Interagency finished pharmaceutical product questionnaire

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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:

1) Please fill in ONE separate form for EACH pharmaceutical product
2) Save this PDF file locally in the same format (PDF)
3) Please fill in ALL relevant fields before returning the form to relevant agency
a. Section 4 Therapeutic Equivalence is ONLY filled out if applicable for the product
4) 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 dosage form
Other	

1.1.1 Strength per dosage

Please, indicate the strength per dosage	

1.1.2 Route of administration

Please choose route of administration: Choose route of administration

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)	

Please provide the formulation of the product (complete qualitative and quantitative composition including active ingredient(s), overages if any 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 (BP, USP, other)

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:	

Please add documentation in **Annex B.**

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 primary packing:	

Please add documentation in **Annex C.**

1.4 Contact details

1.4.1 Supplier/Bidder identification

Company name and address	
Email contact details	
Telephone number	
Activity (e.g. packaging, quality control testing, final release)	

1.4.2 Role regarding the product

Please choose the role of bidder below:

Marketing Authorisation Holder ☐ Manufacturer ☐

Distributor/wholesaler ☐

Other (Please specify)	

1.5 Manufacturer identification

If the Supplier/Bidder identification is the same as Manufacturer, please skip this section.

Name of manufacturer, Manufacturing site and address	
Email contact details	
Telephone number	
Activity (e.g. packaging, quality control testing, final release)	

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.

1.5.1 Has the dossier been submitted to any of the following:

Choose agency

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

1.6 Regulatory (licencing) status

1.6.1 Country of the manufacture

Type of product registration, please choose from dropdownlist:	Choose product registration
Product registered in country	
Competent Authority	
Licence number	

- 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 E**.
- Submit recent as well as historical deficiency letters issued by the WHO Prequalification Programme (PQP)/SRA in relation to the specific product dossier in **Annex F**.

If a CPP cannot be obtained from competent authority, please state the reason and send an equivalent document if any:	

1.6.2 Product registration in other countries

List other countries where the product is **registered and is currently marketed** in the table below.

Country	Competent Authority	Licence number

Provide a copy of the licence in **Annex D.**

1.6.3 WHO prequalification status, if applicable

Has this product been prequalified by WHO/PQP?

Yes ◯ No ◯

If yes, please indicate date of submission WHO reference number	

If the product has been prequalified WHO, please add the acceptance letter for product dossier review, including WHO reference number, in **Annex H.**

If the product is currently under WHO prequalification (PQP) assessment, please attach the acceptance letter signed by your company in **Annex G**.

1.7 Samples for technical evaluation

1.7.1 Samples of finished product

Sample and leaflet/ insert information are required for evaluation. Please provide one sample of one of the applicable finished packed products.

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 in **Annex I.**

1.7.3 Secondary packaging label language

Bilingual English/French ◯ English ◯ French ◯

Other (Please specify)	

Please attach a copy in **Annex I.**

1.7.4 Patient information leaflet/Package insert

Bilingual English/French ◯ English ◯ French ◯

Other (Please specify)	

Please attach a copy 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 and country	API specifications (BP, USP, Ph. Int., other)	GMP certification country of origin (Annex K)	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 1						
API 2						
API 3						
API 4						
API 5						

Please attach a copy of the FPP manufacturer internal API specifications 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.**

2.2 For sterile API

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

Describe the method of sterilization used when applicable	

2.3 Certificate of analysis for API manufacturer

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

2. 4 Certificate of suitability (CEP)

Certificate of suitability to the monograph of the European Pharmacopoeia (CEP) for APIs. Please attach in **Annex P1**, and if available, please fill in the certificate number.

CEP Certificate No	

2.5 Drug master file (DMF)

Is a Drug Master file (DMF/ASMF) available for this API ?	
Has den DMF been registered/submitted?	
If submitted, please specify which country:	

If DMF is available, please provide a copy in **Annex P2.**

Section 3: Finished pharmaceutical product (FPP)

3.1 FPP Manufacturing site GMP status

GMP inspections carried out by a Competent Authority (CA)

FPP site and Country	GMP Certificate No	Valid until	Name of CA and Country	Other inspection of PIC/S member, WHO PQP, MSF, ICRC

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

Please describe if there is any on-going CAPA plan	

3.2 FPP specifications

Please list the specifications used for finished pharmaceutical product:

Standard (BP, USP, In-house, other analytical method)	Edition and year published

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

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 S**. 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	
Provide batch formulae for all proposed batch sizes	

Please provide in **Annex T** a flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters.

3.4.1 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 U**.

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

3.5 Stability studies

3.5.1 Stability of the Finished Pharmaceutical Product (FPP)

	Accelerated study	Long term study	On-going study
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)			
Microbiological test and standard used (BP, USP, other)			
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 in **Annex V**. Also, please attach status report of any on-going stability studies in **Annex X**.

Was the stability testing done on a product of the same formula, same API source, manufactured o 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:	

3.5.2 Stability studies of the API sources

Is there a stability study in place for the 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 W.**

3.5.3 Shelf-life

Please choose the shelf-life as it appears on packaging:

2 years ◯ 3 years ◯ 4 years ◯ 5 years ◯

If No, please describe further:	

3.5.4 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	
Storage conditions	
Other (specify)	
Any special transport conditions (specify)	

3.5.5 Climatic Zones

Product suitable for use in the following ICH Climatic Zones:

Zone I ☐ Zone II ☐ ZoneIII ☐ Zone IVa ☐ Zone IVb ☐

Other:	

3.5.6 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 Y**.

Section 4: Safety/efficacy and/or therapeutic equivalence

ONLY fill in Section 4, if relevant for the product

(WHO Technical Report Series (TRS), No. 902, Annex 11/ TRS No. 937, Annex 7 or recent version)

4.1 For innovator products

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

4.2 Therapeutic Equivalence

Demonstrated ◯ Not demonstrated ◯

Not relevant, please explain	

If demonstrated:

- Attach graphic/pictorial representation of summary study results in **Annex AA.**
- 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 AB**.
- 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).
- Attach schematic representation of study design in **Annex AC**
- Attach study protocol summary in **Annex AD**

4.3 In vivo bioequivalence studies

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

4.3.1 In vivo test - reference product

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

4.3.2 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:	

4.4 Comparative tests

Have comparative in vitro dissolution tests been made according to conditions described in WHO BCS classification document (WHO Technical Report Series, No. 937, or later)?

Yes ◯ No ◯

If No, please specify	

4.4.1 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:	

4.5 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	

Section 5: Signature and Commitment

Please refer to the separate Word file called **'Section 5 – Signature and Commitment'**.

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) and excipients
- ☐ B. Description and composition of primary packaging materials including label mock ups
- ☐ C. Description and composition of secondary packaging materials
- ☐ D. Copy of product registration and market status– Licence No
- ☐ E. Certificate of pharmaceutical product (CPP) according to the WHO Certification Scheme (WHO Technical Report Series, No. 863. An earlier version is not acceptable)
- ☐ F. Recent as well as historical deficiency/acceptance letters issued by PQP/SRA in relation to the specific product dossier
- ☐ G. Copy of the relevant WHO Prequalification acceptance letter signed by your company
- ☐ H. WHO acceptance letter for product dossier review mentioning the WHO reference number assigned by WHO for this specific product
- ☐ I. Copy of primary and secondary packaging/label
- ☐ J. Patient information leaflet/package insert
- ☐ K. GMP certificate of the API manufacturer(s) from the country of origin
- ☐ L. Copy of the internal API(s) specification(s)
- ☐ M. Validated analytical methods if analytical methods for API are in-house analytical method, different from BP, USP and Ph.Int.
- ☐ N. Data on validation of the sterile aspects of the product including recent media fill validation data, as applicable
- ☐ O. Copy of the certificate(s) of analysis of the API from the API manufacturer as well as from the FPP manufacturer
- ☐ P 1. Copy of the certificate of suitability to the European Pharmacopoeia (CEP) and its annexes

- [ ] P 2. Attach a copy of the Technical file
- [ ] Q. Recent/valid GMP certificates/letter of compliance of the FPP manufacturer
- [ ] R. 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
- [ ] S. Copy of the certificate of analysis for the three last batches released
- [ ] T. Flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters
- [ ] U. Data on validation of the sterile aspects of the product including recent media fill validation data as applicable
- [ ] V. Protocol and report for accelerated and long-term stability testing
- [ ] W. Declaration that stability studies have been done or are being done with all declared API sources
- [ ] X. Status report of any ongoing stability studies
- [ ] Y. 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
- [ ] Z. Summary of pharmacology, toxicology and efficacy of the product
- [ ] AA. Graphic/pictorial representation of summary study results
- [ ] AB. Copy of the report of the proof of therapeutic equivalence (BE study) comparative dissolution profile, dissolution tests, and others if any
- [ ] AC. Schematic representation of study design
- [ ] AD. Study protocol summary
- [ ] AE. Copy of the power of attorney