**GHSC-PSM-TO2-2019-MALARIA\_PHARMACEUTICAL-EOI**

**Annex 6 - Finished Pharmaceutical Product Questionnaire [[1]](#footnote-1)**

Potential manufacturers supplying finished pharmaceutical products (FPPs) for USAID | GHS-PSM Project are required to provide documentation of their manufacturing capabilities, technical and specifications standards of the processes used to manufacture the FPP. Incomplete submission of this document may negatively affect the bidder’s eligibility and may result in GHSC-PSM not considering the offer. Documents in languages other than English must include a translation and should be submitted in addition with the original non-translated document.

**For each FPP submitted in the offer, please fill out one separate questionnaire**

**Offeror:**

|  |
| --- |
|  |

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**Section 1: Administrative section**

1.1 **Product identification**

* + 1. Active pharmaceutical ingredient(s) (use INN):

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|  |
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|  |

* + 1. Generic name of the product:

|  |
| --- |
|  |

* + 1. Trade (proprietary) name (if any):

|  |
| --- |
|  |

* + 1. Dosage form:

☐ Tablets ☐ Dispersible Tablet ☐ Capsules ☐ Injectable ☐ Syrups/oral liquids

|  |
| --- |
|  |

☐ Other: (Please specify)

|  |
| --- |
|  |

1.1.5 Strength per dosage unit:

1.1.6 Route of administration:

 **☐** Oral **☐** I.M. **☐** I.V. **☐** S.C. **☐** Other (Please specify)

1.1.7 Please provide the formulation of the product (complete qualitative and quantitative composition including active ingredient(s), overages if any and excipients). Please also indicate the standard for each ingredient (e.g. BP, USP, in-house). Mention specifically if the product is a fixed-dose combination (FDC) or co-packaged: Information should be included as **Annex A** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).

1.1.8 Please state inactive ingredients (excipients) of medical/pharmaceutical relevance, amount in dosage form or per dosage unit (e.g. contains alcohol 10%, paraben…….) (add lines as needed to table below)

|  |  |
| --- | --- |
| **Inactive ingredients (excipients)** | **Amount per dosage unit** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

* 1. **Packaging (Primary and Secondary) and Product Insert**

 Please provide a copy (PDF file) of the FPP packaging (primary and secondary) and insert for all of the languages identified below. Information should be included as **Annex B** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).

* + 1. Primary packaging:

|  |  |
| --- | --- |
| Description and materials used for primary packaging[[2]](#footnote-2)  |  |
| Pack size (quantity of dosage form units per pack) |  |
| Available Languages | ☐ English ☐ French ☐ Portuguese ☐English/French |

* + 1. Secondary packaging:

|  |  |
| --- | --- |
| Description, pack size and material used for secondary packaging materials |  |
| Available Languages | ☐ English ☐ French ☐ Portuguese ☐English/French |

Product Insert:

|  |  |
| --- | --- |
| Available Languages | ☐ English ☐ French ☐ Portuguese ☐English/French |

* 1. **Manufacturer(s) Identification**
		1. List of all sites involved in the manufacturing process of the FPP (add additional lines as needed)

|  |  |
| --- | --- |
| Site 1 |  |
| Site 2 |  |
| Site 3 |  |

* + 1. For each site described in Section 1.3.1, complete the following table:

|  |  |
| --- | --- |
| Name of manufacturer, contract manufacturer if any |  |
| Reference of manufacturing license, date and expiry date, if any |  |
| Physical address. Please specifyunits, and block if existing |  |
| Telephone number, facsimile number and email contact details |  |
| Responsibilities/Activity (e.g. packaging) |  |

* + 1. For each site described in Section 1.3.1, complete the table under 1.4.
	1. **Supplier Identification** (to be filled in if not identical to that indicated in 1.3)

|  |  |
| --- | --- |
| Name of company |  |
| Physical address (complete details required)  |  |
| Telephone number, facsimile number and email contact details |  |
| Link with the FPP offered | **☐** Marketing license holder **☐** Manufacturer**☐** Distributor/wholesaler **☐** Other |

* 1. **Regulatory (licensing) status of the FPP**

1.5.1 In the country of manufacture. Provide a copy of the license (marketing authorization) as **Annex C** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).

**☐** Product registered and currently marketed

|  |
| --- |
|  |

License no.:

**☐** Product registered for marketing in the country of manufacturing but currently not marketed

|  |
| --- |
|  |

License no.:

**☐** Product not registered *(please clarify)*:

|  |
| --- |
|  |

* + 1. 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) as **Annex D** (See Checklist in Section 9of this Questionnaire for file naming nomenclature). If a CPP cannot be obtained from the National Regulatory Authority (NRA), please state the reason and send an equivalent document if any.

1.5.3 Registration in other countries

* List of countries where the product is registered and has been granted a marketing authorization. At a minimum the list must include: Country and Number and Date of expiration of the Registration/Marketing Authorization (if applicable).
* Additionally for each country where the FPP is registered, the bidder must provide a copy of the marketing authorization issued by the corresponding NRA. Information should be submitted as **Annex E** using the template provided (Annex 7 of the RFQ)(See Checklist in Section 9of this Questionnaire for file naming nomenclature).

1.5.4 WHO prequalification status, if applicable

* Is the FPP offered prequalified by WHO/PQP [[3]](#footnote-3) ?

**☐** Yes **☐** No

* If yes, please attach a copy of the relevant WHO/PQP acceptance letter signed by your company as **Annex F** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).
* If no, has your company submitted the FPP for prequalification?

**☐** Yes **☐** No

* If yes, indicate date of submission, WHO acceptance letter for product dossier review mentioning the WHO reference number assigned by WHO for this specific product as **Annex G** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).

1.5.5 NRA and/or WHO/PQP enforcement actions

* Has the offered FPP, or the product dossier, been subject to any NRA/WHO enforcement actions or deficiency letters within the last 5 years?

**☐** Yes **☐** No

* If yes, provide a short description of the enforcement action and the current status and provide a copy of the manufacturer’s response (i.e. CAPA Plan). Additionally, if available provide proof of resolution issued by the corresponding NRA. Information should be included as **Annex H** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).

**Section 2: Active Pharmaceutical Ingredients**

Special considerations:

* Fixed dose combinations containing more than one API must complete this section for each API;
* If more than one API manufacturer is used this section must be replicated for each API manufacturer.

2.1 **Details of Active Pharmaceutical Ingredient (API)**

2.1.1 Manufacturer

|  |  |
| --- | --- |
| Name of manufacturer |  |
| Physical address. Please specifyunits, and block if existing |  |

* GMP certificate from the country of origin: attach a copy of the GMP certificate, if available, in **Annex I** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).
* Last inspection of API manufacturing site performed, when available (please attach GMP certificate or relevant letter) by:

☐Finished product manufacturer

☐WHO Prequalification Programme, Geneva

☐ EDQM

☐ US FDA

☐ PIC/S members

☐ Others (specify)

☐ None of above

|  |
| --- |
|  |

* Outcomes and date:
* Is/are the API used to manufacture this product WHO-prequalified?

**☐** Yes **☐** No

2.1.2 API specifications

**☐** British Pharmacopoeia (BP) (edition/year):

**☐** United States Pharmacopeia (USP) (edition/year):

**☐** The International Pharmacopoeia (Ph.Int.) (edition/year):

**☐** Others (specify):

* Specifications additional to those in the pharmacopoeia referred to above if available

**☐** Yes **☐** No

* Attach a copy of the FPP manufacturer internal API specifications in **Annex J** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).
* 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 **Annex K** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).
* For sterile API:
	+ Please provide the data on validation of the sterile aspects including recent media fill validation data, as applicable, in **Annex L** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).
	+ Describe the method of sterilization used when applicable:

|  |
| --- |
|  |

2.1.3 Certificate of analysis

* 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 for 3 lots within the last 12 months in **Annex M** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).

2.1.4 Suitability of monograph for API

* Are you in a possession of the Certificate of suitability to the monograph of the European Pharmacopoeia (CEP) for APIs?

**☐** Yes **☐** No

|  |
| --- |
|  |

If yes, Certificate No.:

If yes: please attach a copy of the CEP and its annexes in **Annex N** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).

2.1.5 Open part of drug master file (DMF) registered in (country):

* Do you have a Technical file:

**☐** Yes **☐** No

If yes, please attach a copy as **Annex O** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).

**Section 3: Finished Pharmaceutical Product**

3.1 **Manufacturing site GMP status**

* GMP inspections carried out by an NRA

|  |  |  |
| --- | --- | --- |
|  | NRA of country of origin | Any other inspection ofPIC/S member |
| GMP certificate no. |  |   |  |
| Valid until |   |  |  |
| Country |  |  |  |

* Please attach the recent/valid GMP certificates/letter(s) of compliance in **Annex P** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).
* Other GMP inspections carried out by (include information for all that apply in the last 5 years):

|  |  |  |
| --- | --- | --- |
| Agency | Date of audit | Outcome |
| WHO Prequalification Programme |  |  |
| UNICEF Supply Division |  |  |
| MSF International |  |  |
| ICRC |  |  |
| Other (specify) |  |  |

3.2 **FPP Specifications**

|  |  |  |
| --- | --- | --- |
| Standard | Edition | Year published |
| BP |  |  |
| USP |  |  |
| Ph.Int. |  |  |
| In-house | Year documented |
| Specifications additional to those in the pharmacopoeia referredto above (e.g. dissolution, syringe ability) explain: |  |  |
| Other (specify) |  |  |

* Please attach copies of release and shelf-life specifications for the FPP in **Annex Q** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).
	+ 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 **Annex Q**.
* Please attach a copy of the certificate of analysis for the three last batches released in **Annex R** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).

3.3 **Method of manufacture and process validation:**

* Have the manufacturing methods for each standard batch size been validated?

 **☐** Yes **☐** No

* + If no, please clarify:

|  |
| --- |
|  |

* + If yes, please provide details of validation status in the table below:

|  |  |
| --- | --- |
| The batch size of the validated batches (minimum, maximum size) |  |
| The batch numbers of the validated batches |  |
| Manufacturing dates of the validated batches |  |
| 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 a flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters as **Annex S** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).

3.3.1 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 T** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).

* Describe the method of sterilization used including conditions such as temperature , time, pressure, if applicable:

|  |
| --- |
|  |

3.4 **Stability of FPP:**

3.4.1 Is stability testing data available?

**☐** Yes **☐** No

* Please provide the protocol and the report for accelerated and long-term stability testing, including: type and material of container; conditions (temperature/ relative humidity/duration of stability study); number of batches involved in the study (minimum three); batch sizes for each lot tested; date of beginning of the study; and study conclusions. These can be provided in **Annex U** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).

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

**☐** Yes **☐** No

* If no, describe the differences:

|  |
| --- |
|  |

3.4.3 Please specify whether stability studies have been done or are ongoing with all declared API sources:

**☐** Yes **☐** No

* Submit a declaration in **Annex V** that stability studies have been done or are being done with all declared API sources (See Checklist in Section 9of this Questionnaire for file naming nomenclature).
* If no, explain why:

|  |
| --- |
|  |

3.4.4 Do you have ongoing stability data for this product?

**☐** Yes **☐** No

* Attach status report of any ongoing stability studies in **Annex W** (See Checklist in Section 9 of this Questionnaire for file naming nomenclature).

3.4.5 Shelf-life as it appears on packaging:

 **☐** 2 years **☐** 3 years **☐** 4 years **☐** 5 years **☐** Other (please specify):

3.4.6 Specific storage conditions for this product as they appear on the packaging and based on stability studies (e.g. “Do not store above 30 °C – Protect from light”):

|  |  |
| --- | --- |
| Temperature |  |
| Light |  |
| Humidity |  |
| Other (specify) |  |

3.4.7 Product suitable for use in the following ICH Climatic Zones:

**☐** Zone I

**☐** Zone II

**☐** Zone III

**☐** Zone IVa

**☐** Zone IVb

**☐** Other (please specify):

3.4.8 For oral powder for suspension and powder for injection, or injection that may be further diluted, or multidose containers provide in-use stability data and storage conditions after reconstitution and/or dilution in **Annex X** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).

Indicate the period (hours/days) and storage condition until which the product is stable after reconstitution and/or dilution based on the available in-use stability data:

|  |
| --- |
|  |

3.5 **Manufacturing Production Capacity:**

* Please complete the following tables

|  |
| --- |
| Average batch/lot size:Describe the total number of units manufactured **per** batch/lot  |
| 2013 |  |
| 2014 |  |
| 2015 |  |
| 2016 |  |
| 2017 |  |

|  |
| --- |
| Number of batches/lots manufactured per year |
| 2013 |  |
| 2014 |  |
| 2015 |  |
| 2016 |  |
| 2017 |  |

* Are there any planed changes to the FPP production capacity?

**☐** Yes (Please describe planed changes in box below) **☐** No

|  |
| --- |
|  |

* 1. **Manufacturing Consistency Report:**
* For the offered FPP, do you have an analysis of manufacturing consistency in comparison with approved quality specifications for all lots manufactured in the latest calendar year for this product?

**☐** Yes **☐** No

* Attach manufacturing consistency report in **Annex Y** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).
* If no, explain why:

|  |
| --- |
|  |

**Section 4: Testing the offered FPP**

* 1. **Finished Product Specifications (FPS) and Standard Test Procedure (STP)**

If the offered product requires use of in-house FPS and STP complete the following:

* Has method transfer for the in-house method been performed and transferred to an independent 3rd party QC laboratory?

**☐** Yes **☐** No

Note: Skip section 4.1 and proceed to Section 5 if the offered product has already undergone a method transfer at one

(or more) GHSC-PSM QA designated QC laboratory.

* + - If yes, please list the corresponding independent 3rd party Quality Control Laboratory(ies) and complete the following table:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Lab Name | Address | Contact | Method Version | Date of Transfer |
|  |  |  |  |  |
|  |  |  |  |  |

* Are additional materials (ex: placebos, in-house standards) that are not publicly available required to perform the in-house method?

**☐** Yes **☐** No

* + - If yes, please list the additional materials required that are not publicly available:

|  |
| --- |
|  |

- Does the offeror commit to submitting the FPP in-house test method (if applicable), any materials not publicly available (ex: placebo, in-house standards) and the samples required with performing method transfer to one independent 3rd party QC laboratory as designated by GHSC-PSM (if necessary).

**☐** Yes **☐** No

**Section 5: FPP Annual Product Quality Review (PQR)**

**5.1 FPP Annual Product Quality Review (or equivalent):**

* For the offered FPP submit the latest FPP PQR as an Annex in PDF format with following naming convention:
	+ - [Insert Manufacturer name\_ Formulation\_Dose]

**Section 6: Safety/Efficacy and/or Therapeutic Equivalence[[4]](#footnote-4)**

6.1 **For innovator products:**

* Please attach a summary of pharmacology, toxicology and efficacy of the product in **Annex Z** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).

6.2 **For generic products – therapeutic equivalence:**

**☐** Demonstrated

**☐** Not demonstrated

**☐** Not relevant, please explain why

|  |
| --- |
|  |

* If demonstrated:
	+ Attach graphic/pictorial representation of summary study results in **Annex AA** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).
	+ 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** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).
	+ For bioequivalence studies, indicate the stringent regulatory authority (SRA)/WHO/ PIC/S inspection status of the Contract Research Organization (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** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).
	+ Attach study protocol summary in **Annex AD** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).

6.2.1 By in vivo bioequivalence studies

**☐** Yes **☐** No (explain):

|  |
| --- |
|  |

* 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

|  |  |
| --- | --- |
| 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: |  |

* Study results:

|  |
| --- |
|  |

* Study conclusion:

|  |
| --- |
|  |

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

 **☐** Yes **☐** No (explain):

|  |
| --- |
|  |

* Reference product

|  |  |
| --- | --- |
| Generic name |  |
| Dosage form |  |
| Strength |  |
| Brand/trade name |  |
| Manufacturer |  |
| Manufacture 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:

|  |
| --- |
|  |

* + 1. By another method (please describe the method and the study conclusion, briefly)

**☐** Yes **☐** No (explain):

|  |
| --- |
|  |

6.3 **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 7: Pharmacovigilance**

* For the offered FPP, do you have a recent Periodic Benefit-Risk Evaluation Report (PBRER) or Periodic Safety Update Report (PSUR)[[5]](#footnote-5)?

**☐** Yes **☐** No

* Attach the most recent PBRER or PSUR in **Annex AE** (See Checklist in Section 9of this Questionnaire for file naming nomenclature).
* If no, explain why:

|  |
| --- |
|  |

**Section 8: Certification of Authenticity**

I, the undersigned, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*List full name and current title 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 (dd/mm/yyyy) |  |
| Name |  |
| Title |  |
| Signature |  |

**Section 9: Checklist for the Required Annexes**

Annexes to the questionnaire should be in PDF format and should be well indexed to facilitate review

Please ensure that all documents necessary to enable objective evaluation of your product are attached.

Nomenclature assigned for each Annex must follow the indications in the table below. Bidder can only modify *Manufacturer name* and *Product name*. The table below indicates the text that can be modified, which is marked by the text in parenthesis [ ].

**No other special characters than underscores should be used**.

For the *Product name*, please do not use brand names and include the corresponding INN as specified in Section 1.1 of this Questionnaire.

The number of characters used for naming PDF files must not exceed 60 characters. Abbreviations can be used (i.e. *ALu* instead of Artemether/Lumefantrine).

|  |  |  |
| --- | --- | --- |
| **Annex** | **File Name (PDF required)** | **Submitted\*** |
|  | ***ANNEX LETTER. ANNEX NAME \_[Insert Manufacturer name\_ Insert Product name]*** | **🗹 or N/A** |
| A | A. FORM\_Manufacturer name\_Product name  |  |
| B | B. PACK\_Manufacturer name\_Product name |  |
| C | C. MA declaration\_Manufacturer name\_Product name |  |
| D | D. CPP\_Manufacturer name\_Product name |  |
| E | E. REG\_Manufacturer name\_Product name |  |
| F | F. WHO PQ\_Manufacturer name\_Product name |  |
| G | G. WHO DL \_Manufacturer name\_Product name |  |
| H | H. EA\_Manufacturer name\_Product name |  |
| I | I. API GMP\_Manufacturer name\_Product name |  |
| J | J. API SPC\_Manufacturer name\_Product name |  |
| K | K. API MM\_Manufacturer name\_Product name |  |
| L | L. S-API VAL\_Manufacturer name\_Product name |  |
| M | M. API COA\_Manufacturer name\_Product name |  |
| N | N. API CEP\_Manufacturer name\_Product name |  |
| O | O. API DMF\_Manufacturer name\_Product name |  |
| P | P. FPP GMP\_Manufacturer name\_Product name |  |
| Q | Q. FPS\_Manufacturer name\_Product name |  |
| R | R. FPP COA\_Manufacturer name\_Product name |  |
| S | S. FPP MCP\_Manufacturer name\_Product name |  |
| T | T. S-FPP VAL\_Manufacturer name\_Product name |  |
| U | U. FPP STB\_Manufacturer name\_Product name |  |

|  |  |  |
| --- | --- | --- |
| **Annex** | **File Name (PDF required)** | **Submitted\*** |
|  | ***ANNEX LETTER. ANNEX NAME \_[Insert Manufacturer name\_ Insert Product name]*** | **🗹 or N/A** |
| V | V. STB DEC\_Manufacturer name\_Product name |  |
| W | W. STB ONG\_Manufacturer name\_Product name |  |
| X | X. STB DIL\_Manufacturer name\_Product name |  |
| Y | Y. MCR\_Manufacturer name\_Product name |  |
| Z | Z. IP PTE\_Manufacturer name\_Product name |  |
| AA | AA. TE SUM\_Manufacturer name\_Product name |  |
| AB | AB. TE REP\_Manufacturer name\_Product name |  |
| AC | AC. TE SD\_Manufacturer name\_Product name |  |
| AD | AD. TE PRO\_Manufacturer name\_Product name |  |
| AE | AE. PBRER\_Manufacturer name\_Product name |  |

 \*Document has been submitted: **🗹;** Document does not apply to this FPP: Not Applicable (**N/A)**

We hereby certify all technical proposal requirements included in this list were reviewed, approved and authorized for submission by our quality assurance or regulatory affairs representative.

|  |  |
| --- | --- |
| Date (dd/mm/yyyy) |  |
| Name |  |
| Title |  |
| Signature |  |

1. This document has been modified based on the interagency finished pharmaceutical product questionnaire based on the model quality assurance system for procurement agencies as published in the WHO TRS986 [↑](#footnote-ref-1)
2. For example, HDPE bottle, Alu-Alu strip, neutral glass vial. [↑](#footnote-ref-2)
3. WHO Prequalification website: [http://apps.who.int/prequal/.](http://apps.who.int/prequal/) [↑](#footnote-ref-3)
4. As per WHO Technical Report Series (TRS), No. 902, Annex 11/ TRS No. 937, Annex 7 or recent version [↑](#footnote-ref-4)
5. As per ICH Guidelines: <http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/periodic-benefit-risk-evaluation-report.html> [↑](#footnote-ref-5)