Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Nov-2021
Document Type: USP Monographs
DocId: GUID-7BA226F9-BE14-4580-B4D2-9F8F9F227815_2_en-US
DOI: https://doi.org/10.31003/USPNF_M8627_02_01
DOI Ref: hj2ko



# 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-µm 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 × 10-cm; 5-µm packing L9

**Flow rate:** 2.0 mL/min

**Injection volume:** 25 µL

**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-µm pore size.

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

**Injection volume:** 100 µL

**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 |

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | SM22020 Small Molecules 2 |

**Chromatographic Database Information:** Chromatographic Database

**Most Recently Appeared In:**
Pharmacopeial Forum: Volume No. PF 43(5)

**Current DocID: GUID-7BA226F9-BE14-4580-B4D2-9F8F9F227815_2_en-US**

**DOI: https://doi.org/10.31003/USPNF_M8627_02_01**

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