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. ULTRAVIOLET ABSORPTION ⟨197U⟩:** The spectrum of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the test for *Dissolution*.
- **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 stock solution: Weigh and finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to 50 mg of riluzole, 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: 0.05 mg/mL of riluzole in *Mobile phase*, prepared from *Sample stock solution*. Pass this solution through a PVDF (or equivalent) filter of 0.45-µm pore size, and discard the first 5 mL of filtrate. Use the filtrate for analysis.
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: 1 mL/min
Injection size: 20 µL
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 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; 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.
Detector: UV 254 nm
Blank: *Medium*
Cell: 0.5 cm
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of riluzole taken:

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

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 $C_8H_5F_3N_2OS$ is dissolved.
- **UNIFORMITY OF DOSAGE UNITS ⟨905⟩:** Meet the requirements

IMPURITIES
Organic Impurities
- **PROCEDURE**

Mobile phase and **Chromatographic system:** Proceed as directed in the *Assay*.
Standard solution: 2.5 µg/mL of USP Riluzole RS in *Mobile phase*, prepared from the *Standard solution* under 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*
Sample solution: 0.5 mg/mL, *Sample stock solution*
System suitability
Samples: *Standard solution* and *System suitability 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 impurity in the portion of Tablets taken:

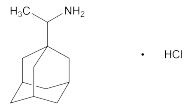
$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

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* (µg/mL)
C_U = nominal concentration of riluzole in the *Sample solution* (µg/mL)
Acceptance criteria
Individual impurities: NMT 0.2%
Total impurities: NMT 1.0%

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in well-closed, light-resistant containers, and store at controlled room temperature.
- **USP REFERENCE STANDARDS ⟨11⟩**

USP Riluzole RS
USP Riluzole Related Compound A RS
4-Trifluoromethoxyphenylamine; 4-trifluoromethoxyanaline.
$C_7H_6F_3NO$ 177.12

Rimantadine Hydrochloride



$C_{12}H_{21}N \cdot HCl$ 215.77
Tricyclo[3.3.1.1^{3,7}]-decane-1-methanamine, α-methyl-, hydrochloride.
α-Methyl-1-adamantanemethylamine hydrochloride [1501-84-4].

» Rimantadine Hydrochloride contains not less than 98.0 percent and not more than 102.0 per-