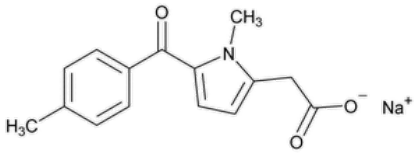
Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-644D2727-FA88-48C7-AE5F-029949003B7F_4_en-US
DOI: https://doi.org/10.31003/USPNF_M84140_04_01
DOI Ref: 8foo1

Tolmetin Sodium



• $2\,H_2O$

$C_{15}H_{14}NNaO_3 \cdot 2H_2O$ 315.30
$C_{15}H_{14}NNaO_3$ 279.27

1*H*-Pyrrole-2-acetic acid, 1-methyl-5-(4-methylbenzoyl)-, sodium salt, dihydrate;

Sodium 1-methyl-5-*p*-toluoylpyrrole-2-acetate dihydrate CAS RN®: 64490-92-2; UNII: 02N1TZF99F.

Anhydrous CAS RN®: 35711-34-3; UNII: WL259637KX.

DEFINITION

Tolmetin Sodium contains NLT 98.0% and NMT 102.0% of tolmetin sodium ($C_{15}H_{14}NNaO_3$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

Change to read:

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

Sample solution: 10 µg/mL in pH 7 phosphate buffer (see *Reagents, Indicators, and Solutions—Buffer Solutions*)

Medium: pH 7 phosphate buffer (see *Reagents, Indicators, and Solutions—Buffer Solutions*)

Acceptance criteria: Meets the requirements

• **C.** Identification Tests—General, *Sodium* ⟨191⟩

Sample solution: 50 mg/mL

Acceptance criteria: Meets the requirements of the test for sodium

ASSAY

• **Procedure**

Sample: 300 mg

Titrimetric system

Mode: Direct titration

Titrant: 0.1 N perchloric acid VS

Endpoint detection: Potentiometric

Analysis: Dissolve the *Sample* by warming in 150 mL of glacial acetic acid. Cool to room temperature, and titrate with *Titrant*. Perform a blank determination, and make any necessary correction. Each mL of *Titrant* is equivalent to 27.93 mg of tolmetin sodium ($C_{15}H_{14}NNaO_3$).

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• **Organic Impurities**

Standard stock solution: 12.5 mg/mL of USP Tolmetin Sodium RS in methanol

Standard solution: 62.5 µg/mL of USP Tolmetin Sodium RS in methanol from *Standard stock solution*

Sample solution: 12.5 mg/mL of Tolmetin Sodium in methanol

Chromatographic system

(See *Chromatography* ⟨621⟩, *Thin-Layer Chromatography*.)

Mode: TLC

Absorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 20 µL

Developing solvent system: Chloroform and glacial acetic acid (95:5)

Analysis

Samples: *Standard stock solution*, *Standard solution*, and *Sample solution*

Develop the chromatogram in the solvent system until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, mark the solvent front, air-dry, and view under short-wavelength UV light.

Acceptance criteria: The R_F value of the principal spot of the *Sample solution* corresponds to that of the *Standard stock solution*. Any other spot of the *Sample solution* does not exceed in size or intensity of the principal spot of the *Standard solution* (0.5%), and the sum of the total impurities, based on a comparison of the intensities of all such other spots with the *Standard solution*, does not exceed 2.0%.

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩

Analysis: Dry a sample under vacuum at 60° for 4 h.

Acceptance criteria: 10.4%–12.4%

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	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 46(5)

Current DocID: GUID-644D2727-FA88-48C7-AE5F-029949003B7F_4_en-US

DOI: https://doi.org/10.31003/USPNF_M84140_04_01

DOI ref: 8foo1