Electronic Common Technical Document (eCTD) STRUCTURE

Electronic Common Technical Document (eCTD) is applicable only for Medicinal Products classified as Conventional and Biological Medicines

The eCTD is organized into five modules:
Module 1 **: Administrative information and prescribing Information.**
Module 2 **: Common Technical Document Summaries.**
Module 3 **: Quality.**
Module 4 **: Non-Clinical Study Reports.**
Module 5 **: Clinical Study Reports.**

In case of New Chemical Entity (NCE-I), Biologicals and Biosimilars (B), all the eCTD Modules are required as per the following eCTD structure.
In case of Investigational New Drugs (IND), Generic products (G), specific eCTD Modules are required as per the following eCTD structure.

Section	Requirments	IND	I	B	G
Module 1	**Administrative Information**				
1	Covering letter	R	R	R	R
1.1	Comprehensive tabel of content	R	R	R	R
1.2	Application form properly filled and signed by the qualified responsible person (MAH), and a soft copy as word document format	R	R	R	R
1.3	Product Information				
1.3.1	Summary of Product Characteristics (SPC) or investigational brochures (for IND)	R	R	R	R
1.3.2	Labeling Information	R	R	R	R
1.3.3	Patient Information Leaflet (PIL)	R	R	R	R
1.3.3.1	Arabic Leaflet		R	R	R
1.3.3.2	English Leaflet	R	R	R	R
1.3.4	Artworks (Mock-ups) (outer label, inner label and leaflet artworks as hard copy and JPEG format soft copy)		R	R	R
1.3.5	Samples (two original finished samples)		R	R	R
1.4	Information on the Experts				
1.4.1	Quality information (soft copy)		R	R	O
1.4.2	Non-clinical information (soft copy)		R	R	O
1.4.3	Clinical information (soft copy)		R	R	O
1.5	Environmental Risk Assessment				
1.5.1	Non-Genetically Modified Organism (Non-GMO)	R	R	R	O
1.5.2	GMO	R	R	R	O
1.6	Pharmacovigilance				
1.6.1	Pharmacovigilance System (soft copy)		R	R	R
1.6.2	Risk Management Plan (soft copy)		R	R	O
1.7	Certificates				
1.7.1	Original legalised valid Certificate of a Pharmaceutical Product (CPP)		R	R	R
1.7.2	Favoring Opinion report for phaze 1,2 & 3 from recognized Authorities	R			

Electronic Common Technical Document (eCTD) STRUCTURE

1.7.3	Copy of valid GMP certificates for the manufacturing site(s)		R	R	R
1.7.4	Certificate of Analysis - Drug Substance (At least 3 batches from non-local and one batch from local manufacturer)		R	R	R
1.7.5	Certificate of Analysis - Finished Product (At least 3 batches from non-local and one batch from local manufacturer)		R	R	R
1.7.6	Alcohol-content declaration		R	R	R
1.7.7	Pork - free declaration	R	R	R	R
1.7.8	TSE/BSE free certificate		R	R	R
1.7.9	API certificate of suitability or US-FDA approval of the DMF				R
1.7.10	Copy of valid GMP certificate for the API source		R	R	R
1.7.11	API Acknowledgment letter		R	R	R
1.7.12	Relation-ship letters & Technical agreement between parties involved in contract manufacturing and/or marketing (if applicable)		R	R	R
1.7.13	Appointment letter for the local applicant/distributor		R	R	R
1.7.14	Copy of the manufacturing site(s) registration certificate(s)		R	R	R
1.7.15	Composition certificate with active ingredient(s), inactive ingredient(s) quantities per unit dose and functions		R	R	R
1.7.16	The diluents and colouring agents in the product formula		R	R	R
1.7.17	Patent letter with copy of the patent reference	R	R	R	R
1.7.18	Registration and Marketing status in other countries (with copies of registration certificates)		R	R	R
1.8	Pricing				
1.8.1	Original legalised Price Certificate		R	R	R
1.8.2	Other documents related (Comparative studies)		R	R	R
1.9	Responses to questions (Updates, questions, querries)	R	R	R	R
Section	**Requirments**	**IND**	**I**	**B**	**G**
Module 2	**Common Technical Document Summaries**				
2.1	Table of contents of Module 2-5	R	R	R	
2.2	Introduction	R	R	R	
2.3	Quality Overall Summary				
2.3.S	Drug Substance				
2.3.S.1	General Information	R	R	R	
2.3.S.2	Manufacture	R	R	R	
2.3.S.3	Characterization		R	R	
2.3.S.4	Control of Drug Substance		R	R	
2.3.S.5	Reference standards or Materials		R	R	
2.3.S.6	Container/Closure System		R	R	
2.3.S.7	Stability		R	R	
2.3.P	Drug Product				
2.3.P.1	Description and Composition of the Drug Product	R	R	R	
2.3.P.2	Pharmaceutical Development		R	R	
2.3.P.3	Manufacture	R	R	R	
2.3.P.4	Control of Excipients		R	R	
2.3.P.5	Control of Drug Product		R	R	
2.3.P.6	Reference Standards or Materials		R	R	
2.3.P.7	Container/Closure System		R	R	
2.3.P.8	Stability		R	R	
2.3.A	Appendices				
2.3.A.1	Facilities and Equipment		R	R	
2.3.A.2	Adventitious Agents Safety Evaluation		R	R	

Electronic Common Technical Document (eCTD) STRUCTURE

2.3.A.3	Novel Excipients		R	R	
2.3.R	Regional Information	R	R	R	
2.4	Nonclinical Overview				
2.5	Overview of the Nonclinical Testing Strategy				
2.5.1	Product Development Rationale		R	R	
2.5.2	Overview of Biopharmaceutics			R	
2.5.3	Overview of Clinical Pharmacology	R	R	R	
2.5.4	Overview of Efficacy	R	R	R	
2.5.5	Overview of Safety	R	R	R	
2.5.6	Benefits and Risks Conclusions	R	R	R	
2.5.7	References	R	R	R	
2.6	Non clinical written and tabulated summaries: Pharmacology, pharmacokinetics Toxicology				
2.6.1	Introduction	R		R	
2.6.2	Pharmacology Written Summary	R		R	
2.6.2.1	Brief Summary	R		R	
2.6.2.2	Primary Pharmacodynamics		R	R	
2.6.2.3	Secondary Pharmacodynamics		R	R	
2.6.2.4	Safety Pharmacology	R	R	R	
2.6.2.5	Pharmacodynamic Drug Interactions		R	R	
2.62.6	Discussion and Conclusions		R	R	
2.6.2.7	Tables and Figures	R	R	R	
2.6.3	Pharmacology Tabulated Summary				
2.6.4	Pharmacokinetics Written Summary				
2.6.4.1	Brief Summary	R	R	R	
2.6.4.2	Methods of Analysis	R	R	R	
2.6.4.3	Absorption	R	R	R	
2.6.4.4	Distribution	R	R	R	
2.6.4.5	Metabolism (interspecies comparison)	R	R	R	
2.6.4.6	Excretion	R	R	R	
2.6.4.7	Pharmacokinetic Drug Interactions	R	R	R	
2.6.4.8	Other Pharmacokinetic Studies	R	R	R	
2.6.4.9	Discussion and Conclusion	R	R	R	
2.6.4.10	Tables and Figures	R	R	R	
2.6.5	Pharmacokinetics Tabulated Summary				
2.6.6	Toxicology Written Summary				
2.6.6.1	Brief Summary	R	R	R	
2.6.62	Single-Dose Toxicity	R	R	R	
2.6.6.3	Repeat-Dose Toxicity	R	R	R	
2.6.6.4	Genotoxicity	R	R	R	
2.6.6.5	Carcinogenecity	R	R	R	
2.6.6.6	Reproductive and Developmental Toxicity	R	R	R	
2.6.6.7	Local Tolerance	R	R	R	
2.6.6.8	Other Toxicity Studies (if available)	R	R	R	
2.6.6.9	Discussion and Conclusion	R	R	R	
2.6.6.10	References	R	R	R	
2.6.7	Toxicology Tabulated Summary				
2.7	Clinical Summary				
2.7.1	Summary of Biopharmaceutic and Associated Analytical Methods				
2.7.1.1	Background and Overview	R	R	R	
2.7.1.2	Summary of Results of Individual Studies	R	R	R	
2.7.1.3	Comparison and Analyses of Results Across Studies	R	R	R	

Electronic Common Technical Document (eCTD) STRUCTURE

2.7.1.4	Appendix	R	R	R	
2.7.2	Summary of Clinical Pharmacology Studies				
2.7.2.1	Background and Overview	R	R	R	
2.7.2.2	Summary of Results of Individual Studies	R	R	R	
2.7.2.3	Comparison and Analyses of Results Across Studies	R	R	R	
2.7.2.4	Special Studies	R	R	R	
2.7.2.5	Appendix				
2.7.3	Summary of Clinical Efficacy				
2.7.3.1	Background and Overview of Clinical Efficacy	R	R	R	
2.7.3.2	Summary of Results of Individual Studies	R	R	R	
2.7.3.3	Comparison and Analyses of Results Across Studies	R	R	R	
2 7 3 3 1	Study Populations	R	R	R	
2.7.3.3.2	Comparison of Efficacy Results Across All Studies	R	R	R	
2.7.3.3.3	Comparison of Results in Sub-Populations	R	R	R	
2.7.3.4	Analysis of Clinical Information Relevant to Dosing	R	R	R	
2.7.3.5	Persistence of Efficacy and/ or Tolerance Effects	R	R	R	
2.7.3.6	Appendix	R	R	R	
2.7.4	Summary of Clinical Safety				
2.7.4.1	Exposure to the Drug				
2.7.4.1.1	Overall Safety Evaluation Plan and Narratives of Safety Studies	R	R	R	
2.7.4.1.2	Overall Extent of Exposure	R	R	R	
2.7.4.1.3	Demographic and Other Characteristics of Study Population	R	R	R	
2.7.4.2	Adverse Events				
2.7.4.2.1	Analysis of Adverse Events by Organ System or Syndrome	R	R	R	
2.7.4.2.2	Narratives	R	R	R	
2.7.4.3	Clinical Laboratory Evaluations	R	R	R	
2.7.4.4	Vital Signs, Physical Findings, Observations Related to Safety	R	R	R	
2.7.4.5	Safety in Special Groups and Situations				
2.7.4.5.1	Intrinsic Factors	R	R	R	
2.7.4.5.2	Extrinsic Factors	R	R	R	
2.7.4.5.3	Drug Interactions	R	R	R	
2.7.4.5.4	Use in Pregnancy and Lactation	R	R	R	
2.7.4.5.5	Overdose	R	R	R	
2.7.4.5.6	Drug Abuse	R	R	R	
2.7.4.5.7	Withdrawal and Rebound	R	R	R	
2.7.4.5.8	Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability	R	R	R	
2.7.4.6	Post-Marketing Data	R	R	R	
2.7.4.7	Appendix	R	R	R	
2.7.5	References	R	R	R	
2.7.6	Synopses of Individual Studies		R	R	

Section	Requirments	IND	I	B	G
Module 3	Quality				
3.1	Table of contents of Module 3		R	R	R
3.2	Body of data				
3.2.S	Drug Substance				

Electronic Common Technical Document (eCTD) STRUCTURE

3.2.S.1.	General Information				
3.2.S.1.1	Nomenclature	R	R	R	R
3.2.S.1.2	Structure	R	R	R	R
3.2.S.1.3	General Properties	R	R	R	R
3.2.S.2	Manufacture				
3.2.S.2.1	Manufacturer(s)	R	R	R	R
3.2.S.2.2	Descrpition of Process and Process Controls		R	R	R
3.2.S.2.3	Control of Materials		R	R	R
3.2.S.2.4	Control of Critical Steps and Intermediates		R	R	R
3.2.S.2.5	Process Validation and/or Evaluation		R	R	R
3.2.S.2.6	Manufacturing Process Development		R	R	R
3.2.S.3	Characterization				
3.2.S.3.1	Elucidation of Structure and Other Characteristics		R	R	R
3.2.S.3.2	Impurities		R	R	R
3.2.S.4	Control of Drug Substance				
3.2.S.4.1	Specifications		R	R	R
3.2.S.4.2	Analytical Procedures		R	R	R
3.2.S.4.3	Validation of Analytical Procedures		R	R	R
3.2.S.4.4	Batch Analyses		R	R	R
3.2.S.4.5	Justification of Specification		R	R	R
3.2.S.5	Reference Standards or Materials		R	R	R
3.2.S.6	Container/Closure Systems		R	R	R
3.2.S.7	Stability				
3.2.S.7.1	Stability Summary and Conclusions	R	R	R	R
3.2.S.7.2	Post -approval Stability Protocol and Commitment		R	R	R
3.2.S.7.3	Stability Data		R	R	R
3.2.P	Drug Product				
3.2.P.1	Description and Composition of the Drug Product	R	R	R	R
3.2.P.2	Pharmaceutical Development				
3.2.P.2.1	Components of the Drug Product				
3.2.P.2.1.1	Drug Substance		R	R	R
3.2.P.2.1.2	Excipients		R	R	R
3.2.P.2.2	Drug Product				
3.2.P.2.2.1	Formulation Development		R	R	R
3.2.P.2.2.2	Overages		R	R	R
3.2.P.2.2.3	Physiochemical and Biological Properties		R	R	R
3.2.P.2.3	Manufacturing Process Development		R	R	R
3.2.P.2.4	Container Closure System		R	R	R
3.2.P.2.5	Microbiological Attributes		R	R	R
3.2.O.2.6	Compatibility		R	R	R
3.2.P.3	Manufacture				
3.2.P.3.1	Manufacturer(s)	R	R	R	R
3.2.P.3.2	Batch Formula	R	R	R	R
3.2.P.3.3	Description of Manufacturing Process and Process Controls		R	R	R
3.2.P.3.4	Controls of Critical Steps and Intermediates		R	R	R
3.2.P.3.5	Process Validation and/or Evaluation		R	R	R

Electronic Common Technical Document (eCTD) STRUCTURE

3.2.P.4	Control of Excipients				
3.2.P.4.1	Specifications		R	R	R
3.2.P.4.2	Analytical Procedures		R	R	R
3.2.P.4.3	Validation of Analytical Procedures		R	R	R
3.2.P.4.4	Justification of Specifications		R	R	R
3.2.P.4.5	Excipients of Human or Animal Origin		R	R	R
3.2.P.4.6	Novel Excipients		R	R	R
3.2.P.5	Control of Drug Product				
3.2.P.5.1	Specifications		R	R	R
3.2.P.5.2	Analytical Procedures		R	R	R
3.2.P.5.3	Validation of Analytical Procedures		R	R	R
3.2.P.5.4	Batch Analyses		R	R	R
3.2.P.5.5	Characterization of Impurities		R	R	R
3.2.P.5.6	Justification of Specifications		R	R	R
3.2.P.6	Reference Standards or Materials		R	R	R
3.2.P.7	Container/Closure System		R	R	R
3.2.P.8	Stability				
3.2.P.8.1	Stability Summary and Conclusions	R	R	R	R
3.2.P.8.2	Post-Approval Stability Protocol and Stability Commitments		R	R	R
3.2.P.8.3	Stability Data	R	R	R	R
3.2.A	Appendices				
3.2.A.1	Facilities and Equipment		R	R	R
3.2.A.2	Adventitious Agents Safety Evaluation	R	R	R	O
3.2.A.3	Excipients		R	R	R
3.2.R	Regional Information				
3.2.R.1	Alcohol Content Declaration		R	R	R
3.2.R.2	Porcine/Pork-content/origin		R	R	R
3.2.R.3	The diluents and colouring agents in the product formula		R	R	R
3.3	Literature References	R	R	R	R
Section	**Requirments**	**IND**	**I**	**B**	**G**
Module 4	**Non-Clinical Study Reports**				
4.1	Table of Contents of Module 4	R	R	R	
4.2	Study Reports				
4.2.1	Pharmacology				
4.2.1.1	Primary Pharmacodynamics	R	R	R	
4.2.1.2	Secondary Pharmacodynamics	R	R	R	
4.2.1.3	Safety Pharmacology	R	R	R	
4.2.1.4	Pharmacodynamics Drug Interactions	R	R	R	
4.2.2	Pharmacokinetics				
4.2.2.1	Analytical Methods and Validation Reports	R	R	R	
4.2.2.2	Absorption	R	R	R	
4.2.2.3	Distribution	R	R	R	
4.2.2.4	Metabolism	R	R	R	
4.2.2.5	Excretion	R	R	R	
4.2.2.6	Pharmacokinetic Drug Interactions	R	R	R	
4.2.2.7	Other Pharmacokinetic Studies	R	R	R	
4.2.3	Toxicology				
4.2.3.1	Single-Dose Toxicity	R	R	R	
4.2.3.2	Repeat-Dose Toxicity	R	R	R	

Electronic Common Technical Document (eCTD) STRUCTURE

4.2.3.3	Genotoxicity	R	R	R	
4.2.3.3.1	In vitro Studies	R	R	R	
4.2.3.3.2	In vivo Studies	R	R	R	
4.2.3.4	Carcinogenecity				
4.2.3.4.1	Long Term Studies	R	R	R	
4.2.3.4.2	Short or medium term studies	R	R	R	
4.2.3.4.3	Other Studies	R	R	R	
4.2.3.5	Reproductive and Development Toxicity				
4.2.3.5.1	Fertility and Embryonic Development	R	R	R	
4.2.3.5.2	Embryo-Fetal Development	R	R	R	
4.2.3.5.3	Pre- and Post-natal Development & Maternal Function	R	R	R	
4.2.3.5.4	Offspring, Juvenile, Second and Third-Generation Studies	R	R	R	
4.2.3.6	Local Tolerance				
4.2.3.7	Other Toxicity Studies				
4.2.3.7.1	Antigenicity	R	R	R	
4.2.3.7.2	Immunogenicity	R	R	R	
4.2.3.7.3	Mechanistic Studies (not included elsewhere)	R	R	R	
4.2.3.7.4	Dependence	R	R	R	
4.2.3.7.5	Metabolites	R	R	R	
4.2.3.7.6	Impurities	R	R	R	
4.2.3.7.7	Other	R	R	R	
4.3	Literature References	R	R	R	O
Section	**Requirments**	**IND**	**I**	**B**	**G**
Module 5	**Clinical Study Reports**				
5.1	Table of Contents of Module 5	R	R	R	R
5.2	Tabular Listing of All Clinical Studies	R	R	R	R
5.3	Clinical Study Reports				
5.3.1	Reports of BiopharmaceuticStudies				
5.3.1.1	Bioavailability (BA) Study Reports	R	R	R	O
5.3.1.2	Comparative BA & BE Study Reports	R	R	R	R
5.3.1.3	In vitro/In vivo Correlation (IV/IVC) study reports	R	R	R	R
5.3.1.4	Reports of Bioanalytical and Analytical Methods for Human Studies	R	R	R	R
5.3.2	Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials				
5.3.2.1	Plasma Protein Binding Study Reports	R	R	R	
5.3.2.2	Reports of Hepatic Metabolism and Drug Interaction Studies	R	R	R	
5.3.2.3	Reports of Studies Using other Human Biomaterials	R	R	R	
5.3.3	Reports of Human Pharmacokinetic Studies				
5.3.3.1	Healthy Subject PK and Tolerability	R	R	R	
5.3.3.2	Patient PK and Initial Tolerability	R	R	R	
5.3.3.3	Intrinsic Factor PK Study Reports	R	R	R	
5.3.3.4	Extrinsic Factor PK Study Reports	R	R	R	
5.3.3.5	Population PK Study Reports	R	R	R	
5.3.4	Reports of Human Pharmacodynamic (PD) Studies				
5.3.4.1	Healthy Subject PD and PK/PD Study Reports	R	R	R	
5.3.4.2	Patient PD and PK/PD Study Reports	R	R	R	
5.3.5	Reorts of Efficacy and Safety Studies				

Electronic Common Technical Document (eCTD) STRUCTURE

5.3.5.1	Study Reports of Controlled Clinical Studies pertinent to the claimed Indication	R	R	R	
5.3.5.2	Study Reports of Uncontrolled Clinical Studies	R	R	R	
5.3.5.3	Reports of Analyses of Data from More than One Study	R	R	R	
5.3.5.4	Other Study Reports	R	R	R	
5.3.6	Reports of Post-Marketing Experience	R	R	R	R
5.3.7	Case Report Forms and Individual Patient Listings	R	R	R	R
5.4	Literature References	R	R	R	R

Summary of eCTD Structure		CTD Modules			
		1	2	3	4 & 5
Types of Drug Submission	Investigational New Drugs	P	P	R	R
	Innovators	R	R	R	R
	Biologicals / Biosimilars	R	R	R	R
	Generics	R		P	P

All documents issued by the concerned Companies or Applicants should be signed and stamped by the issuing company.

IND: Investigational New Drug.
I: Innovators.
B: Biologicals/Biosimilars.
G: Generics.
R: Required.
P: Partially required.
O: Optional (means that it might not be needed at this stage and the Registration & Drug Control Deparment has the right to ask for this information at any time).

END OF DOCUMENT