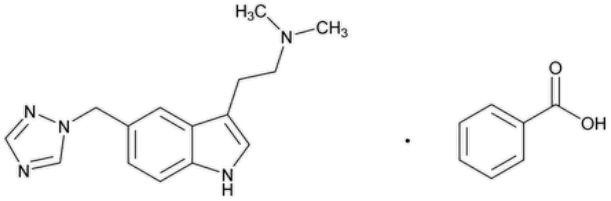
Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-8116D703-9297-46C4-9870-F8CA6FD5614C_5_en-US
DOI: https://doi.org/10.31003/USPNF_M73775_05_01
DOI Ref: u4nwj



# Rizatriptan Benzoate



$C_{22}H_{25}N_5O_2$ 391.47

1*H*-Indole-3-ethanamine, *N*,*N*-dimethyl-5-(1*H*-1,2,4-triazol-1-ylmethyl)-, monobenzoate;

3-[2-(Dimethylamino)ethyl]-5-(1*H*-1,2,4-triazol-1-ylmethyl)indole monobenzoate CAS RN®: 145202-66-0; UNII: WR978S7QHH.

## DEFINITION

Rizatriptan Benzoate contains NLT 98.0% and NMT 102.0% of $C_{22}H_{25}N_5O_2$, calculated on the anhydrous basis.

## IDENTIFICATION

***Change to read:***

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197A, 197K, or 197M▲ (CN 1-May-2020)

[Note—If the spectra obtained show differences, dissolve the substance to be examined and the Reference Standard separately in methanol, evaporate to dryness, and record the new spectra using the residues.]

• **B.** The retention times of the major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the *Assay*.

## ASSAY

• **Procedure**

[Note—Use silanized autosampler vials and freshly prepared solutions.]

**Solution A:** Add 1.0 mL of trifluroacetic acid to 1 L of a solution of acetonitrile and water (4:21), and mix.

**Solution B:** Acetonitrile and trifluroacetic acid (1000:1)

**Standard solution:** 1 mg/mL of USP Rizatriptan Benzoate RS in *Solution A*

**Sample solution:** 1 mg/mL of Rizatriptan Benzoate in *Solution A*

**Mobile phase:** See the gradient table below.

| Time (min) | Solution A (%) | Solution B (%) |
|---|---|---|
| 0 | 100 | 0 |
| 8.0 | 100 | 0 |
| 17.0 | 70 | 30 |
| 20.0 | 70 | 30 |
| 20.1 | 100 | 0 |
| 23.0 | 100 | 0 |

**Chromatographic system**

(See *Chromatography ⟨621⟩, System Suitability*.)

**Mode:** LC

**Detector:** UV 280 nm

**Column:** 4.6-mm × 25-cm; 5-µm packing L11

**Column temperature:** 40°

**Flow rate:** 1.5 mL/min

**Injection size:** 20 µL

**System suitability**

**Sample:** *Standard solution*

[NOTE—The relative retention times for rizatriptan and benzoic acid are 1.0 and about 2.1, respectively.]

**Suitability requirements**

**Tailing factor:** NMT 3.5 for rizatriptan

**Relative standard deviation:** NMT 0.73% for the rizatriptan peak

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of $C_{22}H_{25}N_5O_2$ in the portion of Rizatriptan Benzoate taken:

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

$r_U$ = peak response of rizatriptan from the *Sample solution*

$r_S$ = peak response of rizatriptan from the *Standard solution*

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

$C_U$ = concentration of Rizatriptan Benzoate in the *Sample solution* (mg/mL)

**Acceptance criteria:** 98.0%–102.0% on the anhydrous basis

## IMPURITIES

### Inorganic Impurities

- **Residue on Ignition ⟨281⟩:** NMT 0.1%

### Organic Impurities

- **Procedure**

**Solution A, Solution B,** and **Mobile phase:** Proceed as directed in the *Assay*.

**Sample solution:** 1 mg/mL of Rizatriptan Benzoate in *Solution A*

**System suitability solution:** 1 mg/mL of USP Rizatriptan Benzoate System Suitability Mixture RS in *Solution A*

**Sensitivity solution:** 0.5 µg/mL of Rizatriptan Benzoate obtained by suitable dilution of the *Sample solution* with *Solution A*

**Chromatographic system:** Prepare as directed in the *Assay*.

**System suitability**

**Sample:** *System suitability solution* and *Sensitivity solution*

[NOTE—The relative retention times for rizatriptan, rizatriptan impurity C, and benzoic acid are 1.0, about 1.3, and about 2.1, respectively.]

**Suitability requirements**

**Resolution:** NLT 2.0 between rizatriptan and rizatriptan impurity C, *System suitability solution*

**Signal-to-noise ratio:** NLT 10 for the rizatriptain peak, *Sensitivity solution*

**Analysis**

**Sample:** *Sample solution*

Calculate the percentage of each impurity in the portion of Rizatriptan Benzoate taken:

$$\text{Result} = [r_U/(r_T - r_{BA})] \times 100$$

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

$r_T$ = sum of the areas of all the peaks from the *Sample solution*

$r_{BA}$ = area of the benzoic acid peak from the *Sample solution*

**Acceptance criteria**

**Any individual impurity:** NMT 0.10%

**Total:** NMT 0.3%. [NOTE—Disregard any impurity that is less than 0.05%.]

**SPECIFIC TESTS**

• **Water Determination,** *Method Ia* ⟨921⟩**:** NMT 0.5%

**ADDITIONAL REQUIREMENTS**

• **Packaging and Storage:** Store in well-closed containers at room temperature.

• **USP Reference Standards** ⟨11⟩

USP Rizatriptan Benzoate RS

USP Rizatriptan Benzoate System Suitability Mixture RS

Mixture of rizatriptan benzoate and at least 0.1% of rizatriptan impurity C. Rizatriptan impurity C is 2-{5-[(1*H*-1,2,4-triazol-1-yl)methyl]-1*H*-indol-2-yl}-*N*,*N*-dimethylethanamine.

($C_{15}H_{19}N_5$ 269.35)

**Auxiliary Information** - Please check for your question in the FAQs before contacting USP.

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| RIZATRIPTAN BENZOATE | Documentary Standards Support | SM42020 Small Molecules 4 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | SM42020 Small Molecules 4 |

**Chromatographic Database Information:** Chromatographic Database

**Most Recently Appeared In:**
Pharmacopeial Forum: Volume No. PF 36(1)

**Current DocID: GUID-8116D703-9297-46C4-9870-F8CA6FD5614C_5_en-US**

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