

Oxcarbazepine Oral Suspension

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click <https://www.uspnf.com/rb-oxcarbazepine-oral-susp-20240927>.

DEFINITION
Oxcarbazepine Oral Suspension contains NLT 95.0% and NMT 105.0% of the labeled amount of oxcarbazepine (C₁₅H₁₂N₂O₂).

- IDENTIFICATION**
- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
 - **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

Change to read:

• **PROCEDURE**

Protect all solutions from light.

Buffer: Dissolve 1.36 g of ▲ [sodium acetate](#) ▲ (RB 1-Oct-2024) and 0.6 g of [glacial acetic acid](#) in 1 L of [water](#). Adjust with [glacial acetic acid](#) to a pH of 4.4.

Solution A: [Acetonitrile](#), [tetrahydrofuran](#), [tert-butyl methyl ether](#), and *Buffer* (130:30:9:830)

Solution B: [Acetonitrile](#), [tetrahydrofuran](#), [tert-butyl methyl ether](#), and *Buffer* (670:30:9:290)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	93	7
2	90	10
10	90	10
25	10	90
26	93	7
35	93	7

Diluent: Dissolve 0.1 g of [ascorbic acid](#) and 1 mL of [acetonitrile](#) in 1 L of [water](#).

Standard stock solution: 1 mg/mL of [USP Oxcarbazepine RS](#) in [acetonitrile](#). Sonicate to aid in dissolution.

Standard solution: 0.25 mg/mL of [USP Oxcarbazepine RS](#) from the *Standard stock solution*, prepared as follows. Dilute a suitable volume of the *Standard stock solution* first with *Diluent*, using 70% of the final volume. Allow the solution to equilibrate to room temperature, and then dilute with [acetonitrile](#) to volume.

System suitability stock solution: 0.01 mg/mL of [USP Oxcarbazepine Related Compound A RS](#) and 0.02 mg/mL of [USP Oxcarbazepine Related Compound C RS](#) in [acetonitrile](#)

System suitability solution: 0.5 µg/mL of [USP Oxcarbazepine Related Compound A RS](#) and 1 µg/mL of [USP Oxcarbazepine Related Compound C RS](#) from the *System suitability stock solution*, in *Standard solution*

Sample solution: 0.25 mg/mL of oxcarbazepine from a portion of Oral Suspension, prepared as follows. Dissolve first with *Diluent* using 8% of the final volume, and then fill to 30% of the final volume with [acetonitrile](#). Sonicate for 15 min. Add *Diluent* to fill to 36% of the final volume. Shake the flask vigorously. Allow the solution to equilibrate to room temperature, and dilute with *Diluent* to volume.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 254 nm. For *Identification B*, use a diode array detector in the range of 210–400 nm.

Column: 3.0-mm × 25-cm; 3-μm packing [L1](#)

Column temperature: 50°

Flow rate: 0.6 mL/min

Injection volume: 5 μL

System suitability

Samples: *Standard solution* and *System suitability solution*

[NOTE—See [Table 2](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 1.3 between oxcarbazepine related compound C and oxcarbazepine related compound A, *System suitability solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of oxcarbazepine ($C_{15}H_{12}N_2O_2$) in the portion of Oral Suspension taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of oxcarbazepine from the *Sample solution*

r_S = peak response of oxcarbazepine from the *Standard solution*

C_S = concentration of [USP Oxcarbazepine RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of oxcarbazepine in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

Test 1

Medium: 1% [sodium dodecyl sulfate](#) in [water](#); 890 mL

Apparatus 2: 75 rpm

Time: 30 min

Analysis: Shake manually a bottle of Oral Suspension for about 20 s. Using a 10-mL syringe, draw 10.0 mL of the Oral Suspension. Attach a long needle to the syringe. Deliver carefully 10.0 mL of Oral Suspension through the needle to the bottom of the vessel containing preheated *Medium*. Take about 10 mL of the *Medium* from the vessel to clean the syringe, and transfer it back to the vessel. Start the paddle rotation immediately after introduction of each sample.

Mobile phase: [Methanol](#), [glacial acetic acid](#), and [water](#) (24:1:75)

Standard solution: 0.7 mg/mL of [USP Oxcarbazepine RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter of 1-μm pore size, discarding the first few milliliters.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 310 nm

Column: 4.6-mm × 25-cm; 10-μm packing [L10](#)

Column temperature: 30°

Flow rate: 1.5 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements**Relative standard deviation:** NMT 2.0%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of oxcarbazepine ($C_{15}H_{12}N_2O_2$) dissolved:

$$\text{Result} = (r_U/r_S) \times (C_S/L) \times V \times 100$$

 r_U = peak response from the *Sample solution* r_S = peak response from the *Standard solution* C_S = concentration of [USP Oxcarbazepine RS](#) in the *Standard solution* (mg/mL) L = label claim (mg in 10 mL) V = volume of *Medium*, 900 mL**Tolerances:** NLT 80% (Q) of the labeled amount of oxcarbazepine ($C_{15}H_{12}N_2O_2$) is dissolved.**Test 2:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.**Medium:** 7.5 g/L of [sodium dodecyl sulfate](#) in [water](#); 890 mL, deaerated**Apparatus 2:** 75 rpm**Time:** 15 min**Mobile phase:** [Methanol](#), [glacial acetic acid](#), and [water](#) (24:1:75)

Standard solution: 0.7 mg/mL of [USP Oxcarbazepine RS](#) prepared as follows. Transfer a suitable amount of [USP Oxcarbazepine RS](#) to a suitable volumetric flask. Add 20% of the final volume of [acetonitrile](#) and sonicate for 10 min with frequent vortexing. Add 50% of the final volume of *Medium* and sonicate again for 10 min with frequent vortexing. Make sure [USP Oxcarbazepine RS](#) is fully dissolved at room temperature. If not fully dissolved, sonicate for an additional 10 min or until completely dissolved. Dilute with *Medium* to volume and mix well. Pass a portion of the solution through a suitable filter of 1- μ m pore size, discarding the first few milliliters. [NOTE—Immediately keep it at 10° for the *Analysis*. This solution is stable for 24 h at 10°.]

Sample solution: Use a separate bottle of Oral Suspension for each vessel. After the dissolution *Medium* has reached the appropriate temperature, remove about 10 mL of heated *Medium* from each vessel and set aside for cannula rinsing after sample introduction. Shake manually a bottle of Oral Suspension for about 20 s. Using a 10-mL syringe, draw 10.0 mL of the Oral Suspension. Wipe the syringe with paper towels to remove excess Oral Suspension that may stick to the outside of the syringe. Attach a suitable cannula to the syringe. Deliver carefully 10.0 mL of Oral Suspension through the cannula to the bottom of the vessel. Start the paddle rotation immediately after introduction of each sample. Rinse the cannula into the vessel with 10 mL of the previously removed *Medium*. Pass a portion of the solution under test through a suitable filter of 1- μ m pore size, discarding the first few milliliters. [NOTE—The plunger of the syringe should be pushed at a consistent rate and sample delivery should be completed in about 15 s.]

Chromatographic system(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 310 nm**Column:** 4.6-mm $\times$ 25-cm; 10- μ m packing [L10](#)**Temperatures****Autosampler:** 10°**Column:** 30°**Flow rate:** 1.5 mL/min**Injection volume:** 10 μ L**Run time:** NLT 2 times the retention time of oxcarbazepine**System suitability****Sample:** *Standard solution***Suitability requirements****Tailing factor:** NMT 2.5**Relative standard deviation:** NMT 2.0%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of oxcarbazepine ($C_{15}H_{12}N_2O_2$) dissolved: