Notice to applicant

Submission Guidance for The Common Technical Document for Human Pharmaceutical Products Registration

Year 2025

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Submission Guidance for The Common Technical Document for Human Pharmaceutical Products Registration

- **Scope**

  This guidance is applied on 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 for the registration of human pharmaceutical products. 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.

Section	Requirements	I	G (Imported)	G (Local)
Module 1	**Administrative Information**			
1.1	**Administrative Requirements**			
1.1.1	**Application form** on company letter head signed, stamped and dated **(*Attached (Annex I))**	**R**	**R**	**R**
1.1.2	**Letter of Attorney for Company representative**	**R**	**R**	**R**
1.1.3	**Fees payment receipt** For all relevant services ex: leaflet, bioequivalence, registration dossier submissions	**R**	**R**	**R**
1.1.4	**Action Letter & Name Approval** (For New Products) **Registration License & Preliminary Approval** (For Re-reg Products)	**R**	**R**	**R**
1.1.5	**Pricing Certificate** • Valid Certificate	**R**	**R**	**R**

	• In case of expired one (Provide evidence of submission request for a pricing updating e.g., screenshot) • In case re-evaluation is required kindly submit it.			
1.1.6	**Any Pre-approved letters from EDA concerning product** (e.g., Technical committee decisions, Extension approval…….)	**R**	**R**	**R**
1.1.7	**Variation approvals** (For Re-reg products) **Notes:** • To be arranged by date • Every variation to be submitted in separated sub folder named with the variation type (e.g., Addition of Manufacturer of API, or composition change) in addition to All required studies.	**R**	**R**	**R**
1.1.8	**Pharmacovigilance approval**	**R**	**R**	**R**
1.1.9	**Leaflet** **In case of Rolling Submission** **Approved leaflet** • Valid & Updated Leaflet. **In case of One Submission** • Proposed Leaflet (English and Arabic in Word format (SmPC & PIL) • The most Updated reference for both SmPc & PIL • **In case of imported and innovator products with PIL only**: A Legalized letter from the country of origin clarifying that the attached leaflet (Patient information leaflet) with the specified Trade Name, generic name, concentration, version date and version number is marketed and registered in the country of origin and is to be translated to Arabic language as the patient information leaflet.	**R**	**R**	**R**

	• **<u>For non-English leaflets:</u>** - A Declaration Letter from License Holder commit that the leaflet is translated according to authorized medical translation on their responsibility in accordance with the translation attached. (Signature & Stamp) **Or** - Legalized letter from the head office stating that the scientific office is responsible for the translation and the leaflet is translated medical translation through their scientific office, the medical translation submitted (2 languages: English and Non-English)) should be signed and stamped by the scientific office. - A declaration letter from the scientific office declares that the letter is to be legalized within 6 months • **<u>In case of Non referenced product:</u>** Committee approval (s) • **<u>In case of non-English reference:</u>** Authorized Translation of the Reference **Pharmacology guidelines for warnings and exceptions should be checked*			
1.1.10	**Layout** **<u>In case of Rolling Submission</u>** **Approved layout** **<u>In case of One Submission</u>** **1-Coloured stamped outer and inner layout** (an editable PDF is preferable) **2-Monograph of the product according to the latest edition of the pharmacopoeia** (for the compendial products) **3-Complete image of the original pack**	**R**	**R**	**R**

	(For imported and under-license products) *<u>In case the submitted soft layout is accepted,</u> the hard coloured stamped outer and inner layout must be provided to the unit administrator for signing and stamping by the unit.			
1.1.11	**Inspection Report for Pilot / Production Batches** (New Products)	**NR**	**NR**	**R**
	Inspection Report for a Valid and Marketed Batch (Re-Reg Products)	**R**	**R**	**R**
1.1.12	**Importation approval for each API**	**NR**	**NR**	**R**
1.1.13	**Certificate of Pharmaceutical Product (CPP) / Electronic Certificate of Pharmaceutical Product (eCPP) issued by Competent Authorities in Country of Origin** <u>In Case of Imported or Under license Products</u> • Valid • From the country of origin • Issued and authenticated by the competent authority • Signed and stamped by: - Chamber of Commerce or Notary Public or Foreign Affairs (If applicable) - Legalized by the Egyptian Embassy - The Arab Republic of Egypt is mentioned as Importing Country **eCPP is exempted from legalization* • Date of issue is specified • Trade name of the Product is specified • Dosage form (s) and Strength (s) are specified.	**R**	**R**	**R** For Under-License Products

	• License Holder (address, city, country) is specified • Product must be marketed in the COO for not less than one year (if not marketed, explain why marketing is lacking) • Product composition: - Active Ingredient(s) by its salt or hydrate form (if any) with its (their) quantity (ies) per unit dose is (are) specified - Inactive Ingredient(s) with its (their) quantity (ies) per unit dose is (are) specified (could be as attachment) **Notes:** - Capsule shell composition should be included in case of capsules. - If the Name of the product is different in Egypt, it must be noted (If not stated, a separate legalized declaration on the license holder letter head is required)			
1.1.14	**List of Countries in which the product is registered & marketed**	**R**	**R**	**NR**
1.1.15	**Sameness Letter**	**R**	**R**	**NR**
1.1.16	**Unredacted Assessment Report**	**O**	**O**	**NR**
1.1.17	**Company Documents & Agreements**			
1.1.17.1.	**Factory License for Manufacturer& IDA License**	**R** (For imported bulk only)	**R** (For imported bulk only)	**R**
1.1.17.2.	**The register of trade (valid)**	**R**	**R**	**R**
1.1.17.3.	**Toll Manufacturer License (valid)** (For Toll Products)	**NR**	**NR**	**R**

1.1.17.4	**Scientific Office License**	**R**	**R**	**NR**
1.1.17.5.	**Importers register license**	**R**	**R**	**NR**
1.1.17.6.	**Store License** (If different from factory)	**R**	**R**	**R**
1.1.17.7.	**Agreements** ▪ **Manufacturing between the applicant and the manufacturer.** - Authenticated by the bank Or Legal department of EDA) - Imported products are exempted from submission ▪ **Storage Agreement** - Authenticated by the bank or legal department of EDA - <u>In case of imported products</u>: Legalized by the chamber of commerce & the Egyptian embassy ▪ **Packaging agreement** - In case of Bulk Imported - Authenticated by the bank & Legal department of EDA ▪ **Authorization letter / Agency agreement** - For Under License Products/Imported products - Legalized by the chamber of commerce & the Egyptian embassy	**R**	**R**	**R**
1.1.17.8.	**Declaration letter stating the list of Registered & Under-Registration products owned by the toll company** (For Toll Products) On company letter head signed, stamped and dated	**NR**	**NR**	**R**

1.1.17.9.	**Declaration letter from the license holder specifying the API manufacturers.** (For Under License Products) - Should be legalized if different entity	**NR**	**NR**	**R**
1.1.17.10.	**Declaration letter from the license holder specifying the API manufacturers (Name and Address) + Module 3.** (For Re-reg products) Legalized by the chamber of commerce & the Egyptian embassy	**O**	**O**	**O** For Under-License Products
1.1.17.11.	**Declaration letter from the License Holder stating the form of bulk (strips, Capsules, etc……)** (In case of Imported Bulk Products) Legalized by the chamber of commerce & the Egyptian embassy	**R**	**R**	**NR**
1.1.18	**Solvents "In Case Dosage Form Powder for Injection"** If a solvent is attached with the product, kindly submit the Registration license for the solvent.	**NR**	**NR**	**R**
1.1.19	**The latest recent pharmacopeia for the finished product.** (In case of Pharmacopeia Products)	**NR**	**NR**	**R**
1.1.20	**Letter of Access in case of API Master File**	**NR**	**NR**	**R**
1.2	**Technical Studies/ Approval**			
1.2.1	**Composition Certificate** • Kindly submit as composition on which the studies are conducted & updated Specifications. • On company letter head Signed and Stamped • Trade name of the Product is specified.	**R**	**R**	**R**

	• Dosage form of the Product is specified. • Active Ingredient(s), it's (their) hydrate(s) and salt form(s) with its (their) quantity (ies) per unit dose is (are) specified. • Inactive Ingredient(s) with its (their) quantity (ies) per unit dose is (are) specified. • <u>For the Locally manufactured products</u>, the composition should be submitted on the manufacturer or applicant head letter. • <u>For Under license products</u>: - If the composition is attached with the CPP, it could be written on the applicant head letter. - If the Composition is not attached in the CPP, a legalized composition should be submitted on the license holder or the manufacturer head letter. **<u>N.B:</u>** **1.** Active Ingredient(s) must be identical to that in C.O.A. of supplier (if not: please submit the synonyms) **2.** Attach the equivalence calculation on the company letter head signed and stamped, with reference for the molecular weight. **3.** Active & Inactive ingredients should be separated in composition. **4.** Any Overage should be mentioned. **5.** **<u>Coated tablets:</u>** • Write the core and coat composition separated & mention the weight of tablet. • Coating composition (e.g. Opadry coat) on the supplier head letter should be attached. **6.** **<u>Hard gelatin capsules:</u>** • Write the body and cap. composition separated & mention the size of capsule. • Composition of the capsule shell on the supplier head letter should be attached.			

	7. **In case of pellets**: Composition on supplier letter head should be attached & attach the calculation of pellets (weight /capsule) on company letter head 8. **Premix** Composition on supplier letter head should be attached.			
1.2.2	**Finished Product Documents**			
1.2.2.1.	**CADC certificate + CADC composition (and Renewal Certificate in case of Re-Reg Products)** (In case of Rolling Submission) * Trade Name & Strength Should be Specified. * Manufacturer & License Holder of Finished Pharmaceutical Product should be Specified * Manufacturer of Active Pharmaceutical Ingredient should be Specified. * Batch Number should be Specified. * Chemical, Physical & Microbiological Tests.	**R**	**R**	**R**
1.2.2.2.	**Stability Approval** (In case of Rolling Submission) Notes Regarding Stability study approval: *Trade Name & Strength Should be Specified. *Manufacturer & License Holder of Finished Pharmaceutical Product should be Specified * Manufacturer of Active Pharmaceutical Ingredient should be Specified. * Batch Number should be Specified. *Purpose Of the study should be Specified. *Composition Should be attached.	**R**	**R**	**R**

	*Finished Product Specification should be attached and should comply with EDA Lab Analysis.			
1.2.2.3.	**Bioequivalence /Comparative In-Vitro Study & Approval "if applicable"** (In case of Rolling Submission) Notes Regarding B.E / Comparative study approval: * Trade Name & Strength Should be Specified. * Manufacturer & License Holder of Finished Pharmaceutical Product should be Specified * Manufacturer of Active Pharmaceutical Ingredient should be Specified. * Batch Number should be Specified. * Purpose Of the study should be Specified. * Composition Should be attached.	**R**	**R**	**R**
1.2.2.4	**Technical Affair Approval** (In case of Rolling Submission)	**R**	**R**	**R**
1.2.3	**Active Pharmaceutical Ingredient Documents**			
1.2.3.1	**Certificate of Analysis of Active Substance** * On supplier head letter * Signed and Stamped * Manufacturing date, Expiry date are specified * Batch number is specified	**R**	**R**	**R**
1.2.3.2.	**Specification** * Recent edition of specifications (pharmacopoeias) and/or in-house specifications of all active ingredients. * In house specification of all inactive ingredients “On the company letter head signed and stamped”	**R**	**R**	**R**
1.2.4	**Good manufacturing practice (GMP)**			

1.2.4.1.	**GMP of Manufacturer/s of Finished Product.** • Valid GMP. • Production lines are specified.	**R**	**R**	**R**
1.2.4.2.	**GMP of Manufacturer/s of API**	**R**	**R**	**R**
1.2.4.3	**Certificate of Suitability of the European pharmacopeia (CEP) (If Applicable)** including any annexes. A written commitment in the event that CEP is revised, renewed or withdrawn by EDQM	**O**	**O**	**O**
1.2.5	**Reference**			
1.2.5.1	**The reference (on-line or textbook)** * Latest Edition of the reference textbook (eg. BNF) *Recent on-line reference: FDA, MHRA, EMA, ANSM, Swissmedic, TGA, Pmda, etc. **Note:** • The Reference product should be registered and marketed • The reference product should be identical to the submitted product in terms of the active ingredient, concentration & dosage form. **OR** **Non-Reference Approval** from Evaluation unit of scientific data & drug development for Human Pharmaceuticals	**R**	**R**	**R**
1.2.5.2	**Leaflet of the reference product**	**R**	**R**	**R**

Notes:

1- In order to accept the registration file for assessment soft copies must be fulfilled.
2- Original copies are required to be submitted Hard after the assessment period for Issuing MA license.
3- Regarding imported products, please don't submit any document that is already fulfilled on other modules.
4- All submitted documents should be scanned and searchable PDF files.
5- **Definitions:**
Rolling Submission: A submission that involves submitting data to the regulatory authorities in stages as it becomes available and receiving feedback and guidance from regulatory authority, allowing for an ongoing review process.
One submission: A submission where the entire registration dossier is submitted at once, following international guidelines. This approach ensures that all necessary information is provided upfront, allowing for comprehensive evaluation.

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
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
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
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

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
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
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

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
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

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	R (If applicable)	R (If applicable)
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	R	R
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			
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	R	R
5.3.6	Reports of Post-Marketing Experience	R	NR	NR
5.3.7	Case Report Forms and Individual Listings	R	R	R
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 Registration & Drug Control Department has the right to ask for this information at any time).

Document History:

Version Number	Issue Date	Summary of Change
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)

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

Annexes:

Application form (Annex I)

Annex I

Application form

السيد الدكتور/ رئيس هيئة الدواء المصرية

تحية طيبة وبعد،،،

نتقدم لسيادتكم بملف التسجيل للحصول على رخصة تسويق المستحضر الآتي:

Trade Name: **English and Arabic**		
Registration Request number /Registration number		
Active Ingredient(s) & Strength (s):		
Pharmaceutical dosage form:		
Route of administration:		
Physical Characters:		
Shelf Life:		
Storage Condition:		
Approved Price Pack:	Note: Kindly Specify No. of Units according to the Pricing Certificate & Packaging Material according to the Stability Approval.	
Price:		
Reference drug product (Note: According to bioequivalence approval)		
Name of reference product (RLD, RS,….:		
Name of MAH, Manufacturer and country of origin:		
Reference Link:		
Therapeutic Group: **ATC Code:**		
Approved Indication		
Applicant:		
Company Profile Username:		

Marketing Authorization Holder/License Holder:	
Manufacturer:	
Manufacturer of Solvent/ Accessories (If Applicable):	

Packager:	
Batch releaser:	
Storage Site & Address:	
Type of registration:	
Market status:	
EDA Chairman Decree:	
Batch Type	
Batch Number(s)	

API information submitted as:	□ Prequalification □ CEP	□ DMF □ Full details in the PD
CEP number & issue date: ***"If applicable"***		
API Name /Form/ Specs:		
Name of Manufacturer & country of origin + Address as in the manufacturer's GMP":		
Studies that had been performed on each manufacturer of API		

Note: The above box can be repeated according to No. of APIs in Product

Contact person:	
Telephone number:	
E-mail:	

وأتعهد أنا الموقع أدناه ..... رئيس مجلس إدارة)أو /العضو المنتدب/ المفوض بالإمضاء(شركة ..... بالآتي:

- بأن كافة البيانات المذكورة أعلاه صحيحة ودقيقة وكاملة.
- الالتزام بأحكام قانون حماية حقوق الملكية الفكرية رقم ٨٢ لسنة ٢٠٠٢ ولائحته التنفيذية دون أدنى مسؤولية على هيئة الدواء المصرية.
- الالتزام بطباعة اسم المصنع وعنوانه والشركة مالكة المستحضر (أو اسم الشركة مالكة الحق في التسويق للمستحضرات المستوردة بدلًا من الشركة مالكة المستحضر وذلك طبقاً لشهادة CPP المقدمة) وتاريخ الإنتاج وتاريخ انتهاء الصلاحية ورقم التشغيلة ورقم التسجيل والسعر على العبوة الخارجية وعدم إحداث أي تغيير في المستحضر إلا بعد الحصول على موافقة هيئة الدواء المصرية.
- إخطار هيئة الدواء المصرية بأسماء جميع الموزعين المعتمدين وبأي تغيير يطرأ على البيانات الخاصة بهم والتأكد من أن الموزع المعتمد يطبق قواعد التخزين والتوزيع الجيد (GSP&GDP) ومتابعتها من قبل الإدارة العامة للتفتيش على المصانع.
- عدم تغيير مصادر المادة الخام الفعالة إلا بعد موافقة الإدارة العامة لتسجيل المستحضرات البشرية، وإلا يلغى إخطار التسجيل.
- تحمل المسئولية الكاملة عن تخزين المواد الخام، وعن جميع مراحل تصنيع المستحضر، وعن مطابقة المستحضر للمواصفات الفنية وتخزين المنتج حتى تمام التوزيع وفى حالة التصنيع لدى الغير يشترط أن يكون المصنع مرخصاً وأن يلتزم بجميع الالتزامات الواردة بهذا القرار بقواعد التصنيع الجيد وما ورد بالقرار الوزاري ٥٣٩ لسنة ٢٠٠٧ بشأن اعتماد المدونة المصرية لأساليب التصنيع الجيد للمستحضرات الصيدلية.
- لا يتم نقل مكان التصنيع أو نقل الملكية إلا بعد موافقة الإدارة العامة لتسجيل المستحضرات البشرية، وإلا يلغى إخطار التسجيل.
- لا يتم نقل ملكية المستحضرات المحلية الابعد مرور ثلاث سنوات من التداول المحلي وموافقة الإدارة العامة لتسجيل المستحضرات البشرية،وإلا يلغى إخطار التسجيل(في حالة المستحضرات المقدمة طبقاً للقرار الوزاري /٤٢٥ ٢٠١٥ و قرار رئيس هيئة الدواء المصرية رقم ٤٥٠/٢٠٢٣ الحالة الأولى)
- لا يتم نقل ملكية المستحضرات المحلية الابعد مرور خمس سنوات من التداول المحلي وموافقة الإدارة العامة لتسجيل المستحضرات البشرية،وإلا يلغى إخطار التسجيل (في حالة المستحضرات المقدمة طبقاً للقرار الوزاري /٦٤٥ ٢٠١٨و قرار رئيس هيئة الدواء المصرية رقم ٤٥٠/٢٠٢٣ الحالة الثالثة)
- أن جميع البيانات المقدمة بملف التحليل بالإدارة المركزية للرقابة الدوائية للمستحضر مطابقة لما تم تقديمة بملف التسجيل بهيئة الدواء المصرية وأن

جميع المستندات والبيانات صحيحة وعلى مسئوليتي الخاصة.

- تقديم شهادة ال GMP وشهادة التحليل الخاصة بالمادة الخام، وذلك عند التقدم لإستيراد المادة الخام بهيئة الدواء المصرية.
- إبلاغ الإدارة العامة لليقظة الصيدلية عن أى آثار عكسية خطيرة يتم رصدها عن هذا المستحضرو تقديم تقرير Safety Periodic Report Update، متابعة مأمونية مستحضراتها وتنفيذ جميع أنشطة اليقظة الدوائية وذلك وفقاً للمهل المحددة والقواعد الواردة بأسس الممارسة الجيدة لليقظة الدوائية الصادرة والمفعلة من الإدارة.
- سوف يتم توزيع المستحضر عن طريق الشركات الآتية:
- تم إجراء دراسات إعادة التسجيل (تحليل بالإدارة المركزية للرقابة الدوائية / دراسة الثبات / دراسة التكافؤ الحيوى / معدل الذوبان)

على تشغيلات إنتاجية باستخدام مصدر المادة الخام:.....

- تتعهد الشركة باستكمال الدراسات على تشغيلات إنتاجية باستخدام مصدر المادة الخام:.....
- تم عمل المتغيرات (Variations) الآتية / لم يتم عمل أى متغيرات (Variations) للمستحضر عن آخر إخطار تسجيل للمستحضر

(لإعادة التسجيل) / موافقة طلب الاستعلام (للمستحضرات الجديدة) :

Type of Variation	From	To	Status (Final /Conditioned)

ختم الشركة

رئيس مجلس الإدارة او المفوض إليه بالإمضاء

الاسم :

التوقيع :

التاريخ :