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 degrees\(^1\), 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.

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\(^1\) 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. Storage conditions: Store below 25 C degrees, in a dry place, protected from light.
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 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. 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.
  **Storage conditions:** Store below 25 C degrees, in a dry place, protected from light.
- **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.
  **Storage conditions:** Store below 25 C degrees, in a dry place, protected from light.
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.
  **Storage conditions:** Store below 25 C degrees, in a dry place, protected from light.
- **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.
  **Storage conditions:** Store below 25°C degrees, in a dry place, protected from light.
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.
  **Storage conditions:** Store below 25°C degrees, in a dry place, protected from light.
**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.

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

<table>
<thead>
<tr>
<th>Specifications of the outer box</th>
<th>Laminated, corrugated punched cardboard box</th>
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<tbody>
<tr>
<td><strong>Dimensions:</strong></td>
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<tr>
<td>- Length: 220mm ±5mm</td>
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<td>- Width: 115mm±5mm</td>
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<th>Specifications of the RH inner box</th>
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<td>- Width: 60mm±5mm</td>
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<td>- Height: 85mm±5mm</td>
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- **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:**

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<tr>
<th>Specifications of the outer box</th>
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<td>- Height: 120mm±5mm</td>
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</table>
| Specifications of the RH inner box | Laminated, corrugated punched cardboard box  
Dimensions:  
- Length: 180mm ±5mm  
- Width: 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 the Injection kit | Laminated, corrugated punched cardboard box  
Dimensions:  
- Length: 315mm ±5mm  
- Width: 265mm±5mm  
- Height: 100mm±5mm  
To contain Streptomycin, Water for injection, Syringes + Needles |

| Specifications of the Tablet Kit | Laminated, corrugated punched cardboard box  
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 the 4-FDC inner box | Laminated, corrugated punched cardboard box  
Dimensions:  
- Length: 200mm ±5mm  
- Width: 65mm±5mm  
- Height: 120mm±5mm |

| Specifications of the 3-FDC inner box | Laminated, corrugated punched cardboard box  
Dimensions (may vary): |
### 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:**

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<tr>
<td>To contain Streptomycin, Water for injection, Syringes + Needles</td>
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<th>Specifications of the Tablet Kit</th>
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<tr>
<td>To contain the inner boxes of 4-FDC + RH + E Empty space to be filled with cardboard filler</td>
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<td>Specifications of the RH inner box</td>
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