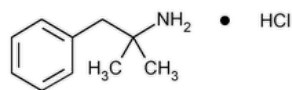


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Phentermine Hydrochloride



$C_{10}H_{15}N \cdot HCl$ 185.69

Benzeneethanamine, α,α -dimethyl-, hydrochloride;

α,α -Dimethylphenethylamine hydrochloride CAS RN®: 1197-21-3; UNII: 0K2I5050TV.

Change to read:

DEFINITION

Phentermine Hydrochloride contains NLT 98.0% and NMT Δ 102.0% Δ (USP 1-May-2022) of phentermine hydrochloride ($C_{10}H_{15}N \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197K Δ or 197A Δ (USP 1-May-2022)

Change to read:

- **B.** Δ The retention time of the phentermine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. Δ (USP 1-May-2022)
- **C.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Chloride](#): Meets the requirements

ASSAY

Change to read:

• PROCEDURE

Δ **Solution A:** Dissolve 2.72 g of [monobasic potassium phosphate](#) in 1000 mL of [water](#).

Mobile phase: [Methanol](#) and *Solution A* (55:45). Adjust with 50% (v/v) [phosphoric acid](#) in [water](#) to a pH of 2.4.

Standard solution: 0.1 mg/mL of [USP Phentermine Hydrochloride RS](#) in *Mobile phase*

Sample solution: 0.1 mg/mL of Phentermine Hydrochloride in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing [L7](#)

Column temperature: 25°

Flow rate: 0.8 mL/min

Injection volume: 10 μ L

Run time: NLT 8 times the retention time of phentermine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of phentermine hydrochloride ($C_{10}H_{15}N \cdot HCl$) in the portion of Phentermine Hydrochloride taken:

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

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

r_S = peak response of phentermine from the *Standard solution*

C_S = concentration of [USP Phentermine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Phentermine Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis ▲ (USP 1-May-2022)

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

Change to read:

• ORGANIC IMPURITIES

▲ **Buffer:** 2 mg/mL of [sodium 1-heptanesulfonate](#) in [water](#). Adjust with 25% (v/v) [phosphoric acid](#) in [water](#) to a pH of 2.3.

Mobile phase: [Acetonitrile](#), [methanol](#), and *Buffer* (20:25:55)

Diluent: [Methanol](#) and [water](#) (35:65)

Sensitivity solution: 0.5 µg/mL of [USP Phentermine Hydrochloride RS](#) in *Diluent*

Standard solution: 0.001 mg/mL each of [USP Phentermine Hydrochloride RS](#) and [USP Phentermine Related Compound A RS](#) in *Diluent*

Sample solution: 1 mg/mL of Phentermine Hydrochloride in *Diluent*

Chromatographic system

(See [Chromatography \(621\)](#), *System Suitability*.)

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

Column temperature: 45°

Flow rate: 1.5 mL/min

Injection volume: 10 µL

Run time: NLT 10 times the retention time of phentermine

System suitability

Samples: *Sensitivity solution* and *Standard solution*

Suitability requirements

Resolution: NLT 3.0 between phentermine and phentermine related compound A, *Standard solution*

Relative standard deviation: NMT 5% for phentermine, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each individual impurity in the portion of Phentermine Hydrochloride taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of each individual impurity from the *Sample solution*

r_S = peak response of phentermine from the *Standard solution*

C_S = concentration of [USP Phentermine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Phentermine Hydrochloride in the *Sample solution* (mg/mL)

F = relative response factor of each impurity (see [Table 1](#))

Acceptance criteria: See [Table 1](#).

Table 1