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Almotriptan Tablets

DEFINITION

Almotriptan Tablets contain an amount of almotriptan malate ($C_{17}H_{25}N_3O_2S \cdot C_4H_6O_5$) equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of almotriptan ($C_{17}H_{25}N_3O_2S$).

IDENTIFICATION

Change to read:

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

Sample: Sonicate 5 powdered Tablets in 25 mL of water. Extract the suspension with 25 mL of [methylene chloride](#), and discard the organic phase. Add another 25 mL of [methylene chloride](#) and 3 mL of [1 N sodium hydroxide](#). Extract the precipitated base into the organic layer. Dry with [anhydrous sodium sulfate](#), and evaporate the organic solvent. Prepare the residue oil as a film on a sodium chloride pellet.

Acceptance criteria: The IR spectrum obtained from the *Sample* is consistent with that of similarly prepared [USP Almotriptan Malate RS](#).

- **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

Protect samples, the Reference Standards, and solutions containing them from light.

Buffer: Add 10 mL of [triethylamine](#) to every 1000 mL of [0.01 M phosphoric acid](#). Adjust with [phosphoric acid](#) to a pH of 6.0.

Mobile phase: [Acetonitrile](#) and *Buffer* (10:90)

Standard solution: 0.5 mg/mL of [USP Almotriptan Malate RS](#) in *Mobile phase*. Sonication may be used to aid in dissolution.

System suitability stock solution: 0.1 mg/mL each of [USP Almotriptan Related Compound B RS](#), [USP Almotriptan Related Compound C RS](#), and [USP Almotriptan Related Compound D RS](#) in [methanol](#). Sonication may be used to aid in dissolution.

System suitability solution: 0.001 mg/mL each of [USP Almotriptan Related Compound B RS](#), [USP Almotriptan Related Compound C RS](#), and [USP Almotriptan Related Compound D RS](#) prepared from the *System suitability stock solution* in *Standard solution*

Sample solution: Nominally 0.5 mg/mL of almotriptan from Tablets prepared as follows. Transfer NLT 8 Tablets into a suitable volumetric flask, and add 80% of the flask volume of *Mobile phase*. Sonicate for NLT 10 min, and dilute with *Mobile phase* to volume. Stir for 30 min, and centrifuge. Pass a portion of the supernatant through a suitable filter of 0.45-µm pore size. Use the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 2.1-mm × 10-cm; 1.8-µm packing [L1](#)

Column temperature: 40°

Flow rate: 0.55 mL/min

Injection volume: 3 µL

System suitability

Samples: *Standard solution* and *System suitability solution*

[NOTE—See [Table 1](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between almotriptan related compound C and almotriptan peaks, *System suitability solution*

Tailing factor: NMT 3.0, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of almotriptan ($C_{17}H_{25}N_3O_2S$) 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 of almotriptan from the *Sample solution*

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

C_s = concentration of [USP Almotriptan Malate RS](#) in the *Standard solution* (mg/mL)

C_u = nominal concentration of almotriptan in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of almotriptan, 335.46

M_{r2} = molecular weight of almotriptan malate, 469.55

Acceptance criteria: 90.0%–110.0% of the labeled amount of almotriptan

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Test 1

Medium: [0.1 N hydrochloric acid](#); 900 mL

Apparatus 2: 50 rpm

Time: 15 min

Standard solution: $(L/600)$ mg/mL of [USP Almotriptan Malate RS](#) in *Medium*, where L is the label claim in mg/Tablet

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size.

Instrumental conditions

Mode: UV

Analytical wavelength

For Tablets labeled to contain 6.25 mg: 228 nm

For Tablets labeled to contain 12.5 mg: 284 nm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of almotriptan ($C_{17}H_{25}N_3O_2S$) dissolved:

$$\text{Result} = (A_u/A_s) \times (C_s/L) \times V \times (M_{r1}/M_{r2}) \times 100$$

A_u = absorbance of the *Sample solution*

A_s = absorbance of the *Standard solution*

C_s = concentration of [USP Almotriptan Malate RS](#) in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium*, 900 mL

M_{r1} = molecular weight of almotriptan, 335.46

M_{r2} = molecular weight of almotriptan malate, 469.55

Tolerances: NLT 80% (Q) of the labeled amount of almotriptan ($C_{17}H_{25}N_3O_2S$) is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: [0.1 N hydrochloric acid](#); 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard stock solution: 0.425 mg/mL of [USP Almotriptan Malate RS](#), equivalent to 0.30 mg/mL of almotriptan, in [water](#)

Standard solution: 0.021 mg/mL of [USP Almotriptan Malate RS](#), equivalent to 0.015 mg/mL of almotriptan, from the *Standard stock solution* in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size, and discard the first 5 mL. Use the remaining filtrate.

Instrumental conditions

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

Mode: UV

Analytical wavelength: 283 nm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of almotriptan ($C_{17}H_{25}N_3O_2S$) dissolved:

$$\text{Result} = (A_u/A_s) \times (C_s/L) \times V \times (M_{r1}/M_{r2}) \times 100$$