

## Section II: Schedule of Requirements

eSourcing reference: ITB 2018/2784

**A. Summary of Requirements** [this section is useful if there are multiple lots to give an overview, if not remove]

### B. Summary of Requirements

UNOPS requirements are comprised of the following:

No.	Item Description	Product strength	Pack Size	Unit	Qty in Unit
1	<b>Iodized oil fluid</b> (equivalent to elemental iodine 200mg) <b>Soft gel capsule</b>	500mg	pls offer manufacturer pack size	Soft Gel Capsule	1,695,000

### C. Technical specifications for Goods

#### 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

#### The bidder shall submit the documentary evidence for the following-

1. The bidder should have Manufacturing and marketing license with 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.

#### Packaging and Labelling Specifications

- a. Packaging and labelling components should also meet specifications suitable for distribution, storage, and use in a climate similar to that prevailing in the Philippines. 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 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 Philippines.
  - If there are enough numbers of cartons to form a pallet, palletisation shall be done and protectively wrapped.
- e. 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;

#### **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 % 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.

**D. Delivery requirements :**

<b>UNOPS Requirements</b>	
<b>Delivery time</b>	<p>Shipment should be delivered by <b>end of November 2018</b>.</p> <p>DOH, Philippine requires the product urgently and it is appreciated to receive the best earliest offer.</p> <p>Along with the shipment, supplier has to provide Certificate of Analysis document (COA) to UNOPS.</p> <p>Supplier shall provide advance notification to UNOPS and consignee for the shipment. In consultation with consignee supplier may need to provide shipping documents much in advance for the DOH to apply for necessary import clearance.</p>
<b>Delivery place and Incoterms rules</b>	CPT (Ninoy Aquino International airport)
<b>Consignee details</b>	Department of Health, Manila, Philippines. Ministry of Health