

Section II: Schedule of Requirements

A. Summary of Requirements

UNOPS requirements are comprised of the following Lots:

Lot No.	Item	General Description	Primary Packaging	Secondary Packaging	Unit	Total Quantity in Unit
1	TB Cat I + III Patient Kit A	4-FDC (Rifampicin 150mg/Isoniazid75mg/Pyrazinamide400mg/Ethambutol hydrochloride 275mg film coated tablets)+2-FDC (Rifampicin 150mg/Isoniazid75mg film coated tablets) - Kit	4-FDC- 6 blisters x 28tablets (168 tablets) 2-FDC -12 blisters x28tablets (336tablets)	Provided in specifications	Kit	93,370
2	2FDC/ RH 150/75 (blister)	Fixed-dose combination of Rifampacin150mg/ Isoniazid 75mg coated tablets	28 tablets /blister	pack of 24 blisters x 28 tablets	Pack	1,041
3	2FDC/ RH 75/50 (strip)	Fixed-dose combination of Rifampicin 75mg/ Isoniazid 50mg dispersible uncoated tablets	28 tablets/strip	pack of 3 strip x 28 tablets	Pack	141,768
4	3FDC/ RHZ 75/50/150 (blister)	Fixed-dose combination of Rifampicin 75mg/ Isoniazid 50mg/ Pyrazinamide 150mg dispersible uncoated tablets	28 tablets/blister	pack of 3 blisters x 28 tablets	Pack	67,176
5	E (100mg) blister	Ethambutol hydrochloride 100mg Film coated tablets	10 tablets/blister	Pack of 10 blister x 10 tablets	Pack	1,999

B. Technical specifications for Goods and Comparative Data Table

1. Standard requirements

The required Finished Pharmaceutical Products (FPPs) should meet the requirements of the pharmaceutical legislation and regulation of the country of origin for manufacturing and distribution of medicines. Country of origin means here the country where the finished product is manufactured.

Good Manufacturing Practices (GMP) standards as set out by the WHO should be adhered to, in all respects for manufacturing, packaging and labeling of products.

FPPs should also be compliant with monographs set by WHO International Pharmacopeia (Int Ph), United States Pharmacopeia (USP), British Pharmacopeia (BP) and European Pharmacopeia.

Labelling and package inserts shall be in English.

2. Bidder's eligibility- Quality Assurance Requirements:

The Technical Evaluation will take into account the following criteria which are in accordance with the Global Fund's Quality Assurance Policy on Pharmaceuticals as stipulated on the Global Fund' website <https://www.theglobalfund.org/en/search/?q=Pharmaceutical+QA+policy>

- a. Finished Pharmaceutical Product (FPP) offered is Prequalified under the WHO Prequalification Programme or
- b. Finished Pharmaceutical Product (FPP) offered is authorized for use by a Stringent Regulatory Authority.
- c. Recommended for use by an Expert Review Panel (ERP) as described in the Section 10 of the Global Fund QA Policy on Pharmaceuticals.

If there are two or more FPPs available for the same Product Formulation that meet the quality standards set out in 'A' or 'B' above, the UNOPS will select the FPP that meets either of those standards.

If it is determined that there is only one or no FPP that meets the quality standards set out in 'A' or 'B', then the UNOPS, if it wishes, may consider the selection of FPP, only upon the approval of the Global Fund that the FPP meets the standard specified in 'C' above.

The bidder shall possess the following documents and shall submit along with the bid:

For A – Products:

- a. The manufacturing license issued by the National Drug Regulatory Authority of the country of manufacturer.
- b. The valid GMP certificated issued under the WHO-Prequalification program certifying the compliance of the manufacturing site with WHO GMP requirements
- c. WHO-Prequalification program approval letter with detail specifications of products as approved by the WHO-Prequalification program

For B- products:

- a. The manufacturing license issued by the National Drug Regulatory Authority of the country of manufacturer.
- b. Copy of approval or registration certificate or marketing authorization from a stringent regulatory authority (SRA);
- c. Copy of GMP (Good Manufacturing Practice) certificate issued by an SRA, a PIC member or the WHO Prequalification Program certifying the compliance of the manufacturing site with WHO GMP requirements

ERP Recommended product:

- a. Documentary evidence that the FPP is Global Fund Expert Review Panel (ERP) recommended
- b. The manufacturing license issued by the National Drug Regulatory Authority of the country of manufacturer
- c. Copy of GMP (Good Manufacturing Practice) certificate issued by an SRA, a PIC member or the WHO Prequalification Program certifying the compliance of the manufacturing site with WHO GMP requirements

Interagency product questionnaire should be completed for all the products offered (Form F) and submitted with the offer including all required annexes. Incomplete interagency product questionnaires will not be considered during the technical analysis.

The bidder shall complete the following table and submit along with the bid:

Brand name if any	INN/Generic name	Strength	Dosage form	Packaging details	A-product	B-Product	ERP-Recommended Product	Manufacturing Site
					Yes/No	Yes/NO	Yes/NO	

Product offered shall have the same specifications as approved under WHO pre-qualification programme or SRA or recommended by ERP, as the case may be. No variations to these specifications will be accepted during the procurement process during the contract period covered by this tender procedure except if these variations have been already approved by the WHO Prequalification Programme or by the stringent regulatory authority before the contract is finalized. Proof of acceptance of these variations will need to be submitted. Non respect of these specifications while supplying will cause rejection of the goods at reception.

3. Packaging and Labeling Specifications

- a. Primary Packaging shall be as approved by the WHO under the pre-qualification program/SRA/recommended by ERP.
- b. Packaging and labelling components (e.g., *bottles, closures, and labelling*) should also meet specifications suitable for distribution, storage, and use in a climate similar to that prevailing in the Myanmar. All packaging must be properly sealed and tamper-proof *and packaging components must meet the latest compendium standards and be approved for pharmaceutical packaging by the manufacturer's National Regulatory Authority*
- c. All labelling and packaging inserts shall be in English
- d. Goods requiring refrigeration or freezing or those that should not fall below a certain minimum temperature for stability must specifically indicate storage requirements on labels and containers and be shipped in special containers to ensure stability in transit from point of shipment to port of entry.
- e. The individual containers shall be packed in carton boxes made of strong corrugated cardboard that are:
 - suitable to be piled at least 5 boxes high;
 - Sufficiently strong to withstand rough handling and exposure to extreme tropical temperatures and air moisture.
 - Final cartons should be shrink-wrapped in a clear plastic which prevent the product during transportation, storage and handling keeping in view the heavy rains in Myanmar.
 - If there are enough numbers of cartons to form a pallet, palletisation shall be done and protectively wrapped.
- f. The label for each pharmaceutical product shall meet the WHO GMP standard and include:
 - The international non-proprietary name (INN) or generic name prominently displayed and above the brand name, where a brand name has been given. Brand names should not be bolder or larger than the generic name;
 - The dosage form; e.g., tablet, ampoule, syrup, etc.
 - The active ingredient "per unit, dose, tablet or capsule, etc.
 - Strength/concentration of the product;
 - Date of manufacture and expiry (in clear language, no code);
 - Batch number;
 - Content per pack;

- Instructions for use;
- Special instructions for storage;
- Name and address of the manufacturer;

The outer case or carton should also display the above information including the following,

- UNOPS Logo and PO number;
- Carton numbering e.g. carton 1/40;
- Any additional cautionary statements;

Packaging for Cat I and III kit:

Item	General Description
Specifications of the outer box	Laminated, corrugated punched cardboard box Dimensions: <ul style="list-style-type: none"> • Length: 220mm ±5mm • Width: 115mm±5mm • Height: 130mm±5mm
Specifications of the 4-FDC inner box	Laminated, corrugated punched cardboard box Dimensions: <ul style="list-style-type: none"> • Length: 200mm ±5mm • Width: 50mm±5mm • Height: 120mm±5mm
Specifications of the 2-FDC inner box	Laminated, corrugated punched cardboard box Dimensions: <ul style="list-style-type: none"> • Length: 150mm ±5mm • Width: 60mm±5mm • Height: 85mm±5mm

4. Quality Control:

If required, UNOPS may arrange for sample testing for each batch through an independent laboratory, which should not influence the Supplier’s regular testing procedures. Suppliers should make provision of providing sufficient samples per batch as required at no extra cost. The samples will be collected at the time of pre-dispatch inspection or post shipment.

In the event a dispute should arise between UNOPS and the Supplier, a counter analysis will be carried out by an independent neutral accredited laboratory agreed by both UNOPS and the Supplier. If the counter analysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective goods. In the event the independent analysis confirms the quality of the product. The UNOPS will meet all costs for such analysis.

Standards of Quality Control for Supply

The successful Supplier will be required to furnish to the Purchaser:

- (a) With each consignment, and for each item a certificate of quality control test results concerning quantitative assay, chemical analysis, sterility, pyrogen, content uniformity, microbial limit, and other tests, as applicable to the Goods being supplied and the manufacturer's certificate of analysis;

- (b) Assay methodology of any or all tests if requested;
- (c) Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.

5. Defect:

On reception, in case of the detection of a defective product either in the quality of a product or in any other aspects such as packaging, the Supplier will be requested to replace the complete batch at its own cost.

6. Shelf life:

All goods must bear the following:

- Date of manufacture; and
- Expiry date

The product shall also have -

- a minimum of 80 % for products with shelf life 2 years or less of remaining shelf life on delivery.
- a minimum of 75% for products with shelf life 3 years or more of remaining shelf life on delivery.

7. Complaints:

Any complaint from UNOPS or its Sub-Recipients will be handled by the Supplier according to its internal standard operating procedures, and pursuant to the provisions relating to provisions as set out in the General Conditions.

8. Recall:

If, after delivery, a batch has to be recalled, for whatever reason, the Supplier will inform UNOPS immediately. The Supplier will replace, at its own cost, all items covered by the recall with goods that fully meet the requirements of the original Purchase Order, and arrange for the collection or destruction of any **defective goods**.

9. Inspections and Tests

UNOPS will have right to conduct pre -shipment inspection and laboratory testing of products. Bidder has to provide all required related documents and other required standards/chemicals etc (In case of the requirement by UNOPS hired testing lab for quality testing) to the UNOPS contacted testing laboratory at own cost.

Regardless of any pre-shipment inspection (and the result thereof) All goods may be subject to inspection/audit and quality control testing by UNOPS/ The Global Fund or its designated representatives, to the extent practicable, at all times and places, including during the period of manufacture and, in any event, prior to final acceptance.

UNOPS/The Global Fund or Sub-Recipients may also carry out quality control testing of the Goods any time during the shelf life of Goods even after the acceptance of Goods by consignee.

C. Delivery requirements and Comparative Data Table:

The requirements are provided in the returnable form G. The Bidder shall complete the Form G and submit along with the bid.