



# FOOD AND DRUGS AUTHORITY

## APPLICATION FOR REGISTRATION OF AN ALLOPATHIC DRUG

*(to be submitted as one original hard-copy and one electronic copy (in pdf on a CD-Rom)  
including Modules 1 and 2 in MS-Word)*

CONFIDENTIAL

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<i>For FDA use only</i>		
Application Number		
Date of submission of the dossier		
Name of the 1 <sup>st</sup> Evaluator		Signature
Name of the 2 <sup>nd</sup> Evaluator		Signature
Date of 1st evaluation		
Date of 2nd Evaluation		
Number of files and CD(s) received		
<b>CONCLUSION OF THE ASSESSMENT</b> <b>RECOMMENDED</b> (no outstanding issues) <b>QUERY RAISED</b> (Indicate the sections where query is raised) <b>REJECTED</b> (indicate the module(s) that led to the rejection) <i>(Please delete which does not apply)</i>		
<b>TYPE OF APPLICATION – HUMAN, BIOLOGICAL OR VETERINARY PRODUCT</b> <i>(Please delete / change which does not apply)</i>		
<b>MODULE 1: ADMINISTRATIVE INFORMATION</b>		
<b>SECTION 1: PARTICULARS OF THE PRODUCT</b>		
<b>1.0 Attach a cover letter</b>		
<b>1.1 Table of content of the application (MODULE 1-5)</b>		
<b>1.2 Application Information</b>		
<i>For FDA use only</i>		
<b>1.2.1</b>	<b>Trade Name/Proprietary of the product</b>	
<i>For FDA use only</i>		
<b>1.2.2</b>	<b>Approved/International Non-proprietary Name (INN)/Generic name of the Active Pharmaceutical Ingredient (API)</b>	
<i>For FDA use only</i>		
<b>1.2.3</b>	<b>Dosage form and route of administration of the product:</b>	
<i>For FDA use only</i>		
<b>1.2.4</b>	<b>Strength of API per unit dosage of the product</b>	
1.2.4.1	Dosage form of the product:	
1.2.4.2	Route(s) of administration	
<i>For FDA use only</i>		
<b>1.2.5</b>	<b>Commercial presentation of the product:</b>	
<i>For FDA use only</i>		
<b>1.2.6</b>	<b>Nature and content of container</b>	
<b>1.2.7</b>	<b>Description of the product</b>	<i>(Add as many rows as necessary)</i>

<b>1.2.8</b>	<b>Country of Origin</b>
<b>1.2.9</b>	<b>Category of distribution</b>
1.2.9.1	POM (Prescription only medicine) <i>(Please delete which does not apply)</i>
1.2.9.2	P (Pharmacist initiated medicine) <i>(Please delete which does not apply)</i>
1.2.9.3	OTC (Over-the-counter medicine) <i>(Please delete which does not apply)</i>
1.2.9.4	<b>VETERINARY DRUGS</b>
<b>1.2.9.4.1</b>	Veterinary Medicines (VM) Prescription
<b>1.2.9.4.2</b>	Veterinary Medicines (General Dealer) – (V.M.G.D)
<b>1.2.10</b>	<b>Pharmacological classification and indication</b>
1.2.10.1	Pharmacological classification
<b>1.2.10.2</b>	Indication
<i>For FDA use only</i>	
<b>1.2.11</b>	<b>Proposed shelf life (in months) and storage conditions:</b>
1.2.11.1	Proposed shelf life:
1.2.11.2	Proposed shelf life (after reconstitution or dilution):
1.2.11.3	Proposed storage conditions:
1.2.11.4	Proposed storage conditions (after reconstitution or dilution):
<i>For FDA use only</i>	
<b>1.2.12 Name and address of Applicant</b>	
(Company) Name: Address: Country: Telephone: Telefax: E-Mail:	
<i>For FDA use only</i>	
<b>1.2.13</b>	<b>Name(s) and complete address (es) of the manufacturer(s)</b>
<b>1.2.13.1</b>	<b>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. <i>(Add as many rows as necessary)</i></b>
Name: Company name: Address: Country: Telephone: Telefax: E-Mail: <b>If the manufacturer is different to 1.1 above, explain the relationship:</b>	
<b>1.2.13.2</b>	<b>Name(s) and complete address(es) of the manufacturer(s) of the active pharmaceutical ingredient(s) (API) <i>(Add as many rows as necessary)</i></b>
Name: Company name: Address: Country: Telephone: Telefax: <b>E-Mail:</b>	

<b>1.2.14</b>	<b>Manufacturing and marketing authorisation(s)/international registration status</b>														
<b>1.2.14.1</b>	Product Marketing Authorisation issued by the national regulatory authority in the country of origin and other countries (If not registered in the country of origin state reasons).														
<input type="checkbox"/> Authorised Country: Date of authorisation (dd-mm-yyyy): Proprietary name: Authorisation number:				<input type="checkbox"/> Withdrawn (by applicant after authorisation) Country: Date of withdrawal (dd-mm-yyyy): Proprietary name: Reason for withdrawal:				<input type="checkbox"/> Refused Country: Date of refusal (dd-mm-yyyy): Reason for Refusal:				<input type="checkbox"/> Suspended/revoked (by competent authority) Country: date of suspension/revocation (dd-mm-yyyy): Reason for suspension/revocation: Proprietary name:			
<b>1.2.14.2</b>	Attach a valid certificate of pharmaceutical product from the country of origin.														
<b>1.2.14.3</b>	Valid Manufacturing authorisation from the country of origin and Good Manufacturing Practice certificate (GMP).														
<b>1.2.14.4</b>	Valid manufacturing contract agreement between the applicant and manufacturer, in addition, for loan license manufacturing a valid manufacturing contract agreement and Supporting documentation from the competent drug regulatory authority for the manufacturing license code should be submitted.														
<b>1.2.15</b>	Copy of Certificate of Suitability of the European Pharmacopoeia (CEP) including any annexes. (if applicable)														
<i>For FDA use only</i>															
<b>1.2.16</b>	<b>Name and complete address of the Authorised Local Representative of the applicant (local agent)</b>														
Name: Company name: Address: Country: Telephone: Telefax: E-Mail:															
<i>For FDA use only</i>															
<b>1.3</b>	<b>Prescribing information</b>														
<b>1.3.1</b>	<b>Product information for health professionals (Products subject to medical prescription)</b>														
<b>1.3.2</b>	<b>Patient Information leaflet</b>														
<b>1.3.3</b>	<b>Labelling (Outer and inner labels)</b>														
<b>1.4</b>	<b>Samples of the product as per FDA sample schedule</b>														
<i>For FDA use only</i>															
<b>1.5</b>	<b>Batch number(s) of the FPPs used in</b> <span style="float: right;"><i>(Add as many rows as necessary)</i></span>														
Clinical/bioequivalence studies															
Stability studies															
Validation/production scale batches															
Comments [e.g., batch size, explanation of NA (not applicable) answers]															
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. <i>(Please delete / change which does not apply)</i>															
API 1															
API 2															
API 3															
<i>Please add / delete as many rows as necessary</i>															
Excipient 1															
Excipient 2															

Excipient 3								
<i>Please add / delete as many rows as necessary</i>								
Subtotal 1								
Purified water/other solvent(s)								
Film coat / capsule shell / printing ink ( <i>Please delete / change which does not apply</i> )								
Proprietary film-coating mixture**								
<i>Please add / delete as many rows as necessary</i>								
Subtotal 2								
Grand total								
Purified water/other solvent(s)								
Equivalence of the composition or justified differences	The compositions of the bioequivalence, stability and validation batches are the same and differences are justified. ( <i>Please delete / change which does not apply</i> )							

\* Each ingredient is expressed as a percentage of the grand total.  
\*\* All components (.....) of the proprietary mixture are described in the compendia

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**OVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULE**

**MODULE 2: CHEMICAL, PHARMACEUTICAL, NON-CLINICAL AND CLINICAL OVERVIEWS AND SUMMARIES**

**2.1 CTD TABLE OF CONTENTS OF MODULES 2, 3, 4, AND 5**

**2.2 INTRODUCTION**

**2.3 QUALITY OVERALL SUMMARY**

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**2.3.S OVERVIEW OF ACTIVE PHARMACEUTICAL INGREDIENT(S) [API(S)]**

2.3.S.1 General Information of the API(S)

2.3.S.1.1 Nomenclature

*For FDA use only*

2.3.S.1.2 Structure

*For FDA use only*

2.3.S.1.3 General Properties of the API(s)

*For FDA use only*

2.3.S.2 Manufacture of the API(S)

2.3.S.2.1 Name and address of API(s) Manufacturer

*For FDA use only*

2.3.S.2.2 Description of Manufacturing Process and Process Controls

2.3.S.2.3 Control of Materials used in Manufacture of API

2.3.S.2.4 Controls of Critical Steps and Intermediates

2.3.S.2.5 Process Validation and/or Evaluation

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2.3.S.3 Characterization of the API(S)

2.3.S.4 Control of the API(S)

2.3.S.5 Reference Standards or Materials of the API(S)

2.3.S.6 Container Closure System of the API(S)

2.3.S.7 Stability of the API(S)

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**2.3.P OVERVIEW OF FINISHED PHARMACEUTICAL PRODUCT [FPP]**

2.3.P.1 Description and Composition of the FPP

2.3.P.2 Pharmaceutical Development of the FPP

2.3.P.3 Manufacture of the FPP

2.3.P.4	Control of Excipients for the FPP
2.3.P.5	Control of the FPP
2.3.P.6	Reference Standards or Materials of the FPP
2.3.P.7	Container Closure System of the FPP
2.3.P.8	Stability of the FPP
<b>2.3. A</b>	<b>APPENDICES</b>
2.3.A.1	Facilities and Equipment
2.3.A.2	Adventitious Agents Safety Evaluation
2.3.A.3	Excipients
	REGIONAL INFORMATION
<i>For FDA use only</i>	
<b>2.4</b>	<b>SUMMARY OF NON-CLINICAL DOCUMENTATION AND CLINICAL DOCUMENTATION</b>
<b>2.4.1</b>	<b>FOR NEW CHEMICAL ENTITIES</b>
2.4.1.1	Non-clinical overview
2.4.1.2	Non-clinical written and tabulated summaries
2.4.1.3	Clinical overview
2.4.1.3	Clinical summary
<i>For FDA use only</i>	
<b>2.5.1</b>	<b>GENERIC DRUG APPLICATIONS</b>
2.5.2	Clinical Overview and Summary
2.5.3	Product Development Rationale
2.5.4	Overview of Biopharmaceutics Studies
2.5.5	Summary of Biopharmaceutics Studies and Associated Analytical Methods
<i>For FDA use only</i>	
<i>For FDA use only</i> <b><u>OVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULE</u></b>	
<b>MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION</b>	
<b>3.1</b>	<b>TABLE OF CONTENTS OF MODULE 3</b>
<b>3.2</b>	<b>BODY OF DATA</b>
<b>3.2.1</b>	<b>PARTICULARS OF ACTIVE PHARMACEUTICAL INGREDIENT(S) [API(S)]</b>
3.2.1.1	General Information of the API(S)
3.2.1.2	Manufacture of the API(S)
3.2.1.3	Characterization of the API(S)
3.2.1.4	Control of the API(S)
3.2.1.5	Reference Standards or Materials of the API(S)
3.2.1.6	Container Closure System of the API(S)
3.2.1.7	Stability of the API(S)
<b>3.2.2</b>	<b>PARTICULARS OF FINISHED PHARMACEUTICAL PRODUCT(S) [FPP(S)]</b>
3.2.2.1	Description and Composition of the FPP(S)
3.2.2.2	Pharmaceutical Development of the FPP(S)
3.2.2.3	Manufacture of the FPP(S)
3.2.2.4	Control of Excipients for the FPP(S)
3.2.2.5	Control of the FPP(S)
3.2.2.6	Reference Standards or Materials of the FPP(S)
3.2.2.7	Container Closure System of the FPP(S)
3.2.2.8	Stability of the FPP(S)
<b>3.2.3</b>	<b>APPENDICES</b>
3.2.3.1	Facilities and Equipment
3.2.3.2	Adventitious Agents Safety Evaluation
3.2.33	Novel Excipients
<b>MODULE 4: NON-CLINICAL STUDY REPORTS FOR NEW CHEMICAL ENTITIES ONLY</b>	
<b>4.1</b>	<b>TABLE OF CONTENTS OF MODULE 4</b>
<b>4.2</b>	<b>STUDY REPORTS</b>
<b>4.3</b>	<b>LITERATURE REFERENCES</b>

## MODULE 5: CLINICAL STUDY REPORTS

<b>5.1</b>	<b>NEW CHEMICAL ENTITIES ONLY</b>
5.1.1	Table of Contents of Module 5
5.1.2	Tabular Listing of All Clinical Studies
5.1.3	Clinical Study Reports
5.1.4	Literature References
<b>5.2</b>	<b>INTERCHANGEABILITY OF GENERIC DRUGS – (GENERIC DRUG APPLICATIONS ONLY)</b>
<b>5.2.1</b>	<b>REPORTS OF BIOPHARMACEUTIC STUDY(IES)</b>
5.2.1.1	Bioavailability (BA) study report
5.2.1.2	<i>In Vitro</i> Dissolution Tests
5.2.2.1.1	In vitro dissolution tests complementary to bioequivalence studies
5.2.2.1.2	In vitro dissolution tests in support of biowaiver
5.2.3	Other Clinical study data done to support efficacy and safety of the product
<b>5.3</b>	<b>SAFETY AND RESIDUES DOCUMENTATION (FOR VETERINARY PRODUCTS ONLY)</b>
5.3.1	Requirements for Animal Safety
5.3.1.1	Laboratory Animal Studies
5.3.1.2	Target Animal Safety Studies
5.3.2	Requirements for Human Safety
5.3.2.1	Laboratory Animal Toxicity Studies
5.3.2.2	Microbiological Safety Studies (for antimicrobial products)
5.3.2.3	Veterinary Antimicrobial Products
5.3.2.4	Residue (Chemistry) Studies/data for food producing species only

### 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:.....