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Cyclobenzaprine Hydrochloride Extended-Release Capsules

DEFINITION

Cyclobenzaprine Hydrochloride Extended-Release Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of cyclobenzaprine hydrochloride ($C_{20}H_{21}N \cdot HCl$).

IDENTIFICATION

Change to read:

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

Standard: Transfer 90 mg of [USP Cyclobenzaprine Hydrochloride RS](#) to a 25-mL volumetric flask. Add 10 mL of water and sonicate for 30 s.

Transfer the solution to a 40-mL vial. Add 10 mL of methylene chloride. Cap the vial and shake. Centrifuge, if necessary, and transfer the lower methylene chloride layer to a watch glass. Evaporate the solvent, and use the residue. [NOTE—The use of a glass vial and a centrifuge speed of NMT 2000 rpm may be suitable. An infrared heat lamp may be used to evaporate the solvent.]

Sample: Transfer a portion of the contents of NLT 10 Capsules containing nominally 90 mg of cyclobenzaprine hydrochloride to a 25-mL volumetric flask. Add 10 mL of water and sonicate for 30 s. Transfer the solution to a 40-mL vial. Add 10 mL of methylene chloride. Cap the vial and shake. Centrifuge, and transfer the lower methylene chloride layer to a watch glass. Evaporate the solvent, and use the residue. [NOTE—The use of a glass vial and a centrifuge speed of NMT 2000 rpm may be suitable. An infrared heat lamp may be used to evaporate the solvent.]

Analysis

Samples: *Standard and Sample*

Acceptance criteria: The maxima of the IR spectrum from the *Sample* correspond to those from the *Standard*.

- **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: Add 3.7 mL of methanesulfonic acid per 1 L of water and adjust with diethylamine to a pH of 3.6.

Mobile phase: Acetonitrile, methanol, and *Buffer* (25.5:21.0:53.5)

Diluent: Acetonitrile and water (50:50)

Standard solution: 0.12 mg/mL of [USP Cyclobenzaprine Hydrochloride RS](#) in *Diluent*

Sample solution: Nominally 0.12 mg/mL of cyclobenzaprine hydrochloride from Capsules prepared as follows. Remove the contents of NLT 20 Capsules, and transfer a suitable portion of the contents to a volumetric flask. Add 80% of the final flask volume of *Diluent*. Stir and sonicate, if necessary. Dilute with *Diluent* to volume, and centrifuge. Use the supernatant.

Chromatographic system

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

Mode: LC

Detector: UV 290 nm

Column: 4.6-mm × 15-cm; 5-μm packing L1

Flow rate: 1.5 mL/min

Injection volume: 20 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 the labeled amount of cyclobenzaprine hydrochloride ($C_{20}H_{21}N \cdot HCl$) in the portion of Capsules 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 Cyclobenzaprine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 50 rpm, wire helix sinkers

Times: 2, 4, 8, and 16 h

Solution A: Transfer 10 empty Capsule shells to a 1-L volumetric flask. Add 80% of the final flask volume of *Medium*, which has been warmed to 37°, and stir until the Capsule shells have dissolved. Allow to cool, and dilute with *Medium* to volume.

Standard solution: ($L/900$) mg/mL of [USP Cyclobenzaprine Hydrochloride RS](#) in *Medium*, where L is the label claim of cyclobenzaprine hydrochloride in mg/Capsule

Sample solution: Centrifuge a portion of the solution under test. Use the supernatant.

Instrumental conditions

Mode: UV

Analytical wavelength: 290 nm

Cell: 1 cm

Blank: A mixture of *Solution A* and *Medium* prepared as follows. Transfer 10% of the final flask volume of *Solution A* to a suitable volumetric flask. Dilute with *Medium* to volume, centrifuge, and use the supernatant.

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Correct the instrument by using the *Blank*.

Calculate the concentration (C_i) of cyclobenzaprine hydrochloride ($C_{20}H_{21}N \cdot HCl$) dissolved at each time point (i):

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

A_U = absorbance from the *Sample solution* at time point i

A_S = absorbance from the *Standard solution*

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

Calculate the percentage of the labeled amount of cyclobenzaprine hydrochloride ($C_{20}H_{21}N \cdot HCl$) dissolved at each time point (i):

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

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

$$\text{Result}_3 = \{[C_3 \times [V - (2 \times V_S)]] + [(C_2 + C_1) \times V_S]\} \times (1/L) \times 100$$

$$\text{Result}_4 = \{[C_4 \times [V - (3 \times V_S)]] + [(C_3 + C_2 + C_1) \times V_S]\} \times (1/L) \times 100$$

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

V = volume of *Medium*, 900 mL

L = label claim (mg/Capsule)

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