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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**

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| --- |
|  |

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

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| --- |
|  |

**ENCLOSURES (mark as X)**

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| --- |
| 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 |