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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 µL

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	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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