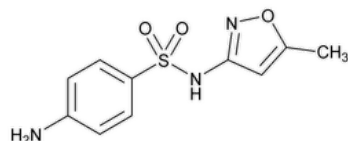


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Sulfamethoxazole



$C_{10}H_{11}N_3O_3S$ 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 5.3

Mobile 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.



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

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)