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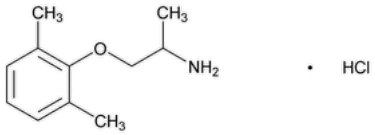
Mexiletine Hydrochloride

Change to read:



$C_{11}H_{17}NO \cdot HCl$ 215.72

2-Propanamine, 1-(2,6-dimethylphenoxy)-, hydrochloride, (±)-;

(±)-1-Methyl-2-(2,6-xylyloxy)ethylamine hydrochloride CAS RN®: ▲5370-01-4.▲ (ERR 1-May-2020)

DEFINITION

Mexiletine Hydrochloride contains NLT 98.0% and NMT 102.0% of mexiletine hydrochloride ($C_{11}H_{17}NO \cdot HCl$), 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.**

Sample solution: 3 mL of a solution (1 in 60)

Analysis: Add 1 mL of 6 N ammonium hydroxide to the *Sample solution*, filter, and acidify the filtrate with 2 mL of nitric acid. Then add 1 mL of silver nitrate TS.

Acceptance criteria: A curdy, white precipitate is formed, and it is soluble in an excess of 6 N ammonium hydroxide (presence of chloride).

ASSAY

• **Procedure**

Buffer: Dissolve 11.5 g of anhydrous sodium acetate in 500 mL of water. Add 3.2 mL of glacial acetic acid, mix, and allow to cool. Adjust with hydrochloric acid to a pH of 4.8 ± 0.1, and dilute with water to 1000 mL.

Mobile phase: Methanol and *Buffer* (600:400)

Standard solution: 2 mg/mL of USP Mexiletine Hydrochloride RS in *Mobile phase*

System suitability solution: 1 mg/mL of 2-phenylethylamine hydrochloride in *Standard solution*

Sample solution: 2 mg/mL of Mexiletine Hydrochloride in *Mobile phase*

Chromatographic system

(See *Chromatography* ⟨621⟩*, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Columns

Guard: Packing L1

Analytical: 3.9-mm × 30-cm; 10-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

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

[Note—The relative retention times for 2-phenylethylamine and mexiletine are 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between the 2-phenylethylamine and mexiletine peaks, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of mexiletine hydrochloride ($C_{11}H_{17}NO \cdot HCl$) in the portion of Mexiletine Hydrochloride taken:

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

r_U = peak area of mexiletine from the *Sample solution*

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

C_S = concentration of USP Mexiletine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = concentration of Mexiletine 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%

• **Organic Impurities**

Mobile phase, System suitability solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 0.2 mg/mL of USP Mexiletine Hydrochloride RS in *Mobile phase*, from the *Standard solution* in the *Assay*

Sample solution: 20 mg/mL of Mexiletine Hydrochloride in *Mobile phase*

System suitability

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

[Note—The relative retention times for 2-phenylethylamine and mexiletine are 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between the 2-phenylethylamine and mexiletine peaks, *System suitability solution*

Relative standard deviation: NMT 3.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

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

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

C_S = concentration of USP Mexiletine Hydrochloride RS in the *Standard solution* (mg/mL)

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

Acceptance criteria

Any individual impurity: NMT 1%

Total impurities: NMT 1.5%

SPECIFIC TESTS

• **pH ⟨791⟩**

Sample solution: 100 mg/mL

Acceptance criteria: 3.5–5.5

• **Loss on Drying ⟨731⟩**

Analysis: Dry at 105° for 2 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards ⟨11⟩**

USP Mexiletine Hydrochloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
MEXILETINE HYDROCHLORIDE	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 39(5)

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