

Status: Currently Official on 16-Feb-2025  
 Official Date: Official as of 01-Aug-2019  
 Document Type: USP Monographs  
 DocId: GUID-2F4BD480-2965-43D8-B9A2-8F719D67248B\_2\_en-US  
 DOI: [https://doi.org/10.31003/USPNF\\_M64190\\_02\\_01](https://doi.org/10.31003/USPNF_M64190_02_01)  
 DOI Ref: fah4y

© 2025 USPC  
 Do not distribute

## Phenylephrine Hydrochloride Nasal Solution

### DEFINITION

Phenylephrine Hydrochloride Nasal Solution contains NLT 90.0% and NMT 115.0% of the labeled amount of phenylephrine hydrochloride ( $C_9H_{13}NO_2 \cdot HCl$ ).

### IDENTIFICATION

**Change to read:**

- A. ▲The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-Aug-2019)

**Add the following:**

- ▲ B. The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-Aug-2019)

### ASSAY

**Change to read:**

- **PROCEDURE**

**Mobile phase:** 1.1 g/L of [sodium 1-octane sulfonate](#) in a mixture of [methanol](#) and [water](#) (50:50). Adjust with [phosphoric acid](#) to a pH of 3.0.

**Diluent:** [Methanol](#) and [water](#) (50:50). Adjust with [phosphoric acid](#) to a pH of 3.0.

**System suitability solution:** 0.1 mg/mL of [USP Phenylephrine Hydrochloride RS](#) and 0.1 mg/mL of [USP Epinephrine Bitartrate RS](#) in *Diluent*

**Standard stock solution:** 2 mg/mL of [USP Phenylephrine Hydrochloride RS](#) in *Diluent*

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

**Sample solution:** Nominally 0.1 mg/mL of phenylephrine hydrochloride in *Diluent*

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 280 nm. ▲For *Identification B*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-Aug-2019)

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

**Flow rate:** 1 mL/min

**Injection volume:** 20  $\mu$ L

**System suitability**

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

**Suitability requirements**

**Resolution:** NLT 1.5 between phenylephrine and epinephrine, *System suitability solution*

**Tailing factor:** NMT 2.0 for the phenylephrine peak, *System suitability solution*

**Relative standard deviation:** NMT 2.0%, *Standard solution*

**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 Nasal Solution taken:

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times 100$$

$r_u$  = peak response from the *Sample solution*

$r_s$  = peak response 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%–115.0%**ADDITIONAL REQUIREMENTS**

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

**Change to read:**

- [USP REFERENCE STANDARDS \(11\)](#)

▲ [USP Epinephrine Bitartrate RS](#)▲ (USP 1-Aug-2019)  
[USP Phenylephrine Hydrochloride RS](#)

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

Topic/Question	Contact	Expert Committee
PHENYLEPHRINE HYDROCHLORIDE NASAL SOLUTION	<a href="#">Documentary Standards Support</a>	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM22020 Small Molecules 2

**Chromatographic Database Information:** [Chromatographic Database](#)**Most Recently Appeared In:**

Pharmacopeial Forum: Volume No. PF 44(1)

**Current DocID:** [GUID-2F4BD480-2965-43D8-B9A2-8F719D67248B\\_2\\_en-US](#)**DOI:** [https://doi.org/10.31003/USPNF\\_M64190\\_02\\_01](https://doi.org/10.31003/USPNF_M64190_02_01)**DOI ref:** [fah4y](#)