

**HPT/PER/GUD/027**

**Rev No.2**



**REPUBLIC OF KENYA**

**PHARMACY AND POISONS BOARD**

**GUIDELINES FOR REGISTRATION OF HERBAL PRODUCTS**

**January 2022**

The author of this document is the **Pharmacy and Poisons Board**, a State Corporation under the Ministry of Health, Republic of Kenya. It may be reproduced or adopted on condition that the recommended citation below is made.

©**Pharmacy and Poisons Board, 2022**

All rights reserved:

No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form, or by any means, electronic, mechanical, photocopying, recording, scanning, or otherwise, without the prior permission in writing from the Pharmacy and Poisons Board.

P. O. Box 27663 00506 Lenana Road Opposite Russian Embassy Nairobi,  
Tel: +254-02-12345/6789, Fax: +254-02-12345,  
Website: [www.Pharmacyboardkenya.org.ke](http://www.Pharmacyboardkenya.org.ke),  
Email: [info@pharmacyboardkenya.org](mailto:info@pharmacyboardkenya.org).

HPT/PER/GUD/035	Guidelines For Registration of Herbal Products	Revision No.2	Effective Date: 30/01/2022 Review Date: 14/10/2026
-----------------	--	---------------	---

**Prepared by: Deputy Director Product Evaluation and Registration**

Sign..... 

Date..... 20<sup>th</sup> 01/2022

**Checked by: Director, Health Product and technologies**

Sign..... 

Date..... 21/01/2022

**Reviewed by: Head Quality Management**

Sign..... 

Date..... 21/01/2022

**Authorized by: Chief Executive Officer**

Sign..... 

Date..... 21/01/2022

## Table of Contents

<b>1. ABBREVIATIONS.....</b>	<b>3</b>
<b>PRIMS- Pharmaceutical Regulatory Information Management System.....</b>	<b>3</b>
<b>2. GLOSSARY OF TERMS.....</b>	<b>3</b>
<b>3. ACKNOWLEDGEMENTS .....</b>	<b>3</b>
<b>4. INTRODUCTION .....</b>	<b>4</b>
<b>5. LANGUAGE .....</b>	<b>7</b>
<b>6. PAYMENT OF FEES.....</b>	<b>7</b>
<i>Application for Retention of Products registered in Kenya .....</i>	<i>8</i>
<i>Verification of compliance to current Good Manufacturing Practices (cGMP).....</i>	<i>8</i>
<b>7. TIMELINES.....</b>	<b>9</b>
<b>8. SPECIFIC TECHNICAL INFORMATION .....</b>	<b>9</b>
8.1 <i>PARTICULARS OF THE APPLICANT.....</i>	<i>9</i>
8.2 <i>PARTICULARS OF THE PRODUCT.....</i>	<i>10</i>
8.3 <i>PARTICULARS OF THE MANUFACTURER.....</i>	<i>11</i>
8.4 <i>COMPOSITION OF PRODUCT.....</i>	<i>12</i>
8.5 <i>QUALITY CONTROL OF RAW MATERIALS.....</i>	<i>13</i>
8.6 <i>QUALITY CONTROL OF THE FINISHED PRODUCT.....</i>	<i>16</i>
8.7 <i>STABILITY STUDIES OF THE FINISHED PRODUCT.....</i>	<i>19</i>
8.8 <i>PHARMACOLOGICAL AND TOXICOLOGICAL INFORMATION.....</i>	<i>20</i>
<i>DECLARATION BY AN APPLICANT.....</i>	<i>21</i>

## **1. ABBREVIATIONS**

PRIMS- Pharmaceutical Regulatory Information Management System

DPER- Directorate of Product Evaluation and Registration

PPB-Pharmacy and Poisons Board

cGMP- Current Good Manufacturing Practices.

## **2. GLOSSARY OF TERMS**

The definition of a Herbal and Complimentary Medicine means any substance or mixture of substances that:

- a. Originates from plants, fungi, algae, seaweeds, lichens, minerals, animals or other substance as determined by the Board, and
- b. is used or purporting to be suitable for use or manufactured or sold for use
- c. to diagnose, treat, mitigate, modify, alleviate or prevent disease or illness or the symptoms or signs thereof or abnormal physical or mental state, of a human being or animal.

## **3. ACKNOWLEDGEMENTS**

The CEO, Pharmacy and Poisons Board would like to thank the following persons for their comments and contributions to the development of this guideline.

### **CONTRIBUTORS:**

Dr. Edwin Burugu, Assistant Principal Regulatory Officer, Drug Product Evaluation and Registration (DPER) Department Directorate of Health Products and Technologies

### **REVIEWERS**

Dr. Ronald Inyangala, Deputy-Director, Senior Principal Regulatory Officer, Drug Product Evaluation and Registration (DPER) Department, HPT

Dr. Peter Mbwiri Ikamati Chief Principal Regulatory officer, Drug Product Evaluation and Registration (DPER) Department, Directorate of Health Products and Technologies

Dr. Jonathan Meriakol, Senior Principal Regulatory officer, Drug Product Evaluation

and Registration (DPER) Department, Directorate of Health Products and Technologies

Dr. Ali Arale, Principal Regulatory Officer, Drug Product Evaluation and Registration (DPER) Department, Directorate of Health Products and Technologies

Dr. James Owuor, Assistant Principal Regulatory Officer, Drug Product Evaluation and Registration (DPER) Department, Directorate of Health Products and Technologies

Dr. Paulyne Wairimu, Assistant Principal Regulatory Officer Product Evaluation and Registration (PER) (MD&IVDs) Department, Directorate of Health Products and Technologies

Dr. Eugene Odame, Senior Regulatory officer, Product Evaluation and Registration (PER) (MD&IVDs), Department, Directorate of Health Products and Technologies

Dr. Sarah Chebet Chesaro, Principal Regulatory officer, Drug Product Evaluation and Registration (DPER) Department, Directorate of Health Products and Technologies

Mr. Alex Mutai, Assistant Principal Regulatory Officer, Blood and Blood Products Department, Directorate of Health Products and Technologies

Ms. Jacqueline Yahuma, Assistant Principal Regulatory Officer, Cosmetics Department, Directorate of Health Products and Technologies

Mr. Henry Chweya, Assistant Principal Regulatory Officer, Border line Products Department, Directorate of Health Products and Technologies

Mr. Peter Mugala, Senior Information and Communication Technology Officer; Drug Product Evaluation and Registration (DPER) Department, Directorate of Health Products and Technologies

Mr. Anthony Kemboi, Information and Communication Technology Officer; Drug Product Evaluation and Registration (DPER) Department, Directorate of Health Products and Technologies

Mr. Victor Kipchumba, Information and Communication Technology Officer Medical Devices Department Directorate of Health Products and Technologies

#### **4. INTRODUCTION**

##### **i. Background**

This guideline presents a common format for presentation of a well-structured application for registration of herbal/complementary medicines to be submitted

to Pharmacy and Poisons Board. This format of technical documentation will significantly reduce the time and resources needed to compile applications for registration of herbal and complementary products and will in future ease the preparation of electronic submissions. This guideline will ensure that only good quality, safe and efficacious herbal and complementary products are available in Kenya; and to contribute towards their accessibility, cost effectiveness and appropriate use with the current state of knowledge.

This guideline has been drawn to address the many issues on the quality of herbal and complementary medicines that have been used for a long period of time in Kenya. These issues include;

- a) Misconception amongst herbalists that documentation requested for by PPB is intended to steal their indigenous knowledge and thus, there has been hesitation to submit applications.
- b) Lack of documented evidence on quality, safety & efficacy of Herbal and complementary products
- c) Unethical practices that include:
  - Adulteration of herbal and complementary products with conventional medicines
  - Advertising of Herbal and complementary products in print media, electronic and bill boards
  - Peddling of products with no therapeutic benefits
  - Unsubstantiated medicinal claims by herbal practitioners.
  - Dealing with herbal products whose toxicological profile is not known
- d) Poor standards of preparation/manufacture and sale of herbal and complementary products

This guideline will focus on the manufacture and registration of herbal and complementary medicines. This guideline applies only to herbal and complementary products. In the case of other medicinal products such as conventional and borderline products, separate guidelines are available and these can be obtained from PPB offices. This guideline provides recommendations for applicants preparing application for herbal and complementary products for submission to the Pharmacy and Poisons Board

(PPB). This guideline prescribes the minimum information required for submission of dossiers, evaluation of products, variation of products and retention of registered products.

This guideline indicates an appropriate format and organization of the data. Applicants are requested to carefully read this guideline, fill in application form, prepare dossiers and submit them online through the Pharmaceutical Regulatory Information Management System (PRIMS)

## **ii. The Legal Framework/Responsibility for Implementation**

The Board is statutorily empowered to undertake various duties in execution of its mandate regarding regulation of health products and health technologies.

The regulation for the evaluation of health product and technologies is governed under the provisions of the Pharmacy and Poisons Act, Cap 244 Laws of Kenya.

## **iii. Scope**

This guideline primarily addresses the organization of the information to be presented in registration of herbal products. It is intended to provide an appropriate format for submission of data for registration. Applicants should not modify the overall organization of the document as outlined in the guideline.



## **5. LANGUAGE**

All applications and supporting documents shall be in English and legible. Where material is not originally in English, a copy in the original language and a full translation should be submitted, the accuracy of which is the responsibility of the applicant. Authentication of the translation has to be done at the nearest Kenyan Embassy or by the national drug regulatory authority of the country from where the document originates. Reports submitted only in a language other than English will not be accepted

For purposes of submission to PPB, an application for registration of herbal and complementary product shall include:

- i. Application through the electronic format available on PRIMIS (including their supporting documents - see Annex I (Application online))
- ii. Three (3) samples of the smallest commercial pack(s) from one batch with batch certificates of analysis.
- iii. A site master file in case the product is manufactured at a plant(s) not inspected and approved by PPB.
- iv. Non-refundable application fee for registration of medicines in Kenya and GMP inspection fees for facilities not yet inspected by PPB

## **6. PAYMENT OF FEES**

Every application shall be accompanied by appropriate fees at the time of application. Any application that will not be accompanied by appropriate fees will not be accepted. Mode of Payment: Payments by crossed or bankers' cheque shall be made payable to Pharmacy And Poisons Board.

### **Application for registration of herbal and complementary products:**

Products imported into Kenya	US\$ 1000
Locally manufactured in Kenya	US\$ 200

**GMP inspection fee:**

Foreign Companies	US\$ 4000
Local Companies	Nil

**Application for Variation of products:**

Products imported into Kenya	US\$ 200
Locally manufactured in Kenya	US\$ 100

**Application for Retention of Products registered in Kenya**

Products Imported into Kenya.	US\$ 300
Products manufactured in Kenya.	US\$ 100

If an application for renewal is made after the expiration of the period of validity of the certificate of registration the application shall be considered as a fresh application - see annex I (Retention)

**Appeal fee:** With respect to an appeal to an original application, a fee of US\$ 300 must be paid at the time of appeal. Any appeal that will not be accompanied by appropriate fees will not be accepted.

**Other Charges:** The Pharmacy and Poisons Board may, at its own discretion, charge an applicant such costs as it may incur for carrying out any laboratory investigations prior to the registration of a product.

Verification of compliance to current Good Manufacturing Practices (cGMP)

If the new application is from a new manufacturing site, PPB will conduct inspection of the site or use other means to verify whether the facility complies with current Good Manufacturing Practices Regulations before a product is registered. No product shall be registered unless the plant complies with cGMP.

Inspection of a facility for the purposes of considering applications for renewal of registration shall be done and if the facility is found not to comply with cGMP, registration of all products manufactured by the facility shall be withdrawn.

## **7. TIMELINES**

The Board will implement the following timelines in processing applications for marketing authorization of herbal and complementary products.

Complete applications will be processed within (180 working days of receiving the application including evaluation of documentation and consideration by a committee on drug registration.

## **WITHDRAWAL OF AN APPLICATION**

When the applicant fails to submit written responses to queries within 6 months from the date of their issuance, it will be deemed that the applicant has withdrawn the application or if the queries have been reissued for a second time and the applicant provides unsatisfactory responses, the product will be disqualified and the application will be rejected. The applicant will be required to apply afresh.

## **VALIDITY OF REGISTRATION**

The registration of herbal and complementary products shall be valid for One Year from the Date of registration unless earlier suspended or revoked by PPB or withdrawn by applicant. The Board will give reasons in writing when it suspends or revokes, or amends conditions of registration. Likewise the applicant shall also give reasons for terminating registration of a product.

## **8. SPECIFIC TECHNICAL INFORMATION**

### **8.1 PARTICULARS OF THE APPLICANT**

a. The Applicant:

The application for the registration of herbal and complementary products shall be made only by:

- The License/patent holder
- The manufacturer

- An authorized Local Technical Representative (LTR) of the manufacturer or License/patent holder
  - The name, physical address, telephone number, fax number, and e-mail address of the applicant shall be provided
- b. Name of the Local Technical Representative (for imported products only)  
Every applicant who is not resident in Kenya shall appoint ONE local technical representative who must be a company incorporated in Kenya and authorized by PPB to deal in herbal and complementary products and must hold a wholesale dealers License.

Evidence shall be made by submitting a power of attorney that complies with Kenyan laws. The local technical representative shall be responsible for facilitating communication with the applicant and when the product is registered, he shall assume all legal responsibilities regarding the product on the Kenyan market.

## **8.2 PARTICULARS OF THE PRODUCT**

- a. Product Name shall mean the (trade or brand) name which is unique to a particular drug and by which it is generally identified (and by which it is registered in the country of manufacture). The applicant may provide evidence from Kenya Industrial Property Institute, KIPI, in regard to the requirements for registration of Trademarks.
- b. Dosage form of the product shall mean the form in which the drug is presented – a macerate, infusions, ashes, decoctions, tablet, capsule, solution, suspension, emulsion, ointment, suppository etc. Strength of the product shall be given per unit dosage form or per specified quantity: e.g. mg per tablet, mg per capsule, mg/ml, mg per 5ml spoonful, mg per g, etc.
- c. Therapeutic use(s) shall mean the intended use should be only the major indication(s) the product may be multi-component with other pharmacological properties but the application should be restricted to the intended use.
- d. Visual description of the product shall mean a full description/appearance of the herbal or complementary product

- including color, size, shape and other relevant features, e.g. green powder, brown liquid, pink film-coated tablets etc.
- e. Type of container: The applicant should state the type of the primary package in which the herbal or complementary product is presented e.g. in HDPE bottles, Aluminum Sachets etc.
  - f. Pack size(s) shall mean the presentation of the product to be registered i.e. list all pack sizes intended for marketing.
  - g. Proposed Shelf life (in months) shall mean the specified length of time prior to use for which a herbal or complementary product is deemed to remain fit for use under prescribed conditions supported by stability studies given in section 7
  - h. Storage conditions: The proposed storage conditions should be indicated on the label and supported by stability studies given in section 7.
  - i. Country of origin shall mean the country of manufacture or production, of the herbal or complementary product to be registered or country of product release.
  - j. Status of registration of the product in the country of origin, authorization/registration number requires the applicant to provide the regulatory situation of the herbal or complementary product to be registered in the country of origin and other countries. List the countries in which this product:
  - k. Has been granted a marketing authorization. (Attach certificate of pharmaceutical product from the registering Authority)
  - l. Has been withdrawn from any market;
  - m. Where an application for marketing in any country has been rejected, suspended, deferred or withdrawn.

### **8.3 PARTICULARS OF THE MANUFACTURER**

- a. Name of the Manufacturer shall mean the name, physical address, telephone number, fax number, and e-mail address of the site of manufacture shall be provided. Where different activities of manufacture of a given product are carried out at different manufacturing sites, the above particulars shall be provided for each site and the activity carried

out at the particular site shall be stated as shown in the table below.

Name of the Manufacturer	Full Physical address of the Manufacturing Site	Activity at the site

b. GMP status of the manufacturing site

If the new application is from a new manufacturing site, PPB will conduct inspection of the site or use other means to verify whether the facility complies with current Good Manufacturing Practices (cGMP) Regulations and/or guidelines.

#### **8.4. COMPOSITION OF PRODUCT**

List all active ingredient(s) and all non-active ingredient(s) used

- (i) Scientific or Botanical Name of the plant(s): Name in Latin (genus and species) of the plant species and family e.g. *Catharanthus roseus* (Apocynaceae), *Azadiracta indica* (Meliaceae)
- (ii) The common name or synonym is the English name. Where not known the local vernacular name may be used e.g. Madagascar periwinkle (*Catharanthus roseus*), Neem Tree (“Muarubaini” - *Azadiracta indica*)
- (iii) Part of Plant used: The part used should be specified e.g. leaf, root, bark, etc.
- (iv) Specification (USP, BP, or In house): The minimum range of specifications for the active ingredient(s) should be as given in recognized pharmacopoeias. Where the material is part of an established monograph then the material must comply with requirements of the monograph. Where the plant material is not subject to any established monograph the applicant must indicate in detail of all tests used to characterize the material with limits as relevant.
- (v) Quantity per dosage unit: The strength of the product shall be given per unit dosage form or per specified quantity: e.g. mg per tablet, mg per capsule, mg/ml, mg per 5ml spoonful, mg per g, etc.

- (vi) Chemical Constituent(s): For each of the active constituent(s) listed (e.g. *Catharanthus roseus*), indicate the major chemical compounds where known e.g. vincristine, or where not known major group of compounds e.g. indole alkaloids.
- (vii) Reason for inclusion: Where a material is included and is not the active ingredient indicate the purpose of its inclusion such as sugar as sweetener, honey as preservative.

The information should be presented as shown in the tables below;

- i. List all active ingredient(s) used

Scientific/ Botanical Name	Common Name or Synonym	Part of Plant used	Specification	Quantity per dosage unit	Chemical Constituent(s)

- ii. List all non-active ingredient(s) used

Scientific /Botanic al Name	Common Name or Synonym	Part of Plant used	Specification	Quantity per dosage unit	Reason for inclusion

### 8.5. QUALITY CONTROL OF RAW MATERIALS

- a. Botanical identification of the Plant used
- b. Botanical name shall mean the name in Latin (genus and species) of the plant species and family e.g. *Catharanthus roseus* (Apocynaceae), *Azadirachta indica* (Meliaceae). The local name of the plant should be supplied in addition to a herbarium specimen (Voucher number) verified by the National museums of Kenya Herbarium, University of Nairobi herbarium, or any other recognized herbarium should be provided. For imported herbal or complementary products, a certificate of identification should be supplied from recognized herbarium.
- c. Brief description of the living plant

A brief description of the living plant, this may include photographs and/or drawings, general appearance and organoleptic properties

d. Macroscopic identification

This is based on shape, size color, surface characteristics, texture, fracture characteristics, appearance of cut surface e.g. for a leaf: Oblong, green coloured leaf, hairy, brittle etc.

e. Microscopic identification

This shall mean the structural features of the part of the plant to identify the diagnostic features e.g. Leaf – type of stomata, cell inclusions etc.

f. Geographical source of the plant used

It the country of origin and the region where the plant is collected, cultivated or wild natural distribution

g. Harvesting and collection of the plant

The method of collection of plant materials from cultivated or wild sources should be described including stage of plant development, time and season. The measures used to control adulteration of the plant material also should be described.

h. Method of drying

The method used for drying the plant material should be described and justified.

i. Storage and preservation of plant material

The method used for storage and preservation of the plant material should be described and justified.

j. Evaluation of plant materials

k. Purity tests

The following purity tests must be done:

- Microbiological tests should be described to demonstrate the absence of pathogenic micro- organisms (e.g. E. coli, P. aeruginosa, S aureus and Salmonella spp etc.)
- Microbial load test (Pharmacopoeial limits)



- Swelling index (where applicable)
- Pesticide residues (where applicable)
- Heavy metals (Mercury, Arsenic and Lead)
- Loss on drying (where applicable)
- Determination of ash value (where applicable)
- Other purity tests (where applicable)

Qualitative and quantitative tests of the plant materials

These should be expressed in the following ways:

Medicinal plant material:

- i. The quantity of plant material must be stated; or
- ii. The quantity of plant material may be given as a range, corresponding to a defined quantity of constituents of known therapeutic activity.

Example: Name of active ingredient Quantity

Sennae folium (a) 900 mg or (b) 830–1000 mg, corresponding to 25 mg of hydroxyanthracene glycosides, calculated as sennoside B

Plant preparation:

- i. The equivalent quantity or the ratio of plant material to plant preparation must be stated (this does not apply to fatty or essential oils); or
- ii. The quantity of the plant preparation may be given as a range, corresponding to a defined quantity of constituents with known therapeutic activity (see example).

The composition of any solvent or solvent mixture used and the physical state of the extract must be indicated. If any other substance is added during the manufacture of the plant preparation to adjust the level of constituents of known therapeutic activity, or for any other purpose, the added substance(s) must be described as “other ingredients” and the genuine extract as the “active ingredient”.

Example: Name of active ingredient Quantity

Sennae folium (a) 125 mg ethanolic extract (8:1) or 125 mg ethanolic extract, equivalent to 1000 mg of Sennae folium or (b) 100–130 mg ethanolic extract (8:1), corresponding to 25 mg of hydroxyanthracene glycosides, calculated as sennoside B

Other ingredient

Dextrose 20–50 mg

The determination of the presence of active components and quantity should be described in detail

- Determination of extractable value (where applicable)
- For example Datura stramonium: the test of presence of alkaloids and the amount of atropine

## **8.6 QUALITY CONTROL OF THE FINISHED PRODUCT**

### 8.6.1. Specification of the Finished Product:

The minimum range of specifications for the finished products should be as given in recognized pharmacopoeias.

- a. Microbiological contamination and tests for other toxins
- b. Uniformity of weight (for tablets, single-dose powders, suppositories,

herbal tea in sachets and capsules, etc.), disintegration time (for tablets, capsules, suppositories and pills), hardness and friability (for example, uncoated tablets), viscosity (for internal and external fluids), consistency (semisolid preparations), and dissolution (tablets or capsules), if applicable.

- c. Physical appearance such as color, odor, form, shape, size and texture
- d. Loss on drying or water content
- e. Identity tests, qualitative determination of relevant substances of the plants (e.g. fingerprint chromatograms)
- f. Quantification of relevant active ingredients if they are identified and the adequate analytical methods are available
- g. Limit tests for residual solvents

#### 8.6.2. Brief Description of the Manufacturing Procedure and In Process Quality Controls

This section will include a description of the manufacturing process and packaging. A summary of the method of manufacture and packaging should include:

- a. Equipment used in the manufacture of the product
- b. The outline of the manufacturing process, in form of a chart, indicating the critical points for in-process controls.
- c. For products that require special environmental conditions, this information must be provided.
- d. Provide batch manufacturing records and batch packaging records for the samples submitted with the application form.
- e. The description of the analytical control procedures and the frequency with which they are performed during the manufacturing process should be made. This refers to parameter at critical stage points during manufacturing to confirm that the processes are conforming with expected values.

#### 8.6.3 Analysis of the Finished Product

Details of the test methods described here should be those applied

to confirm compliance with specifications listed under section 6.1 attaching the certificate of analysis from an independent recognized quality control laboratory

The control tests for the finished product must be such as to allow the qualitative and quantitative determination of the active ingredients. If the therapeutic activity of constituents is known, this must be specified and determined quantitatively. When this is not feasible, specifications must be based on the determination of markers. If either the final product or the preparation contains several plant materials and a quantitative determination of each active ingredient is not feasible, the combined content of several active ingredients may be determined. The need for such a procedure must be justified.

#### 8.6.4 Packaging and Labeling of the Finished Product (include package insert)

The print size and color should be legible and in English or Kiswahili. The product label should have the following:

- a) Name of the product
- b) Composition: The quantitative list of main active ingredients including the common English name of the relevant plants. If the product is imported, plant name should be mentioned along with botanical name
- c) Dosage form
- d) Pack size
- e) Name of manufacturer and physical address of the manufacturing site
- f) Lot/Batch number
- g) Manufacture date and expiry date
- h) Storage conditions

#### 8.6.5 Packaging and Labelling Requirements

This should contain the following information in English:

- a) Name and description of the product

- b) Composition:
- c) Pharmacological properties, where information is available
- d) Therapeutic indications
- e) Dosage: the minimum and maximum as well as average dosage levels, must be stated (if appropriate, specified for children and the elderly).
- f) Contraindications/precautions, Interactions and Cautions/warnings
- g) Withdrawals periods for veterinary herbal and complementary products
- h) Name and address of the manufacturer
- i) Overdose and treatment
- j) Adverse reactions
- k) Special considerations e.g. vaginal, rectal, and urethral preparations
- l) Storage conditions.
- m) Main vehicle/base

## **8.7 STABILITY STUDIES OF THE FINISHED PRODUCT**

The physical and chemical stability of the product in the marketing container should be determined under defined storage conditions to support the shelf-life. This section should include a summary of the studies undertaken (environmental conditions, batches, analytical procedures) and a brief discussion of the results and conclusions, the proposed storage conditions or shelf-life. Long term stability studies should follow ICH guidelines.

## **8.8 PHARMACOLOGICAL AND TOXICOLOGICAL INFORMATION**

The applicant should provide information on:

- Safety of The Product
- Ethno-medical information (Literature search)
- Pharmacological properties including the desirable and undesirable effects associated with the use of the herbal or complementary product including Adverse/Side Effects, Contraindications, Warning and precautions
- Efficacy studies of the product
- Dosage regimen: Therapeutic prescribed amount of the medicine to be administered to the patient. The measures and age group should be included.
- The onset and duration of effect to support the proposed route of administration and frequency of dosage of the medicinal product should be provided
- Pharmacotoxicological Studies: The applicant should provide a report on pharmacotoxicological data which should include pharmacological activity, acute, sub-acute, chronic and sub-chronic tests.
- The pharmacotoxicological test reports should be submitted from but not limited to any of the under listed institutions:
  - (i) Kenya Medical Research Institute
  - (ii) University of Nairobi, School of Pharmacy and Faculty of Veterinary Medicine

## DECLARATION BY AN APPLICANT

The declaration must be signed, dated and authenticated by an Official stamp.  
No Applications will be evaluated without authenticated declaration.

## KEY REFERENCE DOCUMENTS

- a) World Health Organization (WHO) Guidance on variations to a prequalified product dossier.
- b) Pharmacy and Poisons Board (PPB) Guidance on Retention of Product

### Addendum 1

#### GUIDANCE FOR APPLICATION OF VARIATIONS TO A PRODUCT:

The following is a matrix table on the expected timelines to be followed when applying for Retention of Registered Herbal Products through the PRIMS system online

Current process	Timeline	Output
Receive manual applications	Upto Dec 2021	Receiving of variation applications using the table
Projected Automated process development for Application of Variation	Upto Dec 2022	Evaluation of variation using PPB PRIMS system

### Addendum 2

#### GUIDANCE FOR APPLICATION OF RETENTION FOR REGISTERED PRODUCTS:

The following is a matrix table on the expected timelines to be followed when applying for Retention of Registered Herbal Products through the PRIMS system online

Current process	Timeline	Output
Receive manual applications	Upto Dec 2021	Receiving of variation applications using the table

Projected Automated process development for Application of Variation	Upto Dec 2022	Evaluation of variation using PPB PRIMS system
--	---------------	--



**ANNEX I**

SCHEDULE

(r.4)

Form 1

APPLICATION FORM FOR REGISTRATION OF HERBAL AND  
COMPLEMENTARY MEDICINE (Complementary and Alternative Medicine)  
(to be submitted in one hard copy and one electronic copy on a CD-ROM)

**CONFIDENTIAL**

The CEO,  
Pharmacy and Poisons  
Board, P. O. Box  
27663-00506,  
Lenana road,  
NAIROBI.

Application Number		
Date of submission of the dossier		
1 <sup>ST</sup> Evaluator	Name	Signature
2 <sup>ND</sup> Evaluator	Name	Signature
Date of 1st evaluation		
Date of 2nd Evaluation		
Number of volumes of files received		
<b>1. PARTICULARS OF THE APPLICANT</b>		
1.1	Name of the Applicant, Physical Address, Telephone, Fax and Email	
1.2	Name of the Local Technical Representative (for imported products only), Physical Address, Telephone, Fax and Email	
<b>2. PARTICULARS OF THE PRODUCT</b>		
2.1	Product Name of the product	
2.2	Dosage form and strength of the product	
2.3	Therapeutic use(s) of the product	
2.4	Visual description of the product	
2.5	Type of container of the product	
2.6	Pack size(s) of the product	
2.7	Proposed Shelf life (in months) of the product	
2.8	Storage conditions of the product	
2.9	Country of origin of the product	

2.10 Status of registration of the product in the country of origin, authorization/registration number (attach Certificate of Pharmaceutical product)	
<b>3. PARTICULARS OF THE MANUFACTURER</b>	
3.1 Name of the Manufacturer, Physical Address of the manufacturing site, Telephone, Fax and Email	

3.2 GMP status of the manufacturing site

**4. COMPOSITION OF THE PRODUCT**

4.3 List all active ingredient(s) used

Scientific or Botanical Name	Common Name or Synonym	Part of Plant used	Specification (USP, BP, or In house)	Quantity per dosage unit	Chemical Constituent(s)

4.4 List all non-active ingredient(s) used

Scientific or Botanical Name	Common Name or Synonym	Part of Plant used (where applicable)	Specification	Quantity per dosage unit	Reason for inclusion

**5. QUALITY CONTROL OF RAW MATERIALS**

5.1 Botanical identification of the Plant used

5.1.1 Botanical name

5.1.2 Brief description of the living plant

5.1.3 Macroscopic identification

5.1.4 Microscopic identification

5.2 Geographical source of the plant used

5.3 Harvesting of the plant

5.3.1 Stage of plant during harvesting

5.3.2 Time of harvesting

5.3.3 Season of harvesting

5.4 Method of drying

5.5 Storage of plant materials

5.6 Evaluation of plant materials

5.6.1 Purity Tests to include likely adulterants e.g. soil, pesticides, radioactive contamination, microbiological limits, animal droppings, other plant parts, heavy metals etc.

5.6.2 Qualitative and quantitative tests of the plant materials

**6. QUALITY CONTROL OF THE FINISHED PRODUCT**

6.1 Specification of the Finished Product

6.2 Brief Description of the manufacturing procedure and in process quality controls (attach batch manufacturing records)

6.3 Analysis of the Finished Product	
6.4 Certificate Of Analysis from an Independent Recognized Quality Control Laboratory	
6.5 Packaging and Labeling of the Finished Product ( include Package Insert)	
<b>7. STABILITY STUDIES OF THE FINISHED PRODUCT</b>	
<b>8. PHARMACOLOGICAL AND TOXICOLOGICAL INFORMATION</b>	
8.1 Safety of the Product	
8.1.1 Ethno-medical information (Literature search)	
8.1.2 Toxicity Studies	
8.2 Pharmacological Information of the Product	
8.2.1 Efficacy studies of the product	
8.2.2 Dosage regimen	
8.2.3 Adverse/Side Effects	
8.2.4 Contraindications, Warning and precautions	
<p>Declaration by an applicant</p> <ol style="list-style-type: none"> <li>1. I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.</li> <li>2. I further confirm that the information referred to in my application file is available for verification during GMP inspection.</li> <li>3. I also agree that I am obliged to follow the requirements of the Pharmacy and Poisons Board which are related to herbal and complementary medicines.</li> <li>4. I also agree that the undersigned has not marketed or advertised this product in Kenya and will follow the PPB requirements for advertisements of medicines</li> <li>5. I also agree that the undersigned will implement a Pharmacovigilance plan for this product in accordance with PPB requirements</li> <li>6. I also consent to the evaluation of information provided to the Pharmacy and Poisons Board.</li> </ol> <p>Name: .....</p> <p>Position in the company: .....</p> <p>Signature and Date: .....</p> <p>Official stamp: .....</p>	

<b><u>OVERALL COMMENTS AND QUERIES</u></b>	
Conclusion of the assessment RECOMMENDED (no outstanding issues) QUERY RAISED REJECTED (Please delete which does not apply)	

### Revision History

<b>Revision Number</b>	<b>Date</b>	<b>Author/Reviewer</b>	<b>Sections Amended</b>	<b>Reason for change</b>
1.0	August 2021	Burugu	Title	Change in title of the document
			Addendum 2 introduced	Addition for variation to a product
			Addendum 3	Application for Variation
			List of Contributors	List of contributors added
2.0	January 2022	Burugu	Document Number revised	Number designated as HPT/PER/GUD/027
			Citation	Addition of opening and closing citations
			Format	Glossary and Abbreviations added

No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form, or by any means, electronic, mechanical, photocopying, recording, scanning, or otherwise, without the prior permission in writing from the Pharmacy and Poisons Board.

P. O. Box 27663 00506 Lenana Road Opposite Russian Embassy Nairobi,  
Tel: +254-02-12345/6789, Fax: +254-02-12345,  
Website: [www.Pharmacyboardkenya.org.ke](http://www.Pharmacyboardkenya.org.ke),  
Email: [info@pharmacyboardkenya.org](mailto:info@pharmacyboardkenya.org).