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Risedronate Sodium Delayed-Release Tablets

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DEFINITION

Risedronate Sodium Delayed-Release Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of risedronate sodium ($C_7H_{10}NNaO_7P_2$).

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.
- **B.** The UV spectra of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Mobile phase: 1.8 g/L of [edetate disodium](#) in [water](#). Adjust with 1 N [sodium hydroxide](#) solution to a pH of 9.5.

Standard solution: 0.1 mg/mL of [USP Risedronate Sodium RS](#) in *Mobile phase*. Sonicate to dissolve, if necessary.

Sample stock solution: Nominally 1 mg/mL of risedronate sodium from Tablets prepared as follows. Transfer the equivalent of 100 mg of risedronate sodium, from finely powdered Tablets (NLT 20) to a 100-mL volumetric flask and add about 70 mL of *Mobile phase*. Sonicate with intermittent shaking for about 40 min. Dilute with *Mobile phase* to volume.

Sample solution: Nominally 0.1 mg/mL of risedronate sodium from the *Sample stock solution* in *Mobile phase*. Pass the solution through a suitable filter of 0.22-μm pore size, discarding the first 5 mL.

Chromatographic system

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

Mode: LC

Detector: UV 263 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Columns

Guard: 4.0-mm × 5-cm; 10-μm packing [L48](#)

Analytical: 4.0-mm × 25-cm, 10-μm packing [L48](#)

Flow rate: 0.8 mL/min

Injection volume: 20 μL

Run time: NLT 2 times the retention time of risedronate

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of risedronate sodium ($C_7H_{10}NNaO_7P_2$) in the portion of Tablets taken:

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

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

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

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

▲Test 1▲ (RB 1-May-2024)

Acid stage

Acid stage medium: 0.1 N [hydrochloric acid](#); 500 mL

Apparatus 2: 75 rpm

Time: 2 h

Standard stock solution: 0.7 mg/mL of [USP Risedronate Sodium RS](#) in [water](#). Sonicate to dissolve, if necessary.

Acid stage standard solution: 0.007 mg/mL of [USP Risedronate Sodium RS](#) from the *Standard stock solution* in *Acid stage medium*

Acid stage sample solution: After 2 h in the *Acid stage medium*, withdraw 10 mL of the solution under test and pass through a suitable filter of 0.45-μm pore size, discarding the first 5 mL.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV

Analytical wavelength: UV 262 nm

Path length: 0.5 cm

Blank: *Acid stage medium*

Analysis

Samples: *Acid stage standard solution* and *Acid stage sample solution*

Calculate the percentage of the labeled amount of risedronate sodium ($C_7H_{10}NNaO_7P_2$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times (1/L) \times 100$$

A_U = absorbance of the *Acid stage sample solution*

A_S = absorbance of the *Acid stage standard solution*

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

V = volume of *Acid stage medium*; 500 mL

L = label claim (mg/Tablet)

Tolerances: NMT 10% of the labeled amount of risedronate sodium ($C_7H_{10}NNaO_7P_2$) is dissolved.

Buffer stage

Buffer stage medium: pH 6.8 phosphate buffer; 500 mL

Apparatus 2: 75 rpm

Time: 45 min

Buffer stage standard solution: 0.07 mg/mL of [USP Risedronate Sodium RS](#) from the *Standard stock solution* in *Buffer stage medium*

Buffer stage sample solution: After 2 h in *Acid stage medium*, carefully discard the *Acid stage medium*, add 500 mL of *Buffer stage medium* to the same vessel, and continue with *Buffer stage* conditions for another 45 min. After 45 min, withdraw 10 mL of the solution under test and pass through a suitable filter of 0.45-μm pore size, discarding the first 5 mL.

Instrumental conditions: Proceed as directed in the *Acid stage* except for *Blank*.

Blank: *Buffer stage medium*

Analysis

Samples: *Buffer stage standard solution* and *Buffer stage sample solution*

Calculate the percentage of the labeled amount of risedronate sodium ($C_7H_{10}NNaO_7P_2$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times (1/L) \times 100$$

A_U = absorbance of the *Buffer stage sample solution*

A_S = absorbance of the *Buffer stage standard solution*