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Lacosamide Tablets

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click <https://www.uspnf.com/rb-lacosamide-tabs-20220930>.

DEFINITION

Lacosamide Tablets contains NLT 90.0% and NMT 105.0% of the labeled amount of lacosamide ($C_{13}H_{18}N_2O_3$).

IDENTIFICATION

- **A.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **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

Mobile phase: [Acetonitrile](#) and [water](#) (13:87). To each liter add 0.75 mL of [methanesulfonic acid](#).

Diluent 1: [Methanol](#) and [water](#) (1.5: 98.5)

Diluent 2: [Methanol](#) and [water](#) (50:50)

System suitability solution: 1 mg/mL of [USP Lacosamide RS](#) and 2.0 µg/mL each of [USP Lacosamide Related Compound D RS](#) and [USP Lacosamide Related Compound F RS](#) in *Diluent 1*

Standard solution: 1 mg/mL of [USP Lacosamide RS](#) in *Diluent 1*

Sample stock solution: Nominally 2 mg/mL of lacosamide from Tablets (NLT 10) prepared as follows. Transfer the Tablets to an appropriate volumetric flask and add a suitable quantity of *Diluent 2* to the flask. Shake for 30 min to disperse the Tablets. Dilute with [water](#) to volume, sonicate for 10 min, and let settle for 30 min.

Sample solution: Nominally 1 mg/mL of lacosamide from *Sample stock solution* prepared as follows. Transfer a portion of *Sample stock solution* to an appropriate volumetric flask and dilute with [water](#) to volume to obtain a final composition that is the same as *Diluent 1*. Centrifuge the solution and use the supernatant.

Chromatographic system

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

Mode: LC

Detector: UV 215 nm. For *Identification A*, use a diode array detector in the range of 230–300 nm.

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

Temperatures

Autosampler: 10°

Column: 35°

Flow rate: 2 mL/min

Injection volume: 5 µL

Run time: NLT 2.5 times the retention time of lacosamide

System suitability

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

[NOTE—The relative retention times for lacosamide related compound D, lacosamide related compound F, and lacosamide are 0.37, 0.47, and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between lacosamide related compound D and lacosamide related compound F, *System suitability solution*

Tailing factor: NMT 2, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of lacosamide ($C_{13}H_{18}N_2O_3$) in the portion of Tablets 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 [USP Lacosamide RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–105.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)

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

Apparatus 2: 50 rpm with suitable sinker ▲, if necessary ▲ (RB 1-Oct-2022)

Time: 30 min

Mobile phase: [Acetonitrile](#) and [water](#) (30:70). To each liter add 1 mL of [trifluoroacetic acid](#).

Standard solution: (L/900) mg/mL of [USP Lacosamide 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 suitable pore size.

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 5-cm; 3-μm packing [L1](#)

Temperatures

Autosampler: 10°

Column: 35°

Flow rate: 1 mL/min

Injection volume: 2 μL

Run time: NLT 2.5 times the retention time of lacosamide

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of lacosamide ($C_{13}H_{18}N_2O_3$) dissolved:

$$\text{Result} = (r_u/r_s) \times C_s \times V \times (1/L) \times 100$$

r_u = peak response from the *Sample solution*

r_s = peak response from the *Standard solution*

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

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of lacosamide ($C_{13}H_{18}N_2O_3$) is dissolved.

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

IMPURITIES

• ORGANIC IMPURITIES

Mobile phase, Diluent 1, Diluent 2, System suitability solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

Sensitivity solution: 0.001 mg/mL of [USP Lacosamide RS](#) in *Diluent 1*

Standard solution: 0.002 mg/mL of [USP Lacosamide RS](#) in *Diluent 1*

System suitability

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

[NOTE—The relative retention times for lacosamide related compound D, lacosamide related compound F, and lacosamide are 0.37, 0.47, and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between lacosamide related compound D and lacosamide related compound F,