TECHNICAL SPECIFICATION – GENERAL

Our Minimum Requirements	**Your Offer (Please fill-in)** Yes/No
1. Product and Package Specifications	
1.1. The pharmaceuticals and vaccines to be purchased by the Purchaser under this Invitation for Bids are included in the Purchaser's national essential drugs list or national formulary. The required packing standards and labeling must meet Good Manufacturing Practices ("GMP") standards in all respects.	
1.2. Product specifications indicate dosage form (e.g., tablet, liquid, injectable, emulsion, suspension, etc.) and the drug content (exact number of mg or % v/v with acceptable range). The products should conform to standards specified in one of the following compendia: the British Pharmacopoeia, the United States Pharmacopoeia, the French VIPAL pharmacopoeia, Indian Pharmacopoeia, National Formulary of India, or the International Pharmacopoeia the Standards will be the latest edition. In case the pharmaceutical or vaccine product is not included in the specified compendium, the Supplier, upon award of the Contract, must provide the reference standards and testing protocols to allow for quality control testing.	
1.3. Not only the pharmaceutical or vaccine item, but also the packaging components (e.g., bottles and closures) should also meet specifications suitable for use in a climate similar to that prevailing in the country of the Purchaser. Stability of drugs should be strongly adhered with reference to temperature & humidity in relation to area of supply, during transportation of drugs and their storage. All packaging must be properly sealed and tamper-proof.	
1.4. Pharmaceuticals and drugs requiring refrigeration or freezing 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.	
2. Product Information	
2.1. The following information will be required for each pharmaceutical and vaccine product offered by the Bidder: (i) INN (International Non-proprietary Name) (ii) Brand name (if it appears on the label) (iii) Name and address of the manufacturer (iv) Country of Origin (v) Compendia standards (vi) Shelf life of Drugs	
2.2. Upon award, the successful Bidder shall on demand provide a translated version in the language of the bid of the prescriber's information for any specific product the Purchaser may request.	

Our Minimum Requirements	**Your Offer (Please fill-in)** Yes/No
2.3. Failure to include any of this information may, at the discretion of the Purchaser, render the bid non-responsive.	
3. Expiration Date	
3.1. All products must indicate the dates of manufacture and expiry.	
4. Recalls	
4.1. If products must be recalled because of problems with product quality or adverse reactions to the pharmaceutical or vaccine, the Supplier will be obligated to notify the Purchaser, providing full details about the reason leading to the recall, and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable pharmaceuticals or vaccines, or withdraw and give a full refund if the product has been taken off the market due to safety problems.	
5. Labeling Instructions	
5.1. The label for each pharmaceutical and vaccine product shall meet the WHO GMP standard and include: (i) the 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 (ii) the active ingredient, per unit, dose, tablet or capsule, etc. (iii) the applicable pharmacopoeial standard (iv) the Purchaser's logo and code number if required in Part A of these Specifications (v) content per pack (vi) instructions for use (vii) special storage requirements (viii) batch number (ix) date of manufacture and date of expiry.	
5.2. The outer carton should also display the above information.	
6. Details of Packing/Cases	
6.1.All cases should prominently indicate the following: Purchaser's Part A line and Code numbers (ii) the generic name of the product (iii) date of manufacture and expiry (iv) batch number (v) quantity per case	
6.2.No case should contain pharmaceutical or vaccine products from more than one batch.	
7. Unique Identifier	
7.1. The Purchaser shall have the right to request the Supplier to imprint a logo on the containers used for packaging and in certain dosage forms, such as tablets, and this	

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Our Minimum Requirements	**Your Offer (Please fill-in)** Yes/No
will be indicated in Part A of the Technical Specifications. The design of such logo shall be provided to the Supplier at the time of Contract award.	
8. Qualifications of Manufacturer	
8.1. The bidder shall furnish a certificate from the competent FDRA that the manufacturer of the pharmaceutical or vaccine product covered by this Invitation for Bids is licensed to manufacture these products.	
9. Standards and Quality Assurance Requirements	
9.1.All products must:	
(a) Meet the requirements of manufacturing legislation and regulation of pharmaceuticals or vaccines in the country of origin;	
(b) Conform to all the specifications contained herein; and	
(c) be certified by a competent authority in the manufacturer's country according to resolution WHO 28-65-B, of the World Health Organization "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce".	
9.2. The successful Bidder will be required to furnish to the Purchaser: (a) With each consignment, a certificate of quality assurance test results in conformity with the WHO Certification Scheme concerning quantitative assay, chemical analysis, sterility, pyrogen content uniformity, microbial limit and other tests, as applicable to the product being supplied and Part A of these Specifications. (b) Assay methodology of any or all tests if requested. (c) When two or more drugs are combined in single tablet, the information about bio-availability must be supplied. (d) Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.	
9.3. The successful Bidder will also be required to provide the Purchaser with access to its manufacturing facilities to inspect its facilities, quality control procedures for raw materials, test methods, in-process tests, and finished dosage forms.	

THE PRODUCTS OFFERED ARE IN ACCORDANCE WITH THE SPECIFICATIONS AND REQUIREMENTS

YES NO

ANY DEVIATION MUST BE LISTED BELOW:

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Inspection & Tests

Our Requirements	**Please fill-in** Yes/No
The following inspection procedures and tests are required by the Purchaser.	
a) Two sets of samples of required quantity of each item will be drawn at random from each batch by the Purchaser's Inspector.	
b) One set of sealed sample will be sent to an independent laboratory selected by the purchaser for conducting the required test to confirm whether the samples conform to the prescribed specification. **Another set of sealed sample will be retained with the testing lab. as counter sample till the shelf life.**	
c) Inspection note will be issued by the approved inspecting committee on the basis of test report, accepting or rejecting the batch as the case may be.	
d) The Goods will be accepted only after the above inspection procedure has been followed and inspection note issued to accept the consignment.	
e) The Purchaser/consignee shall have the right to draw samples at random from the consignment anytime during the shelf life of the drugs and get them retested to satisfy whether the lots conform to the laid down specifications. In the event of the product failing to conform to specifications, the consignee shall reject that batch of supply and inform the supplier for arranging replacement of the rejected batches at supplier's cost.	