Technical Specifications of Drugs for treatment of XDR TB under RNTCP

(Meant for local purchase of drugs for individual XDR-TB patients only)

CAPREOMYCIN INJECTION (1000 mg.)

Description: Each vial of Capreomycin Injection should contain Capreomycin IP 1000 mg. Capreomycin Injection should conform to the requirements of IP.

Labeling on Vials:

The label should indicate the content of Capreomycin IP in each Vial. The label should incorporate manufacturer's name & address, manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and the storage requirements. The label should also bear a 'Warning' required for "Schedule H Drug". The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Labelling on Millboard/Greyboard Box:

The label should indicate the content of Capreomycin IP in each Vial. The label should incorporate manufacturer's name & address, manufacturing license no., batch no. date of mfg., date of expiry of the individual drug and storage requirements along with the number of the vials in the Box. The label should also bear a 'Warning' required for "Schedule H Drug". The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Storage: Store protected from moisture at a temperature not exceeding 25 degree C.

Shelf Life: Shelf life of Capreomycin would be 24 months. At least $5/6^{th}$ of the total stipulated shelf life must remain at the time of purchase.

STERILE WATER FOR INJECTION

Description:

Clear, colorless, odorless, and free from added substances. Each ampoule should contain 5 ml of Sterile Water for Injection conforming to the requirements of IP.

Packing of Sterile Water for Injection:
IP Type 1, clear, plain glass ampoules or PE ampoule based on BFS technology. Each ampoule should contain 5 ml of Sterile Water for Injection. The ampoule should be sufficiently transparent to permit visual inspection of the contents.

Storage: Store in a single dose container in a cool, dry place.

Labelling on Ampoules:

The label should indicate the content of Sterile Water for Injection IP in each ampoule. The label should incorporate manufacturer's name & address, manufacturing license no., batch no., date of mfg., date of expiry of the individual drug (Water for Injection) and the storage requirements.

Labelling on Millboard/Greyboard Box:
The label should indicate the content of Sterile Water for Injection IP in each ampoule. The label should incorporate manufacturer's name & address, manufacturing license no., batch no. date of mfg., date of expiry of the individual drug (Water for Injection) and storage requirements alongwith the number of the ampoules in the Box.

Shelf Life: Shelf life of Sterile Water for Injection would be at least 24 months. At least $5/6^{th}$ of the total stipulated shelf life must remain at the time of purchase.

Inspection:

The Purchaser should inspect the product prior to the purchase.

CAPREOMYCIN INJECTION (750 mg.)

Description: Each vial of Capreomycin Injection should contain Capreomycin IP 750 mg. Capreomycin Injection should conform to the requirements of IP.

Labeling on Vials:
The label should indicate the content of Capreomycin IP in each Vial.
The label should incorporate manufacturer's name & address, manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and the storage requirements. The label should also bear a 'Warning' required for "Schedule H Drug".
The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Labelling on Millboard/Greyboard Box:
The label should indicate the content of Capreomycin IP in each Vial.
The label should incorporate manufacturer's name & address, manufacturing license no., batch no. date of mfg., date of expiry of the individual drug and storage requirements along with the number of the vials in the Box. The label should also bear a 'Warning' required for "Schedule H Drug".
The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Storage: Store protected from moisture at a temperature not exceeding 25 degree C.

Shelf Life: Shelf life of Capreomycin would be 24 months.
At least $5/6^{th}$ of the total stipulated shelf life must remain at the time of purchase.
(In case of limited procurement, $5/6^{th}$ requirements may be relaxed depending upon the anticipated period of consumption).

STERILE WATER FOR INJECTION

Description:

Clear, colourless, odourless, free from added substances. Each ampoule should contain 5 ml of Sterile Water for Injection conforming to the requirements of IP.

Packing of Sterile Water for Injection:

IP Type 1, clear, plain glass ampoules or PE ampoule based on BFS technology. Each ampoule should contain 5 ml of Sterile Water for Injection. The ampoule should be sufficiently transparent to permit visual inspection of the contents.

Storage: Store in a single dose container in a cool, dry place.

Labelling on Ampoules:

The label should indicate the content of Sterile Water for Injection IP in each ampoule. The label should incorporate manufacturer's name & address, manufacturing license no., batch no., date of mfg., date of expiry of the individual drug (Water for Injection) and the storage requirements.

Labelling on Millboard/Greyboard Box:
The label should indicate the content of Sterile Water for Injection IP in each ampoule. The label should incorporate manufacturer's name & address, manufacturing license no., batch no. date of mfg., date of expiry of the individual drug (Water for Injection) and storage requirements alongwith the number of the ampoules in the Box.

Shelf Life: Shelf life of Sterile Water for Injection would be at least 24 months. At least $5/6^{th}$ of the total stipulated shelf life must remain at the time of purchase.

Inspection:

The Purchaser should inspect the product prior to the purchase.

CAPREOMYCIN INJECTION (500 mg.)

Description: Each vial of Capreomycin Injection should contain Capreomycin IP 500 mg. Capreomycin Injection should conform to the requirements of IP.

Labelling on Vials:
The label should indicate the content of Capreomycin IP in each Vial.
The label should incorporate manufacturer's name & address, manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and the storage requirements. The label should also bear a 'Warning' required for "Schedule H Drug".
The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Labelling on Millboard/Greyboard Box:
The label should indicate the content of Capreomycin IP in each Vial.
The label should incorporate manufacturer's name & address, manufacturing license no., batch no. date of mfg., date of expiry of the individual drug and storage requirements along with the number of the vials in the Box. The label should also bear a 'Warning' required for "Schedule H Drug".
The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Storage: Store protected from moisture at a temperature not exceeding 25 degree C.

Shelf Life: Shelf life of Capreomycin would be 24 months.
At least $5/6^{th}$ of the total stipulated shelf life must remain at the time of purchase.
(In case of limited procurement, $5/6^{th}$ requirements may be relaxed depending upon the anticipated period of consumption).

STERILE WATER FOR INJECTION

Description:
Clear, colourless, odourless, free from added substances. Each ampoule should contain 5 ml of Sterile Water for Injection conforming to the requirements of IP.

Packing of Sterile Water for Injection:

IP Type 1, clear, plain glass ampoules or PE ampoule based on BFS technology. Each ampoule should contain 5 ml of Sterile Water for Injection. The ampoule should be sufficiently transparent to permit visual inspection of the contents.

Storage: Store in a single dose container in a cool, dry place.

Labelling on Ampoules :

The label should indicate the content of Sterile Water for Injection IP in each ampoule. The label should incorporate manufacturer's name & address, manufacturing license no., batch no., date of mfg., date of expiry of the individual drug (Water for Injection) and the storage requirements.

Labelling on Millboard/Greyboard Box:
The label should indicate the content of Sterile Water for Injection IP in each ampoule. The label should incorporate manufacturer's name & address, manufacturing license no., batch no. date of mfg., date of expiry of the individual drug (Water for Injection) and storage requirements alongwith the number of the ampoules in the Box.

Shelf Life: Shelf life of Sterile Water for Injection would be at least 24 months.
At least $5/6^{th}$ of the total stipulated shelf life must remain at the time of purchase.
(In case of limited procurement, $5/6^{th}$ requirements may be relaxed depending upon the anticipated period of consumption).

Inspection:

The Purchaser should inspect the product prior to the purchase.

MOXIFLOXACIN Tablets (400 mg.)

Description: Each Moxifloxacin Tablet should contain Moxifloxacin Ph. Eur.400 mg. The Tablet should be film coated.

Moxifloxacin Tablets should conform to the requirements of .Ph. Eur.

Labelling on Strips:

The label should indicate the content of Moxifloxacin Ph. Eur. in each Tablet.

The label should incorporate manufacturer's name & address, manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and the storage requirements. The label should also bear a 'Warning' required for "Schedule H Drug".

The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Labelling on Millboard/Greyboard Box:

The label should indicate the content of Moxifloxacin Ph.Eur. in each Tablet.

The label should incorporate manufacturer's name & address, manufacturing license no., batch no. date of mfg., date of expiry of the drug and storage requirements along with the number of the strips in the Box. The label should also bear a 'Warning' required for "Schedule H Drug".

The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Storage: Store in cool & dry place away from the direct heat and light.

Shelf Life: Shelf life of Moxifloxacin would be 24 months.
At least $5/6^{th}$ of the total stipulated shelf life must remain at the time of purchase.

CLOFAZIMINE CAPSULES (200 mg.)

Description: Each Clofazimine Capsule IP should contain Clofazimine 200 mg and should conform to the requirements of IP.

Labelling on Strips:

The label should indicate the content of Clofazimine IP in each Capsule.
The label should incorporate manufacturer's name & address, manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and the storage requirements. The label should also bear a 'Warning' required for "Schedule H Drug".
The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Labelling on Millboard/Greyboard Box:

The label should indicate the content of Clofazimine in each Capsule.
The label should incorporate manufacturer's name & address, manufacturing license no., batch no. date of mfg., date of expiry of the drug and storage requirements along with the number of the strips in the Box. The label should also bear a 'Warning' required for "Schedule H Drug".
The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Storage: Store in cool & dry place away from the direct heat and light.

Shelf Life: Shelf life of Clofazimine would be 24 months.
At least $5/6^{th}$ of the total stipulated shelf life must remain at the time of purchase.

CLOFAZIMINE CAPSULES (100 mg.)

Description: Each Clofazimine Capsule IP should contain Clofazimine 100 mg and should conform to the requirements of IP.

Labelling on Strips:

The label should indicate the content of Clofazimine IP in each Capsule.
The label should incorporate manufacturer's name & address, manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and the storage requirements. The label should also bear a 'Warning' required for "Schedule H Drug".
The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Labelling on Millboard/Greyboard Box:

The label should indicate the content of Clofazimine in each Capsule.
The label should incorporate manufacturer's name & address, manufacturing license no., batch no. date of mfg., date of expiry of the drug and storage requirements along with the number of the strips in the Box. The label should also bear a 'Warning' required for "Schedule H Drug".
The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Storage: Store in cool & dry place away from the direct heat and light.

Shelf Life: Shelf life of Clofazimine would be 24 months.
At least $5/6^{th}$ of the total stipulated shelf life must remain at the time of purchase.

LINEZOLID TABLETS (600 mg.)

Description: Each Linezolid Tablet should contain Linezolid IP 600 mg.
Linezolid Tablets should conform to the requirements of IP.

Labelling on Strips:

The label should indicate the contents of Linezolid IP in each Tablet.
The label should incorporate manufacturer's name & address, manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and the storage requirements. The label should also bear a 'Warning' required for "Schedule H Drugs".
The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Labelling on Millboard/Greyboard Box:

The label should indicate the content of Linezolid IP in each Tablet.
The label should incorporate manufacturer's name & address, manufacturing license no., batch no. date of mfg., date of expiry of the drug and storage requirements along with the number of the strips in the Box. The label should also bear a 'Warning' required for "Schedule H Drugs". The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Storage: Store in cool & dry place away from the direct heat and light.

Shelf Life: Shelf life of Linezolid would be 36 months.
At least $5/6^{th}$ of the total stipulated shelf life must remain at the time of purchase.

AMOXYCILLIN (500 mg.) & POTASSIUM CLAVULANATE (125 mg.) TABLETS

Description: Each Amoxicillin and Potassium Clavulanate Tablet should contain Amoxycillin Trihydrate IP equivalent to Amoxicillin 500 mg and Potassium Clavulanate IP equivalent to Clavulanic Acid 125mg. Amoxycillin and Pottasium Clavulanate Tablets should conform to the requirements of IP.

Labelling on Strips:
The label should indicate the content of Amoxycillin Trihydrate IP equivalent to Amoxycillin and Potassium Clavulanate IP equivalent to Clavulanic Acid in each tablet.
The label should incorporate manufacturer's name & address, manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and the storage requirements. The label should also bear a 'Warning' required for "Schedule H Drug".
The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Labelling on Millboard/Greyboard Box:
The label should indicate the content of Amoxycillin Trihydrate IP equivalent to Amoxycillin and Potassium Clavulanate IP equivalent to Clavulanic Acid in each tablet.
The label should incorporate manufacturer's name & address, manufacturing license no., batch no. date of mfg., date of expiry of the individual drug and storage requirements along with the number of the strips in the Box. The label should also bear a 'Warning' required for "Schedule H Drug".
The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Storage: Store in cool & dry place away from the direct heat and light.

Shelf Life: Shelf life of Amoxycillin and Potassium Clavulanate Tablets would be 24 months. At least $5/6^{th}$ of the total stipulated shelf life must remain at the time of purchase.

PYRIDOXINE TABLETS (100 mg.)

Description: Each Pyridoxine Tablet should contain Pyridoxine Hydrochloride IP 100 mg
Pyridoxine Tablets should conform to the requirements of IP.

Labelling on Strips:

The label should indicate the content of Pyridoxine Hydrochloride IP in each Tablet.

The label should incorporate manufacturer's name & address, manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and the storage requirements. The label should also bear a 'Warning' required for "Schedule H Drug".

The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Labelling on Millboard/Greyboard Box:

The label should indicate the content of Pyridoxine Hydrochloride IP in each Tablet.

The label should incorporate manufacturer's name & address, manufacturing license no., batch no. date of mfg., date of expiry of the drug and storage requirements along with the number of the strips in the Box. The label should also bear a 'Warning' required for "Schedule H Drug".

The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Storage: Store in cool & dry place away from the direct heat and light.

Shelf Life: Shelf life of Pyridoxine Hydrochloride would be 36 months.
At least $5/6^{th}$ of the total stipulated shelf life must remain at the time of purchase.

CLARITHROMYCIN Tablets (500 mg.)

Description: Each Clarithromycin Tablet should contain Clarithromycin IP 500 mg
Clarithromycin Tablets should conform to the requirements of IP. The Tablets should be film coated.

Labelling on Strips:
The label should indicate the content of Clarithromycin IP in each Tablet.
The label should incorporate manufacturer's name & address, manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and the storage requirements. The label should also bear a 'Warning' required for "Schedule H Drug".
The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Labelling on Millboard/Greyboard Box:
The label should indicate the content of Clarithromycin IP in each Tablet.
The label should incorporate manufacturer's name & address, manufacturing license no., batch no. date of mfg., date of expiry of the drug and storage requirements along with the number of the strips in the Box. The label should also bear a 'Warning' required for "Schedule H Drug".
The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Storage: Store in cool & dry place away from the direct heat and light.

Shelf Life: Shelf life of Clarithromycin would be 24 months.
At least $5/6^{th}$ of the total stipulated shelf life must remain at the time of purchase.

Sodium Para-Aminosalicylate Granules (100 gm containers)

Description:

Sodium Para Amino Salicylate Granules packed in a multi-dose container contains 100g of Sodium Amino Salicylate Granules. The drug contained in the product should be currently registered in the country of manufacture and should meet all requirements of the licensing authority of the country of manufacture. The drug contained in the product should also be currently registered in India and should meet all the requirements of the licensing authority in India.
Sodium Aminosalicylate Granules should conform to the general requirements of Granules (under its subhead Gastro-resistant Granules) given in BP and the requirements under individual monograph given in IP.
Sodium Aminosalicylate Granules contain Sodium Aminosalicylate.
Each Gram of the Granules should contain -
Sodium Aminosalicylate IP 600 mg (60% w/w)
The granules are **enteric coated**.
The quality of Sodium Aminosalicylate should conform to the requirements of the individual monograph given in IP or other Pharmacopoeia of equivalent accuracy.

Packing

The granules should be packed in a polybag. Each polybag should contain 100 gram of Sodium Para-Aminosalicylate granules. The polybag should be fabricated from Polyethylene. The quality and thickness of Polyethylene should be within the following limits:-

	Micron	mm	g/m^2
Polyethylene	50	0.040 – 0.050	36.9 – 46.1

The polybags should be tropicalized with regard to moisture barrier properties for drug stability under field conditions. The polybag along with a dispenser should be packed in a round container fabricated from white High Density Poly Ethylene (HDPE) provided with temper evident screw on PP cap with EPE/ Induction sealing wad. Quality Assurance should be according to ISO 9001 standards for all the packaging material. The dispenser should be fabricated from polypropylene with two marks for dispensing 8gm. and 10gm.

Labelling

Labelling on Containers:

The label should indicate the content of Sodium Aminosalicylate IP in mg per gram of granules and the content in each container.
All labelling should be in weather-proof ink and should withstand immersion in water and remain intact.
The label should incorporate manufacturer's name & address, manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and storage requirements.
The label should also bear a 'Warning' required for "Schedule H Drugs".

The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Labelling on Millboard/Greyboard Box:
The label should indicate the content of Sodium Aminosalicylate IP in mg per gram of granules
The label should incorporate manufacturer's name & address, manufacturing license no., batch no. date of mfg., date of expiry of the drug and storage requirements alongwith number of Containers in the Box. The label should also bear a 'Warning' required for "Schedule H Drugs".
The label should conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Storage: Store in cool & dry place away from the direct heat and light.

Shelf Life:
Shelf life of Sodium Para-Aminosalicylate would be 24 months. At least $5/6^{th}$ of the total stipulated shelf life must remain at the time of purchase.