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Tolmetin Sodium Tablets

DEFINITION

Tolmetin Sodium Tablets contain an amount of tolmetin sodium equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of tolmetin ($C_{15}H_{15}NO_3$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*:** 197U▲ (CN 1-May-2020)

Standard stock solution: 0.1 mg/mL of USP Tolmetin Sodium RS in methanol

Standard solution: 0.01 mg/mL of USP Tolmetin Sodium RS from the *Standard stock solution* diluted with 0.1 N sodium hydroxide

Sample solution: Transfer a quantity of finely powdered Tablets, equivalent to 10 mg of tolmetin, to a 100-mL volumetric flask. Add 50 mL of methanol, shake for 2 min, and dilute with methanol to volume. Filter a portion of this solution, transfer 10 mL of the filtrate to a second 100-mL volumetric flask, and dilute with 0.1 N sodium hydroxide to volume.

Analysis

Samples: *Standard solution* and *Sample solution*

Acceptance criteria: The UV absorption spectrum of the *Sample solution* exhibits maxima and minima at the same wavelengths as that of the *Standard solution*.

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Buffer: 1.7 g/L of tetrabutylammonium phosphate. Adjust with phosphoric acid to a pH of 2.7 ± 0.1.

Mobile phase: Acetonitrile and *Buffer* (36:64)

Diluent: Acetonitrile and 0.01 N sodium hydroxide (40:60)

System suitability solution: 200 µg/mL of *p*-toluic acid and 500 µg/mL of USP Tolmetin Sodium RS in *Diluent*

Standard solution: 0.65 mg/mL of anhydrous tolmetin sodium from USP Tolmetin Sodium RS in *Diluent*

Sample solution: Weigh and finely powder NLT 20 Tablets. Transfer the powder, nominally equivalent to 60 mg of tolmetin, to a 100-mL volumetric flask. Add about 75 mL of *Diluent*, and shake by mechanical means for 30 min. Dilute with *Diluent* to volume, and pass through a filter of 0.45-µm or finer pore size.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 15-cm; 5-µm packing L7

Column temperature: 40 ± 1.0°

Flow rate: 3 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 1.2 between the *p*-toluic acid and tolmetin sodium peaks, *System suitability solution*

Relative standard deviation: NMT 3.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of tolmetin ($C_{15}H_{15}NO_3$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

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

M_{r1} = molecular weight of tolmetin, 257.29

M_{r2} = molecular weight of anhydrous tolmetin sodium, 279.27

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Solution A: Dissolve 2.0 g of sodium chloride in 7.0 mL of hydrochloric acid, and add water to 1000 mL.

Solution B: Dissolve 6.8 g of monobasic potassium phosphate in 250 mL of water, and add 190 mL of 0.2 N sodium hydroxide and 400 mL of water. Adjust the solution with 0.2 N sodium hydroxide to a pH of 7.4–7.6. Dilute with water to 1000 mL.

Medium: *Solution A* and *Solution B* (336:664). Adjust the solution with small amounts of either solution to a pH of 4.5; 900 mL.

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: USP Tolmetin Sodium RS in *Medium* at a known concentration

Sample solutions: Sample per *Dissolution ⟨711⟩*. Dilute with 0.1 N sodium hydroxide, as needed, and filter.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy ⟨857⟩*.)

Mode: UV

Analytical wavelength: 322 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of tolmetin ($C_{15}H_{15}NO_3$) dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times D \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Tolmetin Sodium RS in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

D = dilution factor of the *Sample solution*

Tolerances: NLT 75% (Q) of the labeled amount of tolmetin ($C_{15}H_{15}NO_3$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **USP Reference Standards ⟨11⟩**

USP Tolmetin Sodium RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
TOLMETIN SODIUM TABLETS	Documentary Standards Support	SM22020 Small Molecules 2

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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