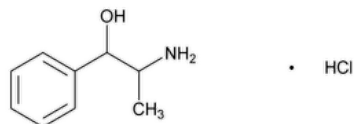


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Phenylpropanolamine Hydrochloride



$C_9H_{13}NO \cdot HCl$ 187.67

Benzenemethanol, α -(1-aminoethyl)-, hydrochloride, (R^*,S^*)-, ($\pm$);

($\pm$)-Norephedrine hydrochloride CAS RN[®]: 154-41-6; UNII: 8D5I63UE1Q.

DEFINITION

Phenylpropanolamine Hydrochloride contains NLT 98.0% and NMT 101.0% of phenylpropanolamine hydrochloride ($C_9H_{13}NO \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)

Change to read:

- **B.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Ultraviolet-Visible Spectroscopy: 197U ▲](#) (CN 1-MAY-2020)

Solution: 500 µg/mL

Medium: Water

Analytical wavelength: 256 nm

Acceptance criteria: Absorptivities, calculated on the dried basis, do not differ by more than 3.0%.

- **C.** [MELTING RANGE OR TEMPERATURE \(741\)](#)

Sample: Dissolve 1 g in 10 mL of water, add 10 mL of saturated sodium carbonate solution, and mix. Separate the precipitate by vacuum filtration, using a sintered-glass filter of medium pore size. Wash with three 5-mL portions of ice-cold water. Dry the crystals at 80° for 1 h.

Acceptance criteria: The *Sample* melts between 101° and 104°.

ASSAY

• PROCEDURE

Sample: 500 mg

Analysis: Dissolve the *Sample* in 50 mL of glacial acetic acid. Add 10 mL of mercuric acetate TS and 2 drops of crystal violet TS, and titrate with 0.1 N perchloric acid VS to a green endpoint. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 18.77 mg of phenylpropanolamine hydrochloride ($C_9H_{13}NO \cdot HCl$).

Acceptance criteria: 98.0%–101.0% on the dried basis

IMPURITIES

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

• LIMIT OF CATHINONE HYDROCHLORIDE

Diluent: Dilute hydrochloric acid (1 in 120)

Standard solution: 100 µg/mL of [USP Cathinone Hydrochloride RS](#) in *Diluent*

Sample solution: 100 mg/mL of Phenylpropanolamine Hydrochloride in *Diluent*

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 285 nm

Cell: 1 cm

Blank: *Diluent*

Analysis: Concomitantly determine the absorbances of the *Sample solution* and the *Standard solution*, using the *Blank*.

Acceptance criteria: The absorbance of the *Sample solution* is NMT than that of the *Standard solution* (NMT 0.10%).

• **LIMIT OF AMPHETAMINE HYDROCHLORIDE**

Mobile phase: Acetonitrile, phosphoric acid, triethylamine, and water (50:8:5:950)

System suitability solution: 5 µg/mL each of [USP Phenylpropanolamine Hydrochloride RS](#) and [USP Dextroamphetamine Sulfate RS](#) in water

Sample stock solution: 250 mg/mL of Phenylpropanolamine Hydrochloride in water. Sonicate if necessary.

Sample solution: 100 mg/mL of Phenylpropanolamine Hydrochloride in water from *Sample stock solution*

Amphetamine standard stock solution: 2.5 µg/mL of [USP Dextroamphetamine Sulfate RS](#) in water

Standard solution: 1 µg/mL of [USP Dextroamphetamine Sulfate RS](#) and 100 mg/mL of Phenylpropanolamine Hydrochloride in water from *Amphetamine standard stock solution* and *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 206 nm

Column: 4.6-mm × 25-cm; 5-µm base-deactivated packing L1

Flow rate: 1 mL/min

Injection volume: 5 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for phenylpropanolamine and amphetamine are 1.0 and 2.1, respectively.]

Suitability requirements

Resolution: NLT 15 between phenylpropanolamine and amphetamine, *System suitability solution*

Column efficiency: NLT 10,000 theoretical plates, *System suitability solution*

Relative standard deviation: NMT 3.0% for amphetamine, *Standard solution*

Analysis

Samples: *Sample solution* and *Standard solution*

Record the chromatograms, and measure the responses at the locus of the amphetamine peak.

Calculate the percentage of amphetamine hydrochloride in the portion of Phenylpropanolamine Hydrochloride taken:

$$\text{Result} = [r_U / (r_S - r_U)] \times (C_S / C_U) \times (M_{r1} / M_{r2}) \times 0.2$$

r_U = amphetamine peak response from the *Sample solution*

r_S = amphetamine peak response from the *Standard solution*

C_S = concentration of [USP Dextroamphetamine Sulfate RS](#) in the *Standard solution* (µg/mL)

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

M_{r1} = molecular weight of amphetamine hydrochloride, 171.67

M_{r2} = molecular weight of amphetamine sulfate, 368.49

Acceptance criteria: NMT 0.001%

SPECIFIC TESTS

• [MELTING RANGE OR TEMPERATURE, Class I \(741\)](#): 191°–196°

• [pH \(791\)](#)

Sample solution: A solution (3 in 100)

Acceptance criteria: 4.2–5.5

• [LOSS ON DRYING \(731\)](#)

Analysis: Dry at 105° for 2 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **LABELING:** Label it to indicate that it is for veterinary use only.

• **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.

• [USP REFERENCE STANDARDS \(11\)](#)