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Sulfacetamide Sodium Topical Suspension

DEFINITION

Sulfacetamide Sodium Topical Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of sulfacetamide sodium ($C_8H_9N_2NaO_3S$).

IDENTIFICATION

• **A.** The retention time of the sulfacetamide 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 (125:3:875)

Internal standard solution: 5 mg/mL of sulfathiazole sodium

Standard stock solution: 0.25 mg/mL of USP Sulfacetamide Sodium RS and 0.1 mg/mL of *p*-hydroxybenzoic acid prepared as follows. Transfer 25 mg of USP Sulfacetamide Sodium RS and 10 mg of *p*-hydroxybenzoic acid to a 100-mL volumetric flask. Dissolve in water, add 5 mL of the *Internal standard solution*, and dilute with water to volume.

Standard solution: 0.02 mg/mL of USP Sulfacetamide Sodium RS and 8 µg/mL of *p*-hydroxybenzoic acid in water from the *Standard stock solution*

Sample stock solution: Transfer 250 mg of Topical Suspension to a 125-mL conical flask, add 5 mL of the *Internal standard solution*, and dilute with 95 mL of water.

Sample solution: 2 mL of the *Sample stock solution* diluted with water to 25 mL. Centrifuge, and use the clear supernatant.

Chromatographic system

(See *Chromatography (621), System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for sulfanilamide, sulfacetamide, sulfathiazole, and *p*-hydroxybenzoic acid are about 0.2, 0.5, 1.0, and 1.2, respectively.]

Suitability requirements

Resolution: NLT 2.0 between sulfathiazole and *p*-hydroxybenzoic acid

Tailing factor: NMT 2

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of anhydrous sulfacetamide sodium ($C_8H_9N_2NaO_3S$) in the portion of Topical Suspension taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak area ratio of sulfacetamide to sulfathiazole from the *Sample solution*

R_S = peak area ratio of sulfacetamide to sulfathiazole from the *Standard solution*

C_S = concentration of USP Sulfacetamide Sodium RS in the *Standard* solution (mg/mL)

C_U = nominal concentration of sulfacetamide sodium in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Minimum Fill ⟨755⟩:** Meets the requirements

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count does not exceed 10^2 cfu/mL, and the total combined molds and yeasts count does not exceed 50 cfu/mL. It meets the requirements of the test for *Pseudomonas aeruginosa*.

• **pH ⟨791⟩:** 6.5–7.5

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers, at controlled room temperature.

• **USP Reference Standards ⟨11⟩**
USP Sulfacetamide Sodium RS

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

Topic/Question	Contact	Expert Committee
SULFACETAMIDE SODIUM TOPICAL 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:
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