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Silver Sulfadiazine Cream

DEFINITION

Silver Sulfadiazine Cream contains NLT 90.0% and NMT 110.0% of the labeled amount of silver sulfadiazine ($C_{10}H_9AgN_4O_2S$).

IDENTIFICATION

• A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#)

Standard solution: Dissolve 35 mg of [USP Sulfadiazine RS](#) in 4 mL of ammonium hydroxide, and add 16 mL of methanol.

Sample solution: Transfer a quantity of Cream equivalent to 50 mg of silver sulfadiazine to a stoppered 50-mL conical flask. Add 4 mL of ammonium hydroxide, and mix until a smooth paste has been obtained. Add 16 mL of methanol, shake for 5 min, and filter.

Developing solvent system: Chloroform, methanol, and ammonium hydroxide (7:4:1). Prepare the developing solvent by first mixing the chloroform and methanol, then adding the ammonium hydroxide.

Acceptance criteria: Meets the requirements

ASSAY

• PROCEDURE

Mobile phase: Acetonitrile, phosphoric acid, and water (99:1:900)

Diluent: Ammonium hydroxide in water (1 in 10)

Internal standard solution: 2 mg/mL of sulfamerazine in *Diluent*

Standard stock solution: 1 mg/mL of [USP Silver Sulfadiazine RS](#) in *Diluent*

Standard solution A: 0.29 mg/mL of [USP Silver Sulfadiazine RS](#) prepared by mixing 10.0 mL of *Standard stock solution*, 20 mL of alcohol, and 5.0 mL of *Internal standard solution*

Standard solution B: 14 µg/mL of [USP Silver Sulfadiazine RS](#) prepared by mixing 2.0 mL of *Standard solution A* and 40 mL of *Mobile phase*

Sample stock solution: Nominally 0.29 mg/mL of silver sulfadiazine prepared as follows. Transfer a quantity of Cream equivalent to 10 mg of silver sulfadiazine to a 50-mL round-bottom centrifuge tube. Add about 30 mL of methanol, tightly seal the tube with a cap containing an inert liner, and mix, using a vortex mixer, for about 15 s. Centrifuge for 15 min. Aspirate, and discard the methanol. Care should be taken to avoid aspirating any of the residue. Transfer 5.0 mL of the *Internal standard solution* into the tube, and add 20 mL of alcohol. Replace the cap, and mix. Heat in a water bath at 60°, with periodic mixing, for 15 min to melt and disperse the Cream. While the mixture is still hot, transfer 10.0 mL of *Diluent* to the tube, and cool to room temperature.

Sample solution: Nominally 14 µg/mL of silver sulfadiazine prepared by mixing 2.0 mL of *Sample stock solution* and 40 mL of *Mobile phase*

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: 10 µL

System suitability

Sample: *Standard solution B*

Suitability requirements

Resolution: NLT 2.0 between sulfadiazine and sulfamerazine

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution B* and *Sample solution*

Calculate the percentage of the labeled amount of silver sulfadiazine ($C_{10}H_9AgN_4O_2S$) in the portion of Cream taken:

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

R_U = peak response ratio from the *Sample solution*

R_S = peak response ratio from *Standard solution B*

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

C_U = nominal concentration of silver sulfadiazine 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 \(62\)](#): It meets the requirements of the tests for absence of *Staphylococcus aureus*, *Escherichia coli*, *Salmonella* species, and *Pseudomonas aeruginosa*. The total aerobic microbial count does not exceed 23 cfu/g, and the total combined molds and yeasts count does not exceed 10 cfu/g.

- [pH \(791\)](#).

Analysis: Determine from the supernatant of a 50-mg/mL mixture of Cream in water

Acceptance criteria: 4.0–7.0

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in collapsible tubes or in tight, light-resistant containers.

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

[USP Silver Sulfadiazine RS](#)

[USP Sulfadiazine RS](#)

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

Topic/Question	Contact	Expert Committee
SILVER SULFADIAZINE CREAM	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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