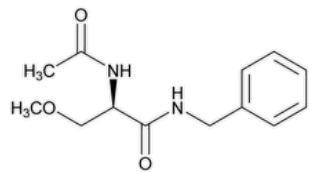


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Add the following:

^Lacosamide



$C_{13}H_{18}N_2O_3$ 250.30
Propanamide, 2-(acetylamino)-3-methoxy-N-(phenylmethyl)-, (2R)-;
(+)-(R)-2-(Acetylamino)-N-benzyl-3-methoxypropanamide. CAS RN[®]: 175481-36-4.

DEFINITION
Lacosamide contains NLT 98.0% and NMT 102.0% of lacosamide ($C_{13}H_{18}N_2O_3$).

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K or 197A
- **B.** The retention 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 Lacosamide S-Enantiomer*.

ASSAY

- **PROCEDURE**
Solution A: To each liter of [water](#) add 1 mL of [trifluoroacetic acid](#).
Solution B: [Acetonitrile](#) and [methanol](#) (50:50). To each liter add 0.3 mL of [trifluoroacetic acid](#).
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	89	11
12.2	69	31
17.5	23	77
18.0	0	100
19.0	0	100
19.1	89	11
24.0	89	11

System suitability solution: 5 mg/mL of [USP Lacosamide RS](#) and 10 µg/mL each of [USP Lacosamide Related Compound B RS](#) and [N-benzylacetamide](#) prepared as follows. Weigh an appropriate amount of [USP Lacosamide RS](#), [USP Lacosamide Related Compound B RS](#), and [N-benzylacetamide](#) into a suitable volumetric flask. Dissolve in 10% of the flask volume of [methanol](#). Dilute with [water](#) to volume.

Standard solution: 5 mg/mL of [USP Lacosamide RS](#) prepared as follows. Weigh an appropriate amount of [USP Lacosamide RS](#) into a suitable volumetric flask. Dissolve in 10% of the flask volume of [methanol](#). Dilute with [water](#) to volume.

Sample solution: 5 mg/mL of Lacosamide prepared as follows. Weigh an appropriate amount of Lacosamide into a suitable volumetric flask. Dissolve in 10% of the flask volume of [methanol](#). Dilute with [water](#) to volume.

Chromatographic system

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

Mode: LC

Detector: UV 258 nm

Column: 4.6-mm × 15-cm; 3.5-μm packing [L7](#)

Autosampler temperature: 10°

Flow rate: 1.2 mL/min

Injection volume: 20 μL

System suitability

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

[NOTE—See [Table 2](#) for relative retention times.]

Suitability requirements

Resolution: NLT 2.0 between *N*-benzylacetamide and lacosamide; NLT 4.5 between lacosamide and lacosamide related compound B, *System suitability solution*

Tailing factor: NMT 2.5, *Standard solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of lacosamide ($C_{13}H_{18}N_2O_3$) in the portion of Lacosamide taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 98.0%–102.0%

IMPURITIES

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

• **LIMIT OF LACOSAMIDE S-ENANTIOMER**

Mobile phase: [Heptane](#), [isopropyl alcohol](#), and [water](#) (90:10:0.3)

System suitability solution: 1 mg/mL of [USP Lacosamide RS](#) and 5 μg/mL of [USP Lacosamide S-Enantiomer RS](#) in *Mobile phase*

Sample solution: 1 mg/mL of Lacosamide in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 25-cm; 10-μm packing [L51](#)

Flow rate: 1 mL/min

Injection volume: 20 μL

Run time: NLT 1.7 times the retention time of lacosamide

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for lacosamide S-enantiomer and lacosamide are 0.75 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between lacosamide S-enantiomer and lacosamide

Signal-to-noise ratio: NLT 10 for S-enantiomer

Analysis