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Phenylephrine Hydrochloride Injection

DEFINITION

Phenylephrine Hydrochloride Injection is a sterile solution of Phenylephrine Hydrochloride in Water for Injection. It 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 phenylephrine 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 absorption spectrum of the phenylephrine peak of the *Sample solution* exhibits maxima and minima at the same wavelengths as those of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-Aug-2019)

ASSAY

Change to read:

• **Procedure**

▲**Solution A:** Phosphoric acid and water (1:1000)

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	98	2
2.5	98	2
6	65	35
6.1	98	2
9	98	2

Standard solution: 0.1 mg/mL of USP Phenylephrine Hydrochloride RS in water

Sample solution: Nominally 0.1 mg/mL of phenylephrine hydrochloride in water from a volume of Injection

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 273 nm. For *Identification B*, use a diode array detector in the range of 245–400 nm.

Column: 4.6-mm × 15-cm; 2.6-µm packing L1

Column temperature: 35°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

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Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.5

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 Injection 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)

▲ (USP 1-Aug-2019)

Acceptance criteria: 90.0%–115.0%

IMPURITIES

Add the following:

▲• **Organic Impurities**

Solution A, Solution B, Mobile phase, and **Sample solution:** Prepare as directed in the *Assay*.

System suitability solution: 0.1 mg/mL of USP Phenylephrine Hydrochloride RS and 0.005 mg/mL of USP Phenylephrine Related Compound F RS in water

Sensitivity solution: 0.1 µg/mL of USP Phenylephrine Hydrochloride RS in water

Standard solution: 0.0002 mg/mL of USP Phenylephrine Hydrochloride RS in water

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

Detector: UV 215 nm

System suitability

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

[Note—The relative retention times for phenylephrine related compound F and phenylephrine are 0.9 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between phenylephrine and phenylephrine related compound F, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of each degradation product in the portion of Injection taken:

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

r_U = peak response of each degradation product 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)

F = relative response factor (see *Table 2*)

Acceptance criteria: See *Table 2*.

Table 2

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Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Phenylephrine	1.0	1.0	—
Phenylephrone (phenylephrine related compound C)[a]	1.2	2.8	0.7
Phenylephrine-citrate adduct[b]	2.9	1.0	0.4
Any unspecified degradation product	—	1.0	0.2
Total degradation products	—	—	1.3

[a] 1-(3-Hydroxyphenyl)-2-(methylamino)ethan-1-one hydrochloride.

[b] 2-Hydroxy-2-(2-{[(*R*)-2-hydroxy-2-(3-hydroxyphenyl)ethyl](methyl)amino}-2-oxoethyl)succinic acid.

▲ (USP 1-Aug-2019)

SPECIFIC TESTS

• **Bacterial Endotoxins Test** ⟨85⟩**:** It contains NMT 25.0 USP Endotoxin Units/mg of phenylephrine hydrochloride.

• **pH** ⟨791⟩**:** 3.0–6.5

• **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products* ⟨1⟩.

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass, protected from light. ▲Store at controlled room temperature.▲ (USP 1-Aug-2019)

Change to read:

• **USP Reference Standards** ⟨11⟩

USP Phenylephrine Hydrochloride RS

▲ USP Phenylephrine Related Compound F RS

(*R*)-2-Methyl-1,2,3,4-tetrahydroisoquinoline-4,8-diol hydrochloride monohydrate.

$C_{10}H_{13}NO_2 \cdot HCl \cdot H_2O$ 233.69▲ (USP 1-Aug-2019)

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PHENYLEPHRINE HYDROCHLORIDE INJECTION	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

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