

Printed on: Fri Jan 09 2026, 12:28:44 pm

Printed by: Ita Aryani

Status: Currently Official on 09-Jan-2026

Official Date: Official as of 22-Sep-2022

Document Type: USP Monographs

DOI: https://doi.org/10.31003/USPNF_M12560_05_01

Printed from: https://online.uspnf.com/uspnf/document/1_GUID-AF4B6A10-B758-43FD-9DF8-33ED331BA2DB_5_en-US

© 2026 USPC

Do not distribute

NOTICE: Revision Bulletin

Posted on: 21-Sep-2022

Carbamazepine Tablets

Expert Committee: Small Molecules 4

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 4 Expert Committee has revised the Carbamazepine Tablets monograph. The purpose of this revision is to add Dissolution Test 4 to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s).

The Carbamazepine Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Yanyin Yang, Senior Scientist II (301-692-3623 or yanyin.yang@usp.org).

Carbamazepine Tablets

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click <https://www.uspnf.com/rb-carbamazepine-tabs-20220930>.

DEFINITION

Carbamazepine Tablets contain NLT 92.0% and NMT 108.0% of the labeled amount of carbamazepine ($C_{15}H_{12}N_2O$).

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197M

Sample solution: Nominally 250 mg of carbamazepine from powdered Tablets in 15 mL of acetone

Analysis: Boil the *Sample solution* for 5 min in a suitable beaker. Filter while hot, using two 5-mL portions of hot acetone to effect transfer.

Evaporate the filtrate with the aid of nitrogen to 5 mL, and cool in an ice bath until crystals are formed. Filter the crystals, wash with 3 mL of cold acetone, and dry under vacuum at 70° for 30 min. Use the crystals.

Acceptance criteria: Meet the requirements

- **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: Methanol, [tetrahydrofuran](#), and water (12:3:85). Add 0.22 mL of [formic acid](#) and then 0.5 mL of [triethylamine](#) to each L.

Diluent: Methanol and water (50:50)

System suitability stock solution: 0.1 mg/mL of [USP Carbamazepine RS](#) and 0.5 mg/mL of [USP Carbamazepine Related Compound A RS](#) in methanol. Sonication may be used to aid in dissolution.

System suitability solution: 0.01 mg/mL of [USP Carbamazepine RS](#) and 0.05 mg/mL of [USP Carbamazepine Related Compound A RS](#) from *System suitability stock solution* in *Diluent*

Standard stock solution: 2 mg/mL of [USP Carbamazepine RS](#) in methanol. Sonication may be used to aid in dissolution.

Standard solution: 0.2 mg/mL of [USP Carbamazepine RS](#) from *Standard stock solution* in *Diluent*

Sample stock solution: Nominally 2 mg/mL of carbamazepine from NLT 20 Tablets prepared as follows. Finely powder the Tablets, and transfer a portion of the powder to a suitable volumetric flask. Add 80% of the final flask volume of methanol, sonicate for 15 min, and allow to cool to room temperature. Dilute with methanol to volume. Pass through a suitable filter and discard the first few mL of filtrate.

Sample solution: Nominally 0.2 mg/mL of carbamazepine from *Sample stock solution* in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 4.0- or 4.6-mm × 25-cm; 7-μm packing L10

Flow rate: 1.5 mL/min

Injection volume: 20 μL

Run time: NLT 1.6 times the retention time of carbamazepine

System suitability

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

[NOTE—See [Table 3](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 1.7 between carbamazepine related compound A and carbamazepine, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of carbamazepine ($C_{15}H_{12}N_2O$) 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 Carbamazepine RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 92.0%–108.0%

PERFORMANCE TESTS

Change to read:

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

For products labeled as 100-mg chewable Tablets

Test 1: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 1*.

Medium: Water containing 1% [sodium lauryl sulfate](#); 900 mL

Apparatus 2: 75 rpm

Time: 60 min

Standard solution: [USP Carbamazepine RS](#) in *Medium*. [NOTE—A volume of methanol NMT 1% of the final total volume of the *Standard solution* may be used to dissolve the carbamazepine.]

Sample solution: Filtered portion of the solution under test, diluted with *Medium* if necessary

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 288 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of carbamazepine ($C_{15}H_{12}N_2O$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

V = volume of the *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of carbamazepine ($C_{15}H_{12}N_2O$) is dissolved. Use [Dissolution \(711\)](#), [Acceptance Table 1](#) with the following exceptions: at S_2 , no unit is less than $Q - 5\%$; at S_3 , no unit is less than $Q - 10\%$; and NMT 2 of the 24 units are less than $Q - 5\%$.

For products labeled as 200-mg Tablets

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

Medium, Apparatus 2, Standard solution, Sample solution, and Instrumental conditions: Proceed as directed in *Test 1*.

Times: 15 and 60 min

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the concentration (C_i) of carbamazepine ($C_{15}H_{12}N_2O$) in the sample withdrawn from the vessel at each time point (i):

$$\text{Result} = (A_U/A_S) \times C_S$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

Calculate the percentage of the labeled amount of carbamazepine ($C_{15}H_{12}N_2O$) dissolved at each time point (i):

$$\text{Result}_1 = C_1 \times V \times (1/L) \times 100$$

$$\text{Result}_2 = [(C_2 \times V_2) + (C_1 \times V_S)] \times (1/L) \times 100$$

C_i = concentration of carbamazepine in the portion of sample withdrawn at the specified time point (i) (mg/mL)

V = volume of the *Medium*, 900 mL

L = label claim (mg/Tablet)

V_2 = volume of the *Medium* at time point 2 (mL)

V_S = volume of the *Sample solution* withdrawn at each time point (i) (mL)

Tolerances: See [Table 1](#).

Table 1

Time Point (i)	Time (min)	Amount Dissolved (%)
1	15	45–75
2	60	NLT 75

Use [Dissolution \(711\)](#), [Acceptance Table 2](#) with the following exceptions. At 15 min: at L_2 , no unit is more than 5% outside the stated range; at L_3 , no unit is more than 10% outside the stated range; and NMT 2 of the 24 units are more than 5% outside the stated range.

At 60 min: at L_2 , no unit is less than $Q - 5\%$; at L_3 , no unit is less than $Q - 10\%$; and NMT 2 of the 24 units are less than $Q - 5\%$.

Test 3: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 3*.

Medium, Apparatus 2, Standard solution, Sample solution, and Instrumental conditions: Proceed as indicated in *Test 1*.

Times: 15 and 60 min

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the concentration (C_i) of carbamazepine ($C_{15}H_{12}N_2O$) in the sample withdrawn from the vessel at each time point (i):

$$\text{Result} = (A_U/A_S) \times C_S$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

Calculate the percentage of the labeled amount of carbamazepine ($C_{15}H_{12}N_2O$) dissolved at each time point (i):

$$\text{Result}_1 = C_1 \times V \times (1/L) \times 100$$

$$\text{Result}_2 = [(C_2 \times V_2) + (C_1 \times V_s)] \times (1/L) \times 100$$

C_i = concentration of carbamazepine in the portion of sample withdrawn at the specified time point (i) (mg/mL)

V = volume of the *Medium*, 900 mL

L = label claim (mg/Tablet)

V_2 = volume of the *Medium* at time point 2 (mL)

V_s = volume of the *Sample solution* withdrawn at each time point (i) (mL)

Tolerances: See [Table 2](#).

Table 2

Time Point (i)	Time (min)	Amount Dissolved (%)
1	15	60–85
2	60	NLT 75

Use [Dissolution \(711\)](#), [Acceptance Table 2](#) with the following exceptions. At 15 min: at L_2 , no unit is more than 5% outside the stated range; at L_3 , no unit is more than 10% outside the stated range; and NMT 2 of the 24 units are more than 5% outside the stated range. At 60 min: at L_2 , no unit is less than $Q - 5\%$; at L_3 , no unit is less than $Q - 10\%$; and NMT 2 of the 24 units are less than $Q - 5\%$.

▲ **Test 4:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 4*.

Medium: [Water](#) containing 1% [sodium dodecyl sulfate](#); 900 mL

Apparatus 2: 75 rpm

Time: 45 min

Standard stock solution: 0.9 mg/mL of [USP Carbamazepine RS](#) in [methanol](#). Sonicate to dissolve as needed.

Standard solution: 9 µg/mL of [USP Carbamazepine RS](#) from *Standard stock solution* in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size and discard the first 3 mL of the filtrate. Dilute with *Medium* to a concentration similar to that of the *Standard solution*.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV

Analytical wavelength: 288 nm

Cell length: 1 cm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of carbamazepine ($C_{15}H_{12}N_2O$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times D \times V \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

D = dilution factor

V = volume of the *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of carbamazepine ($C_{15}H_{12}N_2O$) is dissolved.▲ (RB 22-Sep-2022)

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

IMPURITIES**• ORGANIC IMPURITIES**

Mobile phase, Diluent, and System suitability solution: Proceed as directed in the Assay.

Standard stock solution: 0.02 mg/mL each of [USP Carbamazepine RS](#), [USP Carbamazepine Related Compound B RS](#), and [USP 9-Methylacridine RS](#) in methanol. Sonication may be used to aid in dissolution.

Standard solution: 0.001 mg/mL each of [USP Carbamazepine RS](#), [USP Carbamazepine Related Compound B RS](#), and [USP 9-Methylacridine RS](#) from *Standard stock solution* in *Diluent*

Sample solution: Nominally 1 mg/mL of carbamazepine from NLT 20 Tablets prepared as follows. Finely powder the Tablets, and transfer a portion of the powder to a suitable volumetric flask. Add about 50% of the final flask volume of *Diluent*, sonicate for 15 min, and allow to cool to room temperature. Dilute with *Diluent* to volume. Pass through a suitable filter and discard the first few mL of filtrate.

Chromatographic system: Proceed as directed in the Assay except use a *Run time* of NLT 3.5 times the retention time of carbamazepine.

System suitability

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

[NOTE—See [Table 3](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 1.7 between carbamazepine related compound A and carbamazepine, *System suitability solution*

Relative standard deviation: NMT 10.0% each for carbamazepine, carbamazepine related compound B, and 9-methylacridine, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of carbamazepine related compound B and 9-methylacridine in the portion of Tablets taken:

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

r_U = peak response of carbamazepine related compound B or 9-methylacridine from the *Sample solution*

r_S = peak response of carbamazepine related compound B or 9-methylacridine from the *Standard solution*

C_S = concentration of [USP Carbamazepine Related Compound B RS](#) or [USP 9-Methylacridine RS](#) in the *Standard solution* (mg/mL)

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

Calculate the percentage of other degradation products in the portion of Tablets taken:

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

r_U = peak response of any individual unspecified degradation product 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* (mg/mL)

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

Acceptance criteria: See [Table 3](#). Disregard peaks below 0.05%.

Table 3

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
9-Methylacridine	0.54	0.2
Carbamazepine related compound A ^a	0.87	—
Carbamazepine	1.0	—
Carbamazepine related compound B	3.1	0.2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Any individual unspecified degradation product	—	0.2
Total degradation products	—	0.30

^a This is a process impurity that is controlled in the drug substance. It is not to be reported or included in the total degradation products.

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers, preferably of glass. Protect from light and moisture. Store at controlled room temperature.

• **LABELING:** The labeling indicates the *Dissolution* test with which the product complies.

• **USP REFERENCE STANDARDS (11)**

[USP Carbamazepine RS](#)

[USP Carbamazepine Related Compound A RS](#)

10,11-Dihydrocarbamazepine.

$C_{15}H_{14}N_2O$ 238.29

[USP Carbamazepine Related Compound B RS](#)

5*H*-Dibenz[*b,f*]azepine.

$C_{14}H_{11}N$ 193.25

[USP 9-Methylacridine RS](#)

9-Methylacridine.

$C_{14}H_{11}N$ 193.25

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

Topic/Question	Contact	Expert Committee
CARBAMAZEPINE TABLETS	Documentary Standards Support	SM42025 Small Molecules Therapeutic Areas 4
REFERENCE STANDARDS SUPPORT	RS Technical Services RSTECH@usp.org	SM42025 Small Molecules Therapeutic Areas 4

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 40(4)

DOI: https://doi.org/10.31003/USPNF_M12560_05_01