DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

Annexure – 14

	FORM Title: Application Assessment Checklist for ICH CTD Dossier Module 3 (Testing Part)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F14-01	01	JUN' 22	JUN' 27		29.05.22	1 of 3

APPLICATION ASSESSMENT CHECKLIST (ICH CTD – UPA AND IPA)

This Application Assessment Checklist should be used to ensure the submission of a complete dataset for Module – 3 (Testing Part) in the ICH Common Technical Dossier (ICH CTD) format and assessment report of Module – 3 for UPA and IPA applications only. Colour scanned copies of the original documents should be submitted and original hard copies of documents are not required.

However, DGDA reserves the rights to request for the original or certified true copy of submitted documents if there is any doubt that a submitted scanned document is not an accurate reflection of the original document. The acceptance of the application after screening including assessment does not preclude requests by DGDA for additional documents or changes to the information/documents during evaluation. This Checklist should be completed by checking each item against the dossier according to the application type.

Note:

- Cells with ☐ indicate that the documents shown are mandatory for the selected application type and evaluation route.
- Cells without ☐ indicate that the documents shown are not required for the selected application type and evaluation route.

Legend:

Application type	UPA	Unintroduced Product Application
	IPA	Introduced Product Application
	IND	Indigenous or locally developed
	IMP	Imported
Evaluation route	RT	Routine MA pathway
	EUA	Emergency Use Authorization

Product Name:

Application Date:

10 NOV 2021

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Module 3 – Laboratory Testing Part **Assessment Started on:**

Section	Documents		Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
				UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
				RT	EUA	RT	EUA			Yes	No	NA	
3.2.P.4	Control of inactive pharmaceutical ingredients			☐	☐	☐	☐	☐	☐	☐	☐	☐	
	3.2.P.4.1	Specifications								☐	☐	☐	
	3.2.P.4.2	Analytical procedures								☐	☐	☐	
	3.2.P.4.3	Validation of analytical procedures								☐	☐	☐	
	3.2.P.4.4	Justifications for specifications								☐	☐	☐	
	3.2.P.4.5	Novel excipients								☐	☐	☐	
3.2.P.5	Control of pharmaceutical products									☐	☐	☐	
	3.2.P.5.1	Specifications								☐	☐	☐	
	3.2.P.5.2	Analytical procedures								☐	☐	☐	
	3.2.P.5.3	Validation of analytical procedures								☐	☐	☐	
	3.2.P.5.4	Batch analysis								☐	☐	☐	
	3.2.P.5.5	Characterization of impurities								☐	☐	☐	
	3.2.P.5.6	Justifications for specifications								☐	☐	☐	
3.2.P.6	Reference standards or materials									☐	☐	☐	

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Section	Documents		Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
				UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
				RT	EUA	RT	EUA			Yes	No	NA	
3.2.P.7	Stability			☐	☐	☐	☐	☐	☐	☐	☐	☐	
	3.2.P.8.1	Stability summary and conclusion								☐	☐	☐	
	3.2.P.8.2	Post-approval stability protocol and stability commitment								☐	☐	☐	
	3.2.P.8.3	Stability data								☐	☐	☐	

Assessment Completed on		**Total Duration**	
Assessment Summary		**Assessment Done By/Date**	
Recommendation		**Head of Vaccine & Biologics Sign/Date**	

Note: 1. Estimated Time duration for Dossier assessment is 05 Months through Routine MA pathway.

2. Estimated Time duration for Dossier assessment is 05 days through EUA pathway.

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Issue date: 10 NOV 2021