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Department of Health
OFFICE OF THE SECRETARY
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**ADMINISTRATIVE ORDER**
No. 172 s. 2004

**SUBJECT: Guidelines on the Registration of Herbal Medicines**

I. RATIONALE/ BACKGROUND

Pursuant to the provision of Sections 3(a) and (b) and 26 (a) of R.A. 3720 known as the "Food, Drug and Cosmetic Act", amended by Sections 4 and 19 of E.O. 175 (An Act To Ensure The Safety And Purity Of Foods And Cosmetics, And The Purity, Safety, Efficacy And Quality Of Drugs And Devices Being Made Available To The Public, Vesting The Bureau Of Food And Drugs With Authority To Administer And Enforce The Laws Pertaining Thereto, And For Other Purposes), the following regulations are hereby promulgated governing the registration of drugs herein defined as herbal medicines.

II. SCOPE/ COVERAGE

The Department of Health through its Bureau of Food and Drugs (BFAD) shall ensure the safety, efficacy and good quality of Herbal Medicines.

This Order shall be applicable to all herbal medicines except as provided herein:

1. Medicines/drugs that do not fall within the definition of herbal medicines cited in this regulation shall be governed by other regulations promulgated for drugs in general.

2. Herbal preparations, which are fresh plant material or which have not undergone any process or treatment other than what is essential to their proper drying, packaging, and storage.

III. DEFINITION OF TERMS

For the purpose of this Order, the terms:

**Plant Material** means fresh or dried aerial or underground part(s) of a plant such as leaves, flowers, fruits, seeds, stems, wood, bark, roots,

rhizomes or other plant parts, which maybe entire, fragmented or powdered, including juices, gums, fatty oils, essential oils, and any other substance derived from the plant to be used as is or for further processing such as for galenicals or pharmaceutical dosage forms.

**Herbal Medicines** are finished, labeled medicinal products that contain as active ingredient(s) aerial or underground part(s) of plants or any other plant material, or combination thereof, whether in the crude state or as plant preparations. Herbal medicines may contain excipients in addition to the active ingredient(s).

Additionally, such medicinal plant products shall have specific therapeutic claim(s) and shall be intended for use in the diagnosis, alleviation, cure or treatment of disease, promotion of health or intended to affect or modify the structure or any function of the body of humans or animals.

Drug preparations containing plant material(s) combined with chemically defined therapeutically active substances, including chemically defined isolated constituents of plants used in conventional/western medicines are not considered to be herbal medicines.

**Common Name** refers to the generally accepted local name of the plant as recognized in ethno-botanical or other relevant literature.

**Scientific Name** refers to the binomial nomenclature consisting of the genus and the species to which the specific plant belongs and the name of the author, based on a systematic classification indicating genetic relationships, in which both terms are underlined or italicized and the first letter of the genus is capitalized.

**Official Name** refers to the scientific name, common/local name and the part of the active plant material used in the preparation of the herbal medicine. (ex. *Vitex negundo* L., Lagundi Leaf). Note: This definition also refers to the Official Title as stated in the Philippine Pharmacopoeia.

## IV. POLICIES AND GUIDELINES

1. Only establishments for herbal medicines with a valid license to operate can apply for registration of such products. These establishments can be the manufacturer, trader, importer or distributor of the product.

2. No person shall manufacture, import, export, distribute, sell, offer for sale, advertise, or transfer any herbal medicines which are not registered with the BFAD.

## V. REGISTRATION REQUIREMENTS

1. Notarized letter of application and duly accomplished Form No. 8

2. Certificate of Brand Name Clearance (when applicable)

   Every proposed brand name for an Herbal Medicine shall be submitted for name clearance prior to the filing of an application for registration. This will prevent similarity in brand names with other previously registered products whether Food, Drugs and Devices, Cosmetics or Household Hazardous Substances.

   No imported Herbal Medicine even if it is patented and/or registered in other countries, shall be issued certificate of brand name clearance if the proposed brand name is identical or similar to any brand name registered with the BFAD.

   Application, processing and approval of brand names shall be in accordance with the provisions of Bureau Circular No.21 series of 1999 (Guidelines for the Evaluation of Brand Names for Products to be Registered with the Bureau of Food and Drugs) and Bureau Circular No.8 series of 2003 (Clarification of Guidelines on the Use of BFAD Registered Brand Names).

3. A duly notarized certificate of agreement executed between the manufacturer, trader, importer and/or distributor

4. List of all active plant material(s) and inactive ingredients

   4.1 A complete list of ingredient(s) whether active or inactive with the corresponding amount per unit dose, expressed in the metric system

   4.2 Statement of the active ingredient/s (plant material/s) using scientific name with the common/local name printed below the scientific name. Specific plant part(s) used shall be stated after the common name.

   4.3 Ingredient(s) which are used in the manufacture but which may not be present in the finished product shall be included in the list (e.g. alcohol). Alcohol, if present, in the formulation shall be expressed in percentage (%).

5. Requirements for Raw Materials of Herbal Medicines

   5.1 A certification as to the authenticity of the plant specimen shall be obtained from the Philippine National Museum or any BFAD-recognized taxonomist. In case of imported products, the certificate of authenticity of the plant shall be obtained from the authorized government agency in the country of origin and the Philippine Consulate shall duly authenticate such document.

6. Physical description and tests/quality standards of the finished product

   6.1 Organoleptic and macroscopic description of the finished product
   A description of the appearance, texture, color, odor and taste of the finished product

   6.2 Moisture Content

   6.3 pH (if applicable)

   6.4 Alcohol content (if applicable)

   Standards and limits for specific tests are presented in Annex A.

7. Certificate of analysis of the submitted samples

   An analytical report of the tests carried out to establish the identity, quality and safety of the submitted batch sample/s

8. Full report of methods used, the facilities and quality control procedures in the manufacture, processing and packaging of the finished product

   A complete and detailed description of the manufacturing procedure, including all in-process quality control procedures and the facilities and equipment used in each stage of the manufacturing process

   Full description of the packaging materials used (Refer to Annex C for the Packaging Requirements)

9. Complete quality control procedure(s) for the finished product

   The manufacturer shall conduct quality control tests and procedures. The manufacturer shall establish specifications or limits for such tests where no standard has been set by the BFAD.

   All quality control test procedures for the finished product shall be given in detail including the preparation of test samples for analysis to provide information on how the quality and batch-to-batch uniformity of the product is ensured.

   Data obtained from these tests shall also provide information on the absence of synthetic substances and microbial contaminants.

   A method of identification, and where possible, the quantification of the plant material in the finished product should be defined. If the identification of an active principle is not possible, it should be sufficient to identify a characteristic substance or mixture of substances (e.g. "chromatographic fingerprint") to ensure consistent quality of the product. The finished product should comply with general requirements for the particular dosage form.

10. Stability studies to support claimed shelf-life of the finished product

Stability studies conducted under the following recommended conditions shall be done to determine the most appropriate conditions of storage and to support claimed shelf life:

| | |
|---|---|
| Room temperature: | $30^0C \pm 2^0C$, 75% RH ± 5% RH |
| Elevated Temperature: | $40^0C \pm 2^0C$, 75% RH ± 5% RH |
| Cool temperature: | $8\text{-}15^0C$ |

11. Labels and other labeling materials

The labeling materials for herbal medicines shall conform to the following requirements:

11.1 General Requirements

All information required to appear on the label shall be:

11.1.1 Written in English or in both English and Filipino

11.1.2 Clearly and prominently printed

11.1.3 Sufficiently legible as to distinguish the color contrast, position and spacing of information.

11.1.4 The minimum mandatory information in the labeling materials are:

11.1.4.1 Official name and brand name (if any)

11.1.4.2 Dosage form and dosage strength

11.1.4.3 Therapeutic claim / pharmacologic category

11.1.4.4 Complete name and address of the manufacturer, trader and/or distributor/importer

11.1.4.5 Net content

11.1.4.6 Rx symbol, for prescription product

11.1.4.7 Formulation

11.1.4.8 Indication/s

11.1.4.9 Contraindication(s), precaution(s), warning, wherever applicable

11.1.4.10 Mode of administration / direction for use

11.1.4.11 Batch and/or Lot number

11.1.4.12 Date of manufacture and expiry/expiration date

11.1.4.13 Registration number

11.1.4.14 Storage conditions

11.1.4.15 (For Rx products) Food, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

11.1.5 The principal display panel shall:

11.1.5.1 Contain the particulars required in 11.1.4.1 to 11.1.4.6

11.1.5.2 Conform to the presentation as illustrated in the sample label in Annex B

11.1.6 The following information shall appear outside of the principal display panel:

11.1.6.1 Contain the particulars required in 11.1.4.7 to 11.1.4.15

11.1.6.2 Relevant graphics or illustrations to the identification of the plant material used shall be allowed on the labels as long as it does not obscure or cover pertinent information.

11.1.7 Other information and additional details shall appear on other labeling materials such as inserts/leaflets or secondary packaging.

11.1.8 Formulation

11.1.8.1 The active ingredient stated in its scientific name with the common/local name and part used printed below the scientific name

11.1.8.2 The plant part(s) used stated after the common name

11.1.8.3 The corresponding amount or potency of active ingredient(s) expressed in the metric system

11.1.8.4 Alcohol content expressed in percentage (%).

11.2 Specific Requirement

Official name of the product shall be printed inside an outlined box as illustrated in the sample label in Annex B.

12. Sufficient samples (in market or commercial presentation) for laboratory analysis

Samples of the herbal medicine in commercial presentation with batch and lot no. the same as that on the submitted Certificate of Analysis shall be submitted for the BFAD analysis.

13. Evidence of safety and efficacy

13.1 The following shall be established before the herbal medicines are made available to the public:

13.1.1 Acute Lethal Dose 50 ($LD_{50}$), No-Adverse-Effect Level/Dose and Toxidrome

13.1.2 Pharmacologic Effects in Animals both *In Vivo* and *In Vitro* Studies

13.1.3 Bioassay, when applicable

13.1.4 Non-mutagenicity - including Ames test and Micronucleus test

13.1.5 For products intended to be used for more than ten (10) days: sub-chronic toxicity test conducted over a period of ninety (90) days.

For products to be used for more than thirty (30) days: chronic toxicity test conducted in rodents; mice - over a period of at least nine (9) months; rats - twelve (12) months or equivalent to their lifespan.

For initial registration, the data of at least fifty percent (50%) of the required duration for chronic toxicity test shall be submitted.

13.1.6 For galenical products: Phase I clinical trial

13.1.7 For products in pharmaceutical dosage form: Phases I, II, III clinical trials

13.2 No product shall be registered as Herbal Medicine if:

13.2.1 There is a valid report of adverse drug reaction on the use of the plant material as determined by the BFAD.

13.2.2 There is a valid report of abuse or dependence potential on the use of the plant material.

13.2.3 It contains chemically defined therapeutically active substance(s), including chemically defined isolated constituent(s) of plants used in conventional/western medicine.

13.3 For Herbal Medicines which have been validated by the National Integrated Research Program on Medicinal Plants (NIRPROMP of the PCHRD-DOST), a Memorandum of Agreement (MOA) between NIRPROMP of the PCHRD and the applicant shall be submitted.

13.4 Herbal Medicines which have been validated by other competent research centers (whether local or international), shall require accreditation/approval by the appropriate BFAD committee.

13.5 Additional Requirements for Imported Herbal Medicines

Certificate of Pharmaceutical Product (CPP) issued by the Government Health Agency or any other appropriate agency from the country of origin and duly authenticated by the Philippine Consulate

No herbal medicine from other countries may be registered unless they are freely sold in the country of origin. In case where the product is not freely sold in the country of manufacture, two separate CPPs shall be submitted: the CPP from the country of manufacture and the CPP from a country where the product is freely sold.

13.6 Requirements for Renewal Registration of Herbal Medicines (Refer to Annex D)

## VI. PROCEDURES FOR REGISTRATION

1. Filing of application for registration of Herbal Medicines

A duly licensed herbal medicine establishment files a formal application for registration of herbal medicines. Such establishment can be the manufacturer, trader, or importer-distributor of the product.

The applicant shall submit data and representative samples of the product in support of its request for registration. All information regarding the product shall be fully disclosed.

1.1 Evaluation of submitted documents and samples

The Product Services Division of the BFAD shall evaluate the documents. The quality conformance of the sample products with BFAD-set standards shall be verified at the Laboratory Services Division or any laboratory accredited by the BFAD.

1.2 Final recommendation/action on the application for registration

Final action of approval or denial on the application for registration shall be issued by the BFAD based on the results of the evaluation conducted pursuant to Section 1.1 hereof.

2. Payment of Registration Fees and Costs of Laboratory Analysis

Upon application for registration of herbal medicines, the following non-refundable fees shall be charged for each application:

2.1 Herbal Medicines

2.1.1 Initial registration [for one (1) year]

2.1.1.1 Generic: Php 2,000.00

2.1.1.2 Branded: Php 3,000.00

2.1.2 Renewal registration [for five (5) years]

2.1.2.1 Generic: Php 7,500.00

2.1.2.2 Branded: Php 10,000.00

Note:

1. Initial registration may be valid for 2, 3, 4, or 5 years with payment of corresponding fees.
2. Renewal registration is for five-year duration for herbal medicines starting on the date of expiration of the CPR.

2.2. Cost of laboratory analysis - to be computed based on the test requirements of a specific product

VII. PROHIBITED ACTS AND SANCTIONS

The prohibited acts and sanctions embodied in R.A. 3720 as amended by E.O. 175 as far as applicable are hereby adopted.

VIII. REPEALING CLAUSE

All orders, circulars, rules and regulations, or portions thereof, inconsistent with this Order are hereby repealed or modified accordingly.

IX. EFFECTIVITY

This regulation shall take effect fifteen (15) days after its publication in two newspapers of general circulation.

**MANUEL M. DAYRIT, M.D., MSc.**
**Secretary of Health**

## ANNEX A

**Standards for the Determination of the Identity, Purity and Quality of Herbal Medicines**

1. To establish the identity of the plant material, an herbarium specimen of the medicinal plant shall be prepared from each of the different sources where such plant material has been obtained. Such herbarium specimens shall be submitted for authentication to the National Museum or any BFAD-recognized taxonomist.

2. All herbal medicines shall be free from extraneous matters such as soil, excreta, helminths or parasitic ova, stones, other plants and/or other part(s) of the same plant to be used.

3. Tests and standards shall be in full compliance with the pharmocopeial requirements. For plant materials, which are not included in any official pharmacopeia, the following tests and standards shall be followed:

   3.1 Organoleptic and macroscopic description and illustration of the plant material

   3.2 Ash content
   - 3.2.1 Total Ash
   - 3.2.2 Acid-Insoluble Ash
   - 3.2.3 Water-Soluble Ash

   3.3 Extractable Matter
   - 3.3.1 Ethanol-Soluble Extractive
   - 3.3.2 Water-Soluble Extractive

   3.4 Moisture Content (Loss on Drying/Water Content)

   3.5 Heavy Metals:

   For dried plants, limits for adults are as follows:

   | | |
   |---|---|
   | Lead | - 10 µg/g (ppm) |
   | Cadmium | - 0.3 µg/g (ppm) |
   | Mercury | - 0.5 µg/g (ppm) |
   | Arsenic | - 0.3 µg/g (ppm) |

   The limits for herbal medicines for children shall be recommended by NIRPROMP based on conditions of growth & development of these children, and the pathologic conditions for which the herbal medicine is indicated.

   3.6 Volatile oil (if applicable)

3.7 Pesticide residue - shall conform to the limits as defined in FAO/WHO Codex Alimentarius

3.8 Foreign Matter
All plant materials shall be free from extraneous matter such as soil, excreta, helminths or parasitic ova, stones, other plants and/or plant part(s) other than the specific part(s) used.

3.9 Microbial limits
Test to detect and quantify the following microbial contaminants shall be conducted: aerobic bacteria, Sacchromycetes and Hypomycetes

3.9.1 For untreated plant material harvested under acceptable hygienic conditions intended for further processing:

| Organisms | Unit | Limits |
|---|---|---|
| *Escherichia coli* | cfu/ g | Negative |
| Moulds propagules | cfu/ g | Maximum $10^5$ |
| Staphylococcus | cfu/ g | Negative |

3.9.2 Plant materials that will undergo pre-treatment (e.g. with boiling water as used for herbal teas and infusions) or if the material is to be used for topical dosage form:

| Organisms | Unit | Limits |
|---|---|---|
| Aerobic bacteria | cfu/ g | Maximum $10^7$ |
| Yeasts and moulds | cfu/ g | Maximum $10^4$ |
| *Escherichia coli* | cfu/ g | Negative |
| *Salmonellae* | cfu/ g | Negative |
| *Staphylococcus* | cfu/ g | Negative |
| Other *Enterobacteria* | cfu/ g | Maximum $10^4$ |

3.9.3 Plant materials to be used in drugs for internal use:

| Organisms | Unit | Limits |
|---|---|---|
| Aerobic bacteria | cfu/ g | Maximum $10^5$ |
| Yeasts and moulds | cfu/ g | Maximum $10^3$ |
| *Escherichia coli* | cfu/ g | Negative |
| *Salmonellae* | cfu/ g | Negative |
| *Staphylococcus* | cfu/ g | Negative |
| Other *Enterobacteria* | cfu/ g | Maximum $10^3$ |

3.10 Aflatoxin limits

Total aflatoxin shall conform with the prescribed specification of 20µg/kg and aflatoxin B1 of 10 µg/kg by ELISA Method or Liquid Chromatography.

3.11 Identification Tests

3.11.1 Chemical Tests
Determine the active constituent/s present in the plant(s)

3.11.2 Thin Layer Chromatography (TLC) Profile
The TLC Profile of the plant material shall be established and used as basis in determining the identity, purity and batch-to-batch uniformity of the chemical components present in the plant.

3.11.3 Other chromatographic procedures such as HPLC, GC-Mass Spectroscopy and NMR

3.12 Bioassay
A bioassay method shall be established to demonstrate the claimed pharmacological activity of the plant.

4. The following tests and standards shall be utilized in determining the quality of the finished product:

4.1 Moisture Content –not more than 10%
4.2 pH
4.3 Microbial Limits

4.3.1 For Solid Products

| Organisms | Unit | Limits |
|---|---|---|
| Aerobic bacteria | cfu/ g | Maximum $10^4$ |
| Yeasts and moulds | cfu / g | Maximum $10^3$ |
| *Escherichia coli* | cfu/ g | Negative |
| *Salmonellae* | cfu/ g | Negative |
| *Staphylococcus* | cfu/ g | Negative |
| Other *Enterobacteria* | cfu/ g | Maximum $10^2$ |

4.3.2 For Liquid Products

| Organisms | Unit | Limits |
|---|---|---|
| Aerobic bacteria | cfu/ g | Maximum $10^2$ |
| Yeasts and moulds | cfu/ g | Maximum $10^2$ |
| *Escherichia coli* | cfu/ g | Negative |
| *Salmonellae* | cfu/ g | Negative |
| *Staphylococcus* | cfu/ g | Negative |
| Other *Enterobacteria* | cfu/ g | Maximum $10^2$ |

4.4 Identification Tests
4.4.1 Chemical
4.4.2 Thin Layer Chromatography
4.4.3 Other chromatographic procedures

4.5 Test for synthetic substance(s) as appropriate for the claimed indication such as:
- 4.5.1 Aspirin
- 4.5.2 Paracetamol
- 4.5.3 Dipyrone
- 4.5.4 Phenylbutazone
- 4.5.5 Pyrazolone
- 4.5.6 Corticosteroids
- 4.5.7 Anabolic steroids
- 4.5.8 Gonadal Hormones
- 4.5.9 Ephedrine
- 4.5.10 Sildenafil and other related substances
- 4.5.11 Indomethacin
- 4.5.12 Chlorpheniramine
- 4.5.13 Aminopyrine
- 4.5.14 Caffeine
- 4.5.15 any other synthetic substance

5. Specific Tests Required for Different Dosage Forms

5.1 Tablet
- Weight variation
- Content uniformity
- Disintegration test
- Hardness test
- Friability
- Microbial test

5.2 Capsule
- Weight variation
- Content uniformity
- Microbial test

5.3 Syrup / Liquid
- Viscosity
- pH
- Microbial test

5.4 Suspension
- Suspendability
- Homogeneity
- Viscosity
- Minimum fill
- pH
- Microbial test

5.5 Ointment / cream / semi-solid preparation
- Palpability
- Homogeneity
- pH

- Melting point
- Allergenicity and primary irritation test
- Microbial test

5.6 Suppository / pessary
- Allergenicity and primary irritation test
- Microbial test

6. Galenicals, including decoctions, infusions, extracts (liquids, pillulars, powdered), tinctures, syrups, lotions and emulsions shall pass all the requirements specified in the Pharmacopoeias official in the country.

## ANNEX B

### Label Sample for Herbal Medicines

| INFORMATION PANEL | PRINCIPAL DISPLAY PANEL | INFORMATION PANEL |
|---|---|---|
| **Formulation:**<br>Each tablet contains:<br>*Vitex negundo* L. - 300 mg (Lagundi Leaf)<br><br>**Indications:**<br>For the treatment of broncho-spasm in acute bronchial asthma, chronic bronchitis and other broncho-pulmonary disorders. Also for other forms of cough due to common colds, flu and pharyngitis.<br><br>HMR No. (Herbal Medicine Registration number)<br>Batch/Lot No.:<br>Date Mfd.:<br>Expiry:<br><br>Store at room temperature not exceeding 30 °C | Net Content 100 tablets<br><br>***Vitex negundo* L.**<br>**Lagundi Leaf**<br><br>Brand name, if any<br><br>300 mg Tablet<br><br>Anti-asthma<br>Anti-cough<br><br>Manufactured by:<br><br>For: | **Dosage:**<br>Adult: 2 x 300 mg tablet every 4 - 6 hours<br>Children: 1 x 300 mg tablet every 4 - 6 hours<br><br>**Precautions:**<br>Safety in pregnant and lactating women has not been established.<br><br>**Side Effects:**<br>Only mild side effects on few patients such as itchiness, nausea and vomiting, tachycardia, diarrhea, drowsiness and body malaise were reported without predominating complaint with similar incidence on placebo control<br><br>**Contraindications:**<br>There are no known contra-indications |

The "Principal Display Panel" of the label shall be that part which, either through design or general use, is presented or shown to the consumer under customary conditions of display for retail sale.

The "Information Panel" of the label shall be that part immediately contiguous to the principal display panel and in the case of rectangular, cylindrical or four-sided containers, any of the sides adjacent to the principal display panel except the bottom side which serves as the base of package.

## ANNEX C

### Packaging Requirements

1. For Liquid and Semi-Solid Products in Plastic Container, the following information shall be submitted:

    1.1 General Information
        - shall include the name of materials, name of manufacturer, chemical structure and physico-chemical properties
    1.2 Test Procedures and Limits
        - shall include methods on how different tests were conducted, limits for each tests and results
    1.3 Studies Done on Plastic (to substantiate the claim that the product is safe to use)
        - shall include chemical tests, physical tests, and biological tests (cell toxicity, tissue implantation) for parenteral and ophthalmic preparations

2. For Products in Special Packaging Materials (including materials for accessories), the following information shall be provided:

    2.1 List of different components and maximum allowable content
    2.2 Types of materials used in different parts
    2.3 Nature of polymers
    2.4 Official standards and requirements (must be compliant)
    2.5 Toxicity data
    2.6 Technical properties of materials
    2.7 Detailed construction of non-standardized containers

**ANNEX D**

## CHECKLIST for REGISTRATION of HERBAL MEDICINES*

| REQUIREMENTS | TYPE OF APPLICATION | |
|---|---|---|
| | INITIAL | RENEWAL |
| 1. Letter of Application as B.C. No. 01 s. 2002 | √ | √ |
| 2. Form No. 8 (Revised) | √ | √ |
| 3. Copy of valid Certificate of Brand Name Clearance | √ | |
| 4. Copy of valid agreement between the manufacturer & trader/distributor/importer/exporter | √ | |
| 5. a) Copy of latest Certificate of Product Registration | | √ |
| b) For A.O. No. 54 - valid original Certificate of Product Registration | √ | |
| 6. Copy of valid LTO of the manufacturer/trader/importer/distributor, reflecting the product source(s) | √ | √ |
| 7. Unit Dose and Batch Formulation | √ | √ |
| 8. Technical Specifications of ALL Raw Materials | √ | |
| 9. Certificate of Analysis of Active Raw Material | | |
| a) From the supplier of the active raw material (if applicable) | √ | |
| b) From the manufacturer of the finished product | √ | |
| c) Certification of Authenticity of Plant Specimen from the National Museum (Philippines) or any BFAD-recognized taxonomist | √ | |
| In case of imported products, the certificate shall be issued by the authorized government agency in the country of origin, duly authenticated by the Philippine Consulate. | | |
| 10. Technical Specifications of Finished Product | √ | √ |
| 11. Certificate of Analysis of Finished Product (from the same batch or lot of the representative sample submitted) | √ | √ |
| 12. Master Manufacturing Procedure, Production Equipment, Sampling and In-Process Controls, and Master Packaging Procedure | √ | |
| 13. Identity and Purity Tests including Assay (if applicable) | √ | |
| 14. Stability Studies | | |
| a) Accelerated - at least 6 months data, minimum of 2 batches at 40°C±2°C/75%RH±5% RH | √ | |
| b) Real Time - at least 12 months data, minimum of 2 batches at 30°C±2°C/75%RH±5%RH | | √ |
| c) For products intended to be stored in a refrigerator | | |
| c.1) Accelerated - at least 6 months data, minimum of 2 batches, 25°C±2°C/60%RH±5%RH | √ | |
| c.2) Real Time - at least 12 months data, minimum of 2 batches, 5°C±3°C | | √ |
| 15. Representative Sample in market or commercial presentation (at least 1 year before expiry) | √ | √ |
| 16. Labeling Materials | | |
| a) Facsimile labels with actual color text (3 copies) | √ | |
| b) Actual/Commercial labeling materials (3 copies) | | √ |
| 17. For herbal medicines validated by the NIRPROMP of the PCHRD, a copy of Memorandum of Agreement between the NIRPROMP & the applicant shall be submitted. Otherwise, a copy of approval of BFAD Committee on the registration of the said herbal medicine shall be submitted. | √ | |
| 18. For Imported Products (an English translation shall accompany any document not written in English) | | |
| - Original Certificate of Pharmaceutical Product from the country of manufacture (issued at least 1 year from the date the application for registration was filed) | √ | |
| - For countries not issuing CPP, the following may be accepted: | | |
| a) Government Certificate attesting the Registration Status of the Manufacturer, duly authenticated by the Philippine Consulate | √ | |
| b) Certificate of Free Sale from the country of origin, duly authenticated by the Philippine Consulate. | √ | |
| For products not freely sold in the country of origin, original CPP from a country where the product is freely sold shall be submitted. | | |
| 19. For Liquid and Semi-solid Products in Plastic Container or in Special Packaging Materials, refer to Annex C of A.O. ___ s. 2004. | √ | |
| 20. Evidence of Safety and Efficacy | | |
| a) Acute Lethal Dose 50 ($LD_{50}$), No-Adverse-Effect Level/Dose and Toxidrome | √ | |
| b) Pharmacologic Effects in Animals both *In Vivo* and *In Vitro* Studies | √ | |
| c) Bioassay (when applicable) | √ | |
| d) Non-Mutagenicity - including Ames Test and Micronucleus Test | √ | |
| e) Subchronic/ Chronic Toxicity Test | √ | |
| f) Phase I Clinical Trial (for galenical products) | √ | |
| g) Phases I, II & III Clinical Trials (for products in pharmaceutical dosage form) | √ | |

*Any changes, revisions or modifications shall require prior approval from the BFAD.