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Riluzole Tablets

DEFINITION
Riluzole Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of riluzole ($C_8H_5F_3N_2OS$).

IDENTIFICATION

- **A.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **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 (45:55)

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

Sample stock solution: Nominally 0.5 mg/mL of riluzole prepared as follows. Transfer an equivalent to 50 mg of riluzole, from finely powdered Tablets (NLT 20), to a 100-mL volumetric flask, add 80 mL of *Mobile phase*, sonicate for about 10 min, and stir for another 10 min. Dilute with *Mobile phase* to volume.

Sample solution: Nominally 0.05 mg/mL of riluzole in *Mobile phase*, prepared from the *Sample stock solution*. Pass this solution through a filter of 0.45-µm pore size, and discard the first 5 mL of filtrate. Use the filtrate for analysis. [Note—A PVDF or equivalent filter may be suitable.]

Chromatographic system

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

Mode: LC

Detector: UV 221 nm. For *Identification A*, use a diode array detector in the range of 200–400 nm.

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

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: NLT 2 times the retention time of the riluzole peak

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 the labeled amount of riluzole ($C_8H_5F_3N_2OS$) in the portion of Tablets 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 = nominal concentration of riluzole in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: 0.1 N hydrochloric acid VS; 900 mL, deaerated

Apparatus 2: 50 rpm

Time: 30 min

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

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size.

Instrumental conditions

Mode: UV

Analytical wavelength: 254 nm

Cell: 0.5 cm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of riluzole ($C_8H_5F_3N_2OS$) dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S \times V/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of riluzole ($C_8H_5F_3N_2OS$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Organic Impurities**

Mobile phase, Sample stock solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

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

Standard solution: 2.5 µg/mL of USP Riluzole RS in *Mobile phase*, prepared from the *Standard solution* in the *Assay*

Sample solution: Prepare as directed in the *Sample stock solution*.

System suitability

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

Suitability requirements

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

Tailing factor: NMT 2.0, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each degradation product in the portion of Tablets taken:

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

r_U = peak response of each degradation product 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 = nominal concentration of riluzole in the *Sample solution* (µg/mL)

Acceptance criteria

Any individual degradation product: NMT 0.2%

Total degradation products: NMT 1.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed, light-resistant containers, and store at controlled room temperature.

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 TABLETS	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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