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Phenylephrine Hydrochloride Tablets

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click <https://www.uspnf.com/rb-phenylephrine-hcl-tabs-20211029>.

DEFINITION

Phenylephrine Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of phenylephrine hydrochloride ($C_9H_{13}NO_2 \cdot HCl$).

IDENTIFICATION

- **A.** The UV absorption spectra of the phenylephrine peak of the *Sample solution* and that of the *Standard solution* exhibit maxima and minima at the same wavelengths, as obtained in the Assay.
- **B.** The retention time of the phenylephrine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

It is suggested to use plastic vials for analysis.

Buffer: 3.45 g/L of [monobasic ammonium phosphate](#) in [water](#). Adjust with 10% [phosphoric acid](#) or 10% [ammonium hydroxide](#) solution to a pH of 4.5 ± 0.10 , if necessary.

Solution A: Dilute 10 mL of [glacial acetic acid](#) with [water](#) to 1000 mL.

Mobile phase: [Acetonitrile](#) and *Buffer* (35:65)

Diluent: [Methanol](#) and *Solution A* (30:70)

Standard solution: 0.1 mg/mL of [USP Phenylephrine Hydrochloride RS](#) in *Diluent*

Sample solution: Nominally 0.1 mg/mL of phenylephrine hydrochloride prepared as follows. Transfer NLT 10 Tablets to a suitable volumetric flask, add 50% of the final volume of *Solution A*, and stir vigorously for NLT 30 min. Add 30% of the final volume of [methanol](#) and stir for NLT an additional 90 min. To ensure that particles do not collect above the solvent level, periodically rinse the particulate into the solution with *Solution A*. Allow the resulting solution to cool to room temperature and dilute with *Solution A* to volume. Pass a portion through a suitable filter of 0.45- μ m pore size. Discard the first 2–3 mL of filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 214 nm. For *Identification A*, use a diode array detector in the range of 200–350 nm.

Column: 4.6-mm $\times$ 10-cm; 5- μ m packing [L9](#)

Flow rate: 2.0 mL/min

Injection volume: 25 μ L

Run time: NLT 1.75 times the retention time of phenylephrine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: 0.5–3.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of phenylephrine hydrochloride ($C_9H_{13}NO_2 \cdot HCl$) in the portion of Tablets taken:

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

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

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

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

It is suggested to use plastic vials for analysis.

Medium: [Simulated gastric fluid](#) without [pepsin](#); 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Buffer, Mobile phase, and System suitability: Proceed as directed in the Assay.

Standard solution: ($L/900$) mg/mL of [USP Phenylephrine Hydrochloride RS](#) in *Medium*, where L is the label claim of phenylephrine hydrochloride in mg/Tablet

Sample solution: Pass a portion of the solution under test through a suitable filter of 10–20- μ m pore size.

Chromatographic system: Proceed as directed in the Assay, except for the following.

Injection volume: 100 μ L

Run time: NLT 1.5 times the retention time of phenylephrine

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of phenylephrine hydrochloride ($C_9H_{13}NO_2 \cdot HCl$) dissolved:

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

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

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

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

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of phenylephrine hydrochloride ($C_9H_{13}NO_2 \cdot HCl$) is dissolved.

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

Delete the following:

▲ (RB 1-Nov-2021)

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers, and store at 20°–25°.

Change to read:

• [USP REFERENCE STANDARDS \(11\)](#)

[USP Phenylephrine Hydrochloride RS](#)

▲ (RB 1-Nov-2021)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
PHENYLEPHRINE HYDROCHLORIDE TABLETS	Documentary Standards Support	SM22020 Small Molecules 2



Documents

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