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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

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

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Phenylephrine	1.0	1.0	—
Phenylephrine (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:

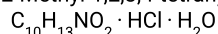
- **PACKAGING AND STORAGE:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass, protected from light. ▲ Store at controlled room temperature. ▲ (USP 1-Aug-2019)

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.



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

Chromatographic Database Information: [Chromatographic Database](#)

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