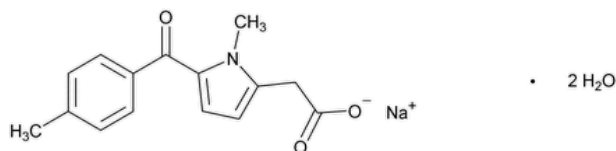


Status: Currently Official on 17-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-644D2727-FA88-48C7-AE5F-029949003B7F_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M84140_04_01
 DOI Ref: 8foo1

© 2025 USPC
 Do not distribute

Tolmetin Sodium



$C_{15}H_{14}NNaO_3 \cdot 2H_2O$ 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](#)