Technical Specification of Injection Paromomycin ⚫ 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
(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.

(Sanjeev Kumar)
ADC(I), CDSCO

(A.S. Pathy)
Dy. Dir.(Proc.)

(Dr. H.S. Tanwar)
Asst.Prof. (RML)

(Dr. Bharat Singh)
CMO, (MSO)

(Dr. Vandana Roy)
Prof. & HOD (MAMC)

(Dr. A.C. Dhariwal)
Director (NVBDPC)

(Dr. N.S. Dharm Shaktu)
DDG, Dte.GHS(Chairman)