

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

Ketorolac Tromethamine Eye Drops

Analytical Profile No.: Keto 079/080/AP 103

Ketorolac Tromethamine Eye Drops contains not less than 90.0% and not more than 110.0% of the stated amount of Ketorolac Tromethamine.

Usual Strength: Each ml contains:

Ketorolac Tromethamine 4 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. Assay: *Determine by liquid chromatography*

[**Note:** Protect all solution from light]

5.1 Diluents: Methanol and water (1:1)

5.2 Test solution: Take 2ml of the test sample equivalent to 8 mg of Ketorolac Tromethamine into 100 ml volumetric flask. Add about 50 ml of diluents, sonicate to dissolve. Cool to ambient temperature and dilute to 100 ml with diluents and mix.

5.3 Reference solution: Weigh accurately about 40mg of Ketorolac Tromethamine WS and transfer into 50 ml volumetric flask. Add about 25 ml of diluents, sonicate to dissolve. Cool to ambient temperature and dilute to 50 ml with diluents. Further dilute 5ml to 50 ml with diluents and mix.

5.4 Chromatographic system:

- **Column:** C18, (150 x 4.6 mm), 5 μ particle size
- **Flow rate:** 1.2 ml/min
- **Wavelength:** 254 nm

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- **Injection volume:** 100 μ l
- **Detector:** UV
- **Column temperature:** Ambient
- **Mobile Phase:** A mixture of 55 volumes of Methanol, 44 volumes of Water and 1 volume of glacial acetic acid

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 Ketorolac Tromethamine in Eye Drops.

6. Other tests: As per pharmacopoeial requirement.

Subject to Approval from DAC