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Add the following:

▲Lacosamide Oral Solution

DEFINITION
Lacosamide Oral Solution 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**

Solution A: To each liter of water add 0.5 mL of trifluoroacetic acid.

Solution B: To each liter of acetonitrile add 0.5 mL of trifluoroacetic acid.

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	75	25
9	75	25
9.01	45	55
12.50	45	55
12.51	75	25
16.00	75	25

Diluent: Acetonitrile and water (25:75)

Standard solution: 1.0 mg/mL of USP Lacosamide RS in *Diluent*

Sample solution: Nominally 1.0 mg/mL of lacosamide from Oral Solution prepared as follows. Transfer a volume of Oral Solution to a suitable volumetric flask. 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 × 25-cm; 5-µm packing L1

Temperatures:

Autosampler: 10°

Column: 30°

Flow rate: 1.5 mL/min

Injection volume: 4 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 1.0%

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 Oral Solution 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

• **Deliverable Volume ⟨698⟩:** Meets the requirements

IMPURITIES

• **Organic Impurities**

Solution A: Acetonitrile and water (10:90). To each liter add 0.56 mL of trifluoroacetic acid.

Solution B: To each liter of acetonitrile add 0.5 mL of trifluoroacetic acid.

Mobile phase: See *Table 2*.

Table 2

Time (min)	Solution A (%)	Solution B (%)
0	100	0
31.00	100	0
31.01	30	70
33.00	30	70
33.01	100	0
38.50	100	0

Diluent: Acetonitrile and water (25:75)

System suitability solution: 1 mg/mL of USP Lacosamide RS and 0.002 mg/mL each of USP Lacosamide Related Compound D RS and USP Lacosamide Related Compound F RS in *Diluent*

Sensitivity solution: 0.001 mg/mL of USP Lacosamide RS in *Diluent*

Standard solution: 0.002 mg/mL of USP Lacosamide RS in *Diluent*

Sample solution: Prepare as directed in the *Assay*.

Chromatographic system: Proceed as directed in the *Assay*, except for the *Injection volume*.

Injection volume: 5 µL

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 0.36, 0.48, and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 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: *Standard solution* and *Sample solution*

Calculate the percentage of each degradation product in the portion of Oral Solution 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 0.1%.

Lacosamide related compound D: NMT 0.80%

Any individual unspecified degradation product: NMT 0.20%

Total degradation products: NMT 2.0%

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count does not exceed 10^2 cfu/mL. The total yeasts and molds count does not exceed 10^1 cfu/mL. It meets the requirements of the test for absence of *Escherichia coli*.

• **pH ⟨791⟩:** 3.8–5.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in light-resistant containers. 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)

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
LACOSAMIDE ORAL SOLUTION	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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