Status: Currently Official on 15-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-A2783DC7-14CE-477B-8174-1D2875FD3629_1_en-US
DOI: https://doi.org/10.31003/USPNF_M48700_01_01
DOI Ref: ze2zq

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Meperidine Hydrochloride Tablets

DEFINITION
Meperidine Hydrochloride Tablets contain 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⟩**

Sample solution: Transfer an amount nominally equivalent to about 50 mg of meperidine hydrochloride from powdered Tablets to a separator, add 10 mL of water, and shake. Add 5 mL of saturated sodium chloride solution and 1 mL of sodium hydroxide solution (1 in 25). Extract with three 20-mL portions of chloroform, filtering the extracts through cotton overlaid with anhydrous sodium sulfate. Evaporate the chloroform on a steam bath, and dissolve the residue in 4 mL of carbon disulfide.

Standard solution: In a second separator, proceed as directed in the *Sample solution*, using 50 mg of USP Meperidine Hydrochloride RS.

Analysis: Proceed as directed in the chapter, beginning with "Determine the absorption spectra".

Acceptance criteria: Meet 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**

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: Transfer an amount nominally equivalent to about 60 mg of meperidine hydrochloride from NLT 20 finely powdered Tablets to a 100-mL volumetric flask. Add about 70 mL of *Mobile phase*, and sonicate for 10 min with occasional shaking. Shake by mechanical means for about 30 min, dilute with *Mobile phase* to volume, mix, and filter.

Sample solution: Nominally equivalent to 0.12 mg/mL of meperidine hydrochloride in *Mobile phase* from the *Sample stock solution*

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 Tablets taken:

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

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

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

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 500 mL

Apparatus 1: 100 rpm

Time: 45 min

Standard solution: A known concentration of USP Meperidine Hydrochloride RS in *Medium*

Sample solution: Filter portions of the solution under test, and suitably dilute with *Medium*, if necessary.

Chromatographic system and **System suitability:** Proceed as directed in the *Assay*.

Analysis: Determine the labeled amount of meperidine hydrochloride ($C_{15}H_{21}NO_2 \cdot HCl$) dissolved by comparing the peak response of meperidine from the *Sample solution* with that from the *Standard solution*.

Tolerances: NLT 75% (*Q*) of the labeled amount of meperidine hydrochloride ($C_{15}H_{21}NO_2 \cdot HCl$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed, light-resistant containers.

• **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 TABLETS	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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-A2783DC7-14CE-477B-8174-1D2875FD3629_1_en-US

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