# Requirements for the Registration of Foreign 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.
3. The application form should be filled by the applicant.
4. The prescribed fees should be paid.
5. All documents should be in English.

## B. Specific Requirements:

1. **Certificate of Pharmaceutical Product (CPP):**
   - As WHO format (or at least containing the same information).
   - Should be valid and issued by the health authority in the exporting country and authenticated by Sudan Ministry of Foreign Affairs.
   - The composition formula in (CPP) should show the active and inactive ingredients with quantitative formula. (If detailed composition formula is not attached with the CPP, a stamped document from the drug authority at country of origin consists of the composition formula should be submitted along with the registration file).
2. **Marketing licensing or authorization in other countries**:
   - Provide a list of the countries in which this product has been granted license for marketing,
   - Photocopy of marketing authorization in each of these countries
3. **Composition formula from the manufacturer**:
   - Provide a list of all components of the dosage form including components of the mixture (e.g. colorants, coating, capsule shell), if any.
   - Provide amount per unit basis and per batch formula (including overages, if any with justification).
   - Function of components.
   - Specification of components.
   - Source of components.
4. **Product information:**

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- Summary of product characteristics (SPC)
- Product Package insert Arabic and/or English.

5. **Label of the product (inner and outer pack) including e.g. (diluent, solvent …..etc.) (refer to attached labelling requirement)**

5.1. Artwork of the finished product (Colored mock-ups) with dimensions.

- Artwork for the shape of the outer pack.
- Artwork for the shape of the inner pack.

5.2. Photos:

- Photo of outer pack for all sides.
- Photo of inner pack for all sides.
- Photo of the tablet or capsule by both sides.

6. **Certificate(s) of analysis of drug substance(s) (on a headed paper) from manufacturer and supplier.**
7. **Certificate of analysis – excipients (In-actives) from manufacturer and supplier.**
8. **Description of manufacturing process and process controls:**
   - Flow diagram of the manufacturing process.
   - Provide a detailed method of manufacturing procedure for the finished product, including packaging and showing all materials used in the manufacturing process even if they do not appear in the final product.
   - In process control contain critical steps tests and specifications.
9. **Declaration from the manufacturer of the finished product that the product is free from Alcohol for oral liquid dosage form.**
10. **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.**
11. **Certificate of analysis of primary packaging materials from supplier.**
12. **Specification(s) of the finished product.**
13. **Certificate of analysis of the finished Product (on original headed paper).**
14. **Stability data of the finished product:**
    - Finished product: According to WHO climatic zone 4A covering the proposed shelf life.
    - For three commercial batches.
    - Recent study (if not recent ongoing stability study along with old one should be attached).

14.1. **Solvent (diluent):**



- In case of solvent (diluent) submit the same requirements of the finished products as in point

14.2. **In-use stability study:**

- A minimum of two batches, at least pilot-scale batches.

15. **Method of analysis and validation of the finished product**

15.1. Method of analysis of the finished product.

15.2. Validation of analytical Procedures (In case of non-pharmacopeia).

15.3. Verification (in case of official Pharmacopeia)

15.4. Comparison study between pharmacopeial method and in-house method with statistical data (in case of submission of in-house method in presence of pharmacopeial method)

16. Bioequivalence studies (if required).

NOTE:

- These requirements apply to all human medicinal product except biological products.
- Company should provide CD as CTD format for originator products.

**General Secretariat**
**National Medicines and Poisons Board**

