

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2021
 Document Type: USP Monographs
 DocId: GUID-0689650C-A41E-46DB-A714-20A506CC9FAB_3_en-US
 DOI: https://doi.org/10.31003/USPNF_M59244_03_01
 DOI Ref: y1vhv

© 2025 USPC
 Do not distribute

Oxcarbazepine Tablets

DEFINITION

Oxcarbazepine Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of oxcarbazepine ($C_{15}H_{12}N_2O_2$).

IDENTIFICATION

Change to read:

- **A.** ▲The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-May-2021)
- **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

Change to read:

PROCEDURE

Buffer: 6.8 g/L of [monobasic potassium phosphate](#) in [water](#). Add 2 mL of [triethylamine](#). Adjust with [phosphoric acid](#) to a pH of 6.0.

Diluent: [Methanol](#) and [water](#) (80:20)

Mobile phase: [Methanol](#), [acetonitrile](#), and *Buffer* (22:16:62)

Standard stock solution: 0.5 mg/mL of [USP Oxcarbazepine RS](#) in *Diluent*. Sonication may be used to aid in dissolution.

Standard solution: 0.1 mg/mL of [USP Oxcarbazepine RS](#) in *Mobile phase* from the *Standard stock solution*

Sample stock solution: Nominally equivalent to 1.2 mg/mL of oxcarbazepine from a portion of finely powdered Tablets (NLT 20), prepared as follows. Transfer a weighed quantity of powdered Tablets, equivalent to 600 mg of oxcarbazepine, to a 500-mL volumetric flask. Add *Diluent* to fill 50% of the final volume. Sonicate for 15 min with intermittent swirling, cool to room temperature, and dilute with *Diluent* to volume. Pass this solution through a suitable glass filter of 2-μm pore size, and discard the first portion of the filtrate.

Sample solution: ▲Nominally▲ (USP 1-May-2021) 0.1 mg/mL of oxcarbazepine in *Mobile phase* from a portion of the filtrate obtained from the *Sample stock solution*

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 210–400 nm.▲ (USP 1-May-2021)

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 10 μL

Temperatures

Sample: 5°

Column: 50°

▲**Run time:** NLT 1.6 times the retention time of oxcarbazepine▲ (USP 1-May-2021)

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: ▲NMT 1.0%▲ (USP 1-May-2021)

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 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 Oxcarbazepine RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Test 1

Medium

For Tablets labeled to contain 150 mg: 0.3% (w/v) [sodium dodecyl sulfate](#) in [water](#); 900 mL, deaerated

For Tablets labeled to contain 300 mg: 0.6% (w/v) [sodium dodecyl sulfate](#) in [water](#); 900 mL, deaerated

For Tablets labeled to contain 600 mg: 1.0% (w/v) [sodium dodecyl sulfate](#) in [water](#); 900 mL, deaerated

Apparatus 2: 60 rpm

Times: 30 and 60 min

Standard stock solution: 0.35 mg/mL of [USP Oxcarbazepine RS](#) in [methanol](#)

Standard solution: Dilute the *Standard stock solution* with the corresponding *Medium* to obtain a final concentration of 0.0175 mg/mL of [USP Oxcarbazepine RS](#).

Sample solution: Use portions of the solution under test passed through a suitable filter of 0.45-μm pore size. The volume of the solution under test withdrawn must be replaced by the same volume of corresponding *Medium*. Dilute with the appropriate *Medium* if necessary, according to the Tablet strength, to obtain a final concentration similar to that of the *Standard solution*.

Instrumental conditions

Mode: UV-Vis

Analytical wavelength: 256 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of oxcarbazepine ($C_{15}H_{12}N_2O_2$) dissolved at 30 min (Q_{30}):

$$Q_{30} = (A_U/A_S) \times (C_S/L) \times D \times V \times 100$$

Calculate the percentage of the labeled amount of oxcarbazepine ($C_{15}H_{12}N_2O_2$) dissolved at 60 min (Q_{60}):

$$Q_{60} = [(A_U/A_S) \times (C_S/L) \times D \times V \times 100] + [Q_{30} \times (V_S/V)]$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

D = dilution factor of the *Sample solution*

V = volume of *Medium*, 900 mL

V_S = volume of the solution under test withdrawn (mL)

Tolerances: NLT 70% (Q) of the labeled amount of oxcarbazepine is dissolved in 30 min; NLT 80% (Q) of the labeled amount of oxcarbazepine is dissolved in 60 min.

Test 2: If the product complies with this test, the labeling indicates that the product meets USP *Dissolution Test 2*.

Medium

For Tablets labeled to contain 150 mg: 0.3% (w/v) [sodium dodecyl sulfate](#) in [water](#); 900 mL, deaerated

For Tablets labeled to contain 300 mg: 0.6% (w/v) [sodium dodecyl sulfate](#) in [water](#); 900 mL, deaerated

For Tablets labeled to contain 600 mg: 1.0% (w/v) [sodium dodecyl sulfate](#) in [water](#); 900 mL, deaerated

Apparatus 2: 60 rpm



Documents

Document Sharing Hub

Times: 30 and 60 min

Standard stock solution: 3.3 mg/mL of [USP Oxcarbazepine RS](#) in [methanol](#). [NOTE—This solution is stable for 22 h at 10°.]

Standard solution: Dilute the *Standard stock solution* with the corresponding *Medium*, according to the Tablet strength, to obtain a final concentration of $(L/900)$ mg/mL, where L is the label claim in mg/Tablet.

Sample solution: Use portions of the solution under test passed through a suitable filter of 0.45-μm pore size. The volume of the solution under test withdrawn must be replaced by the same volume of corresponding *Medium*.

Instrumental conditions

Mode: UV-Vis

Analytical wavelength: 304 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of oxcarbazepine ($C_{15}H_{12}N_2O_2$) dissolved at 30 min (Q_{30}):

$$Q_{30} = (A_U/A_S) \times (C_S/L) \times D \times V \times 100$$

Calculate the percentage of the labeled amount of oxcarbazepine ($C_{15}H_{12}N_2O_2$) dissolved at 60 min (Q_{60}):

$$Q_{60} = [(A_U/A_S) \times (C_S/L) \times D \times V \times 100] + [Q_{30} \times (V_S/V)]$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

D = dilution factor of the *Sample solution*

V = volume of *Medium*, 900 mL

V_S = volume of the solution under test withdrawn (mL)

Tolerances

For Tablets labeled to contain 150 or 300 mg: NLT 70% (Q) of the labeled amount of oxcarbazepine is dissolved in 30 min; NLT 80% (Q) of the labeled amount of oxcarbazepine is dissolved in 60 min.

For Tablets labeled to contain 600 mg: NLT 50% (Q) of the labeled amount of oxcarbazepine is dissolved in 30 min; NLT 80% (Q) of the labeled amount of oxcarbazepine is dissolved in 60 min.

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

IMPURITIES

[NOTE—On the basis of the synthetic route, perform either *Organic Impurities, Procedure 1* or *Organic Impurities, Procedure 2*. If methoxycarbamazepine is a potential degradation product, *Procedure 1* is recommended. If carbamazepinedione or dibenzazepinodione is a potential degradation product, *Procedure 2* is recommended.]

Change to read:

• ORGANIC IMPURITIES, PROCEDURE 1

Buffer: Prepare as directed in the Assay.

Diluent: [Methanol](#) and [water](#) (60:40)

Mobile phase: [Methanol](#), [acetonitrile](#), and *Buffer* (29:21:75)

System suitability solution: 0.5 mg/mL of [USP Oxcarbazepine RS](#) and 1.0 μg/mL of [USP Carbamazepine RS](#) in *Mobile phase*

Standard solution: 0.5 μg/mL of [USP Oxcarbazepine RS](#) in *Mobile phase*

Sample stock solution: Nominally equivalent to 1.2 mg/mL of oxcarbazepine from a portion of finely powdered Tablets (NLT 20), prepared as follows. Transfer a weighed quantity of powdered Tablets, equivalent to 600 mg of oxcarbazepine, to a 500-mL volumetric flask. Add *Diluent* to fill 50% of the final volume. Sonicate for 15 min with intermittent swirling, cool to room temperature, and dilute with *Diluent* to volume. Pass this solution through a suitable glass filter of 2-μm pore size, and discard the first portion of the filtrate.

Sample solution: ▲Nominally 500 μg/mL▲ (USP 1-May-2021) of oxcarbazepine from the *Sample stock solution* in *Mobile phase*

Chromatographic system: Proceed as directed in the Assay, ▲except for the *Run time*.

Run time: NLT 10 times the retention time of oxcarbazepine▲ (USP 1-May-2021)

System suitability