

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2017
 Document Type: USP Monographs
 DocId: GUID-87CFF116-873F-445A-BA83-971652D3D3F8_1_en-US
 DOI: https://doi.org/10.31003/USPNF_M73405_01_01
 DOI Ref: 3f725

© 2025 USPC
 Do not distribute

Ribavirin Capsules

DEFINITION

Ribavirin Capsules 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 major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Mobile phase: Water. Adjust with sulfuric acid to a pH of 2.5.

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

Sample stock solution: Transfer an equivalent to 50 mg of ribavirin, from contents of Capsules (NLT 20), to a 100-mL volumetric flask. Add about 50 mL of *Mobile phase*, and sonicate with occasional shaking for about 20 min. Cool to room temperature, and dilute with *Mobile phase* to volume.

Sample solution: Nominally 0.025 mg/mL of ribavirin in *Mobile phase* from *Sample stock 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 207 nm

Column: 7.8-mm × 15-cm; 7-μm packing L17

Column temperature: 65°

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 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ribavirin ($C_8H_{12}N_4O_5$) in the portion of Capsules 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 = nominal concentration of ribavirin in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Test 1

Medium: Water; 900 mL

Apparatus 1: 100 rpm

Time: 30 min

Determine the percentage of the labeled amount of ribavirin ($C_8H_{12}N_4O_5$) dissolved by using one of the following procedures.

Procedure 1

Mobile phase: Proceed as directed in the Assay.

Standard solution: 22.5 µg/mL of [USP Ribavirin RS](#) in *Medium*

Sample solution: Pass the solution through a suitable filter of 0.45-µm pore size. Transfer 5.0 mL of the filtrate to a 50.0-mL volumetric flask, and dilute with *Medium* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 207 nm

Column: 7.8-mm × 30-cm; 9-µm packing L17

Column temperature: 65°

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution and Sample solution*

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

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

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

L = label claim (mg/Capsule)

V = volume of *Medium*, 900 mL

D = dilution factor of the solution under test

Procedure 2

Sulfuric acid solution: 3% sulfuric acid

Mobile phase: Water. Adjust with *Sulfuric acid solution* to a pH of 2.5.

Standard solution: 0.02 mg/mL of [USP Ribavirin RS](#) in *Medium*

Sample solution: Pass the solution through a suitable filter of 0.8-µm pore size. Transfer 5.0 mL of the filtrate to a 50.0-mL volumetric flask, and dilute with water to volume.

Chromatographic system

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

Mode: LC

Detector: UV 207 nm

Column: 7.8-mm × 10-cm; 9-µm packing L17

Column temperature: 40 ± 2°

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%