

**FOOD AND DRUGS AUTHORITY**

**APPLICATION FOR REGISTRATION OF PHARMACEUTICAL VETERINARY PRODUCT**

*To be submitted as two electronic copies in pdf on CD-ROMs*

CONFIDENTIAL

THE CHIEF EXECUTIVE OFFICER,

FOOD AND DRUGS AUTHORITY

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| **PART 1 ADMNISTRATIVE INFORMATION** | | |
| 1.0 | Attach a cover letter |  |
| 1.1 | Table of content (Parts 1-3) |  |
| **1.2 Application Information** | | |
| 1.2.1 | Trade Name/Proprietary of the product |  |
| 1.2.2 | Approved/International Non-proprietary Name (INN)/Generic  name of the Active Pharmaceutical Ingredient (API) |  |
| 1.2.3 | Strength |  |
| 1.2.4 | Dosage form |  |
| 1.2.5 | Route of administration of the product |  |
| 1.2.6 | Target Species |  |
| 1.2.7 | Pharmacological Classification |  |
| 1.2.8 | Indication |  |
| 1.2.9 | Container- closure system |  |
| 1.2.10 | Commercial presentation |  |
| 1.2.11 | Category of Distribution |  |
| 1.2.12 | Proposed shelf life |  |
| 1.2.13 | Proposed storage conditions |  |
| 1.2.14 | Proposed storage conditions (after re-constitution or dilution  where applicable |  |
| **1.3 Name and address of Applicant** | | |
|  | (Company) Name:  Address:  Country:  Telephone:  Telefax:  E-Mail: |  |
| **1.4 Name and address of Manufacturer(s)** | | |
|  | (Company) Name:  Address:  Country:  Telephone:  Telefax:  E-Mail: |  |
| **1.5 Name and address of local Agent** | | |
|  | (Company) Name:  Address:  Country:  Telephone:  Telefax:  E-Mail: |  |
| **1.6 Certificate of Pharmaceutical Product** | | |
| **1.7 Manufacturing and Marketing authorization (s)/international registration status** | | |
| 1.7.1 | List of the countries in which product has been registered |  |
| 1.7.2 | List of countries in which product has been withdrawn |  |
| 1.7.3 | List of the countries where an application for marketing in any country has been rejected, suspended, deferred or is pending. |  |
| **1.8 Copy of Certificate of Suitability of the European Pharmacopoeia (CEP) including any annexes. (if applicable)** | | |
| **1.9 Labeling Information & Product Samples** | | |
| 1.9.1 | Summary of Product Characteristics |  |
| 1.9.2 | Product information leaflet |  |  |  |
| 1.9.3 | Product labels (Samples of Primary, Secondary and Tertiary labels) |  |
| 1.9.4 | Samples of the product as per FDA sample schedule |  |
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| **PART 2 QUALITY DOCUMENTATION** | | |
| 2.0 | Drug master file of active pharmaceutical ingredient (To be submitted as per CTD format) |  |
| 2.1 | Qualitative and quantitative composition of product (including excipients and their role in the formulation) |  |
| 2.2 | Active ingredients specification and certificate of analysis |  |
| 2.3 | Description of the manufacturing process of product |  |
| 2.4 | Analytical Control Procedures (Control tests carried out at intermediate stages of the production process for finished product) |  |
| 2.5 | Batch manufacturing records for one executed batch of finished product |  |
| 2.6 | Release specification for finished product |  |
| 2.7 | Certificate of analysis of finished product |  |
| 2.8 | Shelf life specification for finished product |  |
| 2.9 | Protocol and report for accelerated stability study |  |
| 2.10 | Protocol and report for long term stability study |  |
| **PART 3 SAFETY & RESIDUE INFORMATION** | | |
| 3.0 | Material safety data for active ingredient(s) |  |
| 3.1 | User safety information |  |
| 3.2 | Environmental risk assessment report |  |
| 3.3 | Residue data on active ingredients |  |

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| **DECLARATION BY AN APPLICANT** |
| 1. I/ we, the undersigned certify that all the information in this application form and accompanying documentation is correct, complete and true to the best of my knowledge. 2. I/ we further confirm that the information referred to in my application dossier is available for verification during current GMP inspection. 3. i/ we understand that the product shall not be imported, distributed for sale or advertised in Ghana until the product has been duly registered by the FDA. 4. I/ we also agree that the applicant will implement a Pharmacovigilance plan for this product in accordance with FDA requirements 5. I/ we also oblige to follow the requirements of the FDA Act, which are related to pharmaceutical products. 6. I/ we also consent to the processing of information provided by the FDA.   Name: …………………………………………………………………..……………………….  Position in the company:……………………………………………………………………….  Signature: …………………………………………………………………………….…………  Date:………………………………………………………………………………………………  Official stamp:…………………………………………………………………………………… |