

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

Metamizole Sodium Injection

Analytical Profile No.: Metami 079/080/AP 129

Metamizole Sodium Injection contains not less than 95.0% and not more than 105.0% of the stated amount of Metamizole Sodium.

Usual Strength: Each ml contains:

Metamizole Sodium 500 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 12.5 EU/ml

6. Assay: *Determine by liquid chromatography*

6.1 Diluent: Methanol

6.2 Test solution: Weigh sample equivalent to 200 mg of Metamizole sodium into 100 ml volumetric flask, add about 70 ml of diluent, sonicate to dissolve, cool to room temperature and make up the volume with same solvent. Further dilute 10ml of this solution to 100 ml with same solvent.

6.3 Reference solution: Weigh accurately and transfer about 20 mg of Metamizole sodium WS to a 100 ml volumetric flask, add about 70 ml of diluent, sonicate to dissolve, cool to room temperature and make up the volume with same solvent.

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6.4 Chromatographic system:

- **Column:** C18, (250 x 4.6) mm, 5 μ particle size
- **Flow rate:** 1.0 ml/min
- **Wavelength:** 300 nm
- **Injection volume:** 20 μ l
- **Detector:** UV
- **Column temperature:** 25°C
- **Mobile Phase:** A mixture of 50 volumes of Buffer, 49 volumes of Methanol and 10 volumes of Acetic Acid
 - **Buffer:** Dissolve 1.0 gm of Tetra methyl ammonium chloride in 500 ml of water

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 Metamizole Sodium in Metamizole Sodium Injection.

7. Other tests: As per pharmacopoeial requirement.