**Please fill out one separate form for each pharmaceutical product**

# Section 1: Administrative Section

## Product identification

* + 1. Active pharmaceutical ingredient(s) (use INN if any):
    2. Generic name of the product:
    3. Trade (proprietary) name (if any):
    4. Dosage form:
* Tablets ☐ Capsules ☐ Injectable ☐ Syrups/oral liquids
* Other: (Please specify)
  + 1. Strength per dosage unit:
    2. Route of administration:
* Oral
* I.M.
* I.V.
* S.C.
* Other (Please specify)
  + 1. 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: **Annex A**
    2. Please state inactive ingredients (excipients) of medical/pharmaceutical relevance, amount in dosage form or per dosage unit (e.g. contains alcohol 10%, paraben…….)

## Packaging

* + 1. Description and materials used for primary packaging2 and pack size (quantity of dosage-form units per pack): **Annex B**
    2. Description, pack size and material used for secondary packaging materials: **Annex C**

# Contact details

## Manufacturer identification

Name, address and activities of the manufacturer and manufacturing site(s) (or contract manufacturer(s):

2 For example, HDPE bottle, Alu-Alu strip, neutral glass vial.

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

## 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:

Fax: Website: Email:

Link with the product

* Marketing licence holder **☐** Manufacturer
* Distributor/wholesaler **☐** Other

## Note for the applicant

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

Has the dossier been submitted to any of the following: ERP, ICRC, MSF, WHO procurement centre, UNFPA, UNICEF?

**☐**Yes **☐**No

Please indicate to which one:

Please provide the date of the submission:

## Regulatory (licencing) status

* + 1. In the country of manufacture. Provide a copy of the licence in **Annex D**
       - Product registered and currently marketed Licence no:
       - Product registered for marketing in the country of manufacturing but currently not marketed

Licence no.:

* + - * Product not registered *(please clarify)* :
* P l e a s e 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.**
* I f a CPP cannot be obtained from the national medicines regulatory authority (NMRA), please state the reason and send an equivalent document if any.
* 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**.
  + 1. In other countries

List other countries where the product is registered and is currently marketed

*(please provide registration number)-*Provide a copy of the licence-**Annex-D**

* + 1. WHO prequalification status, if applicable This product is prequalified by WHO/PQP.3
       - Yes **☐** No

If yes, please attach a copy of the relevant WHO/PQP acceptance letter signed by your

3 WHO Prequalification website: [http://apps.who.int/prequal/.](http://apps.who.int/prequal/)

company in **Annex G**.

* + 1. If submitted for prequalification: indicate date of submission, WHO acceptance letter for product dossier review mentioning the WHO reference number assigned by WHO for this specific product in **Annex H**

## Samples for technical evaluation

* + 1. Samples of finished product and insert information

*You are required to provide a sample of the finished product(s) offered. If you cannot submit with the questionnaire, please state the reason and when you will do so:*

* + 1. Primary packaging label language (attach a copy in **Annex I**):
       - Bilingual English/French
* English
  + French
  + Other (specify)
    1. Secondary packaging label language (attach a copy in **Annex I**):
       - Bilingual English/French
* English
* French
  + Other (specify)
* Multilingual English/French/Spanish

For oral powder for suspension and powder for injection, in-use periods and storage conditions after reconstitution should be stated on the product label/leaflet.

* + 1. Patient information leaflet/Package insert (attach a copy in **Annex J**)
       - Yes **☐** No

# Section 2: Active pharmaceutical ingredients

(If there is more than one active pharmaceutical ingredient or more than one API manufacturer is used, please replicate this section.)

## Details of API used (INN if any)

* + 1. Manufacturer

Manufacturer (name, physical address and country)/manufacturing site:

GMP certificate from the country of origin: attach a copy of the GMP certificate, if available, in

### Annex K.

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
    1. 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 L.

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 M.**

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:

* + 1. 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 in **Annex O.**

* + 1. 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

Certificate of suitability to the monograph of the European Pharmacopoeia (CEP): please attach a copy of the CEP and its annexes in **Annex P1**.

Certificate No.:

* + 1. Open part of drug master file (DMF) registered in (country):

Do you have a Technical file:

* Yes (please attach)-**Annex P2**
* No

# Section 3: Finished pharmaceutical product

## Manufacturing site GMP status

GMP inspections carried out by an NMRA

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

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

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) |  |  |

## Finished pharmaceutical product specification

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

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**.

Please attach a copy of the certificate of analysis for the three last batches released in

### Annex S.

## 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:

* + - * P l e a s e provide in **Annex T** a flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters.
    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**.
       - Describe the method of sterilization used including conditions such as temperature , time, pressure, if applicable:

## Stability of finished product

* + 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 V**.

* + 1. 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:

* + 1. Please specify whether stability studies have been done or are ongoing with all declared API sources:
       - Yes **☐** No

Submit a declaration in **Annex W** that stability studies have been done or are being done with all declared API sources.

If no, explain why:

* + 1. Do you have ongoing stability data for this product?
       - Yes **☐** No

Attach status report of any ongoing stability studies in **Annex X**.

* + 1. Shelf-life as it appears on packaging:
       - 2 years
* 3 years
* 4 years
* 5 years
  + Other (please specify):
    1. 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) |  |  |

* + 1. Product suitable for use in the following ICH Climatic Zones:
       - Zone I
       - Zone II
       - Zone III
       - Zone IVa
       - Zone IVb
       - Other (please specify):
    2. 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 Y**.

Indicate the period (hours/days) a n d s t o r a g e c o n d i t i o n until which the product is stable after reconstitution and/or dilution based on the available in-use stability data:

# Section 4: Safety/efficacy and/or therapeutic equivalence

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

## For innovator products

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

## 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.**
      * P r o v i d e 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**.
      * F o r 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**
    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

Study design (describe in detail):

Number of volunteers:

Country of study:

Contract research organization

|  |  |
| --- | --- |
| Bio batch size: |  |
| Bio batch number: |  |
| Bio batch API(s) source(s): |  |
| Study conclusion: |  |

Study results: Study conclusion:

* + 1. 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):

## 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: Commitment and authorization

## 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:

## 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 AE**.

## Authorization for sharing information with other agency

I, the undersigned confirm that the company has no objection to the information contained herein being shared with the agencies listed in clause 1.5 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: Attachments/annexes

Attachments or 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. This checklist may not be exhaustive.

* + - A. Formulation of the product (complete qualitative and quantitative composition including active ingredient(s) and excipients (1.1.7)
    - B. Description and composition of primary packaging materials (1.2.1)
    - C. Description and composition of secondary packaging materials (1.2.2)
    - D. Copy of product registration and market status– Licence No (1.6.1)
    - E. Certificate of pharmaceutical product (CPP) according to the WHO Certification

Scheme (WHO Technical Report Series, No. 863. An earlier version is not acceptable) (1.6.1)

* + - F. Recent as well as historical deficiency/acceptance letters issued by PQP/SRA in relation to the specific product dossier (1.6.1)
    - G. Copy of the relevant WHO Prequalification acceptance letter signed by your company (1.6.3)
    - H. WHO acceptance letter for product dossier review mentioning the WHO reference number assigned by WHO for this specific product (1.6.4)
    - I. Copy of primary and secondary packaging/label (1.7.1)
    - J. Patient information leaflet/package insert (1.7.4)
    - K. GMP certificate of the API manufacturer(s) from the country of origin (2.1.1)
    - L. Copy of the internal API(s) specification(s) (2.1.2)
    - M. Validated analytical methods if analytical methods for API are in-house analytical method, different from BP, USP and Ph.Int. (2.1.2)
    - N. Data on validation of the sterile aspects of the product including recent media fill validation data, as applicable (2.1.2)
    - O. Copy of the certificate(s) of analysis of the API from the API manufacturer as well as from the FPP manufacturer (2.1.3)
    - P1. Copy of the certificate of suitability to the European Pharmacopoeia (CEP) and its annexes (2.1.4)
    - P2.AttachacopyoftheTechnical file (2.1.5)
    - Q. Recent/valid GMP certificates/letter of compliance of the FPP manufacturer (3.1)
    - 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 (3.2)
    - S. Copy of the certificate of analysis for the three last batches released (3.2)
    - T. Flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters (3.3)
    - U. Data on validation of the sterile aspects of the product including recent media fill validation data as applicable (3.3.1)
    - V. Protocol and report for accelerated and long-term stability testing (3.4.1)
    - W. Declaration that stability studies have been done or are being done with all declared API sources (3.4.3)
    - X. Status report of any ongoing stability studies (3.4.4)
    - 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 (3.4.8)

* + - Z. Summary of pharmacology, toxicology and efficacy of the product (4.1)
    - AA. Graphic/pictorial representation of summary study results (4.2.3)
    - AB. Copy of the report of the proof of therapeutic equivalence (BE study) comparative dissolution profile, dissolution tests, and others if any (4.3)
    - AC. Schematic representation of study design (4.3)
    - AD. Study protocol summary (4.3)
    - AE. Copy of the power of attorney (5.2)