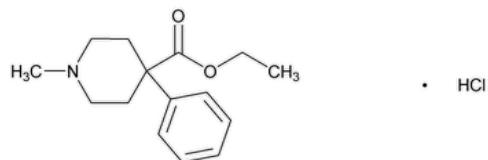


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Meperidine Hydrochloride



$C_{15}H_{21}NO_2 \cdot HCl$ 283.79

4-Piperidinecarboxylic acid, 1-methyl-4-phenyl-, ethyl ester, hydrochloride;

Ethyl 1-methyl-4-phenylisopiecotate hydrochloride CAS RN®: 50-13-5; UNII: N8E7F7Q170.

DEFINITION

Meperidine Hydrochloride contains NLT 98.0% and NMT 102.0% of meperidine hydrochloride ($C_{15}H_{21}NO_2 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

- **A.** [IDENTIFICATION—ORGANIC NITROGENOUS BASES \(181\)](#): Meets the requirements
- **B.** [IDENTIFICATION TESTS—GENERAL, Chloride\(191\)](#)

Sample solution: 10 mg/mL

Acceptance criteria: Meets the requirements

- **C.** 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

Solution A: Transfer about 6.8 g of monobasic potassium phosphate to a 1000-mL volumetric flask. Dissolve in and dilute with water to volume. Add 10 mL of triethylamine, and mix. Adjust with phosphoric acid to a pH of 7.0, and filter.

Mobile phase: Acetonitrile and *Solution A* (550:450), filtered and degassed

Standard stock solution: 0.6 mg/mL of [USP Meperidine Hydrochloride RS](#) in water

Standard solution: 0.12 mg/mL of [USP Meperidine Hydrochloride RS](#) from the *Standard stock solution* in *Mobile phase*

Sample stock solution: 0.6 mg/mL of Meperidine Hydrochloride in water

Sample solution: 0.12 mg/mL of Meperidine Hydrochloride from the *Sample stock solution* in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 2000 theoretical plates

Tailing factor: NMT 2 for the meperidine peak

Relative standard deviation: NMT 2%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of meperidine hydrochloride ($C_{15}H_{21}NO_2 \cdot HCl$) in the portion of Meperidine Hydrochloride taken:

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

r_U = peak response of meperidine from the *Sample solution*

r_S = peak response of meperidine from the *Standard solution*

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

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

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

OTHER COMPONENTS

• CONTENT OF CHLORIDE

Sample solution: Transfer about 500 mg of Meperidine Hydrochloride, previously dried, to a 250-mL conical flask. Add 15 mL of water, 5 mL of glacial acetic acid, 50 mL of methanol, and 0.2 mL of eosin Y TS.

Analysis: Titrate the *Sample solution* with 0.1 N silver nitrate VS to a rose-colored endpoint. Each mL of 0.1 N silver nitrate is equivalent to 3.545 mg of chloride.

Acceptance criteria: 12.2%–12.7% of chloride is found.

IMPURITIES

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

• ORGANIC IMPURITIES

Sample solution: 10 mg/mL in water

Chromatographic system

Mode: GC

Detector: Flame ionization

Column: 2-mm × 2-m glass; 10% phase G3 on support S1A

Temperatures

Column: 190°

Injection port: 255°

Detector: 280°

Carrier gas: Helium

Flow rate: 28 mL/min

Injection volume: 2.0 µL

Analysis

Sample: *Sample solution*

Calculate the area percentage of each peak.

Acceptance criteria: No peak other than the principal peak (except for the solvent peak) constitutes more than 1.0% of the total area.

SPECIFIC TESTS

• [Loss on Drying \(731\)](#)

Analysis: Dry under vacuum at a pressure between 20 and 40 mm of mercury at 80° for 4 h.

Acceptance criteria: NMT 1.0%

• [Melting Range or Temperature \(741\)](#)

Sample: Dried under vacuum at 80° for 4 h

Acceptance criteria: 186°–189°

ADDITIONAL REQUIREMENTS

• PACKAGING AND STORAGE: Preserve in well-closed, light-resistant containers, and store at room temperature.

• [USP Reference Standards \(11\)](#)

[USP Meperidine Hydrochloride RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

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

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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