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# ^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  $\mu$ L**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

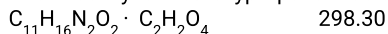
- **PACKAGING AND STORAGE:** Preserve in light-resistant containers. Store at controlled room temperature.

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

[USP Lacosamide RS](#)

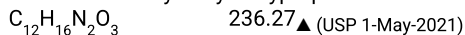
[USP Lacosamide Related Compound D RS](#)

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



[USP Lacosamide Related Compound F RS](#)

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



**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
LACOSAMIDE ORAL SOLUTION	<a href="#">Documentary Standards Support</a>	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM42020 Small Molecules 4

**Chromatographic Database Information:** [Chromatographic Database](#)

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