**Appendix 1 to Annex C – Terms of Reference (TOR)**

**UNRWA Quality Assurance Policy For Pharmaceutical Products**

**QUESTIONNAIRE A:**

**Production Information Questionnaire for Pharmaceutical Products approved by WHO/SRA/PIC.s/Other UN Agencies**

**Questionnaire A:**

**Product Information Questionnaire for Pharmaceutical Products approved by WHO/SRA/PIC.s/other UN Agencies**

**Please complete all the fields in the Questionnaire as required and attach the requested supporting documents.**

**Part 1: MANUFACTURER/SUPPLIER CONTACT DETAILS**

Name of manufacturer:

Name of Supplier (if different from manufacturer):

Physical address of office (include Block number, line number etc.):

Physical address of manufacturing plant:

Postal address:

|  |  |
| --- | --- |
| City: | Country: |
| Telephone: | Fax: |
| E-mail: | Website: |

**Part 2: FINISHED PHARMACEUTICAL PRODUCT**

Please fill out one form separately for each pharmaceutical product

1. **IDENTIFICATION**

|  |  |  |  |
| --- | --- | --- | --- |
| Content | Active Pharmaceutical Ingredient | Amount in dosage form or amount per unit | \*Pharm. form and admin route(s) |
| Active Ingredient 1 |  |  |  |
| Active Ingredient 2 (if applicable) |  |  |  |

\*Pharmaceutical forms (Use all that apply from the selection below)

Inactive Ingredients (excipients) of medical/pharmaceutical relevance, amount in dosage form or per dosage unit (e.g. Contains Alcohol 10%):

Dosage form (tick whichever is applicable):

* **Tablets**
  + Uncoated
  + Sugar coated
  + Film coated
  + Enteric coated
* **Capsules**
* **Syrup/oral liquids**
* **Injection**
  + Microcrystalline Suspension
  + Oily Solution
  + Aqueous Solution
  + Powder for injection
* **Implants**

Route of administration (tick whichever is applicable):

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

A. Include sample of the Finished Pharmaceutical Product with the CoA of the sample.

B. Attach package insert if applicable and patient information leaflet (PIL). Kindly note that SRA or WHO PQT approval must be attached.

1. **PACKAGING**

Number of dosage units per primary packs:

Numbers of primary packs per secondary pack (Multiples of unit packs):

(Fill the below if more than one type of packaging)

Number of dosage units per primary packs:

Numbers of primary packs per secondary pack (Multiples of unit packs):

Number of dosage units per primary packs:

Numbers of primary packs per secondary pack (Multiples of unit packs):

Description and composition of primary packaging materials:

Description and composition of secondary packaging materials:

1. **SHELF LIFE and STORAGE CONDITIONS**

Shelf life as it appears on the packaging:

Shelf life after primary package is opened:

Specific storage conditions for this product as they appear on the packaging and based on stability studies:

Temperature:

Light:

Humidity:

Other (Specify):

1. **REGULATORY STATUS**

Certificate of Pharmaceutical Product No.:

Valid until:

CPP issued by (Name of Agency):

Country:

C. Attach Certificate of Pharmaceutical Product (CPP) according to the WHO Certification Scheme-WHO Technical Report Series No. 863 (earlier version is not acceptable) or equivalent document. All questions on the certificate should be answered and all attachments included.

Tick and fill in all fields that apply:

|  |  |
| --- | --- |
| Product registered and currently marketed in the country of manufacture | |
| License no: | Valid until: |
| Issued by: Agency: | Country: |
| Product registered for marketing in the country of manufacture but not currently marketed: | |
| License no: | Valid until: |
| Issued by: Agency: | Country: |
| Product registered for export only | |
| License no: | Valid until: |
| Issued by: Agency: | Country: |

Product not registered in country of manufacture (please clarify):

D. Attach a list of countries where product is registered, including the specific product name and license number in each country.

E. Copy of registration certificate from Stringent Regulatory Authority OR Approval Letter from WHO Prequalification Team.

**Part 3: MANUFACTURER INFORMATION**

1. **GOOD MANUFACTURING PRACTICES (GMP)**

|  |  |
| --- | --- |
| WHO GMP certificate no: | Valid until: |
| Issued by: | Country: |

GMP inspections carried out by (tick all that apply):

WHO Prequalification Programme Date:       Outcome:

Stringent Regulatory Authority (SRA) Date:       Outcome:

PIC/s member country Date:       Outcome:

Any other UN agency Date:       Outcome:

F. Copy of GMP certificate by WHO/SRA/PIC.s/UN agency

**Part 4: COMMITMENT**

I (Full Name) , certify that:

The product offered is identical in all aspects (i.e. manufacturing, in-process controls, API specifications, in-process specifications, FPP specifications, manufacturing site, labelling, packaging etc.) to that registered and marketed

in       *(name of country) OR* WHO Pre-Qualified by the WHO Prequalification Team*.*

|  |  |  |
| --- | --- | --- |
| Signature: |  | Date: |
| Position: |  | Stamp here: |

**Annex: Checklist of attachments required**

Please attach the following annexes to the questionnaire:

Annex A. Sample of the Finished Pharmaceutical Product with the CoA of the sample.

Annex B. Package Insert if applicable and Patient Information Leaflet (PIL) with evidence of SRA or WHO Pre-Qualification Team approval

Annex C. Certificate of Pharmaceutical Product (CPP) according to the WHO Certification Scheme-WHO Technical Report Series No. 863.

Annex D. List of countries where product is registered, including the specific product name and license number in each country.

Annex E. Registration certificate from SRA[[1]](#footnote-1) or Approval Letter from WHO Pre-Qualification Team.

Annex F. Copy of GMP certificate by WHO/SRA1 /PIC.s/UN agency

**Appendix 1 to Annex C – Terms of Reference (TOR)**

**UNRWA Quality Assurance Policy For Pharmaceutical Products**

**QUESTIONNAIRE B:**

**Production Information Questionnaire for Pharmaceutical Products NOT approved by WHO/SRA/PIC.s/Other UN Agencies**

**Questionnaire B:**

**Product Information Questionnaire for Pharmaceutical Products Not approved by WHO/SRA/PIC.s/other UN Agencies**

UNRWA Product Information Questionnaire for Pharmaceutical Products not approved by WHO/SRA/PIC.s/other UN agency

This questionnaire should be filled by suppliers whose products are NOT approved by WHO or SRA/PICS country NDRA or any other UN agency.

Please do not fill this questionnaire if your product is approved by any of the above mentioned authorities.

Please fill out one separate form for each pharmaceutical product.

**Part 1: Administrative Section**

1. **Product Identification**
   1. Active pharmaceutical ingredient(s) (use INN if any):
   2. Generic name of the product:
   3. Dosage form:

☐ Tablets ☐ Capsules ☐ Injectable ☐ Syrups/oral liquids ☐ Other: (Please specify)

* 1. Strength per dosage form
  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…….):

1. **Packaging**
   1. Description and materials used for primary packaging [[2]](#footnote-2) and pack size (primary packs/secondary packs): Provide all types of packaging available and pack size offered. **Annex B**
   2. Description, pack size and material used for secondary packaging materials: **Annex C**
2. **Manufacturer identification:** (Name, address and activities of the manufacturer and manufacturing site(s) (or contract manufacturer(s))

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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) |
|  |  |  |  |  |
|  |  |  |  |  |

1. **Supplier Identification** (to be filled in if not identical to that indicated in 3 above)

Name of company:

Physical address (complete details required):

Telephone number:

Fax:

Website:

Email:

Link with the product

|  |  |
| --- | --- |
| ☐ Marketing license holder | ☐ Manufacturer |
| ☐ Distributor/Wholesaler | ☐ Other |

1. **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. You are required to submit the sample along with the filled questionnaire. This is a mandatory requirement.*

* 1. Primary packaging label language (attach a copy in **Annex D**):

☐ Bilingual English/Arabic ☐ English ☐ Arabic ☐ other (specify)

* 1. Secondary packaging label language (attach a copy in **Annex D**):

☐ Bilingual English/Arabic ☐ English ☐ Arabic ☐ other (specify)

* 1. Patient information leaflet/Package insert (attach a copy in **Annex E**).

☐ Yes ☐ No

**Part 2: Regulatory Status**

1. **In the country of manufacture, provide a copy of the license in Annex F.**

☐ 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):

* 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 G.**
* If a CPP cannot be obtained from the national medicines regulatory authority (NMRA), please state the reason and send an equivalent document if any.

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 license - **Annex H.**

**Part 3: Active Pharmaceutical Ingredients**

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

1. **Details of API used (INN if any)** 
   1. Manufacturer (name, physical address and country)/manufacturing site:
   2. GMP certificate from the country of origin: attach a copy of the GMP certificate, if available, in **Annex I.**
   3. Last inspection of API manufacturing site performed, when available (please attach GMP certificate or relevant letter) by:

☐ Finished Product Manufacturer

☐ EDQM

☐ US FDA

☐ PIC.s Member

☐ Other (specify)

☐ None of the above

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

☐ Yes ☐ No

1. **API Specification**

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

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

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

☐ European Pharmacopeia (edition/year)

☐ Others (specify):

* 1. 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 J.**

**Part 4: Finished Pharmaceutical Product**

1. **Manufacturing site GMP status**

GMP inspections carried out by an NMRA

|  |  |
| --- | --- |
| NMRA of country of origin |  |
| GMP certificate no. |  |
| Valid until |  |
| Country |  |

* 1. Please attach the recent/valid GMP certificates/letter(s) of compliance in **Annex K.**
  2. Other GMP inspections carried out by (include information for all that apply in the last 5 years, e.g. inspections conducted by NMRA of other countries (should not be SRA/PICS)):

|  |  |  |
| --- | --- | --- |
| **Agency** | **Date of Audit** | **Outcome** |
|  |  |  |
|  |  |  |

1. **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) |  |  |

* 1. 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 L**.
  2. Please attach a copy of the certificate of analysis for the three last batches released in **Annex M.**

1. **Stability of finished product**
   1. Is stability testing data available?

☐ Yes ☐No

* 1. 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 N.**
  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:

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

☐ Yes ☐ No

Submit a declaration in **Annex O.** 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

* 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):

* 1. For oral powder for suspension and powder for injection, or injection that may be further diluted, or multi-dose containers provide 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:

**Part 5: Commitment and Authorization**

1. Commitment

I, the undersigned, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (position in the company, *e.g. General Manager, Authorised Person, Responsible Pharmacist*), acting as responsible for the company \_\_\_\_\_\_\_\_\_\_ (*name of 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 excipients 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.

|  |  |
| --- | --- |
|  |  |
| Bidder (Company Name): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Authorized Representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  Stamp: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

1. Power of Attorney

The manufacturer authorizes a distributor/wholesaler to submit the questionnaire

|  |  |
| --- | --- |
| Date: | Signature: |
| Company stamp | |

Distributor/Wholesaler (Signed by Distributor for Manufacturer under power of attorney), please provide a copy of the power of attorney in **Annex P.**

|  |
| --- |
|  |

**Part 6: Attachments/Annexes**

Please attach the following annexes to the questionnaire:

* Annex A. Formulation of the product (complete qualitative and quantitative composition including active ingredient(s) and excipients (Part 1-Para 1.6)
* Annex B. Description and composition of primary packaging materials (Part1- Para 2.1)
* Annex C. Description and composition of secondary packaging materials (Part1- Para 2.2)
* Annex D. Copy of primary and secondary packaging/label (Part1- Para 5.2, 5.3)
* Annex E. Patient information leaflet/package insert (Part1- Para 5.4)
* Annex F. Copy of product registration and market status– License No (Part2- Para 1)
* Annex G. Certificate of pharmaceutical product (CPP) according to the WHO Certification Scheme (WHO Technical Report Series, No. 863. An earlier version is not acceptable) (Part2- Para1)
* Annex H. List of countries where the product is registered and is currently marketed (Part2-Para 2)
* Annex I. GMP certificate of the API manufacturer(s) from the country of origin (Part3- Para 1.2)
* Annex J. Validated analytical methods if analytical methods for API are in-house analytical method, different from BP, USP and Ph.Int. (Part 3- Para 2.1)
* Annex K. Recent/valid GMP certificates/letter of compliance of the FPP manufacturer (Part 4-Para 1.1)
* 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 (Part4- Para 2.1)
* Annex M. Copy of the certificate of analysis for the three last batches released (Part4- Para 2.2)
* Annex N. Protocol and report for accelerated and long-term stability testing (Part4- Para 3.2)
* Annex O. Declaration that stability studies have been done or are being done with all declared API sources (Part4- Para 3.4)
* Annex P. Copy of the power of attorney (Part 5- Para 2)

1. The national drug regulatory authorities which are members or observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) are considered as Stringent Regulatory Authority (SRA). For details on ICH, please look at [www.ich.org](http://www.ich.org) [↑](#footnote-ref-1)
2. For example, HDPE bottle, Alu-Alu strip, neutral glass vial. [↑](#footnote-ref-2)