



APPLICATION FORM FOR THE REGISTRATION OF HOMEOPATHIC MEDICINE

CHECKLIST

Applicant's
Check list

FDA
double check

- | | | |
|--------------------------|--|--------------------------|
| <input type="checkbox"/> | COVERING LETTER | <input type="checkbox"/> |
| <input type="checkbox"/> | SIGNED DECLARATION | <input type="checkbox"/> |
| <input type="checkbox"/> | FULLY COMPLETED APPLICATION (APPENDIX I-III) | |
| <input type="checkbox"/> | FOR EACH MEDICINAL INGREDIENT, A PHOTOCOPY OF THE MONOGRAPHY FROM THE PHARMACOPOEIA TO WHICH THE APPLICANT ATTESTS | <input type="checkbox"/> |
| <input type="checkbox"/> | FOR HOMEOPATHIC MEDICINES WITH A SPECIFIC USE OR PURPOSE, PHOTOCOPIED FROM AT LEAST ONE HOMEOPATHIC REFERENCE TO SUPPORT THE RECOMMENDED USE OR PURPOSE OF EACH MEDICINAL INGREDIENT | <input type="checkbox"/> |
| <input type="checkbox"/> | EVIDENCE TO SUPPORT THE SAFETY OF NON-MEDICINAL INGREDIENTS | <input type="checkbox"/> |
| <input type="checkbox"/> | QUALITY SUMMARY REPORT | <input type="checkbox"/> |
| <input type="checkbox"/> | SAMPLES (AS PER FDA SAMPLE SCHEDULE) | <input type="checkbox"/> |
| <input type="checkbox"/> | 4 COPIES OF LABEL & PACKAGING MATERIAL | <input type="checkbox"/> |
| <input type="checkbox"/> | 4 COPIES OF PACKAGE INSERT | <input type="checkbox"/> |

**APPLICATION FORM FOR THE REGISTRATION OF HERBAL
MEDICINAL PRODUCTS**

(To be submitted in duplicate)

Addressed to: **THE CHIEF EXECUTIVE
FOOD AND DRUGS BOARD
P.O.BOX CT 2783
CANTONMENTS-ACCRA
GHANA.**

**Samples and printed matter should be forwarded to the Board through the local agent;
customs duty and clearance to be effected by the applicant in all instances.**

Name of Homeopathic Medicine;

Dosage Form:.....Strength:.....Colour:.....

Commercial Presentation(s):.....

Country of Origin:.....

Name of Applicant :.....

Business Address:.....

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Phone:..... Fax:.....

e-mail:.....

Name of Manufacturer:.....

Premises Address

.....

Postal Address:.....

Phone:..... Fax:.....

e-mail.....

Name of Local Agent:.....

Business Address:

Phone:..... Fax:.....

e-mail:

Application fee paid.....

Declaration:

I/We, the undersigned, hereby declare that all information contained herein and in the appendices is correct and true.

Name:

Position:

Signature:.....

Date:.....

Official Stamp

APPENDIX 1

PRODUCT DETAILS

Name of Homeopathic Medicine.....

Name of Applicant.....

Dosage Form..... Strength..... Colour.....

(1) List all active ingredients used as illustrated in the table below:

Ingredient No.	Compendia Monograph	Scientific or Botanical Name	Common Name	Quality per Dosage Unit	
1		Arnica montana	Arnica Montana	D6	

- Attach separate sheet if necessary

(2) List all active ingredients as illustrated in the table below:

Ingredient No.	Source Information	Extracts (if applicable)				Method of Preparation
		Ratio	Quality Crude Equivalent	Original Material		
				Fresh	Dry	

- Attach separate sheets if necessary

NON- MEDICINAL INGREDIENT(S)

Ingredient No.	Scientific or Botanical Name	Common Name	Purpose
1.	Eg: Ethyl Alcohol	Ethanol	Solvent
		Distilled water	Solvent

- Attached separate sheets if necessary

NON- MEDICINAL INGREDIENT(S)

Ingredient No.	Compendia Monograph	Quantity	Source Information

- Attached separate sheets if necessary

(3) List any ingredient(s) liable to cause dependence and/or listed in the UN lists of psychotropic and narcotic drugs.

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APPENDIX II

PARTICULARS OF MANUFACTURING PROCEDURE AND RELATED CONTROLS

(1) Origin or source of the raw materials, steps taken to prevent presence of foreign matter (sand, stones, insects, etc)

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(2) Give a brief summary of the manufacturing procedure.

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(3) State estimated shelf-life of the medicine.

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(4) Provide stability data and justification on which shelf-life has been predicted.

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(5) An acceptable certificate of analysis testifying that the medicine is of proven quality and issued by a recognised public analyst.

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(6) Attach toxicological, pharmacological and clinical information, as well as therapeutic effects of the herbal preparation.*

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*Refer to FDA Guidelines for Registration of Herbal Medicinal Products

(7) Attach text of labels and other written materials available with the herbal/homeopathic medicine, including the underlisted information.

- i. Indication
- ii. Dosage and administration
- iii. Contraindications
- iv. Adverse reactions
- v. Precautions
- vi. Use in pregnancy and lactation
- vii. Treatment of over dosage
- viii. Interactions with other drugs or food
- ix. Storage conditions