Appendix

|  |  |
| --- | --- |
|  | Finished Pharmaceutical Product Questionnaire: Abbreviated |

This questionnaire is used to collect information from vendors with regards to finished pharmaceutical products (FPPs) that fall in any of the categories below:

* Product has been reviewed and approved by a stringent regulatory agency
* Product is WHO-prequalified

Products that do not meet the above criteria may require documentation collected through a more detailed FPP questionnaire.

*Instructions:*

*Fill out the information that is applicable to the product. Complete one questionnaire per product presentation.*

*Complete the fields in this questionnaire as applicable.*

* *Tick or place an X in any of the blocks that are true/applicable.*
* *Add rows to tables to include requested information. Alternatively, you may attach information in a separate sheet using the same format requested.*
* *In some instances, it may be required to duplicate sections, copy the section, and paste as needed. Alternatively, duplicate copies of the section may be completed and attached.*
* *Update the table of contents when completed.*

USAID list of the countries with recognized SRAs:

Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union (European Medicines Agency), Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom, United States.

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# Applicant Information

*The information in this questionnaire can be shared confidentially between USAID and its implementing partners, WHO and The Global Fund for procurement purposes. If approved, the approval (including product identification, manufacturing sites, approved specifications, test methods and publicly available information) may also be shared with other procurement agencies. If the applicant has any objections, mark an X in the box:*  objection to share information as specified above.

|  |  |
| --- | --- |
| Request for Proposal Number |  |
| Questionnaire Submission Date *(DD/MON/YYYY)* |  |
| Company Name (Supplier)  (*name of company submitting bid*) |  |
| Physical address |  |
| Postal address |  |
| Telephone number |  |
| Fax |  |
| Website |  |
| Email |  |
| Link to product | *(Select all that apply)*  Marketing license holder  Distributor or wholesaler  Manufacturer  Other (Specify): |
| Provide contact information for each of the following: | |
| Technical Specifications and Quality Assurance | Name:  Telephone:  Cell phone:  E-mail: |
| Regulatory and patent | Name:  Telephone:  Cell phone:  E-mail: |
| General Inquiries | Name:  Telephone:  Cell phone:  E-mail: |

# Product Identification

|  |  |  |  |
| --- | --- | --- | --- |
| Active pharmaceutical ingredient(s) (use INN when applicable) |  | | |
| Generic name of the product |  | | |
| Brand name (if applicable) |  | | |
| Regulatory Version | US FDA  SRA  NMRA  Only one regulatory version available  Other (Specify) | | |
| Finished Product Presentation  *(quantity of dosage-form units per pack)* |  | | |
| Other pack sizes/dosage forms available (*Specify*). | | |
| Manufacturer Unique Product  Identification Number (Product Code) |  | | |
| Product Type | Single Pharmaceutical Entity | Fixed Dose Combination | Co-pack |
| Dosage form | Tablets | (Select all that apply)  Scored  Solid  Dispersible  Chewable  Buffered (Specify buffers): \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | (Select all that apply)  Film coated  Enteric coated  Sublingual  Bi-layered  Delayed release  Controlled release |
| Capsules | (Select all that apply)  Enteric coated  Sublingual  Delayed release  Controlled release  Other (Specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Injectable | Solution for injection  Powder for injection  Oily injection | |
| Syrups/oral liquids | Solution  Suspension  Powder for solution  Powder for suspension | |
| Oral powder |  | |
| Implant |  | |
| Other (*Specify*): | | |
| Measuring Device | Syringe  Cup  N/A  Other (*Specify*): | | |
| Strength per dosage form or unit |  | | |
| Route of administration | Oral  Intramuscular (I.M.)  Intravenous (I.V.)  Subcutaneous (S.C.)  Other (Specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Shelf-life | 24 months  36 months  48 months  60 months  Other (*Specify*) | | |
| Packaging Type | Blister Pack  Bottle  Vial  Ampule  Other (*Specify*): | | |
| Label Storage Requirements |  | | |
| Product Suitable for use in the following climatic zones: | Zone I;  Zone II;  Zone III;  Zone IVa;  Zone IVb;  Other (Specify)\_\_\_\_\_\_\_\_\_\_ | | |
| FPP Manufacturer and Manufacturing Site Address |  | | |
| US FDA Establishment Identification (FEI number) for each applicable): | | |
| API Manufacturer and Manufacturing Site Address |  | | |
| US FDA Establishment Identification (FEI number) for each applicable): | | |

# FPP Manufacturer Information

*Attach a copy of the most recent Stringent Regulatory Authority GMP Certificate or Inspection Report. (See list of recognized SRAs in Page 1)*

*Attach a copy of the most recent* *WHO Prequalification Programme Inspection Report.*

|  |  |
| --- | --- |
| Manufacturer of Record |  |
| Physical address: |  |
| Postal address |  |
| Telephone number |  |
| Fax |  |
| Website |  |
| e-mail |  |
| FEI Number (for US FDA inspected organizations) |  |
| Name of parent company (when applicable) |  |

# Finished Pharmaceutical Product

*(Reproduce section 4.0 for each FPP component (eg. Placebo))*

## Product Formulation

Attach a copy of the product formulation that includes the qualitative and quantitative composition (including active ingredient(s), overages if any and all excipients). Please also indicate the standard for each ingredient (e.g., BP, Ph. Eur., USP or in-house). Include a product formulation list for each individual FPP component (e.g. placebos, co-packaged products).

## Product Manufacturing

Provide information on the lot size of the validated lots (minimum and maximum size) and the date and reference number for the process validation report

## FPP Specifications and Test Methods

Attach a copy of the release and shelf-life specifications for the finished pharmaceutical product. Please also indicate the standard for specification (e.g., BP, Ph. Eur., USP or in-house).

Attach a copy of the analytical test methods.

Attach a flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters.

Provide a summary of the activities taken to identify the possible presence of nitrosamines (API and FPP). Include a copy of the risk assessment completed.

FOR STERILE PRODUCTS: Provide a description of the product sterilization method, name and address (include FEI number when appropriate) of contract sterilization organization.

## FPP Packaging and Labeling

Attach a copy of the primary packaging and secondary packaging artwork

Attach a copy of the Summary of Product Characteristics (SmPC) or package insert/leaflet

Attach a copy of the patient information leaflet

## FPP Shelf-life and Storage Conditions

Accelerated Stability: Attach report for accelerated stability studies completed. *Verify that information includes: type and material of container; conditions (temperature/relative humidity/duration of stability study); number of lots involved in the study (minimum of three); lot sizes for each lot tested; date of beginning of the study; and API manufacturer and lot*.

Long-Term Stability: Attach report for long-term stability studies completed. *Verify that information includes: type and material of container; conditions (temperature/relative humidity/duration of stability study); number of lots involved in the study (minimum of three); lot sizes for each lot tested; date of beginning of the study; and API manufacturer and lot*.

In Use Stability: Attach report for in-use stability studies completed. *Verify that information includes: type and material of container; conditions (temperature/relative humidity/duration of stability study); number of lots involved in the study (minimum of three); lot sizes for each lot tested; date of beginning of the study; and API manufacturer and lot*.

For oral powder for suspension and powder for injection, or injection that may be further diluted, or multi-dose containers attach in use stability data and storage conditions after reconstitution and/or dilution indicate the period (hours/days) until which the product is stable after reconstitution and/or dilution based on the available in-use stability data.

Transportation Stability: Attach report for transportation stability studies completed. *Verify that information includes: type and material of container; conditions (temperature/relative humidity/duration of stability study); number of lots involved in the study (minimum of three); lot sizes for each lot tested; date of beginning of the study; and study conclusions*.

Ongoing Stability: Attach status report for any ongoing stability. *Verify that information includes: type and material of container; conditions (temperature/relative humidity/duration of stability study); number of lots involved in the study (minimum of three); lot sizes for each lot tested; date of beginning of the study; and study conclusions*.

# Active Pharmaceutical Ingredient(s)

*(Reproduce section 5.0 for each API)*

## API Details and Manufacturer Identification

* *Attach recent, valid GMP certificates or letter (country of origin, SRA, WHO, other) for each business listed*
* *Attach a copy of the API specifications.*
* *Attach a copy of the API analytical methods*

|  |  |
| --- | --- |
| API Name/INN (if any) |  |
| Manufacturer Name |  |
| Physical address: (Specify units and block if existing) |  |
| Postal address |  |
| Telephone number |  |
| Fax |  |
| Website |  |
| e-mail |  |
| FEI Number: (for US FDA inspected organizations) |  |

## API Regulatory and Licensing Status

|  |  |
| --- | --- |
| CEP: A Certificate of Suitability to the monograph of the European Pharmacopoeia (CEP) is available  *Attach a copy of the certificate of suitability to the EU Pharmacopoeia (CEP) and its annexes* | |
| CPQ: A WHO API Prequalification Certificate  *Attach a copy of the WHO Prequalification CPQ,* | |
| DMF: A Drug Master file (DMF) is available: | |
| DMF Number: |  |
| DMF Holder: |  |
| Subject: |  |

# FPP Regulatory and Licensing status

## Licensing Status

* *Attach a copy of the licenses that apply*

|  |  |  |
| --- | --- | --- |
| Product registered and currently marketed in the country of manufacture | | |
|  | Issuing Agency: | |
| Product registered but NOT marketed in the country of manufacture | | |
|  | Issuing Agency: | |
| Product registered for export only | | |
|  | Issuing Agency: |  |
| Product NOT registered in the country of manufacture. (*Please Explain)* | | |

## Certificate of Pharmaceutical Product (CPP)

|  |
| --- |
| A Certificate of Pharmaceutical Product is available   * *Attach a certificate of pharmaceutical product according to the WHO Certification Scheme (WHO Technical Report Series, No. 863). An earlier version is not acceptable.* |
| A Certificate of Pharmaceutical Product is NOT available. *(Please explain):* |

## Stringent Regulatory Authority (SRA) Approval Status

|  |  |
| --- | --- |
| * *Attach a copy of reference National Regulatory Authority (SRA) approval/registration. Note: Include documentation to demonstrate significant post-approval changes relevant to this product (Eg. manufacturing site, product presentation, shelf-life etc).*   The product National Regulatory Authority is a recognized Stringent Regulatory Authority.  *Tick this box also for HIV ARVs that received US FDA tentative approval.*  *(See list of recognized Stringent Regulatory Authorities in Page 1)* | |
| Country/Issuing Agency | License Number or ANDA/NDA number |
| Choose an item.: |  |

## WHO Prequalification Status

|  |
| --- |
| Attach full WHO Public Assessment report (WHOPAR)  WHO reference number: |

## Rest of the World Registration Status

*Provide copies of latest proof of registration for all countries listed below*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Country | Registration Number | Brand Name | Shelf-Life | Label language | Import Status |
| Afghanistan |  |  |  |  |  |
| Bangladesh |  |  |  |  |  |
| DR. Congo |  |  |  |  |  |
| Ethiopia |  |  |  |  |  |
| Ghana |  |  |  |  |  |
| Haiti |  |  |  |  |  |
| India |  |  |  |  |  |
| Liberia |  |  |  |  |  |
| Kenya |  |  |  |  |  |
| Madagascar |  |  |  |  |  |
| Mali |  |  |  |  |  |
| Malawi |  |  |  |  |  |
| Mozambique |  |  |  |  |  |
| Nepal |  |  |  |  |  |
| Nigeria |  |  |  |  |  |
| Pakistan |  |  |  |  |  |
| Philippines |  |  |  |  |  |
| Rwanda |  |  |  |  |  |
| Senegal |  |  |  |  |  |
| S. Sudan |  |  |  |  |  |
| Tanzania |  |  |  |  |  |
| Uganda |  |  |  |  |  |
| Yemen |  |  |  |  |  |
| Zambia |  |  |  |  |  |
| Other Countries | | | | | |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  | | | | | |

*N= 24*

# Product Quality Review

* *Attach the most recent annual product quality review for the finished pharmaceutical product*
* *Provide a listing and summary of product quality incidents for the past 3 years.*
* *Provide a listing of recalls associated with this product for the past 3 years.*

# FPP Release and Third-Party Testing

* *Attach a copy of Certificate of Analysis of the of the last year or 10 consecutive lots per manufacturing site released (whichever is greater); include copies of corresponding COA from third-party laboratory testing (when available).*
* *Attach a copy of the analytical method transfer report with relevant testing laboratories.*

Provide a list of laboratories where analytical method transfer has been completed:

|  |  |  |  |
| --- | --- | --- | --- |
| Laboratory Name | Address | Contact Information | ISO 17025 Certificate |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

As part of the product assessment activities, FHI 360 may request samples of API and/or of the FPP for laboratory analysis. The product will be tested in accordance with established FHI 360 protocols and, when applicable, in accordance with specifications and analytical test methods used by the manufacturer. In instances when a method transfer is required, the manufacturer will be requested to provide method transfer and routine test reference substances required for performing the laboratory QC tests.

# Checklist of Attachments

FPP Manufacturer Information

Recent/valid GMP certificates/letter (Country of Origin, SRA, other)

WHO Prequalification Programme Inspection Report (WHOPIR).

Finished Pharmaceutical Product

Copy of the FPP formulation (verify that all requirements specified in Item 4.0 are included)

Release and shelf-life specifications for the FPP

FPP Analytical Test Methods.

Certificate of Analysis of the last year, or 10 consecutive lots released per manufacturing site

Primary Packaging Artwork

Secondary Packaging Artwork

Package insert/leaflet or Summary of Product Characteristics (SmPC)

Patient information leaflet

Report for accelerated and long-term stability for each FPP presentation

Stability data and storage conditions after reconstitution (For oral powder for suspension and powder for injection)

Report for transportation stability studies completed

Status report for any ongoing stability studies

API Regulatory and Licensing Status

Recent/valid GMP certificates/letter for each business involved in API manufacturing

Copy of the certificate of suitability to the EU Pharmacopoeia (CEP) and its annexes

Copy of WHO Prequalification CPQ

FPP Regulatory and Licensing Status

Copy of the licenses that apply

Certificate of Pharmaceutical Product (CPP)

FPP Registration and Marketing Documentation (SRA, Country of Origin and all other)

WHO Public Assessment report (WHOPAR)

Product Quality Review

Attach the most recent annual product quality review for the Finished Pharmaceutical Product

Listing and summary of product recalls in the past 3 years

Listing and summary of product quality incidents in the past 3 years.

FPP Release and Third-Party Testing

FPP Certificate of Analysis of the last year or 10 consecutive lots per manufacturing site released (whichever is greater); include copies of corresponding CoA from Third Party Laboratory Testing (when available).

Listing of laboratories where analytical method transfer has been completed.

Authorization and Commitment

Copy of Power of Attorney (in instances where a manufacturer authorizes a distributor to submit the questionnaire)

Detailed differences between offered product and refence national regulatory product approval

Authorization to share information

Commitment

# Authorization and Commitment

## Authorization for Sharing Information with Other Agency(ies)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| I, the undersigned [ENTER FULL NAME], confirm that the company has no objection to the information contained herein being shared with USAID and implementing partners, WHO, UNFPA and/or The Global Fund. If approved, the approval (including product identification, manufacturing sites, approved specifications, and publicly available information) may also be shared with other procurement agencies. I, the undersigned, understand that any publicly available information shared with USAID may also be subject to disclosure by USAID under the Freedom of Information Act.  I, the undersigned [ENTER FULL NAME], understand that any publicly available information may also be subject to disclosure by USAID under the Freedom of Information Act and object to sharing the following information: [SPECIFY ORGNIZATION AND INFORMATION NOT TO BE SHARED] | | | | |
|  |  |  |  |  |
| Name |  | Signature |  | Date *(DD/MON/YYYY)* |
| Full title/Position |  | Company name |  |  |
|  |  |  |  |  |

## Commitment

*Provide a copy of a power of attorney in instances where a manufacturer authorizes a distributor to submit the questionnaire.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| I, the undersigned, certify that:  The product offered is identical in all aspects of manufacturing and quality including, formulation, method and site of manufacture, sources of active and excipient starting materials, quality control of the product and starting material, packaging, labeling, shelf-life and product information as one of the following:  National Regulatory Authority [SPECIFY Name of Regulatory Authority] and Product Registration Number [SPECIFY Registration number].  WHO prequalified product identified as [SPECIFY WHO PQ No.]  The information in the questionnaire submitted to FHI360 contains information which is the same as the information in the dossier which is approved by  or  The product offered is intended to be the similar and with some differences to the following:  National Regulatory Authority [SPECIFY Name of Regulatory Authority] and Product Registration Number [SPECIFY Registration number].  WHO prequalified product identified as [SPECIFY WHO PQ No.]   * Describe in detail any differences in any aspect of the product including formula, manufacturing site of API, manufacturing site of FPP, specifications of primary packaging, specifications of secondary packaging, package insert, summary of product characteristics/package insert, patient information leaflet and provide the justification for the changes in an attachment to this submission.   I, further certify that the information provided above is accurate, correct, complete, up-to-date, and true at the time of submission. If any changes occur to the information provided after submission of this product questionnaire, the manufacturer/supplier undertakes to provide the relevant update as soon as possible.  I further certify that I have examined the following statements and I attest to their accuracy.   1. Amendments and variations, as defined in the current Variations guidelines as published in WHO Technical Series, or the reference National Regulatory Authority guidelines on variations; to the questionnaire/dossier approved shall be communicated to FHI 360 within 1 month of approval by the competent authority. 2. The holder of the national registration follows national requirements for handling adverse reaction on its products. 3. The holder of the national registration follows national requirements for handling lot recalls of its products. | | | | |
|  |  |  |  |  |
| Name |  | Signature |  | Date *(DD/MON/YYYY)* |
| Full title/Position |  | Company name |  |  |
|  |  |  |  |  |