

Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-811CCC72-C535-4E79-9606-CC8D7A661391_2_en-US
DOI: https://doi.org/10.31003/USPNF_M79190_02_01
DOI Ref: a4ey6

© 2025 USPC
Do not distribute

Sulfamethizole Tablets

DEFINITION

Sulfamethizole Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of sulfamethizole ($C_9H_{10}N_4O_2S_2$).

IDENTIFICATION

Change to read:

- A. **▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197M](#)** ▲ (CN 1-MAY-2020)

Sample: Equivalent to 500 mg of sulfamethizole from finely powdered Tablets

Analysis: Triturate the *Sample* with 5 mL of chloroform, and transfer to a small filter. Wash with another 5-mL portion of chloroform, and discard the filtrate. Triturate the residue with 10 mL of 6 N ammonium hydroxide for 5 min, add 10 mL of water, and filter. Warm the filtrate until most of the ammonia is expelled, cool, and add 6 N acetic acid until the mixture is distinctly acid. A precipitate of sulfamethizole is formed. Collect the precipitate on a filter, wash it well with cold water, and dry at 105° for 2 h.

Acceptance criteria: The infrared spectrum of the residue matches the infrared spectrum of similarly prepared [USP Sulfamethizole RS](#).

- 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

Mobile phase: Methanol, glacial acetic acid, and water (30:1:69)

Standard stock solution: 0.4 mg/mL of [USP Sulfamethizole RS](#) in methanol

Standard solution: 8 μ g/mL of [USP Sulfamethizole RS](#) from the *Standard stock solution* in *Mobile phase*

Sample stock solution: Nominally 0.4 mg/mL of sulfamethizole prepared as follows. Transfer an equivalent to 40 mg of sulfamethizole from NLT 20 finely powdered Tablets to a 250-mL screw-capped bottle. Add 100.0 mL of methanol to the bottle, cap the bottle, shake by mechanical means for 30 min, and filter.

Sample solution: 8 μ g/mL of sulfamethizole from the *Sample stock solution* in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm \times 30-cm; 10- μ m packing L1

Flow rate: 1 mL/min

Injection volume: 50 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 2000 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of sulfamethizole ($C_9H_{10}N_4O_2S_2$) in the portion of Tablets taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_s = concentration of [USP Sulfamethizole RS](#) in the *Standard solution* ($\mu\text{g}/\text{mL}$)

C_u = nominal concentration of sulfamethizole in the *Sample solution* ($\mu\text{g}/\text{mL}$)

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

- [Dissolution \(711\)](#)

Medium: 0.01 N hydrochloric acid; 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: Prepare a solution having a known concentration of [USP Sulfamethizole RS](#) in *Medium*.

Sample solution: A filtered portion of the solution under test, suitably diluted with *Medium*

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV

Analytical wavelength: Absorption maximum at about 267 nm

Analysis: Calculate the percentage of the labeled amount of sulfamethizole ($\text{C}_9\text{H}_{10}\text{N}_4\text{O}_2\text{S}_2$) dissolved.

Tolerances: NLT 75% (Q) of the labeled amount of sulfamethizole ($\text{C}_9\text{H}_{10}\text{N}_4\text{O}_2\text{S}_2$) 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 Sulfamethizole RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
SULFAMETHIZOLE TABLETS	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: [GUID-811CCC72-C535-4E79-9606-CC8D7A661391_2_en-US](#)

DOI: https://doi.org/10.31003/USPNF_M79190_02_01

DOI ref: [a4ey6](#)