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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)

**Medicines Registration Application**

**Generic Medicine [ ]  New Chemical Entity (New Active Substance) [ ]**

**Biological [ ]  Nutritional Supplement [ ]  Veterinary Medicine [ ]**

**Renewal [ ]  MCA Product Registration Number**

|  |
| --- |
| Brand Name Generic Name  |
| Route of Administration Dosage form / strength  |

**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**

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

**Composition of Product:
(name and quantity of active (pharmaceutical) ingredients & excipients)**

|  |
| --- |
|  |

**INDICATIONS/Claims AND DOSAGES:**

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| --- |
|  |

**PHARMACOLOGICAL CATEGORY/Pharmacotherapeutic group/ATC Code:**

|  |
| --- |
|  |

**REGISTRATION IN OTHER COUNTRIES (Pending or approved):**

|  |
| --- |
|  |

**Dispensing Category (mark as X):**

|  |  |
| --- | --- |
| Prescription Only Medicines (POM): **[ ]**  | Over The Counter Medicines (OTC): **[ ]**  |
| Pharmacy Only Medicine (PM) Controlled Drug (CD):**[ ]** Veterinary Medicine **[ ]**  |

**PACKAGE SIZES AND PRESENTATION**

|  |
| --- |
|  |

**MISCELLANEOUS (Special Conditions, etc.)**

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| --- |
|  |

**ENCLOSURES (mark as X)**

|  |
| --- |
| Container labels **[ ]**  Package insert **[ ]**  Professional Information/SmPC **[ ]**  |
| CTD **[ ]**  Other Documents **[ ]**  Samples **[ ]**  #  |
| Registration certificate(s) from country of origin and others, where applicable **[ ]**  |
| Manufacturing License **[ ]**  GMP Certificate **[ ]**  |

**DECLARATION:**

I, the undersigned certify that the information in the accompanying documentation concerning the application for registration of the medicine 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 |