Interagency finished pharmaceutical product questionnaire[1]

Note for the applicant: *Please note that the information in this questionnaire can be shared confidentially among ICRC, MSF, WHO procurement centre, UNFPA, UNICEF, GDF and TGF for procurement purposes. If you have any objection, please indicate this to the relevant agency that you are dealing with.*

[1] Working document as per WHO TECHNICAL REPORT SERIES, NO. 986 under Annex 3 -Model quality assurance system for procurement agencies -Appendix 6- Interagency finished pharmaceutical product questionnaire based on the model quality assurance system for procurement agencies.

Guidance:

This is an automated PDF form. All data will be extracted and used for the technical evaluation. Please fill in the form in line with following:

- Please fill in ONE separate form for EACH pharmaceutical product and dosage form and strength
- Save this PDF file locally in the same format (PDF)
- Please fill in ALL relevant fields before returning the form to relevant agency
- Return this PDF form in the exact same PDF format: Do NOT print, scan, add pictures, or save in a different format

Interagency finished pharmaceutical product questionnaire

Section 1: Administrative Section

1.1 Product identification

Active pharmaceutical ingredient(s) (use INN if any):	
Generic name of the product:	
Trade (proprietary) name (if any):	
Dosage form, please choose in the dropdown list:	Choose an item.
Other dosage form if not listed	

1.1.1 Strength per dosage

Please, indicate the strength per dosage and specify strength in base and salt if applicable.	

1.1.2 Route of administration

Please choose route of administration: Choose an item.

Other (Please specify)	

1.1.3 Fixed dose or co-packaged product

Please choose the packaging of the product:

Fixed-dose combination (FDC) ☐

Co-packaged ☐

Other (Please specify)	

1.1.4 Formulation

- *Provide the formulation of the product (complete qualitative and quantitative composition including active ingredient(s), justification in case of overages, and excipients in **Annex A.***

1.2 Excipients (inactive ingredients)

Please list the excipients (inactive ingredients) in the product in below table:

Excipient	Amount per dosage unit	Medical/pharmaceutical relevance (binder, filler, other)	Standard : Pharmacopoeia of reference or in house

1.3 Packaging

1.3.1 Primary packaging

Pack size (e.g. blister pack of 10 tablets, or 10 ml ampoule):	
Description of package (bottle, ampoule, other):	
Materials used for primary packing:	
Description tamper proofing of the packaging	
GTIN	

- *Attach as **Annex B***
  - *a copy of the primary packaging specifications (include reference to compendia or in-house methods)*
  - *a copy of the primary packaging artwork.*

1.3.2 Secondary packaging

Total pack size (e.g. 100 tablets per box = 10 tablets x 10 blister cards):	
Description of package (box, bag, other):	
Materials used for secondary packing:	
Description tamper proofing of the packaging	
GTIN	

- *Attach as **Annex C***
  - *a copy of the specifications of the secondary packaging components (include reference to compendia or in-house methods)*
  - *a copy of the secondary packaging artwork.*

1.4 Contact details

1.4.1 Supplier/Bidder identification

Company name and address	
Email contact details	
Telephone number	
GPS co-ordinates	

1.4.2 Role regarding the product

Please choose the role of supplier/bidder below:

Marketing Authorisation Holder ☐

Manufacturer ☐

Distributor/wholesaler ☐

Other (Please specify)	

1.5 Manufacturer identification

Name of manufacturer, Manufacturing site and address (including block, plant, workshop)			
Activity (e.g. packaging, quality control testing, final release)	Choose an item.	Choose an item.	Choose an item.
GPS co-ordinates of the site &/or DUNS number			
Email contact details (for final batch release site only)			
Telephone number (for final batch release site only)			
Activity (e.g. packaging, quality control testing, final release)			
Reference of manufacturing license, date and expiry date			

Name of contracted manufacturer if any, Manufacturing site and address (including block, plant, workshop)			
Activity (e.g. packaging, quality control testing, final release, microbiological testing)	Choose an item.	Choose an item.	Choose an item.
GPS co-ordinates of the site &/or DUNS number			
Reference of manufacturing license, date and expiry date			

1.6 Regulatory (licensing) status of the FPP

1.6.1 Country of the manufacture

Type of product registration, please choose from dropdown list:	Choose an item.
Product registered in country	
Competent Authority	
Marketing authorization number	
Currently marketed yes or no	

- *Please attach a **certificate of pharmaceutical product (CPP)** according to the WHO Certification Scheme (WHO Technical Report Series, No. 863; an earlier version is not acceptable) in **Annex D**.*

- *Please provide copy of the latest MA issued together with the approval history (list of approved variations since the last three year) in **Annex E**.*

If a CPP cannot be obtained from competent authority, please state the reason:	

1.6.2 Product registration in other countries

List other countries where the product is **registered and is currently marketed or not** in the table below.

Country	Competent Authority	Licence number	Currently marketed yes or no
			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.

1.6.3 WHO prequalification status, if applicable

Has this product been submitted to WHO/PQP? Yes ☐ No ☐

If yes, please indicate date of submission WHO reference number:	

- *Please add the acceptance letter for product dossier review, including WHO reference number, in **Annex F**.*

1.6.4 Interagency dossier submission status

Has the dossier been submitted to any of the following:

Choose an item.

If any chosen above, please provide the date of the submission:	

1.7 Samples for technical evaluation

1.7.1 Samples of finished product

- Sample and leaflet/ insert information are required for evaluation. Please provide two samples of one of the applicable finished packed products (in primary and secondary packaging) and *high quality photos of the product, primary and secondary packaging in A**nnex G**.*

If you cannot submit the requested sample, please state the reason:	

1.7.2 Primary packaging label language

Bilingual English/French ☐ English ☐ French ☐

Other (Please specify) :	

- *Please attach a copy of primary packaging/label in **Annex H**.*

1.7.3 Secondary packaging label language

Bilingual English/French ☐ English ☐ French ☐

Other (Please specify) :	

- *Please attach a copy of secondary packaging/label in **Annex I**.*

1.7.4 Patient information leaflet/Package insert and Summary of Product Specifications (SmPC)

Bilingual English/French ☐ English ☐ French ☐

Other (Please specify) :	

- *Attach a copy of the PIL and SmPC in **Annex J**.*

Section 2: Active pharmaceutical ingredients

2.1 Details of API used (INN if any)

Please fill in the table below.

	Name (INN)	API manufacturer name, site, address (including plant, block, workshop, ...) and country	API specifications (BP, USP, Ph. Int., other)	GMP certification country of origin	Last inspection performed by: (1) FPP manufacturer (2) WHO PQ Geneva (3) EDQM (4) US FDA (5) PIC/S (6) Others - specify (7) none of the above	Date and outcome of inspection	API certification ref. number (US DMF, CEP or WHO API CPQ) (1)
API 1							
API 2							
API 3							
API 4							
API 5							

- *Attach GMP certificate of the country of origin in **Annex K**.*
- *Attach a copy of the FPP manufacturer internal API specifications (including stability indicating parameters) in **Annex L**.*
- *If analytical methods are in-house, different from BP, USP and Ph.Int., please attach a copy of the analytical method and analytical validation data in **Annex M**.*
- *(1) Attach copy of the API certification and annexes **Annex N***

2.2 Drug master file (DMF)/Common Technical Document

Is an open part of Drug Master file (DMF/ASMF) available for this API ?	
Has the DMF been registered/submitted for assessment?	
If submitted, please specify which country:	
If submitted, please specify DMF status:	

- *Provide a copy of the open part of the DMF in **Annex O**.*

2.3 For sterile API

- *Please provide the data on validation of the sterile aspects including recent media fill validation data, as applicable, in **Annex P**.*

Describe the method of sterilization for each sterile API used when applicable	

2.4 Certificate of analysis for API manufacturer (s)

- *Please provide a copy of the certificate of analysis of each API from each API manufacturer (s) as well as from the finished pharmaceutical product (FPP) manufacturer in **Annex Q**.*

The Certificate of analysis should include “package type, size & unit”.

2.1 Equivalence between different APIs

- *In case of different sources of APIs, provide in **Annex R** comparative analysis between different validated APIs that demonstrated that they are equivalent (if existing).*

Section 3: Finished pharmaceutical product (FPP)

3.1 FPP Manufacturing site GMP status

GMP inspections carried out by a Competent Authority (CA) (including PIC/S member inspectorate) or WHO PQ Team.

FPP site address	GMP Certificate No	Valid until	Name of CA and Country

- *Please attach the recent/valid GMP certificates/letter(s) of compliance in **Annex S**.*

Please describe if there is any on-going CAPA plan	

3.2 FPP specifications

Please list the standards that the FPP complies with:

Standard (e.g., BP, USP, PhInt, In-house)	Edition and year published

- *Please attach copies of release and shelf-life specifications for the FPP in **Annex T**.*
- *If analytical methods are in-house, different from BP, USP and Ph.Int., attach a copy of the analytical method and analytical validation report in the same **Annex T**.*

3.3 Certificate of Analysis (CoA) for FPP

- *Please attach a copy of the certificate of analysis for the three last batches released in **Annex U**.*

Please list the information of **at least 3 batches** in regards of the **Certificate of Analysis (CoA)** in below table:

Batch number	Batch size	Package size and unit (e.g. 100 tablets jar, or 10 ampoules per package)

3.4 Manufacturing process validation

Please provide details of validation process, hereunder specific batch information in the table below:

The batch size in relevant units (tablet, ampoules, sachets, other)	
Batch numbers	
Manufacturing dates	
Reference number for the process validation report	
If processes are yet to be validated, the reference number for the process validation protocol should be indicated	

- *Please provide in **Annex V** a flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters.*
- Attach a copy of the process validation report (supporting the proposed manufacture lot size) in **annex W**.

Additional information for sterile products

- *Provide the data on validation of the sterile aspects of the product including recent media fill validation data as applicable in **Annex X**.*

Please describe the method of sterilization used including conditions such as temperature, time, pressure:	

3.5 Nitrosamines

Has a risk assessment for the presence of nitrosamines been conducted : Yes ☐ No ☐

If no explain why

Provide in **Annex Y**, a declaration regarding risk assessment (RA) for the presence of nitrosamines in the product and the outcome of the risk assessment, including results of confirmatory testing and control strategies as applicable.

The risk assessment and if applicable the confirmatory testing must have been conducted according to guidelines issued by RAs. RA reports should be made available on request.

3.6 Stability studies

3.6.1 Stability of the Finished Pharmaceutical Product (FPP)

Replicate the table below as per API source

	Stress study (e.g photostability, extreme temperature)	Accelerated study	Long term study	On-going study
API name (s) and source (s)				
Conditions (Celsius/rH%/Climatic zone)				
Duration (months)				
Batch numbers (3 different)				
Batch size of each lot tested				
Container and primary material (e.g. jar of HDPE)				
FPP specification used version and date				
Study Conclusions				

To document the information listed in the table above,

- *please provide the protocol and the report for accelerated and long-term stability testing of the FPP for each source of API. Also, please attach status report of any on-going stability studies in **Annex Z**.*

Was the stability testing done on a product of the same formula, same API source, manufactured at the same site and packed in the same packaging material as the product that will be supplied?

Yes ☐ No ☐

If No, please describe the differences:	

3.6.2 Stability studies of the FPP manufactured with API from each proposed API sources

Is there a stability study of the FPP in place in support of each proposed API source ?

Yes ☐ No ☐ Ongoing ☐

If No, please describe further:	

- *Submit a declaration which states that stability studies have been carried out, or are in progress, with all declared API sources in **Annex AA.***

3.6.3 Shelf-life

Please indicate the recommended shelf-life (number of months) :

3.6.4 Storage conditions

Please specify the storage conditions as described on the packaging and based on stability studies (e.g. "Do not store above 30 °C Protect from light"):

Temperature	
Light	
Humidity	
Other recommendation (specify)	
Any special transport conditions (specify)	

3.6.5 Climatic Zones

Product suitable for use in the following ICH Climatic Zones:

Zone I	Zone II	Zone III	Zone IVa	Zone IVb
☐	☐	☐	☐	☐

Other:	

3.6.6 In-use stability data

In-use stability data (after reconstitution or dilution of product), indicate period (hours/days):	
Please indicate the in-use storage condition:	

- *For oral powder for suspension, powder for injection, injection for further dilution or multidose containers, please provide in-use stability data and storage conditions after reconstitution and/or dilution in **Annex AB**.*

Section 4: Safety/efficacy and/or therapeutic equivalence

(WHO Technical Report Series (TRS), No. 1003, Annex 5 and 6/ TRS No. 992, Annex 8/TRS 929 Annex 5 or recent version)

4.1 For innovator products

- *Please attach a summary of pharmacology, toxicology and efficacy of the product in **Annex AC**.*

4.2 Therapeutic Equivalence

Demonstrated ☐ Not demonstrated ☐

Not relevant, please explain (example: when therapeutic equivalence studies are not required according to WHO TRS 1003 Annex 6)	

If demonstrated:

- *Attach graphic/pictorial representation of summary study results in **Annex AD.***
- *Provide a copy of the report of the proof of therapeutic equivalence (BE study) comparative dissolution profile, dissolution tests, and others, if any, in **Annex AE**.*
- For bioequivalence studies, indicate the stringent regulatory authority (SRA)/ WHO/PIC/S inspection status of the Contract Research Organisation (CRO) (if the CRO has ever undergone inspections in relation to the current or other studies).
- For bioequivalence studies, *attach CRO inspection positive outcome evidence and certificate of Accreditation of Clinical Facility, Clinical Laboratory and Analytical Laboratory as per ISO or GLP Standards in **Annex AF**.*
- *Attach schematic representation of study design in **Annex AG**.*
- *Attach study protocol summary in **Annex AH**.*

4.2.1 In vivo bioequivalence studies

Please specify, if any in vivo bioequivalence studies have been made:	
Study period	

4.2.1.1 In vivo test - reference product

Generic name	
Dosage form	
Strength	
Brand/trade name	
Manufacturer name and site	
Batch number	
Expiry date	

4.2.1.2 In vivo test - study protocol

Contract research organization (CRO) name:	
Country of study:	
Number of volunteers:	
Study design (describe in detail):	
Bio batch size:	
Bio batch number:	
Bio batch API(s) source(s):	
Study conclusion:	

4.2.2 Comparative tests

Have comparative in vitro dissolution tests been made according to conditions described in WHO BCS classification document (WHO Technical Report Series, No. 1006, Annex 6, or later)?

Yes ☐ No ☐

If No, please specify	

4.2.3 Reference product - comparative tests

Generic name	
Dosage form	
Strength	
Brand/trade name	
Manufacturer name and site	
Batch number	
Expiry date	
Name and contact details of laboratory performing tests	
Study results F2 (similarity factor) value (standard 50–100%)	
F1 (difference factor) value:	
Study conclusion:	

4.2.4 Therapeutic equivalence – commitment

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 ☐

If No, explain what the differences are and justify that the differences do not have any impact on the bioavailability	

4.3 Periodic Safety Update Report

- *Provide the latest Periodic Safety Update Report in **Annex AI.***

Section 5: Commitment and authorization

5.1 Commitment

I, the undersigned (*position in the company, e.g. General Manager, Authorized Person, Responsible Pharmacist*), acting as responsible for the company *(name of the company)*, certify that the information provided (above) is correct and true,

(if the product is marketed in the country of origin, select the appropriate box below)

☐ and I certify that the product offered is identical in all aspects of manufacturing and quality to that marketed in (*country of origin*), 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.

☐ and I certify that the product offered is identical to that marketed in *(name of country)*, except:

(e.g. formulation, method and site of manufacture, sources of active and excipient starting materials, quality control of the finished product and starting material, packaging, shelf-life, indications, product information)

If any changes occur to the information after the submission of this product questionnaire, the manufacturer/supplier undertakes to provide the relevant update as soon as possible.

Date: Signature: ___

5.2 Power of attorney

The manufacturer authorizes a distributor to submit the questionnaire

Date: Signature:

Distributor (Signed by Distributor for Manufacturer under power of attorney)

- *Please provide a copy of the power of attorney in **Annex AJ**.*

5.3 Authorization for sharing information with other agency

I, the undersigned confirm that *(name of the company)*, has no objection to each Agency confidentially sharing information in this questionnaire, any of its annexes and/or the results of its review with the agencies listed in 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

Company seal/stamp:

Section 6: Checklist for Annexes and attachments

Attachments or Annexes to the questionnaire should be in separate PDF files and should be named the Annex or Attachment name to facilitate review.

Please fill in this checklist, to ensure that all documentation necessary for the evaluation are attached:

A. ☐ Formulation of the product (complete qualitative and quantitative composition including active ingredient(s), justification in case of overages, and excipients)

B. ☐ Description, composition and specifications including reference to compendia or in-house methods of primary packaging materials including label mock ups

C. ☐ Description, composition and specifications including reference to compendia or in-house methods of secondary packaging materials

D. ☐ Certificate of pharmaceutical product (CPP) according to the WHO Certification Scheme (WHO Technical Report Series, No. 863. An earlier version is not acceptable)

E. ☐ Copy of the latest MA issued together with the approval history (list of approved variations since the last three years)

F. ☐ Copy of the WHO PQ acceptance letter for product dossier, including WHO reference number

G. ☐ High quality photos of the product, primary and secondary packaging

H. ☐ Copy of primary packaging/label

I. ☐ Copy of secondary packaging/label

J. ☐ Patient information leaflet/package insert and SMPC

K. ☐ GMP certificate of the API manufacturer(s) from the country of origin

L. ☐ Copy of the FPP manufacturer internal API specifications (including stability indicating parameters)

M. ☐ Validated analytical methods if analytical methods for API are in-house analytical method, different from BP, USP and Ph.Int.

N. ☐ Copy of the API certification and annexes

O. ☐ Copy of the open part of the DMF

P. ☐ Data on validation of the sterile aspects of the product including recent media fill validation data, as applicable

Q. ☐ Copy of the certificate(s) of analysis of the API from the API manufacturer as well as from the FPP manufacturer

R. ☐ Comparative analysis between different validated API sources that demonstrated that they are equivalent (if existing).

S. ☐ Recent/valid GMP certificates/letter of compliance of the FPP manufacturer

T. ☐ Copies of release and shelf-life specifications for the FPP. If in-house specification is different from BP, USP and Ph.Int., attach copy of the in-house finished product specifications and also validated analytical methods

U. ☐ Copy of the certificate of analysis for the three last batches released

V. ☐ Flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters

W. ☐ Process validation report

X. ☐ Data on validation of the sterile aspects of the product including recent media fill validation data as applicable

Y. ☐ A declaration regarding risk assessment (RA) for the presence of nitrosamines in the product and the outcome of the risk assessment

Z. ☐ Protocol and report for accelerated and long-term stability testing and status report of any ongoing stability studies

AA. ☐ Declaration that stability studies have been done or are being done with all declared API sources

AB. ☐ In-use stability data and storage conditions after reconstitution for oral powder for suspension, powder for injection, or injection that may be further diluted, or multidose containers

AC. ☐ Summary of pharmacology, toxicology and efficacy of the product

AD. ☐ Graphic/pictorial representation of summary study results

AE. ☐ Copy of the report of the proof of therapeutic equivalence (BE study) comparative dissolution profile, dissolution tests, and others if any

AF. ☐ Attach CRO inspection positive outcome evidence and certificate of Accreditation of Clinical Facility, Clinical Laboratory and Analytical Laboratory as per ISO or GLP Standards

AG. ☐ Schematic representation of study design AG. Study protocol summary

AH. ☐Study protocol summary

AI. ☐ Latest Periodic Safety report

AJ. ☐ Copy of the power of attorney