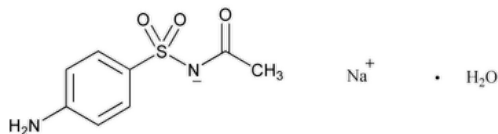


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Sulfacetamide Sodium



$C_8H_9N_2NaO_3S \cdot H_2O$ 254.24
 $C_8H_9N_2NaO_3S$ 236.23
Acetamide, *N*-[(4-aminophenyl)sulfonyl]-, monosodium salt, monohydrate;
N-Sulfanilylacетamide 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