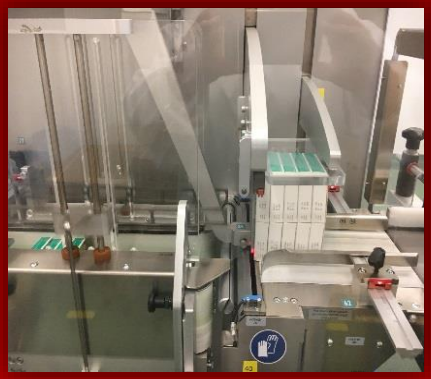
2018



ANTI–TUBERCULOSIS MEDICINES TECHNICAL SPECIFICATIONS, FIRST LINE DRUGS – ITB - IDA/FLD/2018/001

GLOBAL DRUG FACILITY

STBP | Stop TB Partnership

Eligibility criteria for submission of bids for anti-tuberculosis drugs

Only bidders with products in compliance with the GDF Quality Assurance Policy (see http://www.stoptb.org/gdf/drugsupply/quality_sourcing_process.asp) are eligible to participate in the ITB.

The requirements are as following:

A. Products pre-qualified by WHO under the WHO Prequalification Programme (WHO PQP)[1]; or

B. Products approved by a Stringent Regulatory Authority (SRA)[2];

C. In the absence of products meeting the standards "A" and "B" as above, products recommended for use through a quality risk/benefit assessment process by the Expert Review Panel (ERP)[3]. These products are eligible for procurement for a limited period and under the following conditions:

1. The Finished Pharmaceutical Product (FPP) must be manufactured at an approved site as follows:
    - The site must have been inspected by WHO as a part of the WHO PQP (refer to http://apps.who.int/prequal/) and found to be operating at an acceptable level of compliance with WHO Good Manufacturing Practice (GMP) for the specific product; or
    - The site must have been inspected and found acceptable for the manufacture of the specific product by SRA defined as either: an International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) member country, an ICH observer or any country whose regulatory authority is associated with an ICH member through a legally binding mutual recognition agreement; or
    - The site must have been inspected and found acceptable for the manufacture of the specific product by inspectors of a regulatory authority participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S)
2. A product approval as described under either point "A" or "B" is pending, i.e. manufacturers have submitted relevant product dossiers and the dossiers have been accepted for assessment either by WHO PQP or SRA. Approvals under point "C" shall be limited to a maximum duration of 12 months in which manufacturers should obtain approval by WHO PQP or SRA.

Note: A bid submitted for a product for which the bidder has not received regulatory approval status as per GDF Quality Assurance policy and procedures, shall not be considered for the ITB evaluation.

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[1] https://extranet.who.int/prequal/content/prequalified-lists/medicines

[2] https://extranet.who.int/prequal/sites/default/files/documents/75%20SRA%20clarification_February2017_0.pdf

[3] https://extranet.who.int/prequal/sites/default/files/documents/73%20ERP_Feb2016_1.pdf

LIST OF PRODUCTS AND TECHNICAL SPECIFICATIONS

SCHEDULE NO. 1:

Oral solid dosage forms. Fixed dose combinations for adults and children.

ADULTS:

1. ITEM No. 1: 4FDC/ RHZE 150/75/400/275 (blister)

General Description: Fixed-dose combination of Rifampicin 150mg/Isoniazid 75mg/Pyrazinamide 400mg/Ethambutol 275mg film coated tablets.

Primary packaging: 28 tablets/blister

Secondary packaging: pack of 24 blisters x 28 tablets.

2. ITEM No. 2: 3FDC/ RHE 150/75/275 (blister)

General Description: Fixed-dose combination of Rifampicin 150mg/Isoniazid 75mg/Ethambutol 275mg film coated tablets.

Primary packaging: 28 tablets/blister

Secondary packaging: pack of 24 blisters x 28 tablets.

3. ITEM No. 3: 2FDC/ RH 150/75 (blister)

General Description: Fixed-dose combination of Rifampicin 150mg /Isoniazid 75mg film coated tablets

Primary packaging: 28 tablets/blister

Secondary packaging: pack of 24 blisters x 28 tablets

CHILDREN:

4. ITEM No. 6: 3FDC/ RHZ 75/50/150 (blister)

General Description: Fixed-dose combination of Rifampicin 75mg /Isoniazid 50mg/ Pyrazinamide 150mg dispersible tablets.

Primary packaging: 28 or 10 tablets/blister

Secondary packaging: pack of 3 blisters x 28 tablets or 10 blisters x 10 tablets

5. ITEM No. 7: 2FDC/ RH 75/50 (blister)

General Description: Fixed-dose combination of Rifampicin 75mg/Isoniazid 50mg dispersible tablets.

Primary packaging: 28 or 10 tablets/blister

Secondary packaging: pack of 3 blisters x 28 tablets or 10 blisters x 10 tablets

SCHEDULE NO. 2:

Oral solid dosage forms. Single dose formulations for adults and children

ADULTS

6. ITEM No. 1: Ethambutol 400 mg (blister)

General Description: Ethambutol 400mg film coated tablets

Primary packaging: 28 tablets/blister

Secondary packaging: pack of 24 blisters x 28 tablets

7. ITEM No. 2: Isoniazid 300 mg (blister)

General Description: Isoniazid 300mg tablets

Primary packaging: 28 tablets/blister

Secondary packaging: pack of 24 blisters x 28 tablets

8. ITEM No. 3: Pyrazinamide 400 mg (blister)

General Description: Pyrazinamide 400mg tablets

Primary packaging: 28 tablets/blister

Secondary packaging: pack of 24 blisters x 28 tablets

9. ITEM No. 4: Pyrazinamide 500 mg (blister)

General Description: Pyrazinamide 500mg tablets

Primary packaging: 28 or 10 tablets/blister

Secondary packaging: pack of 24 blisters x 28 tablets or 10 blisters x 10 tablets

10. ITEM No. 5: Rifampicin 150 mg (blister)

General Description: Rifampicin 150mg tablets or capsules.

Primary packaging: 10 tablets or capsules/blister

Secondary packaging: pack of 10 blisters x 10 tablets or capsules

11. ITEM No. 6: Rifampicin 300 mg (blister)

General Description: Rifampicin 300mg tablets or capsules.

Primary packaging: 10 tablets or capsules/blister

Secondary packaging: pack of 10 blisters x 10 tablets or capsules

12. ITEM No. 7: Rifabutin 150 mg (blister/container)

General Description: Rifabutin 150mg capsules.

Primary packaging: 100 capsules/HDPE container or 10 capsules/blister.

Secondary packaging: 100 capsules/HDPE container or pack of 10 blisters x 10 capsules.

CHILDREN

13. ITEM No.8: Isoniazid 100 mg (blister/container)

General Description: Isoniazid 100mg tablets or dispersible tablets.

Primary packaging: 10 tablets/blister or 100 tablets/HDPE container

Secondary packaging: pack of 10 blisters x 10 tablets or 100 tablets/HDPE container

14. ITEM No.9: Ethambutol 100 mg (blister/container)

General Description: Ethambutol 100mg tablets or dispersible tablets.

Primary packaging: 10 tablets/blister or 100 tablets/HDPE container

Secondary packaging: pack of 10 blisters x 10 tablets or 100 tablets/HDPE container

15. ITEM No. 10: Pyrazinamide 150 mg (blister/container)

General Description: Pyrazinamide 150mg dispersible tablets

Primary packaging: 10 tablets/blister or 100 tablets/HDPE container

Secondary packaging: pack of 10 blisters x 10 tablets or 100 tablets/HDPE container

SCHEDULE NO. 3: Stop TB patient kit

16. ITEM No. 1: Cat I & III Kit type A

General Description: Stop TB Cat. I + III Patient Kit type A containing

- 6 blisters of 4FDC R150/H75/Z400/E275 (28 tablets/blister)
- 12 blisters of 2FDC R150/H75 (28 tablets/blister

Technical Specifications:

Specifications of the outer box	Laminated, corrugated punched cardboard box Dimensions: • Length: 220mm ±5mm • Width: 115mm±5mm • Height: 130mm±5mm
Specifications of the 4- FDC (RHZE) inner box	Laminated, corrugated punched cardboard box Dimensions: • Length: 200mm ±5mm • Width: 50mm±5mm • Height: 120mm±5mm
Specifications of the 2 FDC (RH) inner box	Laminated, corrugated punched cardboard box Dimensions: • Length: 150mm ±5mm • Width: 60mm±5mm • Height: 85mm±5mm

SCHEDULE NO. 4: Consumables.

17. ITEM No. 1: Water for Injection 5mL ampoule/vial

General Description: Water for injection, sterile, 5mL ampoules/vial

Primary packaging: ampoule/vial

Secondary packaging: pack of 100 ampoules

18. ITEM No. 2: Hypodermic AD syringe with re-use prevention feature, 5 ml with needle (21G, 22G or 23G) and Safety Box for used syringes, 5L

General Description of syringes: Hypodermic automatic disabling (AD) syringes with re-use prevention feature, capacity of 5mL, sterile, with needle on top or bi-packed for reconstitution and injection.

Technical Specifications for syringe and needle:

5mL Sterile, Auto Disable Syringe with 0.2ml graduation, in polypropylene, with Re-Use prevention feature, conform to ISO 7886-4, CE Marked Certificate with needle 21G x 1 1/2", 22G x 1" 1.5" and23G x 1" 1.5" mounted on top or bi-packed, stainless steel, plastic base and protecting cap. Packed in a sterile pack.
Packaging: 100 pieces in a box. Each syringe and needle packed in an individual sterile peel-off pack. Product information on the individual pack: name of the manufacturer; type of product and main characteristics; expiry date; lot number; the word "sterile" or equivalent harmonized symbol, the words "check the integrity of the individual sterilization protection before use" (if space allows), "for single use", CE marking. Information for storage conditions as appropriate.

General Description of Safety boxes: Safety box for used syringes/needles, 5L

Technical Specifications for Safety box:

Puncture resistant containers for collecting and disposing of minimum 100 used AD syringes/ needles. Complies with WHO Performance specification E10/IC.2.
Packaging: 25 boxes in one carton flat-packed for ease of shipment and storage. For construction at the field level.

19. ITEM No. 3: Hypodermic AD syringes with re-use and sharp injury prevention (RUP/SIP) features, 5ml with needle (21G, 22G or 23G) and Safety Box for used syringes, 5L

General Description of syringes: Hypodermic automatic disabling (AD) syringes with re-use prevention and sharp injury prevention features, capacity of 5mL, sterile, with attached retractable needle or bi-packed for reconstitution and injection.

Technical Specifications for syringes:

5mL sterile Auto Disable Syringe with 0.2 ml graduation, in polypropylene, with Re-Use Prevention and Sharp Injury Prevention, conform to ISO 7886-4, with CE Marked Certificate, with retractable or bi-

packed needle 21G x1” or 1 ¼”, 23G x 1 ¼” and 23G x 1, Packed in a sterile blister pack.
Packaging: 100 pieces in a box. Each syringe and needle packed in an individual sterilized peel-off pack. Product information on the individual pack: name of the manufacturer; type of product and main characteristics; expiry date; lot number; the word "sterile" or equivalent harmonized symbol, the words "check the integrity of the individual sterilization protection before use" (if space allows), "for single use", CE marking. Information for storage conditions as appropriate.

Technical Specifications for Safety box:

Puncture resistant containers for collecting and disposing of minimum 100 used AD syringes/ needles. Complies with WHO Performance specification E10/IC.2.
Packaging: 25 boxes in one carton flat-packed for ease of shipment and storage. For construction at the field level.