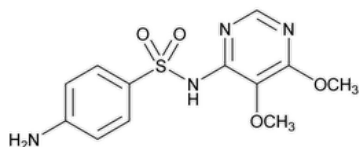


Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-E878783A-72D8-491E-9948-B1356FE5476D_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M79040_04_01
 DOI Ref: oqb4m

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Sulfadoxine



$C_{12}H_{14}N_4O_4S$ 310.33

Benzenesulfonamide, 4-amino-*N*-(5,6-dimethoxy-4-pyrimidinyl)-;

*N*¹-(5,6-Dimethoxy-4-pyrimidinyl)sulfanilamide CAS RN®: 2447-57-6; UNII: 88463U4SM5.

DEFINITION

Sulfadoxine contains NLT 99.0% and NMT 101.0% of sulfadoxine ($C_{12}H_{14}N_4O_4S$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)

Change to read:

- **B.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Ultraviolet-Visible Spectroscopy: 197U](#) ▲ (CN 1-MAY-2020)

Sample solution: 6 µg/mL in 0.1 N sodium hydroxide

Acceptance criteria: Meets the requirements

- **C.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Solution A: Add 1 mL of phosphoric acid to water, and dilute to 1000 mL.

Mobile phase: Acetonitrile and *Solution A* (17:83)

Standard solution: 0.4 mg/mL of [USP Sulfadoxine RS](#) prepared as follows. Dissolve an appropriate amount of [USP Sulfadoxine RS](#) in a suitable container with acetonitrile using 17% of the final volume, then dilute with *Solution A* to volume.

Sample solution: 0.4 mg/mL of sulfadoxine prepared as follows. Dissolve an appropriate amount of sulfadoxine in a suitable container with acetonitrile using 17% of the final volume, then dilute with *Solution A* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 2.0-mm × 10-cm; 3-µm packing L11

Flow rate: 0.3 mL/min

Injection volume: 5 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.8

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sulfadoxine ($C_{12}H_{14}N_4O_4S$) in the portion of Sulfadoxine 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 Sulfadoxine RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 99.0%–101.0% on the dried basis

IMPURITIES

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

• ORGANIC IMPURITIES

Diluent: Alcohol and ammonium hydroxide (9:1)

Standard solution: 0.10 mg/mL of [USP Sulfadoxine RS](#) in *Diluent*

Sample solution: 20 mg/mL of Sulfadoxine in *Diluent*

Chromatographic system

(See [Chromatography \(621\)](#), [Thin-Layer Chromatography](#).)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel

Application volume: 10 µL

Developing solvent system: Chloroform, methanol, and dimethylformamide (20:2:1)

Spray reagent A: 1-in-10 solution of sulfuric acid in alcohol

Spray reagent B: 1-in-200 solution of *N*-(1-naphthyl)ethylenediamine dihydrochloride in alcohol

Analysis

Samples: *Standard solution* and *Sample solution*

Separately apply the *Sample solution* and the *Standard solution* to the *Adsorbent*. Develop the chromatogram in the *Developing solvent system* until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, and air dry. Spray the dried plate with *Spray reagent A*, and expose to nitrous fumes generated by adding 7 M sulfuric acid dropwise to a solution containing 10% sodium nitrite and 3% potassium iodide. Dry the plate in a current of warm air for 15 min, and spray with *Spray reagent B*.

Acceptance criteria: No spot in the *Sample solution*, other than the principal spot, is greater in size and intensity than the spot from the *Standard solution*.

SPECIFIC TESTS

- [MELTING RANGE OR TEMPERATURE \(741\)](#): 197°–200°
- [LOSS ON DRYING \(731\)](#)

Analysis: Dry at 105° for 4 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed, light-resistant containers.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Sulfadoxine RS](#)

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

Topic/Question	Contact	Expert Committee
SULFADOXINE	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:

Pharmacopeial Forum: Volume No. PF 34(2)

Current DocID: GUID-E878783A-72D8-491E-9948-B1356FE5476D_4_en-US

DOI: https://doi.org/10.31003/USPNF_M79040_04_01

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