

**Directorate of National Vector Borne Disease Control Programme**

**Technical Specification of ARTEETHER INJECTION under NVBDCP**

**ARTEETHER INJECTION**

DR. SATYAWAN SINGH OF CDRI MENTIONED THAT SULPHATED ASH RELATED TO SPECIFICATIONS FOR ARTEETHER BULK DRUG AND THEREFORE NEED NOT BE INCLUDED IN THE TECHNICAL SPECIFICATIONS FOR ARTEETHER INJECTIONS. HE ALSO CLARIFIED THAT THE LIMIT OF COMPONENTS OF  $A:30 \pm 5\%$  WAS RANGE OF 25 TO 35. SIMILARLY, THE LIMIT COMPONENT OF  $\beta$  WAS  $70 + 5\%$  WAS RANGE OF 65 TO 75. HE ALSO SAID THAT NEAR NEUTRAL PH WAS ACCEPTABLE.

THE TECHNICAL COMMITTEE AGREED THAT THE SPECIFICATIONS AS GIVEN BY THE DCG(I) MAY BE USED FOR THE PROCUREMENT UNDER NAMP. SPECIFICATIONS RELATED TO ARTEETHER BULK DRUG SUCH AS SULFATED ASH CONTAINED SHOULD NOT BE INCLUDED IN THE ABOVE TECHNICAL SPECIFICATIONS.

THE TECHNICAL COMMITTEE APPROVED THE SPECIFICATIONS OF ARTEETHER INJECTIONS, AS SPECIFIED BY DCG (I), GIVEN BELOW:

- PH neutral
  - Colourless solution
  - Contain not less than 70 mg and not more than 80 mg per ml of Arteether.
  - Limit of components
    - A = 25 to 35%
    - $\beta$  = 75 to 65%
- Assay Arteether: 95 to 105%**

---

The Technical Specification of Arteether Injections under NVBDCP approved by Technical Specification Committee meeting on dated 08.08.2003

PART A

**TECHNICAL SPECIFICATIONS OF**  
**ARTEETHER INJECTIONS**

**Specifications**

**(I) Description of the item :**

ARTEETHER INJECTIONS. Each ampoule contains Arteether 150 mg and arachis oil (q.s.) per 2 ml.

**(II) Technical Specifications:**

- PH neutral
- Colourless solution
- Contains not less than 70 mg and not more than 80 mg per ml of Arteether.
- Limit of components
  - $\alpha = 25$  to 35%
  - $\beta = 65$  to 75%
- Assay Arteether : 95 to 105%
- Sterility and storage condition as per IP 1996

**(III) Shelf Life**

Minimum two years shelf life. Arteether injectable would not pass more than 1/6<sup>th</sup> of their effective life from the date of manufacture at the time when injections are offered for inspection and the remaining useful life that shall still be left would not be less than 5/6<sup>th</sup> of total life of 2 years.

Losses due to premature deterioration as a result of biological and other activities during the life of potency of the Arteether injectable will be made good by the firm at their cost.

**(IV) Packaging:**

**(a) Primary packing:-**

- 3 ampoules should be placed in a corrugated tray made of white duplex board covered with a transparent Polyethylene sheet.
- Such a tray with 3 ampoules should be placed in sliding cardboard box of the appropriate size of 5.5 cm x 7 cm x 2 cm

**(b) Secondary Packing/Inner Carton:**

- 30 small 'tray boxes' each of which containing ampoules should be packed in a bigger card board box, called 'inner carton'.
- This 'Inner Carton' should be of
  - Ply = 3
  - GSM = 120
  - Paper = Virgin Kraft

- Approximate size of the Inner Carton is, 14.5 cm x 18 cm x 11 cm
- The 'Inner Carton' should be packed with thermocol material to prevent breakage

**(a) Outer Shipper of Corrugated Box:**

- Each shipper should be of  
 Ply = 5  
 Paper = Virgin Kraft  
 GSM = 3 liner – 150, 2 flute – 150  
 BS = NLT 8 kgs/cm<sup>2</sup>

**(V) Labelling/Printing**

**(a) On the Injection of Ampoule**

- Name of Injection Product
- Name of manufacturer with address
- 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)

**(b) On the Primary Packing of sliding Cardboard box**

- Name of Injection Product
- Name of manufacturer with address
- 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
- Action of the drug
- Adverse effect/side effects
- Precautions
- Storage condition

**(c) On the Secondary Packing/Inner Carton and  
 And  
 Outer Shipper of Corrugated Box**

- Name of Injection Product
- Name of manufacturer with address
- 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)

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