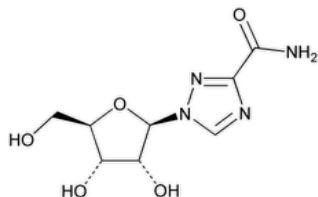


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Ribavirin



$C_8H_{12}N_4O_5$ 244.20

1*H*-1,2,4-Triazole-3-carboxamide, 1-β-*D*-ribofuranosyl-;

1-β-*D*-Ribofuranosyl-1*H*-1,2,4-triazole-3-carboxamide CAS RN[®]: 36791-04-5; UNII: 49717AWG6K.

DEFINITION

Ribavirin contains NLT 98.9% and NMT 101.5% of ribavirin ($C_8H_{12}N_4O_5$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)
- **B.** [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#)

Sample solution: 10 mg/mL

Developing solvent system: Acetonitrile and 0.1 M ammonium chloride (9:2)

Spray reagent: Anisaldehyde, sulfuric acid, glacial acetic acid, and alcohol (5:5:1:90)

Analysis: Proceed as directed in the chapter. Allow the plate to air-dry for 15 min, spray with *Spray reagent*, heat the plate at 110° for 30 min, and locate the spots on the plate by examining the plate in daylight.

Acceptance criteria: Meets the requirements

ASSAY

• PROCEDURE

Mobile phase: Adjust water with sulfuric acid to a pH of 2.5 ± 0.1 . Pass through a suitable filter of 0.5-μm or finer pore size.

Standard solution: 0.025 mg/mL of [USP Ribavirin RS](#) in *Mobile phase*

Sample solution: 0.025 mg/mL of Ribavirin in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 207 nm

Column: 7.8-mm × 10-cm; packing L17

Column temperature: $65 \pm 0.5^\circ$

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: 0.7–1.5

Relative standard deviation: NMT 0.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ribavirin ($C_8H_{12}N_4O_5$) in the portion of Ribavirin 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 Ribavirin RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.9%–101.5% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.25%

• **ORGANIC IMPURITIES**

Mobile phase, Standard solution, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Sample stock solution: 0.5 mg/mL of Ribavirin in *Mobile phase*

Analysis

Sample: *Sample stock solution*

Calculate the percentage of each peak, other than the solvent peak and the ribavirin peak, in the portion of Ribavirin taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = response of the individual peak

r_T = sum of the responses of all the peaks

Acceptance criteria

Any individual impurity: NMT 0.25%

Total impurities: NMT 1.0%

SPECIFIC TESTS

• [OPTICAL ROTATION, Specific Rotation \(781S\)](#).

Sample solution: 10 mg/mL

Acceptance criteria: -33.5° to -37.0° ($t = 20^\circ$)

• [pH \(791\)](#).

Sample solution: 20 mg/mL

Analysis: Add 0.2 mL of a saturated potassium chloride solution to 50 mL of *Sample solution*.

Acceptance criteria: 4.0–6.5

• [LOSS ON DRYING \(731\)](#).

Analysis: Dry a sample at 105° for 5 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers.

• [USP REFERENCE STANDARDS \(11\)](#).

[USP Ribavirin RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
RIBAVIRIN	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

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