyes and in deep wounds with narrow openings (e.g. fistulas) and in body cavities where removal of the gel may be difficult • It is for external use only and should not be taken internally.	New	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**
138.	Navana Pharmaceuticals Limited Beacon Pharmaceuticals Limited	Olanzapine 10mg + Samidorphan 10mg Tablet	Olanzapine USP 10mg + Samidorphan L-Malate INN13.6mg eqv. to Samidorphan	Therapeutic Class: Antipsychotic Therapeutic Code: 028	it is a combination of olanzapine, an atypical antipsychotic, and samidorphan, an opioid antagonist, indicated for the treatment of: • Schizophrenia in adults • Bipolar I disorder in adults • Acute treatment of manic or mixed	Warning: Increased Mortality In Elderly Patients With Dementia-Related Psychosis Contraindications: Patients using opioids. • Patients undergoing acute opioid withdrawal. • If LYBALVI is administered with lithium or valproate, refer to the lithium or valproate		USFDA	**প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
			10mg		episodes as monotherapy and as adjunct to lithium or valproate • Maintenance monotherapy treatment	Prescribing Information for the contraindications for those products. Side effect: Most common adverse reactions (incidence ≥5% and at least twice placebo): • Schizophrenia (LYBALVI): weight increased, somnolence, dry mouth, and headache. • Bipolar I Disorder, Manic or Mixed Episodes (olanzapine): asthenia, dry mouth, constipation, increased appetite, somnolence, dizziness, tremor. • Bipolar I Disorder, Manic or Mixed Episodes, adjunct to Lithium or Valproate (olanzapine): dry mouth, dyspepsia, weight gain, increased appetite, dizziness, back pain, constipation, speech disorder, increased salivation, amnesia, paresthesia. Warning & Precautions: Cerebrovascular Adverse Reactions in Elderly Patients with DementiaRelated Psychosis: Increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack, including fatalities). • Precipitation of Opioid Withdrawal in Patients Who are Dependent on Opioids: LYBALVI can precipitate opioid withdrawal in patients who are dependent on opioids. Prior to initiating LYBALVI, there should be at least a 7-day opioid-free interval from the last use of short-acting opioids, and at least a 14-day opioid-free interval from the last use of long-acting opioids to avoid precipitation of opioid withdrawal. • Orthostatic Hypotension and Syncope: Monitor heart rate and blood pressure and warn patients with known cardiovascular or cerebrovascular disease, and risk of dehydration or syncope. • Leukopenia, Neutropenia, and Agranulocytosis: Perform complete blood counts in patients with a history of a clinically significant low white blood cell				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						(WBC) count. Consider discontinuation if clinically significant decline in WBC in the absence of other causative factors. • Seizures: Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold. • Anticholinergic (Antimuscarinic) Effects: Use with caution with other anticholinergic drugs and in patients with urinary retention, prostatic hypertrophy, constipation, paralytic ileus or related conditions. • Hyperprolactinemia: May elevate prolactin levels.				
139.	Navana Pharmaceuticals Limited	Sitagliptin 100 mg + Simvastatin 10 mg Tablet	Sitagliptin INN 100 mg + Simvastatin INN 10 mg	Therapeutic Class: Antidiabetic Therapeutic Code: 015	Sitagliptin and simvastatin is indicated in patients for whom treatment with both sitagliptin and simvastatin is appropriate. Sitagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Simvastatin is an HMG-CoA reductase inhibitor (statin) indicated as an adjunctive therapy to diet to: • Reduce the risk of total mortality by reducing CHD deaths and reduce the risk of non-fatal myocardial infarction, stroke, and the need for revascularization procedures in patients at high risk of coronary events. • Reduce elevated total-C, LDL-C, Apo B, TG and increase HDL-C in patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia. • Reduce elevated TG in patients with hypertriglyceridemia and reduce TG and VLDL-C in patients with primary dysbetalipoproteinemia. •	Contraindications: • History of a serious hypersensitivity reaction, such as anaphylaxis or angioedema, to any component of this medication. • Concomitant administration of strong CYP3A4 inhibitors. • Concomitant administration of gemfibrozil, cyclosporine, or danazol. • Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels. • Women who are pregnant or may become pregnant. • Nursing mothers. Side Effects: Most common adverse reactions (incidence ≥5%) with simvastatin are: upper respiratory infection, headache, abdominal pain, constipation, and nausea. Adverse reactions reported in ≥5% of patients treated with sitagliptin and more commonly than in patients treated with placebo are: 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	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					Reduce total-C and LDL-C in adult patients with homozygous familial hypercholesterolemia. Important Limitations of Use: • It should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. • It has not been studied in patients with a history of pancreatitis. • It has not been studied in Fredrickson types I and V dyslipidemias. • Patients with severe renal impairment who require sitagliptin 25 mg should not use it due to the unavailability of this dosage strength for it.	in patients treated with sitagliptin compared to placebo. hypokalemia, nausea, and vomiting Warnings and precautions: • There have been postmarketing reports of acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. If pancreatitis is suspected, promptly discontinue it. • Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): Risks increase with higher doses and concomitant use of certain medicines. Predisposing factors include advanced age (≥65), female gender, uncontrolled hypothyroidism, and renal impairment. • Patients should be advised to report promptly any unexplained and/or persistent muscle pain, tenderness, or weakness. It therapy should be discontinued immediately if myopathy is diagnosed or suspected. See Drug Interaction table. • Liver enzyme abnormalities: Persistent elevations in hepatic transaminase can occur. Check liver enzyme tests before initiating therapy and as clinically indicated thereafter. • There have been postmarketing reports of acute renal failure, sometimes requiring dialysis, in patients treated with sitagliptin. Assessment of renal function is recommended prior to initiation of and periodically thereafter. • There is an increased risk of hypoglycemia when it is added to an insulin secretagogue (e.g., sulfonylurea) or insulin therapy. Consider lowering the dose of the sulfonylurea or insulin to reduce the risk of hypoglycemia. • There have been postmarketing reports of serious allergic and hypersensitivity reactions in patients treated with sitagliptin such as				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						anaphylaxis, angioedema, and exfoliative skin conditions including Stevens-Johnson syndrome. In such cases, promptly stop it, assess for other potential causes, institute appropriate monitoring and treatment, and initiate alternative treatment.				
140.	Navana Pharmaceuticals Limited	Sitagliptin 100 mg + Simvastatin 20 mg Tablet	Sitagliptin INN 100 mg + Simvastatin INN 20 mg	Therapeutic Class: Antidiabetic Therapeutic Code: 015	Sitagliptin and simvastatin is indicated in patients for whom treatment with both sitagliptin and simvastatin is appropriate. Sitagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Simvastatin is an HMG-CoA reductase inhibitor (statin) indicated as an adjunctive therapy to diet to: • Reduce the risk of total mortality by reducing CHD deaths and reduce the risk of non-fatal myocardial infarction, stroke, and the need for revascularization procedures in patients at high risk of coronary events. • Reduce elevated total-C, LDL-C, Apo B, TG and increase HDL-C in patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia. • Reduce elevated TG in patients with hypertriglyceridemia and reduce TG and VLDL-C in patients with primary dysbetalipoproteinemia. • Reduce total-C and LDL-C in adult patients with homozygous familial hypercholesterolemia. Important Limitations of Use:	Contraindications: • History of a serious hypersensitivity reaction, such as anaphylaxis or angioedema, to any component of this medication. • Concomitant administration of strong CYP3A4 inhibitors. • Concomitant administration of gemfibrozil, cyclosporine, or danazol. • Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels. • Women who are pregnant or may become pregnant. • Nursing mothers. Side Effects: Most common adverse reactions (incidence ≥5%) with simvastatin are: upper respiratory infection, headache, abdominal pain, constipation, and nausea. Adverse reactions reported in ≥5% of patients treated with sitagliptin and more commonly than in patients treated with placebo are: 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. hypokalemia, nausea, and vomiting Warnings and precautions: • There have been	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					• It should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. • It has not been studied in patients with a history of pancreatitis. • It has not been studied in Fredrickson types I and V dyslipidemias. • Patients with severe renal impairment who require sitagliptin 25 mg should not use it due to the unavailability of this dosage strength for it.	postmarketing reports of acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. If pancreatitis is suspected, promptly discontinue it. • Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): Risks increase with higher doses and concomitant use of certain medicines. Predisposing factors include advanced age (≥65), female gender, uncontrolled hypothyroidism, and renal impairment. • Patients should be advised to report promptly any unexplained and/or persistent muscle pain, tenderness, or weakness. It therapy should be discontinued immediately if myopathy is diagnosed or suspected. See Drug Interaction table. • Liver enzyme abnormalities: Persistent elevations in hepatic transaminase can occur. Check liver enzyme tests before initiating therapy and as clinically indicated thereafter. • There have been postmarketing reports of acute renal failure, sometimes requiring dialysis, in patients treated with sitagliptin. Assessment of renal function is recommended prior to initiation of and periodically thereafter. • There is an increased risk of hypoglycemia when it is added to an insulin secretagogue (e.g., sulfonylurea) or insulin therapy. Consider lowering the dose of the sulfonylurea or insulin to reduce the risk of hypoglycemia. • There have been postmarketing reports of serious allergic and hypersensitivity reactions in patients treated with sitagliptin such as anaphylaxis, angioedema, and exfoliative skin conditions including Stevens-Johnson syndrome. In such cases, promptly stop it, assess for other potential causes, institute appropriate monitoring and treatment, and initiate alternative treatment.				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
141.	Navana Pharmaceuticals Limited	Sitagliptin 100 mg + Simvastatin 40 mg Tablet	Sitagliptin INN 100 mg + Simvastatin INN 40 mg	Therapeutic Class: Antidiabetic Therapeutic Code: 015	Sitagliptin and simvastatin is indicated in patients for whom treatment with both sitagliptin and simvastatin is appropriate. Sitagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Simvastatin is an HMG-CoA reductase inhibitor (statin) indicated as an adjunctive therapy to diet to: • Reduce the risk of total mortality by reducing CHD deaths and reduce the risk of non-fatal myocardial infarction, stroke, and the need for revascularization procedures in patients at high risk of coronary events. • Reduce elevated total-C, LDL-C, Apo B, TG and increase HDL-C in patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia. • Reduce elevated TG in patients with hypertriglyceridemia and reduce TG and VLDL-C in patients with primary dysbetalipoproteinemia. • Reduce total-C and LDL-C in adult patients with homozygous familial hypercholesterolemia. Important Limitations of Use: • It should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. • It has not been studied in patients with a history of pancreatitis. • It has not been studied in Fredrickson	Contraindications: • History of a serious hypersensitivity reaction, such as anaphylaxis or angioedema, to any component of this medication. • Concomitant administration of strong CYP3A4 inhibitors. • Concomitant administration of gemfibrozil, cyclosporine, or danazol. • Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels. • Women who are pregnant or may become pregnant. • Nursing mothers. Side Effects: Most common adverse reactions (incidence ≥5%) with simvastatin are: upper respiratory infection, headache, abdominal pain, constipation, and nausea. Adverse reactions reported in ≥5% of patients treated with sitagliptin and more commonly than in patients treated with placebo are: 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. hypokalemia, nausea, and vomiting Warnings and precautions: • There have been postmarketing reports of acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. If pancreatitis is suspected, promptly discontinue it. • Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): Risks increase with higher doses	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					types I and V dyslipidemias. • Patients with severe renal impairment who require sitagliptin 25 mg should not use it due to the unavailability of this dosage strength for it.	and concomitant use of certain medicines. Predisposing factors include advanced age (≥65), female gender, uncontrolled hypothyroidism, and renal impairment. • Patients should be advised to report promptly any unexplained and/or persistent muscle pain, tenderness, or weakness. It therapy should be discontinued immediately if myopathy is diagnosed or suspected. See Drug Interaction table. • Liver enzyme abnormalities: Persistent elevations in hepatic transaminase can occur. Check liver enzyme tests before initiating therapy and as clinically indicated thereafter. • There have been postmarketing reports of acute renal failure, sometimes requiring dialysis, in patients treated with sitagliptin. Assessment of renal function is recommended prior to initiation of and periodically thereafter. • There is an increased risk of hypoglycemia when it is added to an insulin secretagogue (e.g., sulfonylurea) or insulin therapy. Consider lowering the dose of the sulfonylurea or insulin to reduce the risk of hypoglycemia. • There have been postmarketing reports of serious allergic and hypersensitivity reactions in patients treated with sitagliptin such as anaphylaxis, angioedema, and exfoliative skin conditions including Stevens-Johnson syndrome. In such cases, promptly stop it, assess for other potential causes, institute appropriate monitoring and treatment, and initiate alternative treatment.				
142.	Navana Pharmaceuticals Limited	Sitagliptin 50 mg + Simvastatin 10 mg Tablet	Sitagliptin INN 50 mg + Simvastatin INN 10 mg	Therapeutic Class: Antidiabetic Therapeutic Code: 015	Sitagliptin and simvastatin is indicated in patients for whom treatment with both sitagliptin and simvastatin is appropriate. Sitagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Simvastatin is	Contraindications: • History of a serious hypersensitivity reaction, such as anaphylaxis or angioedema, to any component of this medication. • Concomitant administration of strong CYP3A4 inhibitors. • Concomitant administration of gemfibrozil, cyclosporine, or danazol.	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					an HMG-CoA reductase inhibitor (statin) indicated as an adjunctive therapy to diet to: • Reduce the risk of total mortality by reducing CHD deaths and reduce the risk of non-fatal myocardial infarction, stroke, and the need for revascularization procedures in patients at high risk of coronary events. • Reduce elevated total-C, LDL-C, Apo B, TG and increase HDL-C in patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia. • Reduce elevated TG in patients with hypertriglyceridemia and reduce TG and VLDL-C in patients with primary dysbetalipoproteinemia. • Reduce total-C and LDL-C in adult patients with homozygous familial hypercholesterolemia. Important Limitations of Use: • It should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. • It has not been studied in patients with a history of pancreatitis. • It has not been studied in Fredrickson types I and V dyslipidemias. • Patients with severe renal impairment who require sitagliptin 25 mg should not use it due to the unavailability of this dosage strength for it.	• Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels. • Women who are pregnant or may become pregnant. • Nursing mothers. Side Effects: Most common adverse reactions (incidence ≥5%) with simvastatin are: upper respiratory infection, headache, abdominal pain, constipation, and nausea. Adverse reactions reported in ≥5% of patients treated with sitagliptin and more commonly than in patients treated with placebo are: 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. hypokalemia, nausea, and vomiting Warnings and precautions: • There have been postmarketing reports of acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. If pancreatitis is suspected, promptly discontinue it. • Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): Risks increase with higher doses and concomitant use of certain medicines. Predisposing factors include advanced age (≥65), female gender, uncontrolled hypothyroidism, and renal impairment. • Patients should be advised to report promptly any unexplained and/or persistent muscle pain, tenderness, or weakness. It therapy should be discontinued immediately if myopathy is diagnosed or suspected. See Drug Interaction				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						table. • Liver enzyme abnormalities: Persistent elevations in hepatic transaminase can occur. Check liver enzyme tests before initiating therapy and as clinically indicated thereafter. • There have been postmarketing reports of acute renal failure, sometimes requiring dialysis, in patients treated with sitagliptin. Assessment of renal function is recommended prior to initiation of and periodically thereafter. • There is an increased risk of hypoglycemia when it is added to an insulin secretagogue (e.g., sulfonylurea) or insulin therapy. Consider lowering the dose of the sulfonylurea or insulin to reduce the risk of hypoglycemia. • There have been postmarketing reports of serious allergic and hypersensitivity reactions in patients treated with sitagliptin such as anaphylaxis, angioedema, and exfoliative skin conditions including Stevens-Johnson syndrome. In such cases, promptly stop it, assess for other potential causes, institute appropriate monitoring and treatment, and initiate alternative treatment.				
143.	Navana Pharmaceuticals Limited	Sitagliptin 50 mg + Simvastatin 20 mg Tablet	Sitagliptin INN 50 mg + Simvastatin INN 20 mg	Therapeutic Class: Antidiabetic Therapeutic Code: 015	Sitagliptin and simvastatin is indicated in patients for whom treatment with both sitagliptin and simvastatin is appropriate. Sitagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Simvastatin is an HMG-CoA reductase inhibitor (statin) indicated as an adjunctive therapy to diet to: • Reduce the risk of total mortality by reducing CHD deaths and reduce the risk of non-fatal myocardial infarction, stroke, and the need for revascularization procedures in	Contraindications: • History of a serious hypersensitivity reaction, such as anaphylaxis or angioedema, to any component of this medication. • Concomitant administration of strong CYP3A4 inhibitors. • Concomitant administration of gemfibrozil, cyclosporine, or danazol. • Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels. • Women who are pregnant or may become pregnant. • Nursing mothers. Side Effects:	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					patients at high risk of coronary events. • Reduce elevated total-C, LDL-C, Apo B, TG and increase HDL-C in patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia. • Reduce elevated TG in patients with hypertriglyceridemia and reduce TG and VLDL-C in patients with primary dysbetalipoproteinemia. • Reduce total-C and LDL-C in adult patients with homozygous familial hypercholesterolemia. Important Limitations of Use: • It should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. • It has not been studied in patients with a history of pancreatitis. • It has not been studied in Fredrickson types I and V dyslipidemias. • Patients with severe renal impairment who require sitagliptin 25 mg should not use it due to the unavailability of this dosage strength for it.	Most common adverse reactions (incidence ≥5%) with simvastatin are: upper respiratory infection, headache, abdominal pain, constipation, and nausea. Adverse reactions reported in ≥5% of patients treated with sitagliptin and more commonly than in patients treated with placebo are: 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. hypokalemia, nausea, and vomiting Warnings and precautions: • There have been postmarketing reports of acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. If pancreatitis is suspected, promptly discontinue it. • Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): Risks increase with higher doses and concomitant use of certain medicines. Predisposing factors include advanced age (≥65), female gender, uncontrolled hypothyroidism, and renal impairment. • Patients should be advised to report promptly any unexplained and/or persistent muscle pain, tenderness, or weakness. It therapy should be discontinued immediately if myopathy is diagnosed or suspected. See Drug Interaction table. • Liver enzyme abnormalities: Persistent elevations in hepatic transaminase can occur. Check liver enzyme tests before initiating therapy and as clinically indicated thereafter. • There have been postmarketing reports of acute renal failure, sometimes requiring dialysis, in patients treated with sitagliptin. Assessment of renal function is recommended prior to initiation of and periodically				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						thereafter. • There is an increased risk of hypoglycemia when it is added to an insulin secretagogue (e.g., sulfonylurea) or insulin therapy. Consider lowering the dose of the sulfonylurea or insulin to reduce the risk of hypoglycemia. • There have been postmarketing reports of serious allergic and hypersensitivity reactions in patients treated with sitagliptin such as anaphylaxis, angioedema, and exfoliative skin conditions including Stevens-Johnson syndrome. In such cases, promptly stop it, assess for other potential causes, institute appropriate monitoring and treatment, and initiate alternative treatment.				
144.	Navana Pharmaceuticals Limited	Sitagliptin 50 mg + Simvastatin 40 mg Tablet	Sitagliptin INN 50 mg + Simvastatin INN 40 mg	Therapeutic Class: Antidiabetic Therapeutic Code: 015	Sitagliptin and simvastatin is indicated in patients for whom treatment with both sitagliptin and simvastatin is appropriate. Sitagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Simvastatin is an HMG-CoA reductase inhibitor (statin) indicated as an adjunctive therapy to diet to: • Reduce the risk of total mortality by reducing CHD deaths and reduce the risk of non-fatal myocardial infarction, stroke, and the need for revascularization procedures in patients at high risk of coronary events. • Reduce elevated total-C, LDL-C, Apo B, TG and increase HDL-C in patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia. • Reduce elevated TG in patients with hypertriglyceridemia and reduce TG	Contraindications: • History of a serious hypersensitivity reaction, such as anaphylaxis or angioedema, to any component of this medication. • Concomitant administration of strong CYP3A4 inhibitors. • Concomitant administration of gemfibrozil, cyclosporine, or danazol. • Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels. • Women who are pregnant or may become pregnant. • Nursing mothers. Side Effects: Most common adverse reactions (incidence ≥5%) with simvastatin are: upper respiratory infection, headache, abdominal pain, constipation, and nausea. Adverse reactions reported in ≥5% of patients treated with sitagliptin and more commonly than in patients treated with placebo are: upper respiratory tract infection, nasopharyngitis and headache. In the add-on to	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					and VLDL-C in patients with primary dysbetalipoproteinemia. • Reduce total-C and LDL-C in adult patients with homozygous familial hypercholesterolemia. Important Limitations of Use: • It should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. • It has not been studied in patients with a history of pancreatitis. • It has not been studied in Fredrickson types I and V dyslipidemias. • Patients with severe renal impairment who require sitagliptin 25 mg should not use it due to the unavailability of this dosage strength for it.	sulfonylurea and add-on to insulin studies, hypoglycemia was also more commonly reported in patients treated with sitagliptin compared to placebo. hypokalemia, nausea, and vomiting Warnings and precautions: • There have been postmarketing reports of acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. If pancreatitis is suspected, promptly discontinue it. • Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): Risks increase with higher doses and concomitant use of certain medicines. Predisposing factors include advanced age (≥65), female gender, uncontrolled hypothyroidism, and renal impairment. • Patients should be advised to report promptly any unexplained and/or persistent muscle pain, tenderness, or weakness. It therapy should be discontinued immediately if myopathy is diagnosed or suspected. See Drug Interaction table. • Liver enzyme abnormalities: Persistent elevations in hepatic transaminase can occur. Check liver enzyme tests before initiating therapy and as clinically indicated thereafter. • There have been postmarketing reports of acute renal failure, sometimes requiring dialysis, in patients treated with sitagliptin. Assessment of renal function is recommended prior to initiation of and periodically thereafter. • There is an increased risk of hypoglycemia when it is added to an insulin secretagogue (e.g., sulfonylurea) or insulin therapy. Consider lowering the dose of the sulfonylurea or insulin to reduce the risk of hypoglycemia. • There have been postmarketing reports of serious allergic and hypersensitivity reactions in patients treated with sitagliptin such as				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						anaphylaxis, angioedema, and exfoliative skin conditions including Stevens-Johnson syndrome. In such cases, promptly stop it, assess for other potential causes, institute appropriate monitoring and treatment, and initiate alternative treatment.				
145.	Navana Pharmaceuticals Limited	Sodium Chloride 87.5 mg, Potassium Chloride 149 mg, Sodium Bicarbonate 378 mg, Citric Acid 672 mg, Glucose 1.62 g Effervescent Tablet	Sodium Chloride INN 87.5 mg, Potassium Chloride INN 149 mg, Sodium Bicarbonate INN 378 mg, Citric Acid INN 672 mg, Glucose INN 1.62g	Therapeutic Class: Water for Injection, Electrolytes, Blood Volume Restorers and Caloric Agents Therapeutic Code: 079	Decrease/reduce/relieve symptoms of dehydration in adults Decrease/reduce/relieve symptoms of dehydration in children Maintain/support body electrolyte balance in adults Maintain/support body electrolyte balance in children Helps restore body electrolyte balance in adults Helps restore body electrolyte balance in children.	Warning and precautions: If symptoms persist consult your healthcare practitioner (or words to that effect). Keep out of reach of children (or words to that effect). Contains potassium. If you have kidney disease or are taking heart or blood pressure medicines, consult your doctor or pharmacist before use. Keep out of reach of children. If diarrhoea persists, seek medical advice. Use only as directed (If medicine contains one sugar) contains OR (If medicine contains two or more sugars) Contains sugars. If diarrhoea persists for more than 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years, seek medical advice (or words to that effect). The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).	New	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**
146.	Navana Pharmaceuticals Limited	Rosuvastatin 2.5 mg ODT	Rosuvastatin USP 2.5 mg	Therapeutic Class: Lipid Lowering Therapeutic Code: 061	Hypercholesterolemia & familial hypercholesterolemia	Contraindications: • Known hypersensitivity to product components • Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels • Women who are pregnant or may become pregnant • Nursing mothers. Side effects: Most frequent adverse reactions (rate ≥ 2%) are headache, myalgia, abdominal pain, asthenia, and nausea. Warning and precautions: • Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): Risks	New	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						increase with use of 40 mg dose, advanced age (≥65), hypothyroidism, renal impairment, and combination use with cyclosporine, lopinavir/ritonavir, atazanavir/ritonavir, or certain other lipid-lowering drugs. Advise patients to promptly report unexplained muscle pain, tenderness, or weakness and discontinue it if signs or symptoms appear • Liver enzyme abnormalities and monitoring: Persistent elevations in hepatic transaminases can occur. Monitor liver enzymes before and during treatment.				
147.	Navana Pharmaceuticals Limited	Rosuvastatin 5 mg ODT	Rosuvastatin USP 5 mg ODT	Therapeutic Class: Lipid Lowering Therapeutic Code: 061	Hypercholesterolemia & familial hypercholesterolemia	Contraindications: • Known hypersensitivity to product components • Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels • Women who are pregnant or may become pregnant • Nursing mothers. Side effects: Most frequent adverse reactions (rate ≥ 2%) are headache, myalgia, abdominal pain, asthenia, and nausea. Warning and precautions: • Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): Risks increase with use of 40 mg dose, advanced age (≥65), hypothyroidism, renal impairment, and combination use with cyclosporine, lopinavir/ritonavir, atazanavir/ritonavir, or certain other lipid-lowering drugs. Advise patients to promptly report unexplained muscle pain, tenderness, or weakness and discontinue it if signs or symptoms appear • Liver enzyme abnormalities and monitoring: Persistent elevations in hepatic transaminases can occur. Monitor liver enzymes before and during treatment.	New	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
148.	Beacon Pharmaceuticals Limited	Romiplostim 500mcg Injection as Lyophilized Powder	Romiplostim INN 625.00mcg eqv. to deliver dose 500mcg as Lyophilized Powder	Blood Coagulating Therapeutic Code: 033	It is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Romiplostim should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. Romiplostim should not be used in an attempt to normalize platelet counts.	Contraindications: None Side-effect: The most common adverse reactions (≥ 5% higher patient incidence in Romiplostim versus placebo) are arthralgia, dizziness, insomnia, myalgia, pain in extremity, abdominal pain, shoulder pain, dyspepsia, and paresthesia. Headache was the most commonly reported adverse reaction that did not occur at ≥ 5% higher patient incidence in Romiplostim versus placebo. Warning and Precautions: Romiplostim increases the risk for reticulin deposition within the bone marrow; clinical studies have not ruled out the possibility that reticulin and other fiber deposition may result in bone marrow fibrosis with cytopenias. Monitor peripheral blood for signs of marrow fibrosis. Discontinuation of Romiplostim may result in worsened thrombocytopenia than was present prior to Romiplostim therapy. Monitor complete blood counts (CBCs), including platelet counts, for at least 2 weeks following Romiplostim discontinuation. • Excessive Romiplostim doses may increase platelet counts to a level that produces thrombotic/thromboembolic complications. (5.3) • Assess patients for the formation of neutralizing antibodies if platelet counts importantly decrease following an initial Romiplostim response. (5.4) • Romiplostim may increase the risk for hematological malignancies, especially in patients with myelodysplastic syndrome. (5.5) • Monitor CBCs, including platelet counts and peripheral blood smears, weekly until a stable Romiplostim dose has been achieved. Thereafter, monitor CBCs, including platelet counts and	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						peripheral blood smears, at least monthly. (5.6) • Romiplostim is available only through a restricted distribution program called the Romiplostim NEXUS (Network of Experts Understanding and Supporting Romiplostim and Patients) Program. Under the Romiplostim NEXUS Program, only prescribers and patients registered with the program are able to prescribe, administer, and receive product. To enroll in the Romiplostim NEXUS Program, call 1-877-Romiplostim				
149.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Elemental Iron 100 mg + Folic acid 350 mcg Chewable Tablet	Iron (III)-Hydroxide Polymaltose Complex Pharma Grade 357mg eqv to Elemental Iron 100 mg + Folic acid BP 350 mcg	Therapeutic Class: Drug used in Anemia & other blood disorder Therapeutic Code: 045	1.Iron Deficiency anemia. 2.Folic acid Deficiency anemia	Contra Indications: This combination is contra-indicated in case of- • allergic to iron(III)-hydroxide polymaltose complex, folic acid or any of the other ingredients of this medicine. • an iron overload in the body • disturbed use of iron by the body • reduced number of red blood cells (anaemia), not caused by iron deficiency, such as due to increased red blood cell breakdown and vitamin B12 deficiency. Side effects: Side effects can occur with the following frequency: • Very rare, affects less than 1 user in 10,000: Abdominal pain, constipation, diarrhoea, nausea, vomiting, indigestion, skin rash, itching etc. • Not known, frequency cannot be estimated from the available data: Headache, bloody stool, tooth discolouration, increased appetite etc. Warnings and precautions: • infection or tumour • vitamin B12 deficiency	NEW	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
150.	Beacon Pharmaceuticals Limited	Belumosudil 200mg Tablet	Belumosudil Mesylate INN 242.500 mg eqv. to Belumosudil 200.00mg	Therapeutic Class: Anticancer Therapeutic Code: 010	It is a kinase inhibitor indicated for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy.	Contraindications: None Side effect: The most common (≥ 20%) adverse reactions, including laboratory abnormalities, were infections, asthenia, nausea, diarrhea, dyspnea, cough, edema, hemorrhage, abdominal pain, musculoskeletal pain, headache, phosphate decreased, gamma glutamyl transferase increased, lymphocytes decreased, and hypertension. Warning & Precautions: Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.		USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
151.	Beacon Pharmaceuticals Limited	Abatacept 250mg/Vial as Lyophilized Powder	Abatacept INN 250mg/Vial	Therapeutic Class: Anticancer Therapeutic Code: 010	It is indicated for reducing signs and symptoms, inducing major clinical response, slowing the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more DMARDs, such as methotrexate or TNF antagonists. It may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists. It should not be administered concomitantly with TNF antagonists. It is not recommended for use concomitantly with anakinra.	Contraindications: It should not be administered to patients with known hypersensitivity to Abatacept or any of its components. Side effect: The most serious adverse reactions were serious infections and malignancies (see ADVERSE REACTIONS: Infections and ADVERSE REACTIONS: Malignancies). 13 The most commonly reported adverse events (occurring in ≥10% of patients treated with Abatacept) were headache, upper respiratory tract infection, nasopharyngitis, and nausea. The adverse events most frequently resulting in clinical intervention (interruption or discontinuation of Abatacept) were due to infection. The most frequently reported infections resulting in dose interruption were upper respiratory tract infection (1.0%), bronchitis (0.7%), and herpes zoster (0.7%). The most frequent infections resulting in discontinuation were pneumonia (0.2%), localized infection (0.2%), and		USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						bronchitis (0.1%). Because clinical trials are conducted under widely varying and controlled conditions, adverse reaction rates observed in clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not predict the rates observed in a broader patient population in clinical practice. The data described herein reflect exposure to Abatacept in patients with active RA in placebo-controlled studies (1955 patients with ORENCIA, 989 with placebo). The studies had either a double-blind, placebo-controlled period of 6 months (258 patients with Abatacept, 133 with placebo) or 1 year (1697 patients with Abatacept, 856 with placebo). A subset of these patients received concomitant biologic DMARD therapy, such as a TNF blocking agent (204 patients with Abatacept, 134 with placebo). Warning & Precautions: In controlled clinical trials, patients receiving concomitant Abatacept and TNF antagonist therapy experienced more infections (63%) and serious infections (4.4%) compared to patients treated with only TNF antagonists (43% and 0.8%, respectively) (see ADVERSE REACTIONS: Infections). These trials failed to demonstrate an important enhancement of efficacy with concomitant administration of ORENCIA with TNF antagonist; therefore, concurrent therapy with ORENCIA and a TNF antagonist is not recommended. While transitioning from TNF antagonist therapy to Abatacept therapy, patients should be monitored for signs of infection				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
152.	Beacon Pharmaceuticals Limited	Anifrolumab 300mg/2mL Injection	Anifrolumab INN 300mg/2mL	Therapeutic Class: Anticancer Therapeutic Code: 010	It is a type I interferon (IFN) receptor antagonist indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy. Limitations of Use: The efficacy of Anifrolumab has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Use of Anifrolumab is not recommended in these situations	Contraindications: It is contraindicated in patients with a history of anaphylaxis with anifrolumab-fnia Side effect: Most common adverse drug reactions (incidence ≥5%) are nasopharyngitis, upper respiratory tract infections, bronchitis, infusion related reactions, herpes zoster and cough Warning & Precautions: Serious Infections: Serious and sometimes fatal infections have occurred in patients receiving Anifrolumab. Anifrolumab increases the risk of respiratory infections and herpes zoster. Avoid initiating treatment during an active infection. Consider the individual benefitrisk if using in patients with severe or chronic infections. Consider interrupting therapy with Anifrolumab if patients develop a new infection during treatment. • Hypersensitivity Reactions Including Anaphylaxis: Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported. • Malignancy: Consider the individual benefit-risk in patients with known risk factors for malignancy prior to prescribing Anifrolumab. • Immunization: Avoid use of live or live-attenuated vaccines in patients receiving Anifrolumab. • Not Recommended for Use with Other Biologic Therapies.		USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
153.	Beacon Pharmaceuticals Limited	(Bupivacaine 60mg + Meloxicam 1.8mg)/vial Injection	(Bupivacaine INN 60mg + Meloxicam BP 1.8mg)/vial	Therapeutic Class: Anaesthetics (Local) Therapeutic Code: 005	It contains bupivacaine, an amide local anesthetic, and meloxicam, a nonsteroidal anti-inflammatory drug (NSAID), and is indicated in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy and total knee	Contraindications: It is contraindicated for: • Patients with a known hypersensitivity (e.g. anaphylactic reactions and serious skin reactions) to any local anesthetic agent of the amide-type, NSAIDs, or to any of the other components of this combination. • Patients with a history of asthma, urticaria, or		USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					arthroplasty. Limitations of Use Safety and efficacy have not been established in highly vascular surgeries, such as intrathoracic, large multilevel spinal, and head and neck procedures	other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients • Patients undergoing obstetrical paracervical block anesthesia • Patients undergoing coronary artery bypass graft (CABG) surgery. Side effect: Most common adverse reactions (incidence ≥10% are constipation, vomiting, and headache Warning & Precautions: Dose-Related Toxicity: Monitor cardiovascular and respiratory vital signs and patient's state of consciousness after application of of this combination When using ZYNRELEF with other local anesthetics, overall local anesthetic exposure must be considered through 72 hours Hepatotoxicity: If abnormal liver tests persist or worsen, perform a clinical evaluation of the patient Hypertension: Patients taking some antihypertensive medications may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure. Heart Failure and Edema: Avoid use of ZYNRELEF in patients with severe heart failure unless benefits are expected to outweigh risk of worsening heart failure. Renal Toxicity: Monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia. Avoid use of ZYNRELEF in patients with advanced renal disease unless benefits are expected to outweigh risk of worsening renal function. Hematologic Toxicity: Monitor hemoglobin or				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						hematocrit in patients with any signs or symptoms of anemia				
154.	Beacon Pharmaceuticals Limited	(Bupivacaine 200mg + Meloxicam 8mg)/vial Injection	(Bupivacaine INN 200mg + Meloxicam BP 8mg)/vial	Therapeutic Class: Anaesthetics (Local) Therapeutic Code: 005	It contains bupivacaine, an amide local anesthetic, and meloxicam, a nonsteroidal anti-inflammatory drug (NSAID), and is indicated in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy and total knee arthroplasty. Limitations of Use Safety and efficacy have not been established in highly vascular surgeries, such as intrathoracic, large multilevel spinal, and head and neck procedures	Contraindications: It is contraindicated for: • Patients with a known hypersensitivity (e.g. anaphylactic reactions and serious skin reactions) to any local anesthetic agent of the amide-type, NSAIDs, or to any of the other components of this combination. • Patients with a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients • Patients undergoing obstetrical paracervical block anesthesia • Patients undergoing coronary artery bypass graft (CABG) surgery. Side effect: Most common adverse reactions (incidence ≥10% are constipation, vomiting, and headache Warning & Precautions: Dose-Related Toxicity: Monitor cardiovascular and respiratory vital signs and patient's state of consciousness after application of of this combination When using ZYNRELEF with other local anesthetics, overall local anesthetic exposure must be considered through 72 hours Hepatotoxicity: If abnormal liver tests persist or worsen, perform a clinical evaluation of the patient Hypertension: Patients taking some		USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						antihypertensive medications may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure. Heart Failure and Edema: Avoid use of ZYNRELEF in patients with severe heart failure unless benefits are expected to outweigh risk of worsening heart failure. Renal Toxicity: Monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia. Avoid use of ZYNRELEF in patients with advanced renal disease unless benefits are expected to outweigh risk of worsening renal function. Hematologic Toxicity: Monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia				
155.	Beacon Pharmaceuticals Limited Healthcare Pharmaceuticals Ltd	(Bupivacaine 300mg + Meloxicam 9mg)/vial Injection	(Bupivacaine INN 300mg + Meloxicam BP 9mg)/vial	Therapeutic Class: Anaesthetics (Local) Therapeutic Code: 005	It contains bupivacaine, an amide local anesthetic, and meloxicam, a nonsteroidal anti-inflammatory drug (NSAID), and is indicated in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy and total knee arthroplasty. Limitations of Use Safety and efficacy have not been established in highly vascular surgeries, such as intrathoracic, large multilevel spinal, and head and neck procedures	Contraindications: It is contraindicated for: • Patients with a known hypersensitivity (e.g. anaphylactic reactions and serious skin reactions) to any local anesthetic agent of the amide-type, NSAIDs, or to any of the other components of this combination. • Patients with a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients • Patients undergoing obstetrical paracervical block anesthesia • Patients undergoing coronary artery bypass graft (CABG) surgery. Side effect: Most common adverse reactions (incidence ≥10% are constipation, vomiting, and headache Warning & Precautions:		USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Dose-Related Toxicity: Monitor cardiovascular and respiratory vital signs and patient's state of consciousness after application of of this combination When using ZYNRELEF with other local anesthetics, overall local anesthetic exposure must be considered through 72 hours Hepatotoxicity: If abnormal liver tests persist or worsen, perform a clinical evaluation of the patient Hypertension: Patients taking some antihypertensive medications may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure. Heart Failure and Edema: Avoid use of ZYNRELEF in patients with severe heart failure unless benefits are expected to outweigh risk of worsening heart failure. Renal Toxicity: Monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia. Avoid use of ZYNRELEF in patients with advanced renal disease unless benefits are expected to outweigh risk of worsening renal function. Hematologic Toxicity: Monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia				
156.	Beacon Pharmaceuticals Limited Healthcare Pharmaceuticals Ltd	(Bupivacaine 400mg + Meloxicam 12mg)/vial Injection.	(Bupivacaine INN 400mg + Meloxicam BP 12mg)/vial	Therapeutic Class: Anaesthetics (Local) Therapeutic Code: 005	It contains bupivacaine, an amide local anesthetic, and meloxicam, a nonsteroidal anti-inflammatory drug (NSAID), and is indicated in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy and total knee arthroplasty. Limitations of Use	Contraindications: It is contraindicated for: • Patients with a known hypersensitivity (e.g. anaphylactic reactions and serious skin reactions) to any local anesthetic agent of the amide-type, NSAIDs, or to any of the other components of this combination. • Patients with a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been		USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					Safety and efficacy have not been established in highly vascular surgeries, such as intrathoracic, large multilevel spinal, and head and neck procedures	reported in such patients • Patients undergoing obstetrical paracervical block anesthesia • Patients undergoing coronary artery bypass graft (CABG) surgery. Side effect: Most common adverse reactions (incidence ≥10% are constipation, vomiting, and headache Warning & Precautions: Dose-Related Toxicity: Monitor cardiovascular and respiratory vital signs and patient's state of consciousness after application of of this combination When using ZYNRELEF with other local anesthetics, overall local anesthetic exposure must be considered through 72 hours Hepatotoxicity: If abnormal liver tests persist or worsen, perform a clinical evaluation of the patient Hypertension: Patients taking some antihypertensive medications may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure. Heart Failure and Edema: Avoid use of ZYNRELEF in patients with severe heart failure unless benefits are expected to outweigh risk of worsening heart failure. Renal Toxicity: Monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia. Avoid use of ZYNRELEF in patients with advanced renal disease unless benefits are expected to outweigh risk of worsening renal function. Hematologic Toxicity: Monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
157.	Beacon Pharmaceuticals Limited	Bupivacaine Hydrochloride 660mg/5mL Injection	Bupivacaine Hydrochloride USP 660mg/5mL	Therapeutic Class: Anaesthetics (Local) Therapeutic Code: 005	It contains an amide local anesthetic and is indicated in adults for administration into the subacromial space under direct arthroscopic visualization to produce post-surgical analgesia for up to 72 hours following arthroscopic subacromial decompression. Limitations of Use Safety and effectiveness have not been established in other surgical procedures, including soft tissue surgical procedures, other orthopedic procedures, including for intra-articular administration, and boney procedures, or when used for neuraxial or peripheral nerve blockade.	Warning: Risk Of Potential Adverse Embolic Effects Resulting From Inadvertent Intravascular Injection Contraindications: Patients with a known hypersensitivity (e.g. anaphylactic reactions and serious skin reactions) to any amide local anesthetic, or other components of POSIMIR. • Patients undergoing obstetrical paracervical block anesthesia Side effect: Adverse reactions reported with an incidence greater than or equal to 10% and greater than control following POSIMIR administration in shoulder surgery were dizziness, dysgeusia, dysuria, headache, hypoesthesia, paresthesia, tinnitus, and vomiting (6.1). Adverse reactions reported with an incidence greater than or equal to 10% and greater than control following POSIMIR administration in soft tissue surgical procedures were anemia, bradycardia, constipation, C-reactive protein increased, diarrhea, dizziness, dysgeusia, headache, nausea, post procedural contusion (bruising), procedural pain, pruritus, pyrexia, somnolence, surgical site bleeding, visible bruising, and vomiting Warning & Precautions: Risk of Joint Cartilage Necrosis with Unapproved Intra-articular Use: A study evaluating the effects of POSIMIR and POSIMIR vehicle in dogs following an intra-articular administration demonstrated joint cartilage necrosis • Risk of Systemic Toxicity: Careful and constant monitoring of cardiovascular and respiratory (adequacy of ventilation) vital signs and the patient's state of consciousness should be performed after injection of bupivacaine. • Chondrolysis with Intra-Articular Infusion: Intra-		USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						articular infusions of local anesthetics including POSIMIR following arthroscopic and other surgical procedures is an unapproved use, and there have been postmarketing reports of chondrolysis in patients receiving such infusions.				
158.	Beacon Pharmaceuticals Limited	Margetuximab-cmkb 250mg/10ml Injection	Margetuximab-cmkb INN 250mg/10ml	Therapeutic Class: Anticancer Therapeutic Code: 010	It is a HER2/neu receptor antagonist indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2 positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.	Warning: Left Ventricular Dysfunction And Embryofetal Toxicity Contraindications: None Side effect: The most common adverse drug reactions (>10%) with Margetuximab in combination with chemotherapy are fatigue/asthenia, nausea, diarrhea, vomiting, constipation, headache, pyrexia, alopecia, abdominal pain, peripheral neuropathy, arthralgia/myalgia, cough, decreased appetite, dyspnea, infusion-related reactions, palmar-plantar erythrodysesthesia, and extremity pain. Warning & Precautions: Infusion-Related Reactions (IRRs): Monitor for signs and symptoms. If a significant infusion-associated reaction occurs, slow or interrupt the infusion and administer appropriate medical therapies.		USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
159.	Beacon Pharmaceuticals Limited	Pertuzumab 1200mg +Trastuzumab 600mg + Hyaluronidase USP 30,000 Units/Vial Injection	Pertuzumab INN 1200mg +Trastuzumab INN 600mg + Hyaluronidase USP 30,000 Units/Vial	Therapeutic Class: Anticancer Therapeutic Code: 010	It is a combination of pertuzumab and trastuzumab, HER2/neu receptor antagonists, and hyaluronidase, an endoglycosidase, indicated for: • Use in combination with chemotherapy as: o neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or earlystage breast cancer (either greater than 2 cm in	Warning: Cardiomyopathy, Embryo-Fetal Toxicity, And Pulmonary Toxicity Contraindications: PHESGO is contraindicated in patients with known hypersensitivity to pertuzumab, or trastuzumab, or hyaluronidase, or to any of its excipients. Side effect: Neoadjuvant and Adjuvant Treatment of Breast Cancer		USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					diameter or node positive) as part of a complete treatment regimen for early breast cancer. o adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence • Use in combination with docetaxel for treatment of patients with HER2 positive metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.	• The most common adverse reactions (>30%) with PHESGO were alopecia, nausea, diarrhea, anemia, and asthenia. (6.1) Metastatic Breast Cancer (based on intravenous pertuzumab) • The most common adverse reactions (> 30%) with pertuzumab in combination with trastuzumab and docetaxel were diarrhea, alopecia, neutropenia, nausea, fatigue, rash, and peripheral neuropathy Warning & Precautions: Exacerbation of Chemotherapy-Induced Neutropenia. • Hypersensitivity and Administration-Related Reactions (ARRs): Monitor patients for systemic hypersensitivity reactions. Permanently discontinue PHESGO in patients who experience anaphylaxis or severe hypersensitivity reactions.				
160.	Beacon Pharmaceuticals Limited	Pertuzumab 600mg +Trastuzumab 600mg + Hyaluronidase USP 20,000 Units/Vial Injection	Pertuzumab INN 600mg +Trastuzumab INN 600mg + Hyaluronidase USP 20,000 Units/Vial	Therapeutic Class: Anticancer Therapeutic Code: 010	It is a combination of pertuzumab and trastuzumab, HER2/neu receptor antagonists, and hyaluronidase, an endoglycosidase, indicated for: • <u>Use in combination with chemotherapy as:</u> o neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or earlystage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer. o adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence • Use in combination with docetaxel for treatment of patients with HER2 positive	Warning: Cardiomyopathy, Embryo-Fetal Toxicity, And Pulmonary Toxicity Contraindications: PHESGO is contraindicated in patients with known hypersensitivity to pertuzumab, or trastuzumab, or hyaluronidase, or to any of its excipients. Side effect: Neoadjuvant and Adjuvant Treatment of Breast Cancer • The most common adverse reactions (>30%) with PHESGO were alopecia, nausea, diarrhea, anemia, and asthenia. (6.1) Metastatic Breast Cancer (based on intravenous pertuzumab) • The most common adverse reactions (> 30%) with pertuzumab in combination with trastuzumab and docetaxel were diarrhea, alopecia, neutropenia, nausea, fatigue, rash, and peripheral		USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.	neuropathy Warning & Precautions: Exacerbation of Chemotherapy-Induced Neutropenia. • Hypersensitivity and Administration-Related Reactions (ARRs): Monitor patients for systemic hypersensitivity reactions. Permanently discontinue PHESGO in patients who experience anaphylaxis or severe hypersensitivity reactions.				
161.	Beacon Pharmaceuticals Limited	Ponesimod 20mg Tablet	Ponesimod INN 20mg	Therapeutic Class: Immune-suppressant Therapeutic code: 058	It is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.	Contraindications: • In the last 6 months, experienced myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III/IV heart failure • Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker Side effect: Most common adverse reactions (incidence at least 10%) are upper respiratory tract infection, hepatic transaminase elevation, and hypertension Warning & Precautions: Infections: PONVORY may increase the risk of infections. Obtain a complete blood count (CBC) before initiating treatment. Monitor for infection during treatment and for 1-2 weeks after discontinuation. Do not start PONVORY in patients with active infection. • Liver Injury: Discontinue if significant liver injury is confirmed. Obtain liver function tests before initiating PONVORY. • Increased Blood Pressure (BP): Monitor BP during treatment. • Cutaneous Malignancies: Periodic skin examination is recommended.		USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						• Fetal Risk: Women of childbearing potential should use effective contraception during and for 1 week after stopping PONVORY. • Macular Edema: An ophthalmic evaluation is recommended before starting treatment and if there is any change in vision while taking PONVORY. Diabetes mellitus and uveitis increase the risk				
162.	Beacon Pharmaceuticals Limited	Paracetamol 2.167gm + Dextromethorphan Hydrobromide 0.067 gm + Phenylephrine Hydeochloride 0.033gm / 100ml Syrup	Paracetamol BP 2.167gm + Dextromethorphan Hydrobromide BP 0.067 gm + Phenylephrine Hydeochloride BP 0.033gm / 100ml Syrup	Therapeutic Class: Antitussives, Expectorants and Mucolytic Therapeutic Code: 031	It is indicated for Dry or unproductive cough, Fever, Body aches, Watery eyes, Sneezing.	Contraindications: This is contraindicated in patients hypersensitive to any of the ingredients. Side effects: Most common side effects include: Constipation; diarrhea; dizziness; drowsiness; excitability; headache; loss of appetite; nausea; nervousness or anxiety; trouble		রেফারেন্স নাই।	**প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।**
163.	Beacon Pharmaceuticals Limited	Paracetamol 3.250gm + Dextromethorphan Hydrobromide 0.0100 gm + Guaifenisin 1.00 gm + Phenylephrine Hydrochloride 0.050gm / 100ml Syrup	Paracetamol BP 3.250gm + Dextromethorphan Hydrobromide BP 0.0100 gm + Guaifenisin USP 1.00 gm + Phenylephrine Hydrochloride BP 0.050gm / 100ml Syrup	Therapeutic Class: Antitussives, Expectorants and Mucolytic Therapeutic Code: 031	It relieving congestion, cough, and throat and airway irritation due to colds, flu, or hay fever.	Contraindications: Any known allergies to any of the ingredients. Side effects: Constipation; diarrhea; dizziness; drowsiness; dry mouth, nose, or throat; excitability; headache;		রেফারেন্স নাই।	**প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।**
164.	Beacon Pharmaceuticals Limited	Paracetamol 2.5 gm Guaifenesin 1 gm Phenylephrine HCl 0.05gm/100ml	Paracetamol USP 2.5 gm Guaifenesin USP 1 gm Phenylephrine HCl 0.05gm/100ml	Therapeutic Class: Antitussives, Expectorants and Mucolytic Therapeutic Code: 031	It is indicated for the treatment of minor aches and pain, fever, minor sore throat pain, headache, nasal and sinus congestion, runny nose, sneezing, itchy nose or throat, itchy, watery eyes due to hay fever, cough due to minor	Contraindication: Hypersensitivity to the active ingredient. Precautions: This Combination may cause dizziness or drowsiness or cause blurred vision. There is no specific data on use of this combination during pregnancy & lactation.		রেফারেন্স নাই।	**প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					throat and bronchial irritation and reduces fever.	Side Effects: May cause dryness of the mouth, blurred vision, dizziness, mild nausea, stomach pain, constipation.				
165.	Beacon Pharmaceuticals Limited	Paracetamol 2.167 gm + Diphenhydramine HCl 0.083 gm + Phenylephrine HCl 0.033 gm/ 100ml	Paracetamol BP 2.167 gm + Diphenhydramine HCl USP 0.083 gm + Phenylephrine HCl BP 0.033 gm / 100ml	Therapeutic Class: Antitussives, Expectorants and Mucolytic Therapeutic Code: 031	It is indicated for the treatment of minor aches and pain, fever, minor sore throat pain, headache, nasal and sinus congestion, runny nose, sneezing, itchy nose or throat, itchy, watery eyes due to hay fever, cough due to minor throat and bronchial irritation and reduces fever.	Contraindication: Hypersensitivity to the active ingredient. Precautions: This Combination may cause dizziness or drowsiness or cause blurred vision. There is no specific data on use of this combination during pregnancy & lactation. Side Effects: May cause dryness of the mouth, blurred vision, dizziness, mild nausea, stomach pain, constipation.		রেফারেন্স নাই।	**প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।**
166.	Beacon Pharmaceuticals Limited Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj.	Odevixibat 1200 mcg Capsule	Odevixibat Sesquihydrate INN 1243.893mcg eqv.to Odevixibat 1200 mcg Capsule.	Therapeutic Class: Other Classification Therapeutic Code: 075	It is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC). Limitation of Use: It may not be effective in PFIC type 2 patients with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3).	Contraindications: None Side effect: Most common adverse reactions (>2%) are liver test abnormalities, diarrhea, abdominal pain, vomiting, and fat-soluble vitamin deficiency. Warning & Precautions: Liver Test Abnormalities: Obtain baseline liver tests and monitor during treatment. Dose reduction or treatment interruption may be required if abnormalities occur. For persistent or recurrent liver test abnormalities, consider treatment discontinuation. • Diarrhea: Treat dehydration. Treatment interruption or discontinuation may be required for persistent diarrhea. • Fat-Soluble Vitamin (FSV) Deficiency: Obtain baseline levels and monitor during treatment. Supplement if deficiency is observed. If FSV deficiency persists or worsens despite FSV supplementation, discontinue treatment	New	USFDA	**অনুমোদনের সুপারিশ করা হয়।**	**অনুমোদন করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
167.	Beacon Pharmaceuticals Limited Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj.	Odevixibat 400 mcg Capsule	Odevixibat Sesquihydrate INN 414.631mcg eqv.to Odevixibat 400 mcg Capsule.	Therapeutic Class: Other Classification Therapeutic Code: 075	It is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC). Limitation of Use: It may not be effective in PFIC type 2 patients with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3).	Contraindications: None Side effect: Most common adverse reactions (>2%) are liver test abnormalities, diarrhea, abdominal pain, vomiting, and fat-soluble vitamin deficiency. Warning & Precautions: Liver Test Abnormalities: Obtain baseline liver tests and monitor during treatment. Dose reduction or treatment interruption may be required if abnormalities occur. For persistent or recurrent liver test abnormalities, consider treatment discontinuation. • Diarrhea: Treat dehydration. Treatment interruption or discontinuation may be required for persistent diarrhea. • Fat-Soluble Vitamin (FSV) Deficiency: Obtain baseline levels and monitor during treatment. Supplement if deficiency is observed. If FSV deficiency persists or worsens despite FSV supplementation, discontinue treatment	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
168.	Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj.	Odevixibat 200mcg Oral Pellets	Odevixibat Sesquihydrate INN 207.40mcg eqv. to Odevixibat 200mcg	Therapeutic Class: Other Classification Therapeutic Code: 075	Odevixibat is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis	Contraindication: None Side-effects: Most common adverse reactions (>2%) are liver test abnormalities, diarrhea, abdominal pain, vomiting, and fat-soluble vitamin deficiency. Warnings and precautions: Liver Test Abnormalities: Obtain baseline liver tests and monitor during treatment. Dose reduction or treatment interruption may be required if abnormalities occur. For persistent or recurrent liver	New	**USFDA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						test abnormalities, consider treatment discontinuation. •Diarrhea: Treat dehydration. Treatment interruption or discontinuation may be required for persistent diarrhea •Fat-Soluble Vitamin (FSV) Deficiency: Obtain baseline levels and monitor during treatment. Supplement if deficiency is observed. If FSV deficiency persists or worsens despite FSV supplementation, discontinue treatment				
169.	Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj.	Odevixibat 600mcg Oral pellets	Odevixibat Sesquihydrate INN 622.20mcg eqv. to Odevixibat 600mcg	Therapeutic Class: Other Classification Therapeutic Code: 075	It is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC). Limitation of Use: It may not be effective in PFIC type 2 patients with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3).	Contraindications: None Side effect: Most common adverse reactions (>2%) are liver test abnormalities, diarrhea, abdominal pain, vomiting, and fat-soluble vitamin deficiency. Warning & Precautions: Liver Test Abnormalities: Obtain baseline liver tests and monitor during treatment. Dose reduction or treatment interruption may be required if abnormalities occur. For persistent or recurrent liver test abnormalities, consider treatment discontinuation. • Diarrhea: Treat dehydration. Treatment interruption or discontinuation may be required for persistent diarrhea. • Fat-Soluble Vitamin (FSV) Deficiency: Obtain baseline levels and monitor during treatment. Supplement if deficiency is observed. If FSV deficiency persists or worsens despite FSV supplementation, discontinue treatment	New	**USFDA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
170.	Beacon Pharmaceuticals Limited	Palonosetron 0.005gm/100ml Oral Solution	Palonosetron Hydrochloride INN 0.0056gm eqv to palonosetron 0.005gm/100ml	Therapeutic Class: Antiemetic Therapeutic Code: 018	Indicated for the prevention of acute nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy.	Contra-indication: Palonosetron is contraindicated in patients known to have hypersensitivity to the drug or any of its components Side-effect : The following adverse reactions were reported for palonosetron: Nervous System: <1%: headache, dizziness, dyskinesia. General: <1%: infusion site pain. Dermatological: <1%: allergic dermatitis, skin disorder	0.5mg Tablet, 0.25mg injection	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
171.	Beximco Pharmaceuticals Ltd Opsonin Pharma Limited, Rupatali, Barishal. **Navana Pharmaceuticals Limited**	Ibuprofen 200 mg + Paracetamol 500 mg	Ibuprofen 200 mg + Paracetamol 500 mg	Therapeutic Class: Analgeisc & antipyretic Therapeutic Code: 006	For the temporary relief of mild to moderate pain associated with migraine, headache, backache, period pain, dental pain, rheumatic and muscular pain, pain of non-serious arthritis, cold and flu symptoms, sore throat and fever. This product is especially suitable for pain which requires stronger analgesia than ibuprofen or paracetamol alone.	**Contraindications:** This product is contraindicated: • In patients with a known hypersensitivity to ibuprofen, paracetamol or any other excipients in the product. • In concomitant use with other Paracetamol-containing products – increased risk of serious adverse effects. • In patients with a history of hypersensitivity reactions (e.g. bronchospasm, angioedema, asthma, rhinitis, or urticaria) associated with acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs). • In patients with Active, or a history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding). • In patients with a history of, or an existing gastrointestinal ulceration/perforation or bleeding, including that associated with NSAIDs. • Patients with defects in coagulation.	Ibuprofen 200, 400 mg Tablet ,Paracetamol 500 mg	EMA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Side effects: Common (occurs in less than 1 in 10 people): • Stomach pain or discomfort, feeling or being sick, diarrhea, • Higer levels of liver enzymes • Excessive sweating Uncommon (occurs in less than 1 in 100 people): • Headache and dizziness, wind and constipation, skin rashes, swelling of the face, itching. **Warnings and Precautions:** Paracetamol: The hazards of paracetamol overdose are greater in patients with non-cirrhotic alcoholic liver disease. Immediate medical advice should be sought in the event of an overdose, even if the patient feels well, because of the risk of delayed, serious liver damage. Ibuprofen: Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms and gastrointestinal and cardiovascular risks below and by patients taking the dose with food Elderly: The elderly have an increased				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal. Caution is required in patients with certain conditions: • Respiratory disorders: In patients suffering from, or with a history of, bronchial asthma or allergic disease NSAIDs have been reported to precipitate bronchospasm.				
172.	Beacon Pharmaceuticals Limited The ACME Laboratories Ltd. Dhamrai, Dhaka	Doxofylline 400mg SR + Montelukast 10mg Tablet	Doxofylline INN 400mg SR + Montelukast Sodium USP 10.4mg eqv. to Montelukast 10 mg	Therapeutic Class: Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic Code: 044	It is used for the treatment, control, prevention, & improvement of the following diseases, conditions and symptoms: Asthma Hay fever Exercise-induced asthma Chronic asthma Seasonal allergic rhinitis Perennial allergic rhinitis	Contraindication: Contraindicated in patients who are hypersensitive to any component of this product or to any of its ingredients. It should not be used if you have the following conditions: Allergic reactions Asthma exacerbations Hypersensitivity Lactation Pregnancy Side effect: The following is a list of possible side-effects that may occur from all constituting ingredients of this tablet. This is not a comprehensive list. These side effects are possible, but do not always occur. Nausea, Vomiting, Epigastric pain, Palpitations, Headache, Insomnia		রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
173.	Beacon Pharmaceuticals Limited	Erenumab-aooe 70mg/mL Injection (as prefilled Syringe)	Erenumab-aooe INN 70mg/mL	Therapeutic Class: Drug used in migraine Therapeutic Code: 047	It is a calcitonin gene-related peptide receptor antagonist indicated for the preventive treatment of migraine in adults	Contraindications: None Side effect: The most common adverse reactions in AIMOVIG clinical studies (occurring in at least 3% of treated patients and more often than placebo) are injection site reactions and constipation Warning & Precautions: None		USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
174.	Beacon Pharmaceuticals Limited	Metformin Hydrochoride 250mg Tablet	Metformin Hydrochoride BP 250mg	Therapeutic Class: Antidiabetic Therapeutic Code:015	Indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus	Contraindications: Metformin is contraindicated in patients with: > Unstable and/or insulin-dependent (Type I) diabetes mellitus. > Acute or chronic metabolic acidosis, diabetic ketoacidosis, with or without coma, history of ketoacidosis with or without coma. Diabetic ketoacidosis should be treated with insulin. >In patients with a history of lactic acidosis, irrespective of precipitating factors. > In the presence of renal impairment or when renal function is not known, and also in patients with serum creatinine levels above the upper limit of normal range. Renal disease or renal dysfunction Side effect: ✓Lactic Acidosis Ketoacidosis ✓Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues ✓ Hypersensitivity Reactions ✓bloating/abdominal distention ✓ Vitamin B12 Deficiency ✓ Increased Low-Density Lipoprotein Cholesterol (LDL-C)		রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Warning & Precautions: • Lactic Acidosis: Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. Symptoms included malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Laboratory abnormalities included elevated blood lactate levels, anion gap acidosis, increased lactate/pyruvate ratio; metformin plasma levels generally >5 mcg/mL. • Risk factors include renal impairment, concomitant use of certain drugs, age >65 years old radiological studies with contrast, surgery and other procedures, hypoxic states, excessive alcohol intake, and hepatic impairment. Steps to reduce the risk of and manage metformin associated lactic acidosis in these high risk groups are provided in the Full Prescribing Information. • If lactic acidosis is suspected, discontinue Metformin and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended. • Vitamin B12 Deficiency: Metformin may lower vitamin B12 levels. Monitor hematologica parameters annually and vitamin B12 at 2 to 3 year intervals and manage any abnormalities.				
175.	Beacon Pharmaceuticals Limited	Ponatinib 15mg Tablet	Ponatinib Hydrochloride INN 16.020mg eqv. to Ponatinib 15mg	Therapeutic Class: Anticancer Therapeutic Code: 010	It is a kinase inhibitor indicated for the treatment of adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) that is resistant or intolerant to prior tyrosine kinase inhibitor therapy or Philadelphia chromosome positive	Warning: Arterial Thrombosis And Hepatotoxicity Contraindications: none Side effect: The most common non-hematologic adverse reactions (≥ 20%) were hypertension, rash,	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					acute lymphoblastic leukemia (Ph+ALL) that is resistant or intolerant to prior tyrosine kinase inhibitor therapy. This indication is based upon response rate. There are no trials verifying an improvement in disease-related symptoms or increased survival with Ponatinib.	abdominal pain, fatigue, headache, dry skin, constipation, arthralgia, nausea, and pyrexia. Hematologic adverse reactions included thrombocytopenia, anemia, neutropenia, lymphopenia, and leukopenia Warning & Precautions: Congestive Heart Failure: Monitor patients for signs or symptoms of congestive heart failure and treat as clinically indicated • Hypertension: Monitor for high blood pressure and treat as clinically indicated • Pancreatitis: Monitor serum lipase monthly; interrupt or discontinue Iclusig • Hemorrhage: Interrupt Iclusig for serious or severe hemorrhage • Fluid Retention: Monitor patients for fluid retention. • Embryo-fetal toxicity: Can cause fetal harm. Advise women of potential risk to a fetus				
176.	Beacon Pharmaceuticals Limited	Ponatinib 45mg Tablet	Ponatinib Hydrochloride INN 48.06mg eqv. to Ponatinib 45mg	Therapeutic Class: Anticancer Therapeutic Code: 010	It is a kinase inhibitor indicated for the treatment of adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) that is resistant or intolerant to prior tyrosine kinase inhibitor therapy or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL) that is resistant or intolerant	Warning: Arterial Thrombosis And Hepatotoxicity Contraindications: none Side effect: The most common non-hematologic adverse reactions (≥ 20%) were hypertension, rash, abdominal pain, fatigue, headache, dry skin, constipation, arthralgia, nausea, and pyrexia.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					to prior tyrosine kinase inhibitor therapy. This indication is based upon response rate. There are no trials verifying an improvement in disease-related symptoms or increased survival with Ponatinib.	Hematologic adverse reactions included thrombocytopenia, anemia, neutropenia, lymphopenia, and leukopenia Warning & Precautions: Congestive Heart Failure: Monitor patients for signs or symptoms of congestive heart failure and treat as clinically indicated • Hypertension: Monitor for high blood pressure and treat as clinically indicated • Pancreatitis: Monitor serum lipase monthly; interrupt or discontinue Iclusig • Hemorrhage: Interrupt Iclusig for serious or severe hemorrhage • Fluid Retention: Monitor patients for fluid retention. • Embryo-fetal toxicity: Can cause fetal harm. Advise women of potential risk to a fetus				
177.	Beacon Pharmaceuticals Limited Navana Pharmaceuticals Limited Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria,	Methocarbamol 500mg Tablet	Methocarbamol USP 500mg	Therapeutic Class: Skeleton Muscle Relaxan Therapeutic Code: 070	It is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions. The mode of action of this drug has not been clearly identified, but may be related to its sedative properties. Methocarbamol does not directly relax tense skeletal muscles in man.	Contra-indication: Methocarbamol should not be administered to patients with known or suspected renal pathology. This caution is necessary because of the presence of polyethylene glycol 300 in the vehicle. A much larger amount of polyethylene glycol 300 than is present in recommended doses of Methocarbamol is known to have increased pre-existing acidosis and urea retention in patients with renal impairment. Although the amount present in this preparation is well within the limits of safety, caution dictates this contraindication. Methocarbamol is contraindicated in	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Pabna Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka					patients hypersensitive to methocarbamol or to any of the injection components. Side effect: The following adverse reactions have been reported coincident with the administration of methocarbamol. Some events may have been due to an overly rapid rate of intravenous injection. Body as a whole: Anaphylactic reaction, angioneurotic edema, fever, headache Cardiovascular system: Bradycardia, flushing, hypotension, syncope, thrombophlebitis In most cases of syncope there was spontaneous recovery. In others, epinephrine, injectable steroids, and/or injectable antihistamines were employed to hasten recovery. Digestive system, Dyspepsia, jaundice (including cholestatic jaundice), nausea and vomiting Hemic and lymphatic system: Leukopenia Immune system: Hypersensitivity reactions Nervous system: Amnesia, confusion, diplopia, dizziness or light-headedness, drowsiness, insomnia,				
178.	Beacon Pharmaceuticals Limited Navana Pharmaceuticals Limited Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Methocarbamol 750mg Tablet	Methocarbamol USP 750mg	Therapeutic Class: Skeleton Muscle Relaxan Therapeutic Code: 070	It is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions. The mode of action of this drug has not been clearly identified, but may be related to its sedative properties. Methocarbamol does not directly relax tense skeletal muscles in man.	Contra-indication: Methocarbamol should not be administered to patients with known or suspected renal pathology. This caution is necessary because of the presence of polyethylene glycol 300 in the vehicle. A much larger amount of polyethylene glycol 300 than is present in recommended doses of Methocarbamol is known to have increased pre-existing acidosis and urea retention in patients with renal impairment. Although the amount present in this preparation is well within the limits of safety, caution dictates this contraindication. Methocarbamol is contraindicated in patients hypersensitive to methocarbamol or to any of the injection components. Side effect:	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						The following adverse reactions have been reported coincident with the administration of methocarbamol. Some events may have been due to an overly rapid rate of intravenous injection. Body as a whole: Anaphylactic reaction, angioneurotic edema, fever, headache Cardiovascular system: Bradycardia, flushing, hypotension, syncope, thrombophlebitis In most cases of syncope there was spontaneous recovery. In others, epinephrine, injectable steroids, and/or injectable antihistamines were employed to hasten recovery. Digestive system, Dyspepsia, jaundice (including cholestatic jaundice), nausea and vomiting Hemic and lymphatic system: Leukopenia Immune system: Hypersensitivity reactions Nervous system: Amnesia, confusion, diplopia, dizziness or light-headedness, drowsiness, insomnia,				
179.	Beacon Pharmaceuticals Limited	Fam-Trastuzumab Deruxtecan-nxki 100mg/Vial Lyophilized Powder for Injection	Fam-Trastuzumab Deruxtecan-nxki INN 100mg/Vial.	Therapeutic Class: Anticancer Therapeutic Code: 010	It is a HER2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.	Warning: Interstitial Lung Disease And Embryo-Fetal Toxicity Contraindications: None Side effect: The most common adverse reactions (≥20%) were nausea, fatigue, vomiting, alopecia, constipation, decreased appetite, anemia, neutropenia, diarrhea, leukopenia, cough, and thrombocytopenia Warning & Precautions: Neutropenia: Monitor complete blood counts prior to initiation of ENHERTU and prior to each dose, and as clinically indicated. Manage through treatment interruption or dose reduction. (2.2, 5.2) • Left Ventricular Dysfunction: Assess LVEF prior to initiation of ENHERTU and at regular intervals during treatment as clinically indicated. Manage		USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						through treatment interruption or discontinuation. Permanently discontinue ENHERTU in patients with symptomatic congestive heart failure (CHF)				
180.	Healthcare Pharmaceuticals Ltd	Methenamine 118 mg, Sodium Phosphate Monobasic 40.8 mg, Phenyl Salicylate 36 mg, Methylene Blue 10 mg, Hyoscyamine Sulfate 0.12 mg Capsule	Methenamine USP 118 mg, Sodium Phosphate Monobasic USP 40.8 mg, Phenyl Salicylate INN 36 mg, Methylene Blue USP 10 mg, Hyoscyamine Sulfate USP 0.12 mg	Therapeutic Class: Therapeutic code:	Treatment of symptoms of irritative voiding; relief of local symptoms associated with urinary tract infections; relief of urinary tract symptoms caused by diagnostic procedures	Side Effects: Frequency not defined. Cardiovascular: Flushing, tachycardia Central nervous system: Dizziness Gastrointestinal: Nausea, vomiting, xerostomia Genitourinary: Acute urinary retention, difficulty in micturition, urine discoloration (blue) Ophthalmic: Blurred vision Respiratory: Dyspnea Contraindication: Hypersensitivity to methenamine, hyoscyamine, methylene blue, or any component of the formulation. Note: Contraindications to methenamine and hyoscyamine may also apply; see Methenamine and Hyoscyamine individual monographs for more information.	New	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**
181.	Healthcare Pharmaceuticals Ltd Radiant Pharmaceuticals Limited B-34 & B-46, BSCIC I/E, Tongi, Gazipur-1710, Bangladesh	Naproxen 750 mg SR Tablet	Naproxen USP 750 mg	Therapeutic Class: Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic code: 064	It is a nonsteroidal anti-inflammatory drug indicated for the treatment of: • rheumatoid arthritis (RA) • osteoarthritis (OA) • ankylosing spondylitis (AS) • tendinitis, bursitis • acute gout • primary dysmenorrhea (PD) • the relief of mild to moderate pain	Side Effects: The most frequent adverse events were headache (15%), followed by dyspepsia (14%), and flu syndrome (10%) Contraindication: Known hypersensitivity to naproxen or any components of the drug product • History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs • In the setting of CABG surgery	Existing: Naproxen 250 mg Naproxen 500 mg	USFDA	**প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
182.	Beximco Pharmaceuticals Ltd Opsonin Pharma Limited, Rupatali, Barishal. **Navana Pharmaceuticals Limited**	Ibuprofen 150 mg + Paracetamol 500 mg	Ibuprofen 150 mg + Paracetamol 500 mg	Therapeutic Class: Analgeisc & antipyretic Therapeutic Code: 006	For the temporary relief of mild to moderate pain associated with migraine, headache, backache, period pain, dental pain, rheumatic and muscular pain, pain of non-serious arthritis, cold and flu symptoms, sore throat and fever. This product is especially suitable for pain which requires stronger analgesia than ibuprofen or paracetamol alone.	**Contraindications:** This product is contraindicated: • In patients with a known hypersensitivity to ibuprofen, paracetamol or any other excipients in the product. • In concomitant use with other Paracetamol-containing products – increased risk of serious adverse effects. • In patients with a history of hypersensitivity reactions (e.g. bronchospasm, angioedema, asthma, rhinitis, or urticaria) associated with acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs). • In patients with Active, or a history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding). • In patients with a history of, or an existing gastrointestinal ulceration/perforation or bleeding, including that associated with NSAIDs. • Patients with defects in coagulation. **Side effects:** Common (occurs in less than 1 in 10 people): • Stomach pain or discomfort, feeling or being sick, diarrhea, • Higer levels of liver enzymes • Excessive sweating	Ibuprofen 200, 400 mg Tablet ,Paracetamol 500 mg	EMA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Uncommon (occurs in less than 1 in 100 people): • Headache and dizziness, wind and constipation, skin rashes, swelling of the face, itching. **Warnings and Precautions:** Paracetamol: The hazards of paracetamol overdose are greater in patients with non-cirrhotic alcoholic liver disease. Immediate medical advice should be sought in the event of an overdose, even if the patient feels well, because of the risk of delayed, serious liver damage. Ibuprofen: Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms and gastrointestinal and cardiovascular risks below and by patients taking the dose with food Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal. Caution is required in patients with certain conditions: • Respiratory disorders: In patients suffering				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						from, or with a history of, bronchial asthma or allergic disease NSAIDs have been reported to precipitate bronchospasm.				
183.	Healthcare Pharmaceuticals Ltd The ACME Laboratories Ltd. Dhamrai, Dhaka Navana Pharmaceuticals Limited The IBN SINA Pharmaceutical Industries Ltd.	Oritavancin 1200 mg/Vial	Oritavancin Diphosphate INN 1331.16 mg (Equivalent to Oritavancin 1200 mg)/Vial	Therapeutic Class: Anti-infective Therapeutic code: 023	Oritavancin is a lipoglycopeptide antibacterial drug indicated for the treatment of adult patients with acute bacterial skin and skin structure infections caused or suspected to be caused by susceptible isolates of designated Gram-positive microorganisms. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Oritavancin and other antibacterial drugs, Oritavancin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.	Side Effects: The most common adverse reactions (≥3%) in patients treated with Oritavancin were headache, nausea, vomiting, limb and subcutaneous abscesses, and diarrhea. Contraindication: • Use of intravenous unfractionated heparin sodium is contraindicated for 120 hours (5 days) after Oritavancin administration. • Known hypersensitivity to oritavancin products	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
184.	Healthcare Pharmaceuticals Ltd	Methotrexate Injection 1 gm mg/40 mL (25 mg/ml)	Methotrexate USP Injection 1 gm mg/40 mL (25 mg/ml)	Therapeutic Class: Immune-suppressant Therapeutic code: 058:	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 .	Methotrexate 2.5 mg, 10 mg tablet; 2 mg/ml Injection; 5 mg/2 ml Inj; 50 mg/2 ml	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						fever . gastrointestinal discomfort . headache . leucopenia . malaise . nausea . oral disorders . respiratory disorders . skin reactions . throat complaints . thrombocytopenia . 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				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
185.	Healthcare Pharmaceuticals Ltd	Colesevelam Hydrochloride Sachet 1.875 g	Colesevelam Hydrochloride Sachet 1.875 g	Therapeutic Class: Lipid Lowering Therapeutic code: 061	Colesevelam is a bile acid sequestrant indicated as an adjunct to diet and exercise to: • reduce elevated low-density lipoprotein cholesterol (LDL-C) in adults with primary hyperlipidemia • reduce LDL-C levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia (HeFH) • improve glycemic control in adults with type 2 diabetes mellitus.	Side Effects: Common side-effects include gas, constipation, nausea, vomiting, diarrhea, heartburn, stomach or back pain, headache etc Contraindication: It is contraindicated for a low amount of vitamin A in the body, low vitamin D levels, low vitamin K levels, deficiency of vitamin E, high amount of triglyceride in the blood, stomach or intestinal tract operation, blockage of the esophagus, stomach muscle paralysis and decreased function.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
186.	Healthcare Pharmaceuticals Ltd	Colesevelam Hydrochloride Sachet 3.75 g	Colesevelam Hydrochloride Sachet 3.75 g	Therapeutic Class: Lipid Lowering Therapeutic code: 061	Colesevelam is a bile acid sequestrant indicated as an adjunct to diet and exercise to: • reduce elevated low-density lipoprotein cholesterol (LDL-C) in adults with primary hyperlipidemia • reduce LDL-C levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia (HeFH) • improve glycemic control in adults with type 2 diabetes mellitus.	Side Effects: common side-effects include gas, constipation, nausea, vomiting, diarrhea, heartburn, stomach or back pain, headache etc Contraindication: It is contraindicated for a low amount of vitamin A in the body, low vitamin D levels, low vitamin K levels, deficiency of vitamin E, high amount of triglyceride in the blood, stomach or intestinal tract operation, blockage of the esophagus, stomach muscle paralysis and decreased function.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
187.	Healthcare Pharmaceuticals Ltd Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Ziconotide Acetate 100 mcg/ml Solution for Infusion (intrathecal)	Ziconotide Acetate INN 100 mcg/ml	Therapeutic Class: Analgesics and Antipyretics Analgesic Therapeutic code: 006	Ziconotide solution, intrathecal infusion is an N-type calcium channel antagonist indicated for the management of severe chronic pain in patients for whom intrathecal therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or intrathecal morphine.	Side Effects: The most frequently reported adverse reactions (≥ 25%) in clinical trials were dizziness, nausea, confusional state, nystagmus Contraindication: Patients with a known hypersensitivity to ziconotide or any of its formulation components and in patients with any	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						other concomitant treatment or medical condition that would render intrathecal administration hazardous.				
188.	Healthcare Pharmaceuticals Ltd	Paracetamol 400 mg & Ascorbic Acid 250 mg Eff Tablet	Paracetamol BP 400 mg & Ascorbic Acid USP 250	Therapeutic Class: Analgesic & antipyratic Therapeutic code: 006	This tablet is a common painkiller used to treat aches and pains. It works by blocking chemical messengers in the brain that tell us we have pain. It is effective in relieving pain caused by headache, migraine, nerve pain, toothache, sore throat, period (menstrual) pains, arthritis, and muscle aches.	Side Effects: Side effects from paracetamol are rare but can include: an allergic reaction, which can cause a rash and swelling. flushing, low blood pressure and a fast heartbeat – this can sometimes happen when paracetamol is given in hospital into a vein in your arm. Contraindication: Should not take in case of caloric under nutrition, acute liver failure, liver problems, severe renal impairment, a condition where the body is unable to maintain adequate blood flow called shock, acetaminophen overdose, acute inflammation of the liver due to hepatitis C virus.	Paracetamol 500 mg Tab, 125 mg/ 250 mg/500 mg Supp. Ascorbic Acid 250mg , 1000 mg effervescent tab	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**
189.	Healthcare Pharmaceuticals Ltd	Paracetamol 500 mg & Caffeine 30 mg Effervescent Tablet	Paracetamol BP 500 mg & Caffeine BP 30 mg	Therapeutic Class: Analgesic & antipyratic Therapeutic code: 006	This medicine is for symptomatic treatment of mild to moderate pain and fever in conditions such as headache, toothache and period pains. Do not take this medicine with other paracetamol containing medicines	Side Effects: Side effects from paracetamol are rare but can include: an allergic reaction, which can cause a rash and swelling. flushing, low blood pressure and a fast heartbeat – this can sometimes happen when paracetamol is given in hospital into a vein in your arm. Increased heart rate, Restlessness Contraindication: Should not take in case of caloric under nutrition, acute liver failure, liver problems, severe renal impairment, a condition where the body is unable to maintain adequate blood flow called shock, acetaminophen overdose, acute inflammation of the liver due to hepatitis C virus.	Paracetamol BP 500 mg & Caffeine BP 65 mg Tablet	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
190.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Cenegermin 0.002% Ophthalmic Solution	Cenegermin INN 0.020mg	Therapeutic Class: Eye Preparations Therapeutic code: 052	It is a recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis.	CONTRAINDICATIONS: None SIDE-EFFECT: The most common adverse reactions (incidence >5%) are eye pain, ocular hyperemia, eye inflammation and increased lacrimation.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
191.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Carboxymethylcellulose Sodium 1.0% + Glycerin 0.9% Ophthalmic Solution	Carboxymethylcellulose Sodium BP 100mg + Glycerin BP 90mg/10ml	Therapeutic Class: Eye Preparations Therapeutic code: 052	It is used as a lubricant to relieve irritation and discomfort due to dryness of the eye or due to exposure to wind or sun.	CONTRAINDICATIONS: It is contraindicated in patients with known hypersensitivity to any ingredient of this formulation. SIDE-EFFECT: Vision may be temporarily blurred when this product is first used. Also, minor burning/stinging/irritation may temporarily occur.	New Carboxymethylcellulose Sodium 0.5% + Glycerin 0.9% Ophthalmic Solution	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
192.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Thiamine Mononitrate 10mg + Riboflavin 10mg + Niacinamide 45mg + Pantothenic Acid 50mg + Pyridoxine Hydrochloride 3mg + Cyanocobalamin 15mcg Film Coated Tablet	Thiamine Mononitrate (Vitamin B1) BP 10mg + Riboflavin (Vitamin B2) USP 10mg + Niacinamide (Vitamin B3) USP 45mg + Calcium Pantothenate BP 54.348mg (eq. to Pantothenic Acid (Vitamin B5) 50mg + Pyridoxine Hydrochloride (Vitamin B6) BP 3mg + Cyanocobalamin 1.0% USP 1.5mg (eq. to Vit B12	Therapeutic Class: Vitamins and Combinations Therapeutic Code: 078	Dietary Supplementation deficiency of multivitamin such as Vitamin B-complex.	CONTRAINDICATIONS: This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. SIDE-EFFECT: Allergic sensitization has been reported following administration of folic acid.	New Thiamine Mononitrate 100mg + Pyridoxine HCl 200mg + Cyanocobalamin 200mcg Tablet Thiamine Mononitrate USP 50 mg + Riboflavin USP 25 mg + Pyridoxine HCL USP 10 mg +	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
			15mcg)				Cyanocobalamin 1% USP 0.05 mg (eq. to 0.005mg of cyanocobalamin) Nicotinamide USP 100 mg + Calcium D-Pantothenate USP 25 mg + Folic Acid USP 0.555mg (eq. to 0.5mg of Folic Acid) Ascorbic Acid USP 178.57mg (eq. to 175 mg of Ascorbic Acid) Thiamine mono 10mg Riboflavin10 mg Pyridoxine 3 mg, VitB12 0.005mg, Nicotinamide 50mg Calcium D Panthothinate 12.50mg Folic Acid 1 mg Ascorbic Acid 150mg			

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
193.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Calcium 600mg + Vitamin D3 500IU + Vitamin K2 90mcg Film Coated Tablet	Calcium Carbonate (Coral) BP 1498.382mg (eq. to Elemental Calcium 600mg) + Dry Vitamin D3 (Cholecalciferol) USP 5mg (eq. to Vitamin D3 500IU) + Vitamin K2 INN 0.090mg	Therapeutic Class: Vitamins and Combinations **Therapeutic Code: 078**	It is indicated to support healthy bones, Vitamin D, Vitamin K or Calcium Deficiency in adults and postmenopausal women. Moreover inerali Calcium Delivery.Vitamin D is required for optimal calcium and phosphorous absorption. Vitamin D is required to maintain normal blood levels of calcium and phosphate, which are in turn needed for the normal ineralization of bone, muscle contraction, nerve conduction, and general cellular function in all cells of the body as well as bone growth and maintenance of bone density. Vitamin K is responsible for the carboxylation of the bone protein, osteocalcin, to its active form. Osteocalcin regulates the function of calcium in bone turnover /bone ineralization/bone development. MK-7 may play a role in bone health.; MK-7 may be involved in (bone health/maintenance of healthy bone/normal bone/bone health). May help to increase bone mineral density. For optimal delivery of calcium into the bones. More than 99% of total body	CONTRAINDICATIONS: This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. SIDE-EFFECT: Allergic sensitization has been reported following administration of folic acid.	New Calcium (Coral Calcium) 225 mg + Vitamin D3 800 IU Tablet Calcium (Coral Calcium) 600 mg + Vitamin D3 400 IU Tablet Elemental Calcium 500mg + Vitamin D3 200 IU Tablet Elemental Calcium 500mg + Vitamin D3 400 IU Tablet Elemental Calcium 600mg + Vitamin D3 400 IU Tablet Elemental Calcium 225mg +	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					calcium is stored in the bones and teeth. Clinically trialled dose of Vitamin K2 (MK-7) which may help decrease bone loss in postmenopausal women Supplementation of K2 (MK-7) may help decrease bone loss in postmenopausal women; Maintaining adequate Vitamin K2 (MK-7) levels may help decrease bone loss in postmenopausal women. Calcium is essential for bone mineralisation. D3 is the preferred form of vitamin D/ the form found in the human body. Vitamin D is required for optimal calcium and phosphorous absorption. Adequate serum vitamin D level is required for bone and muscle health. Vitamin D is important for absorption of calcium and phosphorous from the small intestine, extracellular calcium homeostasis and mineralisation of the skeleton.		Vitamin D3 800 IU Tablet Elemental Calcium 800mg + Colecalciferol 10mg + Vitamin k2 180mcg Tablet (DCC 249 Rejected)			
194.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Calcium 350mg + Vitamin D3 300IU Chewable Tablet	Calcium Carbonate (Heavy) USP 874.056mg (eq. to Elemental Calcium 350mg) + Dry Vitamin D3	Therapeutic Class: Vitamins and Combinations Therapeutic Code: 078	• Prevention and treatment of osteoporosis. • For the treatment of hypocalcemia states. • Dietary supplementation. • Healthy bone formation and maintenance.	<u>CONTRAINDICATIONS:</u> This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. <u>SIDE-EFFECT:</u>	New Calcium (Coral Calcium) 225 mg + Vitamin D3 800 IU	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
			(Cholecalciferol) USP 3.0mg (eq. to Vitamin D3 300IU)			Allergic sensitization has been reported following administration of folic acid.	Tablet Calcium (Coral Calcium) 600 mg + Vitamin D3 400 IU Tablet Elemental Calcium 500mg + Vitamin D3 200 IU Tablet Elemental Calcium 500mg + Vitamin D3 400 IU Tablet Elemental Calcium 600mg + Vitamin D3 400 IU Tablet Elemental Calcium 225mg + Vitamin D3 800 IU Tablet			

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
195.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Prenatal Multivitamin and Multimineral Film Coated Tablet	Beta Carotene USP 1.540mg (eq. to Vitamin A 770mcg) + Ascorbic Acid (Vitamin C) USP 85mg + Cholecalciferol (Dry Vitamin D3) USP 10mg (eq. to Vitamin D3 1000IU) + Alpha Tocopheryl Acetate (as Vitamin E Acetate 50%) BP 32.928mg (eq. to Vitamin E 15mg) + Phytonadione (as Vitamin K1 5%) USP 1.8mg + Thiamine Mononitrate USP 1.728mg (eq. to Thiamine 1.4mg) + Riboflavin (Granular Powder) USP 1.4mg + Niacin USP 18mg + Pyridoxine Hydrochloride (Vitamin B6) USP 1.9mg + Folic Acid USP 0.80mg (eq. to Folate DFE 1330mcg) +	Therapeutic Class: Vitamins and Combinations **Therapeutic Code: 078**	Improving the nutritional status of natal to help support growth and healthy development of the body	CONTRAINDICATIONS: This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. SIDE-EFFECT: Allergic sensitization has been reported following administration of folic acid.	New DCC-245 (Rejected) Vitamin A 2,500IU + Vitamin C 92mg + Vitamin D 400IU + Vitamin E 35IU + Vitamin K 30mcg + Thiamin Mononitrate 1.40mg + Riboflavin 1.40mg + Niacin 18mg + Pyridoxine Hydrochloride (Vitamin B6) 1.90mg + Folic Acid 0.80mg + Vitamin B12 2.60mcg + Biotin 0.03mg + Pantothenic Acid 6mg + Calcium 250mg + Ferrous Sulfate 27mg + Phosphorus 20mg + Iodine	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
			Cyanocobalamin (as 0.1%) USP 5.2mg + Biotin USP 0.030mg + Calcium Pantothenate BP 13.044mg (eq. to Pantothenic Acid 6mg) + Calcium Carbonate (from Coral Source) USP 624.250mg (eq. to 250mg Calcium) + Ferrous Fumarate USP 82.134mg (eq. to 27mg Elemental Iron) + Potassium Iodide USP 0.196mg (eq. to Iodine 150mcg) + Magnesium Oxide USP 74.610mg (eq. to Magnesium 45mg) + Zinc Oxide USP 13.692mg (eq. to Zinc 11mg)				220mcg + Magnesium 50mg + Zinc 11mg + Selenium 30mcg + Copper 0.90mg + Manganese 2mg + Chromium 30mcg + Molybdenum 50mcg + Chloride 72mg + Potassium 80mg + DHA (Docosahexaenoic Acid) 200mg + EPA (Eicosapentaenoic Acid) 15 mg.			
196.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Olmesartan Medoxomil 40mg + S-Amlodipine 5mg Film Coated Tablet	Olmesartan Medoxomil BP 40mg + S-Amlodipine Besylate INN 7.485mg (eq. to S-Amlodipine 5mg)	Therapeutic Class: Antihypertensive Therapeutic code: 022	It is a dihydropyridine calcium channel blocker and angiotensin II receptor blocker combination product indicated for the treatment of hypertension, alone or with other antihypertensive agents.	CONTRAINDICATIONS: Anuria, Hypersensitivity to sulfonamide derived drugs. SIDE-EFFECT: • Dizziness • peripheral edema • headache • fatigue	New Amlodipine 5mg + Olmesartan Medoxomil 20mg Tablet Amlodipine 10mg +	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						WARNINGS & PRECAUTIONS: Hypotension in volume- or salt-depleted patients with treatment initiation may occur. Start treatment under close supervision. Increased angina or myocardial infarction with calcium channel blockers may occur upon dosage initiation or increase.	Olmesartan Medoxomil 20mg Tablet			
197.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Olmesartan Medoxomil 20mg + S-Amlodipine 5mg Film Coated Tablet	Olmesartan Medoxomil BP 20mg + S-Amlodipine Besylate INN 7.485mg (eq. to S-Amlodipine 5mg)	Therapeutic Class: Antihypertensive Therapeutic code: 022	It is a dihydropyridine calcium channel blocker and angiotensin II receptor blocker combination product indicated for the treatment of hypertension, alone or with other antihypertensive agents.	CONTRAINDICATIONS: Anuria, Hypersensitivity to sulfonamide derived drugs. SIDE-EFFECT: • Dizziness • peripheral edema • headache • fatigue WARNINGS & PRECAUTIONS: Hypotension in volume- or salt-depleted patients with treatment initiation may occur. Start treatment under close supervision. Increased angina or myocardial infarction with calcium channel blockers may occur upon dosage initiation or increase.	New Amlodipine 5mg + Olmesartan Medoxomil 20mg Tablet Amlodipine 10mg + Olmesartan Medoxomil 20mg Tablet	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
198.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur. The ACME Laboratories Ltd. Dhamrai, Dhaka	Olmesartan Medoxomil 40mg + Cilnidipine 10mg Film Coated Tablet	Olmesartan Medoxomil BP 40mg + Cilnidipine INN 10mg	Therapeutic Class: Antihypertensive Therapeutic code: 022	Hypertension, CKD with hypertension patients, Renal parenchymal hypertension, Diabetic neuropathy and angina pectoris.	CONTRAINDICATIONS: Cardiogenic shock; recent MI or acute unstable angina; severe aortic stenosis. SIDE-EFFECT: Dizziness, Flushing, Headache, Hypotension, Palpitations, Dark urine, Abdominal pain, weakness, Rashes, Dry mouth, Excessive thirst.	New Olmesartan 10, 20 & 40mg Tablet Cilnidipine 5 & 10mg Tablet	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
199.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Olmesartan Medoxomil 40mg + Cilnidipine 5mg Film Coated Tablet	Olmesartan Medoxomil BP 40mg + Cilnidipine INN 5mg	Therapeutic Class: Antihypertensive Therapeutic code: 022	Hypertension, CKD with hypertension patients, Renal parenchymal hypertension, Diabetic neuropathy and angina pectoris.	CONTRAINDICATIONS: Cardiogenic shock; recent MI or acute unstable angina; severe aortic stenosis. SIDE-EFFECT: Dizziness, Flushing, Headache, Hypotension,	New Olmesartan 10, 20 & 40mg Tablet	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Palpitations, Dark urine, Abdominal pain, weakness, Rashes, Dry mouth, Excessive thirst.	Cilnidipine 5 & 10mg Tablet			
200.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur. The ACME Laboratories Ltd. Dhamrai, Dhaka	Olmesartan Medoxomil 20mg + Cilnidipine 10mg Film Coated Tablet	Olmesartan Medoxomil BP 20mg + Cilnidipine INN 10mg	Therapeutic Class: Antihypertensive Therapeutic code: 022	Hypertension, CKD with hypertension patients, Renal parenchymal hypertension, Diabetic neuropathy and angina pectoris.	CONTRAINDICATIONS: Cardiogenic shock; recent MI or acute unstable angina; severe aortic stenosis. SIDE-EFFECT: Dizziness, Flushing, Headache, Hypotension, Palpitations, Dark urine, Abdominal pain, weakness, Rashes, Dry mouth, Excessive thirst.	New Olmesartan 10, 20 & 40mg Tablet Cilnidipine 5 & 10mg Tablet	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**
201.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Olmesartan Medoxomil 20mg + Cilnidipine 5mg Film Coated Tablet	Olmesartan Medoxomil BP 20mg + Cilnidipine INN 5mg	Therapeutic Class: Antihypertensive Therapeutic code: 022	Hypertension, CKD with hypertension patients, Renal parenchymal hypertension, Diabetic neuropathy and angina pectoris.	CONTRAINDICATIONS: Cardiogenic shock; recent MI or acute unstable angina; severe aortic stenosis. SIDE-EFFECT: Dizziness, Flushing, Headache, Hypotension, Palpitations, Dark urine, Abdominal pain, weakness, Rashes, Dry mouth, Excessive thirst.	New Olmesartan 10, 20 & 40mg Tablet Cilnidipine 5 & 10mg Tablet	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**
202.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Telmisartan 80mg + S-Amlodipine 2.5mg Film Coated Tablet	Telmisartan USP 80mg + S-Amlodipine Besylate INN 3.743mg (eq. to S-Amlodipine 2.5mg)	Therapeutic Class: Antihypertensive Therapeutic code: 022	This combination is indicated as initial therapy in patients likely to need multiple antihypertensive agents to achieve their blood pressure goals.	CONTRAINDICATIONS: • Known hypersensitivity (e.g., anaphylaxis or angioedema) to Telmisartan, amlodipine or any other component of this product. • Do not co-administer aliskiren with Telmisartan and amlodipine combination in patients with diabetes. SIDE-EFFECT: Most common side effects of Telmisartan are- Upper respiratory infection (7%), urinary tract infection (1%), back pain	New Telmisartan 4 mg + Amlodipine 5mg Tablet Telmisartan 80mg + Amlodipine 5mg Tablet Telmisartan 20mg, 40mg	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						(3%), diarrhea (3%), Myalgia (3%), Fatigue (1%), Sinusitis (3%), Peripheral edema (1%), chest pain (1%), hypertension (1%), dyspepsia (1%), headache (1%), dizziness (1%) Pharyngitis (1%).	& 80mg Tablet Amlodipine 5 mg Tablet Telmisartan 40mg + Amlodipine 10mg Tablet Telmisartan 80mg + Amlodipine 10mg Tablet			
203.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Telmisartan 80mg + S-Amlodipine 5mg Film Coated Tablet	Telmisartan USP 80mg + S-Amlodipine Besylate INN 7.485mg (eq. to S-Amlodipine 5mg)	**Therapeutic Class: Antihypertensive Therapeutic code: 022**	This combination is indicated as initial therapy in patients likely to need multiple antihypertensive agents to achieve their blood pressure goals.	CONTRAINDICATIONS: • Known hypersensitivity (e.g., anaphylaxis or angioedema) to Telmisartan, amlodipine or any other component of this product. • Do not co-administer aliskiren with Telmisartan and amlodipine combination in patients with diabetes. SIDE-EFFECT: Most common side effects of Telmisartan are- Upper respiratory infection (7%), urinary tract infection (1%), back pain (3%), diarrhea (3%), Myalgia (3%), Fatigue (1%), Sinusitis (3%), Peripheral edema (1%), chest pain (1%), hypertension (1%), dyspepsia (1%), headache (1%), dizziness (1%) Pharyngitis (1%).	New Telmisartan 4 mg + Amlodipine 5mg Tablet Telmisartan 80mg + Amlodipine 5mg Tablet Telmisartan 20mg, 40mg & 80mg Tablet Amlodipine 5 mg Tablet Telmisartan 40mg +	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
							Amlodipine 10mg Tablet Telmisartan 80mg + Amlodipine 10mg Tablet			
204.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Telmisartan 40mg + S-Amlodipine 5mg Film Coated Tablet	Telmisartan USP 40mg + S-Amlodipine Besylate INN 7.485mg (eq. to S-Amlodipine 5mg)	**Therapeutic Class: Antihypertensive Therapeutic code: 022**	This combination is indicated as initial therapy in patients likely to need multiple antihypertensive agents to achieve their blood pressure goals.	CONTRAINDICATIONS: • Known hypersensitivity (e.g., anaphylaxis or angioedema) to Telmisartan, amlodipine or any other component of this product. • Do not co-administer aliskiren with Telmisartan and amlodipine combination in patients with diabetes. SIDE-EFFECT: Most common side effects of Telmisartan are- Upper respiratory infection (7%), urinary tract infection (1%), back pain (3%), diarrhea (3%), Myalgia (3%), Fatigue (1%), Sinusitis (3%), Peripheral edema (1%), chest pain (1%), hypertension (1%), dyspepsia (1%), headache (1%), dizziness (1%) Pharyngitis (1%).	New Telmisartan 4 mg + Amlodipine 5mg Tablet Telmisartan 80mg + Amlodipine 5mg Tablet Telmisartan 20mg, 40mg & 80mg Tablet Amlodipine 5 mg Tablet Telmisartan 40mg + Amlodipine 10mg Tablet Telmisartan 80mg + Amlodipine 10mg Tablet	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
205.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Telmisartan 20mg + S-Amlodipine 5mg Film Coated Tablet	Telmisartan USP 20mg + S-Amlodipine Besylate INN 7.485mg (eq. to S-Amlodipine 5mg)	**Therapeutic Class: Antihypertensive Therapeutic code: 022**	This combination is indicated as initial therapy in patients likely to need multiple antihypertensive agents to achieve their blood pressure goals.	CONTRAINDICATIONS: • Known hypersensitivity (e.g., anaphylaxis or angioedema) to Telmisartan, amlodipine or any other component of this product. • Do not co-administer aliskiren with Telmisartan and amlodipine combination in patients with diabetes. SIDE-EFFECT: Most common side effects of Telmisartan are- Upper respiratory infection (7%), urinary tract infection (1%), back pain (3%), diarrhea (3%), Myalgia (3%), Fatigue (1%), Sinusitis (3%), Peripheral edema (1%), chest pain (1%), hypertension (1%), dyspepsia (1%), headache (1%), dizziness (1%) Pharyngitis (1%).	New Telmisartan 4 mg + Amlodipine 5mg Tablet Telmisartan 80mg + Amlodipine 5mg Tablet Telmisartan 20mg, 40mg & 80mg Tablet Amlodipine 5 mg Tablet Telmisartan 40mg + Amlodipine 10mg Tablet Telmisartan 80mg + Amlodipine 10mg Tablet	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**
206.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Vitamin D3 (as Cholecalciferol) 5000IU + Vitamin K (as Phytonadione) 100mcg + Vitamin K2 (as Menaquinone 7 &	Vitamin D3 (as Cholecalciferol) USP 125 (eq. to Vitamin D3 5000IU) + Vitamin K (as Phytonadione)	Therapeutic Class: Vitamins and Combinations **Therapeutic Code: 078**	This combination synergistically supports healthy cognitive function, promotes bone. Immune & cardiovascular health, inhibit calcium buildup in the arteries.	CONTRAINDICATIONS: This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. SIDE-EFFECT: Allergic sensitization.	New Cholecalciferol (Vitamin D3) 40000 IU, 20000 IU Capsule	**রেফারেন্স নাই।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
		Menaquinone 4) 125mcg Capsule	USP 100mcg + Vitamin K2 (as Menaquinone 7 & Menaquinone 4) INN 125mcg				Cholecalciferol (Vitamin D3) 2000 IU Tablet Phytonadione (Vitamin K1) 1mg Soft Gelatin Capsule Phytonadione (Vitamin K1) 2mg/0.2 ml and 10mg/ml injection			
207.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Vitamin D3 (as Cholecalciferol) 10000IU + Vitamin K (as Phytonadione) 100mcg + Vitamin K2 (as Menaquinone 7 & Menaquinone 4) 125mcg Capsule	Vitamin D3 (as Cholecalciferol) USP 250 (eq. to Vitamin D3 10000IU) + Vitamin K (as Phytonadione) USP 100mcg + Vitamin K2 (as Menaquinone 7 & Menaquinone 4) INN 125mcg	Therapeutic Class: Vitamins and Combinations **Therapeutic Code: 078**	This combination synergistically supports healthy cognitive function, promotes bone. Immune & cardiovascular health, inhibit calcium buildup in the arteries.	CONTRAINDICATIONS: This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. SIDE-EFFECT: Allergic sensitization.	New Cholecalciferol (Vitamin D3) 40000 IU, 20000 IU Capsule Cholecalciferol (Vitamin D3) 2000 IU Tablet Phytonadione (Vitamin K1) 1mg Soft Gelatin Capsule Phytonadione (Vitamin K1)	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
							2mg/0.2 ml and 10mg/ml injection			
208.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Cefoperazone 1000mg + Sulbactam 1000mg Powder for IV/IM Injection	Cefoperazone Sodium & Sulbactam Sodium Powder for Injection (Sterile Material containing Cefoperazone Sodium & Sulbactam Sodium) Ph. Grade 2134.847mg eq. to Cefoperazone 1000mg + Sulbactam 1000mg	Therapeutic Class: Anti-infective Therapeutic code: 023	It is indicated for the treatment of the following infections when caused by susceptible organisms: Respiratory Tract Infections (Upper and Lower), Urinary Tract Infections (Upper and Lower), Peritonitis, Cholecystitis, Cholangitis, and Other Intra-Abdominal Infections, Septicemia Meningitis Skin and Soft Tissue Infections Bone and Joint Infections, Pelvic Inflammatory Disease, Endometritis, Gonorrhea and Other.	CONTRAINDICATIONS: It is contraindicated in patients with known allergy to penicillins, sulbactam, Cefoperazone or any of the cephalosporin. SIDE-EFFECT: Skin rash, hives, eosinophilia, diarrhea, nausea, vomiting, eye inflammation, blood clotting problem and super infection.	New Cefoperazone 1000mg + Sulbactam 100mg/Vial (DCC-250 Rejected) Cefoperazone 500mg/Vial Injection Cefoperazone 1000mg/Vial Injection Cefoperazone 2000mg/Vial Injection	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
209.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Carbetapentane Tannate 60mg + Chlorpheniramine Tannate 5mg + Ephedrine Tannate 10mg + Phenylephrine Tannate 10mg	Carbetapentane Tannate Inn 60mg + Chlorpheniramine Tannate INN 5mg + Ephedrine Tannate INN 10mg + Phenylephrine	**Therapeutic Class:** Anti-tissusives, Expectorants & Mucolytic Therapeutic code: 031	Symptomatic relief of cough associated with respiratory tract conditions such as the common cold bronchial asthma & acute and chronic bronchitis.	CONTRAINDICATIONS: It is contraindicated for newborns, nursing mothers, and patients who are sensitive to any of the ingredients or related compounds. SIDE-EFFECT: Drowsiness, sedation, dryness of mucous membranes, and gastrointestinal effects. Serious side effects with oral antihistamines or	New Carbetapentane Tannate 600mg + Chlorphenira mine Tannate 80mg + Ephedrine	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
		Tablet	Tannate INN 10mg			sympathomimetics have been rare. WARNINGS & PRECAUTIONS: Use with caution in patients with hypertension, cardiovascular disease, hyperthyroidism, diabetes, narrow angle glaucoma, or prostatic hypertrophy. Do not use in patients taking monoamine oxidase (MAO) inhibitors, or for 14 days after stopping treatment with an MAOI.	Tannate 100mg & Phenylephrine Tannate 100mg/100ml Syrup (DCC-231 Rejected).			
210.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Felodipine 2.5mg Extended Release Tablet	Felodipine USP 2.5mg	Therapeutic Class: Antihypertensive Therapeutic code: 022	It is indicated for the treatment of hypertension. It may be used alone or concomitantly with other antihypertensive.	CONTRAINDICATIONS: Felodipine extended release tablets are contraindicated in patients who are hypersensitive to this product SIDE-EFFECT: The most common side effects are dizziness, fatigue, flushing, headache, hypotension and peripheral edema may occur.	New Felodipine 5mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
211.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Felodipine 10mg Extended Release Tablet	Felodipine USP 10mg	Therapeutic Class: Antihypertensive Therapeutic code: 022	It is indicated for the treatment of hypertension. It may be used alone or concomitantly with other antihypertensive.	CONTRAINDICATIONS: Felodipine extended release tablets are contraindicated in patients who are hypersensitive to this product SIDE-EFFECT: The most common side effects are dizziness, fatigue, flushing, headache, hypotension and peripheral edema may occur.	New Felodipine 5mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
212.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Dextromethorphan Hydrobromide 15mg + Phenylephrine Hydrochloride 5mg + Chlorpheniramine Maleate 5mg/5ml Syrup	Dextromethorphan Hydrobromide USP 0.300gm + Phenylephrine Hydrochloride USP 0.100gm + Chlorpheniramine Maleate USP 0.100gm/100ml	Therapeutic Class: Anti-tissusives, Expectorants & Mucolytic Therapeutic code: 031	It is used for the relief of coughs and upper respiratory symptoms, including nasal congestion, associated with allergy or the common cold.	CONTRAINDICATIONS: Hypersensitivity, Monoamine oxidase (MAO) inhibitor therapy. SIDE-EFFECT: Sedation, dizziness, diplopia, vomiting, diarrhea, nausea, anorexia, heartburn, dry mouth, headache, nervousness, weakness, polyuria and dysuria.	New Dextromethorphan Hydrobromide 0.40gm + Phenylephrine HCl 0.20gm + Triprolidine	**রেফারেন্স নাই।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
							HCl 0.05gm/100ml Syrup			
213.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	L-Isoleucine 84mg + L-Leucine 163.8mg + L-Lysine 126mg + L-Methionine 43.68mg + L-Phenylalanine 105mg + L-Threonine 63mg + L-Tryptophan 16.8mg + L-Valine 109.2mg + L-Histidine 42mg + Vitamin B6 0.7mg + Vitamin B12 6mcg Capsules	L-Isoleucine USP 84mg + L-Leucine USP 163.8mg + L-Lysine Hydrochloride USP 157.374mg (eq. to L-Lysine 126mg) + L-Methionine USP 43.68mg + L-Phenylalanine USP 105mg + L-Threonine USP 63mg + L-Tryptophan USP 16.8mg + L-Valine USP 109.2mg + L-Histidine USP 42mg + Pyridoxine Hydrochloride (Vitamin B6) USP 0.7mg + Cyanocobalamin (Vitamin B12) 1.0% USP 0.6mg	Therapeutic Class: Vitamins and Combinations Therapeutic Code: 078	It is indicated for the Illness, Injury and Stress, for maintain healthy Immune system, Tissue and Cell growth and repair.	CONTRAINDICATIONS: • Patients with acute renal failure. • Patients with severe liver disease or hepatic coma. • Hypersensitivity to one or more amino acids. • Inborn errors of amino acid metabolism concerning one or more amino acid components. SIDE-EFFECT: None	New Amino Acid 5%, 10%, 15% Solution 5% Amino Acid, Electrolytes & 7.5% Dextrose IV Infusion 5% Amino Acid, Electrolytes & 10% Dextrose IV Infusion Amino Acids (5%) + Sorbitol + Vitamins + Electrolytes IV Infusion Essential Amino Acids (8.14%) + D-Sorbitol + Electrolytes IV	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
							Infusion 15% Amino acid with 20% Dextrose Infusion			
214.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Paracetamol 500mg + Diphenhydramine Hydrochloride 25mg Film Coated Tablet	Paracetamol BP 500mg + Diphenhydramine Hydrochloride USP 25mg	Therapeutic Class: Analgesics and Antipyretics Therapeutic Code: 006	For the short term treatment of bedtime pain, for example rheumatic and muscle pain, backache, neuralgia, toothache, migraine, headache and period pain which is causing difficulty in getting to sleep.	CONTRAINDICATIONS: Hypersensitivity to paracetamol, diphenhydramine hydrochloride or other constituents. Porphyria. Antihistamines are contraindicated in premature infants or neonates who have increased susceptibility to Antimuscarinic effects. SIDE EFFECTS: Like all medicines, it can have side effects, but not everybody gets them. Older people are more prone to these side effects. When using this product you may experience: • Drowsiness, dizziness, tiredness, blurred vision, or difficulty concentrating, Dry mouth. • Allergic reactions which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath • Chest tightness or thickening of phlegm • Difficulty in passing urine, headaches • Upset Stomach	New Paracetamol 500mg Tablet Diphenhydramine HCl 50mg Tablet	UKMHRA	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
215.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Paracetamol 500 mg and Diphenhydramine Hydrochloride 38 mg Film Coated Tablet	Paracetamol BP 500mg and Diphenhydramine Hydrochloride USP 38 mg	Therapeutic Class: Analgesics and Antipyretics Therapeutic Code: 006	For the short term treatment of bedtime pain, for example rheumatic and muscle pain, backache, neuralgia, toothache, migraine, headache and period pain which is causing difficulty in getting to sleep.	CONTRAINDICATIONS: Hypersensitivity to paracetamol, diphenhydramine hydrochloride or other constituents. Porphyria. Antihistamines are contraindicated in premature infants or neonates who have increased susceptibility to Antimuscarinic effects. SIDE EFFECTS:	New Paracetamol 500mg Tablet Diphenhydramine Hydrochloride	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Like all medicines, it can have side effects, but not everybody gets them. Older people are more prone to these side effects. When using this product you may experience: • Drowsiness, dizziness, tiredness, blurred vision, or difficulty concentrating, Dry mouth. Stop taking this medicine and tell your doctor immediately if you experience: • Allergic reactions which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath • Chest tightness or thickening of phlegm, •Difficulty in passing urine, headaches, Skin rash or peeling or mouth ulcers, •Upset Stomach • Breathing problems. These are more likely if you have experienced them before when taking other painkillers (such as ibuprofen and aspirin), • Seizures or difficulty of muscle coordination • Changes in heart rhythm • Unexplained bruising or bleeding	50mg Tablet			
216.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Paracetamol 325 mg and Diphenhydramine Hydrochloride 12.5 mg Film Coated Tablet	Paracetamol BP 325mg and Diphenhydramine Hydrochloride USP 12.5 mg	Therapeutic Class: Analgesics and Antipyretics Therapeutic Code: 006	For the short term treatment of bedtime pain, for example rheumatic and muscle pain, backache, neuralgia, toothache, migraine, headache and period pain which is causing difficulty in getting to sleep.	<u>CONTRAINDICATIONS:</u> Hypersensitivity to paracetamol, diphenhydramine hydrochloride or other constituents. Porphyria. Antihistamines are contraindicated in premature infants or neonates who have increased susceptibility to antimuscarinic effects. <u>SIDE EFFECTS:</u> Like all medicines, it can have side effects, but not everybody gets them. Older people are more prone to these side effects.	New Paracetamol 500mg Tablet Diphenhydramine Hydrochloride 50mg Tablet	**রেফারেন্স নাই।**	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						When using this product you may experience: • Drowsiness, dizziness, tiredness, blurred vision, or difficulty concentrating, Dry mouth. Stop taking this medicine and tell your doctor immediately if you experience: • Allergic reactions which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath • Chest tightness or thickening of phlegm, •Difficulty in passing urine, headaches, Skin rash or peeling or mouth ulcers, •Upset Stomach • Breathing problems. These are more likely if you have experienced them before when taking other painkillers (such as ibuprofen and aspirin), • Seizures or difficulty of muscle coordination • Changes in heart rhythm • Unexplained bruising or bleeding				
217.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur. The ACME Laboratories Ltd. Dhamrai, Dhaka	Teneligliptin 20mg Film Coated Tablet	Teneligliptin Hydrobromide Hydrate INN 33.333mg (eq. to Teneligliptin 20mg)	Therapeutic Class: Antidiabetic Therapeutic Code: 015	It is a Type 2 diabetes mellitus- The drug product should be used only in patients who have not sufficiently responded to either of the following treatments: Diet and/or exercise therapy alone. Use of sulfonylureas in addition to diet and/or exercise therapy. Use of thiazolidinediones in addition to diet and/or exercise therapy.	<u>CONTRAINDICATIONS:</u> Hypersensitivity, Severe ketosis, diabetic coma or history of diabetic coma, type 1 diabetic patient, Patients with severe infection, surgery, severe trauma (blood sugar control should preferably be done by insulin). <u>SIDE EFFECTS:</u> Abdominal bloating, abdominal discomfort, nausea, abdominal pain, flatulence, Proteinuria, urine ketone-positive, Eczema, rash, itching, allergic dermatitis.	New DCC-250 (Reject)	**রেফারেন্স নাই।**	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
218.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Enalapril Maleate 5mg + Felodipine 5mg Extended Release Tablets	Enalapril Maleate USP 5mg + Felodipine USP 5mg	Therapeutic Class: Antihypertensive Therapeutic Code: 022	Refractory hypertension and in hypertension with coexisting congestive failure.	CONTRAINDICATIONS: Combination of Enalapril and Felodipine is contraindicated in patients who arehypersensitive to any component of this product or to any of its ingredients. SIDE EFFECTS: Hypotension, orthostatic hypotension, rash, pruritus, palpitation, urinary	New DCC-217 (Reject)	**রেফারেন্স নাই।**	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
219.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Bromohexine HCl 4mg + Guaifenesin 100 mg per 5 ml Syrup	Bromohexine HCl BP 0.080gm + Guaifenesin USP 2.0gm per 100 ml	Therapeutic Class: Antitussives, Expectorants and Mucolytic Therapeutic Code: 031	It is indicated for the symptomatic relief of chesty or excessive mucus or productive cough in the following conditions: • Tracheobronchitis • Bronchitis with emphysema • Bronchiectasis • Bronchitis with bronchospasm • Chronic inflammatory pulmonary condition • Pneumonia	CONTRAINDICATIONS: Patients with known hypersensitivity to any of its ingredients. It is contraindicated in patients with sever hypertension and severe coronary artery disease. SIDE EFFECTS: Gastrointestinal side effects may occur occasionally with Bromohexine and transient rise in serum amino transferase values has been reported.	New DCC-244 (Reject)	**রেফারেন্স নাই।**	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
220.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Bisoprolol Fumarate 2.5 mg + Cilnidipine 5 mg Tablet	Bisoprolol Fumarate USP 2.5 mg + Cilnidipine INN 5 mg	Therapeutic Class: Antihypertensive Therapeutic Code: 022	Hypertension	Contra-indications: The Combination of Bisoprolol fumarate andCilnidipine is not recommended for use if youhave a history of allergy to Cilnidipine or any other component of this medicine. Side Effects: Sleepiness, Headache,Ankle swelling,Flushing ,Slow heart rate,Tiredness,Palpitations,Nausea,Edema (swelling),Constipation,Cold extremities Warning & Precautions: This medicine is not recommended for use in pregnant & breastfeeding women unless absolutely necessary. This medicine should be used with caution in patients suffering from heart diseases due to the increased risk of cardiac failure.	NEW	**রেফারেন্স নাই।**	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
221.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Navana Pharmaceuticals Limited	Spironolactone 50mg + Hydrochlorothiazide 50mg FC Tablet	Spironolactone BP 50mg + Hydrochlorothiazide BP 50mg	**Therapeutic Class: Antihypertensive Therapeutic Code: 022**	It is indicated in Congestive heart failure, Cirrhosis of the liver accompanied by edema and/or ascites, Essential hypertensoin	CONTRAINDICATIONS: Hypersensitivity, Anuria, Acute renal insufficiency, Significant impairement of renal excretory function, Hypercalcemia	New DCC-248 (Reject)	**USFDA**	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
222.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Thiamine Mononitrate 100mg + Pyridoxine HCl 100mg + Cyanocobalamin 5 mg FC Tablet	Thiamine Mononitrate (Vitamin B1) USP 100mg + Pyridoxine HCl(Vitamin B6) USP 100mg + Cyanocobalamin (Vitamin B12) USP 5 mg	**Therapeutic Class:** Vitamins and Combination **Therapeutic Code:** 078	Diabetic polyneuropathy, neuralgia, nerve compression syndrome, migraine & other circulatory disorders.	CONTRAINDICATIONS: This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. SIDE EFFECTS: Allergic sensitization has been reported	New DCC-230 Thiamine Mononitrate 100mg + Pyridoxine HCl 200mg + Cyanocobalamin 200mcg Tablet	**রেফারেন্স নাই।**	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
223.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Cefcapene 100mg FC Tablet	Cefcapene Pivoxil Hydrochloride Hydrate INN 137.182 mg (eq. to 100mg Cefcapene)	**Therapeutic Class:** Anti-Infective **Therapeutic Code:** 023	It is indicated in superficial skin infection, deep skin infection, lymphangitis, lymphadentitis, chronic pyoderma. -Secondary infections in trauma, burns, surgical wounds etc., mastitis, periproctic abscess. -Pharyngolaryngitis, tonsillitis (including peritonsillitis and peritonsillar abscess), acute bronchitis, pneumonia, secondary infections in chronic respiratory diseases -Cystitis, pyelonephritis -Urethritis, cervicitis	CONTRAINDICATIONS: This drug is contraindicated in patients with known allergy to penicllin or cephalosporin class of antibiotics or any of the components of this formulation. Patients with a history of shock following exposure to any of the ingredients in this product. Patients with a history of hypersensitivity to any of the ingredients in this product or to other cephalosporin antibiotics. SIDE EFFECTS: Clinically significant adverse reactions are given below. Shock, anaphylactoid reaction, Acute renal failure Agranulocytosis, thrombocytopenia, hemolytic	New DCC-250(Reject)	**রেফারেন্স নাই।**	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						anemia Pseudomembranous colitis, hemorrhagic colitis Toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome, erythroderma.				
224.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Thiamine Mononitrate 300mg + Pyridoxine HCl 100mg + Cyanocobalamin 1 mg + Vitamin E (as d- Alpha Tocopheryl Acid Succinate) 100 IU FC Tablet	Thiamine Mononitrate (Vitamin B1) USP 300mg + Pyridoxine HCl (Vitamin B6) USP 100mg + Cyanocobalamin (Vitamin B12) USP 1 mg + Vitamin E (as d- Alpha Tocopheryl Acid Succinate) USP 112.36 mg (eq. to Vitamin E 100 IU)	**Therapeutic Class:** Vitamins and Combination **Therapeutic Code:** 078	Combination of vitamin B and Vitamin E is indicated for the treatment and prevention of deficiencies in vitamin B complex and vitamin E as manifested by nerve and muscle pain, numbness, poor reflexes, beri-beri and anemia.	CONTRAINDICATIONS: This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. SIDE EFFECTS: Allergic sensitization has been reported	New DCC-230 Thiamine Mononitrate 100mg + Pyridoxine HCl 200mg + Cyanocobalamin 200mcg Tablet	**রেফারেন্স নাই।**	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
225.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Levosulpiride 75 mg Sustained Release Tablet	Levosulpiride INN 75 mg	**Therapeutic Class:** Antipsychotic **Therapeutic Code:** 028	Endogenous and reactive depressive states, somatic disturbances, acute and chronic schizophrenia.	CONTRAINDICATIONS: Levosulpiride is contraindicated in conditions like epilepsy, hyperprolactinaemia, breast feeding, and hypersensitivity to any component of product,gastrointestinal hemorrhage and pheochromocytoma. SIDE EFFECTS: The symptomatic adverse reactions produced by Levosulpiride are more or less tolerable and if they become severe, they can be treated symptomatically, these include sedation, hypotension, gynecomastia, galactorrhea, dyskinesia, tardive dyskinesia hyperprolactinemia.	New DCC-250 (Levosulpiride 25 mg Tablet- Reject)	**রেফারেন্স নাই।**	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
226.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Ambroxol Hydrochloride 75mg + Levocetirizine Dihydrochloride 5 mg Tablet	Ambroxol Hydrochloride BP 75mg + Levocetirizine Dihydrochloride BP 5 mg	**Therapeutic Class:** Antitussives, Expectorants and Mucolytic **Therapeutic Code:** 031	It is a combination of two medicines: Levocetirizine and ambroxol which relieve cough. Levocetirizine is an antiallergic that treats runny nose, watery eyes and sneezing. Ambroxol is a mucolytic which thins and loosens mucus (phlegm), making it easier to cough out.	CONTRAINDICATIONS: Hypersensitivity SIDE EFFECTS: Upset stomach, Dryness in mouth, Headache, Fatigue, Sleepiness, Allergic reaction	New Ambroxol Hydrochloride 0.3gm/100ml Syrup, 6mg/ml PDrop, 75 SR Capsule Levocetirizine Dihydrochloride 5 mg	**রেফারেন্স নাই।**	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
227.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Paracetamol 500 mg and Diphenhydramine Hydrochloride 50 mg Film Coated Tablet	Paracetamol BP 500mg and Diphenhydramine Hydrochloride USP 50 mg	Therapeutic Class: Analgesics and Antipyretics Therapeutic Code: 006	For the short term treatment of bedtime pain, for example rheumatic and muscle pain, backache, neuralgia, toothache, migraine, headache and period pain which is causing difficulty in getting to sleep.	CONTRAINDICATIONS: Hypersensitivity to paracetamol, diphenhydramine hydrochloride or other constituents. Porphyria. Antihistamines are contraindicated in premature infants or neonates who have increased susceptibility to antimuscarinic effects. SIDE EFFECTS: Like all medicines, it can have side effects, but not everybody gets them. Older people are more prone to these side effects. When using this product you may experience: • Drowsiness, dizziness, tiredness, blurred vision, or difficulty concentrating, Dry mouth. Stop taking this medicine and tell your doctor immediately if you experience: • Allergic reactions which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath • Chest tightness or thickening of phlegm, •Difficulty in passing urine, headaches, Skin rash	New Paracetamol 500mg Tablet Diphenhydramine Hydrochloride 50 mg Tablet	**রেফারেন্স নাই।**	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						or peeling or mouth ulcers, •Upset Stomach • Breathing problems. These are more likely if you have experienced them before when taking other painkillers (such as ibuprofen and aspirin), • Seizures or difficulty of muscle coordination • Changes in heart rhythm • Unexplained bruising or bleeding				
228.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Calcium Polycarbophil 625 mg Chewable Tablet	Calcium Polycarbophil USP 625 mg	**Therapeutic Class:** Laxatives **Therapeutic Code:** 060	To treat constipation.	CONTRAINDICATIONS: Hypersensitivity SIDE EFFECTS: Allergic reaction	New DCC-237-Rejected Calcium Polycarbophil 500 mg Tablet	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
229.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Calcifediol 20 mcg Extended Release Capsule	Calcifediol USP 0.20 mg	**Therapeutic Class:** Vitamins and Combination **Therapeutic Code:** 078	Calcifediol is a vitamin D3 analog indicated for the treatment of secondary hyperparathyroidism in adults with stage 3 or 4 chronic kidney disease.	CONTRAINDICATIONS: None SIDE EFFECTS: The most common adverse reactions (≥3% and more frequent than placebo) were anemia, nasopharyngitis, increased blood creatinine, dyspnea, congestive heart failure and constipation.	New DCC-246-Approved Calcifediol 30 mcg Hard Gelatin Extended Release Capsule	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
230.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Pregabalin 75mg + Methylcobalamin 750 mcg Capsule	Pregabalin USP 75mg + Methylcobalamin USP 750 mcg	**Therapeutic Class**: Other Classification **Therapeutic Code:** 075	Neuropathic pain like, peripheral neuropathies, diabetic neuropathy, vertebral syndrome, nerve compression syndrome, fibromyalgia, post-herpetic neuralgia, post-surgical neuropathy etc.	CONTRAINDICATIONS: Methylcobalamin & Pregabalin are contraindicated in patients who have demonstrated hypersensitivity to these molecules or its ingredients. SIDE EFFECTS: Mecobalamin: Generally Mecobalamin is well tolerated. However, a few side effects like GI discomfort & rash may be seen aftger administration of Mecobalamin. Pregabalin: The most common adverse effects reported during therapy with pregabalin are	New DCC-242 (Rejected)	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						dizziness and somnolence. Other common adverse effects include blurred vision, diplopia, increased appetite and weight gain, dry mouth, constipation, vomiting, flatulence, euphoria, confusion, reduced libido, erectile dysfunction, irritability, vertigo, ataxia, tremor, dysarthria, paraesthesia, fatigue, and oedema. Disturbances of attention, memory, coordination, and gait also occur frequently.				
231.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Ascorbic acid 175 mg + Zinc 10 mg + Vitamin B12 12 mcg + Iron 75 mg + Folic Acid 1 mg + Succcinic Acid 150 mg Film Coated Tablet	Ascorbic acid USP 175 mg + Zinc Glycinate INN 32.655 mg (Equivalent to 10 mg Zinc) + Cyanocobalamin 1% (Vitamin B12) USP 1.2 mg (Equivalent 12 mcg Cyanocobalamin) + Ferrous Asparto Glycinate INN 355.927 mg (Equivalent to 75 mg Iron + Folic Acid [As Folate (N5 Methyl Tetrahydrofolic acid) equivalent to 600 mcg and Folic Acid 400 mcg] USP 1 mg + Succcinic Acid USP 150 mg	**Therapeutic Class**: Vitamins and Combination **Therapeutic Code:** 078	Combination used in Iron deficiency.	CONTRAINDICATIONS: This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. SIDE EFFECTS: Allergic sensitization has been reported	New	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
232.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Umbralisib 200 mg Film Coated Tablet	Umbralisib Tosylate INN 260.200 mg (Equivalent to Umbralisib 200 mg)	**Therapeutic Class**: Anticancer **Therapeutic Code:** 010	It is a kinase inhibitor indicated for the treatment of adult patients with: • Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen. • Relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy.	CONTRAINDICATIONS: None SIDE EFFECTS: low blood cell counts; nausea, vomiting, stomach pain, loss of appetite; cold symptoms such as stuffy nose, sneezing, sore throat; Muscle or bone pain; feeling tired; or. abnormal kidney function tests. Warnings And Precautions: • Infections: Monitor for fever and any new or worsening signs and symptoms of infection. Evaluate promptly and treat as needed • Neutropenia, Diarrhea or Non-infectious colitis, Hepatotoxicity, Severe cutaneous reactions, Allergic reactions due to inactive ingredient FD&C Yellow No. 5, Embryo-fetal toxicity	New	**USFDA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
233.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Avapritinib 300 mg Film Coated Tablet	Avapritinib INN 300 mg	**Therapeutic Class**: Anticancer **Therapeutic Code:** 010	It is a kinase inhibitor indicated for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations.	CONTRAINDICATIONS: None SIDE EFFECTS: Stomach pain. Vomiting. Nausea. Diarrhea. Heartburn. Headache, tiredness Warnings And Precautions: Intracranial Hemorrhage, Central Nervous System (CNS) Effects, Embryo-Fetal Toxicity	New	**USFDA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
234.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Incepta Pharmaceuticals	Darolutamide 300 mg Film Coated Tablet	Darolutamide INN 300 mg	**Therapeutic Class**: Anticancer **Therapeutic Code:** 010	It is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer.	CONTRAINDICATIONS: None SIDE EFFECTS: Severe ongoing nausea or diarrhea; Painful or difficult urination;Blood in your urine;Severe headache, Blurred vision, pounding in your neck or ears	New	**USFDA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Ltd.;Zirabo, Savar, Dhaka					WARNINGS AND PRECAUTIONS: Embryo-Fetal Toxicity: NUBEQA can cause fetal harm and loss of pregnancy. Advise males with female partners of reproductive potential to use effective contraception.				
235.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Faropenem 200 mg Film Coated Tablet	Faropenem Sodium Hydrate INN 247 mg (Equivalent to Faropenem 200 mg)	**Therapeutic Class**: Anti-Infective **Therapeutic Code:** 023	• Upper & lower respiratory tract infections • ENT infections • Genitourinary infections • Skin and skin structure infections • Gynaecological infections	CONTRAINDICATIONS: Contraindicated in patients with known hypersensitivity to any of the components of this product or to other drugs in the same class. SIDE EFFECTS: The most frequently reported adverse reactions are diarrhea, abdominal pain, loose bowel movements, nausea and rash.	New DCC-250 (Rejected)	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
236.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Paclitaxel 1000 mg per 100 ml lipid Based Oral Solution	Paclitaxel USP 1000 mg per 100 ml	**Therapeutic Class**: Anticancer **Therapeutic Code:** 010	Overian Carcinoma, Breast carcinoma, Advanced nonsmall-cell lung carcinoma.	CONTRAINDICATIONS: None SIDE EFFECTS: low blood cell counts; nausea, vomiting, stomach pain	New 30 mg/5 ml Injection 6 mg/ml injection Nanoparticle albumin-bound paclitaxel100 mg powder for injection/vial (10ml)	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
237.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Lurbinectedin 4 mg Lyophilized Powder for Injection	Lurbinectedin INN 4 mg	**Therapeutic Class**: Anticancer **Therapeutic Code:** 010	It is an alkylating drug indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.	CONTRAINDICATIONS: None SIDE EFFECTS: Black, tarry stools. Bloody urine.bone, joint, or	New	**USFDA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.	muscle pain. Chest pain or tightness. Difficult or labored breathing.general feeling of discomfort or illness.hoarseness. pale stools. WARNINGS AND PRECAUTIONS: Myelosuppression, Hepatotoxicity, Embryo-Fetal Toxicity				
238.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Navana Pharmaceuticals Limited	Fidaxomicin Powder for Oral Suspension (40mg/ml after reconstitution)	Fidaxomicin INN 4.0gm/100ml	Therapeutic Class: Anti-infective Therapeutic code: 023	Fidaxomicin is a macrolide antibacterial drug indicated in adults (≥ 18 years of age) for treatment of clostridium difficile associated diarrhea (CDAD). It is a macrolide antibacterial indicated in adult and pediatric patients 6 months of age and older for the treatment of C. difficile-associated diarrhea. To reduce the development of drug-resistant bacteria and maintain the effectiveness of this drug and other antibacterial drugs, it should be used only to treat infections that are proven or strongly suspected to be caused by C. difficile.	CONTRAINDICATIONS: None SIDE-EFFECT: The most common adverse reactions are nausea (11%), vomiting (7%), abdominal pain (6%), gastrointestinal hemorrhage (4%), anemia (2%), and neutropenia (2%) WARNINGS AND PRECAUTIONS: It should not be used for systemic infections, Development of Drug Resistant Bacteria: Only use DIFICID for infection proven or strongly suspected to be caused by C. difficile	New Fidaxomicin 200mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
239.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Cefixime 200mg + Clavulanic Acid 125mg Film Coated Tablet	Cefixime Trihydrate USP 223.838mg (eq. to 200mg Cefixime Anhydrous) + Diluted Potassium Clavulanate (Premix with Microcrystalline Cellulose in 1:1 ratio, Potency	Therapeutic Class: Anti-infective Therapeutic code: 023	Cefixime-Clavulanic Acid should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Cefixime-Clavulanic Acid is indicated for the treatment of - • Otitis Media • Pharyngitis and Tonsillitis • Uncomplicated gonorrhea etc. • Uncomplicated Urinary Tract Infections.	CONTRAINDICATIONS: Cefixime is contraindicated in patients with known allergy to the Cephalosporin class of antibiotics. Clavulanic Acid does not inactivate all β-Lactamases. Most chromosomally mediated β-Lactamases, e.g. the enzyme produced by pseudomonas aeruginosa, are resistant to its action. Other organism has different mechanisms of acquired resistance to β-Lactam antibiotics, against which clavulanic acid is ineffective.	New Cefixime 100mg, 200mg & 400mg Capsule Cefixime 200mg/5ml Powder For	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
			40.00% as Clavulanic Acid) BP 312.500mg (eq. to 125mg of Clavulanic Acid)		• Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis.	SIDE-EFFECT: Cefixime-Clavulanic Acid is diarrhea and stool changes. Events like nausea/vomiting, transient elevation in liver transaminase, alkaline phosphatase and jaundice can also occur. Thrombocytosis, thrombocytopenia, leucopenia, hypereosinophilia, neutropenia and agranulocytosis may also occur. Other adverse events that may occur are abdominal pain, abdominal cramps, flatulence, indigestion, headache, vaginitis, vulvaritch, rash, hives, itch, dysuria, chills, chest pain, shortness of breath, mouth ulcers, swollen tongue, sleepiness, thirst, anorexia.	Suspension Cefixime 2.5gm/100ml Paediatric Drop			
240.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Cefixime 200mg + Clavulanic Acid 125mg/5ml Powder for Suspension	Cefixime Trihydrate USP 4.476gm (eq. to 200mg Cefixime Anhydrous) + Diluted Potassium Clavulanate (Premix with Microcrystalline Cellulose in 1:1 ratio, Potency 40.00% as Clavulanic Acid) BP 6.25gm (eq. to 125mg of Clavulanic Acid)	Therapeutic Class: Anti-infective Therapeutic code: 023	Cefixime-Clavulanic Acid should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Cefixime-Clavulanic Acid is indicated for the treatment of - • Otitis Media • Pharyngitis and Tonsillitis • Uncomplicated gonorrhea etc. • Uncomplicated Urinary Tract Infections. • Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis.	CONTRAINDICATIONS: Cefixime is contraindicated in patients with known allergy to the Cephalosporin class of antibiotics. Clavulanic Acid does not inactivate all β-Lactamases. Most chromosomally mediated β-Lactamases, e.g. the enzyme produced by pseudomonas aeruginosa, are resistant to its action. Other organism has different mechanisms of acquired resistance to β-Lactam antibiotics, against which clavulanic acid is ineffective. SIDE-EFFECT: Cefixime-Clavulanic Acid is diarrhea and stool changes. Events like nausea/vomiting, transient elevation in liver transaminase, alkaline phosphatase and jaundice can also occur. Thrombocytosis, thrombocytopenia, leucopenia, hypereosinophilia, neutropenia and agranulocytosis may also occur. Other adverse events that may occur are abdominal pain, abdominal cramps, flatulence, indigestion, headache, vaginitis, vulvaritch, rash, hives, itch, dysuria, chills, chest pain, shortness of breath,	New Cefixime 100mg, 200mg & 400mg Capsule Cefixime 200mg/5ml Powder For Suspension Cefixime 2.5gm/100ml Paediatric Drop	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						mouth ulcers, swollen tongue, sleepiness, thirst, anorexia.				
241.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Ceftriaxone 1000mg + Sulbactam 500mg Powder for IV/IM Injection	Ceftriaxone Sodium & Sulbactam Sodium Powder for Injection (Sterile Material containing Ceftriaxone Sodium & Sulbactam Sodium) INN 1589.400mg (eq. to Ceftriaxone 1000mg & Sulbactam 500mg)	Therapeutic Class: Anti-infective Therapeutic code: 023	It is indicated in infections caused by Ceftriaxone sodium sensitive pathogens and may be used in the clinical settings in: Sepsis Meningitis, Abdominal Infections (e.g. Peritonitis, Infections of the Biliary tract), Infections of the Bones, Joints, Soft Tissue, Skin and of Wounds, Renal and Urinary Tract Infections, Respiratory Tract infections, particularly Pneumonia, and Ear, Nose and Throat Infections, and uncomplicated Gonorrhoea. Ceftriaxone & Sulbactam for Injection may also be used for Pre-operative Prophylaxis of Infections. A single dose given preoperatively may reduce chances of Postoperative Infection.	CONTRAINDICATIONS: Ceftriaxone & Sulbactam for Injection is contraindicated in patients with known allergy to Cephalosporin group of antibiotics. Hypersensitivity to penicillin may pre-dispose the patient to the possibility of allergic cross-reactions. SIDE-EFFECT: The following side effects, reported to occur during Ceftriaxone therapy, may be seen with the combination as well- Gastrointestinal: Diarrhoea, nausea & vomiting (less frequent), stomatitis, and glossitis. Hepatic: Elevations of SGOT/SGPT. Hematological: Eosinophilia, thrombocytopenia, leukopenia, granulocytopenia, hematoma or bleeding. Hemolytic anemia is observed less frequently.	New Ceftriaxone 1000mg/Vial Injection	**রেফারেন্স নাই।**	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
242.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Ceftriaxone 500mg + Sulbactam 250mg Powder for IV/IM Injection	Ceftriaxone Sodium & Sulbactam Sodium Powder for Injection (Sterile Material containing Ceftriaxone Sodium & Sulbactam Sodium) INN 794.700mg (eq. to Ceftriaxone 500mg	Therapeutic Class: Anti-infective Therapeutic code: 023	It is indicated in infections caused by Ceftriaxone sodium sensitive pathogens and may be used in the clinical settings in: Sepsis Meningitis, Abdominal Infections (e.g. Peritonitis, Infections of the Biliary tract), Infections of the Bones, Joints, Soft Tissue, Skin and of Wounds, Renal and Urinary Tract Infections, Respiratory Tract infections, particularly Pneumonia, and Ear, Nose and Throat Infections, and uncomplicated Gonorrhoea.	CONTRAINDICATIONS: Ceftriaxone & Sulbactam for Injection is contraindicated in patients with known allergy to Cephalosporin group of antibiotics. Hypersensitivity to penicillin may pre-dispose the patient to the possibility of allergic cross-reactions. SIDE-EFFECT: The following side effects, reported to occur during Ceftriaxone therapy, may be seen with the combination as well- Gastrointestinal: Diarrhoea, nausea & vomiting (less frequent), stomatitis, and glossitis.	New Ceftriaxone 500mg/Vial Injection	**রেফারেন্স নাই।**	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
			& Sulbactam 250mg)		Ceftriaxone & Sulbactam for Injection may also be used for Pre-operative Prophylaxis of Infections. A single dose given preoperatively may reduce chances of Postoperative Infection.	Hepatic: Elevations of SGOT/SGPT. Hematological: Eosinophilia, thrombocytopenia, leukopenia, granulocytopenia, hematoma or bleeding. Hemolytic anemia is observed less frequently.				
243.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Ceftriaxone 250mg + Sulbactam 125mg Powder for IV/IM Injection	Ceftriaxone Sodium & Sulbactam Sodium Powder for Injection (Sterile Material containing Ceftriaxone Sodium & Sulbactam Sodium) INN 397.350mg (eq. to Ceftriaxone 250mg & Sulbactam 125mg)	Therapeutic Class: Anti-infective Therapeutic code: 023	It is indicated in infections caused by Ceftriaxone sodium sensitive pathogens and may be used in the clinical settings in: Sepsis Meningitis, Abdominal Infections (e.g. Peritonitis, Infections of the Biliary tract), Infections of the Bones, Joints, Soft Tissue, Skin and of Wounds, Renal and Urinary Tract Infections, Respiratory Tract infections, particularly Pneumonia, and Ear, Nose and Throat Infections, and uncomplicated Gonorrhoea. Ceftriaxone & Sulbactam for Injection may also be used for Pre-operative Prophylaxis of Infections. A single dose given preoperatively may reduce chances of Postoperative Infection.	CONTRAINDICATIONS: Ceftriaxone & Sulbactam for Injection is contraindicated in patients with known allergy to Cephalosporin group of antibiotics. Hypersensitivity to penicillin may pre-dispose the patient to the possibility of allergic cross-reactions. SIDE-EFFECT: The following side effects, reported to occur during Ceftriaxone therapy, may be seen with the combination as well- Gastrointestinal: Diarrhoea, nausea & vomiting (less frequent), stomatitis, and glossitis. Hepatic: Elevations of SGOT/SGPT. Hematological: Eosinophilia, thrombocytopenia, leukopenia, granulocytopenia, hematoma or bleeding. Hemolytic anemia is observed less frequently.	New Ceftriaxone 250mg/Vial Injection	**রেফারেন্স নাই।**	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
244.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Olanzapine 5mg + Samidorphan 10mg Film Coated Tablet	Olanzapine INN 5mg + Samidorphan INN 13.600mg (eq. to Samidorphan 10mg)	Therapeutic Class: Antipsychotic Therapeutic code: 028	It is a combination of olanzapine, an atypical antipsychotic, and samidorphan, an opioid antagonist, indicated for the treatment of: • Schizophrenia in adults • Bipolar I disorder in adults- ➢ Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate. ➢ Maintenance monotherapy treatment.	CONTRAINDICATIONS: • Patients using opioids. • Patients undergoing acute opioid withdrawal. • If it is administered with lithium or valproate, refer to the lithium or valproate Prescribing Information for the contraindications for those products. SIDE-EFFECT: • Schizophrenia: weight increased somnolence, dry mouth, and headache. • Bipolar I Disorder, Manic or Mixed Episodes (olanzapine): asthenia, dry mouth, constipation,	New Olanzapine 5mg & 10mg Tablet	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						increased appetite, somnolence, dizziness, tremor. • Bipolar I Disorder, Manic or Mixed Episodes, adjunct to Lithium or Valproate (olanzapine): dry mouth, dyspepsia, weight gain, increased appetite, dizziness, back pain, constipation, speech disorder, increased salivation, amnesia, paresthesia. WARNINGS & PRECAUTIONS: • Increased Mortality in Elderly Patients with Dementia-related Psychosis • Cerebrovascular Adverse Reactions, Including Stroke, in Elderly Patients with Dementia-Related Psychosis • Vulnerability to Life-Threatening Opioid Overdose • Neuroleptic Malignant Syndrome.				
245.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Ceftriaxone 1000 mg and Vancomycin 500mg Powder for IV/IM Injection	Ceftriaxone Sodium & Vancomycin Hydrochloride Powder for Injection (Sterile material containing Ceftriaxone Sodium & Vancomycin Hydrochloride) INN 1552.500mg (Eq. to Ceftriaxone 1000 mg and Vancomycin 500mg)	Therapeutic Class: Anti-Infective Therapeutic Code: 023	It is a combination medicine. It is prescribed to treat various types of bacterial infections. It fights against the microorganisms to prevent their growth and further spread of the infection.	CONTRAINDICATIONS: Liver disease, kidney disease, breast feeding, pregnancy. SIDE EFFECTS: Breathlessness, Rash, Decreased blood pressure, Increased liver enzymes, Allergic reaction, Erythema (skin redness), Itching, Diarrhea.	New Ceftriaxone 1000mg/Vial Injection	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
246.	Radiant Pharmaceuticals Limited B-34 & B-46, BSCIC I/E, Tongi, Gazipur-1710, Bangladesh. Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Calcium (Coral Source) as Calcium Carbonate USP 500mg + Vitamin D_3 as Cholecalciferol USP 800IU Film Coated (Easy to Swallow Coated) Tablet	Calcium Carbonate USP 1250.00mg* (eqv. to 500mg of elemental Calcium) + Cholecalciferol Concentrate Powder USP 9.600mg* (eqv. to 800IU of Vitamin D_3) *Variable quantity, will be varied based on the available potency of API declared by the supplier/source.	Therapeutic Class: Vitamins & combinations. Therapeutic Code: 078	Calcium and Vitamin D_3 deficiency, Osteoporosis, Risk of deficiency of Calcium and Vitamin D_3.	Contraindication: Hypercalcemia, kidney stone, calcium depositions in kidneys. Hypervitaminosis D, severely impaired kidney function/kidney failure. Side Effects: Swollen face, lips, tongue or throat; difficult to swallow; hives and difficulty breathing. Warning and Precaution: • 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 + Vitamin D Tablet Tablet Calcium Carbonate USP 1250mg (eq. to 500mg calcium) and Cholecalciferol (Vit-D3) USP 200IU; Calcium 600 mg + Cholecalciferol 400 IU Tablet Calcium Carbonate USP 1500 mg eq. to Elemental Calcium 600 mg + Vitamin D3 USP 4 mg eq. to 400 IU Cholecalciferol. Calcium 600 mg + Vitamin D3 400 IU Tablet.	BNF UKMHRA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
247.	Radiant Pharmaceuticals Limited B-34 & B-46, BSCIC I/E, Tongi, Gazipur-1710, Bangladesh.	Calcium (Marine Algae Source) 500mg + Vitamin D_3 as Cholecalciferol 800IU Film Coated Tablet	Calcium Carbonate USP 1785.00mg* (eqv. to 500mg of elemental Calcium) + Cholecalciferol Concentrate Powder USP 9.600mg* (eqv. to 800IU of Vitamin D_3) *Variable quantity, will be varied based on the available potency of API declared by the supplier/source.	Therapeutic Class: Vitamins & combinations. Therapeutic Code: 078	Calcium and Vitamin D_3 deficiency, Osteoporosis, Risk of deficiency of Calcium and Vitamin D_3.	Contraindication: Hypercalcemia, kidney stone, calcium depositions in kidneys. Hypervitaminosis D, severely impaired kidney function/kidney failure. Side Effects: Swollen face, lips, tongue or throat; difficult to swallow; hives and difficulty breathing. Warning and Precaution: • 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 + Vitamin D Tablet Tablet Calcium Carbonate USP 1250mg (eq. to 500mg calcium) and Cholecalciferol (Vit-D3) USP 200IU; Calcium 600 mg + Cholecalciferol 400 IU Tablet Calcium Carbonate USP 1500 mg eq. to Elemental Calcium 600 mg + Vitamin D3 USP 4 mg eq. to 400 IU Cholecalciferol. Calcium 600 mg + Vitamin D3 400 IU Tablet.	BNF UKMHRA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
248.	Radiant Pharmaceuticals Limited B-34 & B-46, BSCIC I/E, Tongi, Gazipur-1710, Bangladesh. Ziska Pharmaceuticals Ltd. Navana Pharmaceuticals Limited The ACME Laboratories Ltd. Dhamrai, Dhaka	Sodium Alginate 250.00mg + Sodium Bicarbonate 133.500mg + Calcium Carbonate 80.00mg Chewable Tablet	Sodium Alginate BP 250.00mg + Sodium Bicarbonate BP 133.500mg + Calcium Carbonate USP 80.00mg	Therapeutic Class: Antacid Therapeutic Code: 007	Gastro-oesophageal reflux such as acid regurgitation, heartburn and acid indigestion, for example, following meals or during pregnancy or in patients with symptoms related to reflux oesophagitis.	Contraindication: Hypersensitivity to the active substances or to any of the excipients. Side Effects: Skin rash, itching, dizziness, swelling of face and lips. Warning & Precaution: If symptoms do not improve after 7 days, the clinical situation should be reviewed. This medicinal product contains 235 mg (11 mmol) of sodium per four-tablet dose, equivalent to 12.65% of the WHO recommended maximum daily intake for sodium. The maximum daily dose of this product is equivalent to 50.6% of the WHO recommended maximum daily intake for sodium. This product is considered high in sodium. This should be particularly taken into account for those on a low salt diet (e.g. in some cases of congestive heart failure and renal impairment). Each four-tablet dose contains 320 mg (3.2 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi. Due to its aspartame content this product should not be given to patients with phenylketonuria.		UKMHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
249.	Radiant Pharmaceuticals Limited B-34 & B-46, BSCIC I/E, Tongi, Gazipur-1710, Bangladesh.	Trimetazidine Dihydrochloride 80mg MR Tablet	Trimetazidine Dihydrochloride BP 80mg MR	Therapeutic class: Coronary Vasodilators and Antianginal drug Therapeutic Code: 040	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 anti-anginal pectoris.	Contraindication: Hypersensitivity to the active substance or to any of the excipients, Parkinson disease, parkinsonian symptoms, tremors, restless leg syndrome and other related movement disorders and severe renal impairment (creatinine clearance <30ml/min) Side Effect: Parkinsonian symptoms, (tremor, akinesia, hypertonia), gait instability, other movement disorder.	Trimetazidine Dihydrochloride BP 35mg MR Tablet.	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Warning & Precaution: Trimetazidine can cause or worsen parkinsonian symptoms (tremor, akinesia, hypertonia), which should be regularly investigated, especially in elderly patients. In doubtful cases, patients should be referred to a neurologist for appropriate investigations. The occurrence of movement disorders such as parkinsonian symptoms, restless leg syndrome, tremors, gait instability should lead to definitive withdrawal of trimetazidine. These cases have a low incidence and are usually reversible after treatment discontinuation. The majority of the patients recovered within 4 months after trimetazidine withdrawal. If parkinsonian symptoms persist more than 4 months after drug discontinuation, a neurologist opinion should be sought. Falls may occur, related to gait instability or hypotension, in particular in patients taking antihypertensive treatment. Caution should be exercised when prescribing trimetazidine to patients in whom an increased exposure is expected: -moderate renal impairment, - elderly patients older than 75 years old.				
250.	Radiant Pharmaceuticals Limited B-34 & B-46, BSCIC I/E, Tongi, Gazipur-1710, Bangladesh.	Calcium (Coral Source) as Calcium Carbonate 1000mg + Vitamin D_3 as Cholecalciferol 880IU Effervescent Granules/Sachet	Calcium Carbonate USP 2500.00mg* (eqv. to 1000mg of elemental Calcium) + Cholecalciferol Concentrate Powder USP 8.800mg* (eqv. to 880IU of Vitamin D_3) *Variable quantity, will be varied	Therapeutic Class: Vitamins & combinations Therapeutic Code: 078	Calcium and Vitamin D_3 deficiency, Osteoporosis, Risk of deficiency of Calcium and Vitamin D_3.	Contraindication: Hypercalcemia, kidney stone, calcium depositions in kidneys. Hypervitaminosis D, severely impaired kidney function/kidney failure. Side Effects: Swollen face, lips, tongue or throat; difficult to swallow; hives and difficulty breathing. Warning and Precaution: • Suffer from sarcoidosis • Are taking other medicines containing vitamin D or calcium	Calcium + Vitamin D Tablet Tablet Calcium Carbonate USP 1250mg (eq. to 500mg calcium) and Cholecalciferol (Vit-D3) USP	BNF	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
			based on the available potency of API declared by the supplier/source			• Have poor kidney function or high tendency of kidney stone formation Are immobilized with osteoporosis.	200IU; Calcium 600 mg + Cholecalciferol 400 IU Tablet Calcium Carbonate USP 1500 mg eq. to Elemental Calcium 600 mg + Vitamin D3 USP 4 mg eq. to 400 IU Cholecalciferol. Calcium 600 mg + Vitamin D3 400 IU Tablet.			
251.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagnj, BANGLADESH	Calcium Acetate 435 mg & Magnesium Carbonate 235 mg Film Coated Tablet	Calcium Acetate 435 mg equivalent to 110 mg Calcium & Magnesium Carbonate, heavy 235 mg equivalent to 60 mg Magnesium	Therapeutic Class: Other Classification Therapeutic Code: 075	Treatment of hyperphosphatemia.	Contraindication: Hypercalcaemia, hypermagnesaemia, Myasthenia gravis, third degree AV block. Side effects: Gastrointestinal disorders: Common: Soft stools, gastrointestinal irritation like nausea, anorexia, sensation of fullness, belching and constipation, diarrhea. Metabolism and nutrition disorders: Common: Hypercalcaemia either asymptomatic or symptomatic, asymptomatic hypermagnesaemia. Uncommon: Moderate to severe symptomatic hypercalcaemia, symptomatic hypermagnesaemia. Very rare: Hyperkalaemia, magnesium-induced	New	BNF 81 Page 1101	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						osteal mineralisation disturbances. Warning and Precaution: The use should be preceded by a dietary consultation and may depend on the kind of dialysis treatment the patient is receiving. This should only be administered with caution (only with continuous monitoring of serum calcium, magnesium and phosphate) in case of severe hyperphosphataemia with a calcium-phosphate-product of more than 5.3 mmol2/l2 if • refractory to therapy, • refractory hyperkalaemia, • clinical relevant bradycardia or AV-block II° with bradycardia. Continuous monitoring of serum phosphate, serum magnesium, serum calcium and the calcium-phosphate-product should be performed, especially in case of simultaneous intake of vitamin D preparations and thiazide diuretics.				
252.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagnj, BANGLADESH	Olanzapine BP 20 mg Tablet	Olanzapine BP 20 mg Tablet	Therapeutic Class: Antipsychotic Therapeutic Code: 028	Olanzapine is indicated for- • Schizophrenia and Combination therapy for mania • Preventing recurrence in bipolar disorder • Monotherapy for mania	Contraindication: Hypersensitivity to the active substance or to any of the excipients as well in patients with known risk for narrow-angle glaucoma. Side effects: Common or very common : Anticholinergic syndrome, appetite increased, arthralgia, asthenia, eosinophilia, fever, glycosuria, oedema, sexual dysfunction. Uncommon: Abdominal distension, alopecia. breast enlargement, diabetes mellitus, dysarthria, epistaxis, memory loss, photosensitivity reaction, urinary disorders. Rare or very rare: Hepatic disorders, hypothermia, pancreatitis, rhabdomyolysis, thrombocytopenia. Warnings and Precautions: Precaution should be taken in case of Bone-marrow depression, hyper	Existing Olanzapine 5 mg Tablet & Olanzapine 10 mg Tablet	US FDA BNF-81	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						eosinophilic disorders, low leucocyte count, low neutrophil count, myeloproliferative disease, paralytic ileus.				
253.	Nuvista Pharma Ltd.	Levothyroxine Sodium 12.5 mcg Tablet	Levothyroxine Sodium USP 12.5 mcg	Therapeutic Class: Thyroid and Antithyroid Therapeutic Code: 074	Hypothyroidism: As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. Pituitary Thyrotrophic (Thyroid-Stimulating Hormone, TSH) Suppression: As an adjunct to surgery and radioiodine therapy in the management of thyrotrophic-dependent well-differentiated thyroid cancer.	Warning: Not For Treatment Of Obesity Or For Weight Loss Contraindications: Levothyroxine is contraindicated in patients with untreated subclinical (suppressed serum TSH level with normal T3 and T4 levels) or overt thyrotoxicosis of any etiology and in patients with acute myocardial infarction. Levothyroxine is contraindicated in patients with uncorrected adrenal insufficiency since thyroid hormones may precipitate an acute adrenal crisis by increasing the metabolic clearance of glucocorticoids. Levothyroxine sodium tablets, USP is contraindicated in patients with hypersensitivity to any of the inactive ingredients in Levothyroxine sodium tablets. Side effects: Fatigue, increased appetite, weight loss, heat intolerance, fever, excessive sweating. Central nervous system: headache, hyperactivity, nervousness, anxiety, irritability, emotional liability, insomnia. Musculoskeletal: tremors, muscle weakness, muscle spasm	Exiting 25mcg, 50mcg, 75mcg and 100mcg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
254.	Nuvista Pharma Ltd.	Light Liquid Paraffin 12.6% + White Soft Paraffin 14.5% + Lanolin anhydrous 1% Cream	Light Liquid Paraffin BP 12.6% + White Soft Paraffin BP 14.5% + Lanolin anhydrous BP 1%	Therapeutic Class: Skin and Mucous Membrane Preparations Therapeutic	For the symptomatic relief of dry skin conditions, where the use of an emollient is indicated, such as flaking, chapped skin, ichthyosis, traumatic dermatitis, sunburn, the dry stage of eczema and certain dry cases of	Contraindication: People who are allergic to any ingredients of the cream or lotion. Side Effects: Skin irritation in people hypersensitive to any of the	NEW	BNF-81	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
				Code: 071	psoriasis.	ingredients.				
255.	Nuvista Pharma Ltd. Navana Pharmaceuticals Limited	Sodium sulfate 17.5gm + Potassium sulfate 3.13gm + Magnesium sulfate 1.6gm Oral Solution.	Sodium sulfate BP 17.5gm + Potassium sulfate BP 3.13gm + Magnesium sulfate BP 1.6gm	Therapeutic Class: Laxatives Therapeutic Code: 060	Indications: It is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adult and pediatric patients 12 years of age and older.	Contraindication: • Gastrointestinal obstruction or ileus • Bowel perforation • Toxic colitis or toxic megacolon • Gastric retention • Hypersensitivity to any ingredient Side Effects: Overall discomfort, abdominal fullness, Nausea, abdominal cramping, vomiting, and headache.	NEW	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
256.	Nuvista Pharma Ltd. Navana Pharmaceuticals Limited	Sodium sulfate 1.479gm + magnesium sulfate 0.225gm + Potassium chloride 0.188g Tablet	Sodium sulfate BP 1.479gm + magnesium sulfate BP 0.225gm + Potassium chloride BP 0.188g	Therapeutic Class: Laxatives Therapeutic Code: 060	It is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adult and pediatric patients 12 years of age and older.	Contraindication: • Gastrointestinal obstruction or ileus • Bowel perforation • Toxic colitis or toxic mega colon • Gastric retention • Hypersensitivity to any ingredient Side Effects: Overall discomfort, abdominal fullness, Nausea, abdominal cramping, vomiting, and headache.	NEW	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
257.	Nuvista Pharma Ltd.	Cyproterone Acetate 50mg Tablet	Cyproterone Acetate BP 50mg	Therapeutic Class: Hormone Therapeutic Code: 056	Indications: For control of libido in severe hyper sexuality and/or sexual deviation in the adult male. For the management of patients with prostatic cancer (1) to suppress “flare” with initial LHRH analogue therapy, (2) In long-term palliative treatment where LHRH analogues or surgery are contraindicated", not tolerated, or oral	Contraindication: • Pregnancy. • Lactation. • Liver diseases Dubin-Johnson syndrome, Rotor syndrome. • Previous or existing liver tumours (only if these are not due to metastases from carcinoma of the prostate). • Wasting diseases (with the exception of inoperable carcinoma of the prostate). • Severe chronic depression. • Previous or existing thromboembolic processes. • Severe diabetes with vascular	New	BNF-80	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					therapy is preferred, and (3) in the treatment of hot flushes in patients under treatment with LHRH analogues or who have had an orchiectomy.	changes. • Sickle-cell anaemia. • Hypersensitivity to any of the components of Cyproterone Acetate. Side Effects: • Hot flushes and sweats. Hot flushes are a common side effect of this treatment. ... • Sexual effects. Most men lose their sex drive and have erection problems during hormonal therapy. ... • Weight gain. ... • Mood changes. ... • Breast swelling or tenderness. ... • Tiredness. ... • Breathlessness. ... • Effects on the liver.				
258.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Sucralfate 10% w/v + Oxetacaine 0.2% w/v Oral Suspension	Sucralfate USP 10% w/v + Oxetacaine BP 0.2% w/v Oral Suspension	Therapeutic Class: Proton Pump Inhibitor Therapeutic Code: 067	For the Treatment of acidity, stomach ulcer and heartburn.	Contra Indications: Hypersensitivity Side-effects: Constipation, nausea, vomiting, dizziness, insomnia (difficulty in sleeping), allergic reaction. Warning & Precautions: 1. Avoid drinking anything immediately after taking this medicine as that can reduce its effectiveness. 2. Do not take antacid medicines half an hour before or after taking this medicine. 3. May cause constipation. Drink plenty of water and eat more high-fibre foods. Inform to doctor if it becomes severe or doesn't go away.	NEW	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**
259.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Aluminium Hydroxide 5.82% w/v + Magnesium Hydroxide 1.96% w/v + Oxetacaine 0.20% w/v Oral Suspension	Aluminium Hydroxide BP 5.82% w/v + Magnesium Hydroxide USP 1.96% w/v + Oxetacaine BP	Therapeutic Class: Antacid Therapeutic Code: 007	For the treatment of acidity, heartburn and stomach ulcers.	Contra Indications: Hypersensitivity Side-effects: Constipation, diarrhea, allergic reaction Warning & Precautions: 1. Avoid drinking anything immediately after taking this medicine as that can reduce its effectiveness.	NEW	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
			0.20% w/v Oral Suspension			2. May cause constipation. Drink plenty of water and eat more high-fibre foods. Inform to doctor if it becomes severe or doesn't go away.				
260.	The ACME Laboratories Ltd. Dhamrai, Dhaka Globe Pharmaceuticals Ltd.	Ilaprazole 10 mg Tablet	Ilaprazole INN 10 mg Tablet	Therapeutic Class: Proton Pump Inhibitor Therapeutic Code: 067	Indicated for the treatment of Dyspepsia, Peptic ulcer disease (PUD), Gastroesophageal reflux disease (GERD), Duodenal ulcer	Contra Indications: Ilaprazole should not be prescribed to individuals who are allergic to other PPIs. Side effects: Nausea, Abdominal pain, Constipation, Diarrhoea, Flatulence. Warning & Precautions: Mild to moderate GI discomfort with anorexia, fatigue, weight loss, nausea or vomiting and indigestion.	NEW	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
261.	Nuvista Pharma Ltd.	Elagolix 300mg + Estradiol 1mg + Norethindrone acetate 0.5mg Capsule and Elagolix 300mg Capsule	Elagolix Sodium INN eq. to Elagolix 300mg + Estradiol USP 1mg + Norethindrone acetate USP 0.5mg and Elagolix Sodium INN eq. to Elagolix 300mg	Therapeutic Class: Hormone Therapeutic Code: 056	Indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Limitation of Use: Use of ORIAHNN should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.	Warning: Thromboembolic Disorders And Vascular Events Contraindication: High risk of arterial, venous thrombotic, or thromboembolic disorder. • Pregnancy. • Known osteoporosis. • Current or history of breast cancer or other hormonally-sensitive malignancies. • Known liver impairment or disease. • Undiagnosed abnormal uterine bleeding. • Known hypersensitivity to ingredients • Organic anion transporting polypeptide (OATP) 1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations. Side Effects: •Suicidal Thoughts, Suicidal Behavior, and	NEW	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Worsening Of Mood. Othoughts about Suicide or Dying • Attempts to Commit Suicide • New or Worse Depression • New or Worse Anxiety • Other Unusual Changes in Behavior or Mood • Pay Attention To Any Changes, Especially Sudden Changes In Your Mood, Behaviors, Thoughts, Or Feelings. • Jaundice • Dark Amber-Colored Urine • Feeling Tired (Fatigue or Exhaustion) • Nausea and Vomiting • Generalized Swelling • Right Upper Stomach Area (Abdomen) Pain				
262.	Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj.	Olmesartan Medoxomil 40mg + Hydrochlorothiazide 25mg F/C Tablet	Olmesartan Medoxomil USP 40mg + Hydrochlorothiazide BP 25mg	Therapeutic Class: Anti-hypertensive Therapeutic Code: 022	Indicated for the treatment of hypertension	Contraindication: This combination is contraindicated in patients with known hypersensitivity to olmesartan or hydrochlorothiazide or any other components of this product. It is also contraindicated in patients with anuria and for co-administration with aliskiren in patients with diabetes. Side-effects: Most common side effects are nausea, hyperuricemia, dizziness and upper respiratory infection. Warnings and precautions: Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. Resulting oligohydramnios can be associated with fetal lung hypoplasia and skeletal deformations. Potential neonatal adverse effects include skull hypoplasia, anuria, hypotension, renal failure, and death. When pregnancy is detected, discontinue olmesartan medoxomil and hydrochlorothiazide	Amlodipine 5 mg + Olmesartan 20 mg combination tablet and Olmesartan 20 mg + Hydrochlorothiazide 12.5 mg tablet	**USFDA**	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						tablets as soon as possible.Thiazides crosses the placental barrier and appear in cord blood. Adverse reactions include fetal or neonatal jaundice and thrombocytopenia.				
263.	Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj.	Olmesartan Medoxomil 20mg + Hydrochlorothiazide 25mg F/C Tablet	Olmesartan Medoxomil USP 20mg + Hydrochlorothiazide BP 25mg	Therapeutic Class: Anti-hypertensive Therapeutic Code: 022	Indicated for the treatment of hypertension	Contraindication: This combination is contraindicated in patients with known hypersensitivity to olmesartan or hydrochlorothiazide or any other components of this product. It is also contraindicated in patients with anuria and for co-administration with aliskiren in patients with diabetes. Side-effects: Most common side effects are nausea, hyperuricemia, dizziness and upper respiratory infection. Warnings and precautions: Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. Resulting oligohydramnios can be associated with fetal lung hypoplasia and skeletal deformations. Potential neonatal adverse effects include skull hypoplasia, anuria, hypotension, renal failure, and death. When pregnancy is detected, discontinue olmesartan medoxomil and hydrochlorothiazide tablets as soon as possible.Thiazides crosses the placental barrier and appear in cord blood. Adverse reactions include fetal or neonatal jaundice and thrombocytopenia.	Amlodipine 5 mg + Olmesartan 20 mg combination tablet and Olmesartan 20 mg + Hydrochlorothiazide 12.5 mg tablet	**MHRA**	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
264.	Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl,	Zinc 25mg Capsule	Zinc Acetate Dihydrate BP 83.93mg eqv. to Zinc 25mg	Therapeutic Class: Other Classification Therapeutic Code: 075	Indicated for the treatment of Wilson's disease	Contraindication: This product is contraindicated in patients with known hypersensitivity to Zinc Acetate Dihydrate or any other components of this product.	New Molecule	**MHRA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Narayanganj.					Side-effects: The most common side effects are sideroblastic anaemia, leucopenia, gastric irritation, blood amylase, elevation of lipase and alkaline phosphatase. Warnings and precautions: Zinc acetate is not recommended for the initial therapy of symptomatic patients because of the delay required for zinc-induced increase in enterocytic metallothionein and blockade of copper uptake. Symptomatic patients should be treated initially, using chelating agents. During initial therapy, neurological deterioration may occur as stores of copper are mobilized. Once initial therapy has been completed, and the patient is clinically stable, maintenance treatment with zinc acetate can be considered, but patients may be continued on initial therapy as clinically indicated.				
265.	Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj.	Teriparatide 620 mcg/2.48ml Subcutaneous Solution	Teriparatide BP 620 mcg/2.48ml	Therapeutic Class: Drug used in Osteoporosis Therapeutic Code: 048	Teriparatide is a parathyroid hormone analog (PTH 1-34) indicated for: • Treatment of postmenopausal women with osteoporosis at high risk for fracture (1.1) • Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture (1.2) • Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture	Warning: Potential Risk Of Osteosarcoma Contraindication: Patients with hypersensitivity to teriparatide or to any of its excipients Side-effects: Teriparatide can cause serious side effects, including • Decrease in blood pressure when you change positions. Some people feel dizzy, get a fast heartbeat, or feel faint right after the first few doses. • Increased calcium in your blood. Common side effects of Teriparatide include: nausea,joint aches, pain Warnings and precautions: Patients with Paget's disease of bone, pediatric and young adult patients with open epiphyses, and	New Molecule	**USFDA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						patients with prior external beam or implant radiation involving the skeleton: Should not be treated with Teriparatide • Treatment duration: Use of Teriparatide for more than 2 years during a patient's lifetime is not recommended • Patients with bone metastases, history of skeletal malignancies, metabolic bone diseases other than osteoporosis, or hypercalcemic disorders: Should not be treated with Teriparatide • Laboratory alterations: Teriparatide may increase serum calcium, urinary calcium, and serum uric acid • Urolithiasis: Use with caution in patients with active or recent urolithiasis because of risk of exacerbation • Orthostatic hypotension: Transient orthostatic hypotension may occur with initial doses of Teriparatide.				
266.	Veritas Pharmaceuticals Ltd	Oral Rehydration Salts (ORS) Effervescent Tablet	Sodium Chloride BP 265mg, Potassium Chloride BP 150mg, Citric Acid BP 800mg, Glucose anhydrous BP 1356mg and Sodium Hydrogen Carbonate BP 459mg.	Therapeutic Class: Electrolytes Therapeutic code: 079	Used to treat and prevent dehydration (the loss of too much water) due to Diarrhea children and adults.		New	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
267.	Advanced Chemical Industries Limited, 07 Hajeeganj Road, Godnayl, Narayanganj. Navana Pharmaceuticals	Azelastine Hydrochloride 0.15% Nasal spray	Each 0.137 ml of solution contains 205.5mcg of Azelastine hydrochloride eqv. to 187.67 mcg of Azelastine.	Therapeutic Class: Ear & Nose Preparation Therapeutic Code: 050	Azelastine Nasal Spray is an H1 receptor antagonist indicated for the relief of the symptoms of seasonal and perennial allergic rhinitis in patients 12 years of age and older	Contraindication: None. Side-effects: Side effects of Azelastine Nasal Spray include: unusual taste (bitter), nose pain or discomfort, nosebleeds, headache, fatigue, sleepiness, sneezing	Existing Molecule	**USFDA**	**অনুমোদনের সুপারিশ করা হয়।**	**অনুমোদন করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Limited					Warnings and precautions: • Somnolence may occur. Avoid engaging in hazardous occupations requiring complete mental alertness such as driving or operating machinery when taking Azelastine Nasal Spray. • Avoid concurrent use of alcohol or other central nervous system (CNS) depressants with Azelastine Nasal Spray because further decreased alertness and impairment of CNS performance may occur.				
268.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur	Triheptanoin 100gm/100gm Oral Liquid	Triheptanoin INN 100gm/100gm	Neutritive Agent	TRIHEPTANOIN is indicated as a source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD).	Contraindication: None Side-effects: Most common adverse reactionsare (≥10%): abdominal pain, diarrhea, vomiting, and nausea Warnings and Precautions: • Feeding Tube Dysfunction: Regularly monitor the tube to ensure proper functioning and integrity. • Intestinal Malabsorption in Patients with Pancreatic Insufficiency: Low or absent pancreatic enzymes may reduce absorption of DOJOLVI. Avoid administration of DOJOLVI in patients with pancreatic insufficiency.		USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
269.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Bisoprolol Fumarate 2.5 mg + Cilnidipine 10 mg Tablet	Bisoprolol Fumarate USP 2.5 mg + Cilnidipine INN 10 mg	Therapeutic Class: Antihypertensive Therapeutic Code: 022	Hypertension	Contra-indications: The Combination of Bisoprolol fumarate andCilnidipine is not recommended for use if youhave a history of allergy to Cilnidipine or any other component of this medicine. Side Effects: Sleepiness, Headache, Ankle swelling, Flushing, Slow heart rate, Tiredness, Palpitations, Nausea & Edema (swelling), Constipation, Cold extremities, Constipation, Cold extremities. Warning & Precautions: This medicine is not recommended for use in	NEW	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						pregnant & breastfeeding women unless absolutely necessary. Cardiac Failure: This medicine should be used with caution in patients suffering from heart diseases due to the increased risk of cardiac failure.				
270.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur	Telotristat Ethyl 250mg Tablet	Telotristat Etiprate INN 328.00mg eq. to Telotristat Ethyl 250mg (Free Base)	Therapeutic Class: Antidiarrhoeal Agents Therapeutic Code: 016	Telotristat Ethyl indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy.	Contraindication: Hypersensitivity to the active substance or to any of the excipients of this preparation Side-effects: Most common adverse reactions (≥5%) are nausea, headache, increased GGT, depression, flatulence, decreased appetite, peripheral edema, and pyrexia. Warnings& Precautions: Constipation: Telotristat Ethyl reduces bowel movement frequency; monitor patients for constipation and/or severe persistent or worsening abdominal pain. Discontinue Telotristat Ethyl if severe constipation or abdominal pain develops.		USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
271.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur	Nifurtimox 30mg Tablet	Nifurtimox INN 30mg	Therapeutic Class: Antiprotozoal Therapeutic Code: 027	Nifurtimox is an antiprotozoal, indicated in pediatric patients (birth to less than 18 years of age and weighing at least 2.5 kg) for the treatment of Chagas disease (American Trypanosomiasis), caused by Trypanosoma cruzi. This indication is approved under accelerated approval based on the number of treated patients who became immunoglobulin G (IgG) antibody negative or who showed an at least 20% decrease in optical density on two different IgG antibody tests against antigens of T.	Contraindication: Patients with known hypersensitivity to Nifurtimox or any of the excipients. Patients who consume alcohol during treatment Side-effects: The most frequently reported adverse reactions (≥5%) are vomiting, abdominal pain, headache, decreased appetite, nausea, pyrexia, and rash Warnings: Genotoxicity of Nifurtimox has been demonstrated in humans, in vitro in several bacterial species and mammalian cell systems, and in vivo in rodents. Carcinogenicity has been observed in mice and rats treated chronically with nitrofuran agents which		USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					cruzi. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).	are structurally similar to Nifurtimox. Similar data have not been reported for Nifurtimox. Embryo-Fetal Toxicity: May cause fetal harm. Pregnancy testing is recommended for females of reproductive potential. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception. Advise males to use condoms with female partners of reproductive potential. Precautions: Patients with a Worsening Neurological and Psychiatric Conditions: Patients with a history of brain injury, seizures, psychiatric disease, and serious behavioral alterations may experience worsening of their conditions when receiving Nifurtimox. Administer Nifurtimox under close medical supervision in these patients or if neurological disturbances or psychiatric drug reactions occur. Hypersensitivity reactions including hypotension, angioedema, dyspnea, pruritus, rash or other severe skin reactions have been reported with the use of Nifurtimox, discontinuation of treatment is recommended. Decreased Appetite and Weight Loss: Check body weight every 14 days as dosage may need to be adjusted. Orphyria: Treatment with nitrofuran derivatives, such as Nifurtimox, may precipitate acute attacks of porphyria. Administer Nifurtimox Under close medical supervision in patients with porphyria.				
272.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur	Nifurtimox 120mg Tablet	Nifurtimox INN 120mg	Therapeutic Class: Antiprotozoal Therapeutic Code: 027	Nifurtimox is an antiprotozoal, indicated in pediatric patients (birth to less than 18 years of age and weighing at least 2.5 kg) for the treatment of Chagas disease (American Trypanosomiasis), caused by Trypanosoma cruzi. This indication is	Contraindication: Patients with known hypersensitivity to Nifurtimox or any of the excipients. Patients who consume alcohol during treatment Side-effects: The most frequently reported adverse reactions (≥5%) are vomiting, abdominal pain, headache,		USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					approved under accelerated approval based on the number of treated patients who became immunoglobulin G (IgG) antibody negative or who showed an at least 20% decrease in optical density on two different IgG antibody tests against antigens of T. cruzi. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s)	decreased appetite, nausea, pyrexia, and rash Warnings: Genotoxicity of Nifurtimox has been demonstrated in humans, in vitro in several bacterial species and mammalian cell systems, and in vivo in rodents. Carcinogenicity has been observed in mice and rats treated chronically with nitrofuran agents which are structurally similar to Nifurtimox. Similar data have not been reported for Nifurtimox. Embryo-Fetal Toxicity: May cause fetal harm. Pregnancy testing is recommended for females of reproductive potential. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception. Advise males to use condoms with female partners of reproductive potential. Precautions: Patients with a Worsening Neurological and Psychiatric Conditions: Patients with a history of brain injury, seizures, psychiatric disease, and serious behavioral alterations may experience worsening of their conditions when receiving Nifurtimox. Administer Nifurtimox under close medical supervision in these patients or if neurological disturbances or psychiatric drug reactions occur. Hypersensitivity reactions including hypotension, angioedema, dyspnea, pruritus, rash or other severe skin reactions have been reported with the use of Nifurtimox, discontinuation of treatment is recommended. Decreased Appetite and Weight Loss: Check body weight every 14 days as dosage may need to be adjusted. Orphyria: Treatment with nitrofuran derivatives, such as Nifurtimox, may precipitate acute attacks of porphyria. Administer Nifurtimox Under close medical supervision in patients with porphyria.				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
273.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur	Moclobemide 300mg Tablet	Moclobemide INN 300mg	Monoamine Oxidase Inhibitor	Do	Do		BNF-76	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
274.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur	Acetaminophen 500mg + Butalbital 50mg + Caffeine 40mg Tablet	Acetaminophen USP 500mg + Butalbital USP 50mg + Caffeine USP 40mg	Therapeutic Class: Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic Code: 064	Butalbital, acetaminophen and caffeine oral solution is indicated for the relief of the symptom complex of tension (or muscle contraction) headache. Evidence supporting the efficacy and safety of this combination product in the treatment of multiple recurrent headaches is unavailable. Caution in this regard is required because butalbital is habit-forming and potentially abusable.	Contraindication: Butalbital, Acetaminophen and Caffeine tablets are contraindicated under the following conditions: • Hypersensitivity or intolerance to any component of this product. • Patients with porphyria. Side-effects: The most frequently reported adverse reactions are drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, vomiting, abdominal pain, and intoxicated feeling. Warnings: Butalbital is habit-forming and potentially abusable. Consequently, the extended use of this product is not recommended. Precautions: Butalbital, acetaminophen and caffeine oral solution should be prescribed with caution in certain special-risk patients, such as the elderly or debilitated and those with severe impairment of renal or hepatic function, or acute abdominal conditions.		USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
275.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur	Acetaminophen 325mg + Butalbital 50mg + Caffeine 40mg / 15ml Oral Solution	Acetaminophen USP 325mg + Butalbital USP 50mg + Caffeine USP 40mg / 15ml	Therapeutic Class: Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic Code: 064	Butalbital, acetaminophen and caffeine oral solution is indicated for the relief of the symptom complex of tension (or muscle contraction) headache. Evidence supporting the efficacy and safety of this combination product in the treatment of multiple recurrent headaches is unavailable. Caution in this regard is required because	Contraindication: Butalbital, Acetaminophen and Caffeine tablets are contraindicated under the following conditions: • Hypersensitivity or intolerance to any component of this product. • Patients with porphyria. Side-effects: The most frequently reported adverse reactions are		রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					butalbital is habit-forming and potentially abusable.	drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, vomiting, abdominal pain, and intoxicated feeling. Warnings: Butalbital is habit-forming and potentially abusable. Consequently, the extended use of this product is not recommended. Precautions: Butalbital, acetaminophen and caffeine oral solution should be prescribed with caution in certain special-risk patients, such as the elderly or debilitated and those with severe impairment of renal or hepatic function, or acute abdominal conditions.				
276.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur	Risdiplam 0.75mg/ ml Oral solution	Risdiplam INN 0.75mg / ml	Therapeutic Code: 064	Risdiplam is indicated for the treatment of spinal muscular atrophy (SMA) in patients 2 months of age and older.	Contraindication: None Side-effects: The most common adverse reactions in later-onset SMA (incidence at least 10% of patients treated with Risdiplam and more frequent than control) were fever, diarrhea, and rash. The most common adverse reactions in infantile-onset SMA were similar to those observed in later-onset SMA patients. Additionally, adverse reactions with an incidence of at least 10% were upper respiratory tract infection, pneumonia, constipation, and vomiting. Warnings and Precautions: Potential embryo-foetal toxicity Embryo-foetal toxicity has been observed in animal studies (see section 5.3). Patients of reproductive potential should be informed of the risks and must use highly effective contraception during treatment and until at least 1 month after the last dose in female patients, and 4 months after the last dose in male patients. The pregnancy status of female patients of reproductive potential should be verified prior to initiating Risdiplam therapy (see section		USFDA আমদানির জন্য আবেদন করা হয়েছে। SI: ২৮	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						4.6). <u>Potential effects on male fertility</u> Based on observations from animal studies, male patients should not donate sperm while on treatment and for 4 months after the last dose of Risdiplam . Prior to initiating treatment, fertility preservation strategies should be discussed with male patients of reproductive potential (see sections 4.6 and 5.3). The effects of Risdiplam on male fertility have not been investigated in humans. <u>Retinal toxicity</u> The effects of Risdiplam on retinal structure observed in the non-clinical safety studies have not been observed in clinical studies with SMA patients. However, long-term data are still limited. The clinical relevance of these nonclinical findings in the long-term has therefore not been established (see section 5.3). <u>Use with SMA gene therapy</u> Efficacy data of Risdiplam treatment when used in patients that previously received *SMN1* gene therapy is not available. <u>Excipients</u> *Isomalt* Risdiplam contains isomalt (2.97 mg per mL). Patients with rare hereditary problems of fructose intolerance should not take this medicine. *Sodium* Risdiplam contains 0.375 mg of sodium benzoate				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						per mL. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old). Risdiplam contains less than 1 mmol sodium (23 mg) per 5 mg dose, i.e. is essentially 'sodium-free'.				
277.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Bisoprolol Fumarate 2.5 mg + Cilnidipine 10 mg Tablet	Bisoprolol Fumarate USP 2.5 mg + Cilnidipine INN 10 mg Tablet	Therapeutic Class: Antihypertensive Therapeutic Code: 022	Hypertension	Contra-indications: The Combination of Bisoprolol fumarate andCilnidipine is not recommended for use if youhave a history of allergy to Cilnidipine or any other component of this medicine. Side Effects: Sleepiness, Headache, Ankle swelling, Flushing, Slow heart rate, Tiredness, Palpitations, Nausea & Edema (swelling), Constipation, Cold extremities, Constipation, Cold extremities. Warning & Precautions: This medicine is not recommended for use in pregnant & breastfeeding women unless absolutely necessary. Cardiac Failure: This medicine should be used with caution in patients suffering from heart diseases due to the increased risk of cardiac failure.	NEW	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**
278.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur	Triamterene 37.50mg + Hydrochlorothiazide 25mg Tablet	Triamterene USP 37.50mg + Hydrochlorothiazide USP 25mg	Therapeutic Class: Diuretics Therapeutic Code: 042	This fixed combination drug is not indicated for the initial therapy of edema or hypertension except in individuals in whom the development of hypokalemia cannot be risked. Triamterene and hydrochlorothiazide is indicated for the treatment of hypertension or edema in patients who develop hypokalemia on hydrochlorothiazide alone. Triamterene and hydrochlorothiazide also indicated for those patients who require a	Contraindication: Hyperkalemia: Triamterene and hydrochlorothiazide should not be used in the presence of elevated serum potassium levels (greater than or equal to 5.5 mEq/liter). If hyperkalemia develops, this drug should be discontinued and a thiazide alone should be substituted. Antikaliuretic Therapy or Potassium Supplementation: Triamterene and hydrochlorothiazide should not be given to patients receiving other potassium-conserving agents such		USFDA	**প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					thiazide diuretic and in whom the development of hypokalemia cannot be risked. Hydrochlorothiazide/triamterene may be used alone or as an adjunct to other antihypertensive drugs, such as beta-blockers. This combination may enhance the action of these agents, dosage adjustments may be necessary	as spironolactone, amiloride hydrochloride or other formulations containing triamterene. Concomitant potassium supplementation in the form of medication, potassium-containing salt substitute or potassium-enriched diets should also not be used. Impaired Renal Function: Triamterene and hydrochlorothiazide is contraindicated in patients with anuria, acute and chronic renal insufficiency or significant renal impairment. Hypersensitivity: Triamterene and hydrochlorothiazide should not be used in patients who are hypersensitive to triamterene or hydrochlorothiazide or other sulfonamide-derived drugs. If hyperkalemia is suspected, (warning signs include paresthesias, muscular weakness, fatigue, flaccid paralysis of the extremities, bradycardia and shock) an electrocardiogram (ECG) should be obtained. However, it is important to monitor serum potassium levels because mild hyperkalemia may not be associated with ECG changes. If hyperkalemia is present, Triamterene and hydrochlorothiazide should be discontinued immediately and a thiazide alone should be substituted. If the serum potassium exceeds 6.5 mEq/liter, more vigorous therapy is required. The clinical situation dictates the procedures to be employed. These include the intravenous administration of calcium chloride solution, sodium bicarbonate solution and/or the oral or parenteral administration of glucose with a rapid-acting insulin preparation. Cationic exchange resins such as sodium polystyrene sulfonate may be orally or rectally administered. Persistent hyperkalemia may require dialysis. The development of hyperkalemia associated with potassium-sparing diuretics is accentuated in the				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						presence of renal impairment. Patients with mild renal functional impairment should not receive this drug without frequent and continuing monitoring of serum electrolytes. Cumulative drug effects may be observed in patients with impaired renal function. The renal clearances of hydrochlorothiazide and the pharmacologically active metabolite of triamterene, the sulfate ester of hydroxyl triamterene, have been shown to be reduced and the plasma levels increased following Triamterene and hydrochlorothiazide administration to elderly patients and patients with impaired renal function. Hyperkalemia has been reported in diabetic patients with the use of potassium-conserving agents even in the absence of apparent renal impairment. Accordingly, Triamterene and hydrochlorothiazide should be avoided in diabetic patients. If it is employed, serum electrolytes must be frequently monitored. Because of the potassium-sparing properties of angiotensin-converting enzyme (ACE) inhibitors, Triamterene and hydrochlorothiazide should be used cautiously, if at all, with these agents. Metabolic or Respiratory Acidosis: Potassium-conserving therapy should also be avoided in severely ill patients in whom respiratory or metabolic acidosis may occur. Acidosis may be associated with rapid elevations in serum potassium levels. If Triamterene and hydrochlorothiazide is employed, frequent evaluations of acid/base balance and serum electrolytes are necessary. Acute Myopia and Secondary Angle-Closure Glaucoma: Hydrochlorothiazide, a sulfonamide, can cause an idiosyncratic reaction, resulting in acute transient myopia and acute angle-closure				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						glaucoma. Symptoms include acute onset of decreased visual acuity or ocular pain and typically occur within hours to weeks of drug initiation. Untreated acute angle-closure glaucoma can lead to permanent vision loss. The primary treatment is to discontinue hydrochlorothiazide as rapidly as possible. Prompt medical or surgical treatments may need to be considered if the intraocular pressure remains uncontrolled. Risk factors for developing acute angle-closure glaucoma may include a history of sulfonamide or penicillin allergy. Side-effects: Side effects observed in association with the use of triamterene/hydrochlorothiazide, other combination products containing triamterene/hydrochlorothiazide, and products containing triamterene or hydrochlorothiazide include the following: Gastrointestinal: jaundice (intrahepatic cholestatic jaundice), pancreatitis, nausea, appetite disturbance, taste alteration, vomiting, diarrhea, constipation, anorexia, gastric irritation, cramping. Central Nervous System: drowsiness and fatigue, insomnia, headache, dizziness, dry mouth, depression, anxiety, vertigo, restlessness, paresthesias. Cardiovascular: tachycardia, shortness of breath and chest pain, orthostatic hypotension (may be aggravated by alcohol, barbiturates or narcotics). Renal: acute renal failure, acute interstitial nephritis, renal stones composed of triamterene in association with other calculus materials, urine discoloration. Hematologic: leukopenia, agranulocytosis, thrombocytopenia, aplastic anemia, hemolytic anemia and megaloblastosis. Ophthalmic: xanthopsia, transient blurred vision.				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Hypersensitivity: anaphylaxis, photosensitivity, rash, urticaria, purpura, necrotizing angiitis (vasculitis, cutaneous vasculitis), fever, respiratory distress including pneumonitis. Other: muscle cramps and weakness, decreased sexual performance and sialadenitis. Whenever adverse reactions are moderate to severe, therapy should be reduced or withdrawn. Altered Laboratory Findings: *Serum Electrolytes:* hyperkalemia, hypokalemia, hyponatremia, hypomagnesemia, hypochloremia. *Creatinine, Blood Urea Nitrogen:* Reversible elevations in BUN and serum creatinine have been observed in hypertensive patients treated with triamterene/hydrochlorothiazide. *Glucose:* hyperglycemia, glycosuria and diabetes mellitus. *Other:* Elevated liver enzymes have been reported in patients receiving triamterene/hydrochlorothiazide. Warnings & Precautions: Hyperkalemia: Abnormal elevation of serum potassium levels can occur with all potassium-conserving diuretic combinations, including Triamterene and hydrochlorothiazide. Hyperkalemia is more likely to occur in patients with renal impairment, diabetes (even without evidence of renal impairment), or elderly or severely ill patients. Since uncorrected hyperkalemia may be fatal, serum potassium levels must be monitored at frequent intervals especially in patients first receiving Triamterene and hydrochlorothiazide, when dosages are changed or with any illness that may influence renal function				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
279.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur	Triamterene 75mg + Hydrochlorothiazide 50mg Tablet	Triamterene USP 75mg + Hydrochlorothiazide USP 50mg	Therapeutic Class: Diuretics Therapeutic Code: 042	Do	Do	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
280.	Delta Pharma Ltd.	Methotrexate 15 mg Tablet	Methotrexate BP 15 mg tablet	Therapeutic Class: Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic Code: 064	Methotrexate is indicated in moderate to severe rheumatoid arthritis, malignant disease and psoriasis. Methotrexate is also indicated in the management of children with active polyarticular-course juvenile idiopathic arthritis, who had as insufficient therapeutic response to, or are intolerant of adequate trial of first line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs). Methotrexate is used as maintenance therapy for childhood acute lymphoblastic leukaemia. Other uses include choriocarcinoma, non-Hodgkin's lymphoma and number of solid tumors.	Do	Existing Methotrexate 2.5 mg tablet (DCC 162) & Methotrexate 10 tablet (DCC 210)	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
281.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Beclometasone Dipropionate 87 mcg + Formoterol Fumarate Dihydrate 5 mcg + Glycopyrronium 9 mcg (Glycopyrrolat	Each delivered dose contains 87 micrograms of beclometasone dipropionate, 5 micrograms of formoterol fumarate dihydrate and	Therapeutic Class: Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic Code: 044	**Maintenance treatment of patients with:** • Asthma & COPD (Chronic Obstructive Pulmonary Disease)	**Contraindications:** It is contraindicated in patients who have demonstrated hypersensitivity to beclometasone, glycopyrrolate, formoterol, or any of the excipients. **Side effects:** • Sore throat, • Runny or stuffy nose and sneezing, • Fungal infections of the mouth	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
		e) / Puff Metered Dose Inhaler (MDI)	9 micrograms of glycopyrronium (equivalent to 11 micrograms of glycopyrronium bromide)			**Precautions & warnings:** • Do not use this medicine to treat a sudden attack of breathlessness or wheezing. • Treatment with this medicine should not be stopped abruptly.				
282.	UniMed UniHealth Phr. Ltd. B.k Bari, Gazipur Sadar, Gazipur	Apomorphine Hydrochloride 10 mg/ml Solution (Injection)	Apomorphine Hydrochloride Solution for Injection or infusion 10mg/ml ampoule	Therapeutic Class: Antiparkinsonism Therapeutic Code: 025	Treatment of motor fluctuations ("on-off" phenomena) in patients with Parkinson's disease which are not sufficiently controlled by oral anti-Parkinson medication.	Contra-indication: In patients with respiratory depression, dementia, psychotic diseases or hepatic insufficiency. Apomorphine HCl treatment must not be administered to patients who have an 'on' response to levodopa which is marred by severe dyskinesia or dystonia. Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. APO-go should not be administered to patients who have a known hypersensitivity to apomorphine or any excipients of the medicinal product. APO-go is contraindicated for children and adolescents under 18 years of age.		USFDA আমদানির জন্যও আবেদন করা হয়েছে। SI: ১৮	**অনুমোদনের সুপারিশ করা হয়।**	**অনুমোদন করা হয়।**
283.	NIPRO JMI Pharma Ltd, Rajandrapur, Chaddagram, Cumilla	Gluscose 4 gm Chewable Tablet	Glucose Monohydrate BP equivalent to Glucose 4 gm	**Therapeutic Class:** Water for Injection, Electrolytes, Blood Volume Restorers and Caloric Agents Therapeutic Code: 079	Indications It is used to treat low blood sugar (hypoglycemia).	Contraindication: This product has no significant contraindication. Side effects: This product usually has very few side effects. However, allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing may occur. Warnings and Precautions: Before taking glucose, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain	Dextrose 100% (Powder) Dextrose 100% (Sachet) Dextrose IV Infusion (5%, 20%, 25%, 30%,	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).This product is safe to take during pregnancy when used as directed.It is unknown if this product passes into breast milk. Consult your doctor before breast-feeding.	50%)			
284.	Aristopharma Ltd. Gachha, Gazipur Sadar, Gazipur.	Tafluprost 0.0015g + Timolol 0.50 g /100 ml Eye Drops	Tafluprost INN 0.0015g + Timolol Maleate BP Eqv.to Timolol 0.50 g) / 100 ml	Therapeutic Class: Eye Preparations Therapeutic Code: 052	It is used to treat a type of glaucoma called open angle glaucoma and also a condition known as ocular hypertension in adults. Both of these conditions are linked with an increase in the pressure within your eye and eventually they may affect your eyesight.	Contra-indication : ● If you are allergic to tafluprost, timolol, beta blockers or any of the other ingredients of this medicine (listed in section 6.) ● If you have now or have had in the past respiratory problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough) ● If you have a slow heartbeat, heart failure or disorders of the heart rhythm (irregular heartbeats). Side-effects: Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are not serious. You can usually carry on using the drops, unless the effects are serious. If you are worried, talk to a doctor or pharmacist. Common side effects : The following may affect up to 1 in 10 people: Eye disorders Itching of the eye. Irritation in the eye. Eye pain. Redness of the eye. Changes in the length, thickness and number of eyelashes. Foreign body sensation in the eye. Discolouration of eyelashes. Sensitivity to light. Blurred vision Warnings and Precautions :	Tafluprost 0.0015% Eye Drops, Timolol 0.25% & 0.5% Eye Drops, Brimonidine Tartrate 0.2% +Timolol 0.5 % Eye Drops, Travoprost 0.004% + Timolol 0.5% Eye Drops, Dorzolamide 2 % + Timolol 0.5% Eye Drops	BNF-80, Page No. 1249	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Warnings and precautions Talk to your doctor, pharmacist or nurse before using Taptiqom. Before you use this medicine, tell your doctor if you have now or have had in the past: • coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure • disturbances of heart rate such as slow heart beat • breathing problems, asthma or chronic obstructive pulmonary disease • poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome) • diabetes as timolol may mask signs and symptoms of low blood sugar • overactivity of the thyroid gland as timolol may mask signs and symptoms of thyroid disease • any allergies or anaphylactic reactions • myasthenia gravis (a rare disease causing muscle weakness) • other eye diseases; for example, disease of the cornea (the transparent tissue that covers the front of the eye) or a disease requiring eye surgery.				
285.	M/s. Aristopharma Ltd. Gachha, Gazipur Sadar, Gazipur.	Carboxymethylcellulose Sodium 0.50g + Glycerin 1g + Polysorbate 0.50g) /100 ml Eye Drops	Carboxymethylcellulose Sodium USP 0.50g + Glycerin BP 1g + Polysorbate 80 BP 0.50g) /100 ml Eye Drops	Therapeutic Class: Eye Preparations Therapeutic Code: 052	For the temporary relief of burning and irritation and discomfort due to dryness of the eye or exposure to wind or sun, May be used as a protectant against further irritation.	Contraindications: It is contraindicated in patients with known hypersensitivity to any ingredient of this formulation. Side-effects: Generally well tolerated. It should not be used if allergic condition occurs to any ingredients of the products Warnings and Precautions: Warnings For external us e only Do not use • if this product changes color or becomes	Carboxymethylcellulose Sodium 1% Eye Drops, Carboxymethylcellulose Sodium 0.5% +Glycerin 0.9% Eye Drops,	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						cloudy • if once opened When using this product • do not touch unit dose tip to eye • do not touch tip of container to any surface to avoid contamination Stop use and ask a doctor if experience any of the following: • eye pain • changes in vision • continued redness or irritation of the eye • condition worsens or persists for more than 72 hours Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away. Precaution For external use only. Do not use if the product changes color or becomes cloudy or also if anyone is sensitive to any ingredient of this product. Never touch tip of container with any surface to avoid contamination & replace cap after each use.	Carboxymethylcellulose Sodium 0.25% + Hypromellose 0.30% Eye Drops			
286.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Rosuvastatin 10 mg + Clopidogrel 75 mg Tablet	Rosuvastatin Calcium USP 10.40mg eqv. to Rosuvastatin 10 mg + Clopidogrel Bisulfate USP 97.86mg eqv. to Clopidogrel 75 mg	Therapeutic Class: Anti-platelet agent Therapeutic Code: 026	Prevention of major cardiovascular and cerebrovascular events in patients who are estimated to have a high risk for Acute coronary syndrome, myocardial infarction, angina and stroke , as an adjunct to correction of other risk factors.	Contraindication: *Hypersensitivity to rosuvastatin, aspirin, clopidogrel, non-steroidal anti-inflammatory drugs (NSAIDs), salicylic acid compounds, prostaglandin synthetase inhibitors or to any of the excipients. *Patients with the syndrome of asthma with rhinitis and/or nasal polyps as aspirin may cause severe urticaria, angioedema or bronchospasm (asthma). *Active liver disease *Active, or history of recurrent peptic ulcer and/or gastric/intestinal hemorrhage or other kinds of bleeding *Hemorrhagic diathesis, coagulation disorders such as hemophilia and thrombocytopenia.	NEW	রেফারেন্স নাই।	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						*In patients with myopathy *In patients receiving concomitant cyclosporine Side Effect: Rosuvastatin: Rhabdomyolysis with myoglobinuria and acute renal failure and myopathy (including myositis), Liver enzymes abnormalities, Myalgia, Abdominal pain, Nausea Clopidogrel: Blood and lymphatic system disorders: Increased bleeding tendencies, agranulocytosis, thrombocytopenia. Warning & Precaution: In case of Skeletal Muscle Effects, Liver Enzyme Abnormalities, Thrombotic Thrombocytopenic Purpura (TTP), Acquired Hemophilia, Proteinuria.				
287.	Renata Limited Mirpur, Dhaka	Valsartan 80mg + Cilnidipine 10mg Film Coated Tablet	Valsartan USP 80mg + Cilnidipine INN 10mg	Therapeutic Class: Antihypertensive Therapeutic code: 022	Hypertension Actions Cilnidipine blocks both L-type and N-type calcium channels and inhibits blood pressure elevation due to sympathetic nerve hyperactivity as well as suppresses heart rate increase that occurs when blood pressure falls. Valsartan has stable antihypertensive effects and is widely used in treatment of hypertension.	CONTRAINDICATIONS: Contraindicated in pregnant patients WARNINGS AND PRECAUTIONS: This medication should not beused for the first-line treatment of hypertension.	Valsartan 40, 80, 160 Cilnidipine 5, 10	রেফারেন্স নাই। JP	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।**
288.	Renata Limited Mirpur, Dhaka The ACME Laboratories Ltd. Dhamrai, Dhaka	Vilazodone Hydrochloride 10mg Film Coated Tablet	Vilazodone Hydrochloride INN 10mg	Therapeutic Class: Antidepressants Therapeutic code: 014	Indication • Major Depressive Disorder Actions The mechanism of the antidepressant effect of vilazodone is thought to be related to its enhancement of serotonergic activity in the CNS through selective inhibition of serotonin reuptake. Vilazodone binds with high affinity to the serotonin reuptake site but not to the norepinephrine or	CONTRAINDICATIONS: Monoamine Oxidase Inhibitors: Do not use VILAZODONE concomitantly with an MAOI or within 14 days of stopping or starting an MAOI WARNINGS AND PRECAUTIONS: Clinical Worsening/Suicide Risk: Monitor patients for clinical worsening and suicidal thinking or behavior Serotonin Syndrome or Neuroleptic Malignant (NMS)-like Syndrome: Can occur with treatment. Discontinue and initiate supportive treatment.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					dopamine reuptake site. As a result, vilazodone potently and selectively inhibits the reuptake of serotonin.	Seizures: Can occur with treatment. Use with caution in patients with a seizure disorder. Abnormal Bleeding: Treatment can increase the risk of bleeding. Use with caution in association with nonsteroidal anti-inflammatory drugs (NSAIDs), aspirin, or other drugs that affect coagulation Activation of Mania/Hypomania: Can occur with treatment. Screen patients for bipolar disorder. Discontinuation of Treatment with VILAZODONE: A gradual reduction in dose is recommended rather than an abrupt cessation Hyponatremia: Can occur in association with the syndrome of inappropriate antidiuretic hormone secretion (SIADH)				
289.	Renata Limited Mirpur, Dhaka The ACME Laboratories Ltd. Dhamrai, Dhaka	Vilazodone Hydrochloride 20mg Film Coated Tablet	Vilazodone Hydrochloride INN 20mg	Therapeutic Class: Antidepressants Therapeutic code: 014	Indication • Major Depressive Disorder Actions The mechanism of the antidepressant effect of vilazodone is thought to be related to its enhancement of serotonergic activity in the CNS through selective inhibition of serotonin reuptake. Vilazodone binds with high affinity to the serotonin reuptake site but not to the norepinephrine or dopamine reuptake site. As a result, vilazodone potently and selectively inhibits the reuptake of serotonin.	CONTRAINDICATIONS: Monoamine Oxidase Inhibitors: Do not use VILAZODONE concomitantly with an MAOI or within 14 days of stopping or starting an MAOI WARNINGS AND PRECAUTIONS: Clinical Worsening/Suicide Risk: Monitor patients for clinical worsening and suicidal thinking or behavior Serotonin Syndrome or Neuroleptic Malignant (NMS)-like Syndrome: Can occur with treatment. Discontinue and initiate supportive treatment. Seizures: Can occur with treatment. Use with caution in patients with a seizure disorder. Abnormal Bleeding: Treatment can increase the risk of bleeding. Use with caution in association with nonsteroidal anti-inflammatory drugs (NSAIDs), aspirin, or other drugs that affect coagulation	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Activation of Mania/Hypomania: Can occur with treatment. Screen patients for bipolar disorder. Discontinuation of Treatment with VILAZODONE: A gradual reduction in dose is recommended rather than an abrupt cessation Hyponatremia: Can occur in association with the syndrome of inappropriate antidiuretic hormone secretion (SIADH)				
290.	Renata Limited Mirpur, Dhaka The ACME Laboratories Ltd. Dhamrai, Dhaka	Vilazodone Hydrochloride 40mg Film Coated Tablet	Vilazodone Hydrochloride INN 40mg	Therapeutic Class: Antidepressants Therapeutic code: 014	Indication • Major Depressive Disorder Actions The mechanism of the antidepressant effect of vilazodone is thought to be related to its enhancement of serotonergic activity in the CNS through selective inhibition of serotonin reuptake. Vilazodone binds with high affinity to the serotonin reuptake site but not to the norepinephrine or dopamine reuptake site. As a result, vilazodone potently and selectively inhibits the reuptake of serotonin.	CONTRAINDICATIONS: Monoamine Oxidase Inhibitors: Do not use VILAZODONE concomitantly with an MAOI or within 14 days of stopping or starting an MAOI WARNINGS AND PRECAUTIONS: Clinical Worsening/Suicide Risk: Monitor patients for clinical worsening and suicidal thinking or behavior Serotonin Syndrome or Neuroleptic Malignant (NMS)-like Syndrome: Can occur with treatment. Discontinue and initiate supportive treatment. Seizures: Can occur with treatment. Use with caution in patients with a seizure disorder. Abnormal Bleeding: Treatment can increase the risk of bleeding. Use with caution in association with nonsteroidal anti-inflammatory drugs (NSAIDs), aspirin, or other drugs that affect coagulation Activation of Mania/Hypomania: Can occur with treatment. Screen patients for bipolar disorder. Discontinuation of Treatment with VILAZODONE: A gradual reduction in dose is recommended rather than an abrupt cessation Hyponatremia: Can occur in association with the syndrome of	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						inappropriate antidiuretic hormone secretion (SIADH)				
291.	Renata Limited Mirpur, Dhaka Navana Pharmaceuticals Limited	Carbidopa 36.25 mg + Levodopa 145 mg Extended Release Capsule	Carbidopa USP 36.25 mg + Levodopa USP 145 mg	Therapeutic Class: Antiparkinsonism Therapeutic code: 025	Indication: Indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication Mode of Action: Levodopa Levodopa is the metabolic precursor of dopamine, does cross the blood-brain barrier, and presumably is converted to dopamine in the brain. This is thought to be the mechanism whereby levodopa relieves symptoms of Parkinson's disease. Carbidopa When levodopa is administered orally, it is rapidly decarboxylated to dopamine in extracerebral tissues so that only a small portion of a given dose is transported unchanged to the central nervous system. Carbidopa inhibits the decarboxylation of peripheral levodopa, making more levodopa available for delivery to the brain.	CONTRAINDICATIONS : Carbidopa-Levodopa ER is contraindicated in patients who are currently taking a nonselective monoamine oxidase (MAO) inhibitor (e.g., phenelzine and tranylcypromine) or have recently (within 2 weeks) taken a nonselective MAO inhibitor. Hypertension can occur if these drugs are used concurrently: WARNINGS AND PRECAUTIONS : i. Falling Asleep During Activities of Daily Living and Somnolence ii. Withdrawal-Emergent Hyperpyrexia and Confusion iii. Cardiovascular Ischemic Events iv. Hallucinations/Psychosis v. Impulse Control/Compulsive Behaviors vi. Dyskinesia vii. Peptic Ulcer Disease viii. Glaucoma ix. Melanoma Side effects: Sleepiness and dizziness	Carbidopa 10mg + Levodopa 100mg Tablet Carbidopa 25mg + Levodopa 100mg CR Tablet Carbidopa 50mg + Levodopa 200mg CR Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
292.	Renata Limited Mirpur, Dhaka Navana Pharmaceutical	Carbidopa 48.75mg + Levodopa 195 mg Extended Release Capsule	Carbidopa USP 48.75mg + Levodopa USP 195 mg Extended Release Capsule	Therapeutic Class: Antiparkinsonism Therapeutic	Indication: Indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication	CONTRAINDICATIONS : Carbidopa-Levodopa ER is contraindicated in patients who are currently taking a nonselective monoamine oxidase (MAO) inhibitor (e.g., phenelzine and tranylcypromine) or have recently	Carbidopa 10mg + Levodopa 100mg Tablet Carbidopa	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	s Limited			code: 025	or manganese intoxication Mode of Action: Levodopa Levodopa is the metabolic precursor of dopamine, does cross the blood-brain barrier, and presumably is converted to dopamine in the brain. This is thought to be the mechanism whereby levodopa relieves symptoms of Parkinson's disease. Carbidopa When levodopa is administered orally, it is rapidly decarboxylated to dopamine in extracerebral tissues so that only a small portion of a given dose is transported unchanged to the central nervous system. Carbidopa inhibits the decarboxylation of peripheral levodopa, making more levodopa available for delivery to the brain.	(within 2 weeks) taken a nonselective MAO inhibitor. Hypertension can occur if these drugs are used concurrently: WARNINGS AND PRECAUTIONS : iii. Falling Asleep During Activities of Daily Living and Somnolence iv. Withdrawal-Emergent Hyperpyrexia and Confusion x. Cardiovascular Ischemic Events xi. Hallucinations/Psychosis xii. Impulse Control/Compulsive Behaviors xiii. Dyskinesia xiv. Peptic Ulcer Disease xv. Glaucoma xvi. Melanoma Side effects: Sleepiness and dizziness	25mg + Levodopa 100mg CR Tablet Carbidopa 50mg + Levodopa 200mg CR Tablet			
293.	Renata Limited Mirpur, Dhaka Navana Pharmaceuticals Limited	Carbidopa 23.75mg + Levodopa 95mg Extended Release Capsule	Carbidopa USP 23.75mg + Levodopa USP 95mg	Therapeutic Class: Antiparkinsonism Therapeutic code: 025	Indication: Indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication Mode of Action: Levodopa Levodopa is the metabolic precursor of dopamine, does cross the blood-brain barrier, and presumably is converted to dopamine in the brain. This is thought to be the mechanism whereby levodopa relieves symptoms of Parkinson's disease.	CONTRAINDICATIONS : Carbidopa-Levodopa ER is contraindicated in patients who are currently taking a nonselective monoamine oxidase (MAO) inhibitor (e.g., phenelzine and tranylcypromine) or have recently (within 2 weeks) taken a nonselective MAO inhibitor. Hypertension can occur if these drugs are used concurrently: WARNINGS AND PRECAUTIONS : v. Falling Asleep During Activities of Daily Living and Somnolence vi. Withdrawal-Emergent Hyperpyrexia and Confusion xvii. Cardiovascular Ischemic Events xviii. Hallucinations/Psychosis xix. Impulse Control/Compulsive Behaviors	Carbidopa 10mg + Levodopa 100mg Tablet Carbidopa 25mg + Levodopa 100mg CR Tablet Carbidopa 50mg + Levodopa 200mg CR Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					Carbidopa When levodopa is administered orally, it is rapidly decarboxylated to dopamine in extracerebral tissues so that only a small portion of a given dose is transported unchanged to the central nervous system. Carbidopa inhibits the decarboxylation of peripheral levodopa, making more levodopa available for delivery to the brain.	xx. Dyskinesia xxi. Peptic Ulcer Disease xxii. Glaucoma xxiii. Melanoma Side effects: Sleepiness and dizziness				
294.	Renata Limited Mirpur, Dhaka Navana Pharmaceuticals Limited	Carbidopa 61.25mg + Levodopa 245mg Extended Release Capsule	Carbidopa USP 61.25mg + Levodopa USP 245mg	Therapeutic Class: Antiparkinsonism Therapeutic code: 025	Indication: Indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication Mode of Action: Levodopa Levodopa is the metabolic precursor of dopamine, does cross the blood-brain barrier, and presumably is converted to dopamine in the brain. This is thought to be the mechanism whereby levodopa relieves symptoms of Parkinson's disease. Carbidopa When levodopa is administered orally, it is rapidly decarboxylated to dopamine in extracerebral tissues so that only a small portion of a given dose is transported unchanged to the central nervous system. Carbidopa inhibits the decarboxylation of peripheral levodopa, making more levodopa available for delivery to the brain.	CONTRAINDICATIONS : Carbidopa-Levodopa ER is contraindicated in patients who are currently taking a nonselective monoamine oxidase (MAO) inhibitor (e.g., phenelzine and tranylcypromine) or have recently (within 2 weeks) taken a nonselective MAO inhibitor. Hypertension can occur if these drugs are used concurrently: WARNINGS AND PRECAUTIONS : vii. Falling Asleep During Activities of Daily Living and Somnolence viii. Withdrawal-Emergent Hyperpyrexia and Confusion xxiv. Cardiovascular Ischemic Events xxv. Hallucinations/Psychosis xxvi. Impulse Control/Compulsive Behaviors xxvii. Dyskinesia xxviii. Peptic Ulcer Disease xxix. Glaucoma xxx. Melanoma Side effects: Sleepiness and dizziness	Carbidopa 10mg + Levodopa 100mg Tablet Carbidopa 25mg + Levodopa 100mg CR Tablet Carbidopa 50mg + Levodopa 200mg CR Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
295.	Renata Limited Mirpur, Dhaka Navana Pharmaceuticals Limited	Paracetamol 250mg + Guaifenesin 100mg + Phenylephrine Hydrochloride 5mg Film Coated Tablet	Paracetamol BP 250mg + Guaifenesin USP 100mg + Phenylephrine Hydrochloride BP 5mg	Therapeutic Class: Analgesics and Antipyretics Therapeutic code: 006	Symptomatic relief of colds, chills and influenza including chesty coughs.	CONTRAINDICATIONS : Known hypersensitivity to any of the ingredients. Concomitant use of other sympathomimetic decongestants. Phaeochromocytoma. Closed angle glaucoma. An enlargement of the prostate gland Hepatic or severe renal impairment, hypertension, hyperthyroidism, diabetes, heart disease or those taking tricyclic antidepressants or beta-blocking drugs and those patients who are taking or have taken, within the last two weeks, monoamine oxidase inhibitors. WARNINGS AND PRECAUTIONS: Contains paracetamol. Do not take with any other paracetamol-containing products. The concomitant use with other products containing paracetamol may lead to an overdose. Paracetamol overdose may cause liver failure which may require liver transplant or lead to death. Concomitant use of decongestants and other cough and cold medicines should be avoided. Side effects: The active ingredients are usually well tolerated in normal use. PARACETAMOL Very rare cases of serious skin reactions have been reported. Adverse events from historical clinical trial data are both infrequent and from small patient exposure. Events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by MedDRA System Organ Class. Due to limited clinical trial data, the frequency of these adverse events is not known (cannot be estimated from available data), but post-marketing experience	Guaifenesin 4.00gm + Dextromethorph an hydrobromide 0.30gm + Menthol 0.30gm/100ml syrup. Dextromethorph an HBr 60mg + Guaifenesin 1200mg Extended Release Bi-Layer Tablet Diphenhydramine Hydrochloride 14mg + Guaifenesin 100mg + Levomenthol 1.10mg/5ml syrup	UK MHRA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						indicates that adverse reactions to paracetamol are rare and serious reactions are very rare.				
296.	Renata Limited Mirpur, Dhaka	Pregabalin 82.5 mg Controlled Release Tablet	Pregabalin USP 82.5 mg	Therapeutic Class: Anticonvulsants Therapeutic code: 013	● Neuropathic pain associated with diabetic peripheral neuropathy (DPN) ● Postherpetic neuralgia (PHN) ● Adjunctive therapy for the treatment of partial-onset seizures in patients 1 month of age and older ● Fibromyalgia ● Neuropathic pain associated with spinal cord injury	CONTRAINDICATIONS : Pregabalin ER is contraindicated in patients with known hypersensitivity to pregabalin or any of its components. Angioedema and hypersensitivity reactions have occurred in patients receiving pregabalin therapy WARNINGS AND PRECAUTIONS: Angioedema (e.g., swelling of the throat, head and neck) can occur, and may be associated with life-threatening respiratory compromise requiring emergency treatment. Discontinue Pregabalin ER immediately in these cases. Hypersensitivity reactions (e.g., hives, dyspnea, and wheezing) can occur. Discontinue Pregabalin ERimmediately in these patients. Antiepileptic drugs, including Pregabalin ER, increase the risk of suicidal thoughts or behavior. Respiratory depression: May occur with Pregabalin ER, when used with concomitant CNS depressants or in the setting of underlying respiratory impairment. Monitor patients and adjust dosage as appropriate. Pregabalin ER may cause dizziness and somnolence and impair patients' ability to drive or operate machinery. Increased seizure frequency or other adverse reactions may occur if Pregabalin ER is rapidly discontinued. Withdraw LYRICA gradually over a minimum of 1 week. Pregabalin ER may cause peripheral edema.	Pregabalin 100, 150, 25, 50, Capsule Pregabalin 300 Tablet 300 CR Tablet	USFDA তে Extended Release হিসেবে আছে।	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Exercise caution when co-administering LYRICA and thiazolidinedione antidiabetic agents. Side effects: Pregabalin ER may cause serious side effects including: ● Serious, even life-threatening, allergic reactions ● Swelling of your hands, legs and feet ● Suicidal thoughts or actions Dizziness and sleepiness				
297.	Renata Limited Mirpur, Dhaka	Pregabalin 165 mg Controlled Release Tablet	Pregabalin USP 165 mg	Therapeutic Class: Anticonvulsants Therapeutic code: 013	● Neuropathic pain associated with diabetic peripheral neuropathy (DPN) ● Postherpetic neuralgia (PHN) ● Adjunctive therapy for the treatment of partial-onset seizures in patients 1 month of age and older ● Fibromyalgia ● Neuropathic pain associated with spinal cord injury	CONTRAINDICATIONS : Pregabalin ER is contraindicated in patients with known hypersensitivity to pregabalin or any of its components. Angioedema and hypersensitivity reactions have occurred in patients receiving pregabalin therapy WARNINGS AND PRECAUTIONS: Angioedema (e.g., swelling of the throat, head and neck) can occur, and may be associated with life-threatening respiratory compromise requiring emergency treatment. Discontinue Pregabalin ER immediately in these cases. Hypersensitivity reactions (e.g., hives, dyspnea, and wheezing) can occur. Discontinue Pregabalin ERimmediately in these patients. Antiepileptic drugs, including Pregabalin ER, increase the risk of suicidal thoughts or behavior. Respiratory depression: May occur with Pregabalin ER, when used with concomitant CNS depressants or in the setting of underlying respiratory impairment. Monitor patients and adjust dosage as appropriate. Pregabalin ER may cause dizziness and somnolence and impair patients' ability to drive or operate machinery.	Pregabalin 100, 150, 25, 50, Capsule Pregabalin 300 Tablet 300 CR Tablet	USFDA তে Extended Release হিসেবে আছে।	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Increased seizure frequency or other adverse reactions may occur if Pregabalin ER is rapidly discontinued. Withdraw LYRICA gradually over a minimum of 1 week. Pregabalin ER may cause peripheral edema. Exercise caution when co-administering LYRICA and thiazolidinedione antidiabetic agents. Side effects: Pregabalin ER may cause serious side effects including: ● Serious, even life-threatening, allergic reactions ● Swelling of your hands, legs and feet ● Suicidal thoughts or actions Dizziness and sleepiness				
298.	Renata Limited Mirpur, Dhaka Navana Pharmaceuticals Limited	Bisoprolol Fumarate 5mg + Aspirin 100mg Capsule	Bisoprolol Fumarate USP 5mg + Aspirin BP 100mg	Therapeutic Class: Antihypertensive Therapeutic code: 022	Indication • Treatment of Ischemic heart disease • Myocardial Infarction • Acute coronary syndrome Actions Bisoprolol acts by inhibiting beta-1 receptor in heart muscle resulting in low myocardial contraction. The result is low heart rate and less blood pressure. Aspirin inhibits thromboxane production and helps to recover the endothelium of Blood vessel. Beside that it also inhibits platelet aggregation.	CONTRAINDICATIONS : • Contraindicated in patients with a known sensitivity to beta-blockers or aspirin • Contraindicated in patients with bradycardia • Contraindicated in pregnant patients WARNINGS AND PRECAUTIONS: This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: certain types of heart rhythm problems (such as a slow heartbeat, second- or third-degree atrio-ventricular block), severe heart failure. Should not be used in patients with bradycardia Side effects: Bradycardia, Nausea etc	Amlodipine 5 mg + Bisoprolol Hemifumarate 2.5mg Tablet Bisoprolol Hemifumarate 2.5mg + Hydrochlorothiazide 6.25mg Tablet Bisoprolol Hemifumarate 5mg + Hydrochlorothiazide 6.25 mg Tablet	EMA, UKMHRA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
299.	Renata Limited Mirpur, Dhaka Navana Pharmaceuticals Limited	Bisoprolol Fumarate 10mg + Aspirin 100mg Capsule	Bisoprolol Fumarate USP 10mg + Aspirin BP 100mg	Therapeutic Class: Antihypertensive Therapeutic code: 022	Indication • Treatment of Ischemic heart disease • Myocardial Infarction • Acute coronary syndrome Actions Bisoprolol acts by inhibiting beta-1 receptor in heart muscle resulting in low myocardial contraction. The result is low heart rate and less blood pressure. Aspirin inhibits thromboxane production and helps to recover the endothelium of Blood vessel. Beside that it also inhibits platelet aggregation.	CONTRAINDICATIONS : • Contraindicated in patients with a known sensitivity to beta-blockers or aspirin • Contraindicated in patients with bradycardia • Contraindicated in pregnant patients WARNINGS AND PRECAUTIONS: This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: certain types of heart rhythm problems (such as a slow heartbeat, second- or third-degree atrio-ventricular block), severe heart failure. Should not be used in patients with bradycardia Side effects: Bradycardia, Nausea etc	Amlodipine 5 mg + Bisoprolol Hemifumarate 2.5mg Tablet Bisoprolol Hemifumarate 2.5mg + Hydrochlorothiazide 6.25mg Tablet Bisoprolol Hemifumarate 5mg + Hydrochlorothiazide 6.25 mg Tablet	EMA, UKMHRA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
300.	Renata Limited Mirpur, Dhaka	Diroximel Fumarate 231mg Delayed Release Capsule	Diroximel Fumarate INN 231mg	Therapeutic Class: Other Classification Therapeutic code: 075	Diroximel fumarate is indicated for the treatment of relapsing forms of multiple sclerosis (MS) in adults; specifically active secondary progressive disease and clinically isolated syndrome, as well as relapsing-remitting MS.	CONTRAINDICATIONS : Known hypersensitivity to diroximel fumarate, dimethyl fumarate, or to any of the excipients of Diroximel Fumarate Co-administration with dimethyl fumarate WARNINGS AND PRECAUTIONS: Anaphylaxis and Angioedema: Discontinue and do not restart Diroximel Fumarate if these occur. • Progressive Multifocal Leukoencephalopathy (PML): Withhold Diroximel Fumarate at the first sign or symptom suggestive of PML. • Herpes zoster and other serious opportunistic infections: Consider withholding Diroximel Fumarate in cases of serious infection until the infection has resolved. • Lymphopenia: Obtain a CBC including lymphocyte count before initiating Diroximel Fumarate, after 6 months, and every 6 to 12 months thereafter. Consider interruption of Diroximel Fumarate if lymphocyte counts <0.5 × 109 /L persist for more than six months. • Liver	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Injury: Obtain serum aminotransferase, alkaline phosphatase, and total bilirubin levels before initiating Diroximel Fumarate and during treatment, as clinically indicated. Discontinue Diroximel Fumarate if clinically significant liver injury induced by Diroximel Fumarate is suspected. Side effects: There is no adequate data on the developmental risk associated with the use of Diroximel Fumarate or dimethyl fumarate in pregnant women. In animal studies, administration of diroximel fumarate during pregnancy or throughout pregnancy and lactation resulted in adverse effects on embryofetal and offspring development (increased incidences of skeletal abnormalities, increased mortality, decreased body weights, neurobehavioral impairment) at clinically relevant drug exposures				
301.	Renata Limited Mirpur, Dhaka	Thiamine Mononitrate 3.30mg + Pyridoxine Hydrochloride 20mg + Folic Acid P 0.80mg + Cyanocobalamin 0.50 Tablet	Thiamine Mononitrate USP 3.30mg + Pyridoxine Hydrochloride USP 20mg + Folic Acid USP 0.80mg + Cyanocobalamin USP 0.50	Therapeutic Class: Vitamins & Combinations Therapeutic code: 078	Vitamin B1, B6 B12 & B9 is indicated for the treatment of vitamin B1, B6 B9 & B12 deficiency syndrome. It is also indicated for the supportive treatment of neuritis & non-inflammatory diseases of the nerves,	CONTRAINDICATIONS : Vitamin B1, Vitamin B6 and Vitamin B12 and Folic Acid is contraindicated in patients on levodopa therapy, and in patients with hypersensitivity to any of the ingredients of the preparation. WARNINGS AND PRECAUTIONS: This product may contain inactive ingredients, which can cause allergic reactions or other problems. This product is safe to take during pregnancy when used as directed. Certain spinal cord birth defects may be prevented by maintaining adequate amounts of folic acid during pregnancy. Side effects: Generally well tolerated but allergic reactions may be observed in few cases.	Thiamine Mononitrate USP 3.30mg + Pyridoxine Hydrochloride USP 20mg + Folic Acid USP 0.80mg Tablet	UK as food suppliment. রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
302.	Renata Limited Mirpur, Dhaka	Tebipenem Pivoxil Hydrobromide 300 mg Film Coated Tablet	Tebipenem Pivoxil Hydrobromide INN 300mg	Therapeutic Class: Antibiotic Therapeutic code: 023	Complicated urinary tract infections (cUTI), Acute Pyelonephritis (AP).	CONTRAINDICATIONS : 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. 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. Side effects: The most common adverse effects associated with Tebipenem are mild diarrhea, headache.	New	JP রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
303.	Renata Limited Mirpur, Dhaka Navana Pharmaceuticals Limited	Nabumetone 1000mg Dispersible Tablet	Nabumetone USP 1000mg	Therapeutic Class: Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic code: 064	Nabumetone is indicated for relief of signs and symptoms of osteoarthritis and rheumatoid arthritis.	CONTRAINDICATIONS : Use in patients with active, or a history of recurrent peptic ulcer/ GI haemorrhage, perforation or peptic disease (two or more distinct episodes). Use in patients hypersensitive to Nabumetone or to any of the excipients. Severe heart failure, hepatic failure and renal failure. Use in patients who have shown previous hypersensitivity reactions (e.g. asthma, rhinitis, angiodema or urticaria) in response to ibuprofen, aspirin or other non-steroidal anti-inflammatory drugs. Severe, rarely fatal, anaphylactic like reactions to NSAIDs have been reported in such patients. Use in patients with a history of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy. During the last trimester of pregnancy and in nursing mothers. Patients with current cerebrovascular or	Nabumetone USP 500mg, 750mg, Tablet	US FDA, EMA, UKMHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						other haemorrhage. Side effects: Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms. The use of Nabumetone with concomitant NSAIDs, including cyclooxygenase-2 selective inhibitors should be avoided. WARNINGS AND PRECAUTIONS: More common side effects (Incidence ≥1%) are Diarrhea (14%), dyspepsia (13%), abdominal pain (12%), constipation Dizziness,, headache, fatigue, increased sweating, insomnia, nervousness, somnolence, Pruritus, rash, Tinnitus, edema. Side effects: may cause serious CV side effects, such as MI or stroke, which may result in hospitalization and even death. Although serious CV events can occur without warning symptoms, patients should be alert for the signs and symptoms of chest pain, shortness of breath, weakness, slurring of speech, and should ask for medical advice when observing any indicative signs or symptoms. Patients should be apprised of the importance of this follow-up				
304.	Renata Limited Mirpur, Dhaka	Beclometasone Dipropionate 100 + Formoterol Fumarate Dihydrate 6 + Glycopyrronium 1 mcg/Metered Inhalation	Beclometasone Dipropionate BP 100.00 + Formoterol Fumarate Dihydrate BP 6.00 + Glycopyrronium	Therapeutic Class: Drug used in Bronchial Asthma,Chronic obstructive pulmonary	Indications: • COPD • 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	Formoterol Fumarate dehydrate BP 6.0mcg + Anhydrous Beclometason e	UKMHRA. EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
			Bromide BP 12.50 (Equivalent to 1 mcg of Glycopyrronium)	disease(COPD) Therapeutic code: 044		hypokalaemia may result from beta2-agonist therapy. Side effects: The most frequently reported adverse reactions in patients with COPD or asthma 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.	Dipropionate BP 100mcg/Actuati on HFA Inhaler Formoterol Fumarate dehydrate BP 6.0mcg + Anhydrous Beclometasone Dipropionate BP 200mcg/Actuation			
305.	Renata Limited Mirpur, Dhaka	Cabergoline 1mg Tablet	Cabergoline BP 1mg Tablet	Therapeutic Class: Hormone Therapeutic code: 056	Hypeprolactinemia and parkinsonism.	CONTRAINDICATIONS : ➢ Cardiac valvulopathy - exclude before treatment (does not apply to suppression of lactation) ➢ Avoid in pre-eclampsia ➢ history of pericardial fibrotic disorders history of puerperal psychosis ➢ history of pulmonary fibrotic disorders history of retroperitoneal fibrotic disorders WARNINGS AND PRECAUTIONS: Cardiovascular disease History of peptic ulcer (particularly in acromegaly patients) History of serious mental disorders (especially psychotic disorders) Raynaud's syndrome Side effects:	Cabergoline 0.5mg Tablet	BNF-80	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
306.	Renata Limited Mirpur, Dhaka	Cabergoline 2mg Tablet	Cabergoline BP 2mg Tablet	Therapeutic Class: Hormone Therapeutic code: 056	Hypeprolactinemia and parkinsonism.	CONTRAINDICATIONS : ➢ Cardiac valvulopathy - exclude before treatment (does not apply to suppression of lactation) ➢ Avoid in pre-eclampsia ➢ history of pericardial fibrotic disorders history of puerperal psychosis ➢ history of pulmonary fibrotic disorders history of retroperitoneal fibrotic disorders WARNINGS AND PRECAUTIONS: Cardiovascular disease History of peptic ulcer (particularly in acromegaly patients) History of serious mental disorders (especially psychotic disorders) Raynaud's syndrome Side effects:	Cabergoline 0.5mg Tablet	BNF-80	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
307.	Renata Limited Mirpur, Dhaka	Fluvoxamine Maleate 100 mg Extended Release Capsule	Fluvoxamine Maleate USP 100 mg Extended-Release Capsule	Therapeutic Class: Antidepressants Therapeutic code: 014	Indication • Obsessive Compulsive Disorder (OCD) • Major Depressive Episode	CONTRAINDICATIONS : Hypersensitivity, should not be used with Thioridazine, Terfenadine, Astemizole, Cisapride, Pimozide, Aloestron, Tizanidine, Lactation. 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 may need to be given with caution to patients with hepatic or renal impairment, and to the elderly Side effects: Common Nausea, Vomiting, Loss of appetite, Upset stomach, Drowsiness, Dizziness Dry mouth, Sore Throat, Headache, Somnolence, Weakness, Insomnia, Diarrhea, Muscle pain Less common	Fluvoxamine Maleate BP 100mg Tablet Fluvoxamine Maleate 50 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Absence of or decrease in body movements, Pain, Dyspepsia, Constipation, Heavy menstrual periods, Decreased lipido, Abdominal pain etc.				
308.	Renata Limited Mirpur, Dhaka	Fluvoxamine Maleate 150 mg Extended Release Capsule	Fluvoxamine Maleate USP 150 mg Extended-Release Capsule	Therapeutic Class: Antidepressants Therapeutic code: 014	Indication • Obsessive Compulsive Disorder (OCD) • Major Depressive Episode	CONTRAINDICATIONS : Hypersensitivity, should not be used with Thioridazine, Terfenadine, Astemizole, Cisapride, Pimozide, Aloestron, Tizanidine, Lactation. 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 may need to be given with caution to patients with hepatic or renal impairment, and to the elderly Side effects: 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.	Fluvoxamine Maleate BP 100mg Tablet Fluvoxamine Maleate 50 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
309.	Renata Limited Mirpur, Dhaka The ACME Laboratories Ltd. Dhamrai, Dhaka	Memantine Hydrochloride 21mg + Donepezil Hydrochloride 10mg Extended Release Capsule	Memantine Hydrochloride USP 21mg + Donepezil Hydrochloride USP 10mg	Therapeutic Class: Therapeutic Code:	Moderate to severe dementia in alzhaimers disease	CONTRAINDICATIONS : contraindicated in patients with known hypersensitivity to memantine hydrochloride, donepezil hydrochloride, piperidine derivatives, or to any excipients used in the formulation WARNINGS AND PRECAUTIONS: • likely to exaggerate succinylcholine-type muscle relaxation during anesthesia	Memantine Hydrochloride USP14 mg + Donepezil Hydrochloride USP 10mg DCC-250 Donepezil	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						• may have vagotonic effects on the sinoatrial and • atrioventricular nodes manifesting as bradycardia or heart block • Monitor patients for symptoms of active or occult gastrointestinal bleeding, • especially those at increased risk for developing ulcers • can cause diarrhea, nausea, and vomiting • may cause bladder outflow obstruction Side effects: The most common side effects of memantine HCl include: • headache • diarrhea • dizziness The most common side effects of donepezil HCl include: • diarrhea • not wanting to eat (anorexia) • bruising	Hydrochloride 5mg, 10mg Tablet & Memantine HCl 5mg, 10 mg Tablet			
310.	Renata Limited Rajendrapur, Gazipur Navana Pharmaceuticals Limited	Baricitinib INN 4 mg Film Coated Tablet	Baricitinib INN 4 mg	Therapeutic Class: Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic Code: 064	Baricitinib is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.	CONTRAINDICATIONS : Side-effects: Upper respiratory tract infections, Nausea, herpes simplex and herpex zoster. WARNINGS AND PRECAUTIONS: Serious Infections: Avoid use of Baricitinib in patients with active, serious infection, including localized infections. If a serious infection develops, interrupt Baricitinib therapy until the infection is controlled. Do not give Baricitinib to patients with active tuberculosis. Thrombosis & Gastrointestinal perforations: Use with caution in patients who may be at increased risk. Laboratory Assessment: Recommended due to potential changes in lymphocytes, neutrophils, Side effects: Common or very common Dyslipidaemia . herpes zoster (interrupt treatment) . increased risk of infection .	Baricitinib 2mg Tablet	BNF-80 Page No-1167 EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						nausea . oropharyngeal pain . thrombocytosis ▶ Uncommon Acne . deep vein thrombosis (discontinue permanently) . neutropenia . pulmonary embolism (discontinue permanently) . weight increased ▶ Frequency not known Venous thromboembolism (discontinue permanently)				
311.	Renata Limited Mirpur, Dhaka	Riluzole 50 mg/ 10ml Suspension	Riluzole USP 50 mg/ 10ml	Therapeutic Class: Other Classification Therapeutic Code: 075	indicated for the treatment of amyotrophic lateral sclerosis	CONTRAINDICATIONS : Patients with a history of severe hypersensitivity reactions to riluzole or to any of its components WARNINGS AND PRECAUTIONS: • Hepatic injury: Use of TIGLUTIK is not recommended in patients with baseline elevations of serum aminotransferases greater than 5 times the upper limit of normal; discontinue TIGLUTIK if there is evidence of liver dysfunction Side effects: numbness of the mouth, weakness, nausea, decreased lung function,	Riluzole 50mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
312.	Renata Limited Mirpur, Dhaka Navana Pharmaceuticals Limited	Lurasidone Hydrochloride 80mg Film Coated Tablet	Lurasidone Hydrochloride INN 80mg	Therapeutic Class: Antipsychotic Therapeutic code: 028	Schizophrenia & Depressive Episodes associated with Bipolar I Disorder (bipolar depression), as monotherapy and as adjunctive therapy with lithium or valproate.	Contraindications: Known hypersensitivity to lurasidone HCl or any components in the formulation. Angioedema has been observed with lurasidone [see Adverse Reactions (6.1)]. •Strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, ritonavir, voriconazole, mibefradil, etc.) •Strong CYP3A4 inducers (e.g., rifampin, avasimibe, St. John's wort, phenytoin, carbamazepine, etc.). WARNINGS AND PRECAUTIONS:	Lurasidone HCl 20mg Tablet Lurasidone Hydrochloride 40mg Tablet Lurasidone Hydrochloride 60mg Film coated Tablet.	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis: Increased incidence of cerebrovascular adverse events (e.g., stroke, transient ischemic attack Side Effects: Drowsiness, dizziness, lightheadedness, nausea, shaking, weight gain, mask-like facial expression, inability to keep still, and agitation may occur. This medication may cause a serious drop in blood pressure, especially when starting this medication.				
313.	Renata Limited Mirpur, Dhaka Navana Pharmaceuticals Limited	Levetiracetam 1500 mg Extended Release Tablet	Levetiracetam USP 1500mg	Therapeutic Class: Drug used in Epilepsy Therapeutic Code: 046	Levetiracetam is indicated as adjunctive therapy • Partial onset seizures. • Myoclonic seizures in patients with juvenile myoclonic epilepsy. •Primary generalized Tonic-Clonic seizures.	CONTRAINDICATIONS : Hypersensitivity to the active substance or to any of the excipients. WARNINGS AND PRECAUTIONS: Behavioral abnormalities including psychotic symptoms, suicidal ideation, irritability, and aggressive behavior have been observed; monitor patients for psychiatric signs and symptoms (5.1) Suicidal Behavior and Ideation: Monitor patients for new or worsening depression, suicidal thoughts/behavior, and/or unusual changes in mood or behavior (5.2) Monitor for somnolence and fatigue and advise patients not to drive or operate machinery until they have gained sufficient experience on ELEPSIA XR (5.3) Withdrawal Seizures: ELEPSIA XR must be gradually withdrawn (5.7) Side effects: Common side effects seen flu, sleepiness, irritability,	Levetiracetam 250mg, 500mg, 750mg, 1000mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						nasal congestion, sore throat, and runny nose (nasopharyngitis), dizziness, nausea				
314.	The ACME Laboratories Ltd. Dhamrai, Dhaka Navana Pharmaceuticals Limited	Bupivacaine 29.25 mg + Meloxicam 0.88mg/ ml Injection	(Bupivacaine INN 29.25 mg + Meloxicam USP 0.88mg)/ ml	Therapeutic Class: Anaesthetics (Local) Therapeutic Code: 005	1. Indicated to use in adults to reduce pain from small to medium-sized wounds after an operation. 2. Indicated in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy, and total knee arthroplasty.	Contra Indications: Contraindicated in patients with known hypersensitivity to any amide local anesthetic, NSAIDs, or other components of ZYNRELEF; with history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs; undergoing obstetrical paracervical block anesthesia; or undergoing coronary artery bypass graft (CABG) surgery. Side effects: Constipation, vomiting, headache, dizziness, incision site swelling/redness, slow heart rate. Warning & Precautions: Dose-Related Toxicity; Hepatotoxicity; Hypertension; Heart Failure and Edema; Renal Toxicity; Anaphylactic Reactions; Methemoglobinemia; Serious Skin Reactions; Fetal Toxicity; Hematologic Toxicity	New Bupivacaine 2.5 mg/ml ,5mg/ml Injection Meloxicam 150 mg/30 ml,600mg/30 ml Injection	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
315.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Krill oil 500 mg Soft Gelatin Capsule	Krill oil USP 500mg	Therapeutic Class: Vitamins and Combinations Therapeutic Code: 078	Omega-3 deficiency	Contra Indications: People with allergies to seafood shouldn't use krill oil. It also shouldn't be taken two weeks before or after surgery. Side effects: Krill oil is possibly safe for most adults when used appropriately for a short amount of time (up to three months). The most common side effects of krill oil include stomach upset, decreased appetite, heartburn, fishy burps, bloating, diarrhea, and nausea. Warning & Precautions: Some medications that slow blood clotting include	New	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						aspirin, clopidogrel, diclofenac, ibuprofen, naproxen, dalteparin, enoxaparin, heparin, warfarin.				
316.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Krill oil 1000 mg Soft Gelatin Capsule	Krill oil USP 1000mg	Therapeutic Class: Vitamins and Combinations Therapeutic Code: 078	Omega-3 deficiency	Contra Indications: People with allergies to seafood shouldn't use krill oil. It also shouldn't be taken two weeks before or after surgery. Side effects: Krill oil is possibly safe for most adults when used appropriately for a short amount of time (up to three months). The most common side effects of krill oil include stomach upset, decreased appetite, heartburn, fishy burps, bloating, diarrhea, and nausea. Warning & Precautions: Some medications that slow blood clotting include aspirin, clopidogrel, diclofenac, ibuprofen, naproxen, dalteparin, enoxaparin, heparin, warfarin.	New	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
317.	The ACME Laboratories Ltd. Dhamrai, Dhaka DBL Pharmaceuticals Ltd., Surabari, Kashimpur, Gazipur. The IBN SINA Pharmaceutical Industries Ltd.	Voclosporin 7.9 mg Soft Gelatin Capsule	Voclosporin INN 7.9 mg	Therapeutic Class: Immune-suppressant Therapeutic Code: 058	For the treatment of adult patients with active lupus nephritis (LN).	Contra Indications: Patients who have had a known serious or severe hypersensitivity reaction to Voclosporin or any of its excipients. Side effects: Confusion, numbness and tingling, seizures, changes in alertness, headache , vision changes, muscle tremors. Warning & Precautions: Nephrotoxicity (acute and/or chronic): May occur due to Voclosporin or concomitant nephrotoxic drugs. Monitor renal function; consider dosage reduction. Hypertension: May require antihypertensive therapy; monitor relevant drug interactions. Neurotoxicity: Including risk of posterior reversible	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						encephalopathy syndrome (PRES); monitor for neurologic abnormalities; reduce dosage or discontinue lupkynis. Hyperkalemia: Risk may be increased with other agents associated with hyperkalemia; monitor serum potassium levels. QT Prolongation: Consider obtaining electrocardiograms and monitoring electrolytes in patients at high risk.				
318.	The ACME Laboratories Ltd. Dhamrai, Dhaka Navana Pharmaceuticals Limited	Ingenol Mebutate 0.015% Gel	Ingenol Mebutate INN 0.015%	Therapeutic Class: Skin & Mucous Membrane Preparations Therapeutic Code: 071	Topical treatment of Actinic keratosis on the face and scalp.	Contra Indications: Hypersensitivity to ingenol mebutate or to any of the excipients. Side effects: Local skin reactions, pain, itching, or skin irritation at the treatment area, Infection at the treatment area, nose and throat irritation and headache. Warning & Precautions: Eye disorders can occur after exposure. Local skin reactions can occur including severe reactions (e.g vesiculation/ pustulation, erosion/ ulceration). Avoid contact with the periocular area. If accidental exposure occurs, flush eyes with water and seek medical care. Administration of gel is not recommended until skin is healed from any previous drug or surgical treatment.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
319.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Ingenol Mebutate 0.05% Gel	Ingenol Mebutate INN 0.05%	Therapeutic Class: Skin & Mucous Membrane Preparations Therapeutic Code: 071	Topical treatment of Actinic keratosis on the trunk and extremities.	Contra Indications: Hypersensitivity to ingenol mebutate or to any of the excipients. Side effects: Local skin reactions, pain, itching, or skin irritation at the treatment area, Infection at the treatment area, nose and throat irritation and headache. Warning & Precautions: Eye disorders can occur after exposure. Local skin reactions can occur including severe reactions (e.g vesiculation/ pustulation, erosion/ ulceration). Avoid contact with the periocular area. If accidental exposure occurs, flush eyes with water and seek	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						medical care. Administration of gel is not recommended until skin is healed from any previous drug or surgical treatment.				
320.	The ACME Laboratories Ltd. Dhamrai, Dhaka Beximco Pharmaceuticals Ltd.	Fluticasone Furoate 200mcg + Umeclidinium 62.5mcg + Vilanterol 25mcg DPI Capsule	Fluticasone Furoate INN 200mcg + Umeclidinium Bromide INN 74.20mcg eqv. to Umeclidinium 62.5mcg + Vilanterol Trifenatate INN 40mcg eqv. to Vilanterol 25mcg	Therapeutic Class: Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic Code: 044	The maintenance treatment of asthma in patients aged 18 years and older.	Contra Indications: Primary treatment of status asthmaticus or acute episodes of COPD or asthma requiring intensive measures. Severe hypersensitivity to milk proteins or any ingredients. Side effects: Runny nose and sore throat, Painful and frequent urination, Upper respiratory tract infection (signs of a urinary tract infection), Bronchitis, Flu, Respiratory tract infection, Headache, Inflammation of the sinuses, Back pain. Warning & Precautions: LABA monotherapy increases the risk of serious asthma-related events. Do not use in combination with additional therapy containing a LABA because of risk of overdose. Candida albicans infection of the mouth and pharynx may occur. Monitor patients periodically. Advise the patient to rinse his/her mouth with water without swallowing after inhalation to help reduce the risk, Increased risk of pneumonia in patients with COPD. Monitor patients for signs and symptoms of pneumonia, Potential worsening of infections (e.g., existing tuberculosis; fungal, Bacterial, viral, or parasitic infections; 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, 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	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						immediately if symptoms occur. Assess for decrease in bone mineral density initially and periodically thereafter, Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, this should be discontinued.				
321.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Glucosamine Sulfate 15gm + Chondroitin Sulfate 5gm/100gm Topical Cream	(Glucosamine Sulfate Potassium Chloride USP 19.90gm eqv. to Glucosamine Sulfate 15gm + Chondroitin Sulfate Sodium USP 5.50gm eqv. to Chondroitin Sulfate 5gm)/100gm	Therapeutic Class: Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic Code: 064	Osteoarthritis	Contra Indications: Known hyper sensitivity to any active ingredient of the formulation Side effects: No severe side effects has been found. Warning & Precautions: Precautions should be taken in case of known hypersensitivity to any of the ingredients of this cream.	New Condroitin Sulphate Sodium 3% + Glucosamine Sulphate 2% Cream DCC 241	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
322.	The ACME Laboratories Ltd. Dhamrai, Dhaka Navana Pharmaceuticals Limited	Oxandrolone 2.5 mg Tablet	Oxandrolone USP 2.5 mg	Therapeutic Class: Drug used in Osteoporosis Therapeutic Code: 048	Bone pain associated with osteoporosis, as adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma and in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight,for quick recovery from severe burn, short stature, Alcoholic hepatitis.	Contraindications: Males with known or suspected prostate cancer, women with hypercalcemia associated with metastatic breast cancer, known or suspected pregnancy, Nephrosis, Hypercalcemia. Side effects: Nausea, vomiting, headache, skin color changes, increased or decreased sexual interest, oily skin, hair loss, and acne may occur. Warning & Precautions: Peliosis hepatis, a condition in which the liver contains blood-filled cysts, reported with androgen therapy. Discontinuance of androgen therapy usually results in resolution of liver lesions. Hepatic Adenoma and Carcinoma Liver cell tumors reported with androgen therapy. Discontinuance of androgen therapy often but not always results in regression or cessation of progression of the tumor.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
323.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Estradiol Valerate 1 mg + Medroxyprogesterone Acetate 2.5 mg Tablet	Estradiol Valerate USP 1 mg + Medroxyprogesterone Acetate USP 2.5 mg	Therapeutic Class: Hormone Therapeutic Code: 056	Hormone Replacement therapy (HRT)	Contraindications: Breast cancer, cancer which is sensitive to estrogen, deep vain thrombosis, blood clot in vain, unexplained vaginal bleeding, heart attack, stroke, angina, liver diease. Side effects: Bloating or swelling of face, hands, lower legs and/or feet, cough, difficulty swallowing dizziness, fast heartbeat, hives, itching, loss of appetite and nausea, puffiness or swelling of the eyelids or around the eyes, face, lips or tongue, rapid weight gain, shortness of breath, tightness in chest. Warning & Precaution: one should see doctor more often for check-ups in case of: • fibroids inside womb • growth of womb lining outside womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia) • increased risk of developing blood clots • increased risk of getting a oestrogen-sensitive cancer such as having a 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 • a disease affecting the eardrum and hearing (otosclerosis) .	New	BNF-81 (Page: 804)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
324.	The ACME Laboratories Ltd. Dhamrai, Dhaka Navana Pharmaceuticals Limited Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Sumatriptan 85 mg + Naproxen Sodium 500 mg Tablet	Sumatriptan Succinate USP 119mg eqv. to Sumatriptan 85 mg + Naproxen Sodium BP 500mg	Therapeutic Class: Drug used in migraine Therapeutic Code: 047	Indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older.	Contra Indications: History of coronary artery disease or coronary vasospasm, History of stroke, transient ischemic attack, Uncontrolled hypertension & Third trimester of pregnancy. Side effects: Dizziness, Pain, Discomfort, or stiffness in neck, Dry mouth & Heartbeat problem Warning & Precautions: Cardiovascular Thrombotic Events, Arrhythmias, Cerebrovascular Events etc.	NEW	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
325.	The ACME Laboratories Ltd. Dhamrai, Dhaka Navana Pharmaceuticals Limited	Lorcaserin 10mg Tablet	Lorcaserin HCl Hemihydrate INN 10.40mg eqv. to Lorcaserin 10mg	Therapeutic Class: Other Classification Therapeutic Code: 075	Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults.	Contra Indications: Pregnancy Side effects: Most common adverse reactions (greater than 5%) in non-diabetic patients are headache, dizziness, fatigue, nausea, dry mouth, constipation and in diabetic patients are hypoglycemia, headache, back pain, cough, and fatigue. Warning & Precautions: Use of Antidiabetic Medications: weight loss may cause hypoglycemia.: May cause disturbances in attention or memory. Caution with use of hazardous machinery while on treatment.	NEW	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
326.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Aspirin 81 mg + Pravastatin Sodium 20 mg Tablet	Buffered Aspirin BP 81 Tablet + Pravastatin Sodium USP 20mg	Therapeutic Class: Lipid Lowering Therapeutic Code: 061	Both indicated to reduce the occurrence of cardiovascular events, including death, myocardial infarction or stroke in patients who have clinical evidence of cardiovascular and/or cerebrovascular disease.	Contraindication: Hypersensitivity to any component of this medication. Active liver disease or unexplained, persistent elevations in liver function tests. Side Effect: Muscle damage, Liver damage, Bleeding, Stomach problems, nausea or vomiting. Warning & Precautions: Aspirin: Alcohol Warning, Patients who consume	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						three or more alcoholic drinks every day should be counseled about the bleeding risks involved with chronic, heavy alcohol use while taking aspirin. In case of Coagulation Abnormalities, GI Side Effects, Peptic Ulcer Disease should be cautiously. Pravastatin: Active liver disease or unexplained, persistent elevations in liver function tests.				
327.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Aspirin 81 mg + Pravastatin Sodium 40 mg Tablet	Buffered Aspirin BP 81 mg Tablet + Pravastatin Sodium USP 40mg	Therapeutic Class: Lipid Lowering Therapeutic Code: 061	Both indicated to reduce the occurrence of cardiovascular events, including death, myocardial infarction or stroke in patients who have clinical evidence of cardiovascular and/or cerebrovascular disease.	Contraindication: Hypersensitivity to any component of this medication. Active liver disease or unexplained, persistent elevations in liver function tests. Side Effect: Muscle damage, Liver damage, Bleeding, Stomach problems, nausea or vomiting. Warning & Precautions: Aspirin: Alcohol Warning, Patients who consume three or more alcoholic drinks every day should be counseled about the bleeding risks involved with chronic, heavy alcohol use while taking aspirin. In case of Coagulation Abnormalities, GI Side Effects, Peptic Ulcer Disease should be cautiously. Pravastatin: Active liver disease or unexplained, persistent elevations in liver function tests.	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
328.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Aspirin 81 mg + Pravastatin Sodium 80 mg Tablet	Buffered Aspirin BP 81 mg + Pravastatin Sodium USP 80mg	Therapeutic Class: Lipid Lowering Therapeutic Code: 061	Both indicated to reduce the occurrence of cardiovascular events, including death, myocardial infarction or stroke in patients who have clinical evidence of cardiovascular and/or cerebrovascular disease.	Contraindication: Hypersensitivity to any component of this medication. Active liver disease or unexplained, persistent elevations in liver function tests. Side Effect: Muscle damage, Liver damage, Bleeding, Stomach problems, nausea or vomiting. Warning & Precautions: Aspirin: Alcohol Warning, Patients who consume three or more alcoholic drinks every day should be counseled about the bleeding risks involved with	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						chronic, heavy alcohol use while taking aspirin. In case of Coagulation Abnormalities, GI Side Effects, Peptic Ulcer Disease should be cautiously. Pravastatin: Active liver disease or unexplained, persistent elevations in liver function tests.				
329.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Aspirin 81 mg + Omeprazole 40 mg Delayed Release Tablet	Aspirin BP 81 mg + Omeprazole BP 40 mg	Therapeutic Class: Anti-platelet agent Therapeutic Code: 026	It is a combination of aspirin, an anti-platelet agent, and omeprazole, a proton pump inhibitor (PPI), indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers.	Contra Indications: *History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. * In pediatric patients with suspected viral infections, with or without fever, because of the risk of Reye's Syndrome. *Known hypersensitivity to Aspirin, Omeprazole, substituted Benzimidazoles. *Patients receiving Rilpivirine containing products. Side Effects: Most common adverse reactions in adults (≥ 2%) are: gastritis, nausea, diarrhea, gastric polyps, and non-cardiac chest pain. Warning & Precautions: *Coagulation Abnormalities: Risk of increased bleeding time with aspirin, especially in patients with inherited (hemophilia) or acquired (liver disease or vitamin K deficiency) *bleeding disorders. Monitor patients for signs of increased bleeding. *GI Adverse Reactions (including ulceration and bleeding): Monitor for signs and symptoms and discontinue treatment if bleeding occurs. *Bleeding Risk with Use of Alcohol: Avoid heavy alcohol use (three or more drinks every day). *Reduction in Antiplatelet Activity with Clopidogrel due to Interference with CYP2C19.	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
330.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Aspirin 325 mg + Omeprazole 40 mg Delayed Release Tablet	Aspirin BP 325 mg + Omeprazole BP 40 mg	Therapeutic Class: Anti-platelet agent Therapeutic	It is a combination of aspirin, an anti-platelet agent, and omeprazole, a proton pump inhibitor (PPI), indicated for patients who require aspirin for secondary prevention of cardiovascular	Contra Indications: *History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. * In pediatric patients with suspected viral infections, with or without fever, because of the risk of Reye's	New	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
				Code: 026	and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers.	Syndrome. *Known hypersensitivity to Aspirin, Omeprazole, substituted Benzimidazoles. *Patients receiving Rilpivirine containing products. Side Effects: Most common adverse reactions in adults (≥ 2%) are: gastritis, nausea, diarrhea, gastric polyps, and non-cardiac chest pain. Warning & Precautions: *Coagulation Abnormalities: Risk of increased bleeding time with aspirin, especially in patients with inherited (hemophilia) or acquired (liver disease or vitamin K deficiency) *bleeding disorders. Monitor patients for signs of increased bleeding. *GI Adverse Reactions (including ulceration and bleeding): Monitor for signs and symptoms and discontinue treatment if bleeding occurs. *Bleeding Risk with Use of Alcohol: Avoid heavy alcohol use (three or more drinks every day). *Reduction in Antiplatelet Activity with Clopidogrel due to Interference with CYP2C19.				
331.	The ACME Laboratories Ltd. Dhamrai, Dhaka Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Inclisiran Sodium 284 mg Pre-filled syringe Subcutaneous Injection	Inclisiran Sodium INN 284 mg	Therapeutic Class: Lipid Lowering Therapeutic Code: 061	Indicated in adults with primary Hypercholesterolaemia (heterozygous familial and non-familial) or mixed Dyslipidaemia, as an adjunct to diet: - in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or - alone or in combination with other lipid lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.	Contra Indications: Hypersensitivity to the active substance or to any of the excipients Side effects: Injection site reactions, such as pain, redness or rash. Warning & Precautions: The effect of haemodialysis on inclisiran pharmacokinetics has not been studied. Considering that inclisiran is eliminated renally, haemodialysis should not be performed for at least 72 hours after inclisiran dosing.	New	EMA আমদানির লক্ষেও আবেদন করা হয়েছে। SI: 04	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
332.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Cetrorelix 0.25 mg/ 1 ml Sub-cutaneous Injection	Cetrorelix 0.25 mg/ 1 ml	Therapeutic Class: Fertility Agents Therapeutic Code: 053	Indicated to prevent luteinizing hormone surges in women undergoing assisted reproduction therapy.	Contra Indications: Known hyper sensitivity to any active ingredient of the formulation Side effects: Nausea, vomiting, diarrhea, muscle cramp, indigestion. Warning & Precautions: Ovarian hyperstimulation syndrome may occur. In case of any sign & symptoms leading to severe abdominal pain & nausea, treatment should be discontinued & patient should consult a physician immediately.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
333.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Bisoprolol Fumarate 5 mg + Levamlodipine 2.5mg Tablet	Bisoprolol Fumarate USP 5 mg + Levamlodipine Maleate INN 3.20mg eqv. to Levamlodipine 2.5mg	Therapeutic Class: Antihypertensive Therapeutic Code:022	Hypertension	Contra Indications: This medication is not recommended in the patients suffering from cardiogenic shock,not recommended in the patients having a heart block greater than first degree. Side effects: Drowsiness,Insomnia,Edema (Swelling),Depression,Constipation Warning & Precautions: Caution must be taken while using this medicine in patient with kidney disease. Adjustment of dose might be needed. Consultation with doctor is needed before taking this medicine.	NEW Amlodipine 5 mg + Bisoprolol Hemifumarate 2.5 mg Tablet	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
334.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Telmisartan 40 mg + Levamlodipine 5mg Tablet	Telmisartan USP 40 mg + Levamlodipine Maleate INN 6.40mg eqv. to Levamlodipine 5mg	Therapeutic Class: Antihypertensive Therapeutic Code:022	For the treatment of high blood pressure.	Contra Indications: Known hypersensitivity (e.g., anaphylaxis or angioedema) to Telmisartan, amlodipine or any other component of this product. Side effects: Common cold, backache, diarrhoea, dizziness, drowsiness, confusion, rashes, and weakness. Warning & Precautions: If patients are allergic to Telmisartan 40mg + S-Amlodipine 2.5 mg Tablet or have any kidney or liver problems or severe dehydration, then patients	NEW Amlodipine 5 mg + Telmisartan 80 mg Tablet	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						have to inform beforehand. Pregnant or breastfeeding women should also consult their doctor before taking it. Avoid consumption of alcohol with Telmisartan 40mg + S- Amlodipine 2.5 mg Tablet as it may increase the risk of low blood pressure.				
335.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Evogliptin 5 mg Tablet	Evogliptin INN 5 mg	Therapeutic Class: Antidiabetic Therapeutic Code:015	Type 2 Diabetes mellitus &calcific aortic valve disease (CAVD)	Contra Indications: Hypersensitivity to evogliptin, and/or other DPP-4 inhibitors, and/or any excipient of the drug. Type 1 diabetes mellitus. Diabetic ketoacidosis. Side effects: Hypersensitivity to evogliptin, and/or other DPP-4 inhibitors, and/or any excipient of the drug. Type 1 diabetes mellitus. Diabetic ketoacidosis. Warning & Precautions: Heart failure, Renal impairment,Hepatic impairment, Acute pancreatitis	NEW	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
336.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Efonidipine Hydrochloride Ethanolate 10 mg Tablet	Efonidipine Hydrochloride Ethanolate INN 10mg	Therapeutic Class: 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	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
337.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Efonidipine Hydrochloride Ethanolate 20 mg Tablet	Efonidipine Hydrochloride Ethanolate INN 20 mg	Therapeutic Class: 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	NEW	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						with hepatic impairment.				
338.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Telmisartan 40 mg + Cilnidipine 5 mg Tablet	Telmisartan USP 40 mg + Cilnidipine INN 5 mg	Therapeutic Class: Antihypertensive Therapeutic Code:022	Hypertension	Contra Indications: • Hypersensitivity to the active substance, other calcium channel antagonist or to any of the excipients listed • Advanced Aortic stenosis • Second and third trimesters of pregnancy • Biliary obstructive disorders • Severe hepatic impairment Side effects: Dizziness, head ache, ankle swelling, swelling of face, eyelids, increased potassium level in blood, palpitations, stomach ache. Warning & Precautions: Pregnancy, Hepatic impairment, Renovascular hypertension, Renal impairment and kidney transplantation, Intravascular hypovolaemia, Dual blockade of the renin-angiotensin aldosterone system (RAAS), Other conditions with stimulation of the renin-angiotensin-aldosterone system, Primary aldosteronism, Aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy, Diabetic patients treated with insulin or antidiabetics, Hyperkalaemia, Ethnic differences.	NEW	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
339.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Nebivolol 5 mg + Telmisartan 40 mg Tablet	Nebivolol Hydrochloride INN 5.46mg eqv. to Nebivolol 5 mg + Telmisartan USP 40 mg	Therapeutic Class: Antihypertensive Therapeutic Code:022	Hypertension, Heart failure	Contra Indications: Hypersensitivity to telmisartan or to any of the excipients of Telmisartan, Biliary obstructive disorders and severe hepatic impairment, The concomitant use with aliskiren is contraindicated in patients with diabetes mellitus or renal impairment (GFR <60 mL/min/1.73 m2)	NEW	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Side effects: Headache, Dizziness, Weakness, Cold extremities, Numbness of extremity, Increased potassium level in blood, Slow heart rate, Decreased blood pressure. Warning & Precautions: If allergic to any of these ingredients or if find any other complication, consult with physician during pregnancy & lactation.				
340.	**Beximco Pharmaceuticals Ltd.** **Pharmasia Ltd.** Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Sodium Bicarbonate 2.32 gm + Citric Acid Anhydrous 2.18 gm + Sodium Carbonate 0.50 gm powder for sachet	Sodium Bicarbonate BP 2.32 gm + Citric Acid Anhydrous BP 2.18 gm + Sodium Carbonate BP 0.50 gm / 5 gm powder	Therapeutic Class: Antacid Therapeutic Code: 007	The symptomatic relief of indigestion, flatulence and nausea.	**Contra-indication:** Persons on a restricted sodium diet e.g. those suffering from hypertension or congestive heart failure, should not use this product unless directed by a doctor. Patients with impaired hepatic and renal function. Sodium Carbonate + Sodium Bicarbonate + Citric Acid is contraindicated in patients with a prior hypersensitivity reaction to Sodium Carbonate + Sodium Bicarbonate + Citric Acid or any other ingredient of the preparation. **Side Effects:** Non-serious stomach / gut irritations which could cause wind or bloating.	New	UKMHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
341.	Renata Limited Mirpur, Dhaka Navana Pharmaceuticals Limited	Lurasidone Hydrochloride INN 120mg Film Coated Tablet	Lurasidone Hydrochloride INN 120mg	Therapeutic Class: Antipsychotic Therapeutic code: 028	Schizophrenia & Depressive Episodes associated with Bipolar I Disorder (bipolar depression), as monotherapy and as adjunctive therapy with lithium or valproate.	Contraindications: Known hypersensitivity to lurasidone HCl or any components in the formulation. Angioedema has been observed with lurasidone [see Adverse Reactions (6.1)]. •Strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, ritonavir, voriconazole, mibefradil, etc.) •Strong CYP3A4 inducers (e.g., rifampin, avasimibe, St. John's wort, phenytoin, carbamazepine, etc.). WARNINGS AND PRECAUTIONS: Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis:	Lurasidone HCl 20mg Tablet Lurasidone Hydrochloride 40mg Tablet Lurasidone Hydrochloride 60mg Film coated Tablet.	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Increased incidence of cerebrovascular adverse events (e.g., stroke, transient ischemic attack Side Effects: Drowsiness, dizziness, lightheadedness, nausea, shaking, weight gain, mask-like facial expression, inability to keep still, and agitation may occur. This medication may cause a serious drop in blood pressure, especially when starting this medication.				
342.	Beacon Pharmaceuticals Limited	Chloral Hydrate 500mg/5ml Oral solution	Chloral Hydrate BP 500mg/5ml		Adutls: Chloral Hydrate Oral Solution is used for the short-term (maximum 2 weeks) treatment of severe sleeplessness (insomnia) which is interfering with normal daily life and where non-drug therapies (such as behavioural therapy and sleep hygiene) and other drugs have failed. Chloral Hydrate Oral Solution should be used in addition to non-drug therapies. Children and adolescents aged 2 years and above: Chloral Hydrate Oral Solution is used for the short-term (maximum 2 weeks) treatment of severe sleeplessness (insomnia) in children and adolescents with suspected or definite disorders that affect the development of the neurological system and brain (neurodevelopmental disorder). It is only used when the sleeplessness interferes with normal daily life and	Contraindication: Chloral Hydrate Oral Solution should not be used in patients with a marked hepatic or renal impairment, or in patients with severe cardiac disease. Should not be used in patients susceptible to acute attacks of porphyria. Side-effect: Gastric irritation, abdominal distension and flatulence may occur. Excitement, tolerance, allergic skin reactions, headache and ketonuria have occasionally been reported. There is a danger of abuse or chronic intoxication and the possibility that habituation may develop. In such patients gastritis and parenchymatous renal injury may develop. After long term use, sudden withdrawal may result in delirium. Elderly patients are more susceptible to the undesirable effects of hypnotic medications such as Chloral Hydrate Oral Solution and are therefore more susceptible to ataxia, Confusion, falls and injuries. Warning & Precautions:	143.3mg/5ml	UKMHRA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					other therapies (non-drug therapies and other drugs) have failed. Chloral Hydrate Oral Solution should be used in addition to behavioural therapy and sleep hygiene management. The use of Chloral Hydrate Oral Solution in children and adolescents is not generally recommended and if used should be under the supervision of a medical specialist.					
343.	Beacon Pharmaceuticals Limited **Navana Pharmaceuticals Limited**	Saroglitazar INN 2mg Tablet	Saroglitazar INN 2mg	Therapeutic class: Other Classification Therapeutic code: 075	Saroglitazar Is indicated for the treatment of diabetic dyslipidemia and hyper Triglyceridemia with type II Diabetes mellitus not controlled by statin therapy. In clinical Studies Saroglitazar has demonstrated reduction of triglycerides (TG), Low Density Lipoprotein (LDL) Cholesterol andan increase in HDL Cholestereol.	**Contra-indication:** Hypersensitivity to Saroglitazar or any of the excipients used in the formulation. **Side Effects:** The Most Common Side Effects of Saroglitazar include: Gastritis, Asrhenia, and Pyrexia. **Warnings and Precutions:** Although clinical studies with Saroglitarzar have not demonstrated any potential for myopathies or derangement of liver and/or renal function, Saroglitarzar treatment should be initiated with caution in patients with abnormal liver or renal function, or history of myopathies. Saroglitarzar has not been studied in patients with established New York Heart Association (NYHA) Class III or IV heart failure. Saroglitarzar should be initiated with caution in patients with type 2 diabetes having cardiac disease with episodic congestive heart failure and such patients should be monitored for signs and symptoms of congestiveheart failure. Although during the clinical studies, no significant weight gain and edema was reported with Saroglitarzar, patients who experience rapid increase in weight should be assessed for fluid accumulation and volume-related events such as excessive	New	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
344.	Ziska Pharmaceuticals Ltd. Navana Pharmaceuticals Limited Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka The ACME Laboratories Ltd. Dhamrai, Dhaka	Atogepant 10 mg Tablet	Atogepant INN 10 mg Tablet	Therapeutic Class: Other Classification (CGRP antagonist) Therapeutic code: 075	It is a calcitonin gene-related peptide receptor antagonist indicated for the preventive treatment of episodic migraine in adults.	**Contraindications:** This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. **Side effects:** The most common adverse reactions (at least 4% and greater than placebo) are nausea, constipation, and fatigue. **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 হয়।
345.	Ziska Pharmaceuticals Ltd. Navana Pharmaceuticals Limited Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Incepta Pharmaceuticals Ltd.;Zirabo,	Atogepant 30 mg Tablet	Atogepant INN 30 mg Tablet	Therapeutic Class: Other Classification (CGRP antagonist) Therapeutic code: 075	It is a calcitonin gene-related peptide receptor antagonist indicated for the preventive treatment of episodic migraine in adults.	**Contraindications:** This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. **Side effects:** The most common adverse reactions (at least 4% and greater than placebo) are nausea, constipation, and fatigue. **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 হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Savar, Dhaka The ACME Laboratories Ltd. Dhamrai, Dhaka									
346.	Ziska Pharmaceuticals Ltd. Navana Pharmaceuticals Limited Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka The ACME Laboratories Ltd. Dhamrai, Dhaka	Atogepant 60 mg Tablet	Atogepant INN 60 mg Tablet	Therapeutic Class: Other Classification (CGRP antagonist) Therapeutic code: 075	It is a calcitonin gene-related peptide receptor antagonist indicated for the preventive treatment of episodic migraine in adults.	**Contraindications:** This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. **Side effects:** The most common adverse reactions (at least 4% and greater than placebo) are nausea, constipation, and fatigue. **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 হয়।
347.	Navana Pharmaceuticals Limited	Alprostadil 3 mg/gm Cream	Alprostadil USP 3 mg/gm	Therapeutic Class: Drug used for erectile dysfunction Therapeutic Code: 043	It is used to treat erectile dysfunction (ED) in men 18 years of age or older.	Contraindications: It should not be used in patients with any of the following: - Underlying disorders such as orthostatic hypotension, myocardial infarction and syncope. - Known hypersensitivity to alprostadil or any of the ingredients in it. - Conditions that might predispose them to priapism, such as sickle cell anaemia or trait, thrombocythemia, polycythemia or multiple	New	UKMHRA	**ডাক্তারের প্রেসক্রিপশন অনুযায়ী ব্যবহার করতে হবে এই শর্তে অনুমোদনের সুপারিশ করা হয়।**	**ডাক্তারের প্রেসক্রিপশন অনুযায়ী ব্যবহার করতে হবে এই শর্তে অনুমোদন করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						myeloma or, leukaemia. - Abnormal penile anatomy such as severe hypospadias, in patients with anatomical deformation of the penis, such as curvature, and in patients with urethritis and balanitis (inflammation/infection of the glans of the penis). - Prone to venous thrombosis or who have a hyperviscosity syndrome and are therefore at increased risk of priapism (rigid erection lasting 4 or more hours). - It should not be used in patients for whom sexual activity is inadvisable as in men with unstable cardiovascular or unstable cerebrovascular conditions. - It should not be used for sexual intercourse with a woman with child-bearing potential unless the couple uses a condom barrier. Side Effects: Patient: mild to moderate local aching, burning or pain and redness of the penis, rash, genital pruritus, penile oedema inflammation of the glans penis (balanitis) penile tingling, throbbing numbness, burning. Patient's partner: Mild vaginal burning or itching, vaginitis This effect may be due to the drug or to the act of vaginal penetration. Using a waterbased lubricant can help to make vaginal penetration easier. Warnings and precautions: Talk to your doctor or pharmacist before using it if you have a history of the following local effects that have been observed with the use of it: - Prolonged erections lasting >4				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						hours (priapism) - Symptomatic hypotension (dizziness) - Hepatic and/or renal insufficiency, a lowered dose due to impaired metabolism may be required - Fainting A condom should be used in the following situations: - Your partner is pregnant or breastfeeding - Your partner is of childbearing potential - To prevent sexually transmitted diseases - During oral sex and anal sex Only latex condoms have been studied. It is not known if condoms made of other materials may be damaged.				
348.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Everest Pharmaceuticals Ltd.	Molnupiravir 400 mg Capsule	Molnupiravir INN 400 mg	Therapeutic Class: Antiviral Therapeutic code: 032	It is indicated for treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults with a positive SARS-COV-2 diagnostic test and who have at least one risk factor for developing severe illness	Contraindications: Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Special warnings and precautions for use: Sodium This medicinal product contains less than 1 mmol sodium (23 mg) per dose of 4 capsules, that is to say essentially 'sodium-free'.	Molnupiravir 200 mg Capsule	রেফারেন্স নাই	**রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।**
349.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Molnupiravir 800 mg Capsule	Molnupiravir INN 800 mg	Therapeutic Class: Antiviral Therapeutic code: 032	It is indicated for treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults with a positive SARS-COV-2 diagnostic test and who have at least one risk factor for developing severe illness	Contraindications: Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Special warnings and precautions for use: Sodium This medicinal product contains less than 1 mmol sodium (23 mg) per dose of 4 capsules, that is to say essentially 'sodium-free'.	Molnupiravir 200 mg Capsule	রেফারেন্স নাই	**রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।**
350.	JMI Hospital Requisite Mfg. Ltd.	Hypochlorous Acid USP 0.0030%-0.0050% solution	Hypochlorous Acid USP 0.0030%-0.0050% solution.	Therapeutic Class: Other Class Therapeutic code: 075	Disinfectant.		New	রেফারেন্স নাই	**রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
351.	Navana Pharmaceuticals Limited	Aspirin 325 mg + Omeprazole 40 mg DR Tablet	Aspirin BP 325 mg + Omeprazole BP 40 mg	Therapeutic Class: Other Classification Therapeutic Code:075	It is a combination of aspirin, an anti-platelet agent, and omeprazole, a proton pump inhibitor (PPI), indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers. The aspirin component of this combination is indicated for: • Reducing the combined risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli, • Reducing the combined risk of death and nonfatal MI in patients with a previous MI or unstable angina pectoris, • Reducing the combined risk of MI and sudden death in patients with chronic stable angina pectoris, • Using in patients who have undergone revascularization procedures (Coronary Artery Bypass Graft [CABG] or Percutaneous Transluminal Coronary Angioplasty [PTCA]) when there is a pre-existing condition for which aspirin is already indicated. The omeprazole component is indicated for decreasing the risk of developing aspirin associated gastric ulcers in patients at risk for	Contraindications: • History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. • In pediatric patients with suspected viral infections, with or without fever, because of the risk of Reye's Syndrome. • Known hypersensitivity to aspirin, omeprazole, substituted benzimidazoles or to any of the excipients of this combination. • Patients receiving rilpivirine-containing products. Side Effects: Most common adverse reactions in adults (≥ 2%) are: gastritis, nausea, diarrhea, gastric polyps, and non-cardiac chest pain. Warnings and precautions: • Coagulation Abnormalities: Risk of increased bleeding time with aspirin, especially in patients with inherited (hemophilia) or acquired (liver disease or vitamin K deficiency) bleeding disorders. Patients should monitor the signs of increased bleeding. • GI Adverse Reactions (including ulceration and bleeding): Monitoring for signs and symptoms and discontinuing treatment if bleeding occurs. • Bleeding Risk with Use of Alcohol: Patient should avoid heavy alcohol use (three or more drinks every day). • Reduction in Antiplatelet Activity with Clopidogrel due to Interference with CYP2C19 Metabolism: Considering other	New	USFDA	কম্বিনেশনটির প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	কম্বিনেশনটির প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					developing aspirin-associated gastric ulcers due to age (≥ 55) or documented history of gastric ulcers.	antiplatelet therapy. • Reduction in Efficacy of Ticagrelor: Patient should avoid use with the 325/40 strength of this combination. • Renal Failure: patients with severe renal failure should avoid this combination in patients with severe renal failure. • Gastric Malignancy: In adults, response to gastric symptoms does not preclude the presence of gastric malignancy; Considering additional followup and diagnostic testing. • Acute Interstitial Nephritis: Observed in patients taking PPIs. • Clostridium difficile-Associated Diarrhea: PPI therapy may be associated with increased risk; patient should use lowest dose and shortest duration of treatment. • Bone Fracture: Long-term and multiple daily dose PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist or spine; use lowest dose and shortest duration of treatment. • Cutaneous and Systemic Lupus Erythematosus: Mostly cutaneous; new onset or exacerbation of existing disease; patient should discontinue this combination and refer to specialist for evaluation. • Hepatic Impairment: Patient with all degrees of hepatic impairment should avoid this combination. • Cyanocobalamin (Vitamin B-12) Deficiency: Daily long-term use (e.g., longer than 3 years) of PPI may lead to malabsorption or deficiency. • Hypomagnesemia: Reported rarely with prolonged treatment with PPIs; consider				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						monitoring magnesium levels. • Reduced Effect of Omeprazole with St. John's Wort or Rifampin: Avoid concomitant use. • Interactions with Diagnostic Investigations for Neuroendocrine Tumors: Increased Chromogranin A (CgA) levels may interfere with diagnostic investigations for neuroendocrine tumors; temporarily stop this combination at least 14 days before assessing CgA levels • Bone Marrow Toxicity with Methotrexate, especially in the elderly or renally impaired: Using with PPIs may elevate and/or prolong serum levels of methotrexate and/or its metabolite, possibly leading to toxicity. With high dose methotrexate, consider a temporary withdrawal of this combination. • Premature closure of the ductus arteriosus: Pregnant women starting at 30 weeks gestation should avoid using this. • Abnormal Laboratory Tests: Aspirin has been associated with elevated hepatic enzymes, blood urea nitrogen and serum creatinine, hyperkalemia, proteinuria, and prolonged bleeding time. • Fundic Gland Polyps: Risk increases with long-term use, especially beyond one year. Patient should use the shortest duration of therapy.				
352.	Navana Pharmaceuticals Limited	Aspirin 81 mg + Omeprazole 40 mg DR Tablet	Aspirin BP 81 mg + Omeprazole BP 40 mg	Therapeutic Class: Other Classification Therapeutic Code:075	It is a combination of aspirin, an anti-platelet agent, and omeprazole, a proton pump inhibitor (PPI), indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular	Contraindications: • History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. • In pediatric patients with suspected viral infections, with or without fever, because of	New	USFDA	**কম্বিনেশনটির প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**কম্বিনেশনটির প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					events and who are at risk of developing aspirin associated gastric ulcers. The aspirin component of this combination is indicated for: • Reducing the combined risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli, • Reducing the combined risk of death and nonfatal MI in patients with a previous MI or unstable angina pectoris, • Reducing the combined risk of MI and sudden death in patients with chronic stable angina pectoris, • Using in patients who have undergone revascularization procedures (Coronary Artery Bypass Graft [CABG] or Percutaneous Transluminal Coronary Angioplasty [PTCA]) when there is a pre-existing condition for which aspirin is already indicated. The omeprazole component is indicated for decreasing the risk of developing aspirin associated gastric ulcers in patients at risk for developing aspirin-associated gastric ulcers due to age (≥ 55) or documented history of gastric ulcers.	the risk of Reye's Syndrome. • Known hypersensitivity to aspirin, omeprazole, substituted benzimidazoles or to any of the excipients of this combination. • Patients receiving rilpivirine-containing products. Side Effects: Most common adverse reactions in adults (≥ 2%) are: gastritis, nausea, diarrhea, gastric polyps, and non-cardiac chest pain. Warnings and precautions: • Coagulation Abnormalities: Risk of increased bleeding time with aspirin, especially in patients with inherited (hemophilia) or acquired (liver disease or vitamin K deficiency) bleeding disorders. Patients should monitor the signs of increased bleeding. • GI Adverse Reactions (including ulceration and bleeding): Monitoring for signs and symptoms and discontinuing treatment if bleeding occurs. • Bleeding Risk with Use of Alcohol: Patient should avoid heavy alcohol use (three or more drinks every day). • Reduction in Antiplatelet Activity with Clopidogrel due to Interference with CYP2C19 Metabolism: Considering other antiplatelet therapy. • Reduction in Efficacy of Ticagrelor: Patient should avoid use with the 325/40 strength of this combination. • Renal Failure: patients with severe renal				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						failure should avoid this combination in patients with severe renal failure. • Gastric Malignancy: In adults, response to gastric symptoms does not preclude the presence of gastric malignancy; Considering additional followup and diagnostic testing. • Acute Interstitial Nephritis: Observed in patients taking PPIs. • Clostridium difficile-Associated Diarrhea: PPI therapy may be associated with increased risk; patient should use lowest dose and shortest duration of treatment. • Bone Fracture: Long-term and multiple daily dose PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist or spine; use lowest dose and shortest duration of treatment. • Cutaneous and Systemic Lupus Erythematosus: Mostly cutaneous; new onset or exacerbation of existing disease; patient should discontinue this combination and refer to specialist for evaluation. • Hepatic Impairment: Patient with all degrees of hepatic impairment should avoid this combination. • Cyanocobalamin (Vitamin B-12) Deficiency: Daily long-term use (e.g., longer than 3 years) of PPI may lead to malabsorption or deficiency. • Hypomagnesemia: Reported rarely with prolonged treatment with PPIs; consider monitoring magnesium levels. • Reduced Effect of Omeprazole with St. John's Wort or Rifampin: Avoid concomitant use. • Interactions with Diagnostic Investigations				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						for Neuroendocrine Tumors: Increased Chromogranin A (CgA) levels may interfere with diagnostic investigations for neuroendocrine tumors; temporarily stop this combination at least 14 days before assessing CgA levels • Bone Marrow Toxicity with Methotrexate, especially in the elderly or renally impaired: Using with PPIs may elevate and/or prolong serum levels of methotrexate and/or its metabolite, possibly leading to toxicity. With high dose methotrexate, consider a temporary withdrawal of this combination. • Premature closure of the ductus arteriosus: Pregnant women starting at 30 weeks gestation should avoid using this. • Abnormal Laboratory Tests: Aspirin has been associated with elevated hepatic enzymes, blood urea nitrogen and serum creatinine, hyperkalemia, proteinuria, and prolonged bleeding time. • Fundic Gland Polyps: Risk increases with long-term use, especially beyond one year. Patient should use the shortest duration of therapy.				
353.	Navana Pharmaceuticals Limited	Atorvastatin 40 mg + Ezetemibe 10mg Tablet	Atorvastatin USP 40 mg + Ezetemibe INN 10mg	Therapeutic Class: Lipid Lowering Therapeutic Code:061	It contains a cholesterol absorption inhibitor and an HMG-CoA reductase inhibitor (statin), is indicated as adjunctive therapy to diet to: • Reduce elevated total-C, LDL-C, Apo B, TG, and non-HDL-C, and to increase HDL-C in patients with primary (heterozygous familial and non-familial) hyperlipidemia or mixed hyperlipidemia.	Contraindications: • Active liver disease or unexplained persistent elevations of hepatic transaminase levels. • Hypersensitivity to any component of it. • Women who are pregnant or may become pregnant. • Nursing mothers. Side Effects: • Common adverse reactions (incidence ≥2%	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					• Reduce elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH), as an adjunct to other lipidlowering treatments. Limitations of Use • No incremental benefit of this drug on cardiovascular morbidity and mortality over and above that demonstrated for atorvastatin has been established. This drug has not been studied in Fredrickson Type I, III, IV, and V dyslipidemias.	and greater than placebo) are: increased ALT, increased AST, and musculoskeletal pain. Warnings and precautions: • Patients should be advised to report promptly any unexplained and/or persistent muscle pain, tenderness, or weakness. This combination should be discontinued immediately if myopathy is diagnosed or suspected. • Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): Risks increase with higher doses and concomitant use of certain CYP3A4 inhibitors, fibric acid derivatives, and cyclosporine. Predisposing factors include advanced age (>65), uncontrolled hypothyroidism, and renal impairment. Rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported. • Liver enzyme abnormalities: Persistent elevations in hepatic transaminase can occur. Patient should check liver enzyme tests before initiating therapy and as clinically indicated thereafter.				
354.	Navana Pharmaceuticals Limited	Dried Ferrous Sulfate & Ascorbic Acid (Vitamin C) Modified Release Tablet	Dried Ferrous Sulfate BP 325 mg eqv. to 105 mg Elemental Iron & Ascorbic Acid (Vitamin C) BP 500 mg	Therapeutic Class: Vitamins and Combinations Therapeutic Code:078	It is an iron supplement used to prevent and treat iron-deficiency anaemia and vitamin C deficiency when the two are present together. It should only be used for the prevention and treatment of iron-deficiency anaemia diagnosed by laboratory testing under the supervision of a medical doctor. It should only be taken by pregnant women after the first 13 weeks of	Contraindications: Patients should not take it • If they are allergic to Ferrous Sulphate, Vitamin C (Ascorbic Acid) or any of the other ingredients of this medicine • If they are under 12 years of age • If they have been told that they have an intestinal blockage or diverticular disease of the intestine or if they are already taking medicines containing iron • If they have problems dealing with iron (haemochromatosis, haemosiderosis, iron	New	BNF 80 (Page: 1083)	অনুমোদনের সুপারিশ করা হয়॥	অনুমোদন করা হয়।॥

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					pregnancy. The added vitamin C helps the body to absorb the iron. A controlled release system in the tablet allows release of the iron over several hours and reduces the likelihood of stomach irritation.	overload syndromes). Side Effects: • Patients stools may turn black whilst taking it. If patients have a test for the detection of blood in their stools, tell their doctor they are taking It 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 patients develop any of these symptoms stop taking the tablets and contact their doctor • Feeling sick • Vomiting • Stomach Pain • Diarrhoea • Constipation • Haematemesis (blood in vomiting) and ileus (intestinal obstruction) have been reported. Warnings and precautions: Due to the risk of mouth ulceration and tooth discolouration, tablets should not be sucked, chewed or kept in the mouth but swallowed whole with water.				
355.	Popular Pharmaceuticals Ltd., Tongi, Bangladesh	Lornoxicam 8mg/2ml Injection	Lornoxicam INN 8mg/2ml	Therapeutic Class: Analgesics and Antipyretics Therapeutic Code:006	Short term treatment of moderate pain such as pain after dental surgery, Treatment of pain associated with acute lumbo-sciatica, Symptomatic treatment of pain and inflammation in osteoarthritis and 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	New	EMA	অনুমোদনের সুপারিশ করা হয়॥	অনুমোদন করা হয় ।॥

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						impairment, severe renal impairment (Serum creatinine >700 µmol/L), Thrombocytopenia, History of 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.				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						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;				
356.	Ethical Drugs Ltd**.** Siddhirganj, Narayanganj	Polymyxin B 10,000 units, Bacitracin Zinc 500 units, Gramicidin 0.25mg, Lidocaine 50mg. Ointment	Polymyxin B Sulfate BP 10,000 units, Bacitracin Zinc USP 500 units, Gramicidin USP 0.25mg, Lidocaine BP 50mg	Therapeutic Class: Skin and Mucous Membrane Preparations Therapeutic Code:071	First aid to help prevent infection in minor: Cuts, Scrapes & Burns	Contra-indication: It is contraindicated in individuals who have shown hypersensitivity to any of its components Side-effects: Burning, Dryness, redness & irritation of the skin may occur Warnings and Precaution: For external use only	New	রেফারেন্স নাই।	**রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।**
357.	The IBN SINA Pharmaceutical Industries Ltd.	Aducanumab 300 mg/3 ml Injection	Aducanumab INN 300 mg/3 ml	Therapeutic Class: Other Classification Therapeutic Code:075	Indicated for the treatment of Alzheimer's disease, limited the indication to people with mild cognitive impairment or mild dementia stage of disease.	Contra-Indication : • Allergic to Aducanumab • Pregnancy • Lactation • Chilren Side Effect: The most common side effects include areas of brain swelling, small brain bleeding, headache.	New	USFDA	**অনুমোদনের সুপারিশ করা হয়।**	**অনুমোদন করা হয়।**
358.	The IBN SINA Pharmaceutical Industries Ltd.	Aducanumab 170 mg/1.7 ml Injection	Aducanumab INN 170 mg/1.7 ml	Therapeutic Class: Other Classification Therapeutic Code:075	Indicated for the treatment of Alzheimer's disease, limited the indication to people with mild cognitive impairment or mild dementia stage of disease.	Contra-Indication : • Allergic to Aducanumab • Pregnancy • Lactation • Chilren Side Effect : The most common side effects include areas of brain swelling, small brain bleeding, headache.	New	USFDA	**অনুমোদনের সুপারিশ করা হয়।**	**অনুমোদন করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
359.	The IBN SINA Pharmaceutical Industries Ltd.	Dipyridamole 50 mg/10 ml Injection	Dipyridamole 50 mg/10 ml	Therapeutic Class: Coronary Vasodilators and Antianginal drug Therapeutic Code:040	Indicated to induce pharmacologic vasodilation for myocardial perfusion imaging.	Contra-Indication : Hypersensitivity to dipyridamole. Intravenous administration of dipyridamole is not recommended in states of shock or collapse. Side Effect : :nausea, vomiting, diarrhea, abdominal distress, headache, dizziness. flushing, fainting, hypotension; angina, chest pain, rash, irritation (with undiluted injection), pruritus	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
360.	The IBN SINA Pharmaceutical Industries Ltd.	Secukinumab 75.00 mg /0.5 ml, Pre-filled Syringe	Secukinumab INN 75.00 mg /0.5 ml	Therapeutic Class: Blood Coagulating Therapeutic Code:034	Is indicated for the treatment of moderate to severe plaque psoriasis, active psoriatic arthritis, active ankylosing spondylitis, active non-radiographic axial spondyloarthritis	Contra-Indication: contraindicated in patients with a previous serious hypersensitivity reaction to Secukinumab or to any of the excipients in Secukinumab. Side Effects: Nasopharyngitis, diarrhea, and upper respiratory tract infection.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
361.	The IBN SINA Pharmaceutical Industries Ltd.	Rilonacept 220 mg Powder for Injection	Rilonacept 220 mg	Therapeutic Class: Nonsteroidal anti-inflammatory and drugs used in arthritis Therapeutic Code:064	Indicated for cryopyrin-associated periodic syndromes, including familial cold autoinflammatory syndrome and Muckle-Wells syndrome & also used to maintenance of remission of deficiency of interleukin-1 receptor antagonist	Contra-Indication: None Side Effects: Cough, Hypoesthesia, Sinusitis, Hypersensitivity reaction, Neutropenia, Injection site reactions, Infections, Upper respiratory tract infections	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
362.	The IBN SINA Pharmaceutical Industries Ltd.	Serdexmethylphenidate 26.10 mg + Dexmethylphenidate 5.20 mg Capsule	Serdexmethylphenidate Chloride INN 28 mg Eqv. to Serdexmethylphenidate 26.10 mg + Dexmethylphenidate	Therapeutic Class: Antidepressants Therapeutic Code:014	Indicated in for the treatment of Attention Deficit Hyperactivity Disorder	Contra-Indication: Known hypersensitivity to serdexmethylphenidate, methylphenidate or product components. Concurrent treatment with a monoamine oxidase inhibitor (MAOI), Side Effects: Decreased appetite, Decreased weight, Nausea, Abdominal pain, Dyspepsia, Vomiting, Insomnia, Anxiety, Affect lability, Irritability, Dizziness, Increased blood	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
			Hydrochloride INN 6.01 mg Eqv. to 5.20 mg Dexmethylphenidate			pressure, Tachycardia				
363.	The IBN SINA Pharmaceutical Industries Ltd.	Serdexmethylphenidate 39.2 mg + Dexmethylphenidate 7.80 mg Capsule	Serdexmethylphenidate Chloride INN 42.06 mg Eqv. to Serdexmethylphenidate 39.20 mg + Dexmethylphenidate Hydrochloride INN 9.02 mg Eqv. to 7.80 mg Dexmethylphenidate	Therapeutic Class: Antidepressants Therapeutic Code:014	Indicated in for the treatment of Attention Deficit Hyperactivity Disorder	Contra-Indication: Known hypersensitivity to serdexmethylphenidate, methylphenidate or product components. Concurrent treatment with a monoamine oxidase inhibitor (MAOI), Side Effects: Decreased appetite, Decreased weight, Nausea, Abdominal pain, Dyspepsia, Vomiting, Insomnia, Anxiety, Affect lability, Irritability, Dizziness, Increased blood pressure, Tachycardia	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
364.	The IBN SINA Pharmaceutical Industries Ltd.	Serdexmethylphenidate 52.30 mg +Dexmethylphenidate 10.40 mg Capsule	Serdexmethylphenidate Chloride INN 56.12 mg Eqv. to Serdexmethylphenidate 52.30 mg + Dexmethylphenidate Hydrochloride INN 12.03 mg Eqv. to 10.40 mg Dexmethylphenidate	Therapeutic Class: Antidepressants Therapeutic Code:014	Indicated in for the treatment of Attention Deficit Hyperactivity Disorder	Contra-Indication: Known hypersensitivity to serdexmethylphenidate, methylphenidate or product components. Concurrent treatment with a monoamine oxidase inhibitor (MAOI), Side Effects: Decreased appetite, Decreased weight, Nausea, Abdominal pain, Dyspepsia, Vomiting, Insomnia, Anxiety, Affect lability, Irritability, Dizziness, Increased blood pressure, Tachycardia	New	USFDA	কম্বিনেশনটির প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	কম্বিনেশনটির প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
365.	Beximco Pharmaceuticals Ltd.	Amlodipine 2.5 mg Tablet	Amlodipine BP 2.5 mg	Therapeutic Class: Antidiabetic Therapeutic Code:015	Amlodipine is indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events,	Contra-indication: Amlodipine is contraindicated in patients with known sensitivity to Amlodipine. Side-effects: Cardiovascular: arrhythmia (including ventricular tachycardia and atrial	Amlodipine 5 & 10 Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					primarily strokes and myocardial infarctions. Amlodipine is a calcium channel blocker and may be used alone or in combination with other antihypertensive and antianginal agents for the treatment of hypertension.	fibrillation), bradycardia, chest pain, peripheral ischemia, syncope, tachycardia, vasculitis. Central and Peripheral Nervous System: hypoesthesia, neuropathy peripheral, paresthesia, tremor, vertigo. Gastrointestinal: anorexia, constipation, dysphagia, diarrhea, flatulence, pancreatitis, vomiting, gingival hyperplasia. General: allergic reaction, asthenia, 1back pain, hot flushes, malaise, pain, rigors, weight gain, weight decrease. Musculoskeletal System: arthralgia, arthrosis, muscle cramps, 1myalgia. Psychiatric: sexual dysfunction (male1 and female), insomnia, nervousness, depression, abnormal dreams, anxiety, depersonalization. Warnings and Precautions: Hypotension Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis. Because of the gradual onset of action, acute hypotension is unlikely. Increased Angina or Myocardial Infarction Worsening angina and acute myocardial infarction can develop after starting or increasing the dose of Amlodipine, particularly in patients with severe obstructive coronary artery disease. Patients with Hepatic Failure Because Amlodipine is extensively				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						metabolized by the liver and the plasma elimination half-life (t 1/2) is 56 hours in patients with impaired hepatic function, titrate slowly when administering AMLODIPINE to patients with severe hepatic impairment				
366.	Beximco Pharmaceuticals Ltd.	Diclofenac Sodium 2.32 % Gel	Diclofenac Sodium USP 2.32 % Gel	Therapeutic Class: Analgeisc & antipyretic Therapeutic Code: 006	Indicated for the quick relief from pain, swelling and inflammation due to musculo-skeletal disorders such as sprains, strains, tendinitis, bursitis, hands, neck and shoulder pain, sciatica, muscle stiffness, joint pain, backache and lumbago.	Contra-indication: • 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 in the setting of coronary artery bypass graft (CABG). Side-effects: Usually very well tolerated. Most common side effects (incidence >2% of patients treated with Diclofenac Topical Gel and greater than placebo) are application site reactions, including dermatitis 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.	Diclofenac Sodium 1.16 % Gel	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						• 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 injury. 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. • Hypertension can occur with NSAID treatment. Blood pressure should be monitored closely during treatment with Diclofenac topical gel. • Fluid retention and edema have been observed in some patients taking NSAIDs. Diclofenac topical gel should be used with caution in patients with fluid retention or heart failure. • Anaphylactoid reactions may occur in patients with the aspirin triad or in patients without prior exposure to Diclofenac topical gel and should be discontinued immediately if an analphylactoid reaction occurs.				
367.	Beximco Pharmaceuticals Ltd.	Citric Buffered Normal Saline **(This Diluent to be used with Lefamulin 150 mg/vial injection)**	Trisodium citrate dihydrate USP, Ph.Eur 2.00 mg + Citric acid anhydrous USP, Ph.Eur 0.615 mg + Sodium Chloride USP, Ph.Eur 9.000 mg	Therapeutic Class: Other Classification Therapeutic Code:075	To be used as diluent with Lefamulin Injection which is a pleuromutilin antibacterial indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP) caused by susceptible microorganisms	Contrindications/ Side effects/ Warning and Precautions: Citric Acid Normal Saline is a diluent to be used with Lefamulin 150 mg/vial injection. Contrindications, Side effects, Warning and Precautions are same as Lefamulin 150 mg/vial injection .	New	USFDA এ Lefamulin 150 mg/vial injection এর সঙ্গে Diluent হিসেবে	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
			+ Water for injection USP q.s to 1ml/ml Diluent Infusion (250 mL of 10 mM citrate buffered (pH 5) 0.9% sodium)					ব্যবহারের রেফারেন্স রয়েছে।		
368.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Ziska Pharmaceuticals Ltd. Gazipur.	Celecoxib 56 mg + Tramadol Hydrochloride 44 mg Tablet	Celecoxib BP 56 mg + Tramadol Hydrochloride BP 44 mg	Therapeutic Class: Opioid Analgesics Therapeutic code: 065	It contains tramadol hydrochloride, an opioid agonist, and celecoxib, a nonsteroidal anti-inflammatory drug, and is indicated for the management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Limitations of Use: Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve SEGLENTIS for use in patients for whom alternative treatment options [e.g., non-opioid analgesics]: • Have not been tolerated, or are not expected to be tolerated • Have not provided adequate analgesia, or are not expected to provide adequate analgesia.	Warning: Addiction, abuse, and misuse; risk evaluation and mitigation strategy (rems); lifethreatening respiratory depression; accidental ingestion; cardiovascular thrombotic events; gastrointestinal bleeding, ulceration, and perforation; ultra-rapid metabolism of tramadol and other risk factors for life-threatening respiratory depression in children; neonatal opioid withdrawal syndrome; interactions with drugs affecting cytochrome p450 isoenzymes; risks from concomitant use with benzodiazepines or other CNS depressants. Contraindications: • Children younger than 12 years of age. • Postoperative management in children younger than 18 years of age following tonsillectomy and/or adenoidectomy. • Significant respiratory depression. • Acute or severe bronchial asthma in an unmonitored setting or in absence of resuscitative equipment. • Known or suspected gastrointestinal obstruction, including paralytic ileus. • Hypersensitivity to tramadol, celecoxib, any	New	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						other component of this product, or sulfonamides, or opioids. • History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Side effects : constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.				
369.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur The ACME Laboratories Ltd. Dhamrai, Dhaka	Pilocarpine Hydrochloride 12.5mg/ml Eye Drops	Pilocarpine Hydrochloride USP 12.5mg/ml	Therapeutic Class: Eye Preparations Therapeutic code: 052	It is a cholinergic muscarinic receptor agonist indicated for the treatment of presbyopia in adults.	Warnings and Precautions: Poor Illumination, Risk of Retinal Detachment, Iritis. Contraindications: Hypersensitivity Side Effects : Headache and conjunctival hyperemia	Pilocarpine Hydrochloride 1%, 2% & 4% Eye Drops	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
370.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur The ACME Laboratories Ltd. Dhamrai, Dhaka Incepta Pharmaceutical	Varenicline 0.03mg/Spray Nasal Spray	Varenicline Tartrate INN 0.05mg eqv. to Varenicline 0.03mg/Spray	Therapeutic Class: Ear and Nose Preparations Therapeutic code: 050	It is a cholinergic agonist indicated for the treatment of the signs and symptoms of dry eye disease.	Contra-indication: None. Side effect: Sneezing, cough, and throat and nose irritation.	Varenicline 0.5 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	s Ltd.;Zirabo, Savar, Dhaka									
371.	Beacon pharmaceuticals Limited. Kathali, Bhaluka, Mymensingh	Difelikefalin Acetate 65 mcg /1.3 mL	Difelikefalin Acetate 75.790mcg eqv. to Difelikefalin 65 mcg /1.3 mL intravenous Injection	Therapeutic Class: Opioid Analgesics Therapeutic code: 065	It is a kappa opioid receptor agonist indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD).	Warnings and Precautions: Dizziness, Somnolence, Mental Status Changes, and Gait Disturbances: Dizziness, somnolence, mental status changes, and gait disturbances, including falls, have occurred. Centrally-acting depressant medications, sedating antihistamines, and opioid analgesics should be used with caution during treatment with KORSUVA Contra-indication: None. Side effect: The most common adverse reactions (incidence ≥2% and ≥1% higher than placebo) were diarrhea, dizziness, nausea, gait disturbances, including falls, hyperkalemia, headache, somnolence, and mental status change.	New	USFDA	**অনুমোদনের সুপারিশ করা হয়।**	**অনুমোদন করা হয়।**
372.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Peginesatide (6mg/ml) ready to fill bulk 0.5ml eqv. to Peginesatide 3mg/0.5ml PFS Injection	PeginesatideINN (6mg/ml) ready to fill bulk 0.5ml eqv. to Peginesatide 3mg/0.5ml PFS Injection	Therapeutic Class: DRUG used in Anemia and other Blood disorder Therapeutic Code: 045	Peginesatideis indicated for the treatment of anemia due to chronic kidney disease (CKD) in adult patients on dialysis.	Contraindication: Uncontrolled hypertension and serious allergic reactions to peginesatide. Side-effects: Increased mortality, myocardial infarction, stroke, and thromboembolism hypertension serious allergic reactions. Warning &Precaution: Increased Mortality, Myocardial Infarction, Stroke, and Thromboembolism: Using ESAs to target a hemoglobin level of greater than 11 g/dL increases the risk of serious adverse cardiovascular reactions and has not been	New	USFDA ২০১৯ এ পদটির অনুমোদন বাতিল করে।	**নামঞ্জুরের সুপারিশ করা হয়।**	**নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						shown to provide additional benefits. Use caution in patients with coexistent cardiovascular disease and stroke. Hypertension: Control hypertension prior to initiating and during treatment with peginesatide.				
373.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Peginesatide (8mg/ml) ready to fill bulk 0.5ml eqv. to Peginesatide 4mg/0.5ml PFS Injection	PeginesatideINN (8mg/ml) ready to fill bulk 0.5ml eqv. to Peginesatide 4mg/0.5ml PFS Injection	Therapeutic Class: DRUG used in Anemia and other Blood disorder Therapeutic Code: 045	It indicated for the treatment of anemia due to chronic kidney disease (CKD) in adult patients on dialysis.	Contraindication: Uncontrolled hypertension and serious allergic reactions to peginesatide. Side-effects: Increased mortality, myocardial infarction, stroke, and thromboembolism hypertension serious allergic reactions. Warning &Precaution: Increased Mortality, Myocardial Infarction, Stroke, and Thromboembolism: Using ESAs to target a hemoglobin level of greater than 11 g/dL increases the risk of serious adverse cardiovascular reactions and has not been shown to provide additional benefits. Use caution in patients with coexistent cardiovascular disease and stroke. Hypertension: Control hypertension prior to initiating and during treatment with peginesatide.	New	USFDA ২০১৯ এ পদটির অনুমোদন বাতিল করে।	**নামঞ্জুরের সুপারিশ করা হয়।**	**নামঞ্জুর করা হয়।**
374.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Phenylephrine Hydrochloride 0.1g + Promethazine Hydrochloride 0.125g/100ml Syrup	Phenylephrine Hydrochloride BP/Ph Eur.0.1g + Promethazine Hydrochloride BP/Ph.Eur.0.125 g/100ml	Therapeutic Class: Common Cold Preparations Therapeutic Code: 038	Promethazine hydrochloride and phenylephrine hydrochloride syrup is indicated for the temporary relief of upper respiratory symptoms, including nasal congestion, associated with allergy or the common cold.	Contraindication: Promethazine is contraindicated in individuals known to be hypersensitive or to have had an idiosyncratic reaction to promethazine or to other phenothiazines. Antihistamines are contraindicated for use in the treatment of lower respiratory tract symptoms, including asthma. Phenylephrine is contraindicated in patients with hypertension or with peripheral vascular	New	USFDA	**অনুমোদনের সুপারিশ করা হয়।**	**অনুমোদন করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						insufficiency (ischemia may result with risk of gangrene or thrombosis of compromised vascular beds). Phenylephrine should not be used in patients known to be hypersensitive to the drug or in those receiving a monoamine oxidase inhibitor (MAOI). Side-effects: Promethazine Nervous System: Sedation, sleepiness, occasional blurred vision, dryness of mouth, dizziness; rarely: confusion, disorientation, and extrapyramidal symptoms such as oculogyric crisis, torticollis, and tongue protrusion (usually in association with parenteral injection or excessive dosage). Cardiovascular: Increased or decreased blood pressure. Dermatologic: Rash; rarely: photosensitivity. Hematologic: Rarely: leukopenia, thrombocytopenia; agranulocytosis (1 case). Gastrointestinal: Nausea and vomiting. Phenylephrine Nervous System: Restlessness, anxiety, nervousness, and dizziness. Cardiovascular: Hypertension. Other: Precordial pain, respiratory distress, tremor, and weakness. Warning &Precaution: Animal reproduction studies have not been conducted with the drug combination				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						promethazine and phenylephrine. It is not known whether this drug combination can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Promethazine and phenylephrine should be given to a pregnant woman only if clearly needed. General: Promethazine should be used cautiously in persons with cardiovascular disease or impairment of liver function. Phenylephrine should be used with caution in patients with cardiovascular disease, particularly hypertension. Drug/ Laboratory Test Interactions The following laboratory tests may be affected in patients who are receiving therapy with promethazine hydrochloride. Pregnancy Tests: Diagnostic pregnancy tests based on immunological reactions between HCG and anti- HCG may result in false-negative or false-positive interpretations. Glucose Tolerance Test: An increase in blood glucose has been reported in patients.				
375.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka Aristo Pharma	Ritonavir 100 mg Tablet	Ritonavir USP 100 mg	Therapeutic Class: Antiviral Therapeutic Code: 032	It is an HIV protease inhibitor indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection.	Contraindication: Hypersensitivity to RITONAVIR (e.g., toxic epidermal necrolysis, StevensJohnson syndrome, erythema multiforme, urticaria, angioedema) or any of its ingredients, including ritonavir.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Ltd. Shampur-kadam toli, I/A, Dhaka.					• Co-administration with drugs highly dependent on CYP3A for clearance and for which elevated plasma levels may result in serious and/or lifethreatening events. • Co-administration with potent CYP3A inducers where significantly reduced lopinavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance and cross resistance. Side-effects: Commonly reported adverse reactions to RITONAVIR included diarrhea, nausea, vomiting, hypertriglyceridemia and hypercholesterolemia. Warnings and Precautions: The following have been observed in patients receiving RITONAVIR : • The concomitant use of RITONAVIR and certain other drugs may result in known or potentially significant drug interactions. Consult the full prescribing information prior to and during treatment for potential drug interactions. • Toxicity in preterm neonates: RITONAVIR oral solution should not be used in preterm neonates in the immediate postnatal period because of possible toxicities. A safe and effective dose of RITONAVIR oral solution in this patient population has not been established. • Pancreatitis: Fatalities have occurred; suspend therapy as clinically appropriate. • Hepatotoxicity: Fatalities have occurred. Monitor liver function before and during therapy, especially in patients with underlying hepatic disease, including hepatitis B and				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						hepatitis C, or marked transaminase elevations.				
376.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Pefcitinib 50 mg Tablet	Pefcitinib 50 mg tablet	Therapeutic Class: Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic Code: 064	Pefcitinib is used in the treatment of rheumatoid arthritis to reduces joint inflammation and pain.	Contraindication: None Side-effects: Nasopharengitis,Harpes zoster virus infection,Blood kinase increase Warnings and Precautions: None	New	রেফারেন্স নাই	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।**
377.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Pefcitinib100 mg Tablet	Pefcitinib100 mg tablet	Therapeutic Class: Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic Code: 064	Pefcitinib is used in the treatment of rheumatoid arthritis to reduces joint inflammation and pain.	Contraindication: None Side-effects: Nasopharengitis,Harpes zoster virus infection,Blood kinase increase Warnings and Precautions: None	New	রেফারেন্স নাই	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।**
378.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Tramadol Hydrochloride 75mg+Dexketoprofen 25mg Tablet	Tramadol Hydrochloride BP 75mg+Dexketoprofen INN 25mg Tablet	Therapeutic Class: Analgesics and Antipyretics Therapeutic Code: 006	Symptomatic short term treatment of moderate to severe acute pain in adult patients whose pain is considered to require a combination of tramadol and dexketoprofen.	Contraindication: Hypersensitivity to dexketoprofen, to any other NSAID, or to any of the excipients listed in the composition. patients in whom substances with a similar action (e.g. acetylsalicylic acid, or other NSAIDs) precipitate attacks of asthma, bronchospasm, acute rhinitis, or cause nasal polyps, urticaria or angioneuroticoedema; Side-effects: Thromocytosis Neutropenia	New	রেফারেন্স নাই	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Warnings and Precautions: None				
379.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka Ziska Pharmaceuticals Ltd. Gazipur	Acebrophylline 1g/100ml Syrup	AcebrophyllineINN 1g/100ml Syrup	Therapeutic Class: Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic Code: 044	Acebrophylline is indicated for asthma, bronchitis and other respiratory conditions.	Contraindication: Hypersensitivity to ambroxol, aacebrophylline, theophylline or any other xanthine derivative,Patient suffering from acute myocardial infarction, hypotension, hemodynamic instability and arrhythmias, renal disease or liver disorder. Side-effects: Patients administering Acebrophyllinemight be affected by some adverse events. You must report all reactions that occur to your physician. A list consisting of some examples is given here. Sickness Diarrhea Flatulence Constipation Abdominal discomfortIt is worth noting that other side effects which are not referenced here are also possible. Make sure that you consult your physician immediately if any serious side effects are noticed while you are undergoing treatment with this medicine. Warnings and Precautions: Patients who are taking Acebrophylline should note that if a worsening of their breathing condition occurs, medical attention will be necessary straight away. Your physician will wish to monitor your breathing condition during treatment to	New	রেফারেন্স নাই	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						ensure that the medicine is having the desired effects.				
380.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka Ziska Pharmaceuticals Ltd. Gazipur.	Acebrophylline 200mg Tablet	Acebrophylline INN 200mg Tablet	Therapeutic Class: Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic Code: 044	Acebrophylline is indicated for asthma, bronchitis and other respiratory conditions.	Contraindication: Hypersensitivity to ambroxol, aacebrophylline, theophylline or any other xanthine derivative,Patient suffering from acute myocardial infarction, hypotension, hemodynamic instability and arrhythmias, renal disease or liver disorder. Side-effects: Patients administering Acebrophyllinemight be affected by some adverse events. You must report all reactions that occur to your physician. A list consisting of some examples is given here. Sickness Diarrhea Flatulence Constipation Abdominal discomfortIt is worth noting that other side effects which are not referenced here are also possible. Make sure that you consult your physician immediately if any serious side effects are noticed while you are undergoing treatment with this medicine. Warnings and Precautions: Patients who are taking Acebrophylline should note that if a worsening of their breathing condition occurs, medical attention will be necessary straight away. Your physician will wish to monitor your breathing condition during treatment to	New	রেফারেন্স নাই	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						ensure that the medicine is having the desired effects.				
381.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka Ziska Pharmaceuticals Ltd. Gazipur	Acebrophylline 100mg Capsule	AcebrophyllineINN 100mg Capsule	Therapeutic Class: Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic Code: 044	Acebrophylline is indicated for asthma, bronchitis and other respiratory conditions.	Contraindication: Hypersensitivity to ambroxol, aacebrophylline, theophylline or any other xanthine derivative,Patient suffering from acute myocardial infarction, hypotension, hemodynamic instability and arrhythmias, renal disease or liver disorder. Side-effects: Patients administering Acebrophyllinemight be affected by some adverse events. You must report all reactions that occur to your physician. A list consisting of some examples is given here. Sickness, Diarrhea, Flatulence, Constipation Abdominal discomfortIt is worth noting that other side effects which are not referenced here are also possible. Make sure that you consult your physician immediately if any serious side effects are noticed while you are undergoing treatment with this medicine. Warnings and Precautions: Patients who are taking Acebrophylline should note that if a worsening of their breathing condition occurs, medical attention will be necessary straight away. Your physician will wish to monitor your breathing condition during treatment to ensure that the medicine is having the desired effects.	New	রেফারেন্স নাই	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
382.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Aviptadil 0.5mg/5ml Injection	Aviptadil INN 0.5mg/5ml Injection	Therapeutic Class: Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic Code: 044	Critical COVID-19 With Respiratory Failure (COVID-AIV)	Contraindication: No data available. Side-effects: It is well tolerated with few adverse effects including alterations in blood pressure, heart rate, or ECG Warnings and Precautions: No data available.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
383.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	DelafloxacinMeglumine 649.500mg eqv. to Delafloxacin 450mg/vial Injection	DelafloxacinMeglumine INN 649.500 mg/vial eqv to Delafloxacin 450 mg	Therapeutic Class: Anti-infective Therapeutic Code: 023	Delafloxacinused in skin & skin structure infection	Contraindication: Delafloxacin is contraindicated in patients with known hypersensitivity to delafloxacin or any of the fluoroquinolone class of antibacterial drugs, or any of the components of delafloxacin is contraindicated in patients with known hypersensitivity to delafloxacin or any of the fluoroquinolone class of antibacterial drugs, or any of the components of delafloxacin Side-effects: Disabling and Potentially Irreversible Serious Adverse Reactions Tendinitis and Tendon Rupture Peripheral Neuropathy Warnings and Precautions: Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions from different body systems that can occur together in the same patient. Commonly seen adverse reactions include tendinitis, tendonrupture, arthralgia, myalgia, peripheral neuropathy, and central nervous	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						system effects (hallucinations, anxiety, depression, insomnia, severe headaches, and confusion). These reactions could occur within hours to weeks after starting a fluoroquinolone. Patients of any age or without pre-existing risk factors have experienced these adverse reaction				
384.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Sodium Alginate 250mg + Sodium Bicarbonate 106.5mg + Calcium Carbonate 187.5mg Tablet	Sodium Alginate BP/PhEur 250.0000 mg+ sodium bicarbonate BP/Ph.Eur. 106.5000 +Calcium Carbonate BP/Ph.Eur 187.5000	Therapeutic Class: Antacid,Adsorbent Therapeutic Code: 007	Gastro-Oesophageal reflux Heartburn Acid regurgitation Indigestion which may occur, following meals or during pregnancy Excess stomach acidity (hyperacidity)	Contraindication: Hypersensitivity to sodium alginate, sodium bicarbonate, calcium carbonate, the esters of hydroxybenzoates (parabens) or to any of the excipients(Carbomer, Methyl parahydroxybenzoate (E218), Propyl parahydroxybenzoate (E216),Saccharin sodium, Mint flavor, Sodium hydroxide, Purified water). Should not be used in patients with moderate or severe renal insufficiency. Side-effects: Anaphylactic reaction, Hypersensitivity reaction, Urticaria Warnings and Precautions: Should be particularly taken into account for those on a low salt diet (e.g. in some cases of congestive heart failure and renal impairment). Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.	New	রেফারেন্স নাই	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Treatment of children younger than 12 years of age is not generally recommended, except on medical advice. If symptoms persist, or treatment is required for more than 7 days continuously, medical advice should be sought. As with other antacid products, taking this product can mask the symptoms of other more serious, underlying medical conditions. Contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).				
385.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Sodium Alginate 250mg + Sodium Bicarbonate 133.5mg + Calcium Carbonate 80mg Tablet	Sodium Alginate BP/PhEur 250.0000 mg+ sodium bicarbonate BP/Ph.Eur. 133.5000 +Calcium Carbonate BP/Ph.Eur 80.0000	Therapeutic Class: Antacid,Adsorbent Therapeutic Code: 007	Gastro-Oesophageal reflux Heartburn Acid regurgitation Indigestion which may occur, following meals or during pregnancy Excess stomach acidity (hyperacidity)	Contraindication: Hypersensitivity to sodium alginate, sodium bicarbonate, calcium carbonate, the esters of hydroxybenzoates (parabens) or to any of the excipients(Carbomer, Methyl parahydroxybenzoate (E218), Propyl parahydroxybenzoate (E216), Saccharin sodium, Mint flavor, Sodium hydroxide, Purified water). Should not be used in patients with moderate or severe renal insufficiency. Side-effects: Anaphylactic reaction, Hypersensitivity reaction, Urticaria Warnings and Precautions:	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Should be particularly taken into account for those on a low salt diet (e.g. in some cases of congestive heart failure and renal impairment). Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi. Treatment of children younger than 12 years of age is not generally recommended, except on medical advice. If symptoms persist, or treatment is required for more than 7 days continuously, medical advice should be sought. As with other antacid products, taking this product can mask the symptoms of other more serious, underlying medical conditions. Contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).				
386.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Zuranolone 30 mg Capsule	Zuranolone INN 30mg	Therapeutic Class: Antidepressants Therapeutic Code: 014	Treatment of postpartum depression & major depressive disorder	Contraindication: None Side-effects: None Warnings and Precautions: None	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
387.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Zuranolone 50 mg capsule	Zuranolone INN 50.000	Therapeutic Class: Antidepressants Therapeutic Code: 014	Treatment of postpartum depression & major depressive disorder	Contraindication: None Side-effects: None Warnings and Precautions: None	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
388.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Carboxymethylcellulose 0.5gm + Glycerine 1gm + Polysorbate 80 0.5gm/100ml Ophthalmic Gel Solution	Carboxymethyl Cellulose sodium USP 1.0000 gm/100 ml+Glycerin BP/PhEur .9000 g/100 ml	Therapeutic Class: Eye Preparations Therapeutic Code: 052	For the treatment of: For the temporary relief of burning, irritation and discomfort due to dryness of the eye or exposure to the wind and sun. May be used as a protectant against further irritation.	Contraindication: Do not use if allergic to any of the ingredients Side-effects: eye pain, change in vision, continued eye redness and irritation Warnings and Precautions: For external use only. To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard. Do not touch unit-dose tip to eye. If solution changes color, do not use. Stop use and ask a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
389.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Carboxymethylcellulose 1gm + Glycerine 0.9gm/100ml Opthalmic Gel Solution	Carboxymethyl Cellulose sodium USP .5000 gm/100 ml+Glycerin BP/PhEur 1.0000 gm/100 ml + Polysorbate 80 BP/PhEur .5000 gm/100 ml	Therapeutic Class: Eye Preparations Therapeutic Code: 052	For the treatment of: For the temporary relief of burning, irritation and discomfort due to dryness of the eye or exposure to the wind and sun. May be used as a protectant against further irritation.	Contraindication: Do not use if allergic to any of the ingredients Side-effects: eye pain, change in vision, continued eye redness and irritation Warnings and Precautions: For external use only. To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard. Do not touch unit-dose tip to eye. If solution changes color, do not use. Stop use and ask a doctor if you experience eye pain, changes in vision, continued redness	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						or irritation of the eye, or if the condition worsens				
390.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Paliperidone Palmitate 810mg eqv. to 525mg of Paliperidone/2.625ml Extended-Release Injectable Suspension	Paliperidone Palmitate 810 mgeqv to 525.0000 mg of paliperidone	Therapeutic Class: Antipsychotic Therapeutic Code: 028	PALIPERIDONE PALMITATE, an every-six-month injection, is an atypical antipsychotic indicated for the treatment of schizophrenia in adults after they have been adequately treated with: • A once-a-month paliperidone palmitate extended-release injectable suspension (e.g., INVEGA SUSTENNA) for at least four months or • An every-three-month paliperidone palmitate extended-release injectable suspension (e.g., INVEGA TRINZA) for at least one three-month cycle	Contraindication: Known hypersensitivity to paliperidone, risperidone, or to any excipients in PALIPERIDONE PALMITATE. Side-effects: The most common adverse reactions were upper respiratory tract infection, injection site reaction, weight increased, headache, and parkinsonism. Warnings and Precautions: For external use only. To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard. Do not touch unit-dose tip to eye. If solution changes color, do not use. Stop use and ask a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens Stop use and ask a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens	New	রেফারেন্স নাই	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।**
391.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Duloxetine Hydrochloride 11.225mg eqv.to Duloxetine 10mg Tablet	Duloxetine Hydrochloride BP/ph Eur. 11.225mg eqv.to Duloxetine 10mg	Therapeutic Class: Other Classification Therapeutic Code: 075	Treatment of major depressive disorder. Treatment of diabetic peripheral neuropathic pain. Treatment of generalised anxiety	Contraindication: Known hypersensitivity to paliperidone, risperidone, or to any excipients in PALIPERIDONE PALMITATE. Side-effects: The most common adverse reactions were upper respiratory tract infection, injection site reaction, weight increased, headache, and	New	রেফারেন্স নাই	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					disorder.	parkinsonism. Warnings and Precautions: For external use only. To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard. Do not touch unit-dose tip to eye. If solution changes color, do not use. Stop use and ask a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens Stop use and ask a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens				
392.	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka Aristopharma Ltd, Shampur-Kadam toli, I/A, Dhaka.	Ritonavir 100 mg soft gelatin capsule	Ritonavir USP 100 mg	Therapeutic Class: Antiviral Therapeutic Code: 032	It is an HIV protease inhibitor indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection.	Contraindication: Hypersensitivity to RITONAVIR (e.g., toxic epidermal necrolysis, StevensJohnson syndrome, erythema multiforme, urticaria, angioedema) or any of its ingredients, including ritonavir. • Co-administration with drugs highly dependent on CYP3A for clearance and for which elevated plasma levels may result in serious and/or lifethreatening events. • Co-administration with potent CYP3A inducers where significantly reduced lopinavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance and cross resistance. Side-effects: Commonly reported adverse reactions to RITONAVIR included diarrhea, nausea, vomiting, hypertriglyceridemia and hypercholesterolemia.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Warnings and Precautions: The following have been observed in patients receiving RITONAVIR : • The concomitant use of RITONAVIR and certain other drugs may result in known or potentially significant drug interactions. Consult the full prescribing information prior to and during treatment for potential drug interactions. • Toxicity in preterm neonates: RITONAVIR oral solution should not be used in preterm neonates in the immediate postnatal period because of possible toxicities. A safe and effective dose of RITONAVIR oral solution in this patient population has not been established. • Pancreatitis: Fatalities have occurred; suspend therapy as clinically appropriate. • Hepatotoxicity: Fatalities have occurred. Monitor liver function before and during therapy, especially in patients with underlying hepatic disease, including hepatitis B and hepatitis C, or marked transaminase elevations.				
393.	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka Drug International Ltd.Unit-3.	Ruxolitinib Phosphate 1.98 gm/100 gm eqv. to 1.5 gm Ruxolitimib Cream	Ruxolitinib Phosphate INN 1.9800 g eqv to 1.5000 g Ruxolitinib	Therapeutic Class: Anticancer Therapeutic Code: 010	Is indicated for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.	Contraindication: None Side-effects: The most common adverse reactions (incidence ≥1%) are nasopharyngitis, diarrhea, bronchitis, ear infection, eosinophil count increased, urticaria, folliculitis, tonsillitis, and rhinorrhea. Warnings and Precautions:	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Serious Infections: Serious bacterial, mycobacterial, fungal and viral infections have occurred. Regularly monitor patients for infection and manage it promptly. Non-melanoma Skin Cancers. Basal cell and squamous cell carcinoma have occurred. Perform periodic skin examinations during treatment and following treatment as appropriate. Thrombosis. Thromboembolic events have occurred. Thrombocytopenia, Anemia and Neutropenia: Thrombocytopenia, anemia and neutropenia have occurred. Perform CBC monitoring as clinically indicated.				
394.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Paliperidone Palmitate 410 mg extended release injectable suspension	Paliperidone Palmitate 410 mg eqv to 263.0000 mg of paliperidone	Therapeutic Class: Antipsychotic Therapeutic Code: 028	PALIPERIDONE PALMITATE, an every-six-month injection, is an atypical antipsychotic indicated for the treatment of schizophrenia in adults after they have been adequately treated with: • A once-a-month paliperidone palmitate extended-release injectable suspension (e.g., INVEGA SUSTENNA) for at least four months or • An every-three-month paliperidone palmitate extended-release injectable suspension (e.g., INVEGA TRINZA) for at least one three-month cycle	Contraindication: Known hypersensitivity to paliperidone, risperidone, or to any excipients in PALIPERIDONE PALMITATE. Side-effects: The most common adverse reactions were upper respiratory tract infection, injection site reaction, weight increased, headache, and parkinsonism. Warnings and Precautions: For external use only. To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard. Do not touch unit-dose tip to eye. If solution changes color, do not use. Stop use and ask a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition	Existing Paliperidone 1.5 mg ER Tablet (DCC-245)	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						worsens Stop use and ask a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens				
395.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Paliperidone Palmitate 546 mg extended release injectable suspension	Paliperidone Palmitate INN 546 mg eqv. to 350.0000 mg of paliperidone	Therapeutic Class: Antipsychotic Therapeutic Code: 028	PALIPERIDONE PALMITATE, an every-six-month injection, is an atypical antipsychotic indicated for the treatment of schizophrenia in adults after they have been adequately treated with: • A once-a-month paliperidone palmitate extended-release injectable suspension (e.g., INVEGA SUSTENNA) for at least four months or • An every-three-month paliperidone palmitate extended-release injectable suspension (e.g., INVEGA TRINZA) for at least one three-month cycle	Contraindication: Known hypersensitivity to paliperidone, risperidone, or to any excipients in PALIPERIDONE PALMITATE. Side-effects: The most common adverse reactions were upper respiratory tract infection, injection site reaction, weight increased, headache, and parkinsonism. Warnings and Precautions: For external use only. To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard. Do not touch unit-dose tip to eye. If solution changes color, do not use. Stop use and ask a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens Stop use and ask a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens	Existing Paliperidone 1.5 mg ER Tablet (DCC-245)	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
396.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Insulin Glargine and Lixisenatide injectable solution/3 ml cartridge	Insulin Glargine BP/Ph.Eur 10.9200 eqv. to 300 units of insulin glargine+Lixisenatide INN 0.1000mg/3ml	Therapeutic Class: Antidiabetes Therapeutic Code: 015	For the treatment of Type-2 diabetes mellitus.	Contraindication: Found during: Hypoglycemic episodes Hypersensitivity either of the active drug substances Side-effects: hypoglycemia allergic reactions, nausea, nasopharyngitis	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						diarrhea, upper respiratory tract infection, headache. Warnings and Precautions: Anaphylaxis and serious hypersensitivity reactions Pancreatitis Hyperglycemia Hypoglycemia				
397.	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka	Benzonatate 200mg Capsule	Benzothenate USP 200.000 mg	Therapeutic Class: Common Cold Preparations Therapeutic Code: 038	Benzothenate is indiactaed for the sympathetic relief of cough	Contraindication: Hypersensitivity to Benzothenateopr related compound Side-effects: Hypersensitivity reactions including bronchospasm,cardiovascularcollaps possibly related to local anesthesia from chewing or sucking the capsule CNS: sedation,headache,dizziness GI:Constyipation,nausea Dermatologic:Pruritis,skin eruption Warnings and Precautions: Is chemically related to anesthetic agents of the para-amino-benzoic acid class & has been associated with adverse CNS effects possibly related to a prior sensitivity to related agents or interaction with concominant medication	New	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
398.	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka	Ketoconazole 2gm/100 gm + Zinc Pyrithione50% 2gm/100 gm eqv. to 1gm/100 gm Zinc Pyrithione + Aloe Vera 6gm/100gm Shampoo	Ketoconazole Bp/PhEur 2.000 gm/100 gm+zincpyrithrone 50 % INN 2.000 g/100 g eqv to 1.00 zinc pyrithrone +Aloe vera 6.000	Therapeutic Class: Skin and Mucous Membrane Preparations Therapeutic Code: 071	Ketoconazole Broad spectrum anti-fungal agent Reduces inflammation associated with dandruff & seborrheic dermatitis Relieves scaling &pruritisZPTO Bacteriostatic &fungistatic agent Reduces scaling & itching Alowvera Gives shine & moisture to hair	Contraindication: Shampoo is contraindicated in persons who have known hypersensitivity to the active ingredient or excipients of this formulation. Side-effects:The most common adverse reactions (incidence ≥1%) are nasopharyngitis, diarrhea, bronchitis, ear infection, eosinophil count increased, urticaria, folliculitis, tonsillitis, and rhinorrhea.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					Prevents hair loss & dandruff.	Warnings and Precautions: No data available				
399.	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka Ziska Pharmaceuticals Ltd..Gazipur.	Minoxidil 5 gm/100 ml + Finasteride 0.1 gm/100 ml Topical Solution	Minoxidil USP 5.0000 +Finasteride USP .1000	Therapeutic Class: Skin and Mucous Membrane Preparations Therapeutic Code: 071	This topical solution is indicated for the treatment of androgenic alopecia in men in the age group of 18 to 60 years	Contraindication: Hypersensitivity to Minoxidil.Finasteride or any of the Constituents of the solution Side-effects: The most common side effects are itching & skin irritation of the treated area of the scalp Warnings and Precautions: No data have been provided	New	রেফারেন্স নাই	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।**	**প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।**
400.	M/s ACI Healthcare Limited, Treepordi, Sonargaon, Narayanganj.	Rifampicin 150.00mg, Isoniazid 75.00mg and Ethambutol HCL 275.00mg Film Coated Tablet (3-FDC)	Rifampicin 150.00mg, Isoniazid 75.00mg and Ethambutol HCL 275.00mg	Therapeutic Class: Antitubercular and Antileprotic Therapeutic Code: 030	It is indicated for the initial treatment phase of tuberculosis, caused by Mycobacterium tuberculosis, according to the guidelines of WHO.	Contraindications: Hypersensitivity to the active substances or to any of theexcipients. Acute liver disease, icterus or severe liverimpairment. Optic neuritis(ethambutol). Co-administration of AkuriT-3 Tablets with voriconazole or any HIV or HCV protease inhibitoris contraindicated (see section 4.5). Warnings: Liver toxicity: Rifampicin and/or isoniazid may cause hepatotoxicity (see section 4.8). Whenever possible, the use of AkuriT-3 Tablets should be avoided in patients with preexisting hepatic impairment (ALT> 3 x ULN) due to the risk of liver toxicity Patients should be strongly advised to restrict intake of alcoholic beverages while being treated with AkuriT-3 Tablets. Patient	New	WHO-prequalified.	**অনুমোদনের সুপারিশ করা হয়।**	**অনুমোদন করা হয়।**

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						groups especially at risk for developing hepatitisinclude: - age > 35 years, - daily users of alcohol (patients should be strongly advised to restrict intake of alcoholic beverages, see section 4.5), - patients with active chronic liver disease - intravenous drug users. Furthermore, the following patients should be carefullymonitored: - patients with concurrent use of any chronically administered medication (see section4.5), - existence of peripheral neuropathy or conditions predisposing to neuropathy, - pregnant patients - HIV positive patients.				
401.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka Ziska Pharmaceuticals Ltd. Gazipur.	Dexlansoprazole 30 mg Delayed-Release Tablet	Dexlansoprazole 20 % w/w (Pellets) INN 150.0000 eqv. to Dexlansoprazole 30 mg	Therapeutic Class: Proton Pump inhibitor Therapeutic Code: 067	Healing of Erosive Esophagitis DEXLANSOPRAZOLE delayed-release tablets are indicated in adults for healing of all grades of erosive esophagitis (EE) for up to eight weeks. Maintenance of Healed Erosive Esophagitis DEXLANSOPRAZOLE tablets and DEXLANSOPRAZOLE SoluTab delayed-release orally disintegrating tablets (DEXLANSOPRAZOLE SoluTab) are indicated in adults to maintain healing of EE and relief of heartburn for up to six months. Symptomatic Non-Erosive Gastroesophageal Reflux Disease DEXLANSOPRAZOLE tablets and DEXLANSOPRAZOLE SoluTab are indicated in adults for the treatment of heartburn associated with symptomatic non-	Contraindication: DEXLANSOPRAZOLE is contraindicated in patients with known hypersensitivity to any component of the formulation. Hypersensitivity reactions, including anaphylaxis have been reported. Acute interstitial nephritis (AIN) has been reported with other proton pump inhibitors (PPIs), including lansoprazole of which dexlansoprazole is the R-enantiomer. •PPIs, including DEXLANSOPRAZOLE, are contraindicated with rilpivirine-containing products. Side-effects: Most commonly reported adverse reactions (≥2%): diarrhea, abdominal pain, nausea, upper respiratory tract infection, vomiting, and flatulence. Warnings and Precautions: Gastric Malignancy: Symptomatic response with DEXLANSOPRAZOLE does not preclude the presence of gastric malignancy.	Existing Dexlansoprazole 30 mg DR Capsule	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					erosive gastroesophageal reflux disease (GERD) for four weeks	Acute Interstitial Nephritis: Observed in patients taking PPIs. Cyanocobalamin (Vitamin B-12) Deficiency: Daily long-term use (e.g., longer than 3 years) may lead to malabsorption or a deficiency of cyanocobalamin. Clostridium difficile Associated Diarrhea: PPI therapy may be associated with increased risk. Bone Fracture: Long-term and multiple daily dose PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist or spine. Hypomagnesemia: Reported rarely with prolonged treatment with PPIs. Interactions with Diagnostic Investigations for Neuroendocrine Tumors: Increases in intragastric pH may result in hypergastrinemia and enterochromaffin-like cell hyperplasia and increased chromogranin A levels which may interfere with diagnostic investigations for neuroendocrine tumors.				
402.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Tramadol HCl 5.00mg/1ml oral solution	Tramadol HCl BP 5.00mg/1ml	Therapeutic Class: Opioid Analgesics Therapeutic Code: 065	It is indicated in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Limitations of Use Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve tramadol hydrochloride for use in patients for whom alternative treatment options [e.g., non-opioid analgesics]:	Contraindication: It is contraindicated for: All children younger than 12 years of age. Postoperative management in children younger than 18 years of age following tonsillectomy and/or adenoidectomy. It is also contraindicated in patients with: 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 Side-effects:	Existing Tramadol Hydrochloride 50 mg Tablet	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					Have not been tolerated or are not expected to be tolerated. Have not provided adequate analgesia or are not expected to provide adequate analgesia.	Dizziness, nausea, constipation, headache, somnolence, pruritus, vomiting; respiratory depression, severehypotension, syncope; rare: serious skin reactions or other hypersensitivity (discontinue if occur). Warnings and Precautions: Risk of medication errors; ensure accurate dosing. Abuse potential (monitor). Life-threatening respiratory depression; monitor within first 24–72hrs of initiating therapy and following dose increases. Accidental exposure may cause fatal overdose (esp. in children). Sleep-related breathing disorders (including central sleep apnea (CSA), sleep-related hypoxemia); consider dose reduction if CSA develops. Risk of life-threatening respiratory depression and death related to ultra-rapid metabolizers of tramadol (esp. in children for post-tonsillectomy and/or adenoidectomy pain). Avoid in adolescents 12–18yrs with conditions associated with hypoventilation (eg, post-op status, obstructive sleep apnea, obesity, severe pulmonary disease, neuromuscular disease, concomitant drugs that cause respiratory depression). COPD, cor pulmonale, decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression; monitor and consider non-opioid analgesics..				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
403.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Romiplostim 250 microgram lyophilized powder for injection	Romiplostim INN 500 mcg /ml ready to fill sterile bulk 0.500ml eqv. to 250 mcg/Vial Romiplostin	Therapeutic Class: 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	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
404.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Bamlanivimab 700 mg/20 mL IV infusion and Etesevimab 700 mg/20 mL Infusion IV infusion Combipack.	Bamlanivimab 700 mg/20 mL IV infusion and Etesevimab 700 mg/20 mL Infusion IV infusion Combipack.	Therapeutic Class: Other Classification Therapeutic Code: 075	Bamlanivimab and etesevimab administered together 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 SARSCoV- 2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death Bamlanivimab and etesevimab administered together for the treatment of mild to moderate COVID- 19 in adults and pediatric patients.	Warnings and Precautions: Bamlanivimab and etesevimab are not authorized for use in patients 2 years and older who are hospitalized due to COVID-19. Bamlanivimab and etesevimab are not authorized for use in patients, regardless of age, who: o require oxygen therapy and/or respiratory support due to COVID-19, OR o require an increase in baseline oxygen flow rate and/or respiratory support due to COVID-19 and are on chronic oxygen therapy and/or respiratory support due to underlying non-COVID-19 related comorbidity. etesevimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.	New	USFDA - EUA	**EUA** প্রদানের সুপারিশ করা হয়।	**EUA** প্রদানের করা হয়।
405.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka Aristopharma	Casirivimab 120 mg/ml and Imdevimab 120 mg/ml concentrate for solution for	Casirivimab 300mg/2.5ml (120 mg/ml) and Imdevimab 300mg/2.5ml (120 mg/ml)	Therapeutic Class: Other Classification Therapeutic Code: 075	For the treatment of mild to moderate COVID-19 in adult and pediatric patients	Contraindication: Hypersensitivity including Anaphylaxis and Infusion-Related Reactions Signs and symptoms of infusion related reactions may include: fever, difficulty breathing, reduced oxygen saturation, chills, nausea, arrhythmia (e.g.,	New	USFDA-EUA	**EUA** প্রদানের সুপারিশ করা হয়।	**EUA** প্রদানের করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Ltd, Sampur, Kadamtali I/A, Dhaka.	infusion. For IV use after dilution.	combipack. concentrate for solution for infusion. or Casirivimab 1332mg/11.1ml (120 mg/ml) and Imdevimab 1332mg/11.1ml (120 mg/ml) combipack. concentrate for solution for infusion.			atrial fibrillation, tachycardia, bradycardia) chest pain or discomfort, weakness, altered mental status, headache, bronchospasm, hypotension, hypertension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, vasovagal reactions (e.g., pre-syncope, syncope) dizziness, fatigue, and diaphoresis Side-effects: Anaphylactic reactions , urticaria, pruritus, flushing, pyrexia, shortness of breath, chest tightness, nausea, vomiting, rash Warnings and Precautions: There are limited clinical data available for (casirivimab and imdevimab). Serious and unexpected adverse events may occur that have not been previously reported with its use.				
406.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka Ziska Pharmaceuticals Ltd.. Gazipur	Deflazacort 12 mg Tablet	Deflazacort INN 12 mg	Therapeutic Class: Steroidal Anti inflammatory Therapeutic Code: 072	Deflazacort is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older.	Contraindication: Hypersensitivity to deflazacort or any of the inactive ingredients in Deflazokort. Side-effects: The most common adverse reactions (≥ 10% for EMFLAZA and greater than placebo) are Cushingoid appearance, weight increased, increased appetite, upper respiratory tract infection, cough, pollakiuria, hirsutism, central obesity, and nasopharyngitis. Warnings and Precautions: Alterations in Endocrine Function: Hypothalamic-pituitary-adrenal axis suppression, Cushing's syndrome, and hyperglycemia can occur; Monitor patients for these conditions with chronic use of Deflazokort • Immunosuppression and Increased Risk of	Existing Deflazacort 6 mg Tablet (DCC-242)	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Infection: Increased risk of new, exacerbation, dissemination, or reactivation of latent infections, which can be severe and at times fatal; Signs and symptoms of infection may be masked • Alterations in Cardiovascular/Renal Function: Monitor for elevated blood pressure and sodium, qand for decreased potassium levels • Gastrointestinal Perforation: Increased risk in patients with certain GI disorders; Signs and symptoms may be masked • Behavioral and Mood Disturbances: May include euphoria, insomnia, mood swings, personality changes, severe depression, and psychosis				
407.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Paliperidone 1092/3.5 ml extended release injectable suspension in single dose prefilled syringe	Paliparidone Palmitate INN 1092.0000 mg/3.5ml eqv to 700 mg Paliparidone	Therapeutic Class: Antipsychotic Therapeutic Code: 028	PALIPERIDONE PALMITATE, an every-six-month injection, is an atypical antipsychotic indicated for the treatment of schizophrenia in adults after they have been adequately treated with: • A once-a-month paliperidone palmitate extended-release injectable suspension (e.g., INVEGA SUSTENNA) for at least four months or • An every-three-month paliperidone palmitate extended-release injectable suspension (e.g., INVEGA TRINZA) for at least one three-month cycle	Contraindication: Known hypersensitivity to paliperidone, risperidone, or to any excipients in paliperidone palmitate. Side-effects: The most common adverse reactions were upper respiratory tract infection, injection site reaction, weight increased, headache, and parkinsonism. Warnings and Precautions: For external use only. To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard. Do not touch unit-dose tip to eye. If solution changes color, do not use. Stop use and ask a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition	Existing Paliperidone 1.5 mg Extended Release Tablet (DCC-245).	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						worsens Stop use and ask a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens.				
408.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Paliperidone 1560/5 ml extended release injectable suspension in single dose prefilled syringe	Paliperidone Palmitate INN 1560.0000 mg/5 ml eqv. to 1000 mg Paliparidone.	Therapeutic Class: Antipsychotic Therapeutic Code: 028	PALIPERIDONE PALMITATE, an every-six-month injection, is an atypical antipsychotic indicated for the treatment of schizophrenia in adults after they have been adequately treated with: • A once-a-month paliperidone palmitate extended-release injectable suspension (e.g., INVEGA SUSTENNA) for at least four months or • An every-three-month paliperidone palmitate extended-release injectable suspension (e.g., INVEGA TRINZA) for at least one three-month cycle	Contraindication: Known hypersensitivity to paliperidone, risperidone, or to any excipients in paliperidone palmitate. Side-effects: The most common adverse reactions were upper respiratory tract infection, injection site reaction, weight increased, headache, and parkinsonism. Warnings and Precautions: For external use only. To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard. Do not touch unit-dose tip to eye. If solution changes color, do not use. Stop use and ask a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens Stop use and ask a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens	Existing Paliperidone 1.5 mg Extended Release Tablet (DCC-245).	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
409.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Ziconotide 25 mcg/1ml ; 20 ml vial of infusion	Ziconotide Acetate INN 25 mcg	Therapeutic Class: Analgesics and Antipyretics Therapeutic Code: 006	ZICONOTIDE ACETATE solution, intrathecal infusion is an N-type calcium channel antagonist indicated for the management of severe chronic pain in patients for whom intrathecal therapy is warranted, and who are intolerant of or refractory to other treatment,	Contraindication: Patients with a known hypersensitivity to ziconotide or any of its formulation components and in patients with any other concomitant treatment or medical condition that would render intrathecal administration hazardous. Patients with a pre-existing history of	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					such as systemic analgesics, adjunctive therapies, or intrathecal morphine	psychosis with ziconotide. Contraindications to the use of intrathecal analgesia include conditions such as the presence of infection at the microinfusion injection site, uncontrolled bleeding diathesis, and spinal canal obstruction that impairs circulation of cerebrospinal fluid (CSF). Side-effects: The most frequently reported adverse reactions (≥ 25%) in clinical trials were dizziness, nausea, confusional state, nystagmus. Warnings and Precautions: Cognitive and neuropsychiatric adverse reactions – Cognitive impairment and severe neuropsychiatric symptoms may occur with ZICONOTIDE ACETATEuse Meningitis and other infections - Patients, caregivers, and healthcare providers must be aware of the signs and symptoms of meningitis, including but not limited to fever, headache, stiff neck, altered mental status (e.g., lethargy, confusion, disorientation), nausea or vomiting, and occasionally seizures. Reduced level of consciousness - Patients may become unresponsive or stuporous while receiving ZICONOTIDE ACETATE				
410.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Nabumetone 1 gm Tablet	Nabumetone USP 1 gm	Therapeutic Class: Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic Code: 064	Nabumetone is indicated for acute and chronic treatment of signs and symptoms of osteoarthritis and rheumatoid arthritis.	Contraindication: Nabumetone is contraindicated in patients who have previously exhibited hypersensitivity to it. Nabumetone is contraindicated in patients in whom Nabumetone, aspirin, or other NSAIDs induce asthma, urticaria, or other allergic-type reactions. Fatal asthmatic reactions have been reported in such patients receiving NSAIDs.	Existing Nabumetone 500 mg Tablet, Nabumetone 750 mg Tablet (DCC-245)	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Side-effects: Adverse reaction information was derived from blinded-controlled and open-labeled clinical Trials and fromworldwide marketing experience. In the description below, rates of the more commonevents (greater than 1%) and many of the less common events (less than 1%) represent results of US Clinical studies.Of the 1,677 patients who received RELAFEN during US clinical trials, 1,524 were treated forat least 1 month, 1,327 for at least 3 months, 929 for at least a year, and 750 for at least 2 years. More than 300 patients have been treated for 5 years or longer. Warnings and Precautions: No data available				
411.	Incepta Pharmaceuticals Ltd.;Zirabo, Savar, Dhaka	Anirolumab-fnia 300 mg/2 ml in a single dose vial IV infusion	Anifrolumab-fria (150 mg/ml) ready to fill bulk INN 2.000 eqv. to Anifrolumab–fria 300 mg	Therapeutic Class: Other Classification Therapeutic Code: 075	For the treatment of: Moderate to severe systemic lupus erythematosus.	Contraindication: Anifrolumab-fnia is contraindicated in patients with a history of anaphylaxis with anifrolumab-fnia. Side-effects: Fever, sweating, or chills • muscle aches • cough • shortness of breath • burning when urinating • urinating more often • diarrhea or stomach pain • warm, red, or painful skin or sores. Warnings and Precautions: Stop administration in serious infection Use with caution in patients with Hypersensitivity Reactions Including Anaphylaxis Consider the individual benefit-risk in patients with known risk factors for malignancy.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Avoid use of live or live-attenuated vaccines in patients receiving Anifrolumab-fnia. Not Recommended for Use with Other Biologic Therapies.				
412.	Incepta Pharmaceuticals Ltd.;Dhamrai Unit, Dhaka	Estradiol 0.01g/100g Cream	Estradiol BP/PhEur .01 gm/100 gm	Therapeutic Class: Hormone Therapeutic Code: 056	Estradiol vaginal cream, USP, 0.01% is indicated in the treatment of vulvar and vaginal atrophy.	Contraindication estradiol vaginal cream, USP, 0.01%) should not be used in women with any of the following conditions: Undiagnosed abnormal genital bleeding. Known, suspected, or history of cancer of the breast. Known or suspected estrogen-dependent neoplasia. Active deep vein thrombosis, pulmonary embolism or history of these conditions. Active or recent (for example, within the past year) arterial thromboembolic disease (for example, stroke, myocardial infarction). Side-effects: Genitourinary System Changes in vaginal bleeding pattern and abnormal withdrawal bleeding or flow; breakthrough bleeding; spotting; dysmenorrhea, increase in size of uterine leiomyomata; vaginitis, including vaginal candidiasis; change in amount of cervical secretion; changes in cervical ectropion;	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						application site reactions of vulvovaginal discomfort including burning and irritation; genital pruritus; ovarian cancer; endometrial hyperplasia; endometrial cancer. Breasts: Tenderness, enlargement, pain, nipple discharge, galactorrhea; fibrocystic breast changes; breast cancer. Cardiovascular: Deep and superficial venous thrombosis; pulmonary embolism; thrombophlebitis; myocardial infarction; stroke; increase in blood pressure. Gastrointestinal: Nausea, vomiting; abdominal cramps, bloating; cholestatic jaundice; increased incidence of gallbladder disease; pancreatitis, enlargement of hepatic hemangiomas. Skin: Chloasma or melasma, thatmay persist when drug is discontinued; erythema multiforme; erythema nodosum; hemorrhagic eruption; loss of scalp hair; hirsutism; pruritus, rash. Eyes: Retinal vascular thrombosis, intolerance to contact lenses. Central Nervous System: Headache; migraine; dizziness; mental depression; chorea; nervousness; mood disturbances; irritability; exacerbation of epilepsy, dementia. Warning & Precaution: 1. Addition of a progestin when a woman has not had a hysterectomy Studies of the addition of a progestin for 10 or more days of a cycle of estrogen administration, or daily with estrogen in a continuous regimen, have				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						reported a lowered incidence of endometrial hyperplasia than would be induced by estrogen treatment alone. Endometrial hyperplasia may be a precursor to endometrial cancer. There are, however, possible risks which may be associated with the use of progestins with estrogens compared to estrogen-alone regimens. These include a possible increased risk of breast cancer. 2. Elevated blood pressure In a small number of case reports, substantial increases in blood pressure have been attributed to idiosyncratic reactions to estrogens. In a large, randomized, placebo-controlled clinical trial, a generalized effect of estrogens on blood pressure was not seen. Blood pressure should be monitored at regular intervals with estrogen use. 3. Hypertriglyceridemia: In patients with pre-existing hypertriglyceridemia, estrogen therapy may be associated with elevations of plasma triglycerides leading to pancreatitis and other complications. 4. Impaired liver function and past history of cholestatic jaundice: Estrogens may be poorly metabolized in patients with impaired liver function. For patients with a history of cholestatic jaundice associated with past estrogen use or with pregnancy, caution should be exercised and in the case of recurrence, medication should be discontinued. 5. Hypothyroidism: Estrogen administration leads to increased thyroid-binding globulin				

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)	আবেদন কারী প্রদত্ত USFDA, UKMHRA, EMA and BNF	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						(TBG) levels. Patients with normal thyroid function can compensate for the increased TBG by making more thyroid hormone, thus maintaining free T4 and T3 serum concentrations in the normal range. Patients dependent on thyroid hormone replacement therapy who are also receiving estrogens may require increased doses of their thyroid replacement therapy. These patients should have their thyroid function monitored in order to maintain their free thyroid hormone levels in an acceptable range.				

Annex-B: Proposed Product for Import (Human)

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
1.	**Manufacturer :** Neovii Biotech GmbH Am Haag 6+7 82166 Gräfelfing Germany **Local Agent:** Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000,	Grafalon 20mg /ml (Concentrated solution for infusion)	Anti-human T-lymphocyte immunoglobulin from rabbits	Immune-suppressant Therapeutic Code: 58	Grafalon is indicated in combination with other immunosuppressive medicinal products for the suppression of immune competent cells which are the cause for graft versus host disease after stem cell transplantation. Grafalon is indicated in adult patients for conditioning prior to stem cell transplantation (SCT) Grafalon is indicated for prevention of graft-versus-host disease (GvHD) after stem cell transplantation with matched, HLA-compatible, unrelated donors in adult patients with malignant hematological diseases in combination with standard therapy	**Contra-indication:** Grafalon is contraindicated in patients with bacterial, viral, mycotic or parasitic infections which are not under adequate therapeutic control **Side-effect:** hypersensitivity reactions such as anaphylaxis and other allergic phenomena, enhanced susceptibility to infections, and occurrence of malignan+cies	New	CPP-Germany.	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।।
2.	Medentech Ltd., Clonard Road, Wexford, Co Wexford, Ireland **Local Agent:** Purplefrog, 15 Eskaton Garden, Ramna, Dhaka-1000	Aquatabs 33mg	Troclosen Sodium 58.20% w/w	Antiseptic and Disinfectants Therapeutic Class: 29	Aquatabs 33mg Tablets are used for disinfection of drinking water for human consumption.	Eye Irritant: Category 2- causes serious eye irritation. Target Organ Toxicity (single exposure) : Category -3 May cause respiratory tract irritation. Hazardous to Aquatic Environment-Acute Hazard: Category 1 –Very toxic to aquatic life. Hazardous to Aquatic Environment- Chronic Hazard: Category 1 –Very toxic to aquatic life with long lasting effects.	New	Ireland এর department of Environment –FSC	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
3.	Manufacturer: Lilly France S.A.S,2 rue du colonel Lilly,67640 Fegersheim. France License Holder: Lilly France S.A.S, F-67640 Fegersheim, France, Packaging by EIi Lilly & Company, Indianapolis, IN 46285, USA' Local Agent: Healthcare Pharmaceuticals Ltd	HUMALOG U-200 KwikPen (200 units per mL) 3 ml Prefilled Pen/ Cartridge (600 Units /Pen or Cartridge)	Insulin lispro (200 units per mL)	Therapeutic Class: Antidiabetes Therapeutic code: 015	HUMALOG is a rapid acting human insulin analog indicated to improve glycemic control in adults and children with diabetes mellitus.	Side Effects: Adverse reactions associated with HUMALOG include hypoglycemia, allergic reactions, injection site reactions, lipodystrophy, pruritus, and rash. Contraindication: •Do not use during episodes of hypoglycemia. • Do not use in patients with hypersensitivity to HUMALOG or any of its excipients.	Insulin lispro 100 Units/ ml KwikPen & Cartridge	CPP- USFDA CPP- EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।।
4.	**Manufacturer:** Corden Pharma S.p.A, Italy **Local Representative:** Novartis (Bangladesh)	LEQVIO	Inclisiran INN 284 mg/1.5 mL Solution for injection in Pre-filled Syringe (PFS)	Lipid Lowering Agent Therapeutic Class: 061	Leqvio is indicated in adult with primary hypercholesterolemia (heterozygous familial and non-familial) or mixed dyslipidemia, as an adjunct to diet: In combination with a statin or statin with other lipid-lowering	**Contraindication:** • Hypersensitivity to the active substance or to any of the excipients. **Side Effects:** **General disorders and administration site**	New	EMA স্থানীয়ভাবে উৎপাদনের জন্যও আবেদন করা হয়েছে। SI: ৩৩১	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Limited. Tower One One Seven (Level 5) Plot # 117/A, Tejgaon I/A, Dhaka 1208, Bangladesh.				therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.	**conditions**: adverse events at the injection site				
5.	**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.	Cosentyx	Secukinumab INN 300 mg/2 ml Solution for Injection in Pre-filled Syringe (PFS)	Drugs used in arthritis Therapeutic Class: **064**	**Adult Plaque Psoriasis**: Cosentyx is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. **Paediatric Plaque Psoriasis:** Cosentyx is indicated for the treatment of moderate to severe plaque psoriasis in children and adolescents from the age of 6 years who are candidates for systemic therapy. **Psoriatic arthritis** Cosentyx, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.	**Contraindication:** • Hypersensitivity to the active substance or to any of the excipients. • Clinically important, active infection, e.g. active tuberculosis. **Side Effects:** **Infections and infestations:** Upper respiratory tract infections, Oral herpes. **Nervous system disorder**: Headache, **Respiratory, thoracic and mediastinal disorders**: Rhinorrhoea, **Gastrointestinal disorders**: Diarrhoea, nausea. **General disorders and administrative site conditions**: Fatigue	Cosentyx 150mgl/ml	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					Axial spondyloarthritis (axSpA): **Ankylosing spondylitis (AS, radiographic Axial spondyloarthritis):** Cosentyx is indicated for the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy. **Non-radiographic axial spondyloarthritis (nr-axSpA):** Cosentyx is indicated for the treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs). **Juvenile Idiopathic Arthritis (JIA)** **Enthesitis-Related Arthritis (ERA):** Cosentyx is indicated for the					

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					treatment of active enthesitis-related arthritis in patients 2 years and older. **Juvenile Psoriatic Arthritis (JPsA):** Cosentyx is indicated for the treatment of active juvenile psoriatic arthritis in patients 2 years and older.					
6.	Zenith Micro Control, India Local Agent: SP Trading House, 24-25, Dilkusha C/A, Dhaka	Mi-Fog Plus	Quaternary Ammonium Compound and Biguanide Surface Disinfectant	Antiseptic and Disinfectants Therapeutic Class: 29			New	India **রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স না থাকায় নামঞ্জুর করা হয়।
7.	Japan Bio Products Co., Ltd., L'Atelier Fujiitsu 735 -14, Aza Edamitsu, Fujimitsu -machi, Kurume-shi, Fukuoka -ken, Japan **Local Agent:** Renata Limited Mirpur, Dhaka	Laennec Injection (Human-placental 112 mg/2ml Injection)	Water soluble substance of a product of enzymatic human placental 112 mg/2ml	Liver Therapy	Improvement of hepatic function in chronic liver diseases	**Contraindication :** Patients with a history of hypersensitivity to this product. **Side-effect:** hypersensitivity (such as rash, fever, and itching), injection site indurations, and gynaecomastia.	New	CoPP & FSC from Japan	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
8.	Guerbet Bp 57400 95943 Roissy Charles De Gaulle Cedex 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	LIPIODOL ULTRA FLUIDE 480 mg /ml, solution for injection	Ethyl esters of iodised fatty acids of poppy seed oil 480 mg/ml, solution for injection	Other Classification Therapeutic Class: 75	<u>In diagnostic radiology:</u> • Lymphography. • Diagnosis of hepatic lesions. Selective hepatic arterial diagnosis of the hepatic expansion of hepatic or non-hepatic malign lesions. <u>In interventional radiology</u>: • Visualisation, localisation and vectorisation during transarterial chemoembolisation of intermediate-stage hepatocellular carcinoma in adults. • Embolisation with surgical glue. In combination with surgical glue for vascular embolisation. <u>In endocrinology:</u> The use of LIPIODOL in the prevention of iodine deficiency must be reserved exclusively for countries where it is impossible to use other supplementation methods, particularly iodisation of salt and/or drinking water.	**Contraindications:** <u>Hypersensitivity to LIPIODOL ULTRA FLUIDE (ethyl esters of iodised fatty acids of poppy seed oil).</u> • Pregnant women. • Proven hyperthyroidism. • Trauma injuries, haemorrhages or recent bleeding episodes (risk of extravasation or embolism). • Bronchography (the product would quickly flood the bronchioles and alveoli). <u>Contraindications specific to use in interventional radiology:</u> • Transarterial chemoembolisation: Mixing with LIPIODOL ULTRA FLUIDE to treat hepatocellular carcinoma may cause both ischaemic and toxic effects for the gallbladder. Administration is therefore contraindicated in hepatic areas where the bile ducts are dilated, unless post-procedure drainage is possible. • Intra-arterial injection of LIPIODOL ULTRA FLUIDE may cause total obstruction of the hepatic artery and total suppression of arterial flow. This should only be considered after having made sure, via imaging or angiography, that there is at least partial portal vascular flow.	New	FSC-FRANCE	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						• Embolisation with surgical glue. There are no particular contraindications except for those of embolisation and, especially, the presence of portal thrombosis. <u>Contraindications specific to use in endocrinology:</u> • Large, multi-nodular goitre in patients over 45 years of age, due to the significant risk of hyperthyroidism. • During breast-feeding. **<u>Side-effects:</u>** In diagnostic radiology: • Lymphography: A sharp increase in temperature followed by a fever of 38 °C to 39 °C may occur within 24 hours following the examination. Fat micro-emboli may occur with or without symptoms. In very rare cases, they may resemble organic emboli in their appearance and size. They most commonly present as punctiform opacities on lung X-rays. Temporary increases in temperature are possible. Fat micro-emboli usually occur following an overdose of contrast agent or excessively rapid infusion. Anatomical abnormalities such as lymphovenous fistulas or a decrease in the capacity of				

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						lymph nodes to retain the contrast agent (in elderly patients, or after radiotherapy or cytostatic therapy) make their occurrence more likely. Patients with a right-to-left cardiac shunt and those with a massive pulmonary embolism are particularly at risk for fat micro-emboli in the brain. • Diagnosis of hepatic lesions: The patient's temperature frequently rises and other rarer complications may be seen, such as nausea, vomiting and diarrhoea. In interventional radiology: • Transarterial chemoembolisation: Most adverse reactions are not caused by LIPIODOL ULTRA FLUIDE but rather by anti-cancer medicines or the embolisation itself. The most common adverse reactions to treatment by transarterial chemoembolisation are post-embolisation syndrome (fever, abdominal pain, nausea, vomiting) and temporary changes in liver function tests. Pre-existing hepatocellular deficiency may be exacerbated following use of Lipiodol as part of a hepatic intra-arterial procedure and result in serious				

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						and potentially fatal complications such as hepatic encephalopathy, ascitic oedematous decompensation, hepatic necrosis, liver abscess, pancreatitis or even necrotising pancreatitis. • Embolisation with surgical glue: No adverse reactions have been specifically directly linked to LIPIODOL ULTRA FLUIDE. • In endocrinology: Hyperthyroidism				
9.	**Manufacturer :** Adienne SA Via Zurigo,46 6900 Lugano, Switzerland. **Local Agent:** Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000,	TEPADINA (Powder for concentrated solution for infusion)	Thiotepa 100mg /Vial	Anti Cancer Therapeutic Class: 10	TEPADINA is indicated, in combination with other chemotherapy)- medicinal! Products: with or without total body irradiation (TBI), as conditioning treatment prior to allogeneic or autologous hematopoietic progenitor cell transplantation (HPCT) in hematological diseases in adult and pediatric patients; • when high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumors in adult and pediatric patients	**Contraindication** Thiotepa is contraindicated in patients with a known hypersensitivity (allergy) to this preparation.Therapy is probably contraindicated in cases of existing hepatic, renal, or bone-marrow damage. However, if the need outweighs the risk in such patients, thiotepa may be used in low dosage, and accompanied by hepatic, renal and hemopoietic function tests **Side effects** General: Fatigue, weakness. Febrile reaction and discharge from a subcutaneous lesion may occur as the result of breakdown of	Thiotepa 15 mg /Vial DCC-252 তে অনুমোদিত।	CPP-Switzerland.	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						tumor tissue. Hypersensitivity Reactions: Allergic reactions - rash, urticaria, laryngeal edema, asthma, anaphylactic shock, wheezing. Gastrointestinal: Nausea, vomiting, abdominal pain, anorexia. Neurologic: Dizziness, headache, blurred vision.				
10.	**Manufacturer :** Adienne S.r.l Via Galileo Galilei 19, 20867, Caponago (MB), Italy. **Local Agent:** Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000,	TEPADINA (Powder for concentrated solution for infusion)	Thiotepa 400mg / Vial	Anti Cancer Therapeutic Class: 10	TEPADINA is indicated, in combination with other chemotherapy)- medicinal Products: with or without total body irradiation (TBI), as conditioning treatment prior to allogeneic or autologous hematopoietic progenitor cell transplantation (HPCT) in hematological diseases in adult and pediatric patients; • when high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumors in adult and pediatric patients	**Contraindication** Thiotepa is contraindicated in patients with a known hypersensitivity (allergy) to this preparation.Therapy is probably contraindicated in cases of existing hepatic, renal, or bone-marrow damage. However, if the need outweighs the risk in such patients, thiotepa may be used in low dosage, and accompanied by hepatic, renal and hemopoietic function tests **Side effects** General: Fatigue, weakness. Febrile reaction and discharge from a subcutaneous lesion may occur as the result of breakdown of tumor tissue. Hypersensitivity Reactions: Allergic reactions -	Thiotepa 15 mg /Vial DCC-252 তে অনুমোদিত।	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						rash, urticaria, laryngeal edema, asthma, anaphylactic shock, wheezing. Gastrointestinal: Nausea, vomiting, abdominal pain, anorexia. Neurologic: Dizziness, headache, blurred vision.				
11.	**Manufacturer :** Centre Spécialités Pharmaceutiques 76-78 avenue du Midi F-63800 Cournon d'Auvergne France. **Local Agent:** Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Kigabeq 100 mg (Soluble tablets)	Vigabatrin 100mg	Drug used in Epilepsy Therapeutic Class: 46	Adjunctive treatments of partial seizures with or without secondary generalization not satisfactory controlled with other antiepileptic; monotherapy for management of infentile spasm.	**Contraindication:** Vigabatrin causes permanent bilateral concentric visual field constriction in 30% or more of adult patients; the incidence in pediatric patients is not well defined, but is estimated at 20%. The visual field defect and resultant visual impairment can range in severity from mild to severe, including tunnel vision to within 10 degrees of visual fixation. Vigabatrin can also cause decreased visual acuity due to central retina damage. The onset of the vision disturbance can occur at any time during therapy, even after months or years. The risk increases with increasing dose and duration; there is no known risk-free exposure. Vision may worsen after vigabatrin discontinuation. Vigabatrin should be used at the lowest	New	CPP- EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						dose and shortest duration necessary to achieve clinical goals. Vigabatrin should not be used in patients with other risk factors for irreversible vision loss unless the benefits outweigh the risks. Vigabatrin also should not be used in patients taking other drugs that may cause serious ophthalmic adverse effects **Side Effect:** Serious side effects Get medical advice immediately if your child has the following: Very common side effects (may affect more than 1 in 10 people) Visual field changes – About 33 out of 100 patients treated with vigabatrin may have changes in the visual field (narrow visual field). This visual field defect can range from mild to severe. It is usually detected after months or years of treatment with vigabatrin. The changes in the visual field may be permanent, so it is important to detect them early to avoid progression . If your child has visual disturbances, contact				

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						your child's doctor or hospital immediately. Other side effects include: Very common side effects (may affect more than 1 in 10 people) excitation or restlessness tiredness and pronounced sleepiness joint pain Common side effects (may affect up to 1 in 10 people) - headache - weight gain - shaking (tremor) - swelling (oedema) - dizziness - sensation of numbness or tingling (pins and needles) - reduced concentration and memory				
12.	**Manufacturer :** Luye Pharma AG Am Windfeld 35 83714 Miesbach Germany. **Local Agent:** Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000,	Rivastigmine Luye 13.3 mg /24 hours (Transdermal patch)	One Transdermal patch (12.8 cm2) contains 19.2 mg Rivastigmine	Antiparkinsonism Therapeutic Class: 25	Treatment of patients with: Mild to moderately severe dementia of the Alzheimer's type, Severe dementia of the Alzheimer's type, Mild to moderately severe dementia associated with Parkinson's disease.	**Contraindications:** The use of this medicinal product is contraindicated in patients with known hypersensitivity to the active substances rivastigmine, to other carbamate derivatives or to any of the excipients. Previous history of application site reactions suggestive of allergic contact dermatitis with rivastigmine patch. **Side effects:** Anxiety,	New	CPP-Germany.	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						headache, dizziness, vomiting&nausea.				
13.	**Manufacturer :** Luye Pharma AG Am Windfeld 35 83714 Miesbach Germany. **Local Agent:** Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000,	Rivastigmine Luye 9.5 mg/24 hours. (Transdermal patch)	One Transdermal patch (9.2 cm2) contains 13.8 mg Rivastigmine	Antiparkinsonism Therapeutic Class: 25	Treatment of patients with: Mild to moderately severe dementia of the Alzheimer's type, Severe dementia of the Alzheimer's type, Mild to moderately severe dementia associated with Parkinson's disease.	**Contraindications:** The use of this medicinal product is contraindicated in patients with known hypersensitivity to the active substances rivastigmine, to other carbamate derivatives or to any of the excipients. Previous history of application site reactions suggestive of allergic contact dermatitis with rivastigmine patch. **Side effects:** Anxiety, headache, dizziness, vomiting&nausea.	New	CPP-Germany.	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
14.	**Manufacturer :** Luye Pharma AG Am Windfeld 35 83714 Miesbach Germany. **Local Agent:** Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000	Rivastigmine Luye 4.6 mg/24 hours (Transdermal patch)	One Transdermal patch (4.6 cm2) contains 6.9 mg Rivastigmine	Antiparkinsonism Therapeutic Class: 25	Treatment of patients with: Mild to moderately severe dementia of the Alzheimer's type, Severe dementia of the Alzheimer's type, Mild to moderately severe dementia associated with Parkinson's disease.	**Contraindications:** The use of this medicinal product is contraindicated in patients with known hypersensitivity to the active substances rivastigmine, to other carbamate derivatives or to any of the excipients. Previous history of application site reactions suggestive of allergic contact dermatitis with rivastigmine patch. **Side effects:** Anxiety, headache, dizziness,	New	CPP-Germany.	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						vomiting&nausea.				
15.	**Manufacturer :** ADIENNE Srl SU, Via Galileo Galilei 19, 20867 Caponago MB, Italy. **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000,	PHELINUN 200 mg (Powder and solvent for concentrated solution for infusion)	Melphalan 200mg/40ml (as Melphalan hydrochloride)	Anti Cancer Therapeutic Class: 10	Melphalan for Injection is indicated for the palliative Treatment of patients with multiple myeloma for whom oral therapy is not appropriate.	**Contra-indication:** History of serious allergic reaction to melphalan. **Side-effect:** Most common adverse reactions observed in at least 50% of patients treated with Melphalan are neutrophil count decreased, white blood cell count decreased, lymphocyte count decreased, platelet count decreased, diarrhea, nausea, fatigue, hypokalemia, anemia, and vomiting.	Melphalan 2mg Tablet Melphalan 50 mg/10 ml DCC-251 তে অনুমোদিত।	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
16.	**Manufacturer :** Dr. Franz Köhler Chemie Gmbh Werner-von-Siemens-Str 14-28 64625 Bensheim, Germany. . **Local Agent:** Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor)	Custodiol (Perfusion Solution) Organ preservation solutions	1000 ml solution contain: sodium chloride 0.8766 g eq to 15.0 mmol potassium chloride 0.6710 g eq to 9.0 mmol, magnesium chloride • 6 H2O 0.8132 g Eq. to 4.0 mmol, histidine	Other Classification Therapeutic Class: 75	CUSTODIOL® is indicated for preservation of multiorgan transplants (heart, kidney, liver, pancreas, lung), together with venous or arterial segments. Custodiol is an intracellular crystalloid cardioplegic solution used for myocardial protection in complex cardiac surgery and for organ preservation in transplant surgery	**Contra-indication:** There are no known contraindications when used as directed. **Side-effect:** None	New	CPP-Germany.	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Dhaka-1000,		hydrochloride • H2O 3.7733 g eq. to 18.0 mmol, histidine 27.9289 g eq. to 180.0 mmol, tryptophan 0.4085 g eq. to 2.0 mmol, 5.4651 g mannitol eq. to 30.0 mmol, calcium chloride x 2 H2O eq. to 0.0022 g 0.015 mmol, potassium hydrogen 2-oxopentandioate 0.1842 g eq to 1.0 mmol (Synonym: potassium hydrogen 2-ketoglutarate)							
17.	**Manufacturer :** EVER Pharma Jena GmbH Otto-Schoot-Str.15 07745 Jena Germany .	Cabazitaxel EVER Pharma 10mg/ml, (Concentrated solution for infusion)	Cabazitaxel 10mg/ml	Anti Cancer Therapeutic Class: 10	In combination with oral Prednisone for treatment of Patients with hormonerefractory metastatic Prostate Cancer Previously treated with a docetaxelcontaining treatment regimen	**Contra-indication:** Hypersensitivity to one of the components of Cabazitaxel. Epilepsy. Severe renal impairment. **Side-effect:** Heartburn, change in ability to taste food, loss of appetite,	New	CPP-Germany.	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Local Agent: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000,					weight loss, swelling of the inside of the mouth, headache, joint or back pain, numbness, burning, or tingling in the hands, arms, feet, or legs hair loss				
18.	**Manufacturer :** EVER Neuro Pharma GmbH Oberburgau 3 4866 Unterach Austria. **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000,	Dopaceptin 10 mg/ml, (Solvent for solution for injection in cartridge)	Apomorphine Hemihydrated chlorhydrate 10mg/ml	Opioid Analgesics Therapeutic Class: 65	Treatment of motor fluctuations ("on-off" phenomena) in patients with Parkinson's disease which are not sufficiently controlled by oral anti-Parkinson medication	**Contra-indication:** In patients with respiratory depression, dementia, psychotic diseases or hepatic insufficiency. Apomorphine hydrochloride hemihydrate must not be administered to patients who have an "on" response to levodopa which is marred by severe dyskinesia or dystonia. Concomitant use with ondansetron **Side-effect:** Nausea, Vomiting, Constipation, Diarrhea, Headache, Yawning, runny nose, weakness, arm, leg, or back pain, pain or difficulty in urination, soreness, redness, pain, bruising, swelling, or itching in the place where you injected apomorphin.	New	CPP- Austria & France স্থানীয়ভাবে উৎপাদনের জন্যও আবেদন করা হয়েছে। SI: ২৮২	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
19.	**Manufacturer :** EVER Pharma Jena GmbH Otto-Schoot-Str.15 07745 Jena, Germany **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000,	Dacepton 5 mg/ml (Solution for infusion)	Apomorphine hydrochloride hemihydrate, 5mg/ml	Opioid Analgesics Therapeutic Class: 65	Treatment of motor fluctuations ("on-off" phenomena) in patients with Parkinson's disease which are not sufficiently controlled by oral anti-Parkinson medication	**Contra-indication:** In patients with respiratory depression, dementia, psychotic diseases or hepatic insufficiency. Apomorphine hydrochloride hemihydrate must not be administered to patients who have an "on" response to levodopa which is marred by severe dyskinesia or dystonia. Concomitant use with ondansetron **Side-effect:** Nausea, Vomiting, Constipation, Diarrhea, Headache, Yawning, runny nose, weakness, arm, leg, or back pain, pain or difficulty in urination, soreness, redness, pain, bruising, swelling, or itching in the place where you injected apomorphin.	New	CPP-Germany.	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
20.	**Manufacturer :** Partner Therapeutics, Inc., Lexington, MA 02421, USA.	Leukine 250 mcg Injection	Sargramustim 250 mcg	Immune-suppressant Therapeutic Class:58	To shorten time to neutrophil recovery and to reduce the incidence of severe and life threatening infections and infections resulting in death following induction chemotherapy in adult patients 55 years and older with acute	**Contra-indication:** Do not administer LEUKINE to patients with a history of serious allergic reactions, including anaphylaxis, to human granulocyte-macrophage colony stimulating factor such as sargramostim,	New	CPP-USA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Local Agent: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.				myeloid leukemia (AML). • For the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis and autologous transplantation in adult patients. • For the acceleration of myeloid reconstitution following autologous bone marrowor peripheral blood progenitor cell transplantation in adult and pediatric patients 2 years of age and older. • For the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation in adult and pediatric patients 2 years of age and older. • For treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation in adult and pediatric patients 2 years of age and older. • To increase survival in adult and pediatric patients from birth to 17 years of age acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of	yeast-derived products, or any component of the product. Anaphylactic reactions have been reported with LEUKINE. **Side-effect:** swelling, breathing problems; stomach pain, nausea, vomiting, diarrhea; loss of appetite, weight loss; urination problems; fever, weakness, not feeling well; mouth sores; headache, high blood pressure; numbness, tingling, rash, itching;				

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					Acute Radiation Syndrome					
21.	**Manufacturer :** EVER Pharma Jena GmbH, Brüsseler Str. 18, 07747 Jena, Germany. **Local Agent:** Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Cerebrolysin 2152mg/10ml (Solution for injection)	Cerebrolysin 215.2mg/ml	Neuromuscular Blocking Therapeutic Class: 63	Neurodegenerative disorders of the brain, dementia of Alzheimer's Type.	**Contra-indication:** Hypersensitivity to one of the components of Cerebrolysin. Epilepsy. Severe renal impairment. **Side-effect:** The side effects of Cerebrolysin® are rare and of mild intensity. The most frequently reported adverse reactions with Cerebrolysin® are dizziness, headache, sweating, and nausea	New	CPP-Germany	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
22.	**Manufacturer :** MEDIVATORS Inc. 14605 28th Avenue North Minneapolis, MN 55447, USA. **Local Agent:** Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor)	Rapicide OPA / 28 (High-Level Disinfectant Solution)	Orthro-Phthalaldehyde	Antiseptic and Disinfectants Therapeutic Class: 29	High-level Disinfactant solution for medical devices Sanitization.	**Contra-indication:** None **Side-effect:** None	New	CFG-USA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Dhaka-1000,									
23.	**Manufacturer :** Nikko Pharmaceutical Co. Ltd. Hashima inter Plant 2501-1 Nagama, Japan. **Local Agent:** Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000,	Steriscope 3W/V% Solution	Glutaraldehyde 30.9 g/1000 ml	Antiseptic and Disinfectants Therapeutic Class: 29	Disinfection of the endoscope	**Contra-indication:** None **Side-effect:** None	Glutaraldehyde 2.5% DCC – 252 তে অনুমোদিত।	CPP- Japan	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
24.	**Manufacturer :** Nikko Pharmaceutical Co. Ltd. Hashima inter Plant 2501-1 Nagama, Japan. **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000,	Sterihyde L 20W/V% Solution	Glutaraldehyde 200g/1000ml	Antiseptic and Disinfectants Therapeutic Class: 29	It is a chemical sterilization and sterilizing disinfectant dedicated to medical instruments, devices and devices	**Contra-indication:** None **Side-effect:** None	Glutaraldehyde 2.5% DCC – 252 তে অনুমোদিত।	CPP- Japan	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
25.	**Manufacturer :** SERAG-	LAVANID 1	Polyhexanide 0.02%	Antiseptic and	For the topical irrigation and cleansing of wounds.For	**Contra-indication:** None	New	FSC- Germany.	অনুমোদনের সুপারিশ করা	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	WIESSNER GmbH & Co. KG Zum Kugelfang 8-12 95119 Naila, Germany. **Local Agent:** Zas Industries., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000,		Solution	Disinfectants Therapeutic Class: 29	moistening swabs, tamponades and dressings	**Side-effect:** None			হয়।	
26.	**Manufacturer :** SERAG-WIESSNER GmbH & Co. KG Zum Kugelfang 8-12 95119 Naila, Germany. **Local Agent:** Zas Industries., 80/22 Mymenshing Road	LAVANID 2	Polyhexanide 0.04% Solution	Antiseptic and Disinfectants Therapeutic Class: 29	For the topical irrigation and cleansing of wounds.For moistening swabs, tamponades and dressings	**Contra-indication:** None **Side-effect:** None	New	FSC-Germany.	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
27.	Made for F. Hoffmann-La Roche, Ltd. Basel, Switzerland. by Chugai Pharma Manufacturing Co., Ltd., Japan	Enspryng 120 mg for Subcutaneous Injection (Prefilled syringe)	Satralizumab INN	Immune-suppressant Therapeutic Class: 58	Enspryng is indicated as monotherapy or in combination with immunosuppressive therapy (IST) for the treatment of adult and adolescent patients with neuromyelitis optica spectrum disorder (NMOSD).	**Contraindication**: Enspryng is contraindicated in patients with a known hypersensitivity to satralizumab or any of the excipients. **Side effects**: Headache, Migraine, Injection-related reactions, Arthralgia,	New	Cpp-Japan	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Local agent: Roche Bangladesh Limited					Musculoskeletal stiffness, Rash, Pruritus, Insomnia, Oedema peripheral, Rhinitis allergic, Hyperfibrinogenemia, White blood cell count decreased, Blood bilirubin increased, etc.				
28.	Made in Switzerland. by F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, 4070, Basel, Switzerland **Local agent:** Roche Bangladesh Limited	Evrysdi Power for Oral Solution 0.75 ml/ml	Risdiplam INN	Skeleton Muscle Relaxan Therapeutic Class: 70	Evrysdi is indicated for the treatment of spinal muscular atrophy (SMA)	**Contraindication**: Evrysdi is contraindicated in patients with a known hypersensitivity to risdiplam or any of the excipients. **Side effects:** Gastrointestinal Disorders, Skin and Subcutaneous Tissue Disorders, Gastrointestinal Disorders, Skin and Subcutaneous Tissue Disorders, Includes rash, rash maculo-papular, erythema, dermatitis allergic, rash erythematous, folliculitis, rash papular, etc.	New	CPP - Switzerland স্থানীয়ভাবে উৎপাদনের জন্য আবেদন করা হয়েছে। SI: ২৭৬	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
29.	Made in Switzerland by F. Hoffmann-La Roche Ltd, Basel **Local agent:** Roche Bangladesh Limited	Phesgo 1200 mg/600 mg Solution for subcutaneous Injection	Pertuzumab 1200 mg INN + Trastuzumab 600 mg INN	Anti Cancer Therapeutic Class: 10	**Early Breast Cancer (EBC)** Phesgo is indicated in combination with chemotherapy for the: Neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either >2 cm in diameter or node positive) as part of a complete treatment	**Contraindication**: Phesgo is contraindicated in patients with a known hypersensitivity to pertuzumab, trastuzumab or any of the excipients. **Side effects**: Common or very common: Anemia, Chorioretinopathy, Vision blurred,Retinal detachment, Diarrhea, Nausea, Vomiting, Pyrexia, Chills, Dehydration, Hyponatremia	New	CPP- Switzerland	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					regimen for early breast cancer. Adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence. **Metastatic Breast Cancer (MBC)** Phesgo is indicated in combination with docetaxel for patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.	Photosensitivity Maculo-papular, rash, Acneiform dermatitis, etc.				
30.	Made in Switzerland by F. Hoffmann-La Roche Ltd, Basel **Local agent:** Roche Bangladesh Limited	Phesgo 600 mg/600 mg Solution for subcutaneous Injection	Pertuzumab 600 mg INN + Trastuzumab 600 mg INN	Anti Cancer Therapeutic Class: 10	**Early Breast Cancer (EBC)** Phesgo is indicated in combination with chemotherapy for the: Neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either >2 cm in diameter or node positive) as part of a complete treatment	**Contraindication**: Phesgo is contraindicated in patients with a known hypersensitivity to pertuzumab, trastuzumab or any of the excipients. **Side effects**: Common or very common: Anemia, Chorioretinopathy, Vision blurred,Retinal detachment, Diarrhea, Nausea, Vomiting, Pyrexia, Chills, Dehydration, Hyponatremia Photosensitivity Maculo-	New	CPP-Switzerland	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					regimen for early breast cancer. Adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence. **Metastatic Breast Cancer (MBC)** Phesgo is indicated in combination with docetaxel for patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.	papular, rash, Acneiform dermatitis, etc.				
31.	Made for F. Hoffmann-La Roche, Ltd. Basel, Switzerland. by F. Haffmann-La Roche Ltd. Wurmisweg, 4303 Kaiseragust, Switzerland **Local agent:** Roche Bangladesh Limited	Polivy 30 mg vial powder for concentrate for solution for infusion	Polatuzumab Vedotin 30 mg INN	Anticancer Therapeutic Code: 010	Polivy in combination with bendamustine and rituximab is indicated for the treatment of adult patients with diffuse large B-cell lymphoma who have received at least one prior therapy.	**Contraindication** Polivy is contraindicated in patients with a known hypersensitivity to polatuzumab vedotin or any of the excipients. **Side effects**: Anemia, thrombocytopenia, neutropenia, fatigue, diarrhea, nausea, and pyrexia	Polivy 140 mg/ 20 ml vial DCC-252 তে অনুমোদিত।	CPP-Switzerland	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
32.	Boehringer Ingelheim Pharma GmbH and Co. KG, Germany. **Local agent:**	Glyxambi Film Coated Tablet	Empagliflozin 10mg + Linagliptin 5mg	Antidiabetic Therapeutic Code:015	Glyxambi, fixed dose combination of empagliflozin and linagliptin, is indicated in adults aged 18 years and older with type 2 diabetes mellitus:	**Contraindication:** Hypersensitivity to empagliflozin or linagliptin or any of the excipients. **Side effects:** Common side effects of	Empaglifl ozin 10mg and 25mg Tablet,	USFDA স্থানীয়ভাবে উৎপাদনের জন্যও	পদটি স্থানীয়ভাবে উৎপাদনের জন্য সুপারিশ	পদটি স্থানীয়ভাবে উৎপাদনের জন্য অনুমোদন

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Radiant Export Import Enterprise Lubdhok, 4th Floor, 474P, Road CNo-3, Sector-12, Uttara, Dhaka 1230, Bangladesh.				to improve glycaemic control when metformin and/or sulphonylurea (SU) one of the monocomponents of Glyxambi do not provide adequate glycaemic control when already being treated with the free combination of empagliflozin and linagliptin.	Glyxambi: Urinary tract infection, common cold symptoms, upper respiratory tract infections, genital yeast infection, increased urination, joint pain, nausea, runny or stuffy nose, diarrhoea, cough **Adverse Drug reactions:** **Infections and infestations** Vaginal moniliasis, vulvovaginitis, balanitis and other genital infections Urinary tract infection(including pyelonephritis and urosepsis) Nasopharyngitis **Immune system disorders** Hypersensitivity Angioedema Urticaria **Metabolism and nutrition disorders** Hypoglycaemia (when used with sulphonylurea or insulin) Ketoacidosis **Renal and urinary disorders** Increased urination Dysuria **Respiratory, thoracic & mediastinal disorders** Cough **Skin and subcutaneous tissue disorders** Rash Pruritus	Linagliptin 5 mg Tablet	আবেদন করা হয়েছে। SI: 01 ডিসিসি-২৫২ তম সভায় উক্ত পদটি ডিসিসি-২৫৩ তম সভায় উপস্থাপনের সিদ্ধান্ত প্রদান করা হয়েছিল।	করা হয়েছে। আমদানির প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	করা হয়েছে। আমদানির প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
33.	Boehringer Ingelheim Pharma GmbH and Co. KG, Germany. **Local agent:** Radiant Export Import Enterprise Lubdhok, 4th Floor, 474P, Road CNo-3, Sector-12, Uttara, Dhaka 1230, Bangladesh.	Glyxambi Film Coated Tablet	Empagliflozin 25mg + Linagliptin 5mg	Antidiabetic Therapeutic Code:015	Glyxambi, fixed dose combination of empagliflozin and linagliptin, is indicated in adults aged 18 years and older with type 2 diabetes mellitus: to improve glycaemic control when metformin and/or sulphonylurea (SU) one of the monocomponents of Glyxambi do not provide adequate glycaemic control when already being treated with the free combination of empagliflozin and linagliptin.	**Contraindication:** Hypersensitivity to empagliflozin or linagliptin **or** any of the excipients. **Side effects:** **Common side effects of** Glyxambi: Urinary tract infection, common cold symptoms, upper respiratory tract infections, genital yeast infection, increased urination, joint pain, nausea, runny or stuffy nose, diarrhoea, cough **Adverse Drug reactions:** **Infections and infestations** Vaginal moniliasis, vulvovaginitis, balanitis and other genital infections Urinary tract infection(including pyelonephritis and urosepsis) Nasopharyngitis **Immune system disorders** Hypersensitivity Angioedema Urticaria **Metabolism and nutrition disorders** Hypoglycaemia (when used with sulphonylurea or insulin) Ketoacidosis **Renal and urinary disorders** Increased urination Dysuria **Respiratory, thoracic & mediastinal disorders** Cough **Skin and subcutaneous tissue**	Empagliflozin 10mg and 25mg Tablet, Linagliptin 5 mg Tablet	USFDA স্থানীয়ভাবে উৎপাদনের জন্যও আবেদন করা হয়েছে। SI: 02 ডিসিসি-২৫২ তম সভায় উক্ত পদটি ডিসিসি-২৫৩ তম সভায় উপস্থাপনের সিদ্ধান্ত প্রদান করা হয়েছিল।	পদটি স্থানীয়ভাবে উৎপাদনের জন্য সুপারিশ করা হয়েছে। আমদানির প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	পদটি স্থানীয়ভাবে উৎপাদনের জন্য অনুমোদন করা হয়েছে। আমদানির প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						disorders Rash Pruritus				
34.	**Manufacturer:** Madaus GmbH 51101 Cologne, Germany. **Manufacturing site:** Madaus GmbH Lütticher Straße 5 53842 Troisdorf, Germany **Local Agent:** Janata Traders, 62/2, Purana Paltan, Dhaka	Reparil Gel N 100 g	Escin 1.0g + Diethylamine salicylate 5.0g BP/100 g gel	Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic Code:064	In cases of contusions, crush injuries, sprains, bruises. Painful conditions of the vertebral column. Fluid accumulation due to injury.	Reparil Gel N should not be applied to broken skin, mucous membrane or skin areas exposed to radiotherapy.	New	CPP-Germany	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
35.	**Manufacture**r: Septodont 58, rue du Pont de Créteil 94100 Saint-Maur-des-Fossés FRANCE. **Importer:** Unihealth Ltd., 6/9 Block-F, Lalmatia (Satmasjid Road) Dhaka 1207, Bangladesh.	Xylonor Spray	Lidocaine 15.00 g + Cetrimide 0.15 g/ 100g	Anaesthetics (Local) Therapeutic Code: 005	Xylonor is used for production of topical anaesthesia and disinfection of the mucous membrane in the buccal cavity. Xylonor is indicated in adults, adolescents and children from aged 6.	**Contraindicatio:** hypersensitive (allergic) to lidocaine and/or cetrimide or to any of the other ingredients of this medicine (listed in section 6). **Side Effects:** In order to avoid burns, it is recommended not to drink or eat hot food until effects of Xylonor have worn off.	New	France	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
36.	**Flen Health NV,** Blauwesteenstraat 87, B-2550 Kontich, Belgium **Importer:** BioArt Bangladesh, 290 Middle Pirer Bang Jhilpar, Mirpur PO Box 1216 Dhaka,Bangladesh.	Flamigel® RT Gel	**Active ingredients:** Methyl-p-hydroxybenzoate Eur. Ph. 0.16% (g/g)+Propyl-p-Hydroxybenzoate Eur. Ph. 0.04% (g/g)+Disodium edetate Eur. Ph. 0.05% (g/g)+Cetearyl polycarbonate liquid Materialsspec PCLiquid 1.05% (g/g)+ Cetearylpolycarbonate liquid Materialsspec PCSolid 3.15% (g/g)+Polycrylate copolymer Eur. Ph. 1.3%(g/g)+L-Arginin Eur. Ph. 0.871%(g/g)+Aqua Purificata Eur. Ph. 92.3790% (g/g)+PEG400 Eur. Ph. 1%	Therapeutic class: Other Classification Therapeutic Code:75 -	It is indicated for the symptomatic treatment of low-grade radiotherapy-induced skin reactions such as red, dry, itching, flaking or irritated skin (dry desquamation). It can also be used to treat more severe skin reactions that can develop at a later stage of radiotherapy as partial skin breakdown and appearance of oozing blisters (moist desquamation).Flamigel® RT delays the onset and reduces the incidence of radiotherapy-induced moist desquamation.	**Contraindication :** Do not use Flamigel® RT when there is a known allergic reaction to any of the ingredients **Side-effects:** Irritations or allergic reactions are rare but can occur. Stop immediately using Flamigel® RT if irritation or allergy occurs. **Warning and precautions:** •For external use only. • Do not use Flamigel® RT on the eyelids or in the eyes. If Flamigel® RT comes into contact with the eyes, rinse the eyes with running water and consult a doctor or nurse. • In case of open wounds where the dermis is substantially breached or when moist desquamation occurs over large surfaces (large confluent moist desquamation lesions) it is recommended to apply a treatment for large or deep	New	FSC: Belgium. (মেডিকেল ডিভাইস হিসেবে)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
			(g/g)			wounds. In case of doubt, consult your treating physician or nurse. • On extensive weeping or infected wounds, consult a doctor before using Flamigel® RT because other complementary treatments might be necessary.				
37.	**Flen Health NV,** Blauwesteenstraat 87, B-2550 Kontich, Belgium **Importer:** BioArt Bangladesh, 290 Middle Pirer Bang Jhilpar, Mirpur PO Box 1216 Dhaka,Bangladesh.	Flamigel® Gel	**Active ingredients:** Methyl-p-hydroxybenzoate Eur. Ph. 0.16% (g/g)+Propyl-p-Hydroxybenzoate Eur. Ph. 0.04% (g/g)+Disodium edetate Eur. Ph. 0.05% (g/g)+Cetearyl polycarbonate liquid Materialsspec PCLiquid 1.05% (g/g)+	Therapeutic class: Other Classification Therapeutic Code:75 -	Flamigel® is a hydro-active colloid gel for the treatment of minor wounds which supports the fast healing of skin by covering the wound and creating an optimal moist healing environment. Flamigel® is used post lasertherapy, on superficial burns (including those caused by radiotherapy) and on minor wounds (e.g. grazes, cuts). Flamigel® may also be used in superficial open wounds.	**Contraindication :** Do not use Flamigel® when there is a known allergic reaction to any of the ingredients. **Side-effects:** Irritations or allergic reactions are rare but can occur. Stop immediately using Flamigel® if irritation or allergy occurs. **Warning and precautions:** •For external use only. • Do not use Flamigel® on the	New	FSC: Belgium. (মেডিকেল ডিভাইস হিসেবে)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
			Cetearylpolycarbonate liquid Materialsspec PCSolid 3.15% (g/g)+Polycrylate copolymer Eur. Ph. 1.3%(g/g)+L-Arginin Eur. Ph. 0.871%(g/g)+Aqua Purificata Eur. Ph. 92.3790% (g/g)+PEG400 Eur. Ph. 1% (g/g)			eyelids or in the eyes. If Flamigel® comes into contact with the eyes, rinse the eyes with running water and consult a doctor or nurse. • In case of open wounds where the dermis is substantially breached or when moist desquamation occurs over large surfaces (large confluent moist desquamation lesions) it is recommended to apply a treatment for large or deep wounds. In case of doubt, consult your treating physician or nurse. • On extensive weeping or infected wounds, consult a doctor before using Flamigel® because other complementary treatments might be necessary.				
38.	**Flen Health NV,** Blauwesteenstraat 87, B-2550 Kontich, Belgium **Importer:** BioArt Bangladesh,	Flaminal ® Hydro Gel	**Active ingredients:** Sodium alginate USNF 3.5% (g/g)+Hydroxypropylcellulose Ph. Eur. 2% (g/g)+Potassium Sorbate Ph.	Therapeutic class: Other Classification Therapeutic Code:75	Flaminal ® Hydro is indicated for slightly to moderately exuding wounds such as: • leg ulcers • diabetic ulcers • 2nd degree burns (deep, superficial)	**Contraindications:** Do not use Flaminal ® Hydro when there is a known allergic reaction to any of the ingredients. **Side-effects (frequency and**	New	FSC: Belgium. (মেডিকেল ডিভাইস হিসেবে)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	290 Middle Pirer Bang Jhilpar, Mirpur PO Box 1216 Dhaka,Bangladesh.		Eur. 0.6% (g/g)+Glucose Monohydrate Ph. Eur. 0.825% (g/g)+Potassium Iodide(KI) Ph. Eur. 0.021% (g/g)+Guaiacol Ph. Eur. 0.0025%(g/g) +Lactoperoxydase (1000-1800 Units/ml), Glucoseoxydase (1500-3750 Units/ml) R-materialsspecmyavert 0.1% (g/g)+Potassiumdihydrogenphosphate (anhydrous) Ph. Eur. 0.013% (g/g)+Disodiumhydrogenphosphate (anhydrous) Ph. Eur. 0.0006%	-	• wounds from radiotherapy • oncology wounds • complex grazes • wounds from dermatosurgery	**seriousness):** Irritations or allergic reactions are rare but can occur. Stop immediately using Flaminal ® Hydro if irritation or allergy occurs. **Warning and precautions:** Some wounds may indicate a complementary treatment. Consult a physician or wound specialist. Flaminal ® Hydro can be used on infected wounds under medical supervision. Alginates have a faint odour. This odour has no influence on the healing process. Should there be a sudden distinct odour, consult a physician or wound specialist. Flaminal ® Hydro is not indicated in patients with a known allergy to one of the components (see under "Composition"). Flaminal ® Hydro cannot be used on the eyelids or in the eye. Should it come into				

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
			(g/g)+Macrogol 400 Ph. Eur. 16%(g/g)+Purified Water Ph. Eur. q.s. ad 100% (g/g)			contact with an eye, rinse the eye thoroughly with running water and consult a physician.				
39.	**Flen Health NV,** Blauwesteenstraat 87, B-2550 Kontich, Belgium **Importer:** BioArt Bangladesh, 290 Middle Pirer Bang Jhilpar, Mirpur PO Box 1216 Dhaka,Bangladesh.	Flaminal ® Forte Gel	**Active ingredients:** Sodium alginate USNF 5.5% (g/g) +Potassium Sorbate Ph. Eur. 0.6% (g/g)+Glucose Monohydrate Ph. Eur. 0.825% (g/g)+Potassium Iodide Ph. Eur. 0.021% (g/g)+Guaiacol Ph. Eur. 0.0025%(g/g) +Lactoperoxydase (1000-1800 Units/ml), Glucoseoxydase (1500-3750	Therapeutic class: Other Classification Therapeutic Code:75 -	Flaminal ® Forte is indicated for moderately to highly exuding wounds such as: • highly exuding 2nd degree burns (deep, superficial) • highly exuding leg ulcers • exuding pressure sores • exuding oncology wounds • pre-operative wound-bed preparation	**Contraindications:** Do not use Flaminal ® Forte when there is a known allergic reaction to any of the ingredients. **Side-effects (frequency and seriousness):** Irritations or allergic reactions are rare but can occur. Stop immediately using Flaminal ® Forte if irritation or allergy occurs. **Warning and precautions:** Some wounds may indicate a complementary treatment. Consult a physician or wound specialist. Flaminal ® Forte can be used	New	FSC: Belgium. (মেডিকেল ডিভাইস হিসেবে)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC (UK/USA/Switzerland/Germany/France/ Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
			Units/ml) R-materialsspecmyavert 0.075% (g/g)+Potassiumdihydrogenphosphate (anhydrous) Ph. Eur. 0.013% (g/g)+Disodiumhydrogenphosphate (anhydrous) Ph. Eur. 0.0006% (g/g)+Macrogol 400 Ph. Eur. 16%(g/g)+Purified Water Ph. Eur. q.s. ad 100% (g/g)			on infected wounds under medical supervision. Alginates have a faint odour. This odour has no influence on the healing process. Should there be a sudden distinct odour, consult a physician or wound specialist. Flaminal ® Forte is not indicated in patients with a known allergy to one of the components (see under "Composition"). Flaminal ® Forte cannot be used on the eyelids or in the eye. Should it come into contact with an eye, rinse the eye thoroughly with running water and consult a physician.				

Annex-C: Human Vaccine for locally manufacture

Sl 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)	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF/ MHRA Ref.	২৩.১০.২০২১ তারিখে অনুষ্ঠিত বিশেষজ্ঞ কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
1.	Incepta Vaccine Ltd. ; Zirabo, Savar, Dhaka	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) BP, 13 Serotypes	Each 0.5 ml single dose Pre-filled Syringe (PFS) contains: Pneumococcal Polysaccharide Serotype 1 BP 2.6 mcg + Pneumococcal Polysaccharide Serotype 3 BP 2.5 mcg + Pneumococcal Polysaccharide Serotype 4 BP 3.0 mcg + Pneumococcal Polysaccharide Serotype 5 BP 2.5 mcg + Pneumococcal Polysaccharide Serotype 6A BP 2.5 mcg + Pneumococcal Polysaccharide Serotype 6B BP 6.0 mcg + Pneumococcal Polysaccharide Serotype 7F BP 2.85 mcg + Pneumococcal Polysaccharide Serotype 9V BP 2.5 mcg + Pneumococcal Polysaccharide Serotype 14 BP 2.75 mcg + Pneumococcal Polysaccharide Serotype 18C BP 3.25 mcg + Pneumococcal Polysaccharide Serotype 19A BP 2.6 mcg + Pneumococcal Polysaccharide Serotype 19F BP 2.75 mcg + Pneumococcal Polysaccharide Serotype 23F BP 3.0 mcg	Vaccines Therapeutic Code: 069	PCV 13 is a vaccine indicated for active immunization for the prevention of pneumococcal disease caused by the 13 serotypes contained in the vaccine (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F & 23F).	Yuxi Walvax Biotechnology Co., Ltd.	**China** **GMP Certificate: Yes** **Lot Release Certificate of the Product: Yes**	**Existing** (Prevenar 13 Suspension for Injection Pre-filled Syringe 0.5ml Pneumococcal Polysaccharide serotype 1 2.2µg Pneumococcal Polysaccharide serotype 3 2.2µg Pneumococcal Polysaccharide serotype 4 2.2µg Pneumococcal Polysaccharide serotype 5 2.2µg Pneumococcal Polysaccharide serotype 6A 2.2µg Pneumococcal Polysaccharide serotype 6B 4.4µg Pneumococcal Polysaccharide serotype 7F 2.2µg Pneumococcal Polysaccharide serotype 9V 2.2µg Pneumococcal Polysaccharide serotype 14 2.2µg Pneumococcal Polysaccharide serotype 18C 2.2µg Pneumococcal Polysaccharide serotype 19A 2.2µg Pneumococcal Polysaccharide serotype 19F 2.2µg Pneumococcal Polysaccharide serotype 23F 2.2µg	-	কমিটির সদস্যগণ নিম্নবর্ণিত শর্তে ভ্যাক্সিনটি অনুমোদনের সুপারিশ করেনঃ ১. প্রতিষ্ঠানটি কর্তৃক দাখিলকৃত **Long term stability study report** এ দেখা যাচ্ছে, **sodium chloride content 9th month** এ **8.48 g/L** হতে হ্রাস পেয়ে **7.9 g/L** হয়েছে, কিন্তু **12th month** এ এসে তা বৃদ্ধি পেয়ে **8.4 g/L** হয়েছে। এ বিষয়ে প্রতিষ্ঠানটিকে ব্যখ্যা প্রদানের জন্য বলা যেতে পারে। ২. **Conjugate antigen content Type 1** এর জন্য **24th month** এ **45%** পাওয়া যায়, **30 month** এ **45%** পাওয়া যায় **81%.** **24th month** এ এত কম **Conjugate antigen content** পাওয়ার বিষয়ে প্রতিষ্ঠানটিকে ব্যখ্যা প্রদানের জন্য বলা যেতে পারে।	নিম্নবর্ণিত শর্তে ভ্যাক্সিনটি অনুমোদনের সুপারিশ করা হয়ঃ ১. প্রতিষ্ঠানটি কর্তৃক দাখিলকৃত **Long term stability study report** এ দেখা যাচ্ছে, **sodium chloride content 9th month** এ **8.48 g/L** হতে হ্রাস পেয়ে **7.9 g/L** হয়েছে, কিন্তু **12th month** এ এসে তা বৃদ্ধি পেয়ে **8.4 g/L** হয়েছে। এ বিষয়ে প্রতিষ্ঠানটিকে ব্যখ্যা প্রদানের জন্য বলা যেতে পারে। ২. **Conjugate antigen content Type 1** এর জন্য **24th month** এ **45%** পাওয়া যায়, **30 month** এ পাওয়া যায় **81%.** **24th month** এ এত কম **Conjugate antigen content** পাওয়ার বিষয়ে প্রতিষ্ঠানটিকে ব্যখ্যা প্রদানের জন্য বলা যেতে পারে।	নিম্নবর্ণিত শর্তে ভ্যাক্সিনটি অনুমোদন করা হয়ঃ ১. প্রতিষ্ঠানটি কর্তৃক দাখিলকৃত **Long term stability study report** এ দেখা যাচ্ছে, **sodium chloride content 9th month** এ **8.48 g/L** হতে হ্রাস পেয়ে **7.9 g/L** হয়েছে, কিন্তু **12th month** এ এসে তা বৃদ্ধি পেয়ে **8.4 g/L** হয়েছে। এ বিষয়ে প্রতিষ্ঠানটিকে ব্যখ্যা প্রদানের জন্য বলা যেতে পারে। ২. **Conjugate antigen content Type 1** এর জন্য **24th month** এ **45%** পাওয়া যায়, **30 month** এ পাওয়া যায় **81%.** **24th month** এ এত কম **Conjugate antigen content** পাওয়ার বিষয়ে প্রতিষ্ঠানটিকে ব্যখ্যা প্রদানের জন্য বলা হয়।

Annex-C: Human Vaccine for Import

Sl No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	CPP/ FSC (UK/USA/ Switzerland/Germany/France/ Japan/Australia/EMA)	২৩.১০.২০২১ তারিখে অনুষ্ঠিত বিশেষজ্ঞ কমিটির সভার সিদ্ধান্ত	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত
01.	Serum Institute of India PVT. LTD (710286), Pune-411028, India.	MMR Vaccine (Measles, Mumps and Rubella Vaccine Live, Attenuated (Freeze-Dried))	1000 $CCID_{50}$ of Measles Virus 5000 $CCID_{50}$ of Mumps Virus 1000 $CCID_{50}$ of Rubella Virus Reconstitute with Sterile Water for Injection.	Vaccines Therapeutic Code: 069	MMR vaccine protects against measles, mumps, and rubella (German measles)	Getting vaccinated is important, as these conditions can also lead to serious problems including meningitis, hearing loss and problems during pregnancy.	New	COPP-India WHO Pre-qualified Certificate	দেশে ভ্যাক্সিনটির প্রয়োজন আছে বিধায় অনুমোদনের সুপারিশ করেন।	অনুমোদন করা হয়।
02.	Serum Institute of India PVT. LTD (710286), Pune-411028, India.	Diphtheria - Tetanus (TD) Conjugate Vaccine	Diphtheria -Tetanus Vaccine Adsorbed for Adults and Adolescents 1 doses & 10 doses	Vaccines Therapeutic Code: 069	Diphtheria and Tetanus Toxoids Adsorbed (For Pediatric Use) (DT) is indicated for active immunization of children up to age 7 years against diphtheria and tetanus	Adverse reactions may be local and include redness, warmth, edema, Care is to be taken by the health-care provider for the safe and effective use of DT.	New	COPP-India WHO Pre-qualified Certificate	দেশে ভ্যাক্সিনটির প্রয়োজন আছে বিধায় অনুমোদনের সুপারিশ করেন।	অনুমোদন করা হয়।
03.	M/s. Biological E. Limited, India.	Typhoid Conjugate Vaccine (Monovalent) TYPHIBEV	Typhoid Vi Polysaccharide 1, conjugated to 100µm of CRM197: 25µm, Sodium Chloride and phosphate buffer: q.s, 2-Phenoxyethanol (as preservative): 5mg	Vaccines Therapeutic Code: 069	Prevention of Typhoid fever	Injection site reactions (pain, swelling, redness), Feeling of discomfort, Nausea, Diarrhea, Fever, Headache	New	COPP-India WHO Pre-qualified Certificate	দেশে ভ্যাক্সিনটির প্রয়োজন আছে বিধায় অনুমোদনের সুপারিশ করেন।	অনুমোদন করা হয়।

Annex-D Miscellaneous

১. **Post Approval:** স্থানীয়ভাবে উৎপাদনের লক্ষ্যে যে সব ঔষধের অনুকূলে **Emergency Use Authorization (EUA)** প্রদান করা হয়েছে, সে সব ঔষধের তালিকা ড্রাগ কন্ট্রোল কমিটির সভায় উপস্থাপন করা হয় এবং ড্রাগ কন্ট্রোল কমিটি কর্তৃক নিম্নোক্ত সিদ্ধান্ত গৃহীত হয়ঃ

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	USFDA, UKMHRA, EMA and BNF রেফারেন্স	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
01.	Beximco Pharmaceuticals Ltd. Delta Pharmaceuticals Ltd. Incepta Pharmaceuticals Ltd.	Baricitinib 4mg Tablet	Baricitinib INN 4mg	Therapeutic Class: Nonsteroidal antiinflamatory and drugs used in arthritis. Therapeutic Code: 064	This medicine will be used COVID-19 hospitalized adults requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) under supervision of a qualified specialist physician.	USFDA	**EUA** প্রদানের সুপারিশ করা হয়।	**EUA** প্রদান মঞ্জুর করা হয়।
02.	Aristopharma Ltd. Nuvista Pharma Ltd.	Dexamethasone 6mg Tablet	Dexamethasone USP 6mg	Therapeutic Class: Steroidal Anti inflammatory Therapeutic Code: 072	This medicine will be used COVID-19 hospitalized adults requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) under supervision of a qualified specialist physician.	EMA, UKMHRA, WHO recommended	**EUA** প্রদানের সুপারিশ করা হয়।	**EUA** প্রদান মঞ্জুর করা হয়।
03.	Aristopharma Ltd. Nuvista Pharma Ltd.	Dexamethasone Sodium Phosphate USP 7.895mg eqv. to Dexamethasone 6mg/ml inj	Dexamethasone 6mg/ml inj	Therapeutic Class: Steroidal Anti inflammatory Therapeutic Code: 072	This medicine will be used COVID-19 hospitalized adults requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) under supervision of a qualified specialist physician.	EMA, UKMHRA, WHO recommended	**EUA** প্রদানের সুপারিশ করা হয়।	**EUA** প্রদান মঞ্জুর করা হয়।
04.	Beximco Pharmaceuticals Ltd. Eskayef Pharmaceuticals Ltd. Drug International Ltd. Square Pharmaceuticals Ltd.	Molnupiravir INN 200 mg Capsule	Molnupiravir INN 200 mg	Therapeutic Class: Antiviral Therapeutic code: 032	It is indicated for treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults with a positive SARS-COV-2 diagnostic test and who have at least one risk factor for developing severe illness. Contraindications:	UKMHRA	EUA প্রদানের সুপারিশ করা হয়।	**EUA** প্রদান মঞ্জুর করা হয়। Molnupiravir INN 200 mg Capsule এর patient information এ উল্লেখ করতে হবে,

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	USFDA, UKMHRA, EMA and BNF রেফারেন্স	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Advanced Chemical Industries Ltd. The ACME Laboratories Ltd. Renata Ltd. Incepta Pharmaceutical Ltd.				Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Special warnings and precautions for use: Sodium This medicinal product contains less than 1 mmol sodium (23 mg) per dose of 4 capsules, that is to say essentially 'sodium-free'.			Molnupiravir is not recommended during pregnancy and in women of childbearing potential not using effective contraception. Based on the potential for adverse reactions on the breastfeeding infant from Molnupiravir, breast-feeding should be interrupted during treatment and for 4 days after the last dose of Molnupiravir.

Nirmatrelvir INN 150 mg Tablet এবং Ritonavir 100 mg Tablet এর কো- প্যাক এর অনুকূলে EUA প্রদান মঞ্জুর করা হয়।

২. **Post Approval:** আমদানির লক্ষ্যে যে সব ঔষধের অনুকূলে **Emergency Use Authorization (EUA)** প্রদান করা হয়েছে, সে সব ঔষধের তালিকা ড্রাগ কন্ট্রোল কমিটির সভায় উপস্থাপন করা হয় এবং ড্রাগ কন্ট্রোল কমিটি কর্তৃক নিম্নোক্ত সিদ্ধান্ত গৃহীত হয়ঃ

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	CPP/ FSC (UK/USA/Switzerland/Germany/France/Japan/Australia/EMA)	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
01.	**Manufacturer:** Genetech Inc, 4625 NE Brookwood, Hillsboro, USA **M.A. Holder:** F. Hoffmann-La Roche Limited, Grenzacherstrasse 124, 4070 Basel, Switzerland. **Local Agent:** Radiant Business Consortium Limited; Lubdhok, 3rd Floor, 474P, Road No: 3, Sector 12, Uttara, Dhaka 1230, Bangladesh	Casirivimab and Imdevimab 120mg/ml concentrated for solution for infusion (One multi dose vial contains 1332mg/11.1ml of Casirivimab, One multi dose vial contains 1332mg/11.1ml of Imdevimab (2 multi dose vials of 20ml)	Casirivimab and Imdevimab 120mg/ml concentrated for solution for infusion	Antiviral Therapeutic code: 32	Treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adult and pediatric patients (12 years of age and older weighting at least 40 kg) with positive results of direct SARS-COV-2 viral testing and who are at high risk of progression to severe COVID-19, including hospitalization or death.	**EUA-USFDA**	**EUA** প্রদানের সুপারিশ করা হয়।	**EUA** প্রদান মঞ্জুর করা হয়।
02.	**Manufacturer:** Genetech Inc, 4625 NE Brookwood, Hillsboro, USA **M.A. Holder:** F. Hoffmann-La Roche Limited, Grenzacherstrasse 124, 4070 Basel, Switzerland. **Local Agent:** Radiant Business Consortium Limited; Lubdhok, 3rd Floor, 474P, Road No: 3, Sector 12, Uttara, Dhaka 1230, Bangladesh	Casirivimab and Imdevimab 120mg/ml concentrated for solution for infusion (One vial contains 300mg/2.5ml of Casirivimab, One vial contains 300mg/2.5ml of Imdevimab (2 vials of 6ml)	Casirivimab and Imdevimab 120mg/ml concentrated for solution for infusion	Antiviral Therapeutic code: 32	Treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adult and pediatric patients (12 years of age and older weighting at least 40 kg) with positive results of direct SARS-COV-2 viral testing and who are at high risk of progression to severe COVID-19, including hospitalization or death.	**EUA-USFDA**	**EUA** প্রদানের সুপারিশ করা হয়।	**EUA** প্রদান মঞ্জুর করা হয়।

৩. নিম্নোক্ত পদগুলি দীর্ঘদিন যাবৎ বাজারজাত হয়ে আসছে, কিন্তু কোন ডিসিসি রেফারেন্স পাওয়া যাচ্ছে না বিধায় **Post Approval** এর জন্য ড্রাগ কন্ট্রোল কমিটির সভায় উপস্থাপন করা হয় এবং ড্রাগ কন্ট্রোল কমিটি কর্তৃক নিম্নোক্ত সিদ্ধান্ত গৃহীত হয়ঃ

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	USFDA, UKMHRA, EMA and BNF রেফারেন্স	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
1.	M/S Beacon Pharmaceuticals ltd, Kathali, Bhaluka, Mymensingh	Zonisamide USP 50mg ODT	Zonisamide USP 50mg	Anticonvulsant **Therapeutic** Code: 047	Zonisamide capsules are indicated as adjunctive therapy in the treatment of partial seizures in adults with epilepsy.	**Contraindication**: Zonisamide is contraindicated in patients who have demonstrated hypersensitivity to sulfonamides or zonisamide. **Side-effect**: The most commonly observed adverse events related to treatment with Zonisamide (an incidence at least 4% greater than placebo) in controlled clinical trials and shown in descending order of frequency were somnolence, anorexia, dizziness, ataxia, agitation/irritability, and difficulty with memory and/or concentration.	Zonisamide 50mg Hard Gelatin Capsule DCC-244 তম সভায় Zonisamide USP 50mg Hard Gelatin Capsule হিসেবে অনুমোদিত। প্রতিষ্ঠানটি পদটি ODT হিসেবে অনুমোদনের জন্য আবেদন করেছে। ডিসিসি-২৫২ তে পদটি পোস্ট অ্যাপ্রুভালের জন্য উপস্থাপিত হলে USFDA/ UKMHRA/ EMA/ BNF Ref. এর রেফারেন্স নাই বিধায় রেজিস্ট্রেশন বাতিল করা হয়। বর্তমানে EMA এর রেফারেন্স দাখিল করেছে।	**EMA**	পোস্ট অ্যাপ্রুভালের সুপারিশ করা হয়।	পোস্ট অ্যাপ্রুভাল করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	USFDA, UKMHRA, EMA and BNF রেফারেন্স	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
2.	Healthcare Pharmaceuticals Ltd. Gazipur	Rabeprazole Sodium Enteric Coated Pellets 8.5% w/w Ph. Grade 235.294mg (Contains Rabeprazole Sodium BP 20mg Capsule)					Rabeprazole Sodium BP 20mg Capsule হিসেবে ২৪ টি প্রতিষ্ঠানের রেজিস্ট্রেশন রয়েছে। DCC রেফারেন্স নাই ।	কোন রেফারেন্স দাখিল করেনি।	রেজিস্ট্রেশন বাতিলের সুপাশি করা হয়।	রেজিস্ট্রেশন বাতিল করা হয়।
3.	M/S Incepta Pharmaceuticals Limited, M/S Novartis (Bangladesh) Limited M/S Square Pharmaceuticals Limited	Lamotrigine BP 50mg Tablet	Lamotrigine BP 50mg	Drug used in Epilepsy Therapeutic Code: 46	It is indicated for treatment of Epilepsy, Bipolar disorder	**Contraindication:** Lamotrigine is contraindicated in patients with known hypersensitivity to lamotrigine or any components of this product. **Warnings and precautions**: Life-threatening serious rash, and/or rash-related death, may result. Hypersensitivity reaction may be fatal or life-threatening. Early signs of Hypersensitivity (e.g., fever, lymphadenopathy) may present without rash; if signs present, patient should be evaluated	DCC রেফারেন্স নাই । M/S Incepta Pharmaceuticals Limited, M/S Novartis (Bangladesh) Limited এবং M/S Square Pharmaceuticals Limited এর অনুকূলে Lamotrigine BP 50 mg Tablet হিসেবে রেজিস্ট্রেশন রয়েছে।	**USFDA**	পোস্ট অ্যাপ্রুভালের সুপারিশ করা হয়।	পোস্ট অ্যাপ্রুভাল করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	USFDA, UKMHRA, EMA and BNF রেফারেন্স	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						immediately. Lamotrigine ER should be discontinued if alternate etiology for hypersensitivity signs are not found. Acute multiorgan failure has resulted (some cases fatal) Blood dyscrasias (e.g., neutropenia, thrombocytopenia, pancytopenia), may result, either with or without an associated hypersensitivity syndrome. Suicidal behavior and ideation. Medication errors involving Lamotrigine have occurred. In particular, the names Lamotrigine can be confused with the names of other commonly used medications. Medication errors may also occur between the different formulations of Lamotrigine.				
4.	Beacon Pharmaceuticals Limited	Bromelain 50 mg + Trypsin 1 mg Tablet	Bromelain USP 50 mg + Trypsin BP 1 mg	Enzymes Therapeutic	Bromelain & Trypsin is indicated for	**Contraindications:** Hypersensitivity **Side effects:**	১৯৯৭ সালে সিটি ওভারসিজ নামীয় আমদানিকারক প্রতিষ্ঠানের	**রেফারেন্স নাই।**	রেজিস্ট্রেশন বাতিলের সুপাশি করা হয়।	রেজিস্ট্রেশন বাতিল করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	USFDA, UKMHRA, EMA and BNF রেফারেন্স	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna			Code: 051	inflammatory pains, soft tissue inflammation, edema associated with trauma and surgery such as in gynaecological conditions, breast engorgement, fractures, sprains, injuries, hemorrhoid, anal prolapse	Trypsin seems to be safe when used by healthcare professionals for wound cleaning and healing. It can cause side effects such as pain and burning. Not enough is known about the safety of trypsin for its other uses **Warnings and Precautions:** Allergies: If you are allergic to pineapple, latex, wheat, celery, papain,carrot, fennel, cypress pollen, or grass, pollen, you might have an allergic, reaction to bromelain. Surgery: Bromelain might increase the risk of bleeding during and after surgery. Stop using bromelain at least 2 weeks before a scheduled surgery.	অনুকূলে import রেজিস্ট্রেশন প্রদান করা হয়। কিন্তু কোন ডিসিসি রেফারেন্স পাওয়া যাচ্ছে না।			
5.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Dhaka Unit),	Sodium Chloride 0.9% Nasal Spray	Sodium Chloride BP 0.9mg/Spray	Therapeutic Class: Ear and Nose Preparation Therapeutic	It is indicated for nasal dryness including dry nose resulting from cold and allergy medications. It moistens dry nasal	Side effect: There is no known adverse or side effects observed. However, stinging, sneezing, increased nasal	অপসো স্যালাইন এর অনুকূলে Nasal Spray হিসেবে অনুমোদন রয়েছে। Nasal Spray হিসেবে ডিসিসি রেফারেন্স পাওয়া যাচ্ছে না।	USFDA	পোস্ট অ্যাপ্রুভালের সুপারিশ করা হয়।	পোস্ট অ্যাপ্রুভাল করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	USFDA, UKMHRA, EMA and BNF রেফারেন্স	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Kaliakoir, Gazipur			code: 050	passages from dry climates or from airplane travel, may help dissolve mucus from stuffy noses and clears the nose after surgery. This sterile saline solution is also used to cleanse various parts of the body (wounds, body cavities) and medical equipment (e.g., bandages, catheters, drainage tubes). It is also used as a mixing solution (diluent) for other medications used to irrigate the body (e.g., bacitracin, polymyxin).	discharge, or salty taste may occur in some cases. Precautions & warning: No known side effects observed. Use only as directed. The use of this dispenser by more than one person may spread infection.				
6.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi Industrial Area, Tongi, Gazipur,	Docetaxel Anhydrous USP 20mg/1ml Injection	Docetaxel Anhydrous USP 20mg/1ml Injection	Anti Cancer **Therapeutic** Code: 010	It is indicated for the treatment of patients with locally advanced or metastatic breast cancer	**Contraindication:** Docetaxel is contraindicated in patients who have a history of severe hypersensitivity reactions to docetaxel	Docetaxel Anhydrous USP 20mg/1ml Injection হিসেবে 03 টি প্রতিষ্ঠানের অনুকূলে রেজিস্ট্রেশন রয়েছে।	UKMHRA	পোস্ট অ্যাপ্রুভালের সুপারিশ করা হয়।	পোস্ট অ্যাপ্রুভাল করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	USFDA, UKMHRA, EMA and BNF রেফারেন্স	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Bangladesh.				after failure of prior chemotherapy. As a single agent is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of prior platinum-based chemotherapy. In combination with prednisone it is indicated for the treatment of patients with androgen independent (hormone refractory) metastatic prostate cancer. In combination with cisplatin and	or to other drugs formulated with polysorbate 80. Severe reactions, including anaphylaxis, have occurred. Docetaxel should not be used in patients with neutrophil counts of < 1500 cells/mm^3. **Precaution:** **Hematologic Effects:** In order to monitor the occurrence of myelotoxicity, it is recommended that frequent peripheral blood cell counts be performed on all patients receiving Docetaxel. Patients should not be retreated with subsequent cycles of Docetaxel until neutrophils recover to a level > 1500 cells/mm^3 and platelets recover to a level > 100,000 cells/mm^3.**Hepatic Impairment:** Patients with combined abnormalities of transaminases and alkaline phosphatase should not be treated	যার ডিসিসি রেফারেন্স পাওয়া যাচ্ছে না। ডিসিসি-২১০ এ 20mg/0.5 ml Injection হিসেবে অনুমোদিত।			

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	USFDA, UKMHRA, EMA and BNF রেফারেন্স	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						with Docetaxel.				
7.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi Industrial Area, Tongi, Gazipur, Bangladesh.	Docetaxel Anhydrous USP 80mg/4ml Injection	Docetaxel Anhydrous USP 80mg/4ml Injection	Anti Cancer **Therapeutic** Code: 010	It is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy. As a single agent is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of prior platinum-based chemotherapy. In combination with prednisone it is indicated for the treatment of patients with androgen independent (hormone refractory)	**Contraindication:** Docetaxel is contraindicated in patients who have a history of severe hypersensitivity reactions to docetaxel or to other drugs formulated with polysorbate 80. Severe reactions, including anaphylaxis, have occurred. Docetaxel should not be used in patients with neutrophil counts of < 1500 cells/mm^3. **Precaution:** **Hematologic Effects:** In order to monitor the occurrence of myelotoxicity, it is recommended that frequent peripheral blood cell counts be performed on all patients receiving Docetaxel. Patients should not be retreated with subsequent cycles	Docetaxel Anhydrous USP 80mg/2ml Injection হিসেবে 03 টি প্রতিষ্ঠানের অনুকূলে রেজিস্ট্রেশন রয়েছে। যার ডিসিসি রেফারেন্স পাওয়া যাচ্ছে না। ডিসিসি-২১০ এ 80mg/2 ml Injection হিসেবে অনুমোদিত।	UKMHRA	পোস্ট অ্যাপ্রুভালের সুপারিশ করা হয়।	পোস্ট অ্যাপ্রুভাল করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	USFDA, UKMHRA, EMA and BNF রেফারেন্স	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
					metastatic prostate cancer. In combination with cisplatin and	of Docetaxel until neutrophils recover to a level > 1500 cells/mm³ and platelets recover to a level > 100,000 cells/mm³.**Hepatic Impairment:** Patients with combined abnormalities of transaminases and alkaline phosphatase should not be treated with Docetaxel.				
8.	Opsonin Pharmaceutical Ltd,	Astaxanthin INN 2 mg soft Gelatin Capsule and powder filled hard Gelatin Capsule	Astaxanthin INN 2 mg	Other Classification **Therapeutic** Code: 75	1. Muscle Recovery and physical endurance in sports 2. Relieve Eye fatigue e.g. Macular degeneration 3. Improve Skin Condition (such as a) Fine wrinkles b) Elasticity c) Moisture Levels d) Smoothness e) Spots and freckles		অনেক প্রতিষ্ঠানের অনুকুলেই soft Gelatin Capsule ও powder filled Hard Gelatin Capsule হিসেবে অনুমোদন রয়েছে। কিন্তু ডিসিসি-২৪১ এ পদটি liquid filled Hard Gelatin Capsule হিসেবে অনুমোদিত।	রেফারেন্স নাই	Astaxanthin INN 2 mg soft Gelatin Capsule ও powder filled Hard Gelatin Capsule রেজিস্ট্রেশন বাতিলের সুপাশি করা হয়।	Astaxanthin INN 2 mg soft Gelatin Capsule ও powder filled Hard Gelatin Capsule এর রেজিস্ট্রেশন বাতিল করা হয়।
9.	Opsonin Pharmaceutical Ltd, Belsen	Astaxanthin INN 4 mg soft Gelatin Capsule and	Astaxanthin INN 4 mg	Other Classification **Therapeutic**	1. Muscle Recovery and physical endurance in sports 2. Relieve Eye		অনেক প্রতিষ্ঠানের অনুকুলেই soft Gelatin Capsule ও powder filled Hard Gelatin Capsule হিসেবে	রেফারেন্স নাই	Astaxanthin INN 4 mg soft Gelatin Capsule ও	Astaxanthin INN 4 mg soft Gelatin Capsule ও

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	USFDA, UKMHRA, EMA and BNF রেফারেন্স	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Pharmaceutical Ltd.	powder filled hard Gelatin Capsule		Code: 75	fatigue e.g. Macular degeneration 3. Improve Skin Condition (such as a) Fine wrinkles b) Elasticity c) Moisture Levels d) Smoothness e) Spots and freckles		অনুমোদন রয়েছে। কিন্তু ডিসিসি-২৪১ এ পদটি liquid filled Hard Gelatin Capsule হিসেবে অনুমোদিত।		powder filled Hard Gelatin Capsule রেজিস্ট্রেশন বাতিলের সুপাশি করা হয়।	powder filled Hard Gelatin Capsule এর রেজিস্ট্রেশন বাতিল করা হয়।
10.	Drug International Ltd.	Medroxyprogesterone acetate BP 5mg Tablet	Medroxyprogesterone acetate BP 5mg	Hormone **Therapeutic** Code: 056	Dysfunctional uterine bleeding, secondary amenorrhoea, mild to moderate endometriosis. In combination with an oestrogen product for hormone replacement therapy (HRT) for oestrogen deficiency symptoms in peri- and post-menopausal women.	**Contraindications:** Medroxyprogesterone Acetate is contraindicated in women with any of the following conditions: Undiagnosed abnormal genital bleeding. Known, suspected, or history of breast cancer. Known or suspected estrogen- or progesterone-dependent neoplasia. Active DVT, PE, or a history of these conditions Active arterial thromboembolic disease (for example, stroke and MI), or a history of these conditions.	Medroxyprogesterone acetate BP 5mg Tablet হিসেবে 07 টি প্রতিষ্ঠানের অনুকূলে রেজিস্ট্রেশন রয়েছে। যার ডিসিসি রেফারেন্স পাওয়া যাচ্ছে না।	UKMHRA	পোস্ট অ্যাপ্রুভালের সুপারিশ করা হয়।	পোস্ট অ্যাপ্রুভাল করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	USFDA, UKMHRA, EMA and BNF রেফারেন্স	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						Known anaphylactic reaction or angioedema to Medroxyprogesterone Acetate Known liver impairment or disease. Known or suspected pregnancy. **Side Effect:** The following adverse reactions have been reported in women taking Medroxyprogesterone Acetate tablets, without concomitant estrogens treatment: Genitourinary system: Abnormal uterine bleeding (irregular, increase, decrease), change in menstrual flow, breakthrough bleeding, spotting, amenorrhea, changes in cervical erosion and cervical secretions. Breasts: Breast tenderness, mastodynia or galactorrhea has been reported. Cardiovascular: Thromboembolic disorders including thrombophlebitis and				

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	USFDA, UKMHRA, EMA and BNF রেফারেন্স	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
						pulmonary embolism have been reported. Gastrointestinal: Nausea, cholestatic jaundice. Skin: Sensitivity reactions consisting of urticaria, pruritus, edema and generalized rash have occurred. Acne, alopecia and hirsutism have been reported. Eyes: Neuro-ocular lesions, for example, retinal thrombosis, and optic neuritis. Central nervous system: Mental depression, insomnia, somnolence, dizziness, headache, nervousness.				
11.	JMI Industrial Gas Ltd.	Ethylene Oxide 20% in 80% Carbon Di Oxide	Ethylene Oxide 20% in 80% Carbon Di Oxide	**Therapeutic Class** : Other Classification **Therapeutic Code: 75**	Used in Medical Device sterilization.				Post Approval এর সুপারিশ করা হয়।	পোস্ট অ্যাপ্রুভাল করা হয়।
12.	JMI Industrial Gas Ltd.	Ethylene Oxide 30% in 70% Carbon Di	Ethylene Oxide 30% in 70% Carbon	**Therapeutic Class** : Other	Used in Medical Device sterilization.				Post Approval এর সুপারিশ করা হয়।	পোস্ট অ্যাপ্রুভাল করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	USFDA, UKMHRA, EMA and BNF রেফারেন্স	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
		Oxide	Di Oxide	Classification **Therapeutic Code: 75**						
13.	JMI Industrial Gas Ltd.	Ethylene Oxide 70% in 30% Carbon Di Oxide	Ethylene Oxide 70% in 30% Carbon Di Oxide	**Therapeutic Class** : Other Classification **Therapeutic Code: 75**	Used in Medical Device sterilization.				Post Approval এর সুপারিশ করা হয়।	পোস্ট অ্যাপ্রুভাল করা হয়।

৪. ড্রাগ কন্ট্রোল কমিটির কার্যবিবরণী সংশোধন প্রসঙ্গেঃ

ক্রমিক নং	বিষয়	প্রস্তাবনা	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
১.	Norcolut (Norethisterone) DCC – 140 তম সভা অনুমোদিত কিন্তু কোন strength উল্লেখ ছিল না।	Norethisterone Acetate (Micronized) BP 5.70mg (Eqv. to 5.0 mg Norethisterone) Tablet হিসেবে ডিসিসি-১৪০ তম সভার কার্যবিবরণী সংশোধনের প্রস্তাব করা হয়েছে। UKMHRA এর রেফারেন্স রয়েছে।	Norethisterone Acetate (Micronized) BP 5.70mg (Eqv. to 5.0 mg Norethisterone) Tablet হিসেবে ডিসিসি-১৪০ তম সভার কার্যবিবরণী সংশোধনের সুপারিশ করা হয়।	Norethisterone Acetate (Micronized) BP 5.70mg (Eqv. to 5.0 mg Norethisterone) Tablet হিসেবে ডিসিসি-১৪০ তম সভার কার্যবিবরণী সংশোধন মঞ্জুর করা হয়।
২.	নিম্নোক্ত তিনটি পদ ডিসিসি-২১৬ তম সভায় inhalation powder হিসেবে অনুমেদিত। a) Salmeterol Xinafoate 50mcg + Fluticasone Propionate 100mcg b) Salmeterol Xinafoate 50mcg + Fluticasone	ডিসিসি-২১৬ তম সভার কার্যবিবরণীতে Dry powder inhaler (DPI) Capsule উল্লেখ করার জন্য প্রস্তাব করা হয়েছে।	ডিসিসি-২১৬ তম সভার কার্যবিবরণীতে Dry powder inhaler (DPI) Capsule উল্লেখ করার সুপারিশ করা হয়।	ডিসিসি-২১৬ তম সভার কার্যবিবরণীতে Dry powder inhaler (DPI) Capsule উল্লেখ করার সিদ্ধান্ত গৃহীত হয়।

ক্রমিক নং	বিষয়	প্রস্তাবনা	ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
	Propionate 500mcg c) Salmeterol Xinafoate 50mcg + Fluticasone Propionate 250mcg			
৩.	ডিসিসি-১৮৯ এ নাইট্রোমিন্ট স্প্রে (Glyceryl trinitrate) অনুমোদন করা হয়। যেখানে কোন strength উল্লেখ ছিল না।	**ডিসিসি-১৮৯ এর কার্যবিবরণী নিম্নরূপ সংশোধনের প্রস্তাব করা হলঃ** নাইট্রোমিন্ট স্প্রে (Glyceryl trinitrate) বা নাইট্রোগ্লিসারিন ৪০০ mcg/Metered Inhalation স্প্রে ।	প্রস্তাবিত সংশোধন অনুমোদনের সুপারিশ করা হয়।	প্রস্তাবিত সংশোধন অনুমোদন করা হয়।
৪.	ডিসিসি-২৩৮ তম সভায় Esomeprazole 20 mg Capsule হিসেবে অনুমোদিত। কিন্তু পদটি DR Capsule হিসেবে অনুমোদন করা প্রয়োজন।	**ডিসিসি-২৩৮ এর কার্যবিবরণী নিম্নরূপ সংশোধনের প্রস্তাব করা হলঃ** Esomeprazole 20 mg DR Capsule।	প্রস্তাবিত সংশোধন অনুমোদনের সুপারিশ করা হয়।	প্রস্তাবিত সংশোধন অনুমোদন করা হয়।
৫.	ডিসিসি-২৩৮ তম সভায় Esomeprazole 40 mg Capsule হিসেবে অনুমোদিত। কিন্তু পদটি DR Capsule হিসেবে অনুমোদন করা প্রয়োজন।	**ডিসিসি-২৩৮ এর কার্যবিবরণী নিম্নরূপ সংশোধনের প্রস্তাব করা হলঃ** Esomeprazole 40 mg DR Capsule।	প্রস্তাবিত সংশোধন অনুমোদনের সুপারিশ করা হয়।	প্রস্তাবিত সংশোধন অনুমোদন করা হয়।
৬.	ডিসিসি-২৫২ তম সভায় সিদ্ধান্ত গৃহীত হয় Molnupiravir INN 200 mg Capsule, Molnupiravir INN 200 mg Tablet, Molnupiravir INN 400 mg Tablet, Molnupiravir INN 800 mg Tablet USFDA কর্তৃক EUA প্রদানের পর উক্ত পদসমূহের অনুকূলে EUA/ রেজিস্ট্রেশন প্রদানের বিষয়ে সিদ্ধান্ত নেওয়া হবে।	**ডিসিসি-২৫২ এর কার্যবিবরণী নিম্নরূপ সংশোধনের প্রস্তাব করা হলঃ** Molnupiravir INN 200 mg Capsule, Molnupiravir INN 200 mg Tablet, Molnupiravir INN 400 mg Tablet, Molnupiravir INN 800 mg Tablet USFDA/UKMHRA/EMA/BNF রেফারেন্স থাকলে EUA/রেজিস্ট্রেশন প্রদান করা হবে।	প্রস্তাবিত সংশোধন অনুমোদনের সুপারিশ করা হয়।	প্রস্তাবিত সংশোধন অনুমোদন করা হয়।

৫.রেফারেন্স না থাকার কারণে ডিসিসি-২৫২ তম সভায় বাতিল করা হয়েছিল, বর্তমানে রেফারেন্স থাকায় ড্রাগ কন্ট্রোল কমিটিতে উপস্থাপন করা হয়, যার সিদ্ধান্ত নিম্নরূপঃ

SI.No	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effects, Warnings and Precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA, UKMHRA, EMA এবং BNF Ref.	ডিসিসি টেকনিক্যাল সাব কমিটির সভার সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
1.	Beacon Pharmaceuticals Limited Nuvista Pharma Ltd. (আবেদন-২৫২)	Roxadustat 20mg Tablet	Roxadustat INN 20mg	Drug used in Anemia and	For the treatment of renal anemia in patients on dialysis	**Contra-indication:** None. **Side-effect:** Upper repiratory infection, hypertension, hyperkalemia.	New	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
2.	Beacon Pharmaceuticals Limited Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna (আবেদন-২৫২) Nuvista Pharma Ltd. (আবেদন-২৫২) Beximco Pharmaceuticals Ltd.Tongi, gazipur, dhaka (আবেদন-২৫২)	Roxadustat 50mg Tablet	Roxadustat INN 50mg	other Blood disorder	For the treatment of renal anemia in patients on dialysis	**Contra-indication:** None. **Side-effect:** Upper repiratory infection, hypertension, hyperkalemia.	New	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
3.	Beacon Pharmaceuticals Limited. Beximco Pharma Ltd.	Roxadustat 100mg Tablet	Roxadustat INN 100mg	Therapeutic Code: 045	For the treatment of renal anemia in patients on dialysis	**Contra-indication:** None. **Side-effect:** Upper repiratory infection, hypertension, hyperkalemia.	New	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

৬.পুনঃ বিবেচনার জন্য উপস্থাপনঃ নিম্নোক্ত পদটি ডিসিসি-২৫২ তম সভায় আমদানির লক্ষ্যে অনুমোদনের সুপারিশ করা হয়। পদটির রেফারেন্স ছিল: CPP- Italy.

ক্রমিক নং	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	ডিসিসি টেকনিক্যাল সাব কমিটির সভার সুপারিশ	ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত
1.	Sanofi S.p.A. Viale Europa, 11 21040 Origgio (VA) Italy **Importer** (Sanofi Bangladesh Limited, Station Road, Tongi, Gazipur-1710, Bangladesh For Contact 6/2/A Segun Bagicha, Dhaka-1000)	Enterogermina 2 Billion/5 ml *[One 5ml mini bottle contains spores of polyantibiotic-resistant Bacillus clausii - 2 billion]*	Bacillus clausii spores (strains O/C, N/R, SIN and T) Oral Suspension	**Therapeutic Class:** Other Classification **Therapeutic Code:** 075	• Prevention and treatment of altered intestinal microflora (dysbiosis) and associated symptoms such as diarrhea, abdominal pain/discomfort and subsequent dysvitaminosis • Therapeutic aid for recovery of the intestinal microflora during treatment with antibiotics or chemotherapeutic agents • Acute and chronic gastrointestinal (GI) disorders in breast-feeding infants, due to GI toxic states or intestinal dysbiosis or dysvitaminosis **Latest clinical study/ outcome:** • **Rota Viral Diarrhea [2019]**: Enterogermina facilitates faster recovery from Rota Viral Diarrhea and helps in normalization of immune markers, contributing to protect children against future infections. *Reference: Smiyan Ol. Et al. Optimization of the treatment of rotavirus infection in children by using Bacillus Clausii. Wiad Lek 2019;72(7):1320-1323* • **Childhood Diarrhea [2018]:** Enterogermina have statistically significant beneficial effects on pediatric clinical outcomes. Faster recovery of Paediatric Diarrhea. *Reference: Ianiro G. et al. Nutrients 2018; 10:1074* **Meets WHO Recommendation of an Ideal Probiotic [2018]:** WHO recommends standard criteria of an ideal probiotics as: be consistent to label, contaminant-free, acid resistant in in the GI tract. In line with WHO recommendations, Enterogermina was found to meet all standard criteria of an ideal probiotic. *Reference: Vecchione A et al, Front Med (Lausanne), 2018:5,59*	**Contraindications:**Hypersensitivity to the active ingredient or any of the excipients. **Side-effects:** In post-marketing experience cases of hypersensitivity reactions including rash and urticaria have been reported. **Pregnancy and lactation**: Limited data are available on the use of probiotics including Enterogermina® in pregnant women. Enterogermina® should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the fetus. There are limited available data on the presence of Enterogermina® in human milk, milk production, or the effects on the breastfed infant. Enterogermina® should be used during breastfeeding only if the potential benefits to the mother outweigh the potential risks, including those to the breastfed child.	New	CPP-Italy	পদটির ৬৫ টি দেশে রেজিস্ট্রেশন রয়েছে। নবজাতক শিশুদের জরুরী চিকিৎসায় পদটি ব্যবহৃত হয় এবং এর প্রয়োজন রয়েছে বিধায় অনাপত্তি সনদের মাধ্যমে পদটি আমদানির সুপারিশ করা হয়।	পদটির ৬৫ টি দেশে রেজিস্ট্রেশন রয়েছে। নবজাতক শিশুদের জরুরী চিকিৎসায় পদটি ব্যবহৃত হয় এবং এর প্রয়োজন রয়েছে বিধায় অনাপত্তি সনদের মাধ্যমে পদটি আমদানির অনুমোদন করা হয়।