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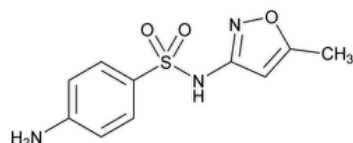
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Sulfamethoxazole


 $C_{10}H_{11}N_3O_3S$ 253.28
Benzenesulfonamide, 4-amino-*N*-(5-methyl-3-isoxazolyl)-;*N*¹-(5-Methyl-3-isoxazolyl)sulfanilamide CAS RN[®]: 723-46-6; UNII: JE42381TNV.

DEFINITION

Sulfamethoxazole contains NLT 98.0% and NMT 102.0% of sulfamethoxazole ($C_{10}H_{11}N_3O_3S$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197K ▲ or 197A ▲ (IRA 1-May-2021)
- B. The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

Change to read:

PROCEDURE

Buffer: 13.6 g/L of [potassium dihydrogen phosphate](#) adjusted with a 20-g/L solution of [potassium hydroxide](#) to a pH of 5.3Mobile phase: [Methanol](#) and *Buffer* (30:70)Standard solution: 0.1 mg/mL ▲ (IRA 1-May-2021) of [USP Sulfamethoxazole RS](#) ▲ (IRA 1-May-2021) in *Mobile phase*. Sonicate at 45° with intermittent shaking to dissolve before final dilution.▲System suitability solution: 0.1 mg/mL each of [USP Sulfamethoxazole RS](#) and [USP Sulfamethoxazole Related Compound A RS](#) in *Mobile phase*. Sonicate at 45° with intermittent shaking to dissolve before final dilution. ▲ (IRA 1-May-2021)Sample solution: 0.1 mg/mL of Sulfamethoxazole in *Mobile phase*. Sonicate at 45° with intermittent shaking to dissolve before final dilution.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4-mm × 25-cm; 5-μm packing [L7](#)

Flow rate: 0.9 mL/min

Injection volume: 20 μL

System suitability

Samples: ▲*System suitability solution* and ▲ (IRA 1-May-2021) *Standard solution*

[NOTE—The relative retention times for sulfamethoxazole and sulfamethoxazole related compound A are 1.0 and 1.2, respectively.]

Suitability requirements

Resolution: NLT 3.5 between sulfamethoxazole and sulfamethoxazole related compound A, ▲*System suitability solution* ▲ (IRA 1-May-2021)Relative standard deviation: NMT 0.73%, ▲*Standard solution* ▲ (IRA 1-May-2021)

Analysis

Samples: *Standard solution* and *Sample solution*Calculate the percentage of sulfamethoxazole ($C_{10}H_{11}N_3O_3S$) in the portion of Sulfamethoxazole taken:

$$\text{Result} = \left(\frac{A_U}{A_S} \right) \times \left(\frac{C_S}{C_U} \right) \times 100$$

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

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

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

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

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

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

IMPURITIES

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

Change to read:

- ORGANIC IMPURITIES

Buffer, Mobile phase, ▲System suitability solution, ▲ (IRA 1-May-2021) and Chromatographic system: Proceed as directed in the Assay.

▲ (IRA 1-May-2021)

Peak identification solution: 1 µg/mL each of [USP Sulfamethoxazole Related Compound A RS](#), [USP Sulfamethoxazole Related Compound B RS](#), [USP Sulfamethoxazole Related Compound C RS](#), [USP Sulfanilic Acid RS](#), and [USP Sulfanilamide RS](#) in *Mobile phase*. Sonicate, if necessary, to dissolve before final dilution.

▲Sensitivity solution: 0.3 µg/mL of [USP Sulfamethoxazole RS](#) in *Mobile phase*. Sonicate, if necessary, to dissolve before final dilution. ▲ (IRA 1-May-2021)

Standard solution: 1 µg/mL each of [USP Sulfamethoxazole RS](#) and [USP Sulfamethoxazole Related Compound F RS](#) in *Mobile phase*. Sonicate, if necessary, to dissolve before final dilution.

Sample solution: 1 mg/mL of Sulfamethoxazole in *Mobile phase*. Sonicate at 45° with intermittent shaking to dissolve before final dilution.

System suitability

Samples: *System suitability solution*, ▲*Sensitivity solution*, ▲ (IRA 1-May-2021) and *Standard solution*

Suitability requirements

Resolution: NLT 3.5 between sulfamethoxazole and sulfamethoxazole related compound A, ▲ (IRA 1-May-2021) *System suitability solution*

Relative standard deviation: NMT 5.0% ▲each ▲ (IRA 1-May-2021) for sulfamethoxazole ▲and sulfamethoxazole related compound F, ▲ (IRA 1-May-2021) *Standard solution*

▲Signal-to-noise ratio: NLT 10, *Sensitivity solution* ▲ (IRA 1-May-2021)

Analysis

Samples: *Peak identification solution*, *Standard solution*, and *Sample solution*

Calculate the percentage of sulfamethoxazole related compound F in the portion of Sulfamethoxazole taken:

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

r_U = peak response of sulfamethoxazole related compound F from the *Sample solution*

r_S = peak response of sulfamethoxazole related compound F from the *Standard solution*

C_S = concentration of [USP Sulfamethoxazole Related Compound F RS](#) in the *Standard solution* (mg/mL)

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

Calculate the percentage of any ▲other ▲ (IRA 1-May-2021) individual impurity in the portion of Sulfamethoxazole taken:

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

r_U = peak response of any ▲other ▲ (IRA 1-May-2021) individual impurity from the *Sample solution*

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

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

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

Acceptance criteria: See [Table 1](#). The reporting threshold is 0.03%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Sulfanilic acid	0.26	0.10
Sulfanilamide	0.35	0.10
Sulfamethoxazole related compound F	0.45	0.10
Sulfamethoxazole related compound C	0.50	0.10
Sulfamethoxazole	1.0	—
Sulfamethoxazole related compound A	1.2	0.10
Sulfamethoxazole related compound B	2.1	0.10
Any individual unspecified impurity	—	0.10
Total impurities	—	0.30

SPECIFIC TESTS

- [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. Store at room temperature.

Change to read:

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

[USP Sulfamethoxazole RS](#)

[USP Sulfamethoxazole Related Compound A RS](#)

N-[4-[*N*-(5-Methylisoxazol-3-yl)sulfamoyl]phenyl]acetamide.

$C_{12}H_{13}N_3O_4S$ 295.31

[USP Sulfamethoxazole Related Compound B RS](#)

4-Amino-*N*-[4-[*N*-(5-methylisoxazol-3-yl)sulfamoyl]phenyl]benzenesulfonamide.

$C_{16}H_{16}N_4O_5S_2$ 408.45

[USP Sulfamethoxazole Related Compound C RS](#)

5-Methylisoxazol-3-amine.

$C_4H_6N_2O$ ▲98.11 ▲ (IRA 1-May-2021)

[USP Sulfamethoxazole Related Compound F RS](#)

4-Amino-*N*-(3-methylisoxazol-5-yl)benzenesulfonamide.

$C_{10}H_{11}N_3O_3S$ 253.28

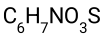
[USP Sulfanilamide RS](#)

4-Aminobenzenesulfonamide.

$C_6H_8N_2O_2S$ 172.20

[USP Sulfanilic Acid RS](#)

4-Aminobenzenesulfonic acid.



173.19

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

Topic/Question	Contact	Expert Committee
SULFAMETHOXAZOLE	Documentary Standards Support	SM12025 Small Molecules Therapeutic Areas 1
REFERENCE STANDARDS SUPPORT	RS Technical Services RSTECH@usp.org	SM12025 Small Molecules Therapeutic Areas 1

Chromatographic Database Information: [Chromatographic Database](#)

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