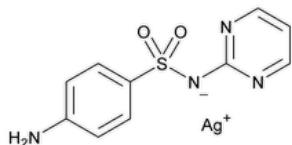


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Silver Sulfadiazine



$C_{10}H_9AgN_4O_2S$ 357.14
Benzenesulfonamide, 4-amino-*N*-2-pyrimidinyl-, monosilver(1+) salt;
*N*¹-2-Pyrimidinylsulfanilamide monosilver(1+) salt CAS RN®: 22199-08-2; UNII: W46JY43EJR.

DEFINITION
Silver Sulfadiazine contains NLT 98.0% and NMT 102.0% of silver sulfadiazine ($C_{10}H_9AgN_4O_2S$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy](#): 197A, 197D, or 197K ▲ (CN 1-May-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C.** [IDENTIFICATION TESTS—GENERAL \(191\), Chemical Identification Tests, Silver](#)
Sample: 1 g in 15 mL of [ammonium hydroxide](#) and 15 mL of [water](#) in a 50-mL volumetric flask. Dilute with [water](#) to volume, and mix.
Acceptance criteria: Meets the requirements

ASSAY

- **PROCEDURE**
Solution A: 0.77 g/L of [ammonium acetate](#) in [water](#). Adjust with [glacial acetic acid](#) to a pH of 5.2 ± 0.1.
Solution B: [Methanol](#)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	98	2
4	98	2
16	40	60
20	40	60
22	20	80
32	20	80
34	98	2
40	98	2

Diluent: [Acetonitrile](#), [ammonium hydroxide](#), and [water](#) (5:6:90)

Standard solution: 0.05 mg/mL of [USP Silver Sulfadiazine RS](#) in *Diluent*. Sonicate, if necessary, to dissolve.

Sample solution: 0.05 mg/mL of Silver Sulfadiazine in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 275 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of silver sulfadiazine ($C_{10}H_9AgN_4O_2S$) in the portion of Silver Sulfadiazine taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

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

OTHER COMPONENTS

• CONTENT OF SILVER

Sample solution: Add 500 mg to 150 mL of [water](#) and 50 mL of [nitric acid](#), and stir for 15 min.

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: [0.1 N potassium thiocyanate VS](#) or [0.1 N ammonium thiocyanate VS](#)

Endpoint detection: Potentiometric

Analysis: Titrate the *Sample solution* with *Titrant* using a silver-based indicator electrode and a double-junction reference electrode. Perform a blank determination, and make any necessary correction. Each mL of [0.1 N potassium thiocyanate VS](#) or [0.1 N ammonium thiocyanate VS](#) is equivalent to 10.79 mg of silver.

Acceptance criteria: 29.3%–30.5% of silver is found.

IMPURITIES

• LIMIT OF NITRATE

Standard solution: 200 μg/mL of nitrate from [potassium nitrate](#)

Sample solution: Add 30.0 mL of [water](#) to 2 g of Silver Sulfadiazine, stir for 20 min, and pass through a suitable, nitrate-free filter.

Instrumental conditions

Mode: UV-Vis

Analytical wavelength: 408 nm

Blank: Deionized water

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Pipet 3 mL of the *Sample solution* and *Blank* into separate test tubes. Pipet 1 mL of the *Standard solution* and 2 mL of [water](#) into a third test tube. Cool the three test tubes in an ice bath. Slowly add 7.0 mL of cold chromotropic acid solution prepared by dissolving 50 mg of chromotropic acid in 100 mL of cold sulfuric acid, to each test tube, while swirling, and allow the test tubes to remain in the ice bath.