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Meperidine Hydrochloride Oral Solution

DEFINITION

Meperidine Hydrochloride Oral Solution 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.**

Sample solution: Transfer a volume of Oral Solution nominally equivalent to about 100 mg of meperidine hydrochloride to a 125-mL separator. Add 40 mL of water and 3 mL of 1 N sodium hydroxide, and extract with three 25-mL portions of *n*-hexane. Wash the combined extracts with two 20-mL portions of water, discard the water, and then extract with three 25-mL portions of 0.1 N hydrochloric acid. Transfer the extracts to a 100-mL volumetric flask, dilute with 0.1 N hydrochloric acid to volume, and mix.

Standard solution: Prepare in a way similar to that for the *Sample solution*, using [USP Meperidine Hydrochloride RS](#).

Acceptance criteria: The UV absorption spectrum of the *Sample solution* exhibits maxima and minima at the same wavelengths as those of the *Standard solution*.

ASSAY

• **PROCEDURE**

Sample solution: Transfer a suitable volume of Oral Solution nominally equivalent to about 250 mg of meperidine hydrochloride to a separator, and add 3 mL of 1 N sodium hydroxide. Extract with five 20-mL portions of chloroform, and filter the extracts through a pledget of cotton into a 250-mL conical flask. Wash the cotton with 5 mL of chloroform, and add the washing to the combined filtrates. Add 10 mL of glacial acetic acid and 2 drops of crystal violet TS.

Analysis: Titrate with 0.1 N perchloric acid VS to a blue endpoint. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 28.38 mg of meperidine hydrochloride ($C_{15}H_{21}NO_2 \cdot HCl$).

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

- [DELIVERABLE VOLUME \(698\)](#): Meets the requirements for oral solution packaged in multiple-unit containers
- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meets the requirements for oral solution packaged in single-unit containers

SPECIFIC TESTS

- [pH \(791\)](#): 3.5–4.1

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, 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 ORAL SOLUTION | 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:

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