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Status: Currently Official on 16-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-D63F6084-D233-4FC3-AF57-8593375D8EE3_2_en-US
DOI: https://doi.org/10.31003/USPNF_M79250_02_01
DOI Ref: r9xn0

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Sulfamethoxazole Oral Suspension

DEFINITION

Sulfamethoxazole Oral Suspension contains NLT 95.0% and NMT 110.0% of the labeled quantity of sulfamethoxazole ($C_{10}H_{11}N_3O_3S$).

IDENTIFICATION

• **A.**

Standard solution: Dissolve 100 mg of USP Sulfamethoxazole RS in 5 mL of ammonium hydroxide. Dilute with methanol to 50.0 mL.

Sample solution: Transfer a quantity of Oral Suspension, equivalent to 100 mg of sulfamethoxazole, into a 50-mL centrifuge tube. Add 5 mL of ammonium hydroxide, and shake gently. Add 25 mL of methanol, shake thoroughly for 3 min, centrifuge, decant the supernatant into a 50-mL volumetric flask, and dilute with methanol to volume.

Chromatographic system

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

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel

Application volume: 50 µL

Developing solvent system: Alcohol, *n*-heptane, chloroform, and glacial acetic acid (25:25:25:7)

Spray reagent: 0.10 g of *p*-dimethylaminobenzaldehyde in 1 mL of hydrochloric acid. Dilute with alcohol to 100 mL.

Analysis

Samples: *Standard solution* and *Sample solution*

Apply the *Samples*, and allow the spots to dry. Develop the chromatogram until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Locate the spots on the plate by lightly spraying with *Spray reagent*.

Acceptance criteria: The R_F value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*.

• **B.**

Sample: Transfer a quantity of Oral Suspension, equivalent to 500 mg of sulfamethoxazole, into a 50-mL centrifuge tube. Add 25 mL of water, mix, and centrifuge. Decant and discard the supernatant, resuspend the residue in 25 mL of water, mix, and centrifuge again. Decant and discard the clear supernatant. Repeat the washing procedure an additional two times.

Analysis: Dissolve the residue from the *Sample* in 10 mL of hydrochloric acid, and add 15 mL of sodium nitrite solution (1 in 100) and 5 mL of sodium hydroxide solution (1 in 10) containing 10 mg of 2-naphthol.

Acceptance criteria: A red-orange precipitate is produced.

ASSAY

• **Procedure**

Sample solution: Mix a volume of Oral Suspension, equivalent to 1 g of sulfamethoxazole, with 20 mL of glacial acetic acid and 40 mL of water.

Titrimetric system

Mode: Direct titration

Titrant: 0.1 M sodium nitrite VS

Endpoint detection: Potentiometric

Analysis: Add 15 mL of hydrochloric acid to the *Sample solution*. Cool to 15°, and titrate immediately with *Titrant*, using a calomel–platinum electrode system. Each mL of 0.1 M sodium nitrite is equivalent to 25.33 mg of sulfamethoxazole ($C_{10}H_{11}N_3O_3S$).

Acceptance criteria: 95.0%–110.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements for oral suspension packaged in single-unit containers

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• **Deliverable Volume ⟨698⟩:** Meets the requirements for oral suspension packaged in multiple-unit containers

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards ⟨11⟩**
USP Sulfamethoxazole RS

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

Topic/Question	Contact	Expert Committee
SULFAMETHOXAZOLE ORAL SUSPENSION	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. 45(4)

Current DocID: GUID-D63F6084-D233-4FC3-AF57-8593375D8EE3_2_en-US
Previous DocID: GUID-D63F6084-D233-4FC3-AF57-8593375D8EE3_1_en-US
DOI: https://doi.org/10.31003/USPNF_M79250_02_01
DOI ref: r9xn0

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