

Status: Currently Official on 16-Feb-2025  
 Official Date: Official as of 01-May-2020  
 Document Type: USP Monographs  
 DocId: 811CCC72-C535-4E79-9606-CC8D7A661391\_2\_en-US  
 DOI: [https://doi.org/10.31003/USPNF\\_M79190\\_02\\_01](https://doi.org/10.31003/USPNF_M79190_02_01)  
 DOI Ref: a4ey6

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# 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 µg/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 µg/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 × 30-cm; 10-µm packing L1

**Flow rate:** 1 mL/min

**Injection volume:** 50 µL

### 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* ( $\mu\text{g/mL}$ )

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

**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	<a href="#">Documentary Standards Support</a>	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	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

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