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Ribavirin Tablets

DEFINITION

Ribavirin Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of ribavirin ($C_8H_{12}N_4O_5$).

IDENTIFICATION

- **A.** The retention time of the ribavirin peak from the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Buffer: 4.0 g/L of sodium dihydrogen phosphate dihydrate in water. Adjust with 5% sodium hydroxide solution to a pH of 5.0 ± 0.05 . Pass the solution through a suitable filter of 0.45- μ m pore size.

Mobile phase: Acetonitrile and *Buffer* (1:49)

Diluent: Acetonitrile and water (3:7)

Standard stock solution: 0.6 mg/mL of [USP Ribavirin RS](#) in *Diluent*

Standard solution: 0.03 mg/mL of [USP Ribavirin RS](#) in *Mobile phase* from the *Standard stock solution*

Sample stock solution: Transfer a portion of ribavirin, equivalent to 1000 mg of ribavirin from finely powdered Tablets (NLT 10), to a 1000-mL volumetric flask. Add about 750 mL of *Diluent*, and sonicate with occasional shaking for 30 min. Cool to room temperature, dilute with *Diluent* to volume, and mix. Centrifuge, and decant the supernatant.

Sample solution: 0.03 mg/mL of ribavirin in *Mobile phase* from the *Sample stock solution*. Pass the solution through a suitable filter of 0.45- μ m pore size.

Chromatographic system

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

Mode: LC

Detector: UV 207 nm

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing L1

Flow rate: 1 mL/min

Injection size: 20 μ L

Run time: 10 min

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 2000 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ribavirin ($C_8H_{12}N_4O_5$) in the portion of Tablets taken:

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

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

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

C_S = concentration of [USP Ribavirin RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Buffer and Mobile phase: Proceed as directed in the Assay.

Standard solution: 0.22 mg/mL of [USP Ribavirin RS](#) in *Medium*

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

Chromatographic system

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

Mode: LC

Detector: UV 225 nm

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

Flow rate: 1 mL/min

Injection size: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 2000 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Calculate the percentage of ribavirin ($C_8H_{12}N_4O_5$) dissolved:

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

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

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

C_S = concentration of [USP Ribavirin RS](#) in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of ribavirin ($C_8H_{12}N_4O_5$) is dissolved.

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

IMPURITIES

• ORGANIC IMPURITIES: PROCEDURE 1

If uracil and/or uridine are known impurities, *Procedure 2* is recommended.

Solution A: 3.4 g/L of potassium dihydrogen phosphate in water. Adjust with 5% potassium hydroxide solution to a pH of 5.00 ± 0.05 . Pass the solution through a suitable filter of 0.45-μm pore size.

Solution B: Acetonitrile

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
30	90	10
40	75	10