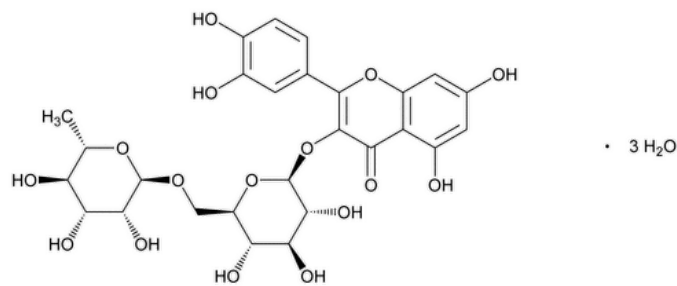


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Rutin

Change to read:



$C_{27}H_{30}O_{16} \cdot 3H_2O$

664.56

3-Rhamnoglucoside of 5,7,3',4'-tetrahydroxyflavonol ▲trihydrate; ▲ (ERR 1-Apr-2019)

2-(3,4-Dihydroxyphenyl)-5,7-dihydroxy-4H-chromen-4-one-3-yl 6-O-α-L-rhamnopyranosyl-β-D-glucoside ▲trihydrate ▲ (ERR 1-Apr-2019) CAS RN®: 250249-75-3.

DEFINITION

Rutin contains NLT 95.0% and NMT 101.0% of rutin ($C_{27}H_{30}O_{16}$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- A. ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)

Change to read:

- B. ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Ultraviolet-Visible Spectroscopy: 197U](#) ▲ (CN 1-MAY-2020)

Analytical wavelength: 210–450 nm

Sample solution: 20 µg/mL of Rutin in [methanol](#). Filter if necessary.

Acceptance criteria: The spectrum exhibits two absorption maxima at 257 nm and 358 nm. The absorptivity at the maximum at 358 nm is 30.5–33.0, calculated on the anhydrous basis.

- C. The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the test for *Quercetin and Other Related Compounds*.

ASSAY

• PROCEDURE

Sample: 200 mg of Rutin

Blank: 20 mL of [dimethylformamide](#)

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: [Tetrabutylammonium hydroxide](#)

Endpoint detection: Potentiometric

Analysis: Dissolve the *Sample* in 20 mL of [dimethylformamide](#), and titrate with *Titrant*. Perform the *Blank* determination and make corrections if necessary.

Calculate the percentage of rutin ($C_{27}H_{30}O_{16}$) in the portion of the *Sample* taken:

$$\text{Result} = \{[(V_s - V_b) \times M \times F]/W\} \times 100$$

V_S = Titrant volume consumed by the *Sample* (mL)

V_B = Titrant volume consumed by the *Blank* (mL)

M = actual Titrant molarity (mmol/mL)

F = equivalency factor, 305.3 mg/mmol

W = Sample weight (mg)

Acceptance criteria: 95.0%–101.0% on the anhydrous basis

IMPURITIES

- **RESIDUE ON IGNITION (281):** NMT 0.1%

- **LIGHT ABSORBING SUBSTANCES**

Analytical wavelength: 450–800 nm

Sample solution: Dissolve 0.200 g of Rutin in 40 mL of [2-propanol](#). Stir for 15 min, dilute with [2-propanol](#) to 50.0 mL, and filter.

Acceptance criteria: The absorbance of any substance is NMT 0.10.

- **METHANOL INSOLUBLE SUBSTANCES**

Sample: 2.5 g

Analysis: Shake the *Sample* for 15 min in 50 mL of [methanol](#) at 20°–25°. Filter under reduced pressure through a sintered-glass filter previously dried for 15 min at 100°–105°, cooled in a desiccator, and tared. Wash the filter three times with 20 mL of [methanol](#). Dry the filter for 30 min at 105°. Allow to cool, and weigh.

Acceptance criteria: The residue weighs NMT 75 mg (3%).

- **QUERCETIN AND OTHER RELATED COMPOUNDS**

Solution A: Mix 50 mL of [tetrahydrofuran](#) with 950 mL of a 15.6 mg/mL solution of [monobasic sodium phosphate](#). Adjust with [phosphoric acid](#) to a pH of 3.0.

Solution B: Mix 400 mL of [tetrahydrofuran](#) with 600 mL of a 15.6 mg/mL solution of [monobasic sodium phosphate](#). Adjust with [phosphoric acid](#) to a pH of 3.0.

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	50	50
10	0	100
20	0	100
21	50	50
25	50	50

Standard solution A: Transfer 10 mg of [USP Rutin RS](#) into a 10-mL volumetric flask, add 2 mL of [methanol](#), and mix to dissolve. Dilute with *Solution B* to volume.

Standard solution B: 20 µg/mL of [USP Rutin RS](#) in *Solution B*, prepared from the dilution of *Standard solution A* with *Solution B*

Standard solution C: 20 µg/mL of [USP Quercetin RS](#) in *Solution B*

Sample solution: Transfer 100 mg of Rutin into a 100-mL volumetric flask, add 20 mL of [methanol](#), and mix to dissolve. Dilute with *Solution B* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4-mm × 25-cm; 5-µm packing [L7](#)

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 20 µL