Notice to applicant

Submission Guidance for The Common Technical Document for Human Pharmaceutical Products

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Submission Guidance for The Common Technical Document for Human Pharmaceutical Products

- **Scope:**

This guidance is applied to local and imported pharmaceutical products. It provides a standardized approach to the submission of regulatory information, making it easier for health authorities to review and evaluate the data.

- **Objective:**

This guidance presents the format for creating a well-organized dossier that will be submitted by applicants to EDA, where a standard structure for technical documentation can help in making the electronic submissions much simpler and takes less time and effort to compile applications. Additionally, a standard document with common parts will make regulatory evaluations and communication with the applicant easier. This is because the format provides clear guidance on what information is required and how it should be presented, reducing the need for additional formatting and rework.

- **CTD Format:**

Section	Requirements	I	G (Imported)	G (Local)
Module 1	Administrative Information			
1.0	Cover Letter			
	Cover Letter	R	R	R
	Tracking Table	R	R	R
1.2	Application Forms			
1.2.1	Application Form	R	R	R
1.2.2	Legal Documents			
1.2.2.1	Letter of Attorney for Company Representative	R	R	R
1.2.2.2	Manufacturing License and IDA License	R	R	R
1.2.2.3	GMP Certificate(s) / Alternative Documents	R	R	R

1.2.2.4	The Register of Trade	R	R	R
1.2.2.5	Toll Manufacturer License	NR	NR	R
1.2.2.6	Scientific Office License	R	R	NR
1.2.2.7	Importers Register License	R	R	NR
1.2.2.8	Store License	R	R	R
1.2.2.9	Authorisation Letter / Agency Agreement	R	R	R
1.2.2.10	Manufacturing Agreement	R	R	R
1.2.2.11	Packaging Agreement	R	R	R
1.2.2.12	Storage Agreement	R	R	R
1.2.2.13	Other Agreements	R	R	R
1.2.2.14	Termination / Waiver	R	R	R
1.2.3	EDA Approvals			
1.2.3.1	Registration Request Approval	R	R	R
1.2.3.3	Name Approval	R	R	R
1.2.3.4	Registration License	R	R	R
1.2.3.5	Preliminary Approval	R	R	R
1.2.3.6	Non-Reference Approval	R	R	R
1.2.3.8	Pricing Certificate	R	R	R
1.2.3.9	Pharmacovigilance Approval	R	R	R
1.2.3.10	Inspection Report	R	R	R
1.2.3.11	Importation Approval for each API	NR	NR	R
1.2.3.12	CADC Report	R	R	R
1.2.3.13	Stability Study Approval	R	R	R
1.2.3.15	Module 3 Approval	R	R	R

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1.2.3.16	Module 5 Approval	R	R	R
1.2.3.17	Pre-approved letters from EDA concerning the product	R	R	R
1.2.3.18	Variation Approvals	R	R	R
1.2.3.20	Registration License for the Solvent	R	R	R
1.2.4	Declarations			
1.2.4.1	Declaration Letter stating the list of Registered & Under-Registration Products owned by the Toll Company	NR	NR	R
1.2.4.2	Declaration Letter from the License Holder specifying the API Manufacturers	R	R	R
1.2.4.3	Declaration letter from the license holder specifying approved pack in Egypt	R	R	R
1.2.4.4	Declaration Letter from the License Holder stating the Form of Bulk (Strips, Capsules, etc.)	R	R	NR
1.2.4.5	Declaration Letter from the Manufacturer of the active substance to inform the applicant in case of modification of the manufacturing Process or Specifications	R	R	R
1.2.4.6	Declaration Letter from API Supplier	R	R	R
1.2.4.7	Declaration Letter for Site Addition	R	R	R
1.2.4.8	Declaration Letter Form LH stating all Variations & Justification for the Change	R	R	R
1.2.4.9	Other declarations requested by Egyptian Drug Authority	R	R	R
1.2.4.10	List of the Countries where the Product is registered & marketed	R	R	R
1.2.5	Reference Product Document / Compendial			
1.2.5.1	The Reference Product Documents	R	R	R
1.2.5.4	The latest recent Pharmacopeia	R	R	R
1.2.6	Imported Products Documents			

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1.2.6.1	Certificate of Pharmaceutical Product (CPP)	R	R	R
1.2.6.2	List of Affiliates / Subsidiaries	R	R	R
1.2.7	Reliance Documents			
1.2.7.1	Sameness Letter	R	R	NR
1.2.7.2	Unredacted Assessment Report	R	R	NR
1.2.7.3	RRA Variation Application with Annexes	R	R	R
1.2.8	Composition Documents			
1.2.8.1	Composition Certificate	R	R	R
1.2.8.2	Specifications	R	R	R
1.2.8.3	Any Composition Calculations	R	R	R
1.2.8.4	Pellets / Premix Composition and Certificates	R	R	R
1.2.8.5	Opadry / Coating Premix Composition	R	R	R
1.2.8.6	Capsule Shell Composition	R	R	R
1.2.8.7	Synonyms Evidence	R	R	R
1.2.9	Certificate of Analysis	R	R	R
1.2.10	Post Approval Changes Requirements			
1.2.10.1	PAC Approval from the COO (Imported Products)	R	R	R
1.2.10.2	Summary of Change for Variation	R	R	R
1.2.10.3	Justification of the proposed Post Approval Change	R	R	R
1.2.10.4	Any additional Documents relevant to Variations	R	R	R
1.2.11	Proof of Payment	R	R	R
1.3	Product Information			
1.3.1	SPC, Labelling and Package Leaflet	R	R	R
1.3.2	Mock up	R	R	R
1.3.5	Product Information already approved in the member states	R	R	R
	Responses to Questions	R	R	R
	Additional Data	R	R	R

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Note:

- **This Notice to Applicants presents the required documents according to the application categories (Innovator, Imported Generic, and Local products).**
- **For detailed guidance on the applicable Module 1 documents for each regulatory activity (New Registration, Renewals, Variation) and submission scenario, applicants should refer to Module 1 Submission Guidance.**

Section	Requirements	I	G (Imported)	G (Local)
Module 2	**Common Technical Document Summaries**			
2.1	**Table of contents of Module 2-5**	**R**	**NR**	**NR**
2.2	**Introduction**	**R**	**NR**	**NR**
2.3	**Quality Overall Summary**			
2.3.S	**Drug Substance**			
2.3.S.1	**General Information**	**R**	**NR**	**NR**
2.3.S.2	**Manufacture**	**R**	**NR**	**NR**
2.3.S.3	**Characterization**	**R**	**NR**	**NR**
2.3.S.4	**Control of Drug Substance**	**R**	**NR**	**NR**
2.3.S.5	**Reference standards or Materials**	**R**	**NR**	**NR**
2.3.S.6	**Container/Closure System**	**R**	**NR**	**NR**
2.3.S.7	**Stability**	**R**	**NR**	**NR**
2.3.P	**Drug Product (or Finished Pharmaceutical Product (FPP))**			
2.3.P.1	**Description and Composition of the FPP**	**R**	**NR**	**NR**
2.3.P.2	**Pharmaceutical Development**	**R**	**NR**	**NR**
2.3.P.3	**Manufacture**	**R**	**NR**	**NR**
2.3.P.4	**Control of Excipients**	**R**	**NR**	**NR**
2.3.P.5	**Control of FPP**	**R**	**NR**	**NR**
2.3.P.6	**Reference Standards or Materials**	**R**	**NR**	**NR**
2.3.P.7	**Container/Closure System**	**R**	**NR**	**NR**

2.3.P.8	Stability	R	NR	NR
2.3.A	Appendices			
2.3.A.1	Facilities and Equipment	R	NR	NR
2.3.A.2	Adventitious Agents Safety Evaluation	R	NR	NR
2.3.A.3	Excipients	R	NR	NR
2.3.R	Regional information			
2.3.R.1	Production documentation	R	NR	NR
2.3.R.1.1	Executed production documents	R	NR	NR
2.3.R.1.2	Master production documents	R	NR	NR
2.3.R.2	Analytical procedures and validation information	R	NR	NR
2.4	Non-Clinical Overview	R	NR	NR
2.5	Clinical Overview			
2.5.1	Product Development Rational	R	NR	NR
2.5.2	Overview of Biopharmaceutics	R	NR	NR
2.5.3	Overview of Clinical Pharmacology	R	NR	NR
2.5.4	Overview of Efficacy	R	NR	NR
2.5.5	Overview of Safety	R	NR	NR
2.5.6	Benefits and Risks Conclusions	R	NR	NR
2.5.7	References	R	NR	NR
2.6	Non-clinical written and tabulated summaries: Pharmacology, pharmacokinetics Toxicology			
2.6.1	Introduction	R	NR	NR
2.6.2	Pharmacology Written Summary			
2.6.2.1	Brief Summary	R	NR	NR
2.6.2.2	Primary Pharmacodynamics	R	NR	NR

2.6.2.3	Secondary Pharmacodynamics	R	NR	NR
2.6.2.4	Safety Pharmacology	R	NR	NR
2.6.2.5	Pharmacodynamic Drug Interactions	R	NR	NR
2.6.2.6	Discussion and Conclusions	R	NR	NR
2.6.2.7	Tables and Figures	R	NR	NR
2.6.3	Pharmacology Tabulated Summary	R	NR	NR
2.6.4	Pharmacokinetics Written Summary			
2.6.4.1	Brief Summary	R	NR	NR
2.6.4.2	Methods of Analysis	R	NR	NR
2.6.4.3	Absorption	R	NR	NR
2.6.4.4	Distribution	R	NR	NR
2.6.4.5	Metabolism (interspecies comparison)	R	NR	NR
2.6.4.6	Excretion	R	NR	NR
2.6.4.7	Pharmacokinetic Drug Interactions	R	NR	NR
2.6.4.8	Other Pharmacokinetic Studies	R	NR	NR
2.6.4.9	Discussion and Conclusion	R	NR	NR
2.6.4.10	Tables and Figures	R	NR	NR
2.6.5	Pharmacokinetics Tabulated Summary	R	NR	NR
2.6.6	Toxicology Written Summary			
2.6.6.1	Brief Summary	R	NR	NR
2.6.6.2	Single-Dose Toxicity	R	NR	NR
2.6.6.3	Repeat-Dose Toxicity	R	NR	NR
2.6.6.4	Genotoxicity	R	NR	NR
2.6.6.5	Carcinogenicity	R	NR	NR

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2.6.6.6	Reproductive and Developmental Toxicity	R	NR	NR
2.6.6.7	Local Tolerance	R	NR	NR
2.6.6.8	Other Toxicity Studies (if available)	R	NR	NR
2.6.6.9	Discussion and Conclusion	R	NR	NR
2.6.6.10	References	R	NR	NR
2.6.7	Toxicology Tabulated Summary	R	NR	NR
2.7	Clinical Summary			
2.7.1	Summary of Biopharmaceutic and Associated Analytical Methods			
2.7.1.1	Background and Overview	R	NR	NR
2.7.1.2	Summary of Results of Individual Studies	R	NR	NR
2.7.1.3	Comparison and Analyses of Results Across Studies	R	NR	NR
2.7.1.4	Appendix	R	NR	NR
2.7.2	Summary of Clinical Pharmacology Studies			
2.7.2.1	Background and Overview	R	NR	NR
2.7.2.2	Summary of Results of Individual Studies	R	NR	NR
2.7.2.3	Comparison and Analyses of Results Across Studies	R	NR	NR
2.7.2.4	Special Studies	R	NR	NR
2.7.2.5	Appendix	R	NR	NR
2.7.3	Summary of Clinical Efficacy			
2.7.3.1	Background and Overview of Clinical Efficacy	R	NR	NR
2.7.3.2	Summary of Results of Individual Studies	R	NR	NR
2.7.3.3	Comparison and Analyses of Results Across Studies	R	NR	NR
2.7.3.3.1	Study Populations	R	NR	NR

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2.7.3.3.2	Comparison of Efficacy Results Across All Studies	R	NR	NR
2.7.3.3.3	Comparison of Results in Sub-Populations	R	NR	NR
2.7.3.4	Analysis of Clinical Information Relevant to Dosing Recommendations	R	NR	NR
2.7.3.5	Persistence of Efficacy and/ or Tolerance Effects	R	NR	NR
2.7.3.6	Appendix	R	NR	NR
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	NR	NR
2.7.4.1.2	Overall Extent of Exposure	R	NR	NR
2.7.4.1.3	Demographic and Other Characteristics of Study Population	R	NR	NR
2.7.4.2	Adverse Events			
2.7.4.2.1	Analysis of Adverse Events by Organ System or Syndrome	R	NR	NR
2.7.4.2.2	Narratives	R	NR	NR
2.7.4.3	Clinical Laboratory Evaluations	R	NR	NR
2.7.4.4	Vital Signs, Physical Findings, Observations Related to Safety	R	NR	NR
2.7.4.5	Safety in Special Groups and Situations			
2.7.4.5.1	Intrinsic Factors	R	NR	NR
2.7.4.5.2	Extrinsic Factors	R	NR	NR
2.7.4.5.3	Drug Interactions	R	NR	NR
2.7.4.5.4	Use in Pregnancy and Lactation	R	NR	NR

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2.7.4.5.5	Overdose	R	NR	NR
2.7.4.5.6	Drug Abuse	R	NR	NR
2.7.4.5.7	Withdrawal and Rebound	R	NR	NR
2.7.4.5.8	Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability	R	NR	NR
2.7.4.6	Post-Marketing Data	R	NR	NR
2.7.4.7	Appendix	R	NR	NR
2.7.5	References	R	NR	NR
2.7.6	Synopses of Individual Studies	R	NR	NR

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Section	Requirements	I	G (Imported)	G (Local)
Module 3	Quality			
3.1	Table of contents of Module 3	R	R	R
3.2	Body of data			
3.2.S	Drug Substance			
3.2.S.1.	General Information			
3.2.S.1.1	Nomenclature	R	R	R
3.2.S.1.2	Structure	R	R	R
3.2.S.1.3	General Properties	R	R	R
3.2.S.2	Manufacture			
3.2.S.2.1	Manufacturer(s)	R	R	R
3.2.S.2.2	Description of Manufacturing 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 Active Pharmaceutical Ingredients			
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
3.2.S.7.2	Post -approval Stability Protocol and Stability Commitment	R	R	R
3.2.S.7.3	Stability Data	R	R	R
3.2.P	Drug Product (or Finished Pharmaceutical Product (FPP))			
3.2.P.1	Description and Composition of the FPP	R	R	R
3.2.P.2	Pharmaceutical Development			
3.2.P.2.1	Components of the FPP			
3.2.P.2.1.1	Active pharmaceutical Ingredients	R	R	R
3.2.P.2.1.2	Excipients	R	R	R
3.2.P.2.2	Finished Pharmaceutical Product			
3.2.P.2.2.1	Formulation Development	R	R	R

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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.P.2.6	Compatibility	R	R	R
3.2.P.3	Manufacture			
3.2.P.3.1	Manufacturer(s)	R	R	R
3.2.P.3.2	Batch Formula	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
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 FPP			
3.2.P.5.1	Specifications	R	R	R
3.2.P.5.2	Analytical Procedures	R	R	R

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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
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
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
3.2.A.3	Excipients	R	R	R
3.2.R	REGIONAL INFORMATION			
3.2.R.1	Production documentation	R	R	R
3.2.R.1.1	Executed production documents	R	R	R
3.2.R.1.2	Master production documents	R	R	R
3.2.R.2	Analytical procedures and validation information	R	R	R
3.3	Literature References	R	R	R

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Section	Requirements	I	G (Imported)	G (Local)
Module 4	Non-Clinical Study Reports			
4.1	Table of Contents of Module 4	R	NR	NR
4.2	Study Reports			
4.2.1	Pharmacology			
4.2.1.1	Primary Pharmacodynamics	R	NR	NR
4.2.1.2	Secondary Pharmacodynamics	R	NR	NR
4.2.1.3	Safety Pharmacology	R	NR	NR
4.2.1.4	Pharmacodynamics Drug Interactions	R	NR	NR
4.2.2	Pharmacokinetics			
4.2.2.1	Analytical Methods and Validation Reports	R	NR	NR
4.2.2.2	Absorption	R	NR	NR
4.2.2.3	Distribution	R	NR	NR
4.2.2.4	Metabolism	R	NR	NR
4.2.2.5	Excretion	R	NR	NR
4.2.2.6	Pharmacokinetic Drug Interactions	R	NR	NR
4.2.2.7	Other Pharmacokinetic Studies	R	NR	NR
4.2.3	Toxicology			
4.2.3.1	Single-Dose Toxicity	R	NR	NR
4.2.3.2	Repeat-Dose Toxicity	R	NR	NR
4.2.3.3	Genotoxicity	R	NR	NR
4.2.3.3.1	In vitro Studies	R	NR	NR
4.2.3.3.2	In vivo Studies	R	NR	NR
4.2.3.4	Carcinogenicity			
4.2.3.4.1	Long Term Studies	R	NR	NR
4.2.3.4.2	Short- or medium-term studies	R	NR	NR

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4.2.3.4.3	Other Studies	R	NR	NR
4.2.3.5	Reproductive and Development Toxicity			
4.2.3.5.1	Fertility and Embryonic Development	R	NR	NR
4.2.3.5.2	Embryo- Fetal Development	R	NR	NR
4.2.3.5.3	Pre- and Post-natal Development & Maternal Function	R	NR	NR
4.2.3.5.4	Offspring, Juvenile, Second and Third-Generation Studies	R	NR	NR
4.2.3.6	Local Tolerance	R	NR	NR
4.2.3.7	Other Toxicity Studies			
4.2.3.7.1	Antigenicity	R	NR	NR
4.2.3.7.2	Immunogenicity	R	NR	NR
4.2.3.7.3	Mechanistic Studies (not included elsewhere)	R	NR	NR
4.2.3.7.4	Dependence	R	NR	NR
4.2.3.7.5	Metabolites	R	NR	NR
4.2.3.7.6	Impurities	R	NR	NR
4.2.3.7.7	Other	R	NR	NR
4.3	Literature References	R	O	O

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Section	Requirements	I	G (Imported)	G (Local)
Module 5	**Clinical Study Reports**			
5.1	**Table of Contents of Module 5**	**R**	**R**	**R**
5.2	**Tabular Listing of All Clinical Studies**	**R**	**R**	**R**
5.3	**Clinical Study Reports**			
5.3.1	**Reports of Biopharmaceutic Studies**			
5.3.1.1	**Bioavailability (BA) Study Reports**	**R**	**O**	**O**
5.3.1.2	**Comparative BA & BE Study Reports**	**R**	**R**	**R**
5.3.1.3	**In vitro/In vivo Correlation (IV/IVC) study reports**	**R**	**O**	**O**
5.3.1.4	**Reports of Bioanalytical and Analytical Methods for Human Studies**	**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** (If applicable)	**R** (If applicable)
5.3.2.2	**Reports of Hepatic Metabolism and Drug Interaction Studies**	**R**	**NR**	**NR**
5.3.2.3	**Reports of Studies Using other Human Biomaterials**	**R**	**NR**	**NR**
5.3.3	**Reports of Human Pharmacokinetic Studies**			
5.3.3.1	**Healthy Subject PK and Initial Tolerability study report**	**R**	**NR**	**NR**
5.3.3.2	**Patient PK and Initial Tolerability study report**	**R**	**NR**	**NR**
5.3.3.3	**Intrinsic Factor PK Study Reports**	**R**	**NR**	**NR**
5.3.3.4	**Extrinsic Factor PK Study Reports**	**R**	**NR**	**NR**
5.3.3.5	**Population PK Study Reports**	**R**	**NR**	**NR**
5.3.4	**Reports of Human Pharmacodynamic (PD) Studies**			

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5.3.4.1	Healthy Subject PD and PK/PD Study Reports	R	NR	NR
5.3.4.2	Patient PD and PK/PD Study Reports	R	NR	NR
5.3.5	Reports of Efficacy and Safety Studies			
5.3.5.1	Study Reports of Controlled Clinical Studies pertinent to the claimed Indication	R	NR	NR
5.3.5.2	Study Reports of Uncontrolled Clinical Studies	R	NR	NR
5.3.5.3	Reports of Analyses of Data from More than One Study	R	NR	NR
5.3.5.4	Other Study Reports	R	NR	NR
5.3.6	Reports of Post-Marketing Experience	R	NR	NR
5.3.7	Case Report Forms and Individual Listings	R	O	O
5.4	Literature References	R	R	R

Summary of CTD Structure		1	2	3	4	5
Types of Drug Submission	Innovators	R	R	R	R	R
	Generics	R	Incorporated in Modules 3, 4 & 5	R	O	P

Abbreviations:

CTD: Common Technical Document
FPP: Finished Pharmaceutical Product
I: Innovators.
G: Generics.
R: Required.
NR: Not Required
P: Partially required
O: Optional (means that it might not be needed at this stage and the General Administration for Human Pharmaceuticals Registration has the right to ask for this information at any time).

References:

1- ICH: The Common Technical Document
https://www.ich.org/page/ctd

2- Singapore Application Dossier: The Common Technical Document for Registration of Pharmaceuticals for Human use
https://www.hsa.gov.sg/therapeutic-products/register/overview/application-dossier

History Table:

Version Number	Issue Date	Summary of Changes
1	14/8/2023	New Issue
2	21/12/2023	Updating module 1
3	31/3/2024	Updating module 1
4	23/7/2024	Updating Module 1 and Module 5
5	1/11/2025	Updating Module 1 - Updating the requirements of leaflet and mock up to be aligned with One Submission (Page 3, 4 and 5). - Updating Annex I application form (Page 28 – Page 30)
6	10/2026	- Updating Module 1 - Updating Module 5 - Removing Annex I application form

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