

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

Rocuronium Bromide Injection

Analytical Profile No.: Rocu 078/079/AP 115

Rocuronium Bromide Injection contains not less than 90.0% and not more than 110.0% of the stated amount of Rocuronium Bromide.

Usual Strength: Each ml contains:

Rocuronium Bromide 10 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: As per IP latest edition

5. Bacterial Endotoxin Test: As per IP latest edition

Limit: NMT 5 EU/mg

6. Assay: *Determine by liquid chromatography*

6.1 Diluent: Acetonitrile and water (90:10)

6.2 Test solution: Take 2ml of the test sample into 20 ml volumetric flask. Make up the volume with diluent and sonicate to dissolve.

6.3 Reference solution: Weigh accurately about 25 mg of Rocuronium Bromide WS and transfer into 25 ml volumetric flask. Make up the volume with diluent and sonicate to dissolve.

6.4 Chromatographic system:

- **Column:** L3, (250 x 4.6) mm, 5 µ particle size
- **Flow rate:** 2 ml/min
- **Wavelength:** 210 nm

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- **Injection volume:** 10 μ l
- **Detector:** UV
- **Column temperature:** 30°C
- **Mobile Phase:** A mixture of 90 volumes of Acetonitrile and 10 volumes of buffer
 - **Buffer:** 4.53 g/lit of Tetramethylammonium Hydroxide Pentahydrate, pH adjusted to 7.4 with phosphoric acid

6.5 Procedure: [Note: the system may need equilibrium for 4 hours.]

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 Rocuronium Bromide in Injection.

7. Other tests: As per pharmacopoeial requirement.