UNFPA Questionnaire for

Pharmaceutical Products SRA approved

Please complete all the fields in the questionnaire as required and attach the requested support documents.

1. **MANUFACTURER CONTACT DETAILS**

Name of manufacturer:

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

Postal address:

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

**SECTION 1: FINISHED DRUG 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%):

Brand/trade name (if any):

Dosage form:

* **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:

⬜ 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 evidence of approval must be attached.

1. **PACKAGING**

Number of dosage units per unit packs:

Numbers of unit 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):

C. Attach copy of the certificate of analysis for the 3 most recently released batches.

1. **REGULATORY STATUS**

Certificate of Pharmaceutical Product No.:       Valid until:

CPP issued by (Name of Agency):       Country:

D. Attach 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.

E. When CPP is not available attach official statement of licensing status.

1. **LICENSING STATUS**

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):

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

G. Copy of registration certificate from Stringent Regulatory Authority OR Approval Letter from WHO PQT

**SECTION 2: MANUFACTURER**

1. **GOOD MANUFACTURING PRACTICE (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:

H. Copy of GMP certificate by SRA OR the most recent WHOPIR.

**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, labeling, packaging etc.) to that registered and marketed

in       *(name of country) OR* WHO Prequalified by the WHO Prequalification Team*.*

|  |  |  |
| --- | --- | --- |
| Signature: |  | Date: |

|  |  |  |
| --- | --- | --- |
| Position |  | Stamp here: |

**Annex: Checklist of attachments required**

Please ensure that all documents necessary to enable objective evaluation of your product are attached. This checklist may not be exhaustive.

A. Sample of the finished product(s) offered together with COA.

B. Package insert/leaflet as approved by the SRA or WHO PQT.

C. Copy of the certificate of analysis for the 3 last batches released.

D. Certificate of Pharmaceutical Product (CPP) according to the WHO Certification Scheme.

E. When CPP is not available attach official statement of licensing status.

F. Product registration list, including name and license number in each country.

G. Copy of registration certificate from a Stringent Regulatory Authority, SRA\*

H. Copy of GMP certificate by SRA OR the most recent WHOPIR \*

\* 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.