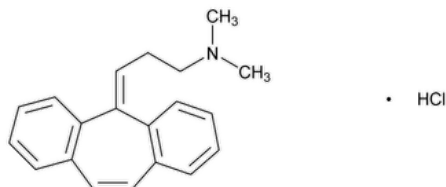


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Cyclobenzaprine Hydrochloride



$C_{20}H_{21}N \cdot HCl$ 311.85

1-Propanamine, 3-(5H-dibenzo[a,d]cyclohepten-5-ylidene)-N,N-dimethyl-, hydrochloride;

N,N-Dimethyl-5H-dibenzo[a,d]cycloheptene- $\Delta^{5,Y}$ -propylamine hydrochloride CAS RN®: 6202-23-9; UNII: 0VE05JYS2P.

DEFINITION

Cyclobenzaprine Hydrochloride contains NLT 98.0% and NMT 102.0% of cyclobenzaprine hydrochloride ($C_{20}H_{21}N \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy](#): 197M ▲ (CN 1-May-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C.** [IDENTIFICATION TESTS—GENERAL \(191\), Chemical Identification Tests, Chloride](#)
Sample solution: 20 mg/mL of Cyclobenzaprine Hydrochloride in [water](#)
Acceptance criteria: Meets the requirements

ASSAY

PROCEDURE

Mobile phase: Dissolve 2.0 g of [ammonium acetate](#) in 350 mL of [water](#). Add 650 mL of methanol, and adjust with 25% [ammonium hydroxide](#) to a pH of 8.9.

Standard solution: 0.2 mg/mL of [USP Cyclobenzaprine Hydrochloride RS](#) in *Mobile phase*

Sample solution: 0.2 mg/mL of Cyclobenzaprine Hydrochloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 226 nm

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

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 10 μ L

Run time: NLT 2 times the retention time of cyclobenzaprine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of cyclobenzaprine hydrochloride ($C_{20}H_{21}N \cdot HCl$) in the portion of Cyclobenzaprine Hydrochloride 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 = concentration of Cyclobenzaprine Hydrochloride in the *Sample solution* (mg/mL)

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

IMPURITIES

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

Change to read:

• ORGANIC IMPURITIES

Buffer: 5.7 g/L of [ammonium acetate](#) in [water](#). Adjust with 25% [ammonium hydroxide](#) to a pH of 7.2.

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

System suitability solution: 0.5 mg/mL of [USP Cyclobenzaprine Hydrochloride RS](#) and 0.75 µg/mL each of [USP Cyclobenzaprine Related Compound A RS](#) and [USP Cyclobenzaprine Related Compound B RS](#) in *Mobile phase*

Standard solution: 0.5 µg/mL of [USP Cyclobenzaprine Hydrochloride RS](#) in *Mobile phase*

Sample solution: 500 µg/mL of Cyclobenzaprine Hydrochloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 240 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 3.5 times the retention time of cyclobenzaprine

System suitability

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

[NOTE—See [Table 1](#) for relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between cyclobenzaprine related compound A and cyclobenzaprine related compound B, *System suitability solution*

Tailing factor: NMT 2.0 for the cyclobenzaprine peak, *System suitability solution*

Relative standard deviation: NMT 5.0% for cyclobenzaprine, *Standard solution*

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of each specified impurity and any individual unspecified impurity in the portion of Cyclobenzaprine Hydrochloride 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 cyclobenzaprine from the *Standard solution*

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

C_U = concentration of Cyclobenzaprine Hydrochloride in the *Sample solution* (µg/mL)

F = relative response factor for each impurity (see [Table 1](#))

Acceptance criteria: See [Table 1](#).

Table 1