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Meperidine Hydrochloride Injection

DEFINITION

Meperidine Hydrochloride Injection is a sterile solution of Meperidine Hydrochloride in Water for Injection. It contains NLT 95.0% and NMT 105.0% of the labeled amount of meperidine hydrochloride ($C_{15}H_{21}NO_2 \cdot HCl$).

IDENTIFICATION

- **A. Identification—Organic Nitrogenous Bases ⟨181⟩:** Meets 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: 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 *Buffer* (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: Transfer a measured volume of Injection equivalent to about 300 mg to a 100-mL volumetric flask, and dilute with water to volume.

Sample solution: Transfer 1.0 mL of the *Sample stock solution* to a 25-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

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

Relative standard deviation: NMT 2%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of meperidine hydrochloride ($C_{15}H_{21}NO_2 \cdot HCl$) in the portion of Injection 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 Meperidine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of meperidine hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–105.0%

SPECIFIC TESTS

- **pH** ⟨791⟩**:** 3.5–6.0
- **Bacterial Endotoxins Test** ⟨85⟩**:** It contains NMT 2.4 USP Endotoxin Units/mg of meperidine hydrochloride.
- **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products* ⟨1⟩.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass.
- **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 INJECTION	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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