

ANNEX B/ SECTION 8: TECHNICAL SPECIFICATIONS

NOTE: The estimated Global need for required below products is provided in Annex H of this ITB. Actual quantity to be ordered in 2015 can vary due to countries demand fluctuations. IDA/GDF make no guarantees in this regard.

SCHEDULE No. 1: Oral solid dosage forms: Fluoroquinolones

- **Item No. 1: Levofloxacin 250 mg tablet (blister)**

General Description: Levofloxacin 250mg film-coated tablets.

Technical Specifications: Each tablet should contain Levofloxacin 250mg and should be biconvex film coated tablets and should be scored with central break-line on one side and plain on other side or plain in both sides.

Packaging Al/PVC/PVDC film blister pack of 5 x 4 tablets x 5 blisters in a carton box or 10 tablets x 10 blisters in a carton box.

Shelf life and storing conditions: minimum accepted 36 months shelf life. Store below 30 C degrees, in a dry place, protected from light.

- **Item No. 2: Levofloxacin 500 mg tablet (blister)**

General Description: Levofloxacin 500mg film-coated tablets.

Technical Specifications: Each tablet contains Levofloxacin 500mg and should be biconvex film coated tablets and should be scored with central break-line on one side and plain on other side or plain in both sides.

Packaging: Al/PVC/PVDC film blister pack of 5 x 4 tablets x 5 blisters in a carton box or 10 tablets x10 blisters in a carton box.

Shelf life and storing conditions: minimum accepted 36 months shelf life. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 3: Levofloxacin 750 mg tablet (blister)**

General Description: Levofloxacin 750mg film-coated tablets.

Technical Specifications: Each tablet should contain Levofloxacin 750 mg and should be biconvex film coated tablets and should be scored with central break-line on one side and plain on other side or plain in both sides.

Packaging: Al/PVC/PVDC film blister pack of 5 x 4 tablets x 5 blisters in a carton box or 10 tablets x10 blisters in a carton box.

Shelf life and storing conditions: minimum accepted 36 months shelf life. Store below 25C degrees, in a dry place, protected from light.

- **Item No. 4: Moxifloxacin 400 mg tablet (blister)**

General Description: Moxifloxacin 400mg film-coated tablets.

Technical Specifications: Each tablet should contain Moxifloxacin 400mg and/or scored tablets.

Packaging: Al/PVC/PVDC film blister of 10 tablets x 10 blister in a carton box.

Shelf life and storing conditions: minimum accepted 36 months shelf life. Store below 25 C degrees, in a dry place, protected from light.

SCHEDULE No. 2: Oral solid dosage forms: Bacteriostatic Second Line Drugs

- **Item No. 1: Ethionamide 250 mg tablet (blister/strip)**

General Description: Ethionamide 250mg film-coated tablets.

Technical Specifications: Each tablet should contain Ethionamide 250mg and should be biconvex film coated tablets and should be scored with central break-line on one side and plain on other side or plain in both sides.

Packaging: Al/PVC/PVDC film blister or Alu/Alu strip of 10 tablets x 10 blisters in a carton box.

Shelf life and storing conditions: minimum accepted 24 months shelf life. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 2: Prothionamide 250 mg tablet (blister)**

General Description: Prothionamide 250mg film-coated tablets.

Technical Specifications: Each tablet should contain Prothionamide 250mg and should be biconvex film coated tablets and should be scored with central break-line on one side and plain on other side or plain in both sides.

Packaging: Al/PVC/PVDC film blister of 10 tablets x 10 blisters in a carton box.

Shelf life and storing conditions: minimum accepted 24 months shelf life. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 3: Cycloserine 250 mg capsules (blister/strip)**

General Description: Cycloserine 250mg hard capsules.

Technical Specifications: Each hard capsule should contain Cycloserine 250mg.

Packaging: Al/PVC/PVDC film blister or Alu/Alu strip of 10 capsules x 10 blisters in a carton box.

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 4: PAS Acid granules (sachet)**

General Description: P-aminosalicylic acid (PAS) 4 g enteric coated delayed-release granules in sachets.

Technical Specifications: Each sachet should contain aminosalicylic acid 4 g.

Packaging: 30 Alu/PET/LLDPE sachets of 4 gr / 1 carton box.

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store in a dry place below 25 °C, protect from light and moisture.

- **Item No. 5: PAS Sodium powder for oral solution (sachet)**

General Description: P-aminosalicylate sodium salt powder for oral solution 5.52 g sachet.

Technical Specifications: Each laminated sachet should contain power P-aminosalicylate sodium salt

Packaging: Alu/PET/Alu/LLDPE laminated sachets in a carton box. The following quantities are preferable: 25 sachets in one carton box or; 300 sachets in one carton box

Shelf life and storing conditions: minimum accepted shelf life 36 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 6: PAS Sodium enteric coated granules (container)**

General Description: P-aminosalicylate sodium enteric coated delayed-release granules 60% w/w, 100 g HDPE container.

Technical Specifications: Each granule contains P-aminosalicylate sodium salt.

Packaging: 100gr in LPDE bag placed in a triple laminated Alu/PET/Alu sachet further packed in HDPE container, includes dosing spoon and an insert.

Shelf life and storing conditions: minimum accepted shelf life 36 months. Store below 25 C degrees, in a dry place, protected from light

- **Item No. 7: PAS Sodium enteric coated granules (sachet)**

General Description: P-aminosalicylate sodium enteric coated delayed-release granules 60% w/w, 9.2 g sachets.

Technical Specifications: Each granule should contain P-aminosalicylate sodium salt

Packaging: 30 PET/Alu/LLDPE sachets of 9.2 g/ 1 carton box.

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 8: Terizidone 250 mg capsule (blister)**

General Description: Terizidone 250 mg capsules

Technical Specifications: Each hard capsule should contain Terizidone 250 mg.

Packaging: Al/PVC/PVDC blister pack of 10 hard capsules x 10 blister in a carton box.

Shelf life and storing conditions: Minimum required 24 months. Store below 25 C degrees, in a dry place, protected from light.

SCHEDULE No.3: Parenteral Injectables

- **Item No. 1: Capreomycin 1 g injectable- powder (vial/ampoule)**

General Description: Capreomycin 1 g powder for injection.

Technical Specifications: Each vial/amp should contain Capreomycin 1 g.

Packaging: 1 vial/ampoule in a carton box.

Shelf life and storing conditions: Minimum required 24 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 2: Kanamycin 1 g injectable – solution (vial/ampoule)**

General Description: Kanamycin 1 g solution for injection.

Technical Specifications: Each vial/amp should contain kanamycin 1 gram as sulphate.

Packaging: 10, 50, 100 vials/ampoules in a carton box.

Shelf life and storing conditions: Minimum required 36 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 3: Kanamycin 1 g powder for injection (vial/ampoule)**

General Description: Kanamycin 1 g powder for solution

Technical Specifications: Each vial/amp should contain kanamycin 1 gram powder as sulphate.

Packaging: 10, 50, 100 vials/ampoules in a carton box.

Shelf life and storing conditions: Minimum required 36 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No.4: Amikacin 500 mg injectable –solution (vial/ampoule)**

General Description: Amikacin 500mg solution for injection (2 ml)

Technical Specifications: Each vial/amp should contain Amikacin 500mg.

Packaging: 10 or 20 or 50 or 100 vials/ampoules in a carton box

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light.

SCCHEDULE No.4: Oral solid dosage forms: Third line anti-TB

- **Item No. 1: Amoxicillin Clavunalate 875 + 125 mg tablet (blister)**

General Description: Amoxicillin Clavunalate 875+ 125 mg film coated tablets

Technical Specifications: Each tablet should contain 1004 mg Amoxicillin Trihydrate equivalent to Amoxicillin base 875 mg + 297.8 mg Clavunalate potassium equivalent to clavulanic acid 125.0 mg.

Packaging: Al/PVC/PVDC film blister pack of 7 tablets per blister x 2 blisters or 10 tablets per blister x 10 blisters /1 carton box

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light,

- **Item No. 2: Amoxicillin Clavunalate 500 +125 mg tablet (blister)**

General Description: Amoxicillin Clavunalate 500+ 125 mg film coated tablets

Technical Specifications: Each tablet should contain 574 mg Amoxicillin Trihydrate equivalent to Amoxicillin base 500 mg and 297.8 mg Clavunalate potassium equivalent to clavulanic acid 125 mg.

Packaging: Al/PVC/PVDC film blister pack of 10 tablets x 2 blisters or 10 tablets per blister x 10 blisters / 1 carton box.

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light,

- **Item No. 3: Amoxicillin Clavunalate 250 +125 mg tablet (blister)**

General Description: Amoxicillin Clavunalate 250+ 125 mg film coated tablets

Technical Specifications: Each tablet should contain 287 mg Amoxicillin Trihydrate equivalent to Amoxicillin base 250 mg and 297.8 mg Potassium Clavulanatec equivalent to clavulanic acid 125 mg.

Packaging: Al/PVC/PVDC blister pack of 7tablets per blister x 2 blisters or 5 tablets per blister x 3 blisters.

Shelf life and storing conditions: minimum accepted shelf life 24 months. Do not store above 25° C degrees, keep in a dry place and protect from light.

- **Item No. 4: Amoxicillin Clavunilate 250+ 62.5 mg powder for oral suspension**

Technical Specifications: 250 mg/62.5 per 5 ml powder for oral suspension. White to off-white powder for reconstitution with water. Each 5 ml of reconstituted suspension contains 287 mg Amoxicillin Trihydrate equivalent to 250 mg of amoxicillin base and 74.40 mg potassium clavunilate equivalent to 62.5 mg of clavunilic acid.

Packaging: Glass bottles with aluminium screw caps or a ROPP, internally lacquered closure, containing a Polymer (PVC) liner, containing powder for reconstitution to 100ml.

Shelf life and storing conditions: minimum accepted shelf life 24 months. Do not store above 25° C degrees; store in original container to protect from moisture.

- **Item No. 5: Amoxicillin Clavunilate 125+31.25 mg powder for oral suspension**

Technical Specifications: 125 mg/31.25 per 5 ml powder for oral suspension. White to off-white powder for reconstitution with water. Each 5 ml of reconstituted suspension contains Amoxicillin Trihydrate equivalent to 125 mg of amoxicillin base and 37.20 mg potassium clavunilate equivalent to 31.25 mg of clavunilic acid.

Packaging: Glass bottles with aluminium screw caps or a ROPP, internally lacquered closure, containing a Polymer (PVC) liner, containing powder for reconstitution to 100ml.

Shelf life and storing conditions: minimum accepted shelf life 24 months. Do not store above 25° C degrees; store in original container to protect from moisture. Reconstituted suspension to store between 2° and 8°C for 7 days. Do not freeze.

- **Item No. 6: Clarithromycin 250 mg tablet (blister)**

General Description: Clarithromycin 250 mg film-coated tablets

Technical Specifications: Each tablet should contained clarithromycin 500 mg

Packaging: Al/PVC/PVDC film blister pack of 7 tablets per blister x 2 blisters or 10 tablets per blister x 2 blisters /1 carton box

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 7: Clarithromycin 500 mg tablet (blister)**

General Description: Clarithromycin 500 film-coated tablets

Technical Specifications: Each tablet should contained clarithromycin 500 mg

Packaging: Al/PVC/PVDC film blister pack of 7 tablets per blister x 2 blisters or 10 tablets per blister x 10 blisters /1 carton box

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 8: Imipenem / Cilastatin 500 mg + 500 mg injectable -powder for solution for IV (vial/ampoule)**

General Description: Imipenem / Cilastatin 500 mg + 500 mg powder for solution for IV infusion

Technical Specifications: Each vial/amp should contain 500 mg of Imipenem monohydrate and 500 mg of Cilastatin sodium.

Packing: 10, 20, 50, 100 vials in a carton box

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 25 C degrees, in a dry place, protected from light.

- **Item No. 9: Linezolid 600 mg tablet (blister)**

General Description: Linezolid 600 mg film-coated tablets

Technical Specifications: Each film coated tablet contains linezolid 600 mg, white oval shaped bevel edged, biconvex film coated tablets

Packaging: Al/PVC/PVDC film blister pack of 10 tablets per blister x 2 blisters /1 carton box;

Shelf life and storing conditions: minimum accepted shelf life 36 months. Do not store above 30° C degrees, keep it in a dry place, protected from light.