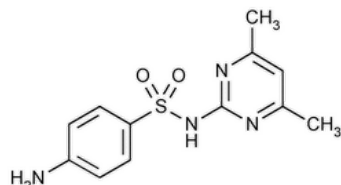


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Sulfamethazine



$C_{12}H_{14}N_4O_2S$ 278.33

Benzenesulfonamide, 4-amino-*N*-(4,6-dimethyl-2-pyrimidinyl)-;

*N*¹-(4,6-Dimethyl-2-pyrimidinyl)sulfanilamide CAS RN[®]: 57-68-1; UNII: 48U51W007F.

DEFINITION

Sulfamethazine contains NLT 99.0% and NMT 100.5% of sulfamethazine ($C_{12}H_{14}N_4O_2S$), calculated on the dried basis.

IDENTIFICATION

• **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), *Infrared Spectroscopy*:** 197K

• **B. PROCEDURE**

Sample: 0.10 g of Sulfamethazine

Analysis: To the *Sample* add 10 mL of [water](#) and just sufficient 0.1 N [sodium hydroxide](#) (4 mg/mL) to give a faint pink spot on phenolphthalein paper. Add 5 drops of [cupric sulfate TS](#).

Acceptance criteria: A yellow-green precipitate is formed, and it becomes brown on standing.

ASSAY

• **PROCEDURE**

Analysis: Proceed as directed in [Nitrite Titration \(451\)](#).

Calculate the percentage of sulfamethazine ($C_{12}H_{14}N_4O_2S$) in the portion of Sulfamethazine taken:

$$\text{Result} = V \times M \times F \times (1/W) \times 100$$

V = volume of *Titrant* consumed by the *Sample* (mL)

M = actual *Titrant* concentration, in molarity (mEq/mL)

F = equivalency factor of sulfamethazine, 278.3 mg/mEq

W = weight of the *Sample* taken (mg)

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

IMPURITIES

• **RESIDUE ON IGNITION (281):** NMT 0.1%

Delete the following:

▲ **SELENIUM (291):**

Sample: 200 mg of Sulfamethazine

Acceptance criteria: NMT 30 ppm▲ (USP 1-Aug-2022)

• **ORDINARY IMPURITIES (466).**

Sample solution: [Acetone](#)

Standard solution: [Acetone](#)

Eluant: [Ethyl acetate](#), [methanol](#), and [ammonium hydroxide](#) (17:6:5)

SPECIFIC TESTS

- [MELTING RANGE OR TEMPERATURE \(741\)](#): 197°–200°

• ACIDITY

Sample: 3.0 g of Sulfamethazine

Sample solution: Digest the *Sample* with 150 mL of [carbon dioxide-free water](#) at 70° for about 5 min, stirring occasionally to maintain suspension of the *Sample*. Cool the mixture rapidly in an ice bath to 20 ± 0.5°, with mechanical stirring. Filter immediately, with vacuum, omitting washing of the solid but drying it thoroughly by suction. Use the filtrate.

Titrimetric system

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

Mode: Direct titration

Titrant 1: [0.1 N sodium hydroxide VS](#)

Titrant 2: [0.1 M sodium nitrite VS](#)

Endpoint detection: Visual

Analysis 1: To 25.0 mL of the *Sample solution* add 2 drops of [thymolphthalein TS](#). Titrate with *Titrant 1*. Record the volume of *Titrant 1* consumed (V_1).

Analysis 2: To a second 25.0-mL portion of the *Sample solution* add 10 mL of [hydrochloric acid](#). Cool the mixture to 15°, and proceed as directed in [Nitrite Titration \(451\)](#). Record the volume of *Titrant 2* consumed (V_2).

$$\text{Result} = V_1 - V_2$$

V_1 = volume of *Titrant 1* consumed by the *Sample solution* in *Analysis 1* (mL)

V_2 = volume of *Titrant 2* consumed by the *Sample solution* in *Analysis 2* (mL)

Acceptance criteria: NMT 0.5 mL

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

Sample: 1 g of Sulfamethazine

Analysis: Dry at 105° for 2 h.

Acceptance criteria: NMT 0.5%

- CLARITY AND COLOR OF SOLUTION

Sample: 1 g of Sulfamethazine

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.

ADDITIONAL REQUIREMENTS

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

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

[USP Sulfamethazine RS](#)

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

Topic/Question	Contact	Expert Committee
SULFAMETHAZINE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

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