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Phendimetrazine Tartrate Tablets

DEFINITION

Phendimetrazine Tartrate Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of phendimetrazine tartrate ($C_{12}H_{17}NO \cdot C_4H_6O_6$).

IDENTIFICATION

• **A.**

Analysis: Shake a quantity of finely powdered Tablets, nominally equivalent to 300 mg of phendimetrazine tartrate, with 50 mL of water. Filter, and transfer the filtrate to a 200-mL separator. Add 3 mL of 12.5 N sodium hydroxide, and extract with two 50-mL portions of chloroform. Extract the combined chloroform extracts in a 250-mL separator with two 15-mL portions of 0.5 N hydrochloric acid, and evaporate the combined aqueous extracts on a steam bath to dryness. Dissolve the residue in 5 mL of acetone, and add 50 mL of anhydrous ether to the solution. On standing, phendimetrazine hydrochloride crystallizes out. Filter the precipitate, wash with anhydrous ether, and dry at 105°.

Acceptance criteria: The phendimetrazine hydrochloride crystals so obtained melt at 189°–193°, but the range between the beginning and end of melting does not exceed 2°.

• **B.** Identification Tests—General, *Tartrate* ⟨191⟩

ASSAY

• **Procedure**

Mobile phase: Dissolve 1.1 g of sodium 1-heptanesulfonate in 575 mL of water, add 400 mL of methanol and 25 mL of dilute acetic acid (14 in 100), and mix. Adjust with glacial acetic acid to a pH of 3.0 ± 0.1, if necessary. Pass through a membrane filter of 0.45-µm pore size, and degas.

Diluent: Dilute acetic acid (14 in 100), methanol, and water (2.5:40:57.5)

Internal standard solution: 0.1 mg/mL of salicylamide in *Diluent*

Standard solution: 0.7 mg/mL of USP Phendimetrazine Tartrate RS in *Internal standard solution*

Sample solution: Transfer a portion of finely powdered Tablets from NLT 20 Tablets, nominally equivalent to 35 mg of phendimetrazine tartrate, to a 50-mL volumetric flask. Add 25 mL of *Internal standard solution*, and sonicate for 15 min. Cool the solution to room temperature, dilute with *Internal standard solution* to volume, mix, and pass through a membrane filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 256 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for salicylamide and phendimetrazine tartrate are 0.5 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between the analyte and internal standard peaks

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of phendimetrazine tartrate ($C_{12}H_{17}NO \cdot C_4H_6O_6$) in the portion of Tablets taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of phendimetrazine tartrate to the internal standard from the *Sample solution*

R_S = peak response ratio of phendimetrazine tartrate to the internal standard from the *Standard solution*

C_S = concentration of USP Phendimetrazine Tartrate RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of phendimetrazine tartrate in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 900 mL

Apparatus 1: 100 rpm

Time: 60 min

Solution A: 0.025 M monobasic potassium phosphate solution. Adjust with 1 N potassium hydroxide to a pH of 7.5.

Mobile phase: Acetonitrile and *Solution A* (65:35). Filter and degas.

Standard solution: USP Phendimetrazine Tartrate RS, similarly prepared as the *Sample solution*

Sample solution: Filter a portion of the solution under test.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4-mm × 15-cm; packing L15

Flow rate: 1.0 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 3.0% from three replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of phendimetrazine tartrate ($C_{12}H_{17}NO \cdot C_4H_6O_6$) dissolved in comparison with the *Standard solution*.

Tolerances: NLT 70% (*Q*) of the labeled amount of phendimetrazine tartrate ($C_{12}H_{17}NO \cdot C_4H_6O_6$) is dissolved.

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

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards ⟨11⟩**

USP Phendimetrazine Tartrate RS

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

Topic/Question	Contact	Expert Committee
PHENDIMETRAZINE TARTRATE 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

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