## RESTRICTED

## ASC SPECIFICATION NO. 307 (A)

- 1. <u>Description</u>. The Sterilizing Sodium Dichloroisocyanurate tablet shall have weight varying from 50 mg to 80 mg and it must be uncoated, white/off white coloured and consists of the following ingredients:
  - a. <u>Active Ingredient.</u> Each tablet contains 8.5 mg ( $\pm$  10%) sodium dichloroisocyanurate (troclosene sodium) in an dissolving base.
  - b. Excipient: Quality Standard (Q.S) to manufacture a tablet having average weight 50 mg to 80 mg ( $\pm$  3 mg).
- 2. <u>Examination</u>. The outfit each water sterilizing tablet shall comply the clause no 1 with the following requirements:
  - a. Acceptable Weight variation. Not more than 2 tablets outside  $\pm$  10% of the actual average. No tablet outside  $\pm$  20% of the actual average.
  - b. <u>Uniformity of content of the active ingredients</u>. Purity when assayed for the chlorine content, the method given in appendix 1 (attached) to this specification shall contain sodium dichloroiscyanurate (troclosene sodium), calculated to the following limit:
    - (1) Available chlorine: 5.2 mg (4.9 mg to 5.5 mg)
    - (2) Dye/Colouring agent: When tablet is dissolved in a litre of water, it shall not produce any appreciable colour.
    - (3) Diameter: 4.75mm (±3%)
    - (4) Hardness: Min 1.5 kg/cm<sup>2</sup>
    - (5) Assay: Each tablet contains 8.5 mg ( $\pm$ 10%) sodium dichloroisocyanurate (troclosene sodium) in an effervescent base.
  - c. Shape. Oval, bi-convex, flat-round plain surface tablet or any other suitable shape.
  - d. <u>Disintegration Time.</u> Not more than 180 Seconds.
  - e. Leak test. Must be 100% leak proof.

## 3. Packing.

- a. <u>Strips</u>. Tablet shall be supplied in strips Alu-Alu blister strip, PVC blister strip, aluminum foil strips or poly lined paper strip and shall be presented 10 tablets per strips.
- b. <u>Cases:</u> The Strips shall be packed in thick paper carton containing 500 or 1000 no tablets in each carton. The cases shall be sufficiently strong to withstand rough handling by rail/road transport without damage to their contents. The cases carton master carton upto 50,000 Tablets.

## 4. Marking.

- a. Strips. The following particulars shall be marked on the respective strips:
  - (1) Name of the content of tablet.
  - (2) Weight of active ingredient per tablet.
  - (3) Lot/Batch no.
  - (4) Expiry date.
  - (5) Country of origin.
  - (6) Certification of Analysis of each batch supplied (from manufacture)
- b. <u>Cases</u>. The following particulars shall be stenciled on one side of the cases:
  - Outfit individual water purification tablets.
  - (2) Quantity: 500/1000 tablets per carton.
  - (3) Name of Manufacture.
  - (4) Manufacture date.
  - (5) Gross weight of carton.
  - (6) Instruction for user.