Government of Nepal
Ministry of Health and Population
Department of Drug Administration
National Medicines Laboratory
Quality and Method Validation Section

Drotaverine Hydrochloride Injection

Analytical Profile No.: Drotav 078/079/AP 113

Drotaverine Hydrochloride Injection contains not less than 90.0% and not more than 110.0% of the stated amount of Drotaverine Hydrochloride.

Usual Strength: Each ml contains:

Drotaverine Hydrochloride 20 mg

1. Identification:

In the Assay, the principle peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

2. pH: As per manufacturer's specification

3. Particulate Matter: As per IP latest edition

4. Sterility Test: As per IP latest edition

5. Bacterial Endotoxin Test: As per IP latest edition

Limit: NMT 35 EU/mg

6. Assay: *Determine by liquid chromatography*

6.1 Diluent: Methanol

6.2 Test solution: Transfer 5 ml of the test sample to 100 ml of volumetric flask, dissolve and make up the volume with diluent. Further dilute 5 ml to 25 ml with diluent.

6.3 Reference solution: Weigh accurately and transfer about 100 mg of Drotaverine Hydrochloride WS to a 100 ml volumetric flask (amber color); dissolve and make up the volume with diluent. Further dilute 5 ml to 25 ml with diluent.

6.4 Chromatographic system:

- **Column:** C18, (250 x 4.6) mm, 5 µ particle size
- **Flow rate:** 1.5 ml/min
- **Wavelength:** 254 nm

- **Injection volume:** 20 µl
- **Detector:** UV
- **Column temperature:** 35°C
- **Mobile Phase:** A mixture of 40 volumes of Methanol, 35 volumes of Acetonitrile and 25 volumes of buffer solution
    - **Buffer:** Dissolve 3.12 g of Sodium dihydrogen orthophosphate in 1000ml of water, pH adjusted to 6.5 with sodium hydroxide

6.5 Procedure:

Inject the reference solution five times and sample solutions. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, tailing factor is not more than 2.0, and the relative standard deviation for replicate injections is not more than 2.0%. Measure the peak responses. Calculate the content of Drotaverine Hydrochloride in Injection.

7. Other tests: As per pharmacopoeial requirement.