

**FOOD AND DRUGS AUTHORITY**

**APPLICATION FORM FOR**

**REREGISTRATION OF ALLOPATHIC DRUG**

*(to be submitted as two electronic copy (Modules 3-5 in pdf on a CD-Rom) including* *Modules 1 and 2 in MS-Word)*

CONFIDENTIAL

THE CHIEF EXECUTIVE OFFICER,

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**Version No: 00**

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| *For FDA use only* | | | | | | |
| **Current Registration** Number | | | |  | | |
| Date of submission of the dossier | | | |  | | |
|  | | | | | |  |
| Number of CD(s) received | | |  | | | |
| **CONCLUSION OF THE ASSESSMENT**  **RECOMMENDED** *(no outstanding issues)*  **QUERY RAISED** *(Indicate the sections where query is*  *raised)*  **REJECTED** *(indicate the module(s) that led to the rejection)*  ***(Please delete which does not apply)*** | | | | |  | |
| **TYPE OF APPLICATION – HUMAN, BIOLOGICAL OR VETERINARY PRODUCT**  (*Please delete / change which does not apply*) | | | | | | |
| **MODULE 1: ADMINISTRATIVE INFORMATION** | | | | | | |
| **SECTION 1: PARTICULARS OF THE PRODUCT** | | | | | | |
| **1.0 Attach a cover letter** | | | | | | |
| **1.1 Table of content** | | | | | | |
| **1.2 Application Information** | | | | | | |
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| *For FDA use only* | | | | | | |
| **1.2.1** | **Trade Name/Proprietary of the product** | | | | | |
| *For FDA use only* | | | | | | |
| **1.2.2** | **Approved/International Non-proprietary Name (INN)/Generic name of the Active Pharmaceutical**  **Ingredient (API)** | | | | | |
| *For FDA use only* | | | | | | |
| **1.2.3** | **Dosage form and route of administration of the product:** | | | | | |
| *For FDA use only* | | | | | | |
| **1.2.4** | **Strength of API per unit dosage of the product** | | | | | |
| 1.2.4.1 | Dosage form of the product: | | | | | |
| 1.2.4.2 | Route*(s)* of administration | | | | | |
| *For FDA use only* | | | | | | |
| 1.2.5 | **Commercial presentation of the product:** | | | | | |
| *For FDA use only* | | | | | | |
| **1.2.6** | | **Nature and content of container** | | | | |
|  | |  | | | | |
| **1.2.7** | | **Description of the product** *(Add as many rows as necessary)* | | | | |
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| **1.2.8** | | **Country of Origin** | | | | |
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| **1.2.9** | | **Category of distribution** |
| 1.2.9.1 | | POM (Prescription only medicine) (*Please delete which does not apply*) |
| 1.2.9.2 | | P (Pharmacist initiated medicine) *(Please delete which does not apply)* |
| 1.2.9.3 | | OTC (Over-the-counter medicine) (*Please delete which does not apply*) |
| **1.2.10** | | **Pharmacological classification and indication** |
| 1.2.10.1 | | Pharmacological classification |
| **1.2.10.2** | | Indication |
|  | | |
| *For FDA use only* | | |
| **1.2.11** | **Shelf life (in months) and storage conditions:** | |
| 1.2.11.1 | Shelf life: | |
| 1.2.11.2 | Shelf life (after reconstitution or dilution): | |
| 1.2.11.3 | Storage conditions: | |
| 1.2.11.4 | Storage conditions (after reconstitution or dilution): | |
|  |  | |
| *For FDA use only* | | |
| **1.2.12 Name and address of Applicant** | | |
| (Company) Name:  Address:  Country:  Telephone:  Telefax:  E-Mail: | | |
|  | | |
| *For FDA use only* | | |
| **1.2.13** | **Name(s) and complete address (es) of the manufacturer(s)** | |
| **1.2.13.1** | **Name(s) and complete address(es) of the manufacturer(s) of the finished pharmaceutical product (FPP), including the final product release if different from the manufacturer.** *(Add as many rows as necessary)* | |
| Name:  Company name:  Address:  Country:  Telephone:  Telefax:  E-Mail:  **If the manufacturer is different to 1.1 above, explain the relationship:** | | |
|  | | |
| **1.2.13.2** | **Name(s) and complete address(es) of the manufacturer(s) of the active pharmaceutical ingredient(s) (API)** *(Add as many rows as necessary)* | |
|  | Name:  Company name:  Address:  Country:  Telephone:  Telefax:  **E-Mail:** | |
|  | | |
| **1.2.14.2** | Attach a valid certificate of pharmaceutical product from the country of origin. | |
| **1.2.14.3** | Valid Manufacturing authorisation from the country of origin and Good Manufacturing Practice certificate (GMP) if applicable. | |
| **1.2.14.4** | Copy of current manufacturing contract agreement between the applicant and manufacturer (if applicable) | |
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| *For FDA use only* | |
| **1.2.16** | **Name and complete address of the Authorised Local Representative of the applicant (local agent)** |
| Name:  Company name:  Address:  Country:  Telephone:  Telefax:  E-Mail: | |
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| **1.3** | **Prescribing information (in word version and pdf)** |
| **1.3.1** | Summary of Product Characteristics |

|  |  |  |  |  |  |  |  |  |  |
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| **1.3.2** | Patient Information leaflet | | | | | | | | |
| **1.3.3** | Labelling (Outer and inner labels) | | | | | | | | |
| **1.3.4** | Samples of the product as per FDA sample schedule | | | | | | | | |
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| **1.4** | Regional summaries | | | | | | | | |
| **1.4.2** | Quality information Summary (QIS) | | | | | | | | |
| *For FDA use only* | | | | | | | | | |
| **1.5** | **Electronic review document** | | | | | | | | |
| **1.5.1** | Quality information Summary (QIS) – MS Word version | | | | | | | | |
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| *For FDA use only* | | | | | | | | | |
| **1.5 Batch formula of the current highest commercial batch size.**  *(Add as many rows as necessary)* | | | | | | | | | |
| Composition of clinical, primary stability and validation/production FPP batches (kg) | | | | | | | | | |
| Ingredients | | Administration Unit | | Bioequivalence ˂batch number˃ | | Primary stability ˂batch number˃ | | Production ˂batch number˃ | |
| Mg | %\* | Kg | %\* | Kg | %\* | kg | %\* |
| Core tablet / capsule contents / injections / suspensions, etc. (*Please delete / change which does not apply*) | | | | | | | | | |
| API 1 | |  |  |  |  |  |  |  |  |
| API 2 | |  |  |  |  |  |  |  |  |
| API 3 | |  |  |  |  |  |  |  |  |
| *Please add / delete as many rows as necessary* | |  |  |  |  |  |  |  |  |
| Excipient 1 | |  |  |  |  |  |  |  |  |
| Excipient 2 | |  |  |  |  |  |  |  |  |
| Excipient 3 | |  |  |  |  |  |  |  |  |
| *Please add / delete as many rows as necessary* | |  |  |  |  |  |  |  |  |
| Subtotal 1 | |  |  |  |  |  |  |  |  |
| Purified water/other solvent(s) | |  |  |  |  |  |  |  |  |
| Film coat / capsule shell / printing ink (*Please delete / change which does not apply*) | | | | | | | | | |
| Proprietary film-coating mixture\*\* | |  |  |  |  |  |  |  |  |
| *Please add / delete as many rows as necessary* | |  |  |  |  |  |  |  |  |
| Subtotal 2 | |  |  |  |  |  |  |  |  |
| Grand total | |  |  |  |  |  |  |  |  |
| Purified water/other solvent(s) | |  |  |  |  |  |  |  |  |
| \* Each ingredient is expressed as a percentage of the grand total.  \*\* All components (……………..) of the proprietary mixture are described in the compendia | | | | | | | | | |
| *For FDA use only*  **OVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULE** | | | | | | | | | |
|  |  | | | | | | | | |
| **MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION** | | | | | | | | | |
| **3.1** | **TABLE OF CONTENTS OF MODULE 3** | | | | | | | | |
| **3.2** | **BODY OF DATA** | | | | | | | | |
| **3.2. P** | **PARTICULARS OF FINISHED PHARMACEUTICAL PRODUCT(S) [FPP(S)]** | | | | | | | | |
| 3.2.P.1 | Description and Composition of the FPP | | | | | | | | |
| 3.2.P.1(a) | Description | | | | | | | | |
| 3.2.P.1(b) | Composition of the FPP(S)- Current highest batch size | | | | | | | | |
| 3.2.P.3 | Manufacture of the FPP(S) | | | | | | | | |
| 3.2.P.3.3 | Current Manufacturing Process description – narrative and flow diagram | | | | | | | | |
| 3.2.P.3.4 | Summary of in-process controls | | | | | | | | |
| 3.2.P.5 | Control of the FPP(S) | | | | | | | | |
| 3.2.P.5.1 | Signed copy of the current version of the FPP Specification (Release and Shelf-life) | | | | | | | | |
| 3.2.P.5.2 | Signed Copy of the current version of method of analysis of the FPP | | | | | | | | |
| 3.2.P.8 | Stability of the FPP(S) | | | | | | | | |
| 3.2.P.8.2 | Stability Protocol | | | | | | | | |
| 3.2.P.8.3 | Stability data | | | | | | | | |
| **DECLARATION BY AN APPLICANT** | | | | | | | | | |
|  | 1. I, 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 further confirm that the information referred to in my application dossier is available for verification during current GMP inspection. 3. 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 also agree that the applicant will implement a Pharmacovigilance plan for this product in accordance with FDA requirements 5. I also agree that I am obliged to follow the requirements of the FDA Act, which are related to pharmaceutical products. 6. I also consent to the processing of information provided by the FDA.     Name: …………………………………………………………………..……………………….  Position in the company:…………………………………………………………………… Signature:  …………………………………………………………………………….…………  Date:………………………………………..  Official stamp:…………………………….. | | | | | | | | |