SCHEDULE (r.4)
Form 1

REPUBLIC OF KENYA

PHARMACY AND POISONS BOARD

APPLICATION FOR REGISTRATION OF A 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
(Revised 2010)

THE REGISTRAR
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Application Number		
Date of submission of the dossier		
Name of the 1st Evaluator		Signature
Name of the 2nd Evaluator		Signature
Date of 1st evaluation		
Date of 2nd Evaluation		
Number of files 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

1.1 Name and address of Applicant

(Company) Name:
Address:
Country:
Telephone:
Telefax:
E-Mail:

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1.2	**Trade Name of the product (Proprietary Product Name)**

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1.3	**International Non-proprietary Name (INN) of the Active Pharmaceutical Ingredient (API)**

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1.4	**Strength of Active Pharmaceutical Ingredient (API) per unit dosage of the product:**

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1.5	**Pharmaceutical Dosage form and route of administration of the product**
1.5.1	Pharmaceutical Dosage form of the product:
1.5.2	Route*(s)* of administration (use current list of standard terms - European Pharmacopoeia)

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1.6	**Packing/pack size of the product:**

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1.7	**Visual description of the product** *(Add as many rows as necessary)*

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1.8	**Proposed shelf life (in months):**
1.8.1	Proposed shelf life (after reconstitution or dilution):
1.8.2	Proposed shelf life (after first opening container):
1.8.3	Proposed storage conditions:
1.8.4	Proposed storage conditions after first opening:

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1.9	**Pharmacotherapeutic group and ATC Code**
1.9.1	Pharmacotherapeutic group:
1.9.2	ATC Code: *(Please use current ATC code)*
1.9.3	If no ATC code has been assigned, please indicate if an application for ATC code has been made: ☐

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1.10	**Legal category**
1.10.1	Proposed dispensing category/classification: Product is subject to medical prescription or not subject to medical prescription (*Please delete which does not apply*)
1.10.2	For products subject to medical prescription: Controlled Drug Substance or Prescription Only Medicine, POM *(Please delete which does not apply)*
1.10.3	For products not subject to medical prescription: The product will be dispensed from Non-pharmacy outlets and

	pharmacies (if applicable) or Pharmacies only (*Please delete which does not apply*)
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1.11	**Country of origin or country of release:**
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1.12	**Product Marketing Authorisation in the country of origin and other countries.** (Attach certificate of pharmaceutical product from competent regulatory authority) **If not registered, state reasons**

☐Authorised Country: Date of authorisation (dd-mm-yyyy): Proprietary name: Authorisation number: ☐ Refused Country: Date of refusal (dd-mm-yyyy): Reason for Refusal:	☐ Withdrawn (by applicant after authorisation) Country: Date of withdrawal (dd-mm-yyyy): Proprietary name: Reason for withdrawal: ☐ Suspended/revoked (by competent authority) Country: date of suspension/revocation (dd-mm-yyyy): Reason for suspension/revocation: Proprietary name:

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1.13	**Pre-registration analysis of the product** (Attach certificate of analysis from a recognized WHO Prequalified Quality Control Laboratory in Kenya and within the Region)
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1.14	**Name(s) and complete address(es) of the manufacturer(s)**
1.14.1	**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:

1.14.2	**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:

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1.15	**Good Manufacturing Practice (GMP) status of the manufacturer (s) of the FPP**
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1.16	**Name and complete address of the Local Technical Representative of Manufacturer**

Name:
Company name:
Address:
Country:
Telephone:
Telefax:
E-Mail:
If the Local Technical Representative is different to 1.1 above, explain and provide evidence for the relationship:

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1.17	**Summary Product Characteristics (SPC)**
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1.18 Batch number(s) of the FPPs used in *(Add as many rows as necessary)*

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. (*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)								
Equivalence of the composition or justified differences			The compositions of the bioequivalence, stability and validation batches are the same and differences are justified. (*Please delete / change which does not apply*)					
* Each ingredient is expressed as a percentage of the grand total. ** All components (……..) of the proprietary mixture are described in the compendia								
For PPB use only **OVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULE**								

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

2.1	**OVERALL TABLE OF CONTENTS OF MODULES 2, 3, 4, AND 5**
2.2	**INTRODUCTION**
2.3	**OVERALL QUALITY SUMMARY**
For PPB use only	
2.3.1	**OVERVIEW OF ACTIVE PHARMACEUTICAL INGREDIENT(S) [API(S)]**
2.3.1.1	General Information of the API(S)
2.2.1.1.1	Nomenclature
For PPB use only	
2.2.1.1.2	Structure
For PPB use only	
2.2.1.1.3	General Properties of the API(s)
For PPB use only	
2.3.1.2	Manufacture of the API(S)
2.3.1.2.1	Name and address of API(s) Manufacturer
For PPB use only	
2.3.1.2.2	Description of Manufacturing Process and Process Controls
2.3.1.2.3	Control of Materials used in Manufacture of API
2.3.1.2.4	Controls of Critical Steps and Intermediates
2.2.1.2.5	Process Validation and/or Evaluation
For PPB use only	

2.3.1.3	Characterization of the API(S)
2.3.1.4	Control of the API(S))
2.3.1.5	Reference Standards or Materials of the API(S)
2.3.1.6	Container Closure System of the API(S)
2.3.1.7	Stability of the API(S)
For PPB use only	
2.3.2	**OVERVIEW OF FINISHED PHARMACEUTICAL PRODUCT(S) [FPP(S)]**
2.3.2.1	Description and Composition of the FPP(S)
2.3.2.2	Pharmaceutical Development of the FPP(S)
2.3.2.3	Manufacture of the FPP(S)
2.3.2.4	Control of Excipients for the FPP(S)
2.3.2.5	Control of the FPP(S)
2.3.2.6	Reference Standards or Materials of the FPP(S)
2.3.2.7	Container Closure System of the FPP(S)
2.3.2.8	Stability of the FPP(S)
2.3.3	**APPENDICES**
2.3.3.1	Facilities and Equipment
2.3.3.2	Adventitious Agents Safety Evaluation
2.3.3.3	Novel Excipients
For PPB use only	
2.4	**SUMMARY OF NON-CLINICAL DOCUMENTATION AND CLINICAL DOCUMENTATION**
2.4.1	**FOR NEW CHEMICAL ENTITIES**
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
For PPB use only	
2.4.2	**GENERIC DRUG APPLICATIONS**
2.4.2.1	Clinical Overview and Summary
2.4.2.1.1	Product Development Rationale
2.4.2.1.2	Overview of Biopharmaceutics Studies
2.4.2.1.3	Summary of Biopharmaceutics Studies and Associated Analytical Methods
2.4.2.1.4	Overview and Summary of *In Vitro* Dissolution Tests complementary to Bioequivalence Studies
2.4.2.1.4	Overview and Summary of *In Vitro* Dissolution Tests in support of a Biowaiver
For PPB use only	
For PPB 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**
3.2.1	**PARTICULARS OF ACTIVE PHARMACEUTICAL INGREDIENT(s) [API(s)]**
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)
3.2.2	**PARTICULARS OF FINISHED PHARMACEUTICAL PRODUCT(S) [FPP(S)]**
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)
3.2.3	**APPENDICES**
3.2.3.1	Facilities and Equipment
3.2.3.2	Adventitious Agents Safety Evaluation
3.2.33	Novel Excipients

MODULE 4: NON-CLINICAL STUDY REPORTS FOR NEW CHEMICAL ENTITIES ONLY

4.1	**TABLE OF CONTENTS OF MODULE 4**
4.2	**STUDY REPORTS**
4.3	**LITERATURE REFERENCES**

MODULE 5: CLINICAL STUDY REPORTS

5.1	**NEW CHEMICAL ENTITIES ONLY**
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
5.2	**INTERCHANGEABILITY OF GENERIC DRUGS – (GENERIC DRUG APPLICATIONS ONLY)**
5.2.1	**REPORTS OF BIOPHARMACEUTIC STUDY(IES)**
5.2.1.1	Bioavailability (BA) study report
5.2.1.2	*In Vitro* 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
5.3	**SAFETY AND RESIDUES DOCUMENTATION (FOR VETERINARY PRODUCTS ONLY)**
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. I agree that the undersigned has not marketed or advertised this product in Kenya and will follow the PPB requirements for advertisements of medicines
4. I also agree that the undersigned will implement a Pharmacovigilance plans for this product in accordance with PPB requirements
5. I also agree that I am obliged to follow the requirements of the Pharmacy and Poisons Act, which are related to pharmaceutical products.
6. I also consent to the processing of information provided by the Pharmacy and Poisons Board.

Name: ……..…….
Position in the company:……
Signature: ……..……
Date:……..
Official stamp:……..