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Cyclobenzaprine Hydrochloride Tablets

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click <https://www.uspnf.com/rb-cyclobenzaprine-hcl-tabs-20230929>.

DEFINITION

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

IDENTIFICATION

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

Sample: Transfer an amount equivalent to 50 mg of cyclobenzaprine hydrochloride from a quantity of finely powdered Tablets to a small flask. Add 10 mL of [methylene chloride](#), swirl to dissolve, and filter. Evaporate the clear filtrate to about 5 mL, transfer to a centrifuge tube, and add 1–2 mL of [ether](#). Evaporate with the aid of a current of air to about 1 mL, and agitate until crystallization occurs. Wash the crystals with several portions of [ether](#), and air-dry.

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

Buffer: 11.4 g/L of [ammonium acetate](#) in water. Adjust with [ammonium hydroxide](#) to a pH of 7.2.

Mobile phase: [Methanol](#) and *Buffer* (65:35)

Standard solution: 0.2 mg/mL of [USP Cyclobenzaprine Hydrochloride RS](#) in *Mobile phase*. Sonication may be used to aid in dissolution.

Sample solution: Nominally 0.2 mg/mL of cyclobenzaprine hydrochloride from NLT 20 finely powdered Tablets in *Mobile phase* prepared as follows. Transfer a suitable amount of the powder to a suitable volumetric flask. Add 60% of the flask volume of *Mobile phase*, and sonicate for 30 min. Allow the solution to cool to room temperature, and then dilute with *Mobile phase* to volume. Centrifuge the solution, and use the supernatant.

Chromatographic system

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

Mode: LC

Detector: UV 226 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L7](#)

Column temperature: 30°

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 0.85%

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 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 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 1: 50 rpm

Time: 30 min

Sample solution: Pass a portion of the solution under test through a suitable filter, and dilute with *Medium* if necessary.

Standard solution: [USP Cyclobenzaprine Hydrochloride RS](#) in *Medium* with a concentration similar to the one expected in the *Sample solution*

Instrumental conditions

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

Mode: UV

Analytical wavelength: 290 nm

Analysis

Samples: *Sample solution* and *Standard solution*

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

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of cyclobenzaprine hydrochloride ($C_{20}H_{21}N \cdot HCl$) is dissolved.

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

IMPURITIES

Change to read:

• ORGANIC IMPURITIES

Buffer and Mobile phase: Proceed as directed in the Assay.

Standard solution: 0.6 µg/mL each of [USP Cyclobenzaprine Hydrochloride RS](#), [USP Cyclobenzaprine Related Compound A RS](#), and [USP Cyclobenzaprine Related Compound B RS](#) in *Mobile phase*

Sample solution: Nominally 400 µg/mL of cyclobenzaprine hydrochloride from NLT 20 finely powdered Tablets in *Mobile phase* prepared as follows. Transfer a suitable amount of the powder to a suitable volumetric flask. Add 75% of the flask volume of *Mobile phase*, and sonicate for 30 min. Allow the solution to cool to room temperature, and then dilute with *Mobile phase* to volume. Centrifuge the solution, and use the supernatant.

Chromatographic system

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

Mode: LC

Detector: UV 226 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L7](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 10 µL

Run time: NLT 3 times the retention time of cyclobenzaprine

System suitability

Sample: *Standard solution*