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Riboflavin Tablets

DEFINITION

Riboflavin Tablets contain NLT 95.0% and NMT 115.0% of the labeled amount of riboflavin ($C_{17}H_{20}N_4O_6$).

ASSAY

• [RIBOFLAVIN ASSAY \(481\)](#), [Chemical Methods, Procedure 1](#)

Sample solution: Transfer a portion of the powder from NLT 20 finely powdered Tablets, equivalent to 20 mg of riboflavin, to a 250-mL flask, and add 150 mL of 0.1 N [hydrochloric acid](#). Shake vigorously, and wash down the sides of the flask with sufficient 0.1 N [hydrochloric acid](#) to ensure that the pH remains below 1.5 during the subsequent period of heating. Heat the mixture on a steam bath, with frequent agitation, until the riboflavin has dissolved, or in an autoclave at 121° for 30 min. Cool, and with vigorous agitation, adjust the mixture with 1 N [sodium hydroxide](#) to a pH of 5–6. Transfer to a 1000-mL volumetric flask, and dilute with water to volume. If the solution is not clear, filter through paper known not to adsorb riboflavin. Dilute an aliquot of the clear solution with water to a final volume that contains 0.1 µg/mL of riboflavin.

Analysis: Proceed as directed in the chapter.

Calculate the percentage of the labeled amount of riboflavin ($C_{17}H_{20}N_4O_6$) in the portion of Tablets taken:

$$\text{Result} = (I_U/I_S) \times (C_S/C_U) \times 100$$

I_U = corrected fluorescence value from the *Sample solution*

I_S = corrected fluorescence value from the *Standard solution*

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

C_U = nominal concentration of riboflavin in the *Sample solution* (µg/mL)

Acceptance criteria: 95.0%–115.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: Known concentration of [USP Riboflavin RS](#) in *Medium*

Sample solution: Filtered portion of the solution under test, suitably diluted with the *Medium* if necessary

Mobile phase: A mixture of [methanol](#), [glacial acetic acid](#), and water (27:1:73) containing 1.40 mg/mL of [sodium 1-hexanesulfonate](#)

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of riboflavin ($C_{17}H_{20}N_4O_6$) dissolved:

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

r_U = peak area of riboflavin from the *Sample solution*

r_S = peak area of riboflavin from the *Standard solution*

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

D = dilution factor for the *Sample solution*

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of riboflavin ($C_{17}H_{20}N_4O_6$) is dissolved.

- **UNIFORMITY OF DOSAGE UNITS (905):** Meet the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- **USP REFERENCE STANDARDS (11).**
[USP Riboflavin RS](#)

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

Topic/Question	Contact	Expert Committee
RIBOFLAVIN TABLETS	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

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