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

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

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

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

[NOTE—See *Table 1* for relative retention times.]

Suitability requirements

Resolution: NLT 8.0 between oxcarbazepine and carbamazepine, *System suitability solution*

Relative standard deviation: NMT 10.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any individual degradation product in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of each individual ▲degradation product▲ (USP 1-May-2021) 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* ▲(µg/mL)▲ (USP 1-May-2021)

C_U = nominal concentration of oxcarbazepine in the *Sample solution* ▲(µg/mL)▲ (USP 1-May-2021)

F = relative response factor for the corresponding ▲degradation product▲ (USP 1-May-2021) (see *Table 1*)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Oxcarbazepine	1.0	1.0	—
Carbamazepine	1.6	1.5	0.5
Dibenzazepinone[a]	2.0	1.0	0.05
Methoxycarbamazepine[b]	2.3	1.3	0.05
Any individual unspecified degradation product	—	1.0	0.10
Total impurities	—	—	0.75

[a] 10(11*H*)-Oxo-5*H*-dibenz[*b,f*]azepine.

[b] 10-Methoxy-5*H*-dibenz[*b,f*]azepine-5-carboxamide.

Change to read:

• **ORGANIC IMPURITIES, PROCEDURE 2**

Buffer A: 4.2 g of tris(hydroxymethyl)amino methane and 0.2 g of edetate disodium in 1 L of water

Buffer B: 18 g of tris(hydroxymethyl)amino methane and 0.9 g of edetate disodium in 1 L of water

Diluent: Acetonitrile and 1.8 g/L of ascorbic acid in water (1:99)

Solution A: Acetonitrile, tetrahydrofuran, and *Buffer A* (5:10:85)

Solution B: Acetonitrile, tetrahydrofuran, and *Buffer B* (70:10:20)

Mobile phase: See *Table 2*.

Table 2

Time (min)	Solution A (%)	Solution B (%)
0	95	5
33.0	30	70
33.1	95	5
45.0	95	5

System suitability stock solution: 1 µg/mL of USP Oxcarbazepine Related Compound C RS and 12 µg/mL of USP Carbamazepine RS in acetonitrile. Sonication may be used to aid in dissolution. [NOTE—The water bath temperature should not exceed 23°.]

System suitability solution: 0.05 µg/mL of USP Oxcarbazepine Related Compound C RS and 0.6 µg/mL of USP Carbamazepine RS▲ ▲(USP 1-May-2021) prepared as follows. Transfer a suitable volume of *System suitability stock solution* to a volumetric flask containing 50% of the final volume of *Diluent*. Allow the solution to reach ambient temperature, and dilute with acetonitrile to volume.

Standard stock solution: 12 µg/mL of USP Carbamazepine RS in acetonitrile. Sonication may be used to aid in dissolution. [NOTE—The water bath temperature should not exceed 23°.]

Standard solution: 0.6 µg/mL of USP Carbamazepine RS from *Standard stock solution* prepared as follows. Transfer a suitable volume of *Standard stock solution* to a flask containing 50% of the final volume of *Diluent* and 20% of the final volume of acetonitrile. Allow the solution to reach ambient temperature, and dilute with acetonitrile to volume.

Sample stock solution: ▲Nominally equivalent to▲ (USP 1-May-2021) 1.5 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 about 375 mg of oxcarbazepine, to a 250-mL volumetric flask. Add 150 mL of acetonitrile, and sonicate for 15 min. Shake for 15 min, and dilute with acetonitrile to volume. Mix, and allow the suspension to settle for 30 min. Use the supernatant. [NOTE—The water bath temperature should not exceed 23°.]

Sample solution: ▲Nominally 300 µg/mL▲ (USP 1-May-2021) of oxcarbazepine from the *Sample stock solution* prepared as follows. Transfer a suitable volume of *Sample stock solution* to a volumetric flask containing 50% of the final volume of *Diluent* and 20% of the final volume of acetonitrile. Allow the solution to warm to ambient temperature, and dilute with acetonitrile to volume. Pass a portion of the solution through a suitable filter of 0.45-µm pore size.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 3.0-mm × 25-cm; 5-µm packing L1

Flow rate: 0.5 mL/min

Injection volume: 20 µL

Temperatures

Sample: 5°

Column: 35°

System suitability

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

[NOTE—See *Table 3* for relative retention times.]

Suitability requirements

Resolution: NLT 1.2 between oxcarbazepine related compound C and carbamazepine, *System suitability solution*

Relative standard deviation: NMT 15%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any individual degradation product in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of each individual ▲degradation product▲ (USP 1-May-2021) from the *Sample solution*

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

C_S = concentration of USP Carbamazepine RS in the *Standard solution* ▲(µg/mL)▲ (USP 1-May-2021)

C_U = nominal concentration of oxcarbazepine in the *Sample solution* ▲(µg/mL)▲ (USP 1-May-2021)

F = relative response factor for the corresponding ▲degradation product▲ (USP 1-May-2021) (see *Table 3*)

Acceptance criteria: See *Table 3*.

Table 3

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Carbamazepinedione[a]	0.72	0.70	0.2
Oxcarbazepine	1.0	1.0	—
Oxcarbazepine related compound C[b]	1.3	—	—
Carbamazepine	1.4	1.0	0.5
Dibenzazepinodione[c]	1.7	2.8	0.2
Any individual unspecified degradation product	—	1.0	0.1
Total impurities	—	—	1.0

[a] 10,11-Dioxo-10,11-dihydro-5*H*-dibenzo[*b*,*f*]azepine-5-carboxamide.

[b] For system suitability and identification purposes only. Process impurity, not included in total.

[c] 5*H*-Dibenzo[*b*,*f*]azepine-10,11-dione.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. Store at controlled room temperature.

• **Labeling:** When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used. If a test for *Organic Impurities* other than *Procedure 1* is used, the labeling states the test with which the article complies.

• **USP Reference Standards** ⟨11⟩

USP Carbamazepine RS

USP Oxcarbazepine RS

USP Oxcarbazepine Related Compound C RS

Acridin-9(10*H*)-one.

$C_{13}H_9NO$ 195.22

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

Topic/Question	Contact	Expert Committee
OXCARBAZEPINE TABLETS	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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 45(3)
Current DocID: GUID-0689650C-A41E-46DB-A714-20A506CC9FAB_3_en-US
DOI: https://doi.org/10.31003/USPNF_M59244_03_01
DOI ref: y1vhv