PFSCM

Partnership for Supply Chain Management

QUESTIONNAIRE

FOR

Finished Pharmaceutical Products

Please complete the fields in the questionnaire as required. Press TAB to move to next field

Request for Proposal Number:	
Dated:	

IMPORTANT NOTE

All certificates and approval documents must be valid (Expired documents will not be considered)

SECTION 1: PREAMBLE

1) CONTACT DETAILS

Name of company submitting BID:	
Physical address:	
Postal address:	

City:		Country:	
Telephone:		FAX:	
E-mail:		Website	

Link with the product

☐	Marketing license holder	☐	Distributor/wholesaler	☐	Manufacturer
☐	Other (Please specify)				

2) CONTACT DETAILS FOR RESPONSIBLE PERSONS

Subject	Name of contact person:	Telephone and cell phone:	Email:
Technical specifications & product quality		Tel: Cell:	
Regulatory & patent			
Commercial/business			
General enquiries			

3) NOTE FOR THE APPLICANT

The information in this questionnaire may be shared confidentially amongst WHO, USAID and The Global Fund for procurement purposes. If you have any objection, please indicate in the section provided at the end of this questionnaire. *Please fill out one form separately for each pharmaceutical product.*

USAID	Most recent submission date:
Global Fund	Most recent submission date:
WHO	Most recent submission date:

SECTION 2:
FINISHED DRUG PRODUCT

4) IDENTIFICATION

☐	**Single Pharmaceutical entity**

Approved Non-Proprietary Name of product (*Pharmaceutical form, including route(s) of administration, Active ingredient, amount in dosage form or amount per unit):

Brand/trade name (if any):	

☐	**Fixed Dose Combination (FDC)**			
Content		Active Pharmaceutical Ingredient	Amount in dosage form or per unit	*Pharmaceutical form, including route(s) of administration
Active Ingredient 1				
Active Ingredient 2				
Active Ingredient 3				

Inactive Ingredients (excipients) of medical/pharmaceutical relevance, amount in dosage form or per dosage unit (e.g. Contains Alcohol 10%):

Brand/trade name (if any):	

☐	Co-pack			
Content		Active Pharmaceutical Ingredient	Amount in dosage form or per unit	*Pharmaceutical form, including route(s) of administration
Content of Item 1 in co-pack				
Content of Item 2 in co-pack				

Inactive Ingredients (excipients) of medical/pharmaceutical relevance, amount in dosage form or per dosage unit (e.g. Contains Alcohol 10%):

Brand/trade name (if any):	

Pharmaceutical forms (Use all that apply from the selection below)

☐	**Tablets**
☐	Scored
☐	Solid
☐	Dispersible
☐	Chewable
☐	Buffered (Specify buffers)_____
☐	Film coated
☐	Enteric coated
☐	Sublingual
☐	Bilayered
☐	Delayed release
☐	Controlled release

☐	**Oral powder**
☐	**Injection**
☐	Solution for injection
☐	Powder for injection
☐	Oily injection

☐	**Capsule**
☐	Enteric coated
☐	Delayed release
☐	Controlled release
☐	Sublingual
☐	Other (Specify) _____
☐	**Oral liquids**
☐	Solution
☐	Suspension
☐	Powder for solution
☐	Powder for suspension

5) PACKAGING

Number of dosage units per unit packs:	
Numbers of unit packs per secondary pack (Multiples of unit packs):	

Language(s) of label, packaging and pack insert

☐	English	☐	French	☐	Other (Specify):	

Attach package insert

Description and composition of primary packaging materials:	
Description and composition of secondary packaging materials:	

Attach logistical information (Volume of unit pack in m^3, Weight of unit pack in Kg, Number of unit packs per shipper carton, Length/Width/Height of shipper carton and Weight of shipper carton in Kg)

6) MONOGRAPH SPECIFICATIONS (Tick and answer as applicable)

		VOLUME	EDITION	YEAR
☐	BP			
☐	USP Edition			
☐	Ph.Int			
☐	Other: specify			

☐	In house. Year documented:	Explain:
Indicate any additional specifications to those in the pharmacopoeia (e.g. dissolution, syringeability):		

Attach a copy of the Internal Finished Product Specifications.

Attach a copy of Certificate of Analysis for the last 3 batches released.

Manufacturing methods for each standard batch size is validated		
☐	**Yes**	
☐	**No**	**Explain:**
List the validated batch size quantities:		

7) STABILITY OF FINISHED PRODUCT

Stability testing data available		
☐	Yes	
☐	No	Explain
Attach copies of study results, including graphical/pictorial interpretations where applicable		
If yes, indicate type and conditions of testing:		

Satisfactory accelerated testing at (state the months):
Type and material of packaging:
Conditions (Temperature/Relative Humidity/Duration):
Number of batches:
Batch sizes:
Date of beginning of the study:
Date of end of study:
Satisfactory real time testing at (state the months):
Type and material of container:
Conditions (Temperature/Relative Humidity/Duration):
Number of batches:
Batch sizes:
Date of beginning of the study:
Date of end of study (if applicable):

Attach copies of testing protocols

Stability testing has been done on a product of the same formula, manufactured on the same site and packed in the same packaging material as the product that will be supplied			
☐	Yes		
☐	No		
If no describe differences:			
Stability testing done on (tick all that applies)			
☐	Pilot batch (Not less than 10% of full production batch)		
☐	Production batch		
Stability studies for this product are ongoing.			
☐	Yes	☐	No
Attach status report of any ongoing stability studies			

8) SHELF LIFE AND STORAGE CONDITIONS

Guaranteed shelf life (based on stability studies):	
Maximum possible shelf life:	
Shelf life as it appears on the packaging:	
Shelf life after primary package is opened or product is reconstituted:	

Product suitable for use in:

☐	Zone I
☐	Zone II
☐	Zone III

☐	Zone IVa
☐	Zone IVb
☐	Other: Specify

Specific storage conditions for this product as they appear on the packaging and based on stability studies:	
Temperature:	
Light:	
Humidity:	
Other (Specify):	

9) SAFETY & EFFICACY AND/OR THERAPEUTIC EQUIVALENCE

FOR INNOVATOR PRODUCTS

Please attach a summary of pharmacology, toxicology and efficacy of the product

FOR GENERIC PRODUCTS: THERAPEUTIC EQUIVALENCE

1.)		**Demonstrated**
a.)	☐	**By in vivo bioequivalence studies**
		Study period (dd/mm/yyyy): from to
		Reference product
		Generic name:
		Dosage form:
		Strength:
		Brand/trade name:
		Manufacturer:
		Manufacture site:
		Batch number:
		Expiry date:
		Study protocol
		CRO Name:
		Country of study:
		Number of volunteers:
		Study design (describe in detail):
		Attach schematic representation of study design. Attach study protocol summary.

	Bio batch size:			
	Bio batch number:			
	Bio batch API(s)			
	Study conclusion:			
	Attach graphic/pictorial representation of summary study results			
b.)	by another method (please describe briefly):			
	Study conclusion:			
	Attach graphic/pictorial representation of summary study results			
c.)	by comparative in vitro dissolution tests according to conditions described in WHO BCS classification document (WHO Technical Report Series N°937 or later)			
	☐ Yes			
	☐ No (explain):	BCS class:		
	Reference product			
	Generic name:			
	Brand/trade name:			
	Manufacturer:			
	Manufacture site:			
	Batch number:			
	Expiry date:			
	Name and contact details of Laboratory performing tests: NB: Reference product must have undergone successful in vivo bioequivalence studies			
	Study results			
	F2 (similarity factor) value:		(Standard 50-100%)	
	F1 (difference factor) value:			
	Study conclusion:			
	Attach graphic/pictorial representation of summary study results			
2.)	☐ Not demonstrated			
3.)	☐ Not relevant, please explain why:			

Attach full reports of all studies done to prove therapeutic equivalence with clear study conclusions.

The product used in the therapeutic equivalence study is essentially the same as the one that will be supplied (same materials from the same suppliers, same formula, and same manufacturing method).

☐	**Yes**
☐	**No (explain what the differences are):**

Please provide (as an attachment) a flow diagram describing the manufacturing and control process of this product with relevant parameters.

10) REGULATORY STATUS

Certificate of Pharmaceutical Product No.:		Valid until:
CPP issued by (Name of Agency):		Country:
Attach CPP according to the WHO Certification Scheme-WHO Technical Report Series No. 863 (earlier version is not acceptable) or equivalent document		
CPP not available (state reason and attach equivalent document if any):		
☐	Not yet WHO prequalified: Date of dossier submission:	(Attach evidence)
☐	Not applied for WHO prequalification (Explain)	

11) LICENSING STATUS

Tick and fill in all fields that apply:		
☐	Product registered and currently marketed in the country of manufacture	
License no.:	Valid until:	
Issued by Agency:	Country:	

☐	Product registered for marketing in the country of manufacture but not currently marketed.	
License no.:	Valid until:	
Issued by Agency:	Country:	

☐	Product registered for export only	
License no.:	Valid until:	
Issued by Agency:	Country:	

☐	Product not registered in country of manufacture (please clarify)

Provide copies of all licenses that apply

This product is registered/licensed and currently marketed in the following countries;			
Country	License No.	Valid Until	Issuing Agency

Attach additional pages if necessary

12) SAMPLES FOR TECHNICAL EVALUATION

Product sample provided conforms in all forms to product offered as it will be supplied on
☐ Yes
☐ No (explain):
Attach a Certificate of Analysis relevant to the sample
NB: If you are not able to provide a Certificate of Analysis, please explain:
Shelf life on sample:
Storage conditions on sample:
Pack insert available Y/N:
Attach copy of label
Attach pack insert

SECTION 3: MANUFACTURER

13) IDENTIFICATION

Repeat this section for each manufacturing site relevant to this product

Name of Manufacturer:	
Physical address of manufacturing site(s) Including unit/block number:	
Postal address:	
City:	Country
Telephone:	FAX:
E-mail:	Website:

Activities of the manufacturer (Fill in all that apply)				
Activities Of Manufacturer	License No.	Valid Until	Issuing Agency	Country
Manufactures APIs (Drug substance)				
Manufactures Finished Pharmaceutical Product				
Primary Packaging				
Secondary Packaging				
Contract Manufacture				
Other (Specify)				

14) GOOD MANUFACTURING PRACTICE (GMP)

WHO GMP certificate no:		Valid until:	
Issued by: Agency:			Country:
GMP inspections carried out by (tick all that apply):			
		Date	Outcome
☐	USFDA		
☐	WHO Prequalification programme		
☐	National Regulatory Authority		
☐	Other (specify)		

Submit copy of GMP certificate for each agency ticked above

SECTION 4:
ACTIVE PHARMACEUTICAL INGREDIENT(S) (APIS)

In case more than one API or manufacturer is used, please replicate this question

15) ACTIVE PHARMACEUTICAL INGREDIENTS(s) –(APIs)

Name of API (INN if available)		
Certificate of suitability to the European Pharmacopoeia (CEP) No.:		
API Expiry date:		
API Retest date:		
The open part of the Drug Master File (DMF) is registered in (Country):		
Name of original manufacturer:		
Physical address of manufacturing site(s) including unit/block number:		
Postal address:		
City:		Country:
Telephone:	FAX:	
E-mail:	Website:	

Activities of Original API Manufacturer (*tick all that apply for each site separately*)

☐ Manufacturer of Intermediates only	
License No.:	Valid until:
Issued by Agency:	Country:

☐ Manufacturer of APIs (Drug substance)	
License No.:	Valid until:
Issued by Agency:	Country:

☐ Repacking and/or reprocessing of API	
License No.:	Valid until:
Issued by Agency:	Country:

☐ Agent/broker for APIs		
License No.:	Valid until:	
Issued by Agency:	Country:	

☐ Manufacturer of Finished Pharmaceutical Product (drug product)	
License No.:	Valid until:
Issued by Agency:	Country:

☐ Other (specify)	
License No.:	Valid until:
Issued by Agency:	Country:

☐ GMP certificate (for API) no.:	
License No.:	Valid until:
Issued by Agency:	Country:

Attach copy of GMP certificate for API/Intermediates manufacturer

Specifications and standard test methods exist for this API
☐ Yes
☐ No

API specifications (tick as appropriate):

		Edition	Volume
☐	BP		
☐	USP		
☐	Ph. Eur.		
☐	Ph. Int.		
☐	Other (specify):		
☐	No pharmacopoeial monograph exists		
Attach a copy of the API(s) internal specifications and analytical methods			

Attach a copy of the in house finished product specifications.

Attach a copy of analytical methods for products with in house specifications or specifications other than those listed above

Attach a copy of the model certificate of analysis for batch release of API.

Attach certificate of analysis of the last 3 production batches of API from the API manufacturer.

Attach certificate of analysis of API from the finished product manufacturer.

SECTION 5:
COMMITMENT AND AUTHORIZATION

16) COMMITMENT

I (Full Name), certify that:

The product offered is identical in all aspects of manufacturing and quality to that USFDA tentatively approved Ref. , including formulation, method and site of manufacture, sources of active and excipient starting materials, quality control of the product and starting material, packaging, shelf-life and product information.

OR

The product offered is identical in all aspects to that registered and marketed in (name of country):

Explain any exceptions:

_____ _____

Signature *Date*

17) AUTHORIZATION

I, the undersigned confirm that the company has no objection to the information contained herein being shared with the agencies listed on page 1 except

I, the undersigned, certify that the information provided above is accurate, correct, complete, up to date and true at the time of submission

Full name:

Full title/position in company:

Company name:

_____ _____

Signature *Date*

Telephone number:

Email:

Company seal/stamp:

Stamp here

Annex: Checklist of attachments required

Please ensure that all documents necessary to enable objective evaluation of your product are attached. This checklist may not be exhaustive.

☐	A. Formulation of the product (complete qualitative and quantitative composition including active ingredient(s) and excipients
☐	B. Flow diagram describing the manufacturing and control processes with relevant parameters
☐	C. GMP certificate(s) of finished pharmaceutical product manufacturing site(s)
☐	D. Certificate of Pharmaceutical Product (CPP) according to the WHO Certification Scheme
☐	E. Copy of the relevant WHO Pre-qualification approval letter signed by your company
☐	F. WHO acceptance letter for product dossier review mentioning the WHO reference number assigned by WHO for this specific product
☐	G. Copy of internal finished product specifications
☐	H. Copy of the certificate of analysis for the 3 last batches released
☐	I. Validated analytical methods if specifications for finished product are in house specifications, different from BP, USP and Int Ph.
☐	J. Protocol and report for accelerated and real time stability testing
☐	K. Description and composition of primary packing materials
☐	L. Description and composition of secondary packaging materials
☐	M. Product registration licenses in country of manufacture
☐	N. Sample of the finished product(s) offered together with COA relevant to sample
☐	O. Label artwork /copy of actual label
☐	P. P.S Package insert/leaflet
☐	Q. Copy of the report of the proof of therapeutic equivalence (BE study, comparative dissolution profile, dissolution tests, etc including graphic presentations).
☐	R. GMP certificate(s) of API manufacturing site
☐	S. Copy of internal API specifications
☐	T. Validated analytical methods in case of in house API specifications
☐	U. Copy of the certificate(s) of analysis of the API from the API manufacturer as well as from the FP manufacturer
☐	V. Copy of the Certificate of suitability to the European Pharmacopoeia CEP and its annexes.