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Contents

List of abbreviations

API - Active Pharmaceutical Ingredient
BP – British Pharmacopoeia
CEP - Certificate of suitability to the monograph of the European Pharmacopoeia
CoA - Certificate of Analysis
CPP - (or CoPP) Certificate of Pharmaceutical Product
DMF – Drug Master File
EP - European Pharmacopoeia
ERP - Expert Review Panel
FPP - Finished Pharmaceutical Product (synonym of medicine)
GMP - Good Manufacturing Practices
IAFPPQ - Inter-Agency Finished Pharmaceutical Product Questionnaire
ICH - International Council for Harmonisation (of Technical Requirements for Pharmaceuticals for Human Use)
INN - International Non-proprietary Name
MA - Marketing Authorization
MAH - Marketing Authorization Holder
MQAS - Model Quality Assurance System
NRA - National Regulatory Authority
PIL - Patient Information Leaflet
SRA - Stringent Regulatory Authorities
TRS - Technical Report Series
USFDA - United States Food and Drugs Administration
USP - United States Pharmacopoeia
WHO - World Health Organization
WHO PQ - WHO Pre Qualification
WLA - WHO Listed Authorities

Glossary

CTD (Common Technical Document)
A harmonized dossier format developed by the International Council for Harmonisation (ICH) for regulatory submissions of medicinal products. The CTD organizes quality, nonclinical and clinical information into five modules: Module 1 is region-specific (administrative/prescribing information), while Modules 2–5 are intended to be common across regions.

International Council for Harmonisation (ICH)
Is a global initiative that unites regulatory authorities and the pharmaceutical industry to harmonize technical requirements for the development and registration of safe, effective, and high-quality medicines.

Manufacturer
Any natural or legal person with responsibility for the design and/or manufacture and quality control of Finished Pharmaceutical Products (FPPs) with the intention of making them available for use, under the manufacturer's name or under the name of a Marketing Authorization Holder.

Marketing Authorization Holder (MAH)
The Marketing Authorization Holder is the entity that holds the marketing authorization for a FPP, whether such a health product is designed and/or manufactured by the MAH itself or on its behalf by another person(s). This authorization allows the MAH to legally market and distribute the product within a country or region.

Maturity Level (ML)

Concept framed by the Global Benchmarking Tool (GBT), allowing WHO and regulatory authorities to assess the overall 'maturity' of the regulatory system on a scale of 1 (existence of some elements of regulatory system) to 4 (operating at advanced level of performance and continuous improvement). The Global Benchmarking Tool (GBT) represents the primary means by which the World Health Organization (WHO) objectively evaluates regulatory systems, as mandated by WHA Resolution 67.20 on Regulatory System Strengthening for medical products.

Pharmaceutical Inspection Co-operation Scheme (PIC/S)

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) is a non-binding, informal co-operative arrangement between Regulatory Authorities in the field of GMP of medicinal products for human or veterinary use. It is open to any authority that has a comparable GMP inspection system.

Supplier

An entity that potentially or actually provides goods or other products (including intellectual property), services, and/or works to the organization. Suppliers may be agents, distributors, importers, manufacturers, traders, etc. who also may bid for UNDP tenders.

Within this document the term supplier refers also to bidders, i.e. any entity that submits an offer in response to a solicitation. Normally, the term 'bidder' is used to refer to the entity responding to a solicitation process. Once a bidder is selected and awarded the contract, they become the supplier and are responsible for fulfilling the terms of the agreement, including delivering the required goods, services, or works.

Solicitation process

A process for organizations to seek and obtain offers from potential suppliers or service providers. Invitation to Bid (ITB), Expression of Interest (EOI), and Request for Quotation (RFQ) are common types of market solicitation documents.

Stringent Regulatory Authority (SRA)

As per interim definition of the WHO (Evaluating and publicly designating regulatory authorities as WHO listed authorities, Policy document, 2021), a SRA is a regulatory authority which is:

a) a member of ICH before 23 October 2015, namely the US Food and Drug Administration, the European Commission, and the Ministry of Health, Labour and Welfare of Japan, also represented by the Pharmaceuticals and Medical Devices Agency; or

b) an ICH observer before 23 October 2015, namely the European Free Trade Association, as represented by Swiss Medic and Health Canada; or

c) a regulatory authority associated with an ICH member through a legally binding, mutual recognition agreement before 23 October 2015, namely Australia, Iceland, Liechtenstein, and Norway.

WHO Listed Authority

A WHO Listed Authority (WLA) is a regulatory authority or a regional regulatory system which has been documented to comply with all the indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking and performance evaluation process.

1. Background

UNDP supports countries implementing large-scale health programmes to increase access to Universal Health Coverage (UHC) within national policies and priorities. As a part of such programs, UNDP procures health products, including Finished Pharmaceutical Products (FPP) for which the UNDP QA Policy provides a framework for their quality assurance.

Criteria for acceptance are that the products should be WHO prequalification (PQ), approved by Stringent Regulatory Authorities (SRA), by WHO Listed Authorities (WLA) or have received positive opinion by the Expert Review Panel (ERP). The Policy also gives the option to assess products based on the Model Quality Assurance System (MQAS) of pharmaceuticals. The WHO PQ and ERP have a limited scope, and the list of products is minimal. UNDP procures a wide range of pharmaceutical products covering many diseases. Since the implementation of the Policy, except for anti-retroviral, anti-malarial, and antituberculosis products, there have been challenges in sourcing affordable quality-assured pharmaceuticals. To improve access to these products, the assessment of products based on the MQAS' Inter-Agency Finished Pharmaceutical Product Questionnaire (IAFPPQ) remains an option for products that WHO PQ does not cover.

The purpose of this document is to describe UNDP requirements related to the MQAS IAFPPQ' sections with the objective to clarify UNDP expectations and minimum acceptance criteria for suppliers that wish to offer pharmaceuticals that do not hold a Marketing Authorization (MA) from SRA or WLA, are not WHO prequalified or have not received ERP positive opinion.

2. Target audience

The intended audience includes Bidders, Suppliers, UNDP Procurement Teams, Technical Specialists in Country Offices, the QA Team and others in the health product management cycle. The UNDP' procurement entity must share this document with suppliers and/or bidders as a part of the solicitation process to ensure compliance with UNDP's expectations regarding the safety, quality and efficacy of FPPs.

3. Instructions to readers

This document is written based on the Interagency finished pharmaceutical product questionnaire based on the model quality assurance system for procurement agencies (WHO TRS986, 2014, Annex 3, Appendix 6).

Suppliers are requested to submit FPP' questionnaires in the form of MQAS IAFPPQ or equivalent questionnaire (collectively referred herein as IAFPPQ), i.e. they must include the same information irrespective of the format AND **all the Attachments/annexes listed in the Annexes checklist at the end of this document**.

Where available, suppliers may submit the supporting dossier information in CTD format, either as (i) the complete CTD dossier or (ii) specific CTD modules/sections (extracts) corresponding to the information requested in the relevant IAFPPQ sections of this document. Any CTD submission (full or partial) shall be clearly labelled according to the CTD module/section structure and, where partial, shall include clear cross-references to the applicable IAFPPQ section(s).

UNDP requirements related to IAFPPQ' section refer to the IAFPPQ version 21 October 2024.

As per UNDP quality surveillance procedures, UNDP may conduct pre-shipment desk inspections to confirm that the product prepared for dispatch remain compliant with the information submitted in the IAFPPQ and the specifications/requirements approved by UNDP. For this purpose, the manufacturer/supplier shall provide, upon request, copies or appropriately redacted extracts of the relevant Batch Manufacturing Records (BMRs), as well

as photographs of the finished pharmaceutical product in its final pack configuration, ready for shipment, to enable verification prior to dispatch.

4. Scope

This document covers the requirements related to FPPs assessed based on the Inter-Agency Finished Pharmaceutical Product Questionnaire (IAFPPQ) of MQAS guidelines.

5. References

Specific references to documents and guidelines have been provided in the document to ease their retrieval. In case any of those references is succeeded by a new version, the last one is considered to apply. References for the latest available updated versions will be indicated in this document during its periodic review or in case a review becomes necessary before the next review date is reached.

Technical and regulatory requirements for FPPs assessed based on the IAFPPQ

The information provided in the IAFPPQ and its annexes shall apply to one specific packaging type/presentation only. A single IAFPPQ shall not combine different packaging types (e.g., blisters, strip packs, bottles or vials, ampoules, pre-filled syringes). Separate IAFPPQs shall be submitted for each packaging type/presentation.

Different pack sizes of the same packaging type/presentation may be included in a single IAFPPQ. However, for each pack size included, the supplier shall submit the corresponding (i) QA-approved artworks (primary and secondary packaging, as applicable), (ii) packaging material specifications (primary and secondary components, as applicable), and (iii) stability study data/reports in the corresponding sections of the IAFPPQ. Pack-size specific evidence shall be provided unless the supplier can justify, with a documented rationale, that the same artwork/specifications/stability evidence applies unchanged across the listed pack sizes.

6. Administrative section (IAFPPQ Section 1)

6.1 Product identification (IAFPPQ 1.1)

Active Pharmaceutical Ingredient(s) (API)

Identify the product using its International Non-proprietary Name (INN). State the API as base, salt, ester, or pro-drug compound, as applicable.

Generic name of the product

Indicate the complete product' name as indicated on the packaging, including strength, formulation and reference pharmacopoeia (if any).

Trade name(s)

If trade name(s) are used and appear on the labelling, packaging and/or the patient information leaflet (PIL) they should be stated in the IAFPPQ.

Dosage form

Specify the relevant pharmaceutical dosage form (e.g., tablets, capsules, syrups, solution for oral use, ophthalmic ointment, etc.) and any attribute associated with the dosage form (e.g. chewable or dispersible tablet, sustained release capsules, etc.). Description of the dosage should include information such as tablet scoring.

Strength per dosage (1.1.1)

Provide the amount of API per dosage unit. If a salt or an ester is used, please specify the amount in base-equivalent (active moiety).

Route of administration (1.1.2)
Specify the intended route of administration (oral, IV, IM, topical, etc.).
The details must be consistent with the information printed on the labels, packaging and PIL.
Fixed dose or co-packaged product (1.1.3)
Specify if the product is a Fixed Dose Combination (FDC) or a Co-packed product.
Formulation (1.1.4)
A copy of the **master formula** must be provided as an attachment to the IAFPPQ, including all the names of the excipients, their amount in the dosage unit and the validated product batch size.

6.2 Excipients (Non-therapeutically active ingredients) (IAFPPQ 1.2)

UNDP requires the supplier to indicate the reference guideline used to identify excipients of known effect and assess their acceptability, e.g. referring to European Medicines Agency (EMA) guidelines on "excipients in the labelling and package leaflet of medicinal products for human use" (EMA/CHMP/302620/2017 Rev. 2) or the USFDA Inactive Ingredient Database.

6.3 Packaging (IAFPPQ 1.3 and 1.7)

Suppliers must comply with the WHO guidelines on packaging for pharmaceutical products (WHO TRS 902, Annex 9) or with the current versions of USP or EP.
UNDP strongly recommends submitting IAFPPQs specific to the type and package presentation, i.e. do not refer to blister and bottle/jar in the same IAFPPQ. Different presentations require different packaging specifications, specific stability studies, specific labels etc.: including them in the same IAFPPQ is source of misunderstandings and mix-ups.

Labelling
The product' label and Patient Information Leaflet should be in line with the WHO 'Guidance relating to development of contents of WHO Public Assessment Report'.

Primary packaging (1.3.1) and secondary packaging (1.3.2)
Clear description of the primary and secondary packaging must be indicated, including materials used (e.g. LDPE bag, HDPE container, aluminum foil, PVC, PVdC, plastic bottle, tube, etc.) and size (volume or number of units contained).

Suppliers are required to provide:

a. **pictures (preferably) or QA approved artworks (if pictures are not available) of the primary and secondary packaging that shall be used for the products offered to UNDP;**
b. **the primary and secondary packaging materials specifications** including the manufacturer's internal reference for each packaging material used for the FPP offered, specifications as per a pharmacopeia monograph, size of containers as applicable (size of bulk containers, plastic and aluminum layers in blisters or strips).

The specifications of primary and secondary packaging offered to UNDP and the one/s used in stability studies must be identical.

Summary of product characteristics/patient information leaflets and/or dose measurement/dose delivery devices (as appropriate) should be included in or joined to the selling packaging.
When used to deliver the FPP, the supplier must provide a **detailed description of the dose measurement/dose delivery device** (materials used, size, picture).
Notes:
The dosage scales/volumes embossed on dose measurement devices must be in metric units. The use of teaspoonfuls and other such measurements is not acceptable.

UNDP might require the supplier to submit the results of studies confirming the reproducibility of the device (e.g. consistent delivery of the intended volume).

Primary and/or secondary packaging information (1.7.2 and 1.7.3)

The information printed or affixed on the secondary packaging or, where there is no secondary packaging, on the primary packaging must be coherent with the information provided in the IAFPPQ and include at minimum:

a. the INN, pharmaceutical dosage form and strength;
b. the route of administration and any special instructions for use e.g. "for use in ears only – not for ophthalmic use"; the use of standard graphics e.g. an eye to visually portray use in the eye is strongly recommended;
c. if appropriate, whether the product is intended for babies, children or adults;
d. the pharmaceutical form and the contents by weight, by volume or by number of doses of the product;
e. a list of those excipients known to have a recognized action or effect;
f. a special warning that the medicinal product must be stored out of the reach and sight of children;
g. a special warning, if this is necessary for the medicinal product;
h. the name and complete address of the manufacturer and marketing authorisation holder. In case of contract manufacture, 'Manufactured by company X for company Y' must be indicated;
i. the batch number;
j. the manufacturing and expiry date in clear terms (e.g. day/month/year);
k. the required storage conditions (information must be coherent with the outcome of the stability studies);
l. the in-use period and storage condition, if a product has a limited shelf-life after the primary package is opened and manipulated.

Patient Information Leaflet (PIL) (1.7.4)

A copy of the PIL including English language must be provided. The PILs including other languages in addition to English (e.g. French, Spanish etc) will also be accepted.

UNDP might require the suppliers to provide a copy of the PIL in other UN languages.

This requirement will be specified in the terms of the solicitation process.

The PIL should provide comprehensive and accurate information to users, ensuring their safe and effective use of the product.

The PIL should as a minimum contain the following information:

a. Product Name and Description: the name and description of the product, including its active ingredients and strengths and the list of excipients;
b. Indications and Intended Use: The specific medical condition or purpose for which the product is intended;
c. Dosage and Administration: Clear instructions on how to use the product, including the recommended dosage, frequency, route of administration, and any special instructions for administration;
d. Contraindications: A list of conditions or situations in which the product should not be used due to potential risks or interactions. This may include specific medical conditions, age restrictions, or concurrent use with other medications;
e. Warnings and Precautions: Important safety information, including potential risks, side effects, and precautions that users should be aware of before using the product;

f. Storage instructions (information must be consistent with the outcome of the stability studies);
g. Product appearance and pack content;
h. Manufacturer and manufacturing site address.

6.4 Manufacturer identification (IAFPPQ 1.5)

To enable objective verification of GMP compliance, the supplier/manufacturer shall clearly and consistently identify the exact manufacturing location of the product, including:
(i) full site address;
(ii) the relevant unit/plant/block/workshop (as applicable); and
(iii) the specific production line(s) (unique line name/number/identifier) used for manufacturing and, where applicable, for primary packaging.

All GMP evidence provided (certificates and/or inspection reports) shall correspond to and cover the above-identified location and the relevant operations performed on the declared line(s). Where more than one line may be used, the supplier shall list all eligible lines and specify the line intended for supply to UNDP.

6.5 Regulatory (licencing) status (IAFPPQ 1.6)

In country of manufacture (1.6.1)

The supplier is requested to share a **copy of the manufacturing license granted by the local NRA (National Regulatory Authority) to the manufacturer.**

Suppliers should specify the marketing status of product offered, e.g. if it is:

- registered and marketed in the country of manufacture; or
- "authorized for export only" by the NRA of the country of manufacture; or
- Both marketed in the country of manufacture and authorized for export; or
- not registered for domestic and not specifically "authorized for export only" by the NRA of the country of manufacture.

Suppliers must submit a **Certificate of Pharmaceutical Product (CPP)** with all the attachments for each FPP according to the WHO Certification Scheme issued by the National Regulatory Authority in the country of manufacture/origin.
The CPP should be presented in the format recommended by WHO in the TRS 863, Annex 3.2
The information included in the CPP should be coherent with the information completed in section 1.6.1 of the IAFPPQ.
If CPP cannot provided, suppliers are required to state the reason and to provide a proof of marketing authorization in the country of origin.

Product registration in other countries (1.6.2)

Suppliers are required to list other countries where the product is registered, including respective license numbers.

Interagency dossier submission status (1.6.4)

Where a product has already been approved by ICRC, MSF or UNICEF, suppliers are strongly encouraged to submit, in addition to the IAFPPQ and its annexes, the **Declaration of equivalence (DoE) IAFPPQ through supplier** (DOE-FPP-003, current version), available on the 'UNDP Tools and Guidance for UNDP Suppliers' website.
On the basis of the DoE, UNDP may grant approval through an abbreviated review. However, UNDP may request clarifications where needed, for example due to outdated information, differences identified in the DoE, or missing supporting documentation.

Samples for technical evaluation (1.7)

Suppliers may be required to submit samples for technical evaluation. This requirement will be specified in the terms of the solicitation process.

When samples are requested, suppliers should submit commercial samples in the packaging offered to UNDP (primary and secondary packaging and PIL).

7. Active Pharmaceutical Ingredients (IAFPPQ Section 2) and starting materials

7.1 Details of APIs used (IAFPPQ 2.1)

Suppliers are required to provide detailed information on each source of API potentially used in the FPP offered to UNDP.

Note: If multiple sources of the same API can be used for manufacturing the FPP offered to UNDP, UNDP might require the bidder to provide proof of equivalence based on a comparative analysis of the APIs, including their particle size.

Detailed information includes:

a. the name of the API (in INN);
b. the address of the API manufacturing site including the identification of the unit, block or workshop (if applicable);
c. the specifications:
   - APIs should preferably comply with the monographs of the WHO International Pharmacopoeia (Int Ph), or the European (EP), British (BP), US (USP) or Japanese pharmacopoeia (JP), current edition;
   - If other specifications are used (e.g. In House), suppliers should provide a copy of the analytical method and analytical validation data;
   - If additional tests are used by the API manufacturer for batch release of the API, they should be stated in the questionnaire;
d. If the FPP manufacturer selects a source of API with a valid CEP, the reference of the CEP should be mentioned in the questionnaire and **a copy of the certificate (CEP)** should be provided. Note: in such cases, it is expected that the quality control of the API, by the API manufacturer (for batch release) and by the FPP manufacturer (for control of incoming batch) will be done as per the specifications of the CEP.
e. **A copy of a GMP certificate issued by the NRA of the country of manufacture**. Evidence of GMP compliance includes the name of the authority/body that performed the GMP inspection/audit and the date of inspection. If the national GMP certificate cannot be provided, suppliers should state the reason and provide another document establishing the compliance of the manufacturing site with GMP guidelines (e.g. letter from regulatory authority) and/or a link to the regulatory authority's website where the information can be verified.

7.2 Drug Master File (DMF) (IAFPPQ 2.2)

The FPP manufacturer should provide **a copy of the open part of a DMF**.

7.3 APIs and starting materials for sterile FPPs (IAFPPQ 2.3)

For sterile FPPs, suppliers shall provide an **API and starting materials declaration** where the sterility status and control of each starting material is clearly described. The declaration shall capture the following information (e.g. in form of a table):

- Substance name (as used in the master formula)
- Substance category (API / excipient / diluent)

- Sterility status / point of sterilization:
  - Supplied as sterile;
  - Sterilized prior to use;
  - Supplied as non-sterile and intended to be sterilized during FPP manufacture
  - Introduced after the final sterilizing step (highest risk)
- Sterilization responsibility (material manufacturer / FPP manufacturer).

With reference to the above information, suppliers shall add in the declaration:

- For APIs supplied as sterile, information about the sterility test method (compendial or validated alternative) and confirmation that sterility testing is performed on each batch, or justified if parametric release is applied.
  Where sterility testing is outsourced, the testing laboratory qualification status shall be provided.
- For APIs or starting materials sterilized prior to use, description of the sterilization method (e.g. moist heat, dry heat, sterile filtration).
- For non-sterile APIs or materials intended to be sterilized during FPP manufacture, information about the acceptance criteria, defined bioburden limits, action limits and escalation procedures for adverse trends; a summary of bioburden monitoring results (trend-based) and confirmation that bioburden levels are controlled and suitable for the selected sterilization process

7.4 Certificates of Analysis for API manufacturer (IAFPPQ 2.4)

Suppliers should provide:

a. **A copy of CoA issued by the API manufacturer for batch release;** and
b. **A copy of CoA issued by the FPP manufacturer for the control of the same batch at receipt;**
c. **A copy of the FPP manufacturer internal API specifications.**

8. Finished Pharmaceutical Product (FPP) (IAFPPQ Section 3)

8.1 FPP manufacturing site GMP status (IAFPPQ 3.1)

The manufacturing site (unit, block, workshop, line) must comply with GMP guidelines of the country of origin NRA **AND** with WHO or equivalent GMP guidelines.

The suppler is required to provide:

a. **a copy of a valid GMP certificate issued by the NRA of the country of manufacture** or, If the national GMP certificate cannot be provided, suppliers should state the reason and provide another document establishing the compliance of the manufacturing site with GMP guidelines (e.g. letter from regulatory authority) and/or a link to the regulatory authority's website where the information can be verified; and
b. **proof of compliance with WHO or equivalent GMP guidelines** which may be:

- A copy of a recent (< 3 years) inspection report or GMP certificate (copy or link to the relevant NRA website) issued by the National Authorities members of either the European Union (EU), UK Medicines and Healthcare products Regulatory Agency (UK MHRA), US Food and Drug Administration (US FDA), Australian Therapeutic Goods Administration (TGA), Health Canada, Swiss Medic.

- A copy of a recent (< 3 years) inspection report or GMP certificate (copy or link to the relevant NRA website) issued by a WLA.
- A reference to a WHO PIR published on the WHO PQT website (WHO Public Inspection Reports (WHOPIRs))
- A copy of a recent (< 3 years) inspection report (copy or link to the relevant NRA website) issued by a NRAs participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S).
- For NRAs (other than SRAs) included in the WHO transitional list, a copy of a recent (< 3 years) GMP **full** inspection report of the manufacturing site (GMP certificate/letter only is **not** considered sufficient).
- For NRA operating at Maturity level 3 (ML3) or Maturity Level 4 (ML4) by WHO for the relevant product stream as assessed using WHO Global Benchmarking Tool (WHO GBT), a copy of a recent (< 3 years) GMP **full** inspection report of the manufacturing site (GMP certificate/letter only is **not** considered sufficient).
- Approval of manufacturing sites by other UN entities or international health procurement organizations provided that the UN entity or international health procurement organization's GMP audits are recognized by at least three different agencies having the same experience in GMP audits.
- Approval of manufacturing sites by a qualified Procurement Agency (PA) provided that:
  - The UNDP-qualified PA shares a recent copy of the inspection report or corresponding summary in line with the WHO Public Inspection report that the UNDP QA Team considers sufficient to conclude the compliance of the manufacturing site with WHO GMP guidelines AND
  - The PA's mandated lead GMP Inspector has a minimum of 10 years of experience as a lead inspector in the inspection of manufacturing sites of FPPs.

If the expiry date is not explicitly mentioned on the certificate (or acceptance letter), UNDP will consider that the certificate remains valid 3 years after the date of its issuance by the NRA unless otherwise specified by the authority.
The relevant information must be indicated in the dedicated table of the IAFPPQ, supported by the **summary, front page or acceptance letter related to the GMP audit report** shared by the corresponding agency/organization that must be attached to the questionnaire.

In the absence of any acceptable evidence of GMP compliance with WHO or equivalent GMP guidelines, the product will be rejected.

8.2 Finished pharmaceutical product specifications (IAFPPQ 3.2)

The supplier is required to provide a **copy of the batch release and shelf-life specifications (FPP specifications)**.
The FPP specifications should preferably comply with the monographs of the WHO Int Ph, BP or USP, current edition.
If other specifications are used or if a monograph is not available for the product in the above-mentioned pharmacopoeia's, the supplier should provide the manufacturer's In House specifications, including the analytical method and analytical validation data.
If, according to the SmPC (Summary of Product Specifications) and PIL, tablet scoring is intended to allow the administration of fractions of the tablet' dose, UNDP might require the supplier to provide evidence of compliance with the relevant pharmacopeial standards for tablet splitting.

8.3 Certificates of Analysis (CoAs) for FPP (IAFPPQ 3.3)

The supplier is required to provide **3 recent (less than 3 years) commercial batch release CoAs**. The size of the batches should be mentioned in the CoAs and should be coherent with the validated batch sizes as mentioned in section 3.4 of the IAFPPQ and in the Master Formula.

8.4 Manufacturing process validation (IAFPPQ 3.4)

The supplier shall submit the **Manufacturing flow diagram** and the **Process validation report,** supporting the proposed manufacture lot size(s).
Additionally, for sterile products (including aseptically processed and terminally sterilized products), the supplier shall submit the following information.

8.4.1 Sterility Assurance Strategy & Governance

Suppliers are required to provide documented evidence demonstrating an effective sterility assurance system by submitting the following documents:
Contamination Control Strategy (CCS) document, including the following information:

- facilities, utilities, equipment, personnel, processes, and environmental controls;
- evidence that the CCS is implemented, maintained, and periodically reviewed.

Validation Master Plan (VMP) specific to sterile operations with clear identification of:

- critical sterilization and aseptic processing steps, equipment's (i.e. tunnels, filling lines, etc) and
- status of validation activities (completed / ongoing / re-validation triggers).

8.4.2 Aseptic Process Validation & Smoke Studies

Provide current and complete validation evidence for aseptic operations by submitting the following documents:
most recent **Aseptic Process Simulation (APS / Media Fills) protocol and final report,** including the following information:

- Summary of:
  - Number of units filled;
  - Incubation conditions and durations;
  - Interventions performed (routine and worst-case);
  - History of APS failures (minimum last 3 years), including root cause investigations CAPAs and effectiveness checks.
- Clear confirmation that APS was designed based on risk assessment to represent routine operations and incorporates worst-case conditions relevant to the line and product (e.g., maximum run duration, worst-case interventions, staffing/shift pattern, set-ups, hold times, and configurations).

Smoke (Airflow Visualization) studies statement confirming smoke study protocol and report are available and conducted and there are no unresolved critical findings.

8.4.3 Sterilization Processes & Validation

For each sterilization method used (terminal sterilization, filtration, irradiation, etc.) the supplier shall provide:
Sterilization validation protocol and report, including:

- Sterilization parameters, load patterns, worst-case configurations with evidence of ongoing process verification;
- Requalification status;
- Confirmation of last successful sterilization validation and date

8.4.4 Batch Manufacturing Records (BMR) – Sterility Focus

Provide **recent (less than 3 years) Batch Manufacturing Record (BMR)** showing evidence of sterility control, including:

- Confirmation of:
  - Approved sterilization method used;
  - Critical process parameters met
- Release confirmation that:
  - Sterility assurance requirements were met
  - No unresolved critical deviations remain

8.4.5 Environmental & Utility Monitoring

Suppliers are required to provide:

The most recent **Periodic Environmental Monitoring (EM) trend report(s) / EM summary report(s),** covering at minimum the last 6–12 months, capturing the trend-based data summaries (not only pass/fail statements for EM) for Grade A/B areas. The report is expected to show:

- graphs by location/sample type;
- alert/action limits;
- excursion counts;
- recurring organisms/locations;
- seasonal/drift analysis;
- CAPA references (if applicable).

The most recent **Utility trend report/Periodic summary report,** including trend-based monitoring data for sterility-relevant utility quality parameters (e.g., WFI, clean steam, nitrogen), as applicable.

8.4.6 Ongoing Review & Management Oversight

Suppliers are required to provide the most recent **Annual Product Quality Reviews (APQR / PQR) showing** evidence of routine review of sterility assurance and trend analysis related to sterility, demonstrating ongoing state of control, including date and summary of last sterility test failure or positive result on the manufacturing line and confirmation that no unresolved sterility failures exist.

8.5 Stability studies (IAFPPQ 3.6)

Summary of stability studies (3.6.1)

Suppliers are required to complete the table in section 3.6.1 for a minimum of 3 batches tested.

Studies protocol (3.6.1)

Suppliers are required to provide a copy of the **protocol designed by the manufacturer to demonstrate the stability of the FPP** offered to UNDP.

- The stability testing parameters should as a minimum include the test recommended by the WHO in the appendix 1 of the guidelines for “stability testing of active pharmaceutical ingredients and finished pharmaceutical products” (WHO TRS 1010– Annex 10).
- The testing frequency should be coherent with the WHO guidelines (section 2.2.6 in TRS 1010 – Annex 10).
- The storage conditions (for accelerated, intermediate and real-time studies) should be coherent with the WHO guidelines (section 2.2.7 in TRS 1010 – Annex 10).

Studies report (3.6.1)

Suppliers are required to provide the **stability studies reports (and relevant data) for a minimum of 3 batches**.

The reports should include:

a. The name of the FPP and the formulation;
b. The sizes of the lots tested;
   Note: the selection of batches to be tested for stability should comply with the rules given in section 2.2.3 of the WHO guidelines (TRS 1010 Annex 10) or ICH Q1 A (The stability batches shall be representative of the intended commercial manufacturing process and scale);
c. The date of manufacture of the batches tested;
d. The date of initiation of the stability studies;
e. The source of API that was used for the FPP tested;
f. The primary packaging details and reference to its specifications;
   Note: those details must be coherent with those given in section 1.3.1 of the IAFPPQ. The product offered and the product placed in stability studies are expected to comply with the manufacturer's internal reference, as per the specifications attached to section 1.3.1 and 1.3.2;
g. If the secondary packaging has protective properties, and labelling clearly indicates that the product is to be stored in the primary and secondary packaging (e.g. "store tablets in blisters in the provided cartons"), or if the product is packaged in a semi-permeable container where components from the secondary packaging can migrate into the product, the secondary packaging details should also be stated in the stability reports.
   Note: those details must be coherent with those given in section 1.3.2 of the IAFPPQ;
h. The testing conditions;
i. results of the chemical, physical and microbiological tests, as per the FPP specifications and the tests conducted on those attributes that are susceptible to change during storage and transport and that can influence the safety, efficacy and quality of the product;
j. The shelf-life specifications
   Note 1: the shelf-life specifications should preferably refer to the monographs of the WHO International, European, British or US pharmacopoeia.
   Note 2: when numerical limits are given, the results should be expressed in numbers or percentage. The wording "complies" is not accepted for such results.

Product formula (3.6.1)

The FPP placed in stability study must be identical to the FPP offered and to be supplied to UNDP in terms of master formula, APIs and API' sources, manufacturing site, primary and secondary packaging type, materials and specifications.

On-going stability studies (3.6.1)

As per WHO and ICH guidelines, at least one batch per year of product manufactured in every strength and every primary packaging type, if relevant, should be included in the stability programme (unless none is produced during that year). Therefore, UNDP requires the supplier to provide the **report related to the ongoing stability studies**.

Stability studies of the FPP manufactured with API from each proposed API sources (3.6.2)

The documents submitted should show that stability studies have been done will all declared API sources OR a **declaration which states that stability studies are in progress with all declared API sources** must be submitted to UNDP.

Shelf life (3.6.3)

The shelf-life, as mentioned in the IAFPPQ and offered to UNDP must be coherent with the outcome of the stability studies submitted to UNDP.

Storage conditions (3.6.4) and Climatic Zones (3.6.5)

The information provided in the table under section 3.6.4 and in 3.6.5 must be coherent with the outcome of the stability studies submitted to UNDP.

The same storage conditions should be mentioned on the packaging and in the patient information leaflet. The language of storage conditions must be aligned with the WHO guidelines (TRS 1010 Annex 10, Appendix 2)

In-use stability data (3.6.6)

If applicable, UNDP requires the supplier to provide a **report of in-use stability testing** related to multi-dose sterile products, bulk containers, products to be used over a prolonged period, products to be reconstituted, e.g. tablets or capsules packed in large containers (500 or 1000 units), ophthalmic preparations (ointments or drops), suspensions and solutions for oral and parenteral use, etc.

A report on 30-day in-use period (or according to the expected period to use all the product) is considered acceptable without further supporting data.

Unless the stability studies and protocol include all the above information and meet the described requirements, the manufacturer will be requested to provide a signed **declaration** clarifying the relevant observations or a commitment to perform the missing studies.

9. Safety/efficacy and/or therapeutic equivalence (IAFPPQ Section 4)

9.1 Proof of therapeutic equivalence for generic products (IAFPPQ 4.2)

If the supplier claims that such proof is unnecessary, it must substantiate its statement by referring to the WHO guidelines (WHO TRS 1052 – Annex 8: Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability). Otherwise, the supplier is required to submit the **proof of therapeutic equivalence (Comparative Dissolution studies or Bioequivalence studies)** as per the requirements described below.

The product tested in the equivalence studies (biobatch) must be identical in all characteristics to the one offered to UNDP and tested in the stability studies submitted, i.e. in terms of API(s), excipients, pack type and size and manufacturing site.

9.2 Proof of therapeutic equivalence (IAFPPQ 4.2)

If, according to the WHO guidelines, a proof of equivalence is needed, the supplier is required to fill out sections 4.2.1 or 4.2.2 (and related sub-sections) of the IAFPPQ depending on whether the proof of equivalence was established through in vivo bioequivalence studies (section 4.2.1) or by comparative in vitro dissolution testing (section 4.2.2).

If the supplier asserts that an in vitro comparative dissolution profile is sufficient to demonstrate the efficacy/safety of the generic product, it must provide a justification based on WHO guidelines: current version of WHO Biowaiver list OR, if the product is not listed, TRS 937 – Annex 8: Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. The comparative dissolution studies should be designed, performed and analyzed according to the WHO recommendations for conducting and assessing comparative dissolution profiles (WHO TRS 986, Annex 6, Appendix 1). If the API(s) used in the FPP is/are not listed in the current version of the WHO Biowaiver list or in WHO TRS 937 – Annex 8, the supplier may justify the request for a

biowaiver by referring to another Biopharmaceutical Classification System (BCS, e.g. ICH M9 Harmonized guideline) or by presenting scientific evidence (along with relevant bibliographic references) on the permeability/solubility profiles of the API(s).

Comparator product (4.2.1.1 or 4.2.2.1)

When an equivalence study is performed, the choice of the comparator product should be based on the WHO "Guidance on the selection of comparator pharmaceutical products for equivalence assessment of interchangeable multisource (generic) products" (WHO TRS 992-Annex 8).

The manufacturer is expected to provide following information related to the comparator used:

a. Manufacturer name;
b. Batch number;
c. Expiry date;
d. Country where the comparator product is marketed and corresponding marketing authorization number.

If the manufacturer is not able to obtain the comparator product recommended by the WHO or if the product is not included in the WHO list of comparator products, the selection of the product should still adhere to the overall principles stated in the guidance note of the WHO.

9.3 Therapeutic equivalence - commitment (IAFPPQ 4.2.3)

The supplier is required to provide a **signed declaration confirming that the product tested in the equivalence studies is identical in all characteristics to the one offered to UNDP and tested in the stability studies submitted**.

If this is not the case, the supplier must provide a scientifically sound explanation of the variations and provide evidence that these variations do not affect the efficacy/safety profile of the product offered.

In the absence of any acceptable proof of therapeutic equivalence (unless justified as per above conditions), the product will be rejected.

10. Related documents

QST-FPP-001 v02 'MQAS IAFPPQ version 21 October 2024'

11. Annexes checklist

Before submitting the product questionnaire to UNDP, please ensure that all documents necessary to enable objective evaluation of your product are attached.

Annexes in italic are required for sterile FPPs only.

Section 1:

☐1. **Master Formula (complete qualitative and quantitative composition including active ingredient(s) and excipients**

☐2. **Pictures or artworks of the primary packaging**

☐3. **Pictures or artworks of the secondary packaging**

☐4. **Primary packaging materials specifications**

☐5. **Secondary packaging materials specifications**

☐6. **Detailed description of the dose measurement/dose delivery device (if applicable)**

☐7. **Patient information leaflet**

☐8. **Manufacturing Licence**

☐9. **Certificate of pharmaceutical product (CPP) according to the WHO Certification Scheme (WHO Technical Report Series, No. 863).**

☐10. **Declaration of equivalence (DoE) IAFPPQ through supplier**

Section 2:

☐11. **Certificate of suitability to the European Pharmacopoeia (CEP) and its annexes (if applicable)**

☐12. **API' manufacturer(s) GMP certificates OR, if not issued by the relevant country NRA, other evidence establishing the compliance of the manufacturing site with GMP guidelines**

☐13. **Open part of a DMF**

☐14. ***API and starting materials declaration***

☐15. **CoA issued by the API manufacturer for batch release**

☐16. **CoA issued by the FPP manufacturer for the control of the same batch of API at receipt**

☐17. **FPP manufacturer internal API specifications**

Section 3:

☐18. **GMP certificate issued by the NRA of the country of manufacture**

☐19. **Proof of compliance with WHO or equivalent GMP guidelines**

☐20. **Batch release specifications**

☐21**. Shelf life specifications**

☐22. **Certificate of analysis for the three last batches released**

☐23. **Manufacturing flow diagram**

☐24. **Process validation report**

☐25. ***Contamination Control Strategy (CCS) document***

☐26. ***Validation Master Plan (VMP)***

☐27. ***Aseptic Process Simulation (APS / Media Fills) protocol and final report***

☐28. ***Smoke (Airflow Visualization) studies statement***

☐29. ***Sterilization validation protocol and report***

☐30. ***Recent (less than 3 years) Batch Manufacturing Record (BMR)***

☐31.***Periodic Environmental Monitoring (EM) trend report(s) / EM summary report(s)***

☐32. ***Annual Product Quality Reviews (APQR / PQR)***

☐33. **Stability study protocol for accelerated and long-term stability testing**

☐34.**Stability studies reports (and relevant data) for a minimum of 3 batches for accelerated and long-term stability testing**

☐35.**Declaration which states that stability studies are in progress with all declared API sources (if applicable)**

☐36. **Ongoing stability studies reports**

☐37. **In-use stability data and storage conditions after opening or reconstitution (if applicable)**

☐38. **Declaration including complementary information related to the stability studies protocol and reports submitted, e.g. API used, primary packaging materials specifications (if applicable)**

Section 4:

☐39. **Comparative Dissolution studies or Bioequivalence studies (as applicable)**

☐40. **Signed declaration confirming that the product tested in the equivalence studies is identical in all characteristics to the one offered to UNDP and tested in the stability studies submitted**.

	Name	**Position**	**Date & Signature**
Author:	Matteo Pedrini	QA specialist for health products	22-Apr-2026 DocuSigned by: AC7F044EDF4426...
Reviewer:	Jean-Michel Caudron	UNDP QA Expert for health products-consultant	23-Apr-2026 DocuSigned by: D316920500E445F...
Approver:	Seloi Mogatle	QA Chief health products	22-Apr-2026 DocuSigned by: 11FAEA2A93054F2...