

**ANNEXESN°14 : INFORMATION SHEET**

*«SALAMA» Madagascar – Appel d’offres International Ouvert AOI 1 25*

[**ANNEXES** 1](#_Toc118210200)

[ANNEXE 14.1 : INFORMATION SHEET FOR MEDICINES 2](#_Toc118210201)

[ANNEXE 14.2: TECHNICAL INFORMATION SHEET ABOUT SUPPLIES OTHER THAN MEDICINES 18](#_Toc118210202)

[ANNEXE 14.3 :TECHNICAL SURVEY FOR SUPPLIES MANUFACTURERS 21](#_Toc118210203)

|  |
| --- |
| ANNEXE 1 : INFORMATION SHEET FOR MEDICINES |
| ONE SHEET FOR EACH PHARMACEUTICAL PRODUCT  |
| 1. **Section1 : Administrative section**
 |  |
|  | * 1. Product identification
 |  |
|  |  | * + 1. Active pharmaceutical ingredient(s) (use INN if applicable) :
 |
|  |  |   |   |   |   |   |   |   |   |   |
|  |  | * + 1. Generic name of the product:
 |  |
|  |  |   |   |   |   |   |   |   |   |   |
|  |  | * + 1. Trade (propriety) name (if applicable):
 |  |
|  |  |   |   |   |   |   |   |   |   |   |
|  |  | * + 1. Dosage form
 |  |
|  |  |  |  |  |  |  |  |  |  |  |
|   | Tablets |  |   | capsules |  |  |  |  |
|   | injectables |  |   | syrups/ oral liquids |  |  |  |  |
|   | other (please specify) |  |  |  |  |  |  |  |
|  |   |   |   |   |   |   |   |   |   |   |
|  |  | * + 1. Dosage
 |  |
|  |  |   |   |   |   |   |   |   |   |   |
|  |  | * + 1. Method of administration:
 |  |
|   | oral |  |   | IM |  |  |  |  |  |
|   | IV |  |   | SC |  |  |  |  |  |
|   | other (please specify) |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  | * + 1. Please provide the formulation of the product (qualitative and quantitative composition including active ingredient(s), overdose if applicable and excipients). Please also indicate standard reference 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)
 |
|  |  |   |   |   |   |   |   |   |   |   |
|  |  |   |   |   |   |   |   |   |   |   |
|  |  |   |   |   |   |   |   |   |   |   |
|  |  | * + 1. 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 and size (quantity of dosage-form units per pack) : Annex B

Please join a certificate of analysis of materials used for packaging : Annex C |
|  |  |   |   |   |   |   |   |   |   |   |
|  |  |   |   |   |   |   |   |   |   |   |
|  |  | * + 1. Description, pack size and material used for secondary packaging materials. Annex D

Please join a certificate of analysis of materials used for packaging : Annex E |
|  |  |   |   |   |   |   |   |   |   |   |
|  |  |   |   |   |   |   |   |   |   |   |
|  |
|  | * 1. Manufacturer identification
 |  |
| Name, adress and activities of manufacturer with production site(s) (or contract manufacture(s)) : |
| Manufacturer's name, contract manufacturer | Manufacturing licence reference, date of issue and expiry date | Address (please specify) | Telephone number, facsimile number and email contact details | Activity (eg: packaging) |
|   |   |   |   |   |
|   |   |   |   |   |
|   |   |   |   |   |
|  |  |
|  | If possible, Attach the results of the studies relating to the complete pharmaceutical development: Annex F |
| * 1. Name of company (to be filled if different from 1.3)
 |   |   |   |   |   |   |   |   |
| Address (details required) |   |   |   |   |   |   |   |
|  |  |  |   |   |   |   |   |   |   |   |
| Telephone number |   |   |   |   |   |   |   |   |
| Fax |   |   |   |   |   |   |   |   |   |
| Website |   |   |   |   |   |   |   |   |   |
| Email |   |   |   |   |   |   |   |   |   |
|  |  |  |  |  |  |  |  |  |  |  |
| Describe the link with the product: |
|   | Marketing licence holder |
|   | Manufacturer |
|   | Wholesaler |
|   | Other |
|  |  |  |  |  |  |  |  |  |  |  |
|  | * 1. Note for the applicant
 |  |
| 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. |
| Did the dossier be submitted to any of the following agencies: ERP, ICRC, MSF, WHO procurement centre, UNFPA, UNICEF? |
| Please provide the date of the submission: |   |   |   |   |
|  | * 1. Regulatory (Licencing) status
 |  |
|  | * + 1. In the country of manufacture
 |  |
|   | Product registered and currently marketed |  |
|  |  | Licence N°: |   |   |   |   |   |   |   |
|  |  | Provide a copy, Annex G |  |  |  |  |  |
|   | Product registered for marketing in the country of manufacturing but not currently Marketed |  |
|  |  | Licence N°: |   |   |   |   |   |   |   |
|   | Product registered for export only |  |
|  |  | Licence N°: |   |   |   |   |   |   |   |
|   | Product not registered (please clarify): |
|   |   |   |   |   |   |   |   |   |   |   |
| * Please attach a certificate of pharmaceutical product (CPP) according to the WHO Certification Scheme, Annex H
 |
| * If a CPP cannot be obtained from the national medicines regulatory authority (NMRA), please state the reason and send an equivalent document.
 |
| * Submit recent as well as historical deficiency letters issued by the WHO prequalification Programme (PQP)/SRA in relation to the specific product. Annex I
 |
|  | * + 1. In the other countries
 |  |
| List of countries where the product is registered and is currently marketed (please provide registration number) |
|   |   | Trade name |   | Country | Registration Number |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |
|  |  |  |  |  |  |  |  |  |  |  |
|  | * + 1. WHO prequalification status, if applicable
 |  |
| This product is prequalified by WHO/PQP. |
|   | YES |  |  |   | NO |  |  |  |  |  |
| If yes, please attached a copy of relevant WHO/PQP acceptance letter signed by your company, Annex J |
|  |  |  |  |  |  |  |  |  |  |  |
|  | * + 1. Submitted for prequalification: indicate date of submission, WHO acceptance letter mentioning the WHO reference number assigned by this last for this specific product, Annex K
 |
|   |   |   |   |   |   |   |   |   |   |   |
|  |  |  |  |  |  |  |  |  |  |  |
| * 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, and relevant inserts/leaflets. (if you cannot submit any of the above with the questionnaire, please state the reason and when you will do so.), Annex L |
|  |  |  |  |  |  |  |  |  |  |  |
|  | * + 1. Label language (attach a copy in Annex L ): primary packaging
 |  |
|   | Bilingual English/French |   | French |  |   | English |  |  |
|   | Other (specify) |  |  |  |  |  |  |  |
|   |   |   |   |   |   |   |   |   |   |   |
|  |  |  |  |  |  |  |  |  |  |  |
|  | * + 1. Label language (attach a copy in Annex L ): secondary packaging
 |  |
|   | Bilingual English/French |   | French |  |   | English |  |  |
|   | Other (specify) |  |  |  |  |  |  |  |
|   |   |   |   |   |   |   |   |   |   |   |
| For oral powder for suspension and for injection, in-use period and storage conditions after reconstitution should be stated on product label |
|  | * + 1. Patient information leaflet (Annex M)
 |  |
|   | YES |  |  |   | NO |  |  |  |  |  |
|  |  | * + 1. Proposed sales resctrictions

  |  |
|  |  | Classification in the list of narcotics |  |
|  |  | Prescription or restricted distribution |  |
|  |  | On medical prescription |  |
|  |  | In pharmacies only |  |
|  |  | Without prescription  |  |
|  |  |  |  |
|  |  |  |  |
| 1. **Section 2: Active pharmaceutical Ingredients**
 |
| (if there is more than one active ingredient or different sources, please replicate this section.)* 1. API for the activz ingredients:
 |
|  | * + 1. Details of API used (INN if applicable):
 |  |
|  |   |   |   |   |   |   |   |   |   |   |
|  |   |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |
|  | * + 1. Manufacturer
 |
|  |  | Manufacturer (name, address and country)/ production site (please list all alternative sources): |
|  |  |   |   |   |   |   |   |   |   |   |
|  |  |   |   |   |   |   |   |   |   |   |
|  |  | GMP certificate from the country of origin: attach a copy of the GMP certificate if available Annex N. |
|  |  | Last inspection of API manufacturing sites performed (when available, please attach GMP certificate or relevant letter) by: |
|   | Manufacturer of finished product |  |  |  |  |
|   | WHO Prequalification Programme, GENEVA |  |  |  |  |
|   | EDQM |  |  |  |  |
|   | US FDA |  |  |  |  |
|   | PIC/S Members |  |  |  |  |
|   | Others (specify) |  |  |  |  |
|   | None of above |  |  |  |  |
|  |  | Outcomes and date: |
|  |  |   |   |   |   |   |   |   |   |   |
|  |  |   |   |   |   |   |   |   |   |   |
|  |  | Did the API(s) use WHO-prequalified? |
|   | YES |  |  |   | NO |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| * + 1. API specifications
 |
|   | British Pharmacopoeia (BP) (edition/year):\_\_\_\_\_ |  |  |  |  |
|   | United States (USP) Pharmacopeia (edition/year):\_\_\_\_\_\_\_ |  |  |
|   | The International Pharmacopoeia (Ph.Int) (edition/year):\_\_\_\_\_\_\_ |  |
|   | Others (specify): |  |  |  |  |
|   |   |   |   |   |   |   |   |   |   |   |
|  | Additional specifications beside pharmacopoeia referred to above if available Annex O |
|   | YES |  |  |   | NO |  |  |  |  |  |
| * Attach a copy of the FPP manufacturer internal API(s) specifications
 |
| * If analytical methods are in-house, different from BP, USP, and Ph.Int, attach a copy of the analytical method an analytical validation data? Annex P
 |
|  |   |   |   |   |   |   |   |   |   |   |
|  | For sterile API: |
|  | Please provide validation data of the sterile aspects of the product including recent media fill validation data, as applicable. Annex Q |
|  | Describe the method of sterilization used when applicable: |
|  |   |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |   |
| * + 1. Certificates 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 R |
|  |  |  |  |  |  |  |  |  |  |  |
| * + 1. Suitability of monograph for API
 |
|  | Are you in a possession of the following information for APIs? |
|  | Certificate of suitability to monograph of European Pharmacopoeia (CEP): |
|  | please attach a copy of the CEP and its annexes (Annex S). |
|  | Certificate N°: |   |   |   |   |   |   |   |   |
|  |  |  |  |  |  |  |  |  |  |
| * + 1. Open part of drug master file (DMF) registered in (country):
 |
|  |  |   |   |   |   |   |   |   |   |   |
|  |  |   |   |   |   |   |   |   |   |   |
|  |  |   |   |   |   |   |   |   |   |   |
|  | Technical file (please attach in Annex T): |
|   | YES |  |  |   | NO |  |  |  |  |  |

* + 1. **the active ingredient synthesized from other materials?**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|   | YES |  |  |   | NO |

If so, attach the complete and consistent list of materials used in the manufacture of the active ingredient with the process steps. Indicate where each material is used: Appendix U

* + 1. Provide data on impurities actually present with analysis results of actual levels of impurities detected complete: Annex V
		2. Provide data on potential impurities that may be introduced during synthesis, purification and storage: Appendix W
		3. Are data relating to stability studies of the active ingredient available?

Please provide protocol and report for accelerated and long-term stability studies, including: container type and materials; conditions (temperature/ relative humidity/ duration of the stability study); number of batches tested in the study (minimum three); lot sizes for each lot tested; start date of the study; and conclusions of the study. (This information can be provided in Annex X)

* 1. **Raw materials for excipients**

**2.2.1. Excipients in the finished pharmaceutical product**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| N° | SUBSTANCE | STANDARD DE REFERENCE[[1]](#footnote-1) |   | QUANTITE[[2]](#footnote-2)/ML | QUANTITE PAR LOT | FONCTION |
|   | QUANTITE²/MG |
|   | QUANTITE²/UNITE |
|   |  |   |   |   |   |
|   |   |   |    |   |   |
|   |   |   |    |   |   |

* 1. **Manufacturer**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| N° | MANUFACTURER NAME | SITE ADRESS | N° OF GMP CERTIFICATE | AUTHORITY PROVIDING GMP  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

\*match the numbers of the excipient in point 2.2.1 with its manufacturer in 2.2.2

Manufacturer's GMP certificate: attach a copy in Annex Y

Attach in Annex Z a copy of the BP, USP and Ph Int, internal specifications of the excipient(s) by the manufacturer of the finished product.

If in-house analytical methods, other than BP, USP and Ph Int, attach a copy of the method and analytical validation data in Appendix AA.

2.2.3 Certificate of Analysis

Please provide a copy of the certificate of analysis of the excipient(s) supplied by the manufacturer of the excipient(s) as well as a copy of the certificate supplied by the manufacturer of the finished pharmaceutical product. In-house analytical methods, different from those of BP, USP, and Ph.Int, attach a copy of the analytical method and corresponding validation data in the same Annex AB.

 2.3 Origin of raw materials

Does the finished pharmaceutical product contain raw materials of animal origin?

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|   | YES |  |  |   | NO |  |
| 1. If so, attach the TSE/BSE Annex AC declaration certificate.

**Section 3: Finished pharmaceutical product** |
|  | * 1. Manufacturing site GMP status
 |
|  | GMP inspections carried out by an NMRA |
| **Agency** | **Date of Audit** | **Outcome** |  |
| **WHO prequalification program** |   |   |  |
| **UNICEF Supply Division** |   |   |  |
| **MSF International** |   |   |  |
| **ICRC** |   |   |  |
| **Other (specify)** |   |   |  |
|  | Please attach the recent/valid GMP certificates/letter (Annex AD) |
|  |  |  |  |  |  |  |  |  |  |  |
|  | Other GMP inspections carried out by : |
|  |  |  | **NRA of country of origin** | **Any other inspection of PIC/S member** |  |
| **GMP certificate no.** |   |   |  |
| **Valid until** |   |   |  |
| **Country** |   |   |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  | * 1. Finished pharmaceutical product specification
 |
| **Standart** | **Edition** | **Published year** |  |
| **BP** |   |   |  |
| **USP** |   |   |  |
| **Ph. Int.** |   |   |  |
| **In-house** |   |   |  |
| **Additional specifications to those in the pharmacopeia referred** |   |   |  |
| **Other ( specify)** |   |   |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  | Please attach copies of release and shelf-life specifications for the FPP in Annex AE. |
|  | 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 Annex R. |
|  |  |  |  |  |  |  |  |  |  |  |
|  | Please attach a copy of the certificate of analysis for the batch (sample) released in Annex AF |
|  |  |  |  |  |  |  |  |  |  |  |
|  | * 1. Method of manufacture and process validation
 |
|  |  | 3.3.1. Did the manufacturing methods for each standard batch size validate? |
|   | 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, the reference number** |   |  |
|  |  |  |  |
|  | Provide batch formulae for all proposed batch sizes: |
|  |   |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |   |
|  | Please provide in Annex AG a flow diagram and brief narrative describing the manufacturing and control process of product. |
| 3.3.2 Please provide the list of materials used in the manufacture of the active ingredient with the process steps where each material is used: Annex AH3.3.3 VehicleIf the finished drug product of the excipients is not monographed in an existing pharmacopoeia, please provide complete information on its manufacture and safety data regarding its use in Appendix AI.3.3.4 Impurities and contamination Annex AJ• Provide tests for the determination of fungal and microbial contamination, research of toxic metals and contaminants (pesticides) for the case of excipients of plant origin (for liquids)• Provide comprehensive data on potential impurities that may be released during synthesis, purification and storage.• Provide comprehensive data on actual impurities contained with analysis results of actual levels of impurities detected.• Provide the methods used for the determination, detection or control of impurities.• Provide complete data on acceptance criteria for impurities. Additional information for sterile products |
|  | 3.3.5. Provide the data on validation of the sterile aspects of product including recent media fill validation data as applicable in Annex AK. |
|  | Describe the method of sterilization used applicable: |
|  |  |   |   |   |   |   |   |   |   |   |
|  |  |   |   |   |   |   |   |   |   |   |
|  |  |   |   |   |   |   |   |   |   |   |
|  | * 1. 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 provide in Annex AL.) |
|  |  |  |  |  |  |  |  |  |  |  |
| * + 1. Did the stability testing be performed on a product with same formula, same API source, manufactured in same site and packed in 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 AM 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 AN. |
| * + 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 (eg “ Do not store above 30°C- protect from light”)
 |
| **Temperature** |   |  |  |
| **Light** |   |  |  |
| **Humidity** |   |  |  |
| **Other (specify)** |   |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| * + 1. Product suitable for use in:
 |
|   | 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 multidose containers provide in use stability data and storage conditions after reconstitution and/or dilution in Annex AO.
 |
| Indicate the period (hours/days) 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** |
|  | * 1. For innovator products
 |
|  | Please attach a summary of pharmacology, toxicology and efficacy of the product in Annex AP. |
|  |  |  |  |  |  |  |  |  |  |  |
|  | * 1. For generic products: therapeutic equivalence
 |
|   | Demonstrated |  |  |  |  |  |  |
|   | Not demonstrated |  |  |  |  |  |  |
|   | Not relevant, please explain why: |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |   |
|  |  |  |  |  |  |  |  |  |  |  |
|  | If demonstrated, |  |  |  |  |  |  |
|  | * + 1. By in vivo equivalence studies
 |
|  | Study period (dd/mm/yyyy): from: |   |  | to |   |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  | Product reference |  |  |  |  |  |
| **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)** |   |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  If possible, attach a certificate of analysis of the reference product in accordance with the specifications Annex AQ |
|  |  |
|  | Study results |  |  |  |  |  |
|  |   |   |   |   |   |   |   |   |   |   |
|  |  |  |  |  |  |  |  |  |  |  |
|  | Study conclusion |  |  |  |  |  |
|  |   |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |   |
|  | If possible, please provide Bioequivalence study report Annex AR |
|  |  |  |  |  |  |  |  |  |  |  |
|  | * + 1. By comparative in vitro dissolution tests according to conditions described in WHO BCS classification document
 |
|   | YES |  |  |   | NO |  |  |  |  |  |
|  | If no, please explain |  |  |  |  |  |
|  |   |   |   |   |   |   |   |   |   |   |
|  | Product reference |  |  |  |  |  |
| **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: |
|  |   |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |   |
|  | If possible, provide In-vitro dissolution study report, Annex AS |
|  | * + 1. By another method (please describe study conclusion briefly):
 |
|  |   |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |   |
|  | Attach graphic/pictorial representation of summary study results in Annex AT |
|  |  |  |  |  |  |  |  |  |  |  |
|  | * 1. 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, please explain what the differences are and justify that the differences do not have any impact on the bioavailability): |
|  |   |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |   |
|  | Provide a copy of the report of the proof of therapeutic equivalence (BE study) comparative dissolution profile, dissolution tests, and others, if any, in Annex AU. |
|  | For bioequivalence studies, indicate the stringent regulatory authority (SRA/WHO/PIC/s inspection status of CRO (if CRO has ever undergone inspections in relation to the current or other studies). |
|  |   |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |   |
|  | Attach schematic representation of study design (Annex AV) |
|  | Attach study protocol summary (Annex AW) |
|  |  |  |  |  |  |  |  |  |  |  |
| 1. **Section 5: Commitment and authorization**
 |
|  | * 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 bellow) |
|  |  |  |  |  |  |  |  |  |  |  |
|   | 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 staring materials, quality control of the finished product and starting material, packaging, shelf-life, indication, 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: |   |   |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  | * 1. 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 (Annex AX). |
|  |  |  |  |  |  |  |  |  |  |  |
|  | * 1. 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 1.5 section 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: |  |  |  |  |
|  |   |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |   |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  | Date: |   |   |  |  | Signature: |   |   |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  | Company seal/stamp: |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1. **Section 6 Attachments/annexes**

Attachments or Annexes to the questionnaire should be in PDF format and should be indexed to facilitate review.

Please ensure that all necessary documents 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

B. Description and composition of primary packaging materials

C. Certificate of analysis of primary packaging materials

D. Description and composition of secondary packaging materials

E. Certificate of analysis of secondary packaging materials

F. Studies related to pharmaceutical development

G. Copy of product registered and currently marketed – License no.

H. Certificate of pharmaceutical product (CPP) according to the WHO Certification Scheme (WHO Technical Report Series, No. 863). An earlier version is not acceptable I. Submit recent as well as historical deficiency/acceptance letters issued by PQP/SRA in relation to the specific product dossier

J. Copy of the relevant WHO Prequalification approval letter signed by your company

K. WHO acceptance letter for product dossier review mentioning the WHO reference number assigned by WHO for this specific product

L. Package insert/leaflet

M. Patient information leaflet

N. GMP certificate of the country of origin

O. Attach a copy of all internal API(s) specifications

P. Validated analytical methods if analytical methods for finished product are in-house analytical method, different from BP, USP and Ph.int.

Q. Please provide the data on validation of the product including recent media fill validation data, as applicable

R. Copy of the certificate(s) of analysis of the API from API manufacturer as well as from the FPP manufacturer

S. Copy of the certificate of suitability to the European Pharmacopoeia (CEP) and its annexes

T. Drug Master File

U. Complete and consistent list of materials used in the manufacture of the active ingredient with the process steps

V. Data on the impurities actually present with analysis results of the actual levels of impurities detected complete

W. Data on potential impurities that may be introduced during synthesis, purification and storage

X. Protocol and report for accelerated and long-term stability

Y. Recent/valid GMP certificates/letter of excipients manufacturer

Z. BP,USP, Ph Int qnd internal specifications of excipients

AA. Method and analytical validation data of excipient(s) specifications

AB. Certificate of analysis of excipients and method of analysis and validation for in house method

AC. Certificate of BSE/TSE declarationAD.

AD. Recent/valid GMP certificates/letter

AE. Copy of internal specifications of pharmaceutical finished product and analytical validated method, in case of in house specification different from BP, USP and Int Ph.

AF. Copy of the certificate of analysis of finished product (sample)

AG. Flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters

AH. List of materials used in the manufacture of the active ingredient with the process steps where each material is used

AI. Complete data on the manufacture of the excipient(s) and on the safety data concerning its use

AJ. Impurities and contaminations

AK. Data relating to the validation of the aseptic manufacturing processes of the product including recent aseptic validation data by the filling test (Media fill), if applicable

AL. Protocol and report for accelerated and long-term stability studies

AM. Declaration stipulating that stability studies have been carried out or are in progress for all declared sources of active ingredient

AN. Ongoing stability study status report

AO. Data on in-use stability and storage conditions after reconstitution for powder for preparation of oral suspension and powder for injection

AP. Summary of Pharmacology, Toxicology and Efficacy

AQ. Certificate of analysis of the reference product for the bioequivalence study

AR. Bioequivalence study report

AS. In-vitro dissolution study report

AT. Graphical representation of the summary of the results of the study

AU. Copy of the report of proof of therapeutic equivalence (bioequivalence study) by comparison of the dissolution profile, dissolution tests, and other possible tests

AV. Schematic representation of the structure of the study

AW. Summary of the study protocol

AX. Copy of power of attorney

# ANNEX 2: TECHNICAL INFORMATION SHEET ABOUT SUPPLIES OTHER THAN MEDICINES

ONE SHEET FOR EACH PRODUCT

Medical disposables, dentistry products, haemodialysis cunsommables

Product identification (Salama)

Article n°:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Usual name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Specifications: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Requested presentation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Requested package: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Product submitted (Suppliers)

Usual name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Specifications: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Requested presentation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Requested package: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Comments about technical specifications of product submitted (indicate if technical specifications requested are not followed):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

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

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

Technical informations about submitted product

Technical reference: Pharmacopeia: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ edition: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Another reference (to indicate): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Own reference (please attached an abstract)

Source:

Manufacturer name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Country of production site: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Available packaging (mention all size): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Weight and capacity of packaging:

Average weight of packaging: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_kg

Average capacity of packaging: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_m3

If applicable, total shelflife of product: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_mois

Sterilization:

* Ethylene oxide
* Gamma radiation
* Other (specify) : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Storage conditions:

* Temperature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Light: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Humidity:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Summary of sample identification (quantity, packaging, presentation….): \_\_\_\_\_\_\_\_\_\_\_\_\_

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

Documents available (to join in annex with the sheet):

* Good Manufacturing Practices certificate of production site about the product
* Marketing authorization of the product from country of origin
* Declaration or export permit
* CE marking attestation

 Reference number:

* ISO 9002 certification or another

 Type of certification: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Reference number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name, qualification and signature of technical responsible: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# ANNEX 3 :TECHNICAL SURVEY FOR SUPPLIES MANUFACTURERS

Please fill the blanks

1. **About the manufacturer**

|  |  |
| --- | --- |
| Company name |  |
| Address of headquarters |  |
| Physical adress |  |
| Fax |  |
| Phone number |  |
| Website  |  |
| Contact (e-mail) |  |

* 1. **Affiliation**

If your company belongs to another company, or is a part of conglomerate or a corporation, please describe your position in that structure.

* 1. **Control**
		1. **Good manufacturing practices**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| GDP standards applied by the manufacturer | OMS | PIC/EU/ICU | FDA | Others (please specify) |
|  |  |  |  |

Please attach a copy of the latest inspection report or GMP certificate.

* + 1. Drug manufacturing authorization

Please write down a list of the dosage forms that the National Regulatory Authority allows you to manufacture

* 1. Controls

Please indicate the date of the last inspection carried out by the regulatory authority or other competent authority:

|  |  |  |
| --- | --- | --- |
| National Regulatory Authority | Date | Comments |
|  |  |  |
|  |  |  |

1. **Manufacture**
	1. **Manufacturing site**

Please quote all the names and addresses of the sites where the pharmaceutical supplies to undergo pre-qualification are manufactured, and the year on which they 5the sites) were made. Please write down the dates of the upgrades and adaptations, and describe their role.

|  |  |  |  |
| --- | --- | --- | --- |
| Site name | Site location (address) | Year of construction and/or upgrade | Activity/role (e.g. : compression, packaging…) |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

* 1. **Ventilation system**

**Does the manufacturing site have a controlled ventilation system?**

  YES  NO

**If “no”, please explain if so: [text]**

* 1. **Quality control**

|  |
| --- |
| Control device |
| Chemical laboratory | In house |  | Outsourced |  |
| Biological laboratory | In house |  | Outsourced  |  |
| Microbiological laboratory | In house |  | Outsourced  |  |

* 1. **Outsourcing**

Do you manufacture products for other companies?

 YES  NO

Please specify what type of product

1. **Products**
	1. Do you manufacture sterilized products?

 YES  NO

Please give a short description of the sterilization process used:

* 1. Production capacity

|  |  |  |
| --- | --- | --- |
| Dosage form unit  | Unit quantity produced per yea | Unit quantity produced last year |
| Tablets |  |  |
| Capsusles |  |  |
| Bulbs |  |  |
| Others, please precise |  |  |

* 1. Do you manufacture penicillin or other beta-lactam, highly sensitizing compounds, hormones or cytotoxic products?

 YES NO

In the case of a positive answer, please confirm if the manufacturing is done in another building, with its own air purifying system.

1. **Stock**

Do you maintain permanent stock?

 YES NO

1. Specify edition [↑](#footnote-ref-1)
2. Specify if unit is in mg , ml or UI [↑](#footnote-ref-2)