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Add the following:

^Lacosamide Injection

DEFINITION

Lacosamide Injection is a sterile solution of Lacosamide in Water for Injection. It contains NLT 90.0% and NMT 105.0% of the labeled amount of lacosamide ($C_{13}H_{18}N_2O_3$). It contains no antimicrobial agents.

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: [Acetonitrile](#) and [water](#) (13:87)

System suitability solution: 1 mg/mL of [USP Lacosamide RS](#) and 2 µg/mL each of [USP Lacosamide Related Compound D RS](#) and [USP Lacosamide Related Compound F RS](#) in *Diluent*

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

Sample solution: Nominally 1 mg/mL of lacosamide from Injection prepared as follows. Transfer an appropriate volume of Injection to a suitable volumetric flask, and dilute with *Diluent* to volume.

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 0.38, 0.48, 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 1.5, *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 Injection 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%

IMPURITIES

• ORGANIC IMPURITIES

Mobile phase, Diluent, 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*

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

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 0.38, 0.48, and 1.0, respectively.]

Suitability requirements

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

Relative standard deviation: NMT 5.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Sample solution and Standard solution*

Calculate the percentage of each degradation product in the portion of Injection taken:

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times 100$$

r_u = peak response of each degradation product from the *Sample solution*

r_s = peak response of lacosamide 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: The reporting threshold is 0.10%.

Lacosamide related compound D: NMT 0.80%

Any individual unspecified degradation product: NMT 0.20%

Total degradation products: NMT 2.0%

SPECIFIC TESTS

- [pH \(791\)](#): 3.8–5.0
- [PARTICULATE MATTER IN INJECTIONS \(788\)](#): Meets the requirements for small-volume injections
- [STERILITY TESTS \(71\)](#): Meets the requirements
- [BACTERIAL ENDOTOXINS TEST \(85\)](#): Meets the requirements

ADDITIONAL REQUIREMENTS

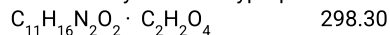
- **PACKAGING AND STORAGE:** Preserve in well-closed Type 1 glass vials. Store at controlled room temperature.

- [USP REFERENCE STANDARDS \(11\)](#).

[USP Lacosamide RS](#)

[USP Lacosamide Related Compound D RS](#)

2-Amino-*N*-benzyl-3-methoxypropanamide oxalate.



[USP Lacosamide Related Compound F RS](#)

2-Acetamido-*N*-benzyl-3-hydroxypropanamide.

