**SECTION 4**

**Criteria for award and checklist of documents required**

Following documents should be attached to the filled-in sections #4-8

Please ensure that all documents necessary to enable objective evaluation are attached to your response to this ITB:

| **Award Criteria** | **Corresponding document** | **Yes** | **No** | **Reference** |
| --- | --- | --- | --- | --- |
| **Compliance of Bidder with Qualifications Requirements** | | | | |
| Minimum 3 years of experience in similar nature and minimum 2 similar contracts fulfilled over the past 3 years | 1. Certificate of Registration of the business, including Articles of Incorporation, or equivalent document if Bidder is not a corporation |  |  |  |
| 2. Statement of Satisfactory Performance (Reference letters) from the Top 3 Clients in terms of Contract Value the past 3 years. Please provide reference letters to prove experience in similar nature of contracts |  |  |  |
| Minimum annual turnover over the past 2 years shall equal to no less than 75% of the total amount to be contracted | 3. Latest Audited Financial Statement (Income Statement and Balance Sheet) including Auditor’s Report for the past 2 years |  |  |  |
| **Compliance of product/quoted with product standards and requirements (please complete checklist for each product quoted)** | | | | |
| The product(s) will be procured on the following options (please refer for details to Section 3, para #2 Product Standards):  **OPTION 1: A+E** A) Approved/registered by a Stringent National Medicines Regulatory Authority (SRA) as defined by WHO  AND E) The product is being manufactured at sites with valid WHO Public Inspection Report (WHOPIR) or GMP Certificate issued by PIC/S authorities  OR  **OPTION 2: B+E**  B) Prequalified by World Health Organization  AND E) The product is being manufactured at sites with valid WHO Public Inspection Report (WHOPIR) or GMP Certificate issued by PIC/S authorities  **OPTION 3: C+E**  C) Recommended by the WHO Expert Review Panel for the Global Fund (also known as Global Fund ERP)  AND E) The product is being manufactured at sites with valid WHO Public Inspection Report (WHOPIR) or GMP Certificate issued by PIC/S authorities  **OPTION 4: D+E (for Lots #2-4 and 6 only)**  D) Medicine’s quality will be found compliant with UNDP internal QA policy against WHO norms and standards for pharmaceutical preparations conducted by UNDP after bid submission  AND  E) The product is being manufactured at sites with valid WHO Public Inspection Report (WHOPIR) or GMP Certificate issued by PIC/S authorities | A) A copy of valid Registration/Approval of Stringent National Medicines Regulatory Authority (SRA) as defined by WHO |  |  |  |
| B) WHO pre-qualification evidence |  |  |  |
| C) Approval of the WHO Expert Review Panel for the Global Fund (also known as Global Fund ERP) |  |  |  |
| D)  1) Filled-in Interagency finished product questionnaire attached as Annex 5 with copies of requested documents,  2) Letter on Acceptance for Assessment for FPP pre-qualification by WHO (if available) and  3) list of previous supplies of product/s quoted |  |  |  |
| E) A copy of valid WHO Public Inspection Report (WHOPIR) or GMP Certificate issued by PIC/S authorities for the manufacturing site(s) of the proposed product(s)  Please provide information manufacturing site, including concrete manufacturing unit/block in the Form 7 Technical Bid Form. |  |  |  |
| FOR LOTS: 1-4 only  Availability of valid registration in Ukraine at the time of supply as defined in Section 3, para #3, Registration/Authorization for use in Ukraine (if, at the moment of the bid submission, the quoted medicinal products are not registered in Ukraine but comply with the quality requirements of this ITB, a Commitment letter shall be provided) | Option A: A copy of a valid registration certificate for every medicinal product quoted issued by the Ministry of Health of Ukraine. If a bid is submitted less than 90 days prior to the product’s registration expiration date, a letter issued by MoH confirming the application and documents package for renewal by the owner must be provided at the time of the submission as part of the documents package |  |  |  |
| Option B: If, at the moment of the bid submission, the quoted medicinal products are not registered in Ukraine but comply with the quality requirements of this ITB, a Commitment letter (Annex 2) from the bidder acknowledging acceptance of the terms and conditions for undertaking a simplified registration procedure (see Section 3a, para #3 Registration/Authorization for use in Ukraine for details) and confirming the ability to comply with submitting the package of documents for state registration will be required.  By submitting the Bid, the Bidder automatically agrees to maintain and renew registration of these products until their shelf life expiration. |  |  |  |
| Compliance with shelf life, packing and labelling requirements (please refer for details to Section 3 of ITB). | Please provide Information on shelf life in the Form 7 Technical Bid Form |  |  |  |
| Acceptability of the Transportation/Delivery Schedule (please refer for details to Section 3 of ITB) | Please provide Information on delivery schedule in the Form 7 Technical Bid Form |  |  |  |

| **List of other documents required for evaluation of Offeror** | **Yes** | **No** | **Reference** |
| --- | --- | --- | --- |
| Company profile (maximum 5 pages) or link to company’s web-site |  |  |  |
| List of Shareholders and Other Entities Financially Interested in the Firm owning 5% or more of the stocks and other interests, or its equivalent if Offeror is not a corporation |  |  |  |
| Valid Certificate of Authorization to act on behalf of the Manufacturer in case the Offeror is not a Manufacturer as per template provided in the Annex 3. |  |  |  |
| All information regarding any past and current litigation during the last five (5) years, in which the Offeror is involved, indicating the parties concerned, the subject of the litigation, the amounts involved, and the final resolution if already concluded. |  |  |  |
| Quality Certificate (e.g., ISO, etc.) and/or other similar certificates, accreditations, awards and citations received by the Offeror, if any |  |  |  |
| Environmental Compliance Certificates, Accreditations, Markings/Labels, and other evidences of the Offeror’s practices which contributes to the ecological sustainability and reduction of adverse environmental impact (e.g., use of non-toxic substances, recycled raw materials, energy-efficient equipment, reduced carbon emission, etc.), either in its business practices or in the goods it manufactures, if any available |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **List of other documents required for evaluation of product quoted (please complete checklist for each product quoted)** | **Yes** | **No** | **Reference** |
| Instruction for the medical use in accordance with the legislation of Ukraine (lots #1-4), Kazakhstan (lots #5-6). In case quoted medicines are not registered, instructions for the use in the original language shall be provided (which is compliant with one accompanied to SRA approval/registration). |  |  |  |
| A copy of the Certificate of Pharmaceutical Product (COPP) from the national regulatory body in the country of manufacture for each product shall be provided. If available WHO type COPPs for products being imported into the countries within WHO certification Scheme are requested to be provided. |  |  |  |
| The Bidder which applies with the patented product shall inform UNDP and provide respective patent certificate/s. The Bidder which have relevant license/s (for example, voluntary license/s) shall provide them.  Every patent case will be assessed by UNDP separately and decision will be made upon additional verification and analysis of existing patent/s and local legislation. |  |  |  |

**Annex 1**

**BRIEF SUMMARY (FOR LOTS #1-4)**

**1. On the simplified procedure of state registration of medicinal products procured with involvement of the international organizations**

The procedure of state registration (re-registration) of medicinal products was approved by the Cabinet of Ministers of Ukraine Resolution No. 376 of 26.05.2005.

State registration of the medicinal products procured by international organizations is provided by the Ministry of Health of Ukraine pursuant to an application and subject to an opinion of the MoH State Expert Centre (hereinafter referred to as the Centre) drawn up on the basis of results of the expert examination of the registration materials for their authenticity, conducted according to the procedure specified by the MoH of Ukraine.

Information on the procedures for state registration may be found under the below links:

1. Law of Ukraine "On Medicines"

<http://zakon2.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80>

2. Decree of the Cabinet of Ministers of Ukraine dated 26.05.2005 № 376

<http://zakon5.rada.gov.ua/laws/show/376-2005-%D0%BF>

3. Decree of MOH of Ukraine dated 03.11.2015 № 721

<http://zakon2.rada.gov.ua/laws/show/z1453-15>

**2. On additional relevant information on VAT for bidders. This information is provided for references only and UNDP should not be hold accountable for any details. Bidders are encouraged to check the details with relevant authorities directly.**

Operations on supply (transfer) of pharmaceuticals and medical products shall be temporarily, until March 31, 2019, exempt from VAT, if importation and/or supply is done under contracts with specialized procurement organizations listed in the Law of Ukraine ‘On Public Procurement’, concluded with the objective of implementing agreements between the central executive body of Ukraine in charge of developing and implementing the national health policy and a relevant specialized procurement organization within the framework of budget programmes for implementation of public health action plans and/or comprehensive programme activities in the health sector.

Provided VAT exemption condition may not be applied under the Ukrainian legislation. VAT amount should be clearly indicated in a separate line (if applicable).

For more information on VAT exemption, please refer to the following legislation documents:

1. Tax Code of Ukraine, Chapter #XX Transitional Provisions, Section #2; Paragraph #38 on conditions of temporary VAT exemption of medicines that are procured by specialized organizations for the National Public Health Programme to the Ministry of Health (MoH) in Ukraine: <http://zakon2.rada.gov.ua/laws/show/2755-17/page45>

2. Decree of the Cabinet of Ministers of Ukraine #1153 dated 02.12.2015 on the procedures of importation, supply and targeted use of medicines, medical devices that are VAT exempted:

<http://zakon3.rada.gov.ua/laws/show/1153-2015-%D0%BF>

***Prices specified shall remain firm and not be increased. In case Offeror increase price after awarding contract, UNDP will consider this as a ground for contract termination, liquidating Bid or Performance Security amount and either awarding the next qualified Bidder or initiating a new bidding process.***

**Annex 2.**

**Commitment letter (FOR LOTS #1-4)**

*(This should be written in the Letterhead of the Bidder. Except for indicated fields, no changes may be made in this template.)*

Insert: Location

Insert: Date

To: [*insert: Name and Address of UNDP focal point]*

Dear Sir/Madam:

We, the undersigned, hereby offer to supply the goods required for [*insert: title of goods and services required as per ITB*] in accordance with your Invitation to Bid dated  **.**

We hereby commit to register the below listed products with Ukrainian registration authorities as the current legislation requires.

Products:

1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. ….

We fully understand and recognize that UNDP is not bound to accept this Bid, that we shall bear all costs associated with its preparation and submission, registration fees and that UNDP will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the evaluation.

We remain,

Yours sincerely,

Authorized Signature [*In full and initials*]:

Name and Title of Signatory:

Name of Firm:

Contact Details:

*[please mark this letter with your corporate seal, if available]*

**Annex 3**

**Certificate of Authorization**

**to act on behalf of the Manufacturer in case the Bidder is not a Manufacturer**

*(This should be written in the Letterhead of the Manufacturer. Certificate shall cover all items for which the company is bidding)*

Insert: Location

Insert: Date

To: [*insert: Name and Address of UNDP focal point]*

Dear Sir/Madam:

We, the undersigned, who is established manufacturer or producer of [*insert name of products*], hereby authorize [*name and address of Bidder*] to submit a Bid, and subsequently sign and implement the contract, against the [*insert: title of goods and services required as per ITB*] for the supply of following products:

Products:

1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. ….

For and on behalf of Manufacturer or Producer:

Yours sincerely,

Authorized Signature [*In full and initials*]:

Name and Title of Signatory:

Name of Firm:

Contact Details:

Section 5

Bid Submission Form

*(This should be written in the Letterhead of the Bidder. Except for indicated fields, no changes may be made in this template.)*

Insert: Location

Insert: Date

To: [*insert: Name and Address of UNDP focal point]*

Dear Sir/Madam:

We, the undersigned, hereby offer to supply the goods and related services required for [*insert: title of goods and services required as per ITB*]in accordance with your Invitation to Bid dated  **.**We are hereby submitting our Bid, which includes the Technical Bid and Price Schedule.

We hereby declare that:

1. All the information and statements made in this Bid are true and we accept that any misrepresentation contained in it may lead to our disqualification;
2. We are currently not on the removed or suspended vendor list of the UN or other such lists of other UN agencies, nor are we associated with, any company or individual appearing on the 1267/1989 list of the UN Security Council;
3. We have no outstanding bankruptcy or pending litigation or any legal action that could impair our operation as a going concern; and
4. We do not employ, nor anticipate employing, any person who is or was recently employed by the UN or UNDP.

We confirm that we have read, understood and hereby fully accept the Schedule of Requirements and Technical Specifications describing the duties and responsibilities required of us in this ITB, and the General Terms and Conditions of UNDP’s Standard Contract for this ITB.

We agree to abide by this Bid for **120 days***.*

We undertake, if our Bid is accepted, to initiate the supply of goods and provision of related services not later than the date indicated in the Data Sheet.

We fully understand and recognize that UNDP is not bound to accept this Bid, that we shall bear all costs associated with its preparation and submission, and that UNDP will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the evaluation.

We remain,

Yours sincerely,

Authorized Signature [*In full and initials*]:

Name and Title of Signatory:

Name of Firm:

Contact Details:

*[please mark this letter with your corporate seal, if available]*

Section 6

Documents Establishing the Eligibility and Qualifications of the Bidder

Bidder Information Form

Date: *[insert date (as day, month and year]of Bid Submission*]

ITB No.: *[insert number of bidding process]*

Page \_\_\_\_\_\_\_\_of \_\_\_\_\_\_\_\_ pages

|  |  |  |
| --- | --- | --- |
| 1. Bidder’s Legal Name *[insert Bidder’s legal name]* | | |
| 2. In case of Joint Venture (JV), legal name of each party: *[insert legal name of each party in JV]* | | |
| 3. Actual or intended Country/ies of Registration/Operation: *[insert actual or intended Country of Registration]* | | |
| 4. Year of Registration in its Location: *[insert Bidder’s year of registration]* | | |
| 5. Countries of Operation | 6. No. of staff in each Country | 7.Years of Operation in each Country |
| 8. Legal Address/es in Country/ies of Registration/Operation:*[insert Bidder’s legal address in country of registration]* | | |
| 9. Value and Description of Top three (3) Biggest Contract for the past five (5) years | | |
| 10. Latest Credit Rating (Score and Source, if any) | | |
| 11. Brief description of litigation history (disputes, arbitration, claims, etc.), indicating current status and outcomes, if already resolved. | | |
| 12. Bidder’s Authorized Representative Information  Name: *[insert Authorized Representative’s name]*  Address: *[insert Authorized Representative’s Address]*  Telephone/Fax numbers: *[insert Authorized Representative’s telephone/fax numbers]*  Email Address: *[insert Authorized Representative’s email address]* | | |
| 13. Are you in the UNPD List 1267.1989 or UN Ineligibility List ? ☐ YES or ☐ NO | | |
| 14. Attached are copies of original documents of:  ☐All eligibility document requirements listed in the Data Sheet  ☐If Joint Venture/Consortium – copy of the Memorandum of Understanding/Agreement or Letter of Intent to form a JV/Consortium, or Registration of JV/Consortium, if registered  ☐If case of Government corporation or Government-owned/controlled entity, documents establishing legal and financial autonomy and compliance with commercial law. | | |

Joint Venture Partner Information Form (if Registered)

Date: *[insert date (as day, month and year) of Bid Submission*]

ITB No.: *[insert number of bidding process]*

Page \_\_\_\_\_\_\_\_ of\_\_\_\_\_\_\_\_pages

|  |  |  |
| --- | --- | --- |
| 1. Bidder’s Legal Name: *[insert Bidder’s legal name]* | | |
| 2. JV’s Party legal name: *[insert JV’s Party legal name]* | | |
| 3. JV’s Party Country of Registration: *[insert JV’s Party country of registration]* | | |
| 4. Year of Registration: *[insert Party’s year of registration]* | | |
| 5. Countries of Operation | 6. No. of staff in each Country | 7.Years of Operation in each Country |
| 8. Legal Address/es in Country/ies of Registration/Operation: *[insert Party’s legal address in country of registration]* | | |
| 9. Value and Description of Top three (3) Biggest Contract for the past five (5) years | | |
| 10. Latest Credit Rating (if any) :Click here to enter text. | | |
| 1. Brief description of litigation history (disputes, arbitration, claims, etc.), indicating current status and outcomes, if already resolved. Click here to enter text. | | |
| 13. JV’s Party Authorized Representative Information  Name: *[insert name of JV’s Party authorized representative]*  Address: *[insert address of JV’s Party authorized representative]*  Telephone/Fax numbers: *[insert telephone/fax numbers of JV’s Party authorized representative]*  Email Address: *[insert email address of JV’s Party authorized representative]* | | |
| 14. Attached are copies of original documents of: *[check the box(es) of the attached original documents]*  ☐All eligibility document requirements listed in the Data Sheet  ☐Articles of Incorporation or Registration of firm named in 2.  ☐In case of government owned entity, documents establishing legal and financial autonomy and compliance with commercial law. | | |

Section 7

Technical Bid Form

|  |
| --- |
| ***INSERT TITLE OF THE ITB*** |

|  |  |
| --- | --- |
| **Name of Bidding Organization / Firm:** |  |
| **Country of Registration:** |  |
| **Name of Contact Person for this Bid:** |  |
| **Address:** |  |
| **Phone / Fax:** |  |
| **Email:** |  |

|  |
| --- |
| **SUBSECTION 3.1: EXPERTISE OF FIRM/ ORGANISATION** |
| *This section should fully explain the Bidder’s resources in terms of personnel and facilities necessary for the performance of this requirement.*  1.1 Brief Description of Bidder as an Entity: Provide a brief description of the organization / firm submitting the Bid, its legal mandates/authorized business activities, the year and country of incorporation, and approximate annual budget, etc. Include reference to reputation, or any history of litigation and arbitration in which the organization / firm has been involved that could adversely affect or impact the delivery of goods and/or performance of related services, indicating the status/result of such litigation/arbitration.  1.2. Financial Capacity: Based on the latest Audited Financial Statement (Income Statement and Balance Sheet) describe the financial capacity (liquidity, stand-by credit lines, etc.) of the bidder to engage into the contract. Include any indication of credit rating, industry rating, etc.  1.3. Track Record and Experiences: Provide the following information regarding corporate experience within at least the last five (5) years which are related or relevant to those required for this Contract.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **Name of project** | **Client** | **Contract Value** | **Period of activity** | **Types of activities undertaken** | **Status or Date Completed** | **References Contact Details (Name, Phone, Email)** | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | |

|  |
| --- |
| **SUBSECTION 3.2 - SCOPE OF SUPPLY, TECHNICAL SPECIFICATIONS, AND RELATED SERVICES** |
| *This section should demonstrate the Bidder’s responsiveness to the specification by identifying the specific components proposed, addressing the requirements, as specified, point by point; providing a detailed description of the essential performance characteristics proposed; and demonstrating how the proposed bid meets or exceeds the specifications.*  2.1. Scope of Supply: Please provide a detailed description of the goods to be supplied, indicating clearly how they comply with the technical specifications required by the ITB **(please see Annex 4 – Annex 4 shall be provided both in excel and PDF format)**; describe how the organization/firm will supply the goods and any related services, keeping in mind the appropriateness to local conditions and project environment.  2.1.1 Please describe the Freight Forwarder details and Arrangements. Ability to provide/coordinate necessary shipping services, including air, sea and cold chain delivery (if required)  2.1.2 Please provide the detailed Implementation Schedule.  **Delivery lead time is a factor of a crucial importance in this project. Please make all possible efforts to propose supply of all requested quantities within shortest timeframe possible. In case partial delivery is proposed, please provide suggested time schedule.**  *A supporting document with full details may be annexed to this section.*  2.2. Technical Quality Assurance Mechanisms: The bid shall also include details of the Bidder’s internal technical and quality assurance review mechanisms, all the appropriate quality certificates, export licenses and other documents attesting to the superiority of the quality of the goods to be supplied as requested by Section 4    2.3 Statement of Full Disclosure: This is intended to disclose any potential conflict in accordance with the definition of “conflict” under Section 5 of this document, if any.  2.4 Other: Any other comments or information regarding the bid and its implementation. |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SUBSECTION 3.3: PERSONNEL** 3.1 Management Structure: Describe the overall management approach toward planning and implementing the contract. Include an organization chart for the management of the contract, if awarded.  3.2 Staff Time Allocation: Provide a spreadsheet will be included to show the activities of each personnel involved in the implementation of the contract. Where the expertise of the personnel is critical to the success of the contract, UNDP will not allow substitution of personnel whose qualifications had been reviewed and accepted during the bid evaluation. (If substitution of such a personnel is unavoidable, substitution or replacement will be subject to the approval of UNDP. No increase in costs will be considered as a result of any substitution).  3.3 Qualifications of Key Personnel. Provide the CVs for key personnel (Team Leader) that will be provided to support the implementation of this project. CVs should demonstrate qualifications in area of expertise relevant to the Contract. Please use the format below:   |  |  |  |  | | --- | --- | --- | --- | | **Name:** | |  | | | **Role in Contract Implementation:** | |  | | | **Nationality:** | |  | | | **Contact information:** | |  | | | **Countries of Relevant Work Experience:** | |  | | | **Language Skills:** | |  | | | **Education and other Qualifications:** | |  | | | **Summary of Experience:** *Highlight experience in the region and on similar projects.* | | | | | Relevant Experience (From most recent): | | | | | **Period: From – To** | **Name of activity/ Project/ funding organization, if applicable:** | | **Job Title and Activities undertaken/Description of actual role performed:** | | *e.g. June 2010-January 2011* |  | |  | | *Etc.* |  | |  | | *Etc.* |  | |  | | **References (minimum of 3):** | *Name*  *Designation*  *Organization*  *Contact Information – Address; Phone; Email; etc.* | | | | **Declaration:**  I confirm my intention to serve in the stated position and present availability to serve for the term of the proposed contract. I also understand that any willful misstatement described above may lead to my disqualification, before or during my engagement.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of the Nominated Team Leader/Member Date Signed | | | | |  | | | | |

***Annex 5***

INTER-AGENCY FINISHED PHARMACEUTICAL PRODUCT QUESTIONNAIRE

BASED ON THE MODEL QUALITY ASSURANCE SYSTEM

FOR PROCUREMENT AGENCIES

# Section 1: Administrative section

* 1. **Product identification**
     1. Active pharmaceutical ingredient(s) (use INN if any):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1.1.2 Generic name of the product:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1.1.3 Trade (proprietary) name (if any):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1.1.4 Dosage form:

⬜ Tablets ⬜ 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 (Annex A)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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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…….)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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* 1. **Packaging**

1.2.1 Description and materials used for primary packaging[[1]](#footnote-1) and pack size (quantity of dosage-form units per pack)**:** Annex B

1.2.2 Description and materials used for secondary packaging materials and pack size: Annex C

## Contact details

**1.3 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 license, date and expiry date, if any** | **Physical address.**  **Please specify units, block if existing** | **Telephone number, facsimile number and email contact details** | **Activity (e.g. packaging)** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**1.4 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 license holder  Manufacturer

Distributor/wholesaler  Other

* 1. **Note for the applicant**

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

Has the dossier been submitted to any of the following agencies (ERP, ICRC, MSF, The Union, WHO procurement center, UNICEF)?

Please provide the date of the submission: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* 1. **Regulatory (Licensing) status**
     1. In the country of manufacture
* Product registered and currently marketed – License no.:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Provide a copy in Annex D

* Product registered for marketing in the country of manufacturing but not currently marketed – License no.:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* Product registered for export only – License 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 in Annex E. An earlier version is not acceptable).
* If a CPP cannot be obtained from the national drug regulatory authority (NDRA), please state the reason and send equivalent document if any.
* Submit recent as well as historical deficiency/acceptance 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)*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* + 1. WHO prequalification status, if applicable

This product is prequalified by WHO/PQP.[[2]](#footnote-2)

* Yes ⬜ No

If yes, please attach a copy of the relevant WHO/PQP acceptance letter signed by your company (Annex G)

* + 1. 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 (Annex H)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* 1. **Samples for technical evaluation**
     1. Samples of insert information

## Please relevant inserts/leaflets. ((Annex I)

* + 1. Label language (attach a copy): primary packaging

⬜ Trilingual English/French/Spanish ⬜ Bilingual English/French

⬜ English ⬜ French ⬜ Other (specify)

* + 1. Label language (attach a copy): secondary packaging

Trilingual English/French/Spanish ⬜ Bilingual English/French

⬜ English ⬜ French ⬜ Other (specify)

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

1.7.4 Patient information leaflet (Annex J)

⬜ Yes (attach a copy) ⬜ No

# Section 2. Active pharmaceutical ingredients

(In case of more than one active ingredient or more than one manufacturer is used, please replicate this section)

### 2.1 Details of API used (INN if any):

2.1.1 Manufacturer

Manufacturer  (name, physical address + country)/manufacturing site (please list all alternative sources): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Last inspection of API manufacturing sites 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 the API used to manufacture this product is/are WHO-prequalified?

Yes  No

2.1.2 API specifications

API specifications from the FPP manufacturer:

# BP (Edition/Year):

# USP (Edition/Year):

# The International Pharmacopoeia (Ph.Int.) (Edition/Year)

# Others (specify):

# Specifications additional to those in the pharmacopoeia referred to above if available.

*Attach a copy of the FPP manufacturer internal API(s) 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 from the FPP manufacturer in Annex M
* Please provide a copy of the certificate of analysis of the API from API manufacturer and FPP manufacturer (Annex N)

For sterile API,

Please provide the data on validation of the sterile aspects of the product including recent media fill validation data as applicable in Annex O

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 in Annex N

2.1.4 Suitability of monograph for API

Are you in a possession of the following information for APIs?

Certificate of suitability to the European Pharmacopoeia (CEP): please attach a copy of the CEP and its annexes (Annex P)

Certificate No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Technical file (please attach Annex Q):

⬜ Yes ⬜ No

# Section 3: Finished product

### 3.1 Manufacturing site GMP status

GMP inspections carried out by a NDRA

|  |  |  |  |
| --- | --- | --- | --- |
|  | **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 (Annex R)

Other GMP inspections carried out by (complete the table below):

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

### 3.2 Finished 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, syringeability): explain |  | |
| Other ( specify) |  | |

If analytical methods are in-house specifications, different from BP, USP and Ph.Int., attach a copy of the in-house finished product specifications and analytical validation data in the Annex S.”

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

**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 |  |
| 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 then reference number for the process validation protocol should be indicated. |  |

Provide batch formulae for all proposed batch sizes:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* Please provide in Annex U a flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters.

**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 V

Describe the method of sterilization used when applicable

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### 3.4 Stability of finished product

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 W.)

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 Xthat stability studies have been done or are being done with all declared API sources

If no, explain why: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3.4.4 Do you have on going stability data for this product?

⬜ Yes ⬜ No

Attach status report of any ongoing stability studies in Annex Y

3.4.5 Shelf-life as it appears on packaging

⬜ 2 years ⬜ 3 years ⬜ 4 years ⬜ 5 years

Other: (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:

Zone I

Zone II

Zone III

Zone IVa

Zone IVb

Other (specify):

3.4.8 For oral powder for suspension and powder for injection, or injection that may further diluted, or multi dose containers provide in-use stability data and storage condition after reconstitution and /or dilution in Annex Z

Indicate the period 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, No. 902 Annex 11/ TRS 937, Annex 7 or later)

### 4.1 For innovator products

Please attach a summary of pharmacology, toxicology and efficacy of the product

### 4.2 For generic products: THERAPEUTIC EQUIVALENCE

⬜ Demonstrated

⬜ Not demonstrated

Not relevant, please explain why:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**If demonstrated,**

4.2.1 By in vivo bioequivalence studies

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:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4.2.2. 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:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4.2.3 By another method (please describe study conclusion briefly):

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Attach graphic/pictorial representation of summary study results in Annex AA

### 4.3 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 (explain what the differences are and justify that the differences do not have any impact on the bioavailability):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* Provide a copy of the protocol and report of the proof of therapeutic equivalence (BE study) comparative dissolution profile, dissolution tests, others if any in Annex AB
* For bioequivalence studies indicate the stringent regulatory authority (SRA)/WHO/PIC(S) inspection status of the CRO (if the CRO has ever received inspections in relation to the current or other studies).
* Attach schematic representation of study design

# Section 5: Commitment and authorization

**5.1 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:

………………………………………………

**5.2 Power of attorney**

**The manufacturer authorizes a distributor to submit the questionnaire**

*[SIGNATURE]*

**Distributor (**Signed by Distributor for Manufacturer under power of attorney )  
  
Please provide a copy of the power of attorney (Annex AC)

**5.3 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 on page 2 (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), overages if any and excipients (1.1.7)

B. Description and composition of primary packing materials (1.2.1)

C. Description and composition of secondary packaging materials (1.2.2)

D. Copy of product registered and currently marketed – License no. (1.6.1)

E. Certificate of pharmaceutical product (CPP) according to the WHO Certification

Scheme (WHO Technical Report Series, No. 863 in the Annex. Earlier version is not acceptable) (1.6.1)

F. Submit 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 approval 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. Package insert/leaflet (1.7.1)

J. Patient Information Leaflet (1.7.4)

K. GMP certificate from the country of origin (2.1.1)

L. Copy of the FPP manufacturer internal API(s) specifications (2.1.2)

M. Copy of the FPP manufacturer analytical method and analytical validation data of the API in-house specifications (different from BP, USP and Ph. Int.) (2.1.2)

N. Copy of the certificate(s) of analysis of the API from the API manufacturer as

well as from the FP manufacturer (2.1.2 and 2.1.3)

O. Copy of validation of the sterile aspects of the product including recent media fill validation data for sterile API (2.1.2)

P. Copy of the certificate of suitability to the European Pharmacopoeia CEP and its

annexes (2.1.4)

Q. Open part of drug master file (DMF) (2.1.4)

R. Recent/valid GMP certificates/letter (3.1)

S. If specifications are in house specifications, different from BP, USP and Ph.Int., attach copy of the in-house finished product specifications and also validated analytical methods (3.2.1)

T. Copy of the certificates of analysis for the three last batches released (3.2.1)

U. Flow diagram and brief narrative describing the manufacturing and control

process of this product with relevant parameters (3.3)

V. Data on validation of the sterile aspects of the product including recent media fill

validation data as applicable (3.3)

W. Protocol and report for accelerated and real time stability testing (3.4.1)

X. Submit a declaration that stability studies have been done or being done with all

declared API source (3.4.3)

Y. Attach status report of any ongoing stability studies (3.4.4)

Z. For oral powder for suspension and powder for injection, provide in-use stability data and storage condition after reconstitution (3.4.8)

AA. Attach graphic/pictorial representation of summary study results (4.2.3)

AB. Provide a copy of the report of the proof of therapeutic equivalence (BE study)

comparative dissolution profile, dissolution tests, others if any (4.3)

AC. Copy of the power of attorney (5.2)

Section 8

Price Schedule Form

The Bidder is required to prepare the Price Schedule as indicated in the Instruction to Bidders.

**Please refer to Annex 6 (excel sheet) with the Price Schedule Form.**

**Annex 6 shall be provided both in Excel and PDF format.**

Section 9

FORM FOR BID SECURITY

*(This must be finalized using the official letterhead of the Issuing Bank. Except for indicated fields, no changes may be made in this template.)*

|  |  |
| --- | --- |
|  |  |

To: UNDP

WHEREAS (hereinafter called “the Bidder”) has submitted a Bid to UNDP dated , to deliver goods and execute related services for(hereinafter called “the Bid”):

AND WHEREAS it has been stipulated by you that the Bidder shall furnish you with a Bank Guarantee by a recognized bank for the sum specified therein as security in the event that the Bidder:

1. Fails to sign the Contract after UNDP has awarded it;
2. Withdraws its Bid after the date of the opening of the Bid;
3. Fails to comply with UNDP’s variation of requirement, as per ITB Section 3; or
4. Fails to furnish Performance Security, insurances, or other documents that UNDP may require as a condition to rendering the contract effective.

AND WHEREAS we have agreed to give the Bidder such this Bank Guarantee:

NOW THEREFORE we hereby affirm that we are the Guarantor and responsible to you, on behalf of the Bidder, up to a total of [*amount of guarantee*] [*in words and numbers*], such sum being payable in the types and proportions of currencies in which the Price Bid is payable, and we undertake to pay you, upon your first written demand and without cavil or argument, any sum or sums within the limits of *[amount of guarantee as aforesaid*] without your needing to prove or to show grounds or reasons for your demand for the sum specified therein.

This guarantee shall be valid until 30 days after the date of validity of the bids.

### SIGNATURE AND SEAL OF THE GUARANTOR BANK

Date

Name of Bank

Address

1. For example, HDPE bottle, Alu-Alu strip, neutral glass vial. [↑](#footnote-ref-1)
2. WHO Prequalification website link: <http://apps.who.int/prequal/>. [↑](#footnote-ref-2)