

**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

P.O. BOX CT 2783

CANTONMENT-ACCRA

GHANA.

Fax:

Telephone:

Mobile:

WEBSITE: www.fdaghana.gov.gh

For Inquiries email: fdaghana.gov.gh

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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| 1.7.2 | List of countries in which product has been withdrawn  |  |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:…………………………………………………………………………………… |