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**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  Tel Email Website  |

**Marketing Authorisation Holder:**

|  |
| --- |
| Name.  |
| Premises/Business Address  Tel Email Website  |

**APPLICANT:**

|  |
| --- |
| Name  |
| Address + Full Contact Details  Tel Email Website  |

**STATUS OF APPLICANT (mark as X)**

|  |
| --- |
| Manufacturer **[ ]** Marketing Authorisation Holder **[ ]** Pharmaceutical Company **[ ]** Importer **[ ]** National Representative **[ ]**  Other **[ ]**  (please specify)   |

**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**  |
| --- | --- | --- | --- | --- |
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**Particulars of Manufacturing and Related Controls**

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| --- |
| **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)**       |

**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.)**

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|  |

**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:

Signature of Applicant: Date:

**OFFICIAL USE**

|  |
| --- |
| Application no:  |
| Comments |