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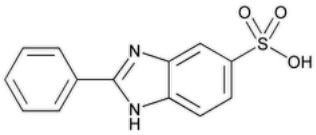
Ensulizole



$C_{13}H_{10}N_2O_3S$ 274.30

1*H*-Benzimidazole-5-sulfonic acid-2-phenyl-;

2-Phenylbenzimidazole-5-sulfonic acid CAS RN®: 27503-81-7; UNII: 9YQ9DI1W42.

DEFINITION

Ensulizole contains NLT 98.0% and NMT 102.0% of ensulizole ($C_{13}H_{10}N_2O_3S$), calculated on the dried basis.

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197K or 197A

Change to read:

• **B.** The retention time of the major peak of the *Sample solution*▲ corresponds to that▲ (ERR 1-Apr-2024) of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Solution A: 1 mL/L of trifluoroacetic acid in water

Solution B: 0.5 mL/L of trifluoroacetic acid in acetonitrile

Diluent: Dimethylformamide and water (20:80)

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	85	15
5	85	15
15	15	85
35	15	85
40	85	15
45	85	15

Standard solution: 0.04 mg/mL of USP Ensulizole RS in *Diluent*. Sonication may be necessary for complete dissolution.

Sample solution: 0.04 mg/mL of Ensulizole in *Diluent*. Sonication may be necessary for complete dissolution.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 300 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ensulizole ($C_{13}H_{10}N_2O_3S$) in the portion of Ensulizole taken:

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

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

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

C_S = concentration of USP Ensulizole RS in the *Standard solution* (mg/mL)

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

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

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩**

Analysis: Dry at 105° for 4 h.

Acceptance criteria: NMT 2.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers in a cool place.

• **USP Reference Standards ⟨11⟩**

USP Ensulizole RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ENSULIZOLE	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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