



Republic of Sudan
Federal Ministry of
Health
National Medicines &
Poisons Board
Secretariat General

Requirements for the registration of
Foreign Plant



A. General Requirements:

1. The application form should be filled by the applicant
2. Any required Document certificate in language rather than English or Arabic should submit a translation from authorized body approved by NMPB.

B. Specific Requirements

1. Requirement(s) for registration of foreign plant for human and veterinary medicine:

1. A valid copy of manufacturing license issued by the competent authority in the country of origin.
2. A valid copy of GMP certificate issued by the competent authority in country of origin.
3. Update Site Master File.

2. Requirement(s) for registration of foreign plant for dietary supplement and health product:

1. A valid copy of manufacturing license issued by the competent authority in the country of origin.
2. A valid copy of GMP certificate issued by the competent authority in country of origin or ISO 22000 or HACCP certificate.

3. Requirement(s) for registration of foreign plant for cosmetic product:

1. A valid copy of manufacturing license issued by the competent authority in the country of origin.
2. A valid copy of GMP certificate issued by the health authority in country of origin or ISO 22716.
3. Free sale certificate for a cosmetic product issued from competent authority in the country of origin.

4. Requirement(s) for registration of foreign plant for medical device product:

1. A valid copy of manufacturing license issued by the competent authority in the country of origin (except European countries, USA, Canada, Australia).
2. A valid copy of GMP certificate issued by the health authority in country of origin or ISO 13485.
3. Attach CE Certificate as supportive
4. Document for European countries.



General Secretariat
National Medicines and Poisons Board