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	FORM Title: Application Assessment Checklist for ICH CTD Dossier Module 1, 2 and 3					
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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 – 1, 2, 3 (CMC part) in the ICH Common Technical Dossier (ICH CTD) format and assessment report of Module – 1, 2, 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:

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Module 1 – Administrative Information

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	
1.1		Module 1 table of contents								☐	☐	☐	
1.2		Application letter								☐	☐	☐	
1.3		Information about product								☐	☐	☐	
1.4		Product labelling and packaging information								☐	☐	☐	
	1.4.1	Summary Product Characteristics (SmPC)								☐	☐	☐	
	1.4.2	Patients' information leaflet (PIL)								☐	☐	☐	
	1.4.3	Package and Labels (outer and inner)		☐	☐	☐	☐	☐	☐	☐	☐	☐	
1.5		Information about the experts								☐	☐	☐	
	1.5.1	Name and qualification of head of Quality Assurance								☐	☐	☐	
	1.5.2	Name and qualification of head of quality control								☐	☐	☐	
	1.5.3	Name and qualification of head of product development or R&D								☐	☐	☐	
	1.5.4	Name and qualification of head of production								☐	☐	☐	

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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	
1.6	Specific Requirements for Amendment Application of Registered Products									☐	☐	☐	
	1.6.1	Literature based submissions								☐	☐	☐	
	1.6.2	Variations/amendment								☐	☐	☐	
	1.6.3	Copy of registration								☐	☐	☐	
1.7	Environmental risk assessment									☐	☐	☐	
1.8	Good Manufacturing Practices									☐	☐	☐	
	1.8.1	Last date of inspection of each site		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	1.8.2	Inspection report or equivalent								☐	☐	☐	
	1.8.3	Latest GMP certificate								☐	☐	☐	
	1.8.4	Batch release procedure								☐	☐	☐	
	1.8.5	Active pharmaceuticals ingredients								☐	☐	☐	
	1.8.6	Finished product release control tests for imported products								☐	☐	☐	
	1.8.7	Finished product release responsibility criteria for imported products								☐	☐	☐	

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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	
1.8	1.8.8	Confirmation of contract		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	1.8.9	Certificate of pharmaceutical products								☐	☐	☐	
	1.8.10	Proof of current registration of responsible pharmacist								☐	☐	☐	
	1.8.11	Sample and documents								☐	☐	☐	
	1.8.12	Confirmation of submission of sample								☐	☐	☐	
	1.8.13	Batch manufacturing record of the sample								☐	☐	☐	
	1.8.14	Certificate of analysis of sample								☐	☐	☐	
	1.8.15	Certified copy of permit to manufacture								☐	☐	☐	
	1.8.16	Inspection flow diagram								☐	☐	☐	
	1.8.17	Organogram								☐	☐	☐	
1.9	1.9.1	list of the countries to which an application for the same product has been submitted								☐	☐	☐	
	1.9.2	information and signature of the manufacturers authorized agent								☐	☐	☐	
	1.9.3	number of manufacturer or importers already manufacturing/importing this product								☐	☐	☐	

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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	
1.9	1.9.4	Estimated market for this product/product group in Bangladesh		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	1.9.5	Registration certificates or marketing authorization								☐	☐	☐	
	1.9.6	Foreign prescribing and patient information								☐	☐	☐	
	1.9.7	Data set of similarities								☐	☐	☐	
1.10		Pharmacovigilance plan								☐	☐	☐	
1.11		Details of compliance with screening outcomes								☐	☐	☐	
1.12		Information on price								☐	☐	☐	
	1.12.1	Proposed maximum retail price or indicative price								☐	☐	☐	
	1.12.2	Estimated price per dose, per day treatment and cost of the recommended course of treatment								☐	☐	☐	
1.13		Pediatric development program								☐	☐	☐	
1.14		Risk management plan								☐	☐	☐	

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Module 2 – Quality Overall Summary

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	
2.1	Module Table of Contents									☐	☐	☐	
2.2	Background of the quality overall summary									☐	☐	☐	
2.3	Body data of quality overall summary									☐	☐	☐	
2.3.S	Active pharmaceutical ingredients									☐	☐	☐	
	2.3.S.1	General information		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	2.3.S.2	Manufacture (Name and address of the manufacturer)								☐	☐	☐	
	2.3.S.3	Characterization								☐	☐	☐	
	2.3.S.4	Control of active pharmaceutical ingredients								☐	☐	☐	
	2.3.S.5	Reference standards or materials								☐	☐	☐	
	2.3.S.6	Container closure system											
	2.3.S.7	Stability								☐	☐	☐	

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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	
	2.3.P.1	Control of inactive pharmaceutical ingredient								☐	☐	☐	
	2.3.P.2	Control of pharmaceutical products								☐	☐	☐	
	2.3.P.3	Reference standards or materials								☐	☐	☐	
	2.3.P.4	Container closure system								☐	☐	☐	
	2.3.P.5	Stability								☐	☐	☐	
2.3.A		Appendices		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	2.3.A.1	Facilities and equipment								☐	☐	☐	
	2.3.A.2	Adventitious agent safety evaluation								☐	☐	☐	
	2.3.A.3	Novel excipients								☐	☐	☐	
	2.3.A.4	Regional information								☐	☐	☐	

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Section	Documents		Submitted By (Sign & Seal) Appendices	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
				UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
				RT	EUA	RT	EUA			Yes	No	NA	
2.4	Nonclinical Overview									☐	☐	☐	
2.5	Clinical Overview									☐	☐	☐	
2.6	Nonclinical Written and Tabulated Summaries									☐	☐	☐	
	2.6.1	Introduction								☐	☐	☐	
	2.6.2	Pharmacology Written summary								☐	☐	☐	
	2.6.3	Pharmacology Tabulated summary								☐	☐	☐	
	2.6.4	Pharmacokinetic Written summary								☐	☐	☐	
	2.6.5	Pharmacokinetic Tabulated summary								☐	☐	☐	
	2.6.6	Toxicology Written summary		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	2.6.7	Toxicology Tabulated summary								☐	☐	☐	
2.7	Clinical Summary									☐	☐	☐	
	2.7.1	Summary of Biopharmaceutic Studies and Associated Analytical Methods								☐	☐	☐	
	2.7.2	Summary of Clinical Pharmacology studies								☐	☐	☐	
	2.7.3	Summary of Clinical Efficacy (indication)								☐	☐	☐	
	2.7.4	Summary of Clinical Safety								☐	☐	☐	
	2.7.5	References								☐	☐	☐	
	2.7.6	Synopses of individual Studies								☐	☐	☐	

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Module 3 – Quality (CMC Part)

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	
3.1	Module Table of contents									☐	☐	☐	
3.2	Body of data									☐	☐	☐	
3.2.S	Active pharmaceutical ingredients									☐	☐	☐	
3.2.S.1	General information									☐	☐	☐	
	3.2.S.1.1	Nomenclature								☐	☐	☐	
	3.2.S.1.2	Structure								☐	☐	☐	
	3.2.S.1.3	General properties								☐	☐	☐	
3.2.S.2	Manufacture									☐	☐	☐	
	3.2.S.2.1	Name and address of the manufacturer		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	3.2.S.2.2	Description of manufacturing process and process control								☐	☐	☐	
	3.2.S.2.3	Control of materials								☐	☐	☐	
	3.2.S.2.4	Control of critical steps and intermediates								☐	☐	☐	
	3.2.S.2.5	Process validation and/or evaluation								☐	☐	☐	
	3.2.S.2.6	Manufacturing process development								☐	☐	☐	
3.2.S.3	Characterization									☐	☐	☐	
	3.2.S.3.1	Elucidation of structure and other characteristics								☐	☐	☐	

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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.S.3	3.2.S.3.2	Impurities								☐	☐	☐	
3.2.S.4	Control of active pharmaceutical ingredients									☐	☐	☐	
	3.2.S.4.1	Specifications								☐	☐	☐	
	3.2.S.4.2.	Analytical procedures								☐	☐	☐	
	3.2.S.4.3	Validation of analytical procedures								☐	☐	☐	
	3.2.S.4.4	Batch analysis								☐	☐	☐	
	3.2.S.4.5	Justification for specifications								☐	☐	☐	
3.2.S.5	Reference standards or materials			☐	☐	☐	☐	☐	☐	☐	☐	☐	
3.2.S.6	Container closure system									☐	☐	☐	
3.2.S.7	Stability									☐	☐	☐	
	3.2.S.7.1	Stability summary and conclusions								☐	☐	☐	
	3.2.S.7.2	Post approval stability protocol and stability commitment								☐	☐	☐	
	3.2.S.7.3	Stability data								☐	☐	☐	
3.2.P	Pharmaceutical product									☐	☐	☐	
3.2.P.1	Description and composition of the pharmaceutical product									☐	☐	☐	

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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.2	Pharmaceutical development									☐	☐	☐	
	3.2.P.2.1	Component of pharmaceutical product								☐	☐	☐	
		3.2.P.2.1.1 Active pharmaceutical substances								☐	☐	☐	
		3.2.P.2.1.2 Inactive pharmaceutical ingredients or excipients								☐	☐	☐	
	3.2.P.2.2	Final pharmaceutical product								☐	☐	☐	
		3.2.P.2.2.1 Formulation development								☐	☐	☐	
		3.2.P.2.2.2 Overages								☐	☐	☐	
		3.2.P.2.2.3 Physicochemical and biological properties		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	3.2.P.2.3	Manufacturing process development								☐	☐	☐	
	3.2.P.2.4	Container closure system								☐	☐	☐	
	3.2.P.2.5	Microbiological attributes								☐	☐	☐	
	3.2.P.2.6	Compatibility								☐	☐	☐	
3.2.P.3	Manufacture									☐	☐	☐	
	3.2.P.3.1	Manufacturer								☐	☐	☐	
	3.2.P.3.2	Batch formula								☐	☐	☐	

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				UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
				RT	EUA	RT	EUA			Yes	No	NA	
3.2.P.3	3.2.P.3.3	Description of manufacturing process and process control								☐	☐	☐	
	3.2.P.3.4	Control of critical steps and intermediates								☐	☐	☐	
	3.2.P.3.5	Process validation and/or evaluation								☐	☐	☐	
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	Excipients of human or animal origin								☐	☐	☐	
	3.2.P.4.6	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								☐	☐	☐	

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				UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
				RT	EUA	RT	EUA			Yes	No	NA	
3.2.P.5	3.2.P.5.5	Characterization of impurities								☐	☐	☐	
	3.2.P.5.6	Justifications for specifications								☐	☐	☐	
3.2.P.6	Reference standards or materials									☐	☐	☐	
3.2.P.7	Container closure system									☐	☐	☐	
3.2.P.8	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								☐	☐	☐	
3.2.A	Appendices									☐	☐	☐	
	3.2.A.1	Facilities and equipment								☐	☐	☐	
	3.2.A.2	Adventitious agent safety evaluation								☐	☐	☐	
	3.2.A.3	Novel excipients								☐	☐	☐	
	3.2.A.4	Regional information								☐	☐	☐	

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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.