MEDICINES CONTROL AGENCY

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HERBAL MEDICINES REGISTRATION APPLICATION

Registration Application Type: **New Registration** ☐ **Renewal** ☐

If renewal, MCA Product Registration Number: .....

Name of Herbal Medical Product .....

Dosage form and Strength .....

Claimed Indications .....

Presentation(s) .....

MANUFACTURER:

Name. .....

Premises/Business Address .....

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Tel ..... Email ..... Website .....

MARKETING AUTHORISATION HOLDER:

Name. .....

Premises/Business Address .....

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Tel ..... Email ..... Website .....

APPLICANT:

Name .....

Address + Full Contact Details .....

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Tel ..... Email ..... Website .....

STATUS OF APPLICANT (mark as X)

Manufacturer ☐	Marketing Authorisation Holder ☐	Pharmaceutical Company ☐
Importer ☐	National Representative ☐	Other ☐ (please specify)

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LIST ALL ACTIVE INGREDIENTS USED

Scientific or Botanical name	Common name or Synonym	Part of plant used	Specification (USP, BP, etc)	Quantity per dosage unit	Reason for inclusion of ingredient

LIST ALL EXCIPIENTS USED

Approved name	Common name or Synonym	Specification (USP, BP, etc)	Quantity per dosage unit	Reason for inclusion of ingredient

PARTICULARS OF MANUFACTURING AND RELATED CONTROLS

Origin or source of the raw materials, steps taken to prevent presence of foreign matter

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Brief summary of the manufacturing procedure

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Estimated shelf-life of the herbal medicine (Provide stability data and justification on which shelf-life has been predicted)

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DISPENSING CATEGORY (mark as X):

Prescription Only Medicines (POM):	☐	Over The Counter Medicines (OTC):	☐
Pharmacy Only Medicine (PM):	☐	Controlled Drug (CD):	☐

MISCELLANEOUS (Special Conditions, etc.)

ENCLOSURES (mark as X)

Container labels ☐ Package insert ☐ Professional Information/SmPC ☐

Samples ☐ # ..... Certificates of Analysis ☐ Registration certificate ☐

Manufacturing License ☐ GMP Certificate ☐ CPP ☐ Stability study report ☐

Quality data ☐ Toxicological data ☐ Pharmacological data ☐ Clinical data ☐

Others ☐ (specify) .....

DECLARATION:

I, the undersigned certify that the information in the accompanying documentation concerning the application for registration of the herbal medicinal product indicated herein is true and reflects the total information available. I also agree that I am obliged to comply with the requirements of the Agency related to the stated products at any time in the future.

Name of Applicant: .....

Position/Designation: .....

Address and Contact Details: .....

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Signature of Applicant: ..... Date: .....

OFFICIAL USE

Application no: .....

Comments