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

Analytical profile of 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.

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: As per IP latest edition

5. Bacterial Endotoxin Test: Limit: NMT 35.0 EU/mg

5. Assay: *Determine by liquid chromatography*

5.1 Test solution: Transfer 5 ml of injection to 100 ml volumetric flask. Dissolve and make up the volume with methanol. Further dilute 5 ml of this solution to 25 ml with methanol and mix.

5.2 Reference solution: Weigh accurately about 100 mg of Drotaverine HCl WS and transfer into 100 ml volumetric flask. Dissolve in methanol by sonication and make up the volume with methanol. Further dilute 5 ml of this solution to 25 ml with methanol and mix.

5.4 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 1000 ml of water. Adjust pH to 6.5 with NaOH.

5.5 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 in Injection.

6. Other tests: As per pharmacopoeial requirement.