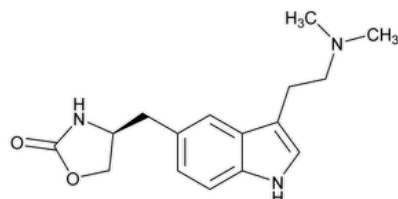


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Zolmitriptan



$C_{16}H_{21}N_3O_2$ 287.36

2-Oxazolidinone, 4-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-, (S)-;

(S)-4-((3-[2-(Dimethylamino)ethyl]indol-5-yl)methyl)oxazolidin-2-one;

(S)-4-[[3-[2-(Dimethylamino)ethyl]indol-5-yl]methyl]-2-oxazolidinone CAS RN®: 139264-17-8; UNII: 2FS66TH3YW.

DEFINITION

Zolmitriptan contains NLT 97.0% and NMT 102.0% of zolmitriptan ($C_{16}H_{21}N_3O_2$), calculated on the anhydrous and solvent-free basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197K ▲ (CN 1-May-2020)
- **B.** The migration time of the major peak of the *Sample solution* corresponds to that of the *System suitability solution*, as obtained in the test for *Limit of Zolmitriptan R-Isomer and Other Impurities*.

ASSAY

Change to read:

• PROCEDURE

Mobile phase: [Acetonitrile](#) and [water](#) (135:865). For every liter of the mixture add 1 mL of [trifluoroacetic acid](#) and 0.25 mL of [triethylamine](#).

System suitability solution: 0.12 µg/mL of [USP Zolmitriptan Related Compound E RS](#) and 25 µg/mL of [USP Zolmitriptan RS](#) in *Mobile phase*

Standard solution: 0.025 mg/mL of [USP Zolmitriptan RS](#) in *Mobile phase*

Sample solution: 0.025 mg/mL of Zolmitriptan in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 225 nm

Column: 4.0-mm × 12.5-cm; 5-µm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: ▲NLT ▲ (IRA 1-May-2020) 3 times the retention time of zolmitriptan

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for zolmitriptan and zolmitriptan related compound E are 1.0 and 1.6, respectively.]

Suitability requirements

Resolution: NLT 5 between zolmitriptan and zolmitriptan related compound E

Tailing factor: NMT 2.0 for zolmitriptan

▲**Relative standard deviation:** NMT 0.73% ▲ (IRA 1-May-2020)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of zolmitriptan ($C_{16}H_{21}N_3O_2$) in the portion of Zolmitriptan taken:

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

r_U = peak response $\blacktriangle$ of zolmitriptan $\blacktriangle$ (IRA 1-May-2020) from the *Sample solution*

r_S = peak response $\blacktriangle$ of zolmitriptan $\blacktriangle$ (IRA 1-May-2020) from the *Standard solution*

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

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

Acceptance criteria: 97.0%–102.0% on the anhydrous and solvent-free basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• **LIMIT OF ZOLMITRIPTAN RELATED COMPOUND H**

Perform this test only if zolmitriptan related compound H is a known process impurity. If this test is performed, then this is to be included in total impurities.

Standard solution: 0.1 mg/mL of [USP Zolmitriptan Related Compound H RS](#) in [methanol](#)

Sample solution: 200 mg/mL of Zolmitriptan in [methanol](#)

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.32-mm $\times$ 15-m; 1- μ m coating of dimethylpolysiloxane phase [G1](#)

Temperatures

Injection port: 200°

Column: 130°

Detector: 250°

Carrier gas: Helium at 6 mL/min

Injection volume: 3 μ L

Injection type: Split, split ratio 10:1

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of zolmitriptan related compound H in the portion of Zolmitriptan taken:

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

r_U = peak response of zolmitriptan related compound H from the *Sample solution*

r_S = peak response of zolmitriptan related compound H from the *Standard solution*

C_S = concentration of [USP Zolmitriptan Related Compound H RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: NMT 0.1% of zolmitriptan related compound H

Change to read:

• **LIMIT OF ZOLMITRIPTAN R-ISOMER AND OTHER IMPURITIES**

Buffer: 19.1 g/L of [sodium borate decahydrate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 2.2.

Run buffer: 50 mg/mL of [hydroxypropyl- \$\beta\$ -cyclodextrin](#) in *Buffer*

Diluent: 0.02 M [hydrochloric acid](#)

Internal standard solution: 0.05 mg/mL of [tryptamine hydrochloride](#) in *Diluent*