TO
ALL PRIVATE TRADITIONAL HERBAL CLINICS
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Sub: Registration of Herbal Companies & Products.

Reference to the Ministerial Decision No. 86/2000 regarding the registration of Pharmaceutical companies, products & pricing of the products, and according to the Ministerial Decision No. 02/2001 regarding the registration of Herbal Companies and their products. It was decided to start the process of registration of herbal companies and products. Therefore you are requested to submit the registration files for companies (from which you are importing or intend to import). The registration files should be submitted according to the enclosed guidelines. Please note that in case for import of any herbal drugs a Licensed Drug Stores should be available according to the Ministerial Decision No. 84/2000 which clarify the requirements for the same. Registration Fees will be as follows:-

- Herbal Company - OR 100/=
- Herbal Product - OR 75/=
- Drug Store - OR 300/=

You are requested to take prompt action to submit the requirements within 6 months from the date of this circular. Clearance will not be granted for any consignment after the specified time limit.

The herbal manufacturing companies those are submitted for registration will be inspected by the MOH Inspection Team & after the registration of company, you have to submit products files for registration within one year from the date of registration otherwise registration of the company will be cancelled and No import would be allowed in any case.

Cooperation of all are kindly requested.

Yours faithfully,

Ph. (MRS) SAWSAN AHMED JAFFAR
DIRECTOR GENERAL / CHAIRPERSON OF TCRHC&P

Enclo: a/a
Criteria for Registration of Alternative Medicine Preparations

Herbal Preparations – Ayurvedic Preparations
Chinese Herbal Preparations – Homeopathic Preparations
Due to the increase of demand for Alternative Medicine Preparations (Herbal Preparations, Ayurvedic Preparations, Chinese Herbal Preparations and Homeopathic Medicinal preparations) by Omani residents, the directorate general of pharmaceutical affairs and drug control, Ministry of Health started to give regulations and guidelines to make the availability of these preparations, within a legal framework, in the Sultanate of Oman. These regulations and guidelines are focusing on ensuring consumer protection by guaranteeing that the preparations imported into the Sultanate of Oman, are of highest quality to ensure consumers safety.

DEFINATIONS

**Alternative Medicine:** Any form of Treatment or therapy outside the realm of conventional modern medicine.

**Complementary Medicine (CM):** Treatment or therapy done along with or in addition to conventional medicine, as the two practices complement each other.

**Medicinal Plant:** A plant used for medical purposes like healing or protection of human beings.

**Herbal Medicine:** The use of plants, plant parts, their water or solvent extracts, essential oils, gums, resins, exudates or other forms of advanced products made from plant parts to treat, cure, or prevent a disease in humans.

**Herb:** Plant or plant part valued for its medicinal quality.

**Herbal Preparation:** Preparation used in healing purposes and the main ingredient is a medicinal plant.

**Ayurveda:** Ayurveda is an India's traditional, natural system of medicine that has been practiced for more than 5,000 years.

**Ayurvedic Preparation:** Preparation used for healing or prevention of diseases in human according to the science of Ayurveda.

**Chinese Herbal Medicine (CHM):** A traditional Chinese medicine that uses combinations of herbs to treat specific diseases.

**Chinese Herbal Preparation:** Preparation for healing or prevention of diseases in human according to the Chinese Herbal Medicine science.

**Homeopathy:** System of medicine based on the principle saying "let like be cured by like". A homeopathic prescription is made on the basis of the match between the syndrome initiated in healthy individuals (the pathogenesis), and the syndrome manifested by a sick patient. An extremely small dose of the homeopathic medicine, which can provoke, in a healthy person, the syndrome most similar to that manifested by the patient is prescribed, with the intention of stimulating and directing the body is self-healing capacity.

**Homeopathic Medicinal preparations:** Preparations formulated for use on the principle that they are capable of producing in a healthy person symptoms similar to those which administered to alleviate. Homeopathic Medicinal preparations are prepared from one or more substances called stocks, in accordance with a homeopathic manufacturing procedure. A homeopathic preparation is usually designated by the Latin name of the stock, followed by the degree of dilution as specified in any of the recognized homeopathic pharmacopoeias.
Raw Homeopathic Materials: Raw Homeopathic Materials are of botanical, chemical, mineral or zoological origin which must be mentioned in the known homeopathic pharmacopoeias. A raw material of zoological origin must be shown to be free from any pathologic agent.

Mother Tinctures: Liquid preparations obtained by the solvent action of a suitable vehicle upon raw materials of botanical or zoological origin. They may also be obtained from plant juices with or without the addition of vehicle. It is used for preparation of subsequent homeopathic dilutions.

Potentisation: Dilutions or triturations are obtained from stocks by a process of potentisation in accordance with a homeopathic manufacturing procedure: for a liquid preparation this means successive appropriate succussions; for solid preparation it means successive appropriate triturations. The potentisation steps are usually one of the following:

a- One part of the stock plus 9 parts of the vehicle; they may be designated as 'nX', or 'nXH', 'nO', 'On' or 'nOH', where each dilution 'Decimal' or ten fold dilution and 'n' is the number of dilutions such that the total dilution is $10^n$, (e.g.: $2X = 10^{-2}$ and $3X = 10^{-3}$ and $4X = 10^{-4}$).

b- One part of the stock plus 99 parts of the vehicle; they may be designated as 'nC', 'Cn' or 'nCH', where each dilution is 'Centesimal' or hundred fold dilution and 'n' is the number of dilutions, (the total dilution is $100^{-n}$). (e.g.: $2C = 10^{-4}$ and $3C = 10^{-6}$ and $4C = 10^{-8}$).

Glycerol macerates: Liquid preparations obtained from raw materials of botanical or zoological origin by using glycerol or a mixture of glycerol and either ethanol of a suitable concentration or a solution of sodium chloride of a suitable concentration.

Homeopathic Pharmacopoeia: A Homeopathic Pharmacopoeia is an official publication dealing with recognized drugs giving their standards for source, identity, purity, doses, and manufacturing and analytical specifications. The following homeopathic pharmacopoeias are recognized, for the purposes of this

a- Homeopathic Pharmacopoeia of the United States.

b- German Homoeopathic Pharmacopoeia.

c- French Homeopathic Pharmacopoeia.

d- British Homoeopathic Pharmacopoeia.

e- Indian Homoeopathic Pharmacopoeia.

Materia Medica: A homeopathic Materia Medica is a source giving details of the indications for homeopathic medicines. These indications are derived from 'proves' and clinical experience.

Manufacturer: A manufacturing company is the company holds a manufacturing license and GMP certificate from the competent authority in the country of origin to produce the alternative medicine products.
Requirements For Registration of Herbaceutical Companies, Herbaceutical Preparations and pricing of these Preparations

- In accordance with the ministerial decree No. 86/2000 which deals with the registration of pharmaceutical companies, its Products and Pricing of these products.
- And with the ministerial decree No. 2/2001 which deals with registration of herbaceutical companies and its products.
- The following criteria for Registration of Herbaceutical Companies and Herbaceutical Preparations were undertaken:

Registration of The Manufacturers of Herbal Preparations

1- Application for registration of a herbal preparations will not be accepted, unless the the local agent is licensed and the manufacturer is registered in the Oman Ministry of Health as per form C.

2- The representative or the legal agent must submit a file in Arabic and/or English containing the following:
   a- Copy of the medical store license issued by M.O.H.
   b- legal agent appointment letter issued by the manufacturer and attested true from the Oman Embassy/Consulate in the country of origin or its representative.
   c- Registration certificate of the legal representative or local agent in Ministry of Economy and Commerce.

3- Duly filled Application Form (form C).

4- Manufacturing authorization certificate of the manufacturer (attested true from the competent authority in the country of origin).

5- The Ministry of Health has the right to request an inspection visit before registration in Sultanate of Oman. The manufacturer and the local agent in the Sultanate of Oman must give full co-operation to facilitate this visit for the purpose of confirming that the company is applying the basics of GMP.

6- Site Master Profile + CD showing different production departments if possible.

7- List of the countries where the company or its products are registered.

8- List of products manufactured and/or marketed by the company including:
   a- Products trade names.
   b- Composition “Active and inactive ingredients should be mentioned in details”.
   c- Category of the preparation.
d- Pharmaceutical dosage form.
e- Registration number and date of issue for each product.
f- Date of marketing in the country of origin.
g- Other countries where the product is registered and marketed.

9- Good Manufacturing Practice Certificate (attested true from the Oman Embassy/Consulate or representative in the country of origin.

Registration of The Herbaceutical Preparations

To register a herbaceutical preparation, two separate files for each product should be submitted to Department of Drug Control containing the informations and documents required:

A- Drug registration requirements file.
B- Quality Control Laboratory (QCL) requirements file.

A- Drug registration requirements file

1- A copy of the registration certificate of the manufacturer(s) issued by Oman Ministry of Health.

2- Duly filled Application Form (Form D).

3- CPP or FSC issued by the competent authorities in the country of origin and attested true from the Oman Embassy/Consulate or representative in the country of origin indicating:
   a- Product trade name.
   b- Pharmacopoeial name of each of the herbal ingredients.
   c- Pharmaceutical dosage form.
   d- Pack size (in weight, volume or number of doses).
   e- Registration number and date of issue in the country of origin.
   f- Herbal preparation must be with the same active constituents and concentration in the country of origin.
   g- Active and inactive ingredients should be mentioned in details with the scientific name of the plant, macroscopical and microscopical characters of these plants.
   h- Literature and pack insert should contain the same informations as in the country of origin.
   i- The manufacturing company is registered and fulfills the requirements of the Good Manufacturing Practice and subject to periodical inspection by the competent authorities in the country of origin.
   j- The name and address of the manufacturing company.
   k- Drug interactions.
   l- Sales category (OTC, POM).
   m- Date of registration and marketing in the country of origin.

4- The product labels, inner and outer packs should be in English and Arabic and must have the full informations, like:
   a. Product name.
   b. Active ingredients and concentrations.
   c. Route of administration.
   d. Manufacturing and expiry date.
   e. Batch number.
   f. Storage conditions.
   g. Dosage form.
h. Warnings and contraindications.
i. Must be used under supervision of physician.
j. Pack size.

5- Scientific report from the manufacturer indicating:
a- Origin of every ingredient and its pharmacological effect and therapeutic uses.
b- Dose, side effects, adverse reactions, precautions, toxicity and antidote.
c- List of countries where the product is marketed or registered especially in Europe or USA.
d- Drug interactions.
e- Date of cultivation and harvesting of herbs.
f- Alcohol content specified in % and must not exceed the limits mentioned in the Minstrial decree No. 86/2000.

6- A letter from the manufacturer indicating that the preparation is free from steroids, sex hormones, pesticides, insect debris, heavy metals, aflatoxins and animal excreta.

7- A letter from the manufacturer indicating that the preparation is free from adulteration with synthetic materials.

8- A leaflet (pack insert) in English and Arabic indicating:
a. Product trade name.
b. Active and inactive ingredients and concentrations should be mentioned in details.
c. Dosage form.
d. Indications and dosage.
e. Route of administration.
f. Side effects, adverse reactions, precautions, toxicity and antidote.
g. Storage conditions.
h. Contraindications.
i. Drug interaction.
j. Use in pregnancy, lactation, children and elderly people.
k. Name and address of the manufacturer.

9- Packaging material specifications.

10- The registration of herbal preparation will be cancelled in the following cases:
a. Proved to be poisonous or having serious side effects.
b. Registration is cancelled or production of the herbal preparation is banned or suspended in the country of origin or any other countryon grounds of safety, quality or lack of efficacy.
c. The submitted certificates are not true.

11- Clinical trials: The applicant should submit documented information of the clinical trials performed in humans (if available) or any published scientific papers.

12- The applicant should submit an authenticated Price Certificate showing the following:
i. Ex-Factory price in the country of origin.
ii. Wholesale price in the country of origin.
iii. Retail price in the country of origin.
iv. CIF price to Oman or any Gulf country “Main Port”
v. CIF approved/proposed for GCC countries and any other Arab countries.
B. Central Quality Control Lab. Requirements

The following requirements should be submitted in a separate file:

1- Composition formula stating the qualitative and quantitative particulars of the active substance(s) and excipients. (The composition of any solvent or solvent mixture added, must be indicated)

2- Manufacturing process: Description of the method of preparation of the finished product should be provided. The description should include details of the process together with the controls exercised.

3- Controls and Specifications:

   A. Starting material:
      A comprehensive specification must be submitted for each ingredient. This must be established on the basis of recent scientific data and must give particulars of (scientific names of medicinal plants used, geographical source, and cultivation and collection techniques, time of harvesting, identification techniques, tests for toxic heavy metals, adulterants and tests for microbial contaminations).

   B. Finished product:

      i. Description: A qualitative description of the dosage form should be provided (e.g., size, shape, color, homogeneity). The acceptance criteria should include the final acceptable appearance at the end of the shelf life.

      ii. Identification: Identification tests should establish the specific identity of the active ingredient(s) in the product and optimally should be discriminatory with regard to substitutes/adulterants those are likely to occur.

      iii. Assay: In case of products containing constituents of known therapeutic activity, validated assays of the content of these constituents are required along with details of the analytical procedure(s) in the finished product. In cases where use of a non-specific assay is justified, other supporting analytical procedures should be used to achieve overall specificity. In the case of products containing preparations where the constituents responsible for the therapeutic activity are unknown, assay of marker substances or other justified determinations are required.

      iv. Impurities: Organic and inorganic impurities are included in this category i.e. contaminants such as pesticides/fumigant residues, heavy metals, residual solvents arising from the manufacture of the product and major impurities arising from degradation of the product constituents.

      v. Microbial limits: It is required to specify the total count of aerobic microorganisms, yeasts and moulds and the absence of specific objectionable bacteria. These limits should comply with the international compendia. The frequency of testing should be justified.

      vi. Specific tests/criteria:

          Tablets (coated and uncoated) hard & soft capsules:
- Composition formula of the empty capsule shell, stating the type and quantities of the colorants used.

- Dissolution/ disintegration: In case of immediate release products and without constituents with known therapeutic activity, the test for in vitro active ingredient release can be omitted.

- Hardness/Friability: The acceptance criteria should be included in the specifications.

- Uniformity of dosage units: This term includes both uniformity of content and uniformity of mass; a pharmacopoeial procedure should be used if appropriate.

- Water content: A test for water content should be included when appropriate.

Oral liquids: One or more of the following tests will normally be applicable to oral liquids and to powder intended for reconstitution as oral liquids:

- pH: Acceptance criteria for pH should be provided where applicable and the proposed range justified.

- Antimicrobial preservatives content: For oral liquids needing an antimicrobial preservative, acceptance criteria for preservative content must be stated. These criteria should be based on the levels necessary to maintain microbiological product quality throughout the shelf life. The lowest specified concentration of antimicrobial preservative should be demonstrated to be effective in controlling microorganisms preservative effectiveness test.

- Antioxidant content

- Extractables: Where data demonstrate the need, tests and acceptance criteria for extractables from the container – closure system component (e.g. rubber, stopper, cap liner, plastic bottle, etc) are considered appropriate for oral solutions packaged in non-glass systems or glass containers with non-glass closures. The container/closure components should be listed.

- Alcohol content: Where it is declared quantitatively on the label, the alcohol content should be specified.

- Viscosity

- Specific gravity

Creams/Ointments/Lotions/Shampoos:

- Rheological properties (Viscosity, spreadability & homogeneity)

- PH

Powders

- Bulk density
4- Reference standards as per the circular No. 20/2005 dated 16.03.05

a. Working standards along with its certificates of analysis for active ingredient(s), preservative(s), antioxidant(s), any degradation or related substances, stated in the finished products specifications and method of analysis, should be submitted.

b. Primary standards are required whenever it is applicable.

c. Product placebo is required whenever it is applicable.

5- Analysis requirements as chromatographic columns and chemical reagents will be requested upon need.

6- Products sample (10 numbers) with the relevant batch analysis certificate.

7- Stability study supporting the product proposed shelf life as per the GCC guidelines.

Priority will be given for the registration of products according to their therapeutic importance.

- Registration is valued for 5 years.

Applications for registration must be submitted to:
Department of Drug Control
Ministry of Health
Sultanate of Oman
Muscat
P.O.B. 393
Postal Code 100
Application Form For Registration of Herbaceutical or Homeopathic Manufacturer

This Application Form to be filled by the applicant by typing ONLY (original & one photocopy).
- All the documents submitted with this application should either be in English and/or Arabic.
- Arrangement of the documents in the folder should follow the same sequence followed in this form.

Part I: (To be filled by legal local agent)

1- Type of application: New [ ] Re-registration [ ]

2- Cash receipt for R.O. 100/-: Attached [ ] Not attached [ ]
   - Receipt No.: [ ]
   - Date: [ ]

3- Name and Address of the Local Agent in Oman
   اسم وعنوان الوكيل المحلي في عمان

4- Copy of store license issued by M.O.H.: Attached [ ] Not attached [ ]

5- A letter from the herbaceutical or homeopathic company confirming that the applicant is the local Agent in the Sultanate
   خطاب من الشركة المصنعة بأن المتقدم بالطلب هو الوكيل المحلي بالسلطنة

6- Photocopy of Ministry of Commerce & Industry, Oman certificate indicating that the applicant is the Agent of the herbaceutical or homeopathic company in the Sultanate
   نسخة من شهادة وزارة الصناعة والتجارة بالسلطنة بأن المتقدم هو الوكيل للشركة المصنعة للمستحضر العشبي

Name & Signature of the authorized person
Local Agent

Stamp of the Local Agent

Name & Signature
Local Agent
**Part II**: (To be filled by the Company)

1- Type of the Company: نوع الشركة
   - Parent [ ]
   - Subsidiary [ ]

2- Manufacturer Name: اسم الشركة
   
3- Address of the Company in the Country of Origin:

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<tr>
<th>Address</th>
<th>Manufacturing Plant</th>
<th>Administration Office</th>
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<td>E-mail</td>
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4- Legalized license of the manufacturer of herbal products in the country of origin

   Attached [ ] Not attached [ ]

   a- Manufacturer License No.

   b- Date of first Licensing

5- Legalized Certificate issued by the Health Authorities stating that the manufacturer fulfills the requirements of current Good Manufacturing Practice (cGMP) and the manufacturing plant is subjected to periodic inspection

   Attached [ ] Not attached [ ]

6- Capital asset of the manufacturer

   Attached [ ] Not attached [ ]
7- An undertaking letter from the manufacturer that the finished products exported to the Sultanate will have the same composition & specifications as those marketed in the country of origin

Attached [ ] Not attached [ ]

8- No. of employees & their qualifications in the following departments:

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<tr>
<th>Department</th>
<th>Qualifications</th>
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<td>Ph.D.</td>
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<td>Research</td>
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<td>Production</td>
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<td>Quality Control</td>
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<td>Packaging</td>
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<td>Others</td>
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<td>Grand Total</td>
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9- List of manufacturing equipment / instruments

Attached [ ] Not attached [ ]

10- Statement of Affiliated Branches & their activities

Attached [ ] Not attached [ ]

11- Statement of full responsibility of the parent company towards its affiliated branch (applied for its registration)

Attached [ ] Not attached [ ]

12- Status of registration in other countries:
   a- Legalized list of countries where the company is registered

Attached [ ] Not attached [ ]

b- Photocopies of legalized registration certificate of the company / its products (CPP / FSC) in at least three countries with advanced drug control system

Attached [ ] Not attached [ ]

c- List of products manufactured by the company indicating trade names, generic names and countries where these products are registered and marketed and when

Attached [ ] Not attached [ ]
d- Photocopies of registration certificates of the company and/or the range of its products registered in Gulf Countries if available

Attached ☐  Not attached ☐
مرفة ☐ غير مرقة ☐

13- Research & Development Department:

a- List of the company patented products within the last 10 years indicating the following: Trade, Generic, Chemical names, Dosage forms, Strength, Therapeutic category, Patent number, date and country Where the patent granted.

Attached ☐  Not attached ☐
مرفة ☐ غير مرقة ☐

b- Photocopy of patent certificates for any of the products / molecules

Attached ☐  Not attached ☐
مرفة ☐ غير مرقة ☐

c- Development made by the Company

Attached ☐  Not attached ☐
مرفة ☐ غير مرقة ☐

Name of authorized person of the company اسم الشخص المسئول بالشركة

Signature of the authorized person توقيع الشخص المسئول بالشركة

Company official seal ختم الشركة

Address (P.O. Box, City, Postal Code, Country) العنوان (صندوق البريد - المدينة - الرمز البريدي - البلد)
Application Form for Registration of Herbaceutical Preparation

1- Name of local agent  

2- Address of the local agent  
   Street:  
   City:  
   P.O. Box:  
   Postal Code:  
   Tel. No.:  
   Fax. No.:  
   E-mail:  

3- Agency appointment letter  

   Attached  
   Not attached  

4- Registration of the local agent in ministry of economics and commerce  

   Number  
   Date  

5- Drug Trade name  

6- Pack size  

7- Pharmacopical name  

Name & Signature of the authorized person  
Local Agent  
Stamp of the Local Agent  

Name of local agent  
Address of the local agent  
Agency appointment letter  
Registration of the local agent in ministry of economics and commerce  
Drug Trade name  
Pack size  
Pharmacopical name  

8- Name & address of Marketing Company: 


9- Name & address of Manufacturer 


10- Photocopy of Company Registration Certificate in Oman: 

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11- Steps of manufacture

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12- List of other countries in which the product is registered 

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13- GMP Certificate and letter of relationship in case if the marketing company is not the manufacturer: 

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14- Scientific report including the following:
   a- List of active constituents

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   b- List of inactive constituents

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   c- Source of raw materials and date of cultivation and harvesting

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<td>Section</td>
<td>Details</td>
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<td>d- Pharmacological actions</td>
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<td>e- Medicinal uses</td>
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<td>f- Contraindications</td>
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<td>g- Side Effects</td>
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<td>h- Precautions and warnings</td>
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<tr>
<td>i- Uses during pregnancy</td>
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<td>j- Drug interactions</td>
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<td>k- Dosage and route of administration</td>
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<td>l- Overdose</td>
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<td>m- Effect on driving</td>
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<td>n- Shelf life</td>
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<td>o- Storage conditions</td>
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<td>p- Legal Category in Country of origin</td>
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OTC [ ]  POM [ ]  Controlled [ ]
15- Drug Stability “Annex”

16- Description of Packaging material (composition and suitability)

17- Specimens of Inner and outer packs and labels

18- Methods of quality control applied

19- Scientific report

20- Publications and literatures

21- Legalized price certificate containing:

22- Composition formula of the finished product

23- Specifications & method of analysis of the raw materials

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24- Certificate of analysis (COA) of the finished products

Attached ☐  Not attached ☐

25- Reference standards of the active ingredients with their COA

Attached ☐  Not attached ☐

26- Manufacturing formula and process

Attached ☐  Not attached ☐

27- Stability studies.

Attached ☐  Not attached ☐

28- Finished product specifications (FPS)

Attached ☐  Not attached ☐

29- Detailed method of analysis (MOA) of the finished product with limits of acceptance.

Attached ☐  Not attached ☐

30- 10 samples + Batch Analysis Certificate “BACs”.

Attached ☐  Not attached ☐

31- Qualitative and Quantitative Specifications of different dosage forms of herboceutical products

Attached ☐  Not attached ☐
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<tr>
<th>Received</th>
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**Comments**

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<th>Checked by (QCL):</th>
</tr>
</thead>
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<tr>
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<td>فحص بواسطة &quot;المختبر المركزي&quot;</td>
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<tr>
<th>Signature:</th>
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<td>التوقيع</td>
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<th>Date:</th>
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<tbody>
<tr>
<td>التاريخ</td>
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Record No: ————————

Date: ————————
SULTANATE OF OMAN
MINISTRY OF HEALTH

E - Form E
"Application For Registration Certificate of Homeopathic Product"

1- Name of local agent

2- Address of the local agent
   Street: 
   City: 
   P.O. Box: 
   Postal Code: 
   Tel. No.: 
   Fax. No.: 
   E-mail:

3- Agency appointment letter

4- Registration of the local agent in ministry of economics and commerce
   Number 
   Date

5- Drug Trade name
   Dosage form

6- Pack size
   Strength

7- Pharmacopoeical name

Name & Signature of the authorized person
Local Agent

Stamp of the Local Agent

22
8- Name & address of Marketing Company:

9- Name & address of Manufacturer

10- Photocopy of Company Registration Certificate in Oman:

11- Steps of manufacture

12- GMP Certificate and letter of relationship in case if the marketing company is not the manufacturer:

13- Copies of registration certificates/Approval of Marketing in other countries

14- Legalized price certificate containing:
   - Ex-factory price in country of origin
   - Wholesale price in country of origin
   - Retail price in country of origin
   - Export price to Gulf Countries
   - CIF price to Oman

15- Product (labeled) name (Should be Pharmacopoeial name)

16- Latin name
<table>
<thead>
<tr>
<th>No.</th>
<th>Description</th>
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<tbody>
<tr>
<td>17</td>
<td>English name</td>
<td>Nisil</td>
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<tr>
<td>18</td>
<td>Vehicle used</td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>Alcohol content in the finished product (if applicable)</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Reference pharmacopoea</td>
<td></td>
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<td>21</td>
<td>Potencies</td>
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</tr>
<tr>
<td></td>
<td>Stock's potency</td>
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<tr>
<td></td>
<td>Minimum potency of the finished product</td>
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<tr>
<td></td>
<td>Allot Potency of the finished product</td>
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<td>22</td>
<td>Pharmaceutical dosage form</td>
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<tr>
<td>23</td>
<td>Route of administration</td>
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</tr>
<tr>
<td>23</td>
<td>Duration of treatment</td>
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<td>24</td>
<td>Homeopathic Speciality (Multi-ingredients):</td>
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<td>Product (labelled) name (Should be Pharmacopoeal name)</td>
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<td>Dosage form</td>
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<td>26</td>
<td>Route of administration</td>
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<td>Dispensing mode in the country of origin</td>
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<td>Alcohol content in the finished product (if applicable)</td>
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<td>Homeopathic active principles</td>
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<tr>
<td>Name and Pharmacopoeia used</td>
<td>Plant or animal part</td>
<td></td>
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<th>Potency</th>
<th>Quantity</th>
<th>Unit</th>
<th>per</th>
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<th>Potency</th>
<th>Quantity</th>
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**This part may be completed for both Homeopathic single remedies and specialities, where applicable.**

30- Excipients: (Separate sheet may be attached)

<table>
<thead>
<tr>
<th>Name</th>
<th>Quantity</th>
<th>Units</th>
<th>Per</th>
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</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Quantity</th>
<th>Units</th>
<th>Per</th>
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</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Quantity</th>
<th>Units</th>
<th>Per</th>
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</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Quantity</th>
<th>Units</th>
<th>Per</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td></td>
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<tr>
<td>-----------------------------</td>
<td>---</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Quantity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Units</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Per</strong></td>
<td></td>
<td></td>
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<table>
<thead>
<tr>
<th>31- Container</th>
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<table>
<thead>
<tr>
<th>32- Description of the container and closure (optional)</th>
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<table>
<thead>
<tr>
<th>33- Shelf life</th>
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<table>
<thead>
<tr>
<th>34- Storage conditions:</th>
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<table>
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<tr>
<th>35- Packaging of the product:</th>
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<table>
<thead>
<tr>
<th>Outer pack</th>
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<table>
<thead>
<tr>
<th>Container</th>
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<table>
<thead>
<tr>
<th>Number of containers</th>
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<table>
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<th>Quantity per container</th>
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<table>
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<th>Type of container</th>
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<table>
<thead>
<tr>
<th>Storage conditions</th>
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<table>
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<tr>
<th>36- Indications:</th>
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<table>
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<th>37- Dosage &amp; Direction of use:</th>
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<tbody>
<tr>
<td>No.</td>
<td>Description</td>
</tr>
<tr>
<td>-----</td>
<td>-----------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>38</td>
<td>Special precautions</td>
</tr>
<tr>
<td>40</td>
<td>Trials performed in humans (if available) or any published scientific papers.</td>
</tr>
<tr>
<td>41</td>
<td>Composition formula of the finished product</td>
</tr>
<tr>
<td>42</td>
<td>Specifications &amp; method of analysis of the raw materials</td>
</tr>
<tr>
<td>43</td>
<td>Certificate of analysis (COA) of the finished products</td>
</tr>
<tr>
<td>44</td>
<td>Reference standards of the active ingredients with their COA</td>
</tr>
<tr>
<td>45</td>
<td>Manufacturing formula and process</td>
</tr>
<tr>
<td>46</td>
<td>Stability studies.</td>
</tr>
<tr>
<td>47</td>
<td>Finished product specifications (FPS).</td>
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<tr>
<td>48</td>
<td>Detailed method of analysis (MOA) of the finished product with limits of acceptance.</td>
</tr>
<tr>
<td>49</td>
<td>10 samples + Batch Analysis Certificate &quot;BACs&quot;</td>
</tr>
</tbody>
</table>
50- Qualitative and Quantitative Specifications of different dosage forms of herbaceutical products
الخصائص النوعية والكمية للأشكال الصيدلانية المختلفة للمستحضرات العشبية

Attached  □  Not attached  □
مرفقة  غير مرفقة

Name of authorized person of the company
اسم الشخص المسئول بالشركة

Signature of the authorized person
توقيع الشخص المسئول

Company official seal
خاتم الشركة المعتمد

Address (P.O. Box, City, Postal Code, Country)
العنوان (صندوق البريد - المدينة - الرمز البريدي - البلد)