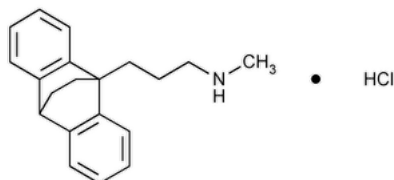


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Maprotiline Hydrochloride



$C_{20}H_{23}N \cdot HCl$ 313.86

9,10-Ethanoanthracene-9(10H)-propanamine, N-methyl-, hydrochloride;

N-Methyl-9,10-ethanoanthracene-9(10H)-propylamine hydrochloride CAS RN®: 10347-81-6; UNII: 7C8J54PVFI.

DEFINITION

Maprotiline Hydrochloride contains NLT 98.0% and NMT 102.0% of maprotiline hydrochloride ($C_{20}H_{23}N \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K or 197A
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Change to read:

- **C. IDENTIFICATION TESTS—GENERAL (191), Chemical Identification Tests, Chloride**

Sample solution: 5 mg/mL

Acceptance criteria: Responds to ▲the tests for amine hydrochloride▲ (USP 1-May-2021)

ASSAY

PROCEDURE

Ammonia solution: 70 g/L of [ammonium hydroxide](#) solution

Mobile phase: Dissolve 0.58 g of [ammonium acetate](#) in 200 mL of [water](#), and add 2 mL of *Ammonia solution*, 150 mL of [2-propanol](#), and 650 mL of [methanol](#). Adjust with drops of [glacial acetic acid](#) to a pH of 8.1.

System suitability solution: 1 mg/mL of [USP Maprotiline Hydrochloride RS](#) and 0.1 mg/mL of [USP Maprotiline Related Compound D RS](#) in *Mobile phase*

Standard solution: 1.0 mg/mL of [USP Maprotiline Hydrochloride RS](#) in *Mobile phase*

Sample solution: 1.0 mg/mL of Maprotiline Hydrochloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 272 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L3](#)

Autosampler temperature: 4°

Flow rate: 1 mL/min

Injection volume: 20 μL

Run time: NLT 1.5 times the retention time of maprotiline

System suitability

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

[NOTE—The relative retention times for maprotiline related compound D and maprotiline are 0.9 and 1.0, respectively.]

Suitability requirements

Resolution: 1.8–3.2 between the maprotiline related compound D and maprotiline peaks, *System suitability solution*. [NOTE—If necessary, adjust the pH of *Mobile phase*, in increments of 0.1 pH unit, by adding a 50% (v/v) solution of acetic acid if the *Resolution* is less than 1.8, or by adding the *Ammonia solution* if the *Resolution* is greater than 3.2.]

Tailing factor: 0.9–2.0, *Standard solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of maprotiline hydrochloride ($C_{20}H_{23}N \cdot HCl$) in the portion of Maprotiline 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 Maprotiline Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Maprotiline 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, PROCEDURE 1**

▲ **Ammonia solution:** Prepare as directed in the Assay. ▲ (USP 1-May-2021)

Mobile phase: Dissolve 0.6 g of [ammonium acetate](#) in 200 mL of [water](#), and add 2 mL of ▲ *Ammonia solution* ▲ (USP 1-May-2021), 150 mL of [2-propanol](#), and 650 mL of [methanol](#). Adjust with diluted glacial acetic acid to a pH of 8.3.

System suitability solution: 1 mg/mL of [USP Maprotiline Hydrochloride RS](#) and 0.1 mg/mL of [USP Maprotiline Related Compound D RS](#) in *Mobile phase*

Standard stock solution: 0.2 mg/mL of [USP Maprotiline Hydrochloride RS](#) in [methanol](#)

Standard solution: 0.002 mg/mL of [USP Maprotiline Hydrochloride RS](#) in *Mobile phase*, from *Standard stock solution*

Sample solution: 1 mg/mL of Maprotiline Hydrochloride in *Mobile phase*. [NOTE—A small quantity of methanol, NMT 10% of the final volume, can be used to aid the dissolution.]

Chromatographic system

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

Mode: LC

Detector: UV 272 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L3](#)

Autosampler temperature: 4°

Flow rate: 1 mL/min

Injection volume: 20 μL

Run time: NLT 1.5 times the retention time of maprotiline

System suitability

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

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

Suitability requirements

Resolution: 1.8–3.2 between the maprotiline related compound D and maprotiline peaks, *System suitability solution*. [NOTE—If necessary, adjust the pH of the *Mobile phase*, in increments of 0.1 pH unit, by adding a 50% (v/v) solution of acetic acid if the *Resolution* is less than 1.8, or by adding ▲ *Ammonia solution* ▲ (USP 1-May-2021) if the *Resolution* is greater than 3.2.]

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Maprotiline Hydrochloride taken:

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

r_U = peak area of any impurity from the *Sample solution*

r_S = peak area of maprotiline from the *Standard solution*

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

C_U = concentration of Maprotiline Hydrochloride in the *Sample solution* (mg/mL)

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

Acceptance criteria: See [Table 1](#). ▲ The reporting threshold is 0.05%. ▲ (USP 1-May-2021)

Table 1