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 PPB OFFICES, LENANA ROAD, DRUG REGISTRATION DEPARTMENT, P.O. BOX 27663-00506, NAIROBI. Fax: 2713431 Telephone: Nairobi 2716905/6; 3562107 Mobile: 0720 608811; 0733 884411 WEBSITE: www.pharmacyboardkenya.org For Inquiries email: drugreg@pharmacyboardkenya.org, info@pharmacyboardkenya.org

Applicatio		
Date of su	bmission of the dossier	
Name of t	he 1 st	
Evaluator		Signature
Name of t	he 2 nd	
Evaluator		Signature
Date of 1s	t evaluation	
Date of 2r	d Evaluation	
	f files received	
	JSION OF THE ASSESSMENT	
	MENDED (no outstanding issues)	
	RAISED (Indicate the sections where query is	
raised)	(Indedie me sections where query is	
· · · · · · · · · · · · · · · · · · ·	ED (indicate the module(s) that led to the rejection)	
	elete which does not apply)	
	F APPLICATION – HUMAN, BIOLOGICAL OR VE	FERINARY PRODUCT
III LOI		(Please delete / change which does not apply)
	MODULE 1: ADMINISTRA	
SECTIO	DN 1: PARTICULARS OF THE PRODUCT	
	e and address of Applicant	
1.1 Ivaiii	e and address of Appricant	
(Company	y) Name:	
Address:		
Country:		
Telephone		
Telefax:		
E-Mail:		
For PPB us	se only	
1.2	Trade Name of the product (Proprietary Produc	et Name)
-		,
For PPB us		
1.3	International Non-proprietary Name (INN) of the	ne Active Pharmaceutical Ingredient (API)
D D D D D		
For PPB us	se only	
<i>For PPB u</i> : 1.4		API) per unit dosage of the product:
1.4	Strength of Active Pharmaceutical Ingredient (A	API) per unit dosage of the product:
1.4 For PPB us	Strength of Active Pharmaceutical Ingredient (A	
1.4	Strength of Active Pharmaceutical Ingredient (A	
1.4 For PPB us 1.5	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin	
1.4 For PPB us	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product:	nistration of the product
I.4 For PPB us 1.5 1.5.1 1.5.2	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard te	nistration of the product
1.4 For PPB us 1.5 1.5.1	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard to se only	nistration of the product
1.4 For PPB us 1.5 1.5.1 1.5.2 For PPB us 1.6	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard te se only Packing/pack size of the product:	nistration of the product
I.4 For PPB us 1.5 1.5.1 1.5.2 For PPB us 1.6 For PPB us	Strength of Active Pharmaceutical Ingredient (A see only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard test only Packing/pack size of the product: see only	nistration of the product
1.4 For PPB us 1.5 1.5.1 1.5.2 For PPB us 1.6	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard te se only Packing/pack size of the product:	nistration of the product
I.4 For PPB us 1.5 1.5.1 1.5.2 For PPB us 1.6 For PPB us	Strength of Active Pharmaceutical Ingredient (A see only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard test only Packing/pack size of the product: see only	nistration of the product erms - European Pharmacopoeia)
1.4 For PPB us 1.5 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard to se only Packing/pack size of the product: se only Visual description of the product	nistration of the product erms - European Pharmacopoeia)
1.4 For PPB us 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7	Strength of Active Pharmaceutical Ingredient (A see only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard teste only Packing/pack size of the product: see only Visual description of the product see only	nistration of the product erms - European Pharmacopoeia)
1.4 For PPB us 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7 For PPB us 1.8	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard test only Packing/pack size of the product: se only Visual description of the product se only Proposed shelf life (in months):	nistration of the product erms - European Pharmacopoeia)
1.4 For PPB us 1.5 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7 For PPB us 1.8 1.8.1	Strength of Active Pharmaceutical Ingredient (A see only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard teste only Packing/pack size of the product: see only Visual description of the product see only	nistration of the product erms - European Pharmacopoeia)
1.4 For PPB us 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7 For PPB us 1.8	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard test only Packing/pack size of the product: se only Visual description of the product se only Proposed shelf life (in months):	nistration of the product erms - European Pharmacopoeia)
1.4 For PPB us 1.5 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7 For PPB us 1.8 1.8.1	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard to se only Packing/pack size of the product: See only Visual description of the product see only Proposed shelf life (in months): Proposed shelf life (after reconstitution or dilution):	nistration of the product erms - European Pharmacopoeia)
1.4 For PPB us 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7 For PPB us 1.8.1 1.8.1 1.8.2	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard te se only Packing/pack size of the product: se only Visual description of the product se only Proposed shelf life (in months): Proposed shelf life (after reconstitution or dilution): Proposed shelf life (after first opening container):	nistration of the product erms - European Pharmacopoeia)
1.4 For PPB us 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7 For PPB us 1.8.1 1.8.2 1.8.3	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard test only Packing/pack size of the product: se only Visual description of the product se only Proposed shelf life (in months): Proposed shelf life (after reconstitution or dilution): Proposed shelf life (after first opening container): Proposed storage conditions: Proposed storage conditions after first opening:	nistration of the product erms - European Pharmacopoeia)
1.4 For PPB us 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7 For PPB us 1.8.1 1.8.2 1.8.3 1.8.4	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard test only Packing/pack size of the product: se only Visual description of the product se only Proposed shelf life (in months): Proposed shelf life (after reconstitution or dilution): Proposed shelf life (after first opening container): Proposed storage conditions after first opening: Se only	nistration of the product erms - European Pharmacopoeia)
1.4 For PPB us 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7 For PPB us 1.8.1 1.8.2 1.8.3 1.8.3 1.8.4 For PPB us 1.8.4 For PPB us 1.8.3 1.8.4	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard te se only Packing/pack size of the product: se only Visual description of the product se only Proposed shelf life (in months): Proposed shelf life (after reconstitution or dilution): Proposed shelf life (after first opening container): Proposed storage conditions after first opening: se only	nistration of the product erms - European Pharmacopoeia)
1.4 For PPB us 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7 For PPB us 1.8.1 1.8.2 1.8.3 1.8.4 For PPB us 1.8.4 For PPB us 1.9 1.9.1	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard to se only Packing/pack size of the product: se only Visual description of the product se only Proposed shelf life (in months): Proposed shelf life (after reconstitution or dilution): Proposed shelf life (after first opening container): Proposed storage conditions: Proposed storage conditions after first opening: se only Pharmacotherapeutic group and ATC Code Pharmacotherapeutic group:	histration of the product prms - European Pharmacopoeia) (Add as many rows as necessary)
1.4 For PPB us 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7 For PPB us 1.8.1 1.8.2 1.8.3 1.8.4 For PPB us 1.9 1.9.1 1.9.2	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard to se only Packing/pack size of the product: se only Visual description of the product se only Proposed shelf life (in months): Proposed shelf life (after reconstitution or dilution): Proposed shelf life (after first opening container): Proposed shelf life (after first opening: Proposed storage conditions: Proposed storage conditions after first opening: se only Pharmacotherapeutic group and ATC Code Pharmacotherapeutic group: ATC Code:	histration of the product prms - European Pharmacopoeia) (Add as many rows as necessary) (Add as many rows as necessary) (Please use current ATC code)
1.4 For PPB us 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7 For PPB us 1.8.1 1.8.2 1.8.3 1.8.4 For PPB us 1.9 1.9.1 1.9.2 1.9.3	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard test only Packing/pack size of the product: se only Visual description of the product se only Proposed shelf life (in months): Proposed shelf life (after first opening container): Proposed storage conditions: Proposed storage conditions after first opening: se only Proposed storage conditions after first opening: ATC Code: If no ATC code has been assigned, please indicate if an another store storage indicate if an another store store indicate if an another store indicate	histration of the product prms - European Pharmacopoeia) (Add as many rows as necessary) (Add as many rows as necessary) (Please use current ATC code)
1.4 For PPB us 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7 For PPB us 1.8.1 1.8.2 1.8.3 1.8.4 For PPB us 1.9 1.9.1 1.9.2 1.9.3 For PPB us	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard term se only Packing/pack size of the product: se only Visual description of the product se only Proposed shelf life (in months): Proposed shelf life (after reconstitution or dilution): Proposed shelf life (after first opening container): Proposed storage conditions: Proposed storage conditions after first opening: se only Pharmacotherapeutic group: ATC Code: If no ATC code has been assigned, please indicate if an isse only	histration of the product prms - European Pharmacopoeia) (Add as many rows as necessary) (Add as many rows as necessary) (Please use current ATC code)
1.4 For PPB us 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7 For PPB us 1.8.1 1.8.2 1.8.3 1.8.4 For PPB us 1.9 1.9.1 1.9.2 1.9.3	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard test only Packing/pack size of the product: se only Visual description of the product se only Proposed shelf life (in months): Proposed shelf life (after first opening container): Proposed storage conditions: Proposed storage conditions after first opening: se only Proposed storage conditions after first opening: ATC Code: If no ATC code has been assigned, please indicate if an another store storage indicate if an another store store indicate if an another store indicate	histration of the product prms - European Pharmacopoeia) (Add as many rows as necessary) (Add as many rows as necessary) (Please use current ATC code)
1.4 For PPB us 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7 For PPB us 1.8.1 1.8.2 1.8.3 1.8.4 For PPB us 1.9 1.9.1 1.9.2 1.9.3 For PPB us 1.9.3 For PPB us 1.9.1 1.9.2 1.9.3 For PPB us 1.9.1 1.9.1 1.9.2 1.9.3 For PPB us 1.9.1 1.9.2 1.9.3 For PPB us 1.9.3 For PPB us 1.9.3 For PPB us 1.9.3 For PPB us 1.9.3 For PPB us 1.10	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of administration (use current list of standard term Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard term se only Packing/pack size of the product: se only Visual description of the product se only Proposed shelf life (in months): Proposed shelf life (after reconstitution or dilution): Proposed shelf life (after first opening container): Proposed storage conditions: Proposed storage conditions after first opening: se only Pharmacotherapeutic group and ATC Code Pharmacotherapeutic group: ATC Code: If no ATC code has been assigned, please indicate if an asse only Legal category	nistration of the product erms - European Pharmacopoeia) (Add as many rows as necessary) (Add as many rows as necessary) (Please use current ATC code) application for ATC code has been made:
1.4 For PPB us 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7 For PPB us 1.8.1 1.8.2 1.8.3 1.8.4 For PPB us 1.9 1.9.1 1.9.2 1.9.3 For PPB us	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of administration (use current list of standard term Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard term se only Packing/pack size of the product: se only Visual description of the product se only Proposed shelf life (in months): Proposed shelf life (after reconstitution or dilution): Proposed shelf life (after first opening container): Proposed storage conditions: Proposed storage conditions after first opening: se only Pharmacotherapeutic group and ATC Code Pharmacotherapeutic group: ATC Code: If no ATC code has been assigned, please indicate if an asse only Legal category Proposed dispensing category/classification: Product is an asse	istration of the product erms - European Pharmacopoeia) (Add as many rows as necessary) (Add as many rows as necessary) (Please use current ATC code) application for ATC code has been made:
1.4 For PPB us 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7 For PPB us 1.8.1 1.8.2 1.8.3 1.8.4 For PPB us 1.9 1.9.1 1.9.2 1.9.3 For PPB us 1.10 1.10.1	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard test only Packing/pack size of the product: se only Packing/pack size of the product: se only Visual description of the product se only Proposed shelf life (in months): Proposed shelf life (after reconstitution or dilution): Proposed shelf life (after first opening container): Proposed storage conditions: Proposed storage conditions after first opening: se only Pharmacotherapeutic group and ATC Code Pharmacotherapeutic group: ATC Code: If no ATC code has been assigned, please indicate if an asse only Legal category Proposed dispensing category/classification: Product is sprescription	inistration of the product erms - European Pharmacopoeia) (Add as many rows as necessary) (Add as many rows as necessary) (Please use current ATC code) application for ATC code has been made:
1.4 For PPB us 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7 For PPB us 1.8.1 1.8.2 1.8.3 1.8.4 For PPB us 1.9 1.9.1 1.9.2 1.9.3 For PPB us 1.9.3 For PPB us 1.9.1 1.9.2 1.9.3 For PPB us 1.9.1 1.9.1 1.9.2 1.9.3 For PPB us 1.9.1 1.9.2 1.9.3 For PPB us 1.9.3 For PPB us 1.9.3 For PPB us 1.9.3 For PPB us 1.9.3 For PPB us 1.10	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of administration (use current list of standard term Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard term se only Packing/pack size of the product: se only Visual description of the product se only Proposed shelf life (in months): Proposed shelf life (after reconstitution or dilution): Proposed shelf life (after first opening container): Proposed storage conditions: Proposed storage conditions after first opening: se only Pharmacotherapeutic group and ATC Code Pharmacotherapeutic group: ATC Code: If no ATC code has been assigned, please indicate if an asse only Legal category Proposed dispensing category/classification: Product is an asse	istration of the product prms - European Pharmacopoeia) (Add as many rows as necessary) (Add as many rows as necessary) (Please use current ATC code) application for ATC code has been made: (Please delet which does not apply) Drug Substance or Prescription Only Medicine, POM
1.4 For PPB us 1.5.1 1.5.2 For PPB us 1.6 For PPB us 1.7 For PPB us 1.8.1 1.8.2 1.8.3 1.8.4 For PPB us 1.9 1.9.1 1.9.2 1.9.3 For PPB us 1.10 1.10.1	Strength of Active Pharmaceutical Ingredient (A se only Pharmaceutical Dosage form and route of admin Pharmaceutical Dosage form of the product: Route(s) of administration (use current list of standard test only Packing/pack size of the product: se only Packing/pack size of the product: se only Visual description of the product se only Proposed shelf life (in months): Proposed shelf life (after reconstitution or dilution): Proposed shelf life (after first opening container): Proposed storage conditions: Proposed storage conditions after first opening: se only Pharmacotherapeutic group and ATC Code Pharmacotherapeutic group: ATC Code: If no ATC code has been assigned, please indicate if an asse only Legal category Proposed dispensing category/classification: Product is sprescription	nistration of the product prms - European Pharmacopoeia) (Add as many rows as necessary) (Add as many rows as necessary) (Please use current ATC code) application for ATC code has been made:

	pharmacies (if applicable) or Pharmacies only (<i>Please delete which does not apply</i>)				
For PPB u					
1.11	Country of origin or country of release:				
For PPB u	se only				
1.12		the country of origin and other countries. (Attach certificate of			
1.12		t regulatory authority) If not registered, state reasons			
Author	rised	Withdrawn (by applicant after authorisation)			
Country:		Country:			
	Date of authorisation (dd-mm-yyyy):Date of withdrawal (dd-mm-yyyy):				
Proprietar		Proprietary name:			
Authorisa	tion number:	Reason for withdrawal:			
	_				
Refuse	ed	Suspended/revoked (by competent authority)			
Country:		Country:			
	fusal (dd-mm-yyyy):	date of suspension/revocation (dd-mm-yyyy):			
Reason to	r Refusal:	Reason for suspension/revocation:			
For PPB u	as orth	Proprietary name:			
<i>For PPB и</i> 1.13	Pre-registration analysis of the produ				
1.13	1 10-10gistration analysis of the prout				
		nized WHO Prequalified Quality Control Laboratory in Kenya and within			
	the Region)				
For PPB u					
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),			
1.1.1.1	including the final product release if diffe				
Name:					
Company	name:				
Address:					
Country:					
Telephone	2:				
Telefax:					
E-Mail:					
If the man	nufacturer is different to 1.1 above, explain th	e 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	2:				
Telefax:					
E-Mail: <i>For PPB u</i>	se only				
1.15) status of the manufacturer (s) of the FPP			
1.15	Good Manufacturing Practice (GMP) status of the manufacturer (s) of the FFF			
For PPB u					
1.16	Name and complete address of the Lo	ocal Technical Representative of Manufacturer			
Name:					
Company	name.				
Address:	name.				
Country:					
Telephone					
Telefax:					
E-Mail:					
	al Technical Representative is different to 1.1	l above, explain and provide evidence for the relationship:			
For PPB u					
1.17	Summary Product Characteristics (S	PC)			
For PPB u	se only				
-	•				
1.18 Bat	ch number(s) of the FPPs used in	(Add as many rows as necessary)			

	ioequivalence studies								
Stability s	tudies								
Validation/production scale batches									
Comment	s [e.g., batch size, explan	ation of 1	NA (not a	pplicable) a	answers]		•		
Compositi	ion of clinical, primary st	ability a	nd validat	ion/product	ion FPP ba	atches (kg)			
Ingredients			stration	Bioequivalence <batch number=""></batch>		Primary stability <batch number=""></batch>		Production <batch number=""></batch>	
ingreatent		Mg %*		Kg	%*	Kg %*		kg %*	
Core table	et / capsule contents / inje	0		Ŭ		0		6	
API 1	t / eupsuie contents / inje		Juspension			/ chunge wi			
API 2									
API 3									
	d / delete as many rows								
as necesso									
Excipient									
Excipient									
Excipient									
	d / delete as many rows								
as necesso	-								
Subtotal 1	V								
	vater/other solvent(s)								
	/ capsule shell / printing	int (Dlac	nga dalata	/ change w	hiah daar 1	ot apply)			
		IIIK (Pieu	ise delele	/ change wi	nich does i	ioi appiy)			
mixture**	y film-coating								
	delete as many rows as								
necessary	uelele as many rows as								
Subtotal 2									
Grand tota									
	vater/other solvent(s)								
	ce of the composition or	iustified		The comp	ositions of	the bioequi	ivalence, sta	bility and vali	dation batches
difference	-	Justinea							change which
uniterence				does not a		terenees ure	Justinea. (I	icuse aciere /	enange which
* Each ing	gredient is expressed as a	percenta	ge of the						
	mponents ()					l in the com	pendia		
For PPB u							<u>P</u>		
	OVERAL	L OUER	RIES ANI	DRECOM	MENDAT				
						IONS FOR	K THIS MU	JUULE	
					MENDAI	<u>TONS FOR</u>	<u>x THIS MC</u>	<u>JDULE</u>	
				DRECOM	MENDAI	<u>TONS FOR</u>	<u>x 1118 M(</u>	DULE	
MODI	U F 2. CHFMIC								
MODU	ULE 2: CHEMIC	,	HARM	IACEU	TICAL	, NON-(CLINIC		CLINICAL
MODU	ILE 2: CHEMIC	,	HARM	IACEU	TICAL		CLINIC		CLINICAL
		OV	HARN ERVI	IACEU EWS Al	TICAL ND SUI	., NON-(MMARI	CLINIC IES	CAL AND	CLINICAL
2.1	OVERALL TABL	OV	HARN ERVI	IACEU EWS Al	TICAL ND SUI	., NON-(MMARI	CLINIC IES	CAL AND	CLINICAL
2.1 2.2	OVERALL TABL	OV E OF C	HARN ERVI CONTE	IACEU EWS AI NTS OF	TICAL ND SUI	., NON-(MMARI	CLINIC IES	CAL AND	CLINICAL
2.1	OVERALL TABL	OV E OF C	HARN ERVI CONTE	IACEU EWS AI NTS OF	TICAL ND SUI	., NON-(MMARI	CLINIC IES	CAL AND	CLINICAL
2.1 2.2	OVERALL TABL INTRODUCTION OVERALL QUAL	OV E OF C	HARN ERVI CONTE	IACEU EWS AI NTS OF	TICAL ND SUI	., NON-(MMARI	CLINIC IES	CAL AND	CLINICAL
2.1 2.2 2.3 For PPB us	OVERALL TABL INTRODUCTION OVERALL QUAL e only	OV E OF C ITY SI	HARN ERVII CONTE	IACEU EWS Al NTS OF RY	TICAL ND SUI MODUI	, NON- MMARI LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	CLINICAL
2.1 2.2 2.3 <i>For PPB us</i> 2.3.1	OVERALL TABL INTRODUCTION OVERALL QUAL e only OVERVIEW OF AC	OV E OF C ITY SU CTIVE I	HARN ERVI CONTE	IACEU EWS Al NTS OF RY	TICAL ND SUI MODUI	, NON-0 MMARI LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	CLINICAL
2.1 2.2 2.3 <i>For PPB us</i> 2.3.1 2.3.1.1	OVERALL TABL INTRODUCTION OVERALL QUAL e only OVERVIEW OF AC General Information of	OV E OF C ITY SU CTIVE I	HARN ERVI CONTE	IACEU EWS Al NTS OF RY	TICAL ND SUI MODUI	, NON-0 MMARI LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	CLINICAL
2.1 2.2 2.3 <i>For PPB us</i> 2.3.1 2.3.1.1 2.2.1.1.1	OVERALL TABL INTRODUCTION OVERALL QUAL e only OVERVIEW OF AC General Information of Nomenclature	OV E OF C ITY SU CTIVE I	HARN ERVI CONTE	IACEU EWS Al NTS OF RY	TICAL ND SUI MODUI	, NON-0 MMARI LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	CLINICAL
2.1 2.2 2.3 <i>For PPB us</i> 2.3.1 2.3.1.1 2.2.1.1.1 <i>For PPB us</i>	OVERALL TABL INTRODUCTION OVERALL QUAL e only OVERVIEW OF AC General Information of Nomenclature e only	OV E OF C ITY SU CTIVE I	HARN ERVI CONTE	IACEU EWS Al NTS OF RY	TICAL ND SUI MODUI	, NON-0 MMARI LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	
2.1 2.2 2.3 <i>For PPB us</i> 2.3.1 2.3.1.1 2.2.1.1.1 <i>For PPB us</i> 2.2.1.1.2	OVERALL TABL INTRODUCTION OVERALL QUAL e only OVERVIEW OF AC General Information of Nomenclature e only Structure	OV E OF C ITY SU CTIVE I	HARN ERVI CONTE	IACEU EWS Al NTS OF RY	TICAL ND SUI MODUI	, NON-0 MMARI LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	
2.1 2.2 2.3 <i>For PPB us</i> 2.3.1 2.3.1.1 2.2.1.1.1 <i>For PPB us</i> 2.2.1.1.2 <i>For PPB us</i>	OVERALL TABL INTRODUCTION OVERALL QUAL e only OVERVIEW OF AC General Information of Nomenclature e only Structure e only	OV E OF C ITY SU CTIVE I	HARN ERVI CONTE	IACEU EWS Al NTS OF RY	TICAL ND SUI MODUI	, NON-(MMAR) LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	
2.1 2.2 2.3 For PPB us 2.3.1 2.3.1.1 2.2.1.1.1 For PPB us 2.2.1.1.2 For PPB us 2.2.1.1.3	OVERALL TABL INTRODUCTION OVERALL QUAL e only OVERVIEW OF AC General Information of t Nomenclature e only Structure e only General Properties of th	OV E OF C ITY SU CTIVE I	HARN ERVI CONTE	IACEU EWS Al NTS OF RY	TICAL ND SUI MODUI	, NON-(MMAR) LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	
2.1 2.2 2.3 <i>For PPB us</i> 2.3.1 2.3.1.1 2.2.1.1.1 <i>For PPB us</i> 2.2.1.1.2 <i>For PPB us</i> 2.2.1.1.3 <i>For PPB us</i>	OVERALL TABL INTRODUCTION OVERALL QUAL e only OVERVIEW OF AC General Information of t Nomenclature e only Structure e only General Properties of th e only	OV E OF C ITY SU CTIVE I the API(s)	HARN ERVI CONTE	IACEU EWS Al NTS OF RY	TICAL ND SUI MODUI	, NON-(MMAR) LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	
2.1 2.2 2.3 For PPB us 2.3.1 2.3.1.1 2.2.1.1.1 For PPB us 2.2.1.1.3 For PPB us 2.3.1.2	OVERALL TABL INTRODUCTION OVERALL QUAL e only OVERVIEW OF AC General Information of t Nomenclature e only Structure e only General Properties of th e only Manufacture of the API	OV E OF C ITY SU CTIVE I the API(s) (S)	HARM ERVII CONTE UMMA PHARM S)	IACEU EWS AI NTS OF RY ACEUTIO	TICAL ND SUI MODUI	, NON-(MMAR) LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	
2.1 2.2 2.3 For PPB us 2.3.1 2.3.1.1 2.2.1.1.1 For PPB us 2.2.1.1.2 For PPB us 2.2.1.1.3 For PPB us 2.3.1.2 2.3.1.2	OVERALL TABL INTRODUCTION OVERALL QUAL e only OVERVIEW OF AC General Information of to Nomenclature e only Structure e only General Properties of th e only Manufacture of the API Name and address of AI	OV E OF C ITY SU CTIVE I the API(s) (S)	HARM ERVII CONTE UMMA PHARM S)	IACEU EWS AI NTS OF RY ACEUTIO	TICAL ND SUI MODUI	, NON-(MMAR) LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	
2.1 2.2 2.3 For PPB us 2.3.1 2.3.1.1 2.2.1.1.1 For PPB us 2.2.1.1.2 For PPB us 2.3.1.2 2.3.1.2 2.3.1.2.1 For PPB us	OVERALL TABL INTRODUCTION OVERALL QUAL e only OVERVIEW OF AC General Information of Nomenclature e only Structure e only General Properties of th e only Manufacture of the API Name and address of Al e only	OV E OF C ITY SU CTIVE I the API(S) e API(s) (S) PI(s) Mar	HARM ERVII CONTE UMMA PHARM 5)	IACEU EWS AI NTS OF RY ACEUTIO	TICAL ND SUI MODUI	, NON-(MMAR) LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	
2.1 2.2 2.3 For PPB us 2.3.1 2.3.1.1 2.2.1.1.1 For PPB us 2.2.1.1.2 For PPB us 2.3.1.2 2.3.1.2 2.3.1.2.1 For PPB us	OVERALL TABL INTRODUCTION OVERALL QUAL e only OVERVIEW OF AC General Information of to Nomenclature e only Structure e only General Properties of th e only Manufacture of the API Name and address of AI	OV E OF C ITY SU CTIVE I the API(S) e API(s) (S) PI(s) Mar	HARM ERVII CONTE UMMA PHARM 5)	IACEU EWS AI NTS OF RY ACEUTIO	TICAL ND SUI MODUI	, NON-(MMAR) LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	
2.1 2.2 2.3 For PPB us 2.3.1 2.3.1.1 2.2.1.1.1 For PPB us 2.2.1.1.3 For PPB us 2.3.1.2 2.3.1.2.1 For PPB us 2.3.1.2.2	OVERALL TABLE INTRODUCTION OVERALL QUAL e only OVERVIEW OF AC General Information of 1 Nomenclature e only Structure e only General Properties of th e only Manufacture of the API Name and address of AI e only Description of Manufac	OV E OF C ITY SU CTIVE I the API(s) e API(s) Mar turing Pr	HARM ERVII CONTE UMMA PHARM S)	IACEU EWS AI NTS OF RY ACEUTIO	TICAL ND SUI MODUI	., NON-0 MMARI LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	
2.1 2.2 2.3 For PPB us 2.3.1 2.3.1.1 2.2.1.1.1 For PPB us 2.2.1.1.2 For PPB us 2.3.1.2 2.3.1.2 2.3.1.2.1 For PPB us	OVERALL TABL INTRODUCTION OVERALL QUAL e only OVERVIEW OF AC General Information of Nomenclature e only Structure e only General Properties of th e only Manufacture of the API Name and address of Al e only	OV E OF C ITY SU CTIVE I the API(s) e API(s) Mar turing Pr	HARM ERVII CONTE UMMA PHARM S)	IACEU EWS AI NTS OF RY ACEUTIO	TICAL ND SUI MODUI	., NON-0 MMARI LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	
2.1 2.2 2.3 For PPB us 2.3.1 2.3.1.1 2.2.1.1.1 For PPB us 2.2.1.1.3 For PPB us 2.3.1.2 2.3.1.2.1 For PPB us 2.3.1.2.2	OVERALL TABLE INTRODUCTION OVERALL QUAL e only OVERVIEW OF AC General Information of 1 Nomenclature e only Structure e only General Properties of th e only Manufacture of the API Name and address of AI e only Description of Manufac	OV E OF C ITY SU CTIVE I the API(s) e API(s) Mar turing Pr	HARM ERVII CONTE UMMA PHARM S)	IACEU EWS AI NTS OF RY ACEUTIO	TICAL ND SUI MODUI	., NON-0 MMARI LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	
2.1 2.2 2.3 For PPB us 2.3.1 2.3.1.1 2.2.1.1.1 For PPB us 2.2.1.1.3 For PPB us 2.3.1.2 2.3.1.2.1 For PPB us 2.3.1.2.2	OVERALL TABL INTRODUCTION OVERALL QUAL e only OVERVIEW OF AC General Information of t Nomenclature e only Structure e only General Properties of th e only Manufacture of the API Name and address of AI e only Description of Manufac	OV E OF C ITY SU CTIVE I the API(S) e API(s) PI(s) Mar turing Pr d in Mar	HARM ERVII CONTE UMMA PHARM S)	IACEU EWS AI NTS OF RY ACEUTIO	TICAL ND SUI MODUI	., NON-0 MMARI LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	
2.1 2.2 2.3 For PPB us 2.3.1 2.3.1.1 2.2.1.1.1 For PPB us 2.2.1.1.2 For PPB us 2.3.1.2 2.3.1.2.1 For PPB us 2.3.1.2.2 2.3.1.2.2 2.3.1.2.3	OVERALL TABLE INTRODUCTION OVERALL QUAL e only OVERVIEW OF AC General Information of 1 Nomenclature e only Structure e only General Properties of th e only Manufacture of the API Name and address of AI e only Description of Manufac	OV E OF C ITY SU CTIVE I the API(S) e API(s) PI(s) Mar turing Pr d in Mar	HARM ERVII CONTE UMMA PHARM S)	IACEU EWS AI NTS OF RY ACEUTIO	TICAL ND SUI MODUI	., NON-0 MMARI LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	
2.1 2.2 2.3 For PPB us 2.3.1 2.3.1.1 2.2.1.1.1 For PPB us 2.2.1.1.2 For PPB us 2.3.1.2 2.3.1.2.1 For PPB us 2.3.1.2.2 2.3.1.2.2 2.3.1.2.3 2.3.1.2.4	OVERALL TABL INTRODUCTION OVERALL QUAL e only OVERVIEW OF AC General Information of to Nomenclature e only Structure e only Structure e only General Properties of th e only Manufacture of the API Name and address of AI e only Description of Manufac Control of Materials use	OV E OF C ITY SU CTIVE I the API(S) e API(S) (S) PI(S) Mar turing Pr d in Mar	HARM ERVII CONTE UMMA PHARM S)	IACEU EWS AI NTS OF RY ACEUTIO	TICAL ND SUI MODUI	., NON-0 MMARI LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	
2.1 2.2 2.3 For PPB us 2.3.1 2.3.1.1 2.2.1.1.1 For PPB us 2.2.1.1.2 For PPB us 2.3.1.2 2.3.1.2.1 For PPB us 2.3.1.2.2 2.3.1.2.2 2.3.1.2.3 2.3.1.2.4	OVERALL TABL INTRODUCTION OVERALL QUAL e only OVERVIEW OF AC General Information of t Nomenclature e only Structure e only General Properties of th e only Manufacture of the API Name and address of AI e only Description of Manufac	OV E OF C ITY SU CTIVE I the API(S) e API(S) (S) PI(S) Mar turing Pr d in Mar	HARM ERVII CONTE UMMA PHARM S)	IACEU EWS AI NTS OF RY ACEUTIO	TICAL ND SUI MODUI	., NON-0 MMARI LES 2, 3, 4	CLINIC IES 4, AND 5	CAL AND	

0.0.1.0	
2.3.1.3	Characterization of the API(S)
2.2.1.1	
2.3.1.4	Control of the API(S))
2215	
2.3.1.5	Reference Standards or Materials of the API(S)
2216	
2.3.1.6	Container Closure System of the API(S)
2.3.1.7	Stability of the API(S)
2.3.1.7 For PPB us	
rorrbus	se 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 us	se 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
1 / /1 1 /	
2.4.1.3	Clinical overview
	Clinical overview Clinical summary
2.4.1.3 2.4.1.3	Clinical overview Clinical summary
2.4.1.3 2.4.1.3 For PPB us	Clinical overview Clinical summary se only
2.4.1.3 2.4.1.3 <i>For PPB us</i> 2.4.2	Clinical overview Clinical summary se only GENERIC DRUG APPLICATIONS
2.4.1.3 2.4.1.3 <i>For PPB us</i> 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2	Clinical overview Clinical summary se only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies
2.4.1.3 2.4.1.3 <i>For PPB us</i> 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3	Clinical overview Clinical summary se only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods
2.4.1.3 2.4.1.3 <i>For PPB us</i> 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4	Clinical overview Clinical summary se only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of In Vitro Dissolution Tests complementary to Bioequivalence Studies
2.4.1.3 2.4.1.3 <i>For PPB us</i> 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 2.4.2.1.4	Clinical overview Clinical summary se only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests in support of a Biowaiver
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 2.4.2.1.4 For PPB us	Clinical overview Clinical summary se only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests in support of a Biowaiver se only
2.4.1.3 2.4.1.3 <i>For PPB us</i> 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 2.4.2.1.4	Clinical overview Clinical summary see only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests in support of a Biowaiver see only see only
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 2.4.2.1.4 For PPB us	Clinical overview Clinical summary se only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests in support of a Biowaiver se only
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 2.4.2.1.4 For PPB us	Clinical overview Clinical summary see only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests in support of a Biowaiver see only see only
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 2.4.2.1.4 For PPB us	Clinical overview Clinical summary see only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests in support of a Biowaiver see only see only See ONLY Clinical Overview and Summary of <i>In Vitro</i> Dissolution Tests in support of a Biowaiver See ONLY OVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULE
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 2.4.2.1.4 For PPB us For PPB us	Clinical overview Clinical summary GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests in support of a Biowaiver see only OVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULE MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 2.4.2.1.4 For PPB us For PPB us 3.1	Clinical overview Clinical summary see only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests in support of a Biowaiver see only see only Methods Studies
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 2.4.2.1.4 For PPB us For PPB us	Clinical overview Clinical summary GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests in support of a Biowaiver see only OVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULE MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 2.4.2.1.4 For PPB us For PPB us 3.1	Clinical overview Clinical summary se only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests in support of a Biowaiver se only se only MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION TABLE OF CONTENTS OF MODULE 3
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 2.4.2.1.4 For PPB us For PPB us 500 PPB us 3.1 3.2 3.2.1	Clinical overview Clinical summary See only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests in support of a Biowaiver See only See only MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION TABLE OF CONTENTS OF MODULE 3 BODY OF DATA PARTICULARS OF ACTIVE PHARMACEUTICAL INGREDIENT(s) [API(s)]
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 2.4.2.1.4 For PPB us For PPB us For PPB us 3.1 3.2 3.2.1.1	Clinical overview Clinical summary se only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of In Vitro Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of In Vitro Dissolution Tests in support of a Biowaiver se only Se only OVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULE MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION TABLE OF CONTENTS OF MODULE 3 BODY OF DATA PARTICULARS OF ACTIVE PHARMACEUTICAL INGREDIENT(s) [API(s)] General Information of the API(S)
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 For PPB us For PPB us For PPB us 3.1 3.2 3.2.1 3.2.1.1 3.2.1.2	Clinical overview Clinical summary se only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of In Vitro Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of In Vitro Dissolution Tests in support of a Biowaiver se only MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION TABLE OF CONTENTS OF MODULE 3 BODY OF DATA PARTICULARS OF ACTIVE PHARMACEUTICAL INGREDIENT(s) [API(s)] General Information of the API(S) Manufacture of the API(S)
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 2.4.2.1.4 For PPB us For PPB us For PPB us 3.1 3.2 3.2.1.1 3.2.1.2 3.2.1.3	Clinical overview Clinical summary se only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests in support of a Biowaiver se only See only OVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULE MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION TABLE OF CONTENTS OF MODULE 3 BODY OF DATA PARTICULARS OF ACTIVE PHARMACEUTICAL INGREDIENT(s) [API(s)] General Information of the API(S) Manufacture of the API(S)
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 2.4.2.1.4 For PPB us For PPB us For PPB us 5.1 3.2.1 3.2.1.1 3.2.1.2 3.2.1.4	Clinical overview Clinical summary se only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests in support of a Biowaiver se only CVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULE MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION TABLE OF CONTENTS OF MODULE 3 BODY OF DATA PARTICULARS OF ACTIVE PHARMACEUTICAL INGREDIENT(s) [API(s)] General Information of the API(S) Characterization of the API(S) Control of the API(S)) Control of the API(S)
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 2.4.2.1.4 For PPB us For PPB us For PPB us 3.1 3.2 3.2.1.1 3.2.1.2 3.2.1.3 3.2.1.4 3.2.1.5	Clinical overview Clinical summary se only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests in support of a Biowaiver se only se only OVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULE MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION TABLE OF CONTENTS OF MODULE 3 BODY OF DATA PARTICULARS OF ACTIVE PHARMACEUTICAL INGREDIENT(s) [API(s)] General Information of the API(S) Manufacture of the API(S) Control of the API(S) Reference Standards or Materials of the API(S)
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 2.4.2.1.4 For PPB us For PPB us For PPB us 3.1 3.2 3.2.1.1 3.2.1.2 3.2.1.4 3.2.1.5 3.2.1.6	Clinical overview Clinical summary se only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests in support of a Biowaiver se only OVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULE MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION TABLE OF CONTENTS OF MODULE 3 BODY OF DATA PARTICULARS OF ACTIVE PHARMACEUTICAL INGREDIENT(s) [API(s)] General Information of the API(S) Characterization of the API(S) Control of the API(S) Container Closure System of the API(S) Container Closure System of the API(S)
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 For PPB us For PPB us For PPB us 500 PPB us 501 PPB us 502 PPB us 503 PPB us 503 PPB us 503 PPB us 503 PPB us 503 PPB us 504 PPB us 505 PPB us	Clinical overview Clinical summary se only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of In Vitro Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of In Vitro Dissolution Tests in support of a Biowaiver se only MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION TABLE OF CONTENTS OF MODULE 3 BODY OF DATA PARTICULARS OF ACTIVE PHARMACEUTICAL INGREDIENT(s) [API(s)] General Information of the API(S) Contrainer Closure System of the API(S) Stability of the API(S)
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 For PPB us For PPB us For PPB us 500 PPB us 501 PPB us 502 PPB us 503 PPB us 503 PPB us 503 PPB us 504 PPB us 504 PPB us 505 PPB us	Clinical summary ee only GENERIC DRUG APPLICATIONS Clinical summary Product Development Rationale Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests in support of a Biowaiver see only See only CVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULE MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION TABLE OF CONTENTS OF MODULE 3 BODY OF DATA PARTICULARS OF ACTIVE PHARMACEUTICAL INGREDIENT(s) [API(s)] General Information of the API(S) Characterization of the API(S) Control of the API(S) Control of the API(S) Container Closure System of the API(S) FARTICULARS OF FINISHED PHARMACEUTICAL PRODUCT(S) [FPP(S)]
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 For PPB us For PPB us For PPB us 500 PPB us 501 PPB us 502 PPB us 503 PPB us 503 PPB us 503 PPB us 504 PPB us 505 PPB us	Clinical summary ce only GENERIC DRUG APPLICATIONS Clinical summary re only GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview and Summary of Disolution Tests complementary to Bioequivalence Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of In Vitro Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of In Vitro Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of In Vitro Dissolution Tests in support of a Biowaiver se only See only OVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULE MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION TABLE OF CONTENTS OF MODULE 3 BODY OF DATA PARTICULARS OF ACTIVE PHARMACEUTICAL INGREDIENT(s) [API(s)] General Information of the API(S) Container Closure System of the API(S) Container Closure System of the API(S) Stability of the API(S) PARTICULARS OF FINISHED PHARMACEUTICAL PRODUCT(S) [FPP(S)] Description and Composition of the FPP(S)
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 For PPB us For PPB us For PPB us 507 PPB us	Clinical summary see only GENERIC DRUG APPLICATIONS Clinical summary Product Development Rationale Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests in support of a Biowaiver see only OVERALL OUERIES AND RECOMMENDATIONS FOR THIS MODULE MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION TABLE OF CONTENTS OF MODULE 3 BODY OF DATA PARTICULARS OF ACTIVE PHARMACEUTICAL INGREDIENT(s) [API(s)] General Information of the API(S) Characterization of the API(S) Control of the API(S) Control of the API(S) Reference Standards or Materials of the API(S) Container Closure System of the API(S) FARTICULARS OF FINISHED PHARMACEUTICAL PRODUCT(S) [FPP(S)] Description and Composition of the FPP(S) Pharmaceutical Development of the FPP(S)
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 2.4.2.1.4 2.4.2.1.4 For PPB us For PPB us For PPB us 507 PPB us 50	Clinical summary Clinical summary Clinical summary GENERIC DRUG APPLICATIONS Clinical Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies Summary of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of In Vitro Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of In Vitro Dissolution Tests in support of a Biowaiver se only OVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULE MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION TABLE OF CONTENTS OF MODULE 3 BODY OF DATA PARTICULARS OF ACTIVE PHARMACEUTICAL INGREDIENT(s) [API(s)] General Information of the API(S) Characterization of the API(S) Control of the API(S) Reference Standards or Materials of the API(S) Stability of the API(S) PARTICULARS OF FINISHED PHARMACEUTICAL PRODUCT(S) [FPP(S)] Description and Composition of the FPP(S) Pharmaceutical Development of the FPP(S)
2.4.1.3 2.4.1.3 For PPB us 2.4.2 2.4.2.1 2.4.2.1.1 2.4.2.1.2 2.4.2.1.3 2.4.2.1.4 For PPB us For PPB us For PPB us 507 PPB us	Clinical summary see only GENERIC DRUG APPLICATIONS Clinical summary Product Development Rationale Overview and Summary Product Development Rationale Overview of Biopharmaceutics Studies and Associated Analytical Methods Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests complementary to Bioequivalence Studies Overview and Summary of <i>In Vitro</i> Dissolution Tests in support of a Biowaiver see only OVERALL OUERIES AND RECOMMENDATIONS FOR THIS MODULE MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION TABLE OF CONTENTS OF MODULE 3 BODY OF DATA PARTICULARS OF ACTIVE PHARMACEUTICAL INGREDIENT(s) [API(s)] General Information of the API(S) Characterization of the API(S) Control of the API(S) Control of the API(S) Reference Standards or Materials of the API(S) Container Closure System of the API(S) FARTICULARS OF FINISHED PHARMACEUTICAL PRODUCT(S) [FPP(S)] Description and Composition of the FPP(S) Pharmaceutical Development 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
N	IODULE 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
51	
5.1	NEW CHEMICAL ENTITIES ONLY
5.1.1	Table of Contents of Module 5 The base of the first
5.1.2	Tabular Listing of All Clinical Studies
5.1.3	Clinical Study Reports 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.
	 I also consent to the processing of information provided by the Pharmacy and Poisons Board.
	Name:
	Position in the company:
	Signature:
	Date:
	Official stamp: