

Section II: Schedule of Requirements

A. Summary of Requirement

UNOPS requirements are comprised of the following:

Lot No.	Item Description	Strength	Pack Size	Unit	Total Quantity in Unit
1	Benzathine Penicillin	2.4 million IU	50 vials/pack	Pack	1,573
2	Co-trimoxazole DS tablet	960 mg	500 tabs/pack	Pack	2,541
3	Co-trimoxazole (suspension)	240 mg/5 mL	Bottle of 100 ml	Bottle	434
4	Fluconazole	100 mg	Any	Tab/Cap	3,100
5	Amphotericin B deoxycholate injection	50 mg	Vial/Injection	Vial/Injection	260
6	Flucytosine	500 mg	Any (100 tabs/pack or less than 100 tabs/pack)	Tab	1,560
7	Fluconazole infusion	200 mg/100 ml	Vial/Injection	Vial/Injection	780
8	Fluconazole	400 mg	Any	Tab/Cap	2,100
9	Fluconazole Capsule	200 mg	Any	Cap	6,600
10	Azithromycin	500 mg	3 tabs/pack	Pack	2,666
11	Azithromycin	500 mg	3 tabs/pack	Pack	1,467
12	Cefixime Tablet/Film coated tablet	200 mg	Any	Tab	4,400

***Please quote lot 10 and 11 separately as they belong to different projects**

B. Quality Assurance and Other Requirements

1. Standard requirements

These products 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 labelling of products.

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

Labelling and package inserts shall be in English.

2. Quality Assurance Requirements

The below quality assurance documents are required to be provided along with your offer

1. The bidder should have Manufacturing license with the competent National Drug Regulatory Authority (NDRA) of the country the manufacturer.
2. A GMP certificate issued by the NDRA of the country of Manufacturer based on the WHO Guidelines.
3. For the items when there was no monograph for the ingredients, the bidder should provide a documents of the In-House-Specification (IHS) along with the offer.

3. Packaging and Labelling Specifications

- a. 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 Cambodia. 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.*
- b. All labelling and packaging inserts shall be in English.
- c. 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.
- d. The packaging shall be done separately for each product.
- 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 that prevents the product during transportation, storage and handling keeping in view the heavy rains in Cambodia.
 - If there are enough numbers of cartons to form a pallet, palletisation shall be done and protectively wrapped.
- f. Outer/shipper cartons must be clearly marked only as follows:

- 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
 - The active ingredient per unit
 - Strength/concentration of the product;
 - Date of manufacture and expiry (in clear language, no code);
 - Batch number;
 - Content per pack;
 - Instructions for storage;
 - Name and address of the manufacturer;
 - Carton numbering (e.g. 'carton 1/40')
- g. All Inner boxes must have the information as follows:
- 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
 - The active ingredient per unit
 - 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;

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 as samples per batch as required at no extra cost. The samples will be collected at the time of pre-dispatch inspection.
- 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.
- 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 including removal, shipping and destruction of the defective product as appropriate.

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. Shelf life

All goods must bear the following:

- Date of manufacture; and
- Expiry date

Remaining shelf life of 80 % on delivery for products with total shelf life

UNOPS reserves the right to accept for any deviation to the above shelf life due to urgent requirement subject to the acceptability of the end users. **For any deviation to this, the product expiry date has to be accepted by UNOPS. No shipment shall be made without UNOPS approval of shorter expiry dates.**

The bidder shall offer only the products where the Shelf life requirement is met as above

6. 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.

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**.

B. Delivery requirements and Comparative Data Table:

UNOPS Requirements	
Delivery Schedule	100% Quantity within 30 days of signed PO or Please offer the earliest delivery time.
Delivery place and Incoterms rules	Shipment by air. CPT - Phnom Penh Airport as per Incoterms 2020. Custom clearance to be done by UNOPS Note: Please offer the Air mode of transport only. .
Consignee Details	National Center for HIV/AIDS, Dermatology And STDs, Ministry of Health, #245 H, Phum Kean Klang, Khan Chrouy, Changva, Phnom Penh Cambodia
Submission of Shipping documents	<p>At the time of offering the product for inspection, it is advisable that the supplier submit the DRAFT shipping documents in advance to UNOPS for applying Tax Exemption. Supplier shall not ship the goods till Tax Exemption Certificate (TEC) is received and UNOPS has provided clearance to ship the Goods.</p> <p><u>Submission of FINAL shipping documents:</u></p> <p>After the satisfactory test report and receipt of TEC, as informed by UNOPS, the supplier shall submit immediately all the final shipping documents to UNOPS for customs clearance.</p>
UNOPS Right to vary requirements	At the time the Contract is awarded, UNOPS reserves the right to vary the quantity of the goods and associated services specified above, provided this does not exceed +/- 20%, without any change in the unit prices or other terms and conditions of the ITB

Note: The shipping documents will be required to be provided to the consignee almost 3 weeks in advance for applying for the Tax exemption and Import permit.

The shipment shall be made within 10 working days only after the dispatch clearance is issued by UNOPS.

Note - The time between the days when shipping documents are provided to UNOPS and the day dispatch clearance is issued is not included in the delivery times mentioned above.