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**MEDICINES CONTROL AGENCY**

Kairaba Avenue, K.S.M.D. Pipeline, The Gambia. Telephone: (+220)4380632, [www.mca.gm](http://www.mca.gm)

**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 |