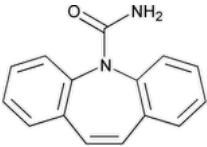


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Carbamazepine

Change to read:



C₁₅H₁₂N₂O 236.27

▲ (USP 1-Dec-2023)

5*H*-Dibenz[*b,f*]azepine-5-carboxamide CAS RN®: 298-46-4; UNII: 33CM23913M.

DEFINITION

Carbamazepine contains NLT 98.0% and NMT 102.0% of carbamazepine (C₁₅H₁₂N₂O), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197M ▲ or 197A ▲ (USP 1-Dec-2023)
- **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

Solution A: Add 0.5 mL of [triethylamine](#) and 0.5 mL of [formic acid](#) to 1000 mL of [water](#).

Solution B: Add 0.25 mL of [formic acid](#) to 1000 mL of [methanol](#).

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20
3	80	20
12	60	40
18	45	55
20	45	55
20.1	80	20
23	80	20

Diluent: [Methanol](#) and [water](#) (50:50)

System suitability stock solution: 0.02 mg/mL each of [USP Carbamazepine RS](#) and [USP Carbamazepine Related Compound A RS](#) prepared as follows. ▲ Transfer suitable amounts of [USP Carbamazepine RS](#) and [USP Carbamazepine Related Compound A RS](#) to a suitable volumetric flask. Add 50% of the flask volume of [methanol](#) to dissolve. ▲ (USP 1-Dec-2023) Dilute with [water](#) to volume.

System suitability solution: 0.002 mg/mL each of [USP Carbamazepine RS](#) and [USP Carbamazepine Related Compound A RS](#) from the *System suitability stock solution* in *Diluent*

Standard solution: 0.1 mg/mL of [USP Carbamazepine RS](#) prepared as follows. ▲ Transfer a suitable amount of [USP Carbamazepine RS](#) to a suitable volumetric flask. Add 50% of the flask volume of [methanol](#) to dissolve. ▲ (USP 1-Dec-2023) Dilute with [water](#) to volume.

Sample solution: 0.1 mg/mL of Carbamazepine prepared as follows. ▲Transfer a suitable amount of sample to a suitable volumetric flask. Add 50% of the flask volume of [methanol](#) to dissolve. ▲(USP 1-Dec-2023) Dilute with [water](#) to volume. Pass through a suitable filter of 0.2-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 2.1-mm × 10-cm; 1.8-µm packing [L10](#)

Column temperature: 40°

Flow rate: 0.3 mL/min

Injection volume: 2 µL

System suitability

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

Suitability requirements

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

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of carbamazepine ($C_{15}H_{12}N_2O$) in the portion of Carbamazepine taken:

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

r_U = peak response ▲ of carbamazepine ▲(USP 1-Dec-2023) from the *Sample solution*

r_S = peak response ▲ of carbamazepine ▲(USP 1-Dec-2023) from the *Standard solution*

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

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

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• [CHLORIDE AND SULFATE \(221\), Chloride](#)

Sample solution: Boil 1.0 g of Carbamazepine in 20.0 mL of [water](#) for 10 min, cool, adjust the volume to 20 mL, and filter. Use a 10.0-mL portion of the filtrate.

Acceptance criteria: 0.014%; the *Sample solution* contains no more chloride than corresponds to 0.10 mL of 0.020 N [hydrochloric acid](#).

• [RESIDUE ON IGNITION \(281\)](#)

Sample: 2.0 g of Carbamazepine

Acceptance criteria: NMT 0.1%

Change to read:

• ORGANIC IMPURITIES

Solution A, Solution B, Mobile phase, Diluent, and Chromatographic system: Proceed as directed in the Assay.

▲**Sensitivity stock solution:** 0.03 mg/mL each of [USP Carbamazepine RS](#), [USP Carbamazepine Related Compound A RS](#), and [USP Carbamazepine Related Compound B RS](#), prepared as follows. Transfer suitable amounts of [USP Carbamazepine RS](#), [USP Carbamazepine Related Compound A RS](#), and [USP Carbamazepine Related Compound B RS](#) to a suitable volumetric flask. Add 50% of the flask volume of [methanol](#) to dissolve. Dilute with [water](#) to volume.

Sensitivity solution: 0.0003 mg/mL each of [USP Carbamazepine RS](#), [USP Carbamazepine Related Compound A RS](#), and [USP Carbamazepine Related Compound B RS](#) from the *Sensitivity stock solution* in *Diluent* ▲(USP 1-Dec-2023)

Standard stock solution: ▲0.03 mg/mL of [USP Carbamazepine RS](#), and 0.05 mg/mL each of [USP Carbamazepine Related Compound A RS](#) and [USP Carbamazepine Related Compound B RS](#), prepared as follows. Transfer a suitable amount of [USP Carbamazepine RS](#), [USP Carbamazepine Related Compound A RS](#), and [USP Carbamazepine Related Compound B RS](#) to a suitable volumetric flask. Add 50% of the flask volume of [methanol](#) to dissolve. ▲(USP 1-Dec-2023) Dilute with [water](#) to volume.

Standard solution: ▲0.0006 ▲(USP 1-Dec-2023) mg/mL ▲(USP 1-Dec-2023) of [USP Carbamazepine RS](#), ▲and 0.001 mg/mL each of ▲(USP 1-Dec-2023) [USP Carbamazepine Related Compound A RS](#) and [USP Carbamazepine Related Compound B RS](#) from the *Standard stock solution* in *Diluent*

Sample solution: 1.0 mg/mL of Carbamazepine prepared as follows. ▲Transfer a suitable amount of sample to a suitable volumetric flask. Add 50% of the flask volume of [methanol](#) to dissolve. ▲(USP 1-Dec-2023) Dilute with [water](#) to volume. Pass through a suitable filter of 0.2-µm pore size.