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Phenylephrine Hydrochloride Ophthalmic Solution

DEFINITION

Phenylephrine Hydrochloride Ophthalmic Solution is a sterile, aqueous solution of Phenylephrine Hydrochloride. It contains NLT 90.0% and NMT 115.0% of the labeled amount of phenylephrine hydrochloride ($C_9H_{13}NO_2 \cdot HCl$). It may contain a suitable antimicrobial agent and buffer and may contain suitable antioxidants.

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 Ophthalmic Solution taken:

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

r_U = peak response from the *Sample solution*

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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%

SPECIFIC TESTS

• **Sterility Tests ⟨71⟩:** It meets the requirements.

• **pH ⟨791⟩:** 4.0–7.5 for buffered Ophthalmic Solution and 3.0–4.5 for unbuffered Ophthalmic Solution

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers of NMT 15-mL size.

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 OPHTHALMIC 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

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