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Ketorolac Tromethamine Injection

DEFINITION

Ketorolac Tromethamine Injection is a sterile solution of Ketorolac Tromethamine. It contains NLT 90.0% and NMT 110.0% of the labeled amount of ketorolac tromethamine ($C_{15}H_{13}NO_3 \cdot C_4H_{11}NO_3$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The UV spectrum of the ketorolac peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

[NOTE—Protect all solutions from light.]

Mobile phase: Methanol, water, and glacial acetic acid (55:44:1)

Diluent: Methanol and water (1:1)

Standard solution: 0.05 mg/mL of [USP Ketorolac Tromethamine RS](#) in *Diluent*

Sample solution: Nominally equivalent to 0.05 mg/mL of ketorolac tromethamine in *Diluent* from Injection

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 254 nm. For *Identification test B*, use a diode array detector in the range of 200–600 nm.

Column: 4.6-mm × 25-cm; 5-μm packing L1

Flow rate: 1.2 mL/min

Injection volume: 100 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5 for the ketorolac peak

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ketorolac tromethamine ($C_{15}H_{13}NO_3 \cdot C_4H_{11}NO_3$) in each mL of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of ketorolac from the *Sample solution*

r_S = peak response of ketorolac from the *Standard solution*

C_S = concentration of [USP Ketorolac Tromethamine RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of ketorolac tromethamine in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• ORGANIC IMPURITIES

[NOTE—Protect all solutions from light.]

Mobile phase, Diluent, and Chromatographic system: Proceed as directed in the Assay.

Standard stock solution: 0.10 mg/mL each of [USP Ketorolac Tromethamine RS](#), [USP Ketorolac Related Compound A RS](#), [USP Ketorolac Related Compound B RS](#), [USP Ketorolac Related Compound C RS](#), and [USP Ketorolac Related Compound D RS](#) in *Diluent* prepared as follows. Transfer [USP Ketorolac Tromethamine RS](#), [USP Ketorolac Related Compound A RS](#), [USP Ketorolac Related Compound B RS](#), [USP Ketorolac Related Compound C RS](#), and [USP Ketorolac Related Compound D RS](#) to a suitable volumetric flask. Add 4% of the volume of the flask with methanol. Sonicate and dilute with *Diluent* to volume.

Standard solution: 0.2 µg/mL each of [USP Ketorolac Tromethamine RS](#), [USP Ketorolac Related Compound A RS](#), [USP Ketorolac Related Compound B RS](#), [USP Ketorolac Related Compound C RS](#), and [USP Ketorolac Related Compound D RS](#) in *Diluent* from the *Standard stock solution*

Sample solution: Prepare nominally equivalent to 0.2 mg/mL of ketorolac tromethamine in *Diluent*.

System suitability

Sample: *Standard solution*

[NOTE—See [Table 1](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 2 between ketorolac related compound C and ketorolac

Relative standard deviation: NMT 2.8% for all the peaks

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amounts of ketorolac related compound A, ketorolac related compound B, ketorolac related compound C, and ketorolac related compound D in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of ketorolac related compound A, ketorolac related compound B, ketorolac related compound C, or ketorolac related compound D from the *Sample solution*

r_S = peak response of ketorolac related compound A, ketorolac related compound B, ketorolac related compound C, or ketorolac related compound D from the *Standard solution*

C_S = concentration of the corresponding related compound in the *Standard solution* (mg/mL)

C_U = nominal concentration of ketorolac tromethamine in the *Sample solution* (mg/mL)

Calculate the percentage of any unspecified impurity in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of any unspecified impurity from the *Sample solution*

r_S = peak response of ketorolac from the *Standard solution*

C_S = concentration of [USP Ketorolac Tromethamine RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of ketorolac tromethamine in the *Sample solution* (mg/mL)

Acceptance criteria: See [Table 1](#). Disregard any impurity peak less than 0.05%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Ketorolac related compound A	0.4	0.20
Ketorolac related compound B	0.6	0.5
Ketorolac related compound C	0.8	0.5
Ketorolac	1.0	
Ketorolac related compound D	2.1	