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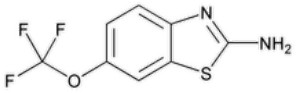
Riluzole



$C_8H_5F_3N_2OS$ 234.20

2-Benzothiazolamine, 6-(trifluoromethoxy)-;

2-Amino-6-(trifluoromethoxy)benzothiazole CAS RN®: 1744-22-5; UNII: 7LJ087RS6F.

DEFINITION

Riluzole contains NLT 98.0% and NMT 102.0% of the labeled amount of $C_8H_5F_3N_2OS$, calculated on the anhydrous basis.

IDENTIFICATION

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

• **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

• **Procedure**

Mobile phase: Acetonitrile and water (9:11)

Standard solution: 0.05 mg/mL of USP Riluzole RS in *Mobile phase*

Sample solution: 0.05 mg/mL of Riluzole in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 221 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 2.0 mL/min

Injection size: 20 µL. [Note—Monitor for 3 times the retention time of riluzole.]

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_8H_5F_3N_2OS$ in the portion of Riluzole 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 Riluzole RS in the *Standard solution* (mg/mL)

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

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

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IMPURITIES

Inorganic Impurities

- **Residue on Ignition ⟨281⟩:** NMT 0.1%, a 1.5-g of sample used

Organic Impurities

- **Procedure**

Mobile phase: Proceed as directed in the *Assay*.

System suitability solution: 500 µg/mL of USP Riluzole RS and 0.5 µg/mL USP Riluzole Related Compound A RS in *Mobile phase*

Standard solution: 0.5 µg/mL of USP Riluzole RS in *Mobile phase*

Sample solution: 500 µg/mL of Riluzole in *Mobile phase*

Chromatographic system: Proceed as directed in the *Assay*, and use an injection volume of 100 µL.[Note—Monitor for 11 times the retention time of riluzole.]

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0, *Standard solution*

Resolution: NLT 1.5 between Riluzole and riluzole related compound A, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Identify the impurities using the relative retention times shown in *Impurity Table 1*. Calculate the percentage of each impurity in the portion of Riluzole taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

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

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

C_S = concentration of USP Riluzole RS in the *Standard solution* (µg/mL)

C_U = concentration of Riluzole in the *Sample solution* (µg/mL)

F = relative response factor relative to riluzole

Acceptance criteria

Individual impurities: See *Impurity Table 1*.

Total impurities: NMT 1.0%

Impurity Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Riluzole	1.0	—	—
Riluzole related compound A[a]	1.3	0.16	0.1
Bromoriluzole[b]	1.9	0.54	0.2
Dibromotrifluoro methoxyaniline[c]	7.4	0.28	0.1
Any unspecified impurity	—	1.0	0.1

[a] 4-(Trifluoromethoxy)aniline.

[b] 4-Bromo-6-(trifluoromethoxy)benzothiazol-2-amine.

[c] 2,6-Dibromo-4-(trifluoromethoxy)aniline.

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SPECIFIC TESTS

• **Water Determination, *Method I* ⟨921⟩:** NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers

Change to read:

• **USP Reference Standards ⟨11⟩**

USP Riluzole RS

USP Riluzole Related Compound A RS

▲4-(Trifluoromethoxy)aniline.▲ (ERR 1-Apr-2021)

$C_7H_6F_3NO$ ▲177.13▲ (ERR 1-Apr-2021)

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

Topic/Question	Contact	Expert Committee
RILUZOLE	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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