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Etidronate Disodium Tablets

DEFINITION

Etidronate Disodium Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of etidronate disodium ($C_2H_6Na_2O_7P_2$).

IDENTIFICATION

Change to read:

- **A.** **▲** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy*: 197A or 197M **▲** (CN 1-May-2020)

Standard: Recrystallize [USP Etidronate Disodium RS](#) from [water](#) and dry it at 105° for 1 h.

Sample: Recrystallize the sample from [water](#) and dry it at 105° for 1 h.

Analysis and Acceptance criteria ▲ **for (197M):** **▲** (CN 1-May-2020) The spectra of [trifluorovinyl chloride polymer](#) and mineral oil dispersions of the *Sample*, separately prepared, exhibit maxima in the regions of 4000–1350 cm^{-1} and 1350–450 cm^{-1} , respectively, only at the same wavelengths as those of similar preparations of the *Standard*. **▲** **▲** (CN 1-May-2020)

- **B.** 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: 35–40 mM [ammonium nitrate](#) solution in [water](#). Adjust with dilute [ammonium hydroxide](#) to a pH of 7.0.

Standard solution: 0.73–0.75 mg/mL of [USP Etidronic Acid Monohydrate RS](#) in [1 N sodium hydroxide VS](#) and *Mobile phase* (1:150)

Sample solution: Transfer a quantity of finely powdered Tablets (NLT 20), nominally equivalent to 160–170 mg of etidronate disodium, to a 200-mL volumetric flask, and dilute with *Mobile phase* to volume. Agitate the solution for at least 5 min, and pass through a nylon filter of 0.45- μ m pore size.

Chromatographic system

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

Mode: LC

Detector: Refractive index

Column: 4.6-mm $\times$ 15-cm; 10- μ m packing [L23](#)

Temperatures

Detector: 32°

Column: 32°

Flow rate: 1.5 mL/min

Injection volume: 20 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of etidronate disodium ($C_2H_6Na_2O_7P_2$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

C_U = nominal concentration of etidronate disodium in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of etidronate disodium, 249.99

M_{r2} = molecular weight of etidronic acid monohydrate, 224.04

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Medium: [Water](#); 900 mL

Apparatus 1: 100 rpm

Time: 30 min

Mobile phase: Prepare as directed in the Assay.

Standard solution

For products labeled to contain 200 mg of etidronate disodium: Transfer 20 mg of [USP Etidronic Acid Monohydrate RS](#) to a 100-mL volumetric flask, dissolve in 50 mL of water, add 2.0 mL of [0.1 N sodium hydroxide VS](#), and dilute with [water](#) to volume.

For products labeled to contain 400 mg of etidronate disodium: Transfer 20 mg of [USP Etidronic Acid Monohydrate RS](#) to a 50-mL volumetric flask, dissolve in 25 mL of [water](#), add 2.0 mL of [0.1 N sodium hydroxide VS](#), and dilute with [water](#) to volume.

Sample solution: Transfer a portion of the solution under test to an HPLC vial.

Chromatographic system

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

Mode: LC

Detector: Refractive index

Column: 4.6-mm × 15-cm; 10-μm packing [L23](#)

Temperatures

Detector: 32°

Column: 32°

Flow rate: 1.5 mL/min

Injection volume: See [Table 1](#).

Table 1

Tablet Strength (mg)	Injection Volume (μL)
200	100
400	50

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution and Sample solution*

Calculate the percentage of the labeled amount of etidronate disodium ($C_2H_6Na_2O_7P_2$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (M_{r1}/M_{r2}) \times (1/L) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

V = volume of *Medium*, 900 mL

M_{r1} = molecular weight of etidronate disodium, 249.99

M_{r2} = molecular weight of etidronic acid monohydrate, 224.04

L = label claim (mg/Tablet)

Tolerances: NLT 70% (Q) of the labeled amount of etidronate disodium ($C_2H_6Na_2O_7P_2$) is dissolved.

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

IMPURITIES

• LIMIT OF PHOSPHITE AND PHOSPHATE

Mobile phase: 20 mM [ammonium nitrate](#) solution in water. Adjust with dilute [ammonium hydroxide](#) to a pH of 7.0.

Standard solution: A mixture of 0.04 mg/mL of dibasic sodium phosphite, on the anhydrous basis from [USP Etidronate Disodium Related Compound A RS](#), and [anhydrous dibasic sodium phosphate](#) in *Mobile phase*