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Rizatriptan Benzoate Orally Disintegrating Tablets

DEFINITION

Rizatriptan Benzoate Orally Disintegrating Tablets contain an amount of rizatriptan benzoate ($C_{15}H_{19}N_5 \cdot C_7H_6O_2$) equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of rizatriptan ($C_{15}H_{19}N_5$).

IDENTIFICATION

- **A.** The retention times of the major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the Assay.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Buffer: Transfer 3.4 g of [monobasic potassium phosphate](#) and 2.0 g of [1-heptanesulfonic acid, sodium salt](#) to a 1-L volumetric flask. Add 900 mL of [water](#). Adjust with 50% (w/w) [sodium hydroxide](#) to a pH of 7.5, and dilute with [water](#) to volume.

Mobile phase: [Acetonitrile](#) and *Buffer* (16:84)

Diluent: [Acetonitrile](#) and 0.025 M [monobasic potassium phosphate](#) (10:90)

Standard solution: 0.07 mg/mL of [USP Rizatriptan Benzoate RS](#) in *Diluent*

Sample stock solution: Nominally 0.5 mg/mL of rizatriptan in *Diluent* prepared as follows. Transfer NLT 10 Tablets to a suitable volumetric flask. Add 25%–50% of the flask volume of *Diluent*, and swirl until the Tablets have disintegrated completely. Dilute with *Diluent* to volume.

Sample solution: Nominally 0.05 mg/mL of rizatriptan free base from the *Sample stock solution* in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 226 nm. For *Identification B*, use a diode array detector in the range of 210–400 nm.

Column: 4.6-mm × 25-cm; 5-μm packing [L7](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 μL

Run time: NLT 1.5 times the retention time of rizatriptan

System suitability

Sample: *Standard solution*

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

Suitability requirements

Tailing factor: NMT 3.5

Relative standard deviation: NMT 2.0% for the rizatriptan peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of rizatriptan ($C_{15}H_{19}N_5$) 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 Rizatriptan Benzoate RS](#) in the *Standard solution* (mg/mL)

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

M_{r1} = molecular weight of rizatriptan free base, 269.35

M_{r2} = molecular weight of rizatriptan benzoate, 391.47

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Test 1

Medium: [water](#); 900 mL

Apparatus 2: 50 rpm

Time: 5 min

Standard solution: (L/625) mg/mL of [USP Rizatriptan Benzoate RS](#) in *Medium*, where L is the label claim of rizatriptan in mg/Tablet

Sample solution: Pass a portion of the solution under test through a suitable membrane filter of 10-µm pore size.

Instrumental conditions

Mode: UV

Analytical wavelengths: 278 and 320 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of rizatriptan ($C_{15}H_{19}N_5$) dissolved:

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

A_U = absorbance of rizatriptan from the *Sample solution*, corrected for the absorbance at 320 nm

A_S = absorbance of rizatriptan from the *Standard solution*, corrected for the absorbance at 320 nm

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

V = volume of *Medium*, 900 mL

M_{r1} = molecular weight of rizatriptan free base, 269.35

M_{r2} = molecular weight of rizatriptan benzoate, 391.47

L = label claim of rizatriptan (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of rizatriptan ($C_{15}H_{19}N_5$) is dissolved.

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

Medium: [Water, deaerated](#); 900 mL

Apparatus 2: 50 rpm

Time: 10 min

Buffer: Dissolve 2.7 g of [monobasic potassium phosphate](#) in 1 L of [water](#). Add 2 mL of [triethylamine](#) and adjust with diluted [phosphoric acid](#) (1 in 10) to a pH of 5.0.

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

Standard solution: (L/625) mg/mL of [USP Rizatriptan Benzoate 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 membrane filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 225 nm

Column: 4.6-mm × 15-cm; 5-µm packing [L7](#)

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 20 µL

Run time: NLT 2 times the retention time of rizatriptan

System suitability

Sample: *Standard solution*

Suitability requirements