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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, *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 Tablets 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%.

**Any individual unspecified degradation product:** NMT 0.20%

**Total degradation products:** NMT 2.0%

## ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers, and 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

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

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| LACOSAMIDE TABLETS | Documentary Standards Support | SM42020 Small Molecules 4 |

**Chromatographic Database Information:** Chromatographic Database

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