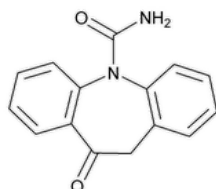


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Oxcarbazepine



$C_{15}H_{12}N_2O_2$ 252.27

5*H*-Dibenz[*b,f*]azepine-5-carboxamide, 10,11-dihydro-10-oxo-;

10,11-Dihydro-10-oxo-5*H*-dibenz[*b,f*]azepine-5-carboxamide CAS RN®: 28721-07-5; UNII: VZI5B1W380.

DEFINITION

Oxcarbazepine contains NLT 98.0% and NMT 102.0% of oxcarbazepine ($C_{15}H_{12}N_2O_2$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)

[NOTE—If the spectrum obtained shows differences, dissolve the substance to be examined in chloroform, and evaporate to dryness. Compare the spectrum of the residue to that of a similarly prepared [USP Oxcarbazepine RS](#).]

- **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

Buffer: 6.8 g/L of monobasic potassium phosphate in water. For each liter prepared, add 2 mL of triethylamine, and mix. Adjust with phosphoric acid to a pH of 6.0 ± 0.1 .

Mobile phase: Methanol, acetonitrile, and *Buffer* (11:8:31)

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

Sample solution: 0.1 mg/mL of Oxcarbazepine in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 25-cm; 5-μm packing L1

Column temperature: 50°

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 oxcarbazepine ($C_{15}H_{12}N_2O_2$) in the portion of Oxcarbazepine 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 = concentration of Oxcarbazepine in the *Sample solution* (mg/mL)

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

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• **ORGANIC IMPURITIES, PROCEDURE 1**

[NOTE—If oxcarbazepine related compound A and oxcarbazepine related compound B are known process impurities, *Organic Impurities, Procedure 2* is recommended.]

Mobile phase: Prepare as directed in the Assay.

System suitability solution: 0.1 mg/mL each of [USP Oxcarbazepine RS](#) and [USP Carbamazepine RS](#) in *Mobile phase*

Standard solution: 0.25 µg/mL of [USP Oxcarbazepine RS](#) in *Mobile phase*

Sample solution: 0.5 mg/mL of Oxcarbazepine in *Mobile phase*

Chromatographic system: Proceed as directed in the Assay, except to use a run time 10 times the retention time of oxcarbazepine.

System suitability

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

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 each impurity in the portion of Oxcarbazepine taken:

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

r_U = peak response of each impurity 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 = concentration of Oxcarbazepine in the *Sample solution* (mg/mL)

F = relative response factor (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 ^a	1.7	1.9	0.5
Oxcarbazepine related compound E	2.1	1.2	0.05
Methoxycarbamazepine ^b	2.5	1.6	0.05
Carbamazepine related compound B ^c	7.4	1.3	0.05

