Requirements for the Registration of innovator and biological Human Medicinal Products

A. General Requirements:

1. The manufacturing plants should be registered within the NMPB.
2. The pharmaceutical product with the same specification should be registered and freely sold in the country of origin and if not please give justifications (Justification should be attached).
3. The application form should be filled by the applicant.
4. The prescribed fees should be paid.
5. All documents should be in English and/or Arabic.

B. Specific Requirements:

1. **Modules 1**: Regional Administrative Information.
2. **Modules 2**: Common Technical Document Summaries.
3. **Modules 3**: QUALITY.
4. **Modules 4**: Non-Clinical Study Reports.
5. **Modules 5**: Clinical Study Reports.

NOTE: Refer to Annex 1 (CTD check list).

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Annex (1)

(Check List Regarding CTD Submission for Drug Registration Purposes)

Drug Name : **Dosage form:** **Concentration:**
Application Type: (check one) ☐ Innovator drug ☐ Biological drug ☐ Biosimilar drug
Submission type : (check one) ☐ Complete manufacturing ☐ Contract manufacturing ☐ Under License
Pack Size: **Pack Type:**
Manufacturer: **Country:** **Marketing Authorization Holder (MAH):** **Country:**
Applicant Name:

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Section	Requirements	Company		
		Yes	No	N.A
Module 1	**Regional Administrative Information**			
1.1	**Comprehensive Table of content**			
1.2	**Product Information**			
1.2.1	Summary of Product Characteristics (SPC)			
1.2.2	Product Package insert Arabic and/or English.			
1.3	**Label of the product (Inner and outer pack) including e.g. (diluent, solvent …..etc.)**			
1.3.1	**Artwork of the finished product (Colored Mock-ups) with dimensions.**			
1.3.1.1	Artwork for the shape of the outer Pack.			
1.3.1.2	Artwork for the shape of the inner Pack			
1. 3.2	**Photos**			
1.3.2.1	Photo of outer Pack for all sides.			
1.3.2.2	Photo of inner Pack for all sides.			
1.3.2.3	Photo of the tablet or capsule by both sides.			
1.4	**Summary of B.E**			
1.5	**Information on the experts**			
1.6	**Environmental Risk Assessment**			
1.7	**Pharmacovigilance**			
1.8	**Certificates**			
1.8.1	**CPP (Certificate of Pharmaceutical Product)(Valid)**			
1.8.1.1	As WHO format			
1.8.1.2	Issued by the Health authority in the exporting country			
1.8.1.3	Authenticated by Sudan Ministry of Foreign Affairs			
1.8.1.4	The composition formula in (CPP) should show the active and inactive ingredients with quantities			
1.8.2	**Certificate(s) of analysis - Drug Substance(s) (on a headed paper and printed) from manufacturer and supplier**			
1.8.3	**Certificate of analysis - Finished Product (on a headed paper and printed)**			
1.8.4	**Certificate of analysis – Excipients from manufacturer and supplier**			
1.8.5	**Declaration from the manufacturer of the finished product that the product is free from Alcohol for oral liquid dosage form.**			
1.8.6	**Certificate stating that the product is free from (TSE) and a halal certificate if the source of the active, inactive and/or any other substance within the product is from animal origin**			
1.9	**Marketing licensing or authorization in other countries:**			
1.9.1	A list of the countries in which this product has been granted license for marketing.			
1.9.2	Photocopy of marketing authorization in each of these countries.			
1.10	**The diluents and coloring agents in the product formula**			
1.11	**Patent Information**			
1.12	**Letter of access or acknowledgment to DMF**			
1.13	**Responses to questions**			

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Module 2	Common Technical Document Summaries			
2.1	**Table of Contents of Module 2-5**			
2.2	**Introduction**			
2.3	**Quality Overall Summary**			
2.3.S	**Drug substance**			
2.3.S.1	General Information			
2.3.S.2	Manufacture			
2.3.S.3	Characterization			
2.3.S.4	Control of Drug Substance			
2.3.S.5	Reference Standards or Materials			
2.3.S.6	Container/Closure System			
2.3.S.7	Stability			
2.3.P	**Drug Product**			
2.3.P.1	Description and Composition of the Drug Product			
2.3.P.2	Pharmaceutical Development			
2.3.P.3	Manufacture			
2.3.P.4	Control of Excipients			
2.3.P.5	Control of Drug Product			
2.3.P.6	Reference Standards or Materials			
2.3.P.7	Container/Closure System			
2.3.P.8	Stability			
2.3.A	**Appendices**			
2.3.A.1	Facilities and Equipment			
2.3.A.2	Adventitious Agents Safety Evaluation			
2.3.A.3	Novel Excipients			
2.3.R	**Regional Information**			
2.4	**Non clinical Overview**			
2.5	**Clinical Overview**			
2.6	**Non-Clinical Written and Tabulated Summaries**			
2.6.1	**Introduction**			
2.6.2	**Pharmacology Written Summary**			
2.6.3	**Pharmacology Tabulated Summary**			
2.6.4	**Pharmacokinetics Written Summary**			
2.6.5	**Pharmacokinetics Tabulated Summary**			
2.6.6	**Toxicology Written Summary**			
2.6.7	**Toxicology Tabulated Summary**			
2.7	**Clinical Summary**			
2.7.1	**Summary of Biopharmaceutic and Associated Analytical Methods**			
2.7.2	**Summary of Clinical Pharmacology Studies**			
2.7.3	**Summary of Clinical Efficacy**			
2.7.4	**Summary of Clinical Safety**			
2.7.5	**References**			
2.7.6	**Synopses of Individual Studies**			



Module 3	QUALITY			
3.1	**TABLE OF CONTENTS OF MODULE 3**			
3.2	**BODY OF DATA**			
3.2.S	**DRUG SUBSTANCE**			
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	Manufacturer(s)			
3.2.S.2.2	Description of Manufacturing Process and Process Controls			
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			
3.2.S.3.2	Impurities			
3.2.S.4	**Control of the Drug Substance**			
3.2.S.4.1	Specifications			
3.2.S.4.2	Analytical Procedures(Include but not limited to			
3.2.S.4.3	Validation of Analytical Procedures			
3.2.S.4.4	Batch Analyses (3 batches)			
3.2.S.4.5	Justification of Specification			
3.2.S.5	**Reference Standards or Materials**			
3.2.S.6	**Container/Closure Systems**			
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 Commitments			
3.2.S.7.3	Stability Data			
3.2.P	**DRUG PRODUCT**			
3.2.P.1	**Description and Composition of the Drug Product**			
3.2.P.2	**Pharmaceutical Development**			
3.2.P.2.1	Components of the Drug Product			
3.2.P.2.2	Drug Product			
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(s)			
3.2.P.3.2	Batch Formula			
3.2.P.3.3	Description of Manufacturing Process and Process Controls			
3.2.P.3.4	Controls of Critical Steps and Intermediates			
3.2.P.3.5	Process Validation and/or Evaluation			
3.2.P.4	**Control of Excipients**			
3.2.P.4.1	Specifications			

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3.2.P.4.2	Analytical Procedures, include but not limited to			
3.2.P.4.3	Validation of Analytical Procedures			
3.2.P.4.4	Justification of 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 Drug Product**			
3.2.P.5.1	Specifications			
3.2.P.5.2	Analytical Procedures(Include but not limited to			
3.2.P.5.3	Validation of Analytical Procedures			
3.2.P.5.4	Batch Analyses (3 batches)			
3.2.P.5.5	Characterization of Impurities			
3.2.P.5.6	Justification of 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 Conclusions			
3.2.P.8.2	Post-Approval Stability Protocol and Stability Commitments			
3.2.P.8.3	Stability Data			
3.2.A	**Appendices**			
3.2.R	**Regional Information**			
3.2.R.1	Alcohol Content Declaration			
3.2.R.2	Porcine/Pork - content/origin			
3.2.R.3	The diluents and coloring agents in the product formula			
3.3	**Literature References**			



Module 4	**Non-Clinical Study Reports**			
4.1	**Table of Contents of Module 4**			
4.2	**Study Reports**			
4.2.1	Pharmacology			
4.2.2	Pharmacokinetics			
4.2.3	Toxicology			
4.3	**Literature References**			
Module 5	**Clinical Study Reports**			
5.1	**Table of Contents of Module 5**			
5.2	**Tabular Listing of All Clinical Studies**			
5.3	**Clinical study Reports**			
5.4	**Literature References**			

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