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Phentermine Hydrochloride Capsules

DEFINITION

Phentermine Hydrochloride Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of phentermine hydrochloride ($C_{10}H_{15}N \cdot HCl$).

IDENTIFICATION

- **A.**

Sample solution: Stir a portion of the Capsule contents in acetone to prepare a solution containing a nominal concentration at about 1 mg/mL of phentermine hydrochloride.

Analysis: Filter the *Sample solution* using an acetone resistant filter. Transfer 1 mL of the clear filtrate to a mortar containing about 200 mg of potassium bromide, triturate with a pestle, and air-dry to allow the acetone to evaporate. Place in an oven at 125° for 30 min to dry the mixture.

Acceptance criteria: The IR absorption spectrum of a potassium bromide dispersion prepared from the residue exhibits maxima only at the same wavelengths as that of a similar preparation of USP Phentermine Hydrochloride RS.

- **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**

Mobile phase: 1.1 g of sodium 1-heptanesulfonate in 575 mL of water. Add 25 mL of dilute glacial acetic acid (14 in 100) and 400 mL of methanol. Adjust dropwise, if necessary, with glacial acetic acid to a pH of 3.3 ± 0.1. Pass through a membrane filter of 0.5-µm pore size. The volume of methanol may be adjusted to provide a suitable retention time for phentermine hydrochloride (about 8 min).

Diluent: 0.04 M phosphoric acid

Standard solution: 0.4 mg/mL of USP Phentermine Hydrochloride RS in *Diluent*

Sample solution: Remove, as completely as possible, the contents of NLT 20 Capsules, and weigh. Transfer a portion of the mixed powder, nominally equivalent to about 20 mg of phentermine hydrochloride, to a 50-mL volumetric flask. Add 40 mL of *Diluent*, and sonicate for 15 min. Dilute with *Diluent* to volume, and mix. Pass through a membrane filter of 0.5-µm pore size, discarding the first few mL of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of phentermine hydrochloride ($C_{10}H_{15}N \cdot HCl$) in the portion of Capsules 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 Phentermine Hydrochloride RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution,** *Procedure for a Pooled Sample*⟨711⟩

Medium: Water; 900 mL. Use 500 mL for Capsules containing 15 mg or less of phentermine hydrochloride.

Apparatus 2: 50 rpm

Time: 45 min

Analysis: Determine the amount of phentermine hydrochloride ($C_{10}H_{15}N \cdot HCl$) dissolved, by using the *Procedure* set forth in the *Assay*, making any necessary modifications including concentration of the analyte in the volume of the *Sample solution* taken.

Tolerances: NLT 75% (*Q*) of the labeled amount of phentermine hydrochloride ($C_{10}H_{15}N \cdot HCl$) is dissolved.

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

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards** ⟨11⟩

USP Phentermine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
PHENTERMINE HYDROCHLORIDE CAPSULES	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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