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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*

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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.

$C_{11}H_{16}N_2O_2 \cdot C_2H_2O_4$ 298.30

USP Lacosamide Related Compound F RS

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

$C_{12}H_{16}N_2O_3$ 236.27▲ (USP 1-May-2021)

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Topic/Question	Contact	Expert Committee
LACOSAMIDE INJECTION	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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