

ANNEX B - TECHNICAL SPECIFICATIONS / PRODUCT LIST

SCHEDULE NO. 1: Oral solid dosage forms: Fixed dose combinations for adults

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

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

Technical Specifications: Each tablet should contain Rifampicin 150 mg / Isoniazid 75 mg / Pyrazinamide 400 mg / Ethambutol 275 mg, film coated tablets, plain on both sides. Packaging: Al/PVC/PVDC film blister pack of 28 tablets x 24 blisters.

Minimum total shelf life: 24 months.

Storage conditions: Store below 25 C degrees¹, in a dry place, protected from light.

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

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

Technical Specifications: Each tablet should contain Rifampicin 150 mg / Isoniazid 75 mg / Ethambutol 275 and film coated tablets, plain on both sides. Packaging: Al/PVC/PVDC film blister pack of 28 tablets x 24 blisters.

Minimum total shelf life: 24 months.

Storage conditions: Store below 25 C degrees, in a dry place, protected from light.

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

General Description: Rifampicin 150 mg / Isoniazid 75 mg film-coated tablets.

Technical Specifications: Each tablet should contain Rifampicin 150 mg / Isoniazid 75 mg and film coated tablets, plain on both sides.

Packaging: Al/PVC/PVDC film blister pack of 28 tablets x 24 blisters.

Minimum total shelf life: 24 months.

Storage conditions: Store below 25 C degrees, in a dry place, protected from light.

¹ The preferred storage condition for all GDF medicines is "do not store above 30 C".



Item No. 4: 2 FDC/ RH 150/150 (blister)

General Description: Rifampicin 150 mg / Isoniazid 150 mg film-coated tablets.

Technical Specifications: Each tablet should contain Rifampicin 150 mg / Isoniazid 150 mg and film

coated tablets, plain on both sides.

Packaging: Al/PVC/PVDC film blister pack of 28 tablets x 24 blisters.

Minimum total shelf life: 24 months.

Storage conditions: Store below 25 C degrees, in a dry place, protected from light.

Item No. 5: 2 FDC/ EH 400/150 (blister)

General Description: Ethambutol 400 mg / Isoniazid 150 mg film-coated tablets.

Technical Specifications: Each tablet should contain Ethambutol 400 mg / Isoniazid 150 mg and film coated tablets, plain on both sides.

Packaging Al/PVC/PVDC film blister pack of 28 tablets x 24 blisters.

Minimum total shelf life: 24 months.



SCHEDULE NO. 2: Oral solid dosage forms: Fixed dose combinations for children

Item No. 1: 3 FDC/ RHZ 60/30/150 (blister)

General Description: Rifampicin 60 mg/ Isoniazid 30 mg/ Pyrazinamide 150 mg dispersible tablets.

Technical Specifications: Rifampicin 60 mg/ Isoniazid 30 mg/ Pyrazinamide 150 mg and uncoated tablets, plain surface on both sides. The tablet should not be divided.

Packaging: Al/PVC/PVDC film blister pack of 28 tablets x3 blisters or Alu/Alu strips of 6 tablets x14 strips.

Minimum total shelf life: 24 months.

Storage conditions: Store below 25 C degrees, in a dry place, protected from light.

Item No. 2: 2FDC/ RH 60/60 (blister)

General Description: Rifampicin 60 mg / Isoniazid 60 mg dispersible tablets.

Technical Specifications: Rifampicin 60 mg/Isoniazid 60 mg and uncoated tablets, break-lines on both sides. Packaging: Al/PVC/PVDC film blister pack of 28 tablets x 3 blisters or Alu/Alu strips of 6tablets x 14 strips.

Minimum total shelf life: 24 months.

Storage conditions: Store below 25 C degrees, in a dry place, protected from light.

Item No. 3: 2FDC/ RH 60/30 (blister)

General Description: Rifampicin 60 mg/Isoniazid 30 mg dispersible tablets.

Technical Specifications: Rifampicin 60 mg/Isoniazid 30 mg uncoated tablets, break-lines on both sides. Packaging: Al/PVC/PVDC film blister pack of 28 tablets x3 blisters or Alu/Alu strips of 6 tablets x14 strips.

Minimum total shelf life: 24 months.

Storage conditions: Store below 25 C degrees, in a dry place, protected from light.

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

General Description: Rifampicin 75 mg/ Isoniazid 50 mg/ Pyrazinamide 150 mg dispersible tablets.

Technical Specifications: Rifampicin 75 mg/ Isoniazid 50 mg/ Pyrazinamide 150 mg uncoated tablets, plain surface on both sides. The tablet should not be divided.

Packaging: Al/PVC/PVDC film blister pack of 28 tablets x3 blisters or Alu/Alu strips of 6 tablets x14 strips.

Minimum total shelf life: 24 months.



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

General Description: Rifampicin 75 mg/Isoniazid 50 mg dispersible tablets.

Technical Specifications: Rifampicin 75 mg/Isoniazid 50 mg uncoated tablets, break-lines on both sides.

Packaging: Al/PVC/PVDC film blister pack of 28 tablets x3 blisters or Alu/Alu strips of 6 tablets x14 strips.

Minimum total shelf life: 24 months.



SCHEDULE NO. 3: Oral solid dosage forms: Single dose formulations for adults

Item No. 1: Ethambutol 400 mg (blister)

General Description: Ethambutol 400mg film-coated tablets.

Technical Specifications: Each tablet should contain Ethambutol 400 mg film coated tablets, plain

on either sides or break-line in one side and plain surface on the other side.

Packaging: Al/PVC/PVDC film blister pack of 28 tablets x 24 blisters or 9 tablets x 10 strips.

Minimum total shelf life: 24 months.

Storage conditions: Store below 25 C degrees, in a dry place, protected from light.

Item No. 2: Isoniazid 300 mg (blister)

General Description: Isoniazid 300mg film-uncoated tablets.

Technical Specifications: Each tablet should contain Isoniazid 300 mg uncoated tablets and plain

surfaces in both sides or break-line in one surface and plain surface on the other side.

Packaging: Al/PVC/PVDC film blister pack of 28 tablets x 24 blisters or 9 tablets x 10 strips

Minimum total shelf life: 24 months.

Storage conditions: Store below 25 C degrees, in a dry place, protected from light.

Item No. 3: Pyrazinamide 400 mg (blister)

General Description: Pyrazinamide 400mg film- coated tablets.

Technical Specifications: Each tablet should contain Pyrazinamide 400mg film coated tablets and

plain on both sides or plain in one side and break-line in one side.

Packaging: Al/PVC/PVDC film blister pack of 28 tablets x 24 blisters.

Minimum total shelf life: 24 months.

Storage conditions: Store below 25 C degrees, in a dry place, protected from light.

Item No. 4: Pyrazinamide 500 mg (blister)

General Description: Pyrazinamide 500mg film- coated tablets.

Technical Specifications: Each tablet should contain Pyrazinamide 500mg film coated tablets and

plain on both sides or plain in one side and break-line in one side.

Packaging: Al/PVC/PVDC film blister pack of 28 tablets x 24 blisters or 10 tablets x 10 blisters.

Minimum total shelf life: 24 months.



Item No. 5: Rifabutin (Rfb) 150 mg hard capsules (blister)

General Description: Capsules for oral administration containing 150 mg of rifabutin.

Technical Specifications: Each hard gelatin capsules contains 150 mg of Rifabutin Packaging: Al/PVC/ blister package of 30 capsules

Minimum total shelf life: 24 months.

Storage conditions: Store below 25 C degrees, in a dry place, protected from light.

Item No. 6: Rifampicin 150 mg (blister)

General Description: Rifampicin 150 mg coated tablet or capsule.

Technical Specifications: Each coated tablet or capsule should contain Rifampicin 150mg .

Packaging: PVC/Al or Alu/Alu blister pack of 10 tablets/capsules x 10 blisters.

Minimum total shelf life: 24 months.

Storage conditions: Store below 25 C degrees, in a dry place, protected from light.

Item No. 7: Rifampicin 300 mg (blister)

General Description: Rifampicin 300 mg coated tablet or capsule.

Technical Specifications: Each coated tablet or capsule should contain Rifampicin 300mg.

Packaging: PVC/Al or Alu/Alu blister pack of 10 tablets/capsules x 10 blisters.

Minimum total shelf life: 24 months.



SCHEDULE NO. 4: Oral solid dosage forms: Single dose formulations for children

Item No.1: Isoniazid 100 mg (blister)

General Description: Isoniazid 100 mg dispersible or uncoated tablets.

Technical Specifications: Each tablet should contain Isoniazid 100mg dispersible or uncoated tablets and plain surface on either sides or break line in one surface.

Packaging: Al/PVC/PVDC film blister pack of 10 tablets x 10 blisters or 25 x 40 blisters.

Minimum total shelf life: 24 months.

Storage conditions: Store below 25 C degrees, in a dry place, protected from light.

Item No.2: Ethambutol 100 mg (blister)

General Description: Ethambutol 100 mg dispersible or coated tablets.

Technical Specifications: Each tablet should contain Ethambutol 100mg film dispersible or coated

tablets and plain surface on both sides or break line in one surface.

Packaging: Al/PVC/PVDC film blister pack of 25 tablets x 20 blisters or 10 tablets x10 blisters.

Minimum total shelf life: 24 months.



SCHEDULE NO.5: Parental Injectable

Item No. 1: Streptomycin 1 g injectable (vial/amp)

General Description: Streptomycin 1 g powder for injection.

Technical Specifications: Each vial should contain streptomycin 1 gram as sulphate, with or without solvent water for injection. For vials small glass bottle colourless, clear, with closed with a rubber stopper and a metal cap are required.

Packaging: the following options are preferable:

- 1 vials in a carton box.
- 20 vials in a carton box.
- 50 vials in a box
- 100 vials in a box

Minimum total shelf life: 24 months.



SCHEDULE NO.6: Water for injection

Item No. 1: Water for Injection 5 ml or 3 ml ampoule

General Description: Water for injection, sterile, 5 or 3 ml ampoules

Technical Specifications:

Injection, sterile distilled water free from pyrogens, ampoules. 5 or 3 ml plastic ampoules of polyethylene, watertight, light and unbreakable and does not react with the water, twist off top pods are required.

Parenteral preparation indicated only for diluting or dissolving drugs that require dilution or must be dissolved in an aqueous vehicle prior to injection. (intravenous, intramuscular or subcutaneous injection), according to instructions of the manufacturer of the drug to be administered. Packaging: the following options are preferable:

- 20 ampoules in a box
- 50 ampoules in a box
- 100 ampoules in a box

Minimum total shelf life: minimum 24 months.

Storage conditions: Information for particular storage conditions as appropriate.



SCHEDULE NO.7: Medical Devices

Item No. 1: Hypodermic AD syringes with re-use prevention feature, 5 ml (21 G) and Safety Box for used syringes and needles, 5lt

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

Technical Specifications for syringes:

2 or 3 parts Single use, Sterilized, Auto Disable Syringe, needle mounted on top 5 ml, 21 G 1" or 1 ¼", capacity 5ml, graduation 0.2 ml, polypropylene, Prevented from Re-use, ISO 7886-4, CE Marked Certificate. Needle on top or bi-packed, stainless steel, plastic base and protecting cap. Packed in a sterile ribbon pack.

Preferable packaging: 100 pieces in a box. Each syringe and needle packed in an individual sterilized peel-off pack made of paper and/or plastic. Product information: 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.

Preferable total shelf life: 5 years. Information for particular storage conditions as appropriate.

General Description of Safety boxes: Safety box for used syringes/needles, 5 lt box of 25

Technical Specifications for Safety boxes: Syringe disposal container for safe handling and disposing of minimum 100 AD syringes. Complies with WHO Performance specification E10/IC.2. Puncture resistant containers for collecting and disposing of used AD syringes/ needles. Preferable packaging: 25 boxes in one carton flat-packed for ease of shipment and storage. For

Preferable packaging: 25 boxes in one carton flat-packed for ease of shipment and storage. For construction at the field level.

Item No. 2: Hypodermic AD syringes with re-use prevention feature, 5 ml (23 G) and Safety Box for used syringes and needles, 5lt.

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

Technical Specifications for syringes:

2 - 3 parts Single use, Sterilized, Auto Disable Syringe, needle mounted on top 5 ml, 23G x 1" or 1 ¼", capacity 5ml, graduation 0.2 ml, polypropylene, Prevented from Re-use, ISO 7886-4, CE Marked Certificate. Needle on top or bi-packed, stainless steel, plastic base and protecting cap. Packed in a sterile ribbon pack.

Preferable packaging: 100 pieces in a box. Each syringe and needle packed in an individual sterilized peel-off pack made of paper and/or plastic. Product information: 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.

Preferable total shelf life: 5 years. Information for particular storage conditions as appropriate.

General Description of Safety boxes: Safety box for used syringes/needles, 5 lt box of 25

Technical Specifications for Safety boxes: Syringe disposal container for safe handling and disposing of minimum 100 AD syringes. Complies with WHO Performance specification E10/IC.2. Puncture resistant containers for collecting and disposing of used AD syringes/ needles.



Preferable packaging: 25 boxes in one carton flat-packed for ease of shipment and storage. For construction at the field level.

Item No. 3: Hypodermic AD syringes with re-use and sharp injury prevention (RUP/SIP) features, 5 ml (21 G)

General Description of syringes: Hypodermic syringes with automatic disabling (AD) feature, capacity of 5ml, sterile, with attached retractable needle (preferable) or bi-packed for reconstitution and injection.

Technical Specifications for syringes:

2 - 3 parts Single use, sterile, Auto Disable Syringe, with attached retractable needle or bi-packed in 21 G x 1" or 1 ¼", capacity 5ml, graduation 0.2 ml, polypropylene, Prevented from Re-use, ISO 7886-4, CE Marked Certificate. Attached retractable needle or bi-packed, stainless steel, plastic base and protecting cap. Packed in a sterile ribbon or blister pack.

Preferable packaging: 100 pieces in a box. Each syringe and needle packed in an individual sterilized peel-off pack made of paper and/or plastic. Product information: 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.

Preferable total shelf life: 5 years. Information for particular storage conditions as appropriate.

Item No. 4: Hypodermic AD syringes with re-use and sharp injury prevention (RUP/SIP) features, 5 ml (23 G)

General Description of syringes: Hypodermic syringes with automatic disabling (AD) feature, capacity of 5ml, sterile, with attached retractable needle (preferable) or bi-packed for reconstitution and injection.

Technical Specifications for syringes:

2 - 3 parts Single use, sterile, Auto Disable Syringe, with attached retractable needle or bi-packed in 23 G x 1" or 1 ¼", capacity 5ml, graduation 0.2 ml, polypropylene, Prevented from Re-use, ISO 7886-4, CE Marked Certificate. Attached retractable needle or bi-packed, stainless steel, plastic base and protecting cap. Packed in a sterile ribbon or blister pack.

Preferable packaging: 100 pieces in a box. Each syringe and needle packed in an individual sterilized peel-off pack made of paper and/or plastic. Product information: 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.

Preferable total shelf life: 5 years. Information for particular storage conditions as appropriate.

Item No. 5: Safety Box for used syringes and needles, 5Lt.

General Description of Safety boxes: Safety box for used syringes/needles, 5 Lt box of 25

Technical Specifications for Safety boxes: Syringe disposal container for safe handling and disposing of minimum 100 AD syringes. Shall comply with WHO Performance specification E10/IC.2. Puncture resistant containers for collecting and disposing of used AD syringes/ needles.

Preferable packaging: 25 boxes in one carton flat-packed for ease of shipment and storage. For construction at the field level.



SCHEDULE NO.8: STOP-TB patient kits

Item No. 1: Cat I & III Kit A

General Description: Stop TB Cat. I+III Patient Kit A 6 blisters (168) 4-FDC tablets R150/H75/Z400/E275) 12 blisters (336) 2-FDC tablets (R150/H75)

Technical Specifications:

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

Item No. 2: Cat I & III Kit C

General Description: Stop TB Cat. I+III Patient Kit C 6 blisters (168) 4-FDCs (R150/H75/Z400/E275) 6 blisters (168) 2-FDC tablets (R150/H150)

Technical Specifications:

Specifications of	Laminated, corrugated punched cardboard box
the outer box	Dimensions:
	Length: 220mm ±5mmWidth: 90mm±5mmHeight: 130mm±5mm
Specifications of	Laminated, corrugated punched cardboard box
the 4-FDC inner box	Dimensions:
	Length: 200mm ±5mmWidth: 50mm±5mmHeight: 120mm±5mm



Specifications of	Laminated, corrugated punched cardboard box
the RH inner box	Dimensions:
	Length: 180mm ±5mmWidth: 30mm±5mm
	Height: 90mm±5mm

■ Item No. 3: Cat II Kit A

General Description: Stop TB Cat. II Patient Kit A: 9 blisters (252) 4-FDC tablets (R150/H75/Z400/E275), 60 vials of Streptomycin 1gr, 60 vials of water for injection 5 or 3ml, 60, auto-disabling syringes & needles, 15 blisters (420) 3-FDC tablets (R150/H75/E275)

Technical Specifications:

Specifications of the outer box	Laminated, corrugated punched cardboard box Dimensions: • Length: 330mm ±5mm • Width: 270mm±5mm • Height: 195mm±5mm To contain the Tablet kit and the Injection kit
Specifications of	Laminated, corrugated punched cardboard box
the Injection kit	Dimensions:
	 Length: 315mm ±5mm Width: 265mm±5mm Height: 100mm±5mm To contain Streptomycin, Water for injection, Syringes + Needles
Specifications of	Laminated, corrugated punched cardboard box
the Tablet Kit	Dimensions:
	 Length: 330mm ±5mm Width: 220mm±5mm Height: 85mm±5mm To contain the inner boxes of 4-FDC + 3-FDC Empty space to be filled with cardboard filler
Specifications of	Laminated, corrugated punched cardboard box
the 4-FDC inner box	Dimensions:
	Length: 200mm ±5mmWidth: 65mm±5mmHeight: 120mm±5mm
Specifications of	Laminated, corrugated punched cardboard box
the 3-FDC inner box	Dimensions (may vary):





 Length: 150mm ±5mm Width: 65mm±5mm Height: 85mm±5mm 	
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■ Item No. 4 Cat II Kit C

General Description: 9 blisters (252) 4-FDC tablets (R150/H75/Z400/E275) 7 blisters (196), 2-FDC (RH 150/150), 7 blisters (196) E400, 60 vials of Streptomycin 1gr, 60 vials of water for injection 5 or 3ml,60 auto-disabling syringes & needles

Technical Specifications:

Specifications of	Laminated, corrugated punched cardboard box
the outer box	Dimensions:
THE GUIST DOX	 Length: 220mm ±5mm Width: 90mm±5mm Height: 130mm±5mm
Specifications of	Laminated, corrugated punched cardboard box
the Injection kit	Dimensions:
	 Length: 315mm ±5mm Width: 265mm±5mm Height: 100mm±5mm
	To contain Streptomycin, Water for injection, Syringes + Needles
Specifications of	Laminated, corrugated punched cardboard box
the Tablet Kit	Dimensions:
	 Length: 330mm ±5mm Width: 220mm±5mm Height: 85mm±5mm
	To contain the inner boxes of 4-FDC + RH + E
	Empty space to be filled with cardboard filler
Specifications of	Laminated, corrugated punched cardboard box
the 4-FDC inner box	Dimensions:
	Length: 200mm ±5mmWidth: 50mm±5mm



	Height: 120mm±5mm
Specifications of	Laminated, corrugated punched cardboard box
the RH inner box	Dimensions:
	Length: 180mm ±5mm
	Width: 30mm±5mm
	Height: 90mm±5mm
Specifications of	Laminated, corrugated punched cardboard box, (as
the E inner box	per attached detailed specifications)
	Dimensions:
	Length: 170mm ±5mm
	Width: 60mm±5mm
	Height: 100mm±5mm