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Add the following:

^Carbamazepine Extended-Release Capsules

DEFINITION

Carbamazepine Extended-Release Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of carbamazepine (C₁₅H₁₂N₂O).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Solution A: [Water](#), [triethylamine](#), and [phosphoric acid](#) (100: 0.1: 0.1)

Solution B: [Methanol](#)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	90	10
2	90	10
25	10	90
30	10	90
31	90	10
35	90	10

Standard solution: 0.08 mg/mL of [USP Carbamazepine RS](#) in [methanol](#)

Sample solution: 0.08 mg/mL of carbamazepine in [methanol](#). Pass a portion of the solution through a suitable filter, discarding the first 3 mL of filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 230 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of carbamazepine (C₁₅H₁₂N₂O) in the portion of Capsules taken:

Result = (r_U/r_S) × (C_S/C_U) × 100

r_U = peak response of carbamazepine 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: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Medium: 0.05 M phosphate buffer, pH 6.8 (dissolve 6.8 g of [potassium phosphate monobasic](#) and 0.8 g of [sodium hydroxide](#) in 1000 mL of [water](#), adjust with 1 N [sodium hydroxide](#) or with [phosphoric acid](#) to a pH of 6.8); deaerated. See [Table 2](#).

Table 2

Strength (mg)	Medium Volume (mL)
100	500
200	750
300	1000

Apparatus 2: 75 rpm, with apex vessels

Times: 1, 4, and 8 h

Standard stock solution: 1 mg/mL of [USP Carbamazepine RS](#) in [methanol](#)

Standard solution: Prepare a solution of [USP Carbamazepine RS](#) in *Medium* as directed in [Table 3](#).

Table 3

Strength (mg)	Concentration (mg/mL)
100	0.20
200	0.27
300	0.30

Sample solution: Pass a portion of the solution under test through a suitable filter.

Instrumental conditions

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

Mode: UV

Analytical wavelength: 285 nm, with a background correction at 490 nm

Cell: 0.05-cm flow cell

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 at each time point (*i*):

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

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) (see [Table 3](#))

V = volume of *Medium* (see [Table 2](#))

L = label claim for carbamazepine (mg/Capsule)

Tolerances: See [Table 4](#).