

SECTION 4: 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 2016 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: Ofloxacin 200mg tablet (blister)**

General Description: Ofloxacin 200 mg film-coated tablets.

Technical Specifications: Each light yellow colored, oblong shaped, film-coated tablets, plain on both faces.

Packaging¹: Al/PVC/PVDC film blister pack of 10 tablets x 10 blisters in a carton box

Shelf life and storing conditions²: minimum accepted 36 months shelf life. Store below 30 C degrees, in a dry place, protected from light.

- **Item No. 2: Ofloxacin 400mg tablet (blister)**

General Description: Ofloxacin 400 mg film-coated tablets.

Technical Specifications: Each light yellow colored, oblong shaped, film-coated tablets, plain on both faces.

Packaging: Al/PVC/PVDC film blister pack of 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. 3: Levofloxacin 250 mg tablet (blister)**

General Description: Levofloxacin 250mg film-coated tablets.

Technical Specifications: Each pink colored, capsule shaped, biconvex, film-coated tablets with central break-line on one side and plain on the other side.

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.

¹ The number of blisters in a carton box is the preferred number and/or indicative.

² The preferred storage condition for all GDF medicines is “store below 30° C”.

- **Item No. 4: Levofloxacin 500 mg tablet (blister)**

General Description: Levofloxacin 500mg film-coated tablets.

Technical Specifications: Each peach colored, capsule shaped, biconvex, film-coated tablets with central break-line on one side and plain on the other side.

Packaging: Al/PVC/PVDC film blister pack of 10 tablets x10 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. 5: Levofloxacin 750 mg tablet (blister)**

General Description: Levofloxacin 750mg film-coated tablets.

Technical Specifications: Each brownish red colored, oval shaped, biconvex film coated tablets debossed 'T' & 64 on either side of a deep score line on one side of the tablet and deep score line on the other side.

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

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

- **Item No. 6: Moxifloxacin 400 mg tablet (blister/strips)**

General Description: Moxifloxacin 400mg film-coated tablets.

Technical Specifications: Each brick-red colored, capsule shaped, biconvex, film-coated tablets, plain on both the sides. Excipients with known effects: 50 mg lactose monohydrate per tablet.

Packaging: Al/PVC/PVDC or Alu/Alu strips 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

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

General Description: Ethionamide 250mg film-coated tablets.

Technical Specifications: Each orange coloured, circular, biconvex, film-coated tablets, plain on both sides.

Packaging: Al/PVC/PVDC and Alu/Alu strips of 10 tablets per blister in a carton box.

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

- **Item No. 2: Ethionamide 125 mg tablet (blister/strips)**

General Description: Ethionamide 125mg film-coated tablets.

Technical Specifications: Each yellow coloured, circular, biconvex, film-coated tablets, plain on both sides.

Packaging: Al/PVC/PVDC and Alu/Alu strips of 10 tablets per blister in a carton box.

Shelf life and storing conditions: minimum accepted 24 months shelf life. Store below 30 C degrees, protected from light.

- **Item No. 3: Prothionamide 250 mg tablet (blister)**

General Description: Prothionamide 250mg film-coated tablets.

Technical Specifications: Each orange coloured, circular, biconvex film coated tablet with score 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 36 months shelf life. Store below 30 C degrees, in a dry place, protected from light.

- **Item No. 4: Cycloserine 250 mg tablet (blister/strip)**

General Description: Cycloserine 250mg hard capsules.

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

Packaging: Al/PVC/PVDC 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. 5: Cycloserine 250 mg capsule (loose)**

General Description: Cycloserine 250mg hard capsules.

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

Packaging: 40 or 50 capsules in LPDE bag placed in HDPE container (with a silica gel bag, sealed with aluminium tagger seal) and a screw cap.

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

Loose product will be ordered only in case of specific requirement by the client. No market share can be allocated for loose products.

- **Item No. 6: 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 humidity.

- **Item No. 7: PAS Sodium powder for oral solution (sachet)**

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

Technical Specifications: Each laminated sachet should contains 5.52 g of aminosalicylic acid sodium salt dehydrate, which is equivalent to 4 g of aminosalicylic acid. Powder of almost white to cream colour. Nonuniformity of colour is allowed.

Packaging: Alu/PET/Alu/LLDPE laminated sachets in a carton box. The following quantities are preferable: 25 sachets in one carton box or; 30 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 and humidity.

- **Item No. 8: 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 container contains brick red coloured, P-aminosalicylate sodium delayed-release granules 60% w/w, 100g (equivalent to 43.5 g p-aminosalicylic acid)

Packaging: 100g granules packed in LPDE bag and placed in a triple laminated Alu/PET/Alu sachet, which is further packed in HDPE container. The container includes 2 g measuring spoon (with 1 g markings) 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. 9: 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 sachet contains brick red coloured, P-aminosalicylate sodium delayed-release granules 60% w/w, 9.2 g sachets (equivalent to 4 g p-aminosalicylic acid)

Packaging: 9.2 g granules packed in a triple laminated PET/Alu/LLDPE sachet, such 30 sachets are contained in a box with leaflet.

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. 10: Terizidone 250 mg capsule (blister)**

General Description: Terizidone 250 mg capsules

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

Packaging: Al/PVC/PVDC blister pack of 10 hard capsules x 10 blister in a carton box or 50 capsules in HDPE container.

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/Injectable

- **Item No. 1: Capreomycin 1 g powder for injection (vial)**

General Description: Capreomycin 1 g powder for injection.

Technical Specifications: Each glass vial should contain capreomycin sulphate equivalent to 1 g capreomycin (base).

Packaging: 1 vial in a carton box

Shelf life and storing conditions: Minimum required 24 months. Store below 30 C degrees, in a dry place, protected from light.

- **Item No. 2: Capreomycin 0.75 g powder for injection (vial)**

General Description: Capreomycin 0.75 g powder for injection.

Technical Specifications: Each glass vial should contain capreomycin sulphate equivalent to 0.75 g capreomycin (base).

Packaging: 1 vial in a carton box.

Shelf life and storing conditions: Minimum required 24 months. Store below 30 C degrees, in a dry place, protected from light

- **Item No. 3: Capreomycin 0.5 g powder for injection (vial)**

General Description: Capreomycin 0.5 g powder for injection.

Technical Specifications: Each amp should contain Capreomycin 0.5 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. 4: Kanamycin 1 g injectable solution (ampoule)**

General Description: Kanamycin 1 g solution for injection.

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

Packaging: 1, 10, 50, 100, 240 ampoules 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. 5: Kanamycin 1 g powder for injection (vial)**

General Description: Kanamycin 1 g powder for solution with / or without water for injection.

Technical Specifications: Each vial 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. 6: Kanamycin 0.5 g solution for injection (ampoule)**

General Description: Kanamycin 0.5 g solution for injection.

Technical Specifications: Each amp should contain 0.5 g kanamycin monosulphate.

Packaging: 1 or 10 ampoules in a carton, 240 per carton box.

Shelf life and storing conditions: Minimum required 24 months. Store below 30 C degrees, in a dry place, protected from light.

- **Item No.7: Amikacin 500mg/2ml solution (ampoule)**

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

Technical Specifications: Each amp should contain 667.4 mg amikacin sulphate equivalent to 500mg amikacin.

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

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 30 C degrees, in a dry place, protected from light.

SCHEDULE No.4: Oral solid dosage forms: Group V medicines

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

General Description: Amoxicillin Clavunilate 875+ 125 mg coated tablets

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

Packaging: Al/PVC/PVDC film blister pack 10 tablets per blister /1 carton box

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

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

General Description: Amoxicillin Clavunilate 500+ 125 mg coated tablets

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

Packaging: Al/PVC/PVDC film blister pack of 10 tablets / 1 carton box.

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

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

General Description: Amoxicillin Clavunilate 250+ 125 mg 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 10 tablets / 1 carton box.

Shelf life and storing conditions: minimum accepted shelf life 36 months. Do not store above 25^o C degrees, keep in a dry place and protect from light.

- **Item No. 4: Amoxicillin/Clavulanic 250+ 62.5 mg powder for oral suspension (bottle)**

General Description: 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 clavulanic 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/Clavulanic 125+31.25 mg powder for oral suspension (bottle)**

General Description: 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 clavulanic 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. 6: Clarithromycin 250 mg tablet (blister)**

General Description: Clarithromycin 250 mg coated tablets

Technical Specifications: Each tablet should contained clarithromycin 500 mg

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

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 30 C degrees, in a dry place, protected from light.

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

General Description: Clarithromycin 500 coated tablets

Technical Specifications: Each tablet should contain clarithromycin 500 mg

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

Shelf life and storing conditions: minimum accepted shelf life 24 months. Store below 30 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)**

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: 1, 10, 20, 50, 100 vials in a carton box

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

▪ **Item No. 9: Meropenem 1g injectable –powder for solution for IV (vial)**

General Description: Meropenem 1g powder for solution for IV infusion.

Technical Specifications: Each vial should contain 1g white to pale yellow crystalline powder.

Packing: 1, 10, 20, 50, 100 vials in a carton box

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

▪ **Item No. 10: Linezolid 600 mg tablet (blister)**

General Description: Linezolid 600 mg coated tablets

Technical Specifications: Each white to off-white oval/capsule shaped, coated tablet with or without score line should contain linezolid 600 mg.

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

Shelf life and storing conditions: minimum accepted shelf life 24 months. Do not store above 30° C degrees, keep it in a dry place, protected from light.

▪ **Item No. 11: Clofazimine 100 mg capsule (bottle/blister)**

General Description: Clofazimine 100 mg capsule

Technical Specifications: Each soft capsule contains 100mg micronized clofazimine.

Packaging: Al/PVC/PVDC film blister pack of 10 tablets per blister /1 carton box or 100 capsules per HPDE bottle;

Shelf life and storing conditions: minimum accepted shelf life 24 months. Do not store above 30° C degrees, keep it in a dry place, protected from light.

SCHEDULE No. 5. Oral solid dosage forms: other medicines

▪ **Item No. 1 Pyrazinamide 750mg tablets (blister)**

General Description: Pyrazinamide 750mg coated tablets.

Technical Specifications: Each biconvex un/coated tablet should contain Pyrazinamide 750 mg, scored with central break-line on one side and plain on other side or unscored and plain in both sides.

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

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

▪ **Item No. 2 Pyrazinamide 500mg tablets (blister)**

General Description: Pyrazinamide 500mg un/coated tablets.

Technical Specifications: Each white un/coated tablet should contain Pyrazinamide 500 mg, scored with central break-line on one side and plain on other side or unscored and plain in both sides.

Packaging: Alu/PVC/PVDC film blister pack of 28 tablet or 10 tablet per blister per pack/ 10 or 24 in a carton box.

Shelf life and storing conditions: minimum accepted 48 months shelf life. Store below 30C degrees, in a dry place, protected from light.

▪ **Item No. 3 Ethambutol 600mg tablets (blister)**

General Description: Ethambutol 600mg film coated tablets.

Technical Specifications: Each white, capsule shaped, biconvex coated tablet should contain Ethambutol 600 mg, with plain surface on both sides.

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

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

▪ **Item No. 4 Ethambutol 800mg tablets (blister)**

General Description: Ethambutol 800mg film coated tablets.

Technical Specifications: Each white, capsule shaped, biconvex coated tablet should contain Ethambutol 800 mg, with plain surface on both sides.

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

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

▪ **Item No. 5 Pyridoxine 100mg tablets (blister)**

General Description: Pyridoxine 100mg uncoated tablets.

Technical Specifications: Each white, flat, bevelled edge, uncoated tablet should contain Pyridoxine 100 mg, having break-line on one side and plain surface on the other sides.

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

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

▪ **Item No. 6 Pyridoxine 50mg tablets (blister)**

General Description: Pyridoxine 50mg uncoated tablets.

Technical Specifications: Each white, flat, bevelled edge, uncoated tablet should contain Pyridoxine 50 mg, having break-line on one side and plain surface on the other sides.

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

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

▪ **Item No. 7 Rifapentine 150mg tablets (blister)**

General Description: Rifapentine 150mg film coated tablets.

Technical Specifications: Each round, convex, film coated tablet should contain Rifapentine 150 mg, having break-line on one side and plain surface on the other sides.

Packaging: Al/PVC/PVDC film blister pack of 8 or 10 tablets per blister 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