

**Technical Specification of Injection Paromomycin [REDACTED] for Kala-azar
Under NVBDCP**

Description of Store: Paromomycin IM injection 1x2 ml ampoules containing 375 mg of Paromomycin per ml.

Shelf life: Minimum 2 years when stored below 30°C and protected from light.

Special precautions for storage:

Store below 30°C. Protect from light. Do not freeze.

DO NOT STORE partially used ampoules for future patient use.

Nature and Content of Container:

2-ml Type 1 amber glass ampoules, supplied in packs of 10 ampoules.

Instructions for Use and Handling and Disposal:

For single use only. Any unused paromomycin from opened ampoules should be discarded.

Labeling/Printing

• **On the injection of Ampoule**

- Name of injection product
- Name of manufacture with address
- IM use only
- License No.
- Lot No. and Batch No.
- Manufacturing and expiry date
- The contents of injection per ml
- Govt. of India supply Not for Sale
(Preferably in red colour, or in any contrast colour)

• **On the Primary Packing of sliding Cardboard box**

- Name of injection product
- Name of manufacture with address
- IM use only
- License No.
- Lot No. and Batch No.
- Manufacturing and expiry date
- The contents of injection per ml
- Govt. of India supply Not for Sale

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(Preferably in red colour, or in any contrast colour)

- Dosage-Adult/Children
- Indications for use
- Adverse effect/Side effects
- Precautions
- Storage condition


(C) On the Secondary Packing/Inner Carton and Outer shipper of Corrugated Box

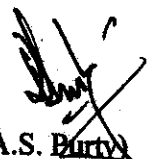
- Name of injection Product
 - Name of manufacturer with address
 - IM use only
 - License No.
 - Lot No. and Batch No.
 - Manufacturing and expiry date
 - The contents of the container
 - Govt. of India Supply Not for Sale
- (Preferably in red colour, or in any contrast colour)


- Precaution for transportation.
- Storage condition
- The box should be packed with thermocol material to prevent breakage.

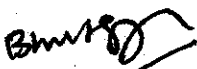
Good Manufacturing Practices (GMP): The manufacturing facility must confirm to GMP as per Schedule 'M' of the Drugs & Cosmetic Act.

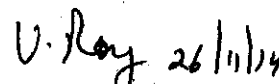
Product Should be COPP complying.

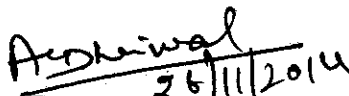

(Sahjeev Kumar)
ADC(I), CDSCO

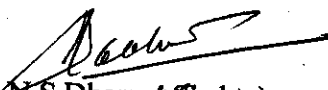

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