**ANNEX 3**

**UNFPA Questionnaire for**

**Pharmaceutical Products under FTP**

**Please complete all the fields in the questionnaire as required and attach the requested supporting documents. Please fill out one form separately for each pharmaceutical product.**

1. **MANUFACTURER DETAILS**

 Name of manufacturer:

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

|  |  |
| --- | --- |
| City:        | Country:       |
| Telephone:       | Fax:       |
| E-mail:       | Website:       |
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A. Include a copy of registration certificate or evidence that the product is registered in the country of intended use.

**2) FINISHED DRUG PRODUCT**

1. **IDENTIFICATION**

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| --- | --- | --- |
| Content | Active Pharmaceutical Ingredient | Amount in dosage form or amount per unit (Strength) |
| Active Ingredient 1 |       |       |
| Active Ingredient 2 (if applicable) |       |       |

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

Brand/trade name (if any):

Dosage form (select below):

* **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 (select below):

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

1. **PACKAGING**

Number of dosage units per unit packs:

Description of primary packaging materials:

B. Attach package insert and/or patient information leaflet (PIL).

C. Picture/photo of the finished pharmaceutical product and labelling.

D. Certificate of analysis for at least one recently released batch (not more than 1 year old).

1. **SHELF LIFE and STORAGE CONDITIONS**

Shelf life as it appears on the packaging:

Temperature:

Light:

Humidity:

Other (Specify):

1. **REGULATORY STATUS**

Registration Number of Pharmaceutical Product:       Valid until:

Regulatory issued by (Name of Agency):       Country:

E. Valid GMP certificate for Finished Pharmaceutical Products (FPP).

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**3) DECLARATION BY BIDDER/MANUFACTURER**

F. Filled out declaration from bidder/manufacturer.

[*Company letterhead*]

**Declaration by bidder/manufacturer**

I, the undersigned certify that all the information in this declaration and all accompanying documentation is correct and updated. I further certify that I have examined the following statements and I attest to their accuracy.

1. The holder of the national registration follows national requirements for handling adverse reaction on its products.
2. The holder of the national registration follows national requirements for handling batch recalls of its products.
3. The formula to be supplied is exactly the same as the formula approved by National Regulatory Authority (NRA), ………… *(insert name of NRA)*. The strength, specifications (API, excipients and FPP), etc. are exactly the same as the formula approved NRA.
4. The primary packaging is exactly the same in all aspects, including specifications, as the primary packaging approved for use in the same product as approved by the NRA .
5. The secondary packaging is exactly the same in all aspects, including specifications, as the primary packaging approved for use in the same product as approved by the NRA.
6. The information in the questionnaire/dossier submitted to UNFPA contains information which is the same as the information in the dossier which is approved by the NRA.
7. The package insert, summary of product characteristics, patient information leaflet submitted in the submission are the same as those approved by the NRA.
8. Where there are 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, patient information leaflet, I have stipulated these and the justification for the changes in a separate document and submitted to UNFPA.

Name: Signature:

Position in Company: Date:

**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. Copy of the registration certificate or evidence that the product is registered in the country of intended use.

☐ B. Package insert and patient information leaflet (PIL).

☐ C. Picture/photo of the finished pharmaceutical product and labelling.

☐ D. Certificate of analysis for at least one recently released batch (not more than 1 year old).

☐ E. Valid GMP certificate for Finished Pharmaceutical Product (FFP).

☐ F. Filled out declaration from bidder/manufacturer.