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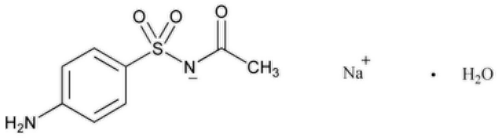
Sulfacetamide Sodium



$C_8H_9N_2NaO_3S \cdot H_2O$ 254.24
$C_8H_9N_2NaO_3S$ 236.23

Acetamide, *N*-[(4-aminophenyl)sulfonyl]-, monosodium salt, monohydrate;

N-Sulfanilylacetamide monosodium salt monohydrate CAS RN®: 6209-17-2; UNII: 4NRT660KJQ.

Anhydrous CAS RN®: 127-56-0; UNII: 30760ZE777.

DEFINITION

Sulfacetamide Sodium contains NLT 99.0% and NMT 100.5% of sulfacetamide sodium ($C_8H_9N_2NaO_3S$), calculated on the anhydrous basis.

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** **Identification Tests—General** ⟨191⟩, *Sodium*

  Sample solution: 1 g in 25 mL of water

  Analysis: Adjust the *Sample solution* with 6 N acetic acid to a pH of 4–5, and filter. Wash the precipitate with water, and use the filtrate.

  Acceptance criteria: The filtrate responds to test *A*.
- **C.**

  Sample solution: 100 mg in 5 mL of water

  Analysis: Add 5 drops of cupric sulfate TS to the *Sample solution*.

  Acceptance criteria: A light bluish green precipitate is formed, and it remains unchanged on standing.
- **D.**

  Sample solution: 500 mg in 10 mL of dilute hydrochloric acid (1 in 10)

  Analysis 1: To about one-half of the *Sample solution* add 2 mL of trinitrophenol TS.

  Acceptance criteria 1: A very heavy flocculent or almost gelatinous precipitate is formed.

  Analysis 2: To the remainder of the *Sample solution* add 3 drops of formaldehyde TS.

  Acceptance criteria 2: A white precipitate is formed, and it changes to orange on standing (distinction from sulfamethoxypyridazine).

ASSAY

- **Procedure**

  Solution A: 1% glacial acetic acid

  Solution B: Methanol

  Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	90	10
5	90	10

Time (min)	Solution A (%)	Solution B (%)
9.5	10	90
9.6	90	10
14	90	10

Standard solution: 0.2 mg/mL of USP Sulfacetamide Sodium RS in water

Sample solution: 0.2 mg/mL of Sulfacetamide Sodium in water

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 0.8 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: 0.9–1.8

Relative standard deviation: NMT 0.5% for sulfacetamide

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sulfacetamide sodium ($C_8H_9N_2NaO_3S$) in the portion of Sulfacetamide Sodium taken:

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

r_U = peak response of sulfacetamide from the *Sample solution*

r_S = peak response of sulfacetamide from the *Standard solution*

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

C_U = concentration of Sulfacetamide Sodium in the *Sample solution* (mg/mL)

Acceptance criteria: 99.0%–100.5% on the anhydrous basis

IMPURITIES

Delete the following:

▲• **Selenium ⟨291⟩**

Sample: 200 mg

Acceptance criteria: 30 ppm▲ (USP 1-Dec-2021)

• **Organic Impurities**

Mobile phase: Methanol, water, and glacial acetic acid (10:89:1)

System suitability solution: 0.2 mg/mL of USP Sulfacetamide Sodium RS and 0.05 mg/mL of USP Sulfanilamide RS in *Mobile phase*

Standard solution: 2 µg/mL of USP Sulfacetamide Sodium RS and 4 µg/mL of USP Sulfanilamide RS in *Mobile phase*

Sample solution: 2 mg/mL of Sulfacetamide Sodium in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 0.8 mL/min

Injection volume: 10 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 5.0 between sulfacetamide and sulfanilamide, *System suitability solution*

Tailing factor: NMT 1.5 for sulfacetamide, *Standard solution*

Relative standard deviation: NMT 2.0% for sulfacetamide, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sulfanilamide in the portion of Sulfacetamide Sodium taken:

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

r_U = peak response of sulfanilamide from the *Sample solution*

r_S = peak response of sulfanilamide from the *Standard solution*

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

C_U = concentration of Sulfacetamide Sodium in the *Sample solution* (mg/mL)

Calculate the percentage of any unspecified impurity in the portion of Sulfacetamide Sodium taken:

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

r_U = peak response of any unspecified impurity from the *Sample solution*

r_S = peak response of sulfacetamide from the *Standard solution*

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

C_U = concentration of Sulfacetamide Sodium in the *Sample solution* (mg/mL)

Acceptance criteria: See *Table 2*.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Sulfanilamide	0.6	0.2
Sulfacetamide	1.0	—
Any unspecified impurity	—	0.10
Total impurities	—	0.5

SPECIFIC TESTS

- **pH** ⟨791⟩

Sample solution: 50 mg/mL

Acceptance criteria: 8.0–9.5

- **Water Determination** ⟨921⟩, *Method I*: NMT 8.1%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers.
- **USP Reference Standards** ⟨11⟩

USP Sulfacetamide Sodium RS

USP Sulfanilamide RS

p-Aminobenzenesulfonamide.

$C_6H_8N_2O_2S$ 172.20

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

Topic/Question	Contact	Expert Committee
SULFACETAMIDE SODIUM	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

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