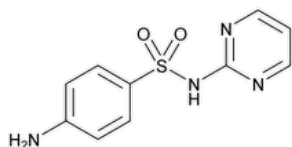


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Sulfadiazine



$C_{10}H_{10}N_4O_2S$ 250.28

Benzenesulfonamide, 4-amino-*N*-2-pyrimidinyl;

*N*¹-2-Pyrimidinylsulfanilamide CAS RN®: 68-35-9; UNII: 0N7609K889.

DEFINITION

Sulfadiazine contains NLT 98.0% and NMT 102.0% of sulfadiazine ($C_{10}H_{10}N_4O_2S$), calculated on the dried basis.

IDENTIFICATION

• **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197K

• **B.**

Sample: 50 mg

Analysis: Carefully melt the *Sample* in a small test tube.

Acceptance criteria: A reddish brown color develops upon melting, and the fumes evolved during decomposition do not discolor moistened lead acetate test paper (distinction from sulfathiazole).

• **C.**

Sample: 1 g

Analysis 1: Gently heat the *Sample* in a small test tube until a sublimate is formed. Collect a few milligrams of the sublimate with a glass rod, and mix in a test tube with 1 mL of a solution (1 in 20) of [resorcinol](#) in alcohol. Add 1 mL of [sulfuric acid](#), and mix by shaking.

Acceptance criteria 1: A deep red color appears at once.

Analysis 2: Cautiously dilute the mixture obtained in *Analysis 1* with 25 mL of ice-cold water, and add an excess of 6 N [ammonium hydroxide](#).

Acceptance criteria 2: A blue or reddish blue color is produced.

ASSAY

• PROCEDURE

Mobile phase: [Acetonitrile](#), [water](#), and [glacial acetic acid](#) (12:87:1)

Standard solution: 1 mg/mL of [USP Sulfadiazine RS](#) in [0.025 N sodium hydroxide](#)

Sample solution: 1 mg/mL of Sulfadiazine in [0.025 N sodium hydroxide](#)

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 254 nm

Column: 4-mm × 30-cm; packing [L1](#)

Flow rate: 2 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sulfadiazine ($C_{10}H_{10}N_4O_2S$) in the portion of Sulfadiazine taken:

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

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

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

C_S = concentration of [USP Sulfadiazine RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

Delete the following:

- ▲ [SELENIUM \(291\)](#)

Sample: 200 mg

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

- [ORDINARY IMPURITIES \(466\)](#)

Diluent: [Toluene](#) and [dimethylformamide](#) (2:1)

Standard solutions: 0.008, 0.041, 0.08, and 0.17 mg/mL of [USP Sulfadiazine RS](#) in *Diluent*

Sample solution: 8.3 mg/mL of Sulfadiazine in *Diluent*

Eluant: [Chloroform](#), [methanol](#), and [ammonium hydroxide](#) (30:12:1)

Visualization: 11

Acceptance criteria: Meets the requirements

SPECIFIC TESTS

- **CLARITY AND COLOR OF SOLUTION**

Sample: 1 g

Analysis: Dissolve the *Sample* in a mixture of 20 mL of [water](#) and 5 mL of [1 N sodium hydroxide](#).

Acceptance criteria: The solution is clear and not more deeply colored than pale yellow.

- **ACIDITY**

Sample: 2 g

Analysis: Digest the *Sample* with 100 mL of [water](#) at about 70° for 5 min. Cool at once to room temperature, and filter. To 25.0 mL of the filtrate add 2 drops of [phenolphthalein TS](#) and titrate with [0.10 N sodium hydroxide](#).

Acceptance criteria: NMT 0.20 mL is required to produce a pink color.

- [LOSS ON DRYING \(731\)](#)

Analysis: Dry at 105° for 2 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed, light-resistant containers.

- [USP REFERENCE STANDARDS \(11\)](#)

[USP Sulfadiazine RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
SULFADIAZINE	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1