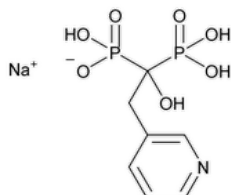


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Risedronate Sodium



$C_7H_{10}NNaO_7P_2$ 305.09
 $C_7H_{10}NNaO_7P_2 \cdot H_2O$ 323.12
 $C_7H_{10}NNaO_7P_2 \cdot 2.5 H_2O$ 350.13

Phosphonic acid, [1-hydroxy-2-(3-pyridinyl)ethylidene]bis-, monosodium salt;
 Sodium trihydrogen [1-hydroxy-2-(3-pyridyl) ethylidene]diphosphonate;
 Hemi-pentahydrate CAS RN[®]: 329003-65-8; UNII: HU2YAQ2740.
 Monohydrate CAS RN[®]: 353228-19-0; UNII: F67L43UT5C.

DEFINITION

Risedronate Sodium contains one or two-and-one-half molecules of hydration. The monohydrate form contains NLT 98.0% and NMT 102.0% of risedronate sodium ($C_7H_{10}NNaO_7P_2$), calculated on the dried basis. The hemi-pentahydrate form contains NLT 98.0% and NMT 102.0% of risedronate sodium ($C_7H_{10}NNaO_7P_2$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy](#): 197K or 197A▲ (USP 1-May-2020)
- **B.** [IDENTIFICATION TESTS—GENERAL \(191\), Chemical Identification Tests, Sodium](#): Meets the requirements of test A. [NOTE—Complete dissolution of the sample is achieved only after the addition of the 15% potassium carbonate.]

Add the following:

- ▲ **C.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-May-2020)

ASSAY

Change to read:

• PROCEDURE

Mobile phase: 1.8 g/L of [edetate disodium](#) in [water](#). Adjust with [1 N sodium hydroxide](#) to a pH of 9.5 ± 0.1 .

Standard solution: ▲ 1.0 mg/mL of [USP Risedronate Sodium RS](#) and 0.1 mg/mL of [USP Risedronate Related Compound A RS](#) in *Mobile phase*▲ (USP 1-May-2020)

Sample solution: 1.1 mg/mL of Risedronate Sodium in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 263 nm

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

Flow rate: 0.8 mL/min

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 2.3 between risedronate related compound A and risedronate

Tailing factor: NMT 1.6 for the risedronate peak

Relative standard deviation: NMT 1.0% for the risedronate peak ▲▲ (USP 1-May-2020)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of risedronate sodium ($C_7H_{10}NNaO_7P_2$) in the portion of Risedronate Sodium taken:

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

r_U = peak response ▲ of risedronate ▲ (USP 1-May-2020) from the *Sample solution*

r_S = peak response ▲ of risedronate ▲ (USP 1-May-2020) from the *Standard solution*

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

C_U = concentration of Risedronate Sodium in the *Sample solution* (mg/mL)

Acceptance criteria

Monohydrate: 98.0%–102.0% on the dried basis

Hemi-pentahydrate: 98.0%–102.0% on the anhydrous basis

IMPURITIES

Change to read:

• **ORGANIC IMPURITIES, PROCEDURE 1**

[NOTE—Perform both *Procedure 1* and *Procedure 2*.]

Mobile phase, Standard solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

Diluted standard solution: ▲0.005 mg/mL of [USP Risedronate Sodium RS](#) and 0.5 µg/mL of [USP Risedronate Related Compound A RS](#) in *Mobile phase* from the *Standard solution* ▲ (USP 1-May-2020)

System suitability

Samples: *Standard solution* and *Diluted standard solution*

Suitability requirements

Resolution: NLT 2.3 between risedronate related compound A and risedronate, *Standard solution*

Tailing factor: NMT 1.6 for the risedronate peak, *Standard solution*

Relative standard deviation: NMT 1.0% for the risedronate peak, ▲▲ (USP 1-May-2020) *Standard solution*; NMT 15% for the risedronate related compound A peak, ▲▲ (USP 1-May-2020) *Diluted standard solution*

Analysis

Samples: *Sample solution* and *Diluted standard solution*

Calculate the percentage of each impurity in the portion of Risedronate Sodium taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response of risedronate from the *Diluted standard solution*

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

C_U = concentration of Risedronate Sodium in the *Sample solution* (mg/mL)

F = relative response factor (see [Table 1](#))

Table 1

Acceptance criteria: ▲The reporting threshold is 0.05%. ▲ (USP 1-May-2020)

Any individual impurity: NMT 0.10%