Requirements for Registration of Herbal, Dietary Supplements, and Medicated Cosmetic Products

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1. Good Manufacturing Practices (GMP) certificate or ISO certificate:

Should be issued by the competent authorities and legalised document, including the following:

- Certificate number and issue date
- Inspection date(s) and validity
- Licensed product categories
- Licensed product Lines
- Licensed manufacturing activities

2. Free sale certificate:

Should be issued by the competent authorities and legalised document, including the following:

- Certificate No. and Date
- Exporting country
- Importing country
- Product Trade Name
- Product Active Ingredients.
- Product (type) class
- Package Size
- Shelf life
- Storage Condition
- Registration number and date in the country of origin
- MAH
- Manufacturing Company

3. A certified authorization letter issued by the MAH to the agent, including the product name and specifications.

4. Certificate of Composition.

Should be issued by the manufacturer or MAH, including the following:

- Active and inactive ingredients, their uses, and concentrations
- Indications
- Dose
- Adverse effects
- Drug-drug and drug-food interactions (if any)
- Safety use in humans
- Storage conditions
- Shelf life

5. Certificate of Analysis:

Should be issued by the manufacturer or MAH, including the following:

- Physical examination
- Identification by chemical, spectroscopic, or chromatographic tests
- Quality standards (pH, osmolarity, viscosity, volume, etc., as appropriate)
- Limits and results of the assay for the main active ingredient(s)
- Performance characteristics according to dosage form type (e.g., disintegration or dissolution)
- Other quality standards (friability, hardness, water, pH, loss on drying, ash, residue on Ignition, etc., as appropriate)
- Heavy metals concentration
- Microbial limits
- Any other materials or documents if required.

6. Method of Analysis:

Should be issued by the manufacturer or MAH, including the following:

- validated method for the quantitative determination of the main active ingredient(s)
- Bacterial endotoxin test in case of dermal filler products (in case requested by the analyst)
- Working or reference standard material for the active ingredient(s)

7. Stability Study:

Should be issued by the manufacturer and according to the GCC stability guidelines.

8. CIF Price Certificate:

Should be issued by the MAH, including the following:

- Ex-Price in the country of origin
- Wholesale price in the country of origin
- Retail price in the country of origin
- CIF price proposed to Qatar ports
- CIF to other GCC state(s).
- CIF price for the adjacent country in the region

9. Copy of the product label and leaflet signed and stamped as marketed in the country of origin

10. Copy of the product(s) registration certificate in GCC countries or any other countries (If available)

11. In case of a medical claim or any scientific information written on the outer package, a copy of the reference supporting the claim should be submitted

12. Pharmacological, toxicological, and clinical studies (if required)

13. Declaration letter of freedom of the product from hormones, anabolic steroids, anti-inflammatory steroids, psychotropic drugs, alcohol, heavy metals, pathogenic bacteria and , and pork derivatives

14. Transmissible Spongiform Encephalopathies TSE/BSE-free certificate (if applicable)

15. Samples of the products as mentioned in the table below

No	Dosage form	Quantity of Samples Required
1	Tablets and hard gelatin capsules: containing refined raw materials	6 Sealed Packs (in all cases, not less than 100 tablets)
2	Tablets and hard gelatin capsules: containing botanical origin and/or refined raw materials.	6 Sealed Packs (in all cases, not less than 240 tablets or capsules)
3	Soft gelatin capsules	6 Sealed Packs (In all cases, not less than 240 capsules)
4	Semisolid preparations (ointments, creams, and gels)	10 units for weight content more than 15g 20 units for weight content less than 15 g
5	Sachets	Minimum 60 sachets
6	Syrups, oral suspensions, and oral drops	6 Sealed Bottles if it less than 150 ml 4 Sealed Packs if it more than 150 ml
7	Powders	3 Packs (if it is more than 250g) 4 Packs (if it is less than 250 g)
8	Herbal tea bags	6 Sealed Packs (In all cases, not less than 200 tea bags)
9	Eye drops	12 Sealed Units (If it is less than 10 ml). 10 Sealed Units If it is more than 10 ml).
10	Contact lens care products	6 Sealed Packs (If it is less than 100 ml) 4 Sealed Packs (if it is more than 100 ml)
11	Dermal fillers	12 units (1 ml unit)
12	Any other dosage form containing active pharmaceutical ingredient/s	Not less than 10 Units, or according to the sample size required in the manufacturer's method of analysis

16. Two (2) CDs containing all required documents

17. Any other materials or documents, if required

General Specification of the Product Label and Leaflet:

All information on the product label or leaflet should be written in Arabic and/or English language, including the following:

- The brand name of the product
- The generic name (if any)
- Pharmaceutical dosage form
- The pack size
- A list of active ingredient(s) with their quantities or unit dose (the names of herbs should be written in scientific Latin names and common English names)
- Indications, doses, and routes of administration
- Adverse effects and contra-indications
- Uses in pregnancy, lactation, childhood, and the elderly
- The name of manufacturing and distributing companies
- The batch or lot number, dates of production and expiration date are written with indelible ink or engraved
- Storage conditions
- Labels should be free from obscene pictures and sentences
- Product class (food or dietary supplement , herbal product , etc.)

Note: Legalised means authentication of the document from the embassy of Qatar and the Ministry of Foreign Affairs in the country of origin