Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Dec-2020
Document Type: USP Monographs
DocId: GUID-E68E3468-294D-40BF-A0E9-CD4A6367EBC9_2_en-US
DOI: https://doi.org/10.31003/USPNF_M71588_02_01
DOI Ref: d6egc

Pseudoephedrine Hydrochloride Oral Solution

DEFINITION

Pseudoephedrine Hydrochloride Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$).

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-Dec-2020)

Change to read:

• **B.**

Sample solution: 5 mg/mL of pseudoephedrine from ▲a volume of Oral Solution equivalent to 120 mg of pseudoephedrine hydrochloride▲ (USP 1-Dec-2020) in 0.1 N hydrochloric acid

Acceptance criteria: The *Sample solution* is dextrorotatory.

ASSAY

Change to read:

• **Procedure**

▲**Solution A:** 0.1 M potassium phosphate, 1.0% triethylamine, and 0.4% phosphoric acid in a mixture of methanol and water (10:90) prepared as follows. Dissolve 17.4 g of potassium phosphate dibasic in 800 mL of a mixture of methanol and water (10:90) into a 1-L volumetric flask. Pipet 10.0 mL of triethylamine and 4.0 mL of phosphoric acid into the flask. Dilute with a mixture of methanol and water (10:90) to volume.

Solution B: 0.1 M potassium phosphate, 1.0% triethylamine, and 0.4% phosphoric acid in a mixture of methanol and water (50:50) prepared as follows. Dissolve 17.4 g of potassium phosphate dibasic in 800 mL of a mixture of methanol and water (50:50) into a 1-L volumetric flask. Pipet 10.0 mL of triethylamine and 4.0 mL of phosphoric acid into the flask. Dilute with a mixture of methanol and water (50:50) to volume.

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	75	25
7	25	75
10	0	100
15	0	100
15.1	75	25
17	75	25

Standard solution: 0.3 mg/mL each of USP Pseudoephedrine Hydrochloride RS and USP Sodium Benzoate RS in water

Sample solution: Nominally 0.3 mg/mL of pseudoephedrine hydrochloride in water. Prepare by adding a suitable amount of Oral Solution to an appropriate flask and diluting with water to volume.

Chromatographic system

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

Mode: LC

Detector: UV 257 nm

Column: 3.0-mm × 10-cm; 1.8-µm packing L1

Column temperature: 50°

Flow rate: 0.25 mL/min

Injection volume: 7 µL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for sodium benzoate and pseudoephedrine are 0.85 and 1.00, respectively.]

Suitability requirements

Resolution: NLT 2.0 between sodium benzoate and pseudoephedrine

Relative standard deviation: NMT 2.0% for both sodium benzoate and pseudoephedrine

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) in the portion of Oral Solution taken:

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

r_U = peak response of pseudoephedrine from the *Sample solution*

r_S = peak response of pseudoephedrine from the *Standard solution*

C_S = concentration of USP Pseudoephedrine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of pseudoephedrine hydrochloride in the *Sample solution* (mg/mL)▲ (USP 1-Dec-2020)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **UNIFORMITY OF DOSAGE UNITS ⟨905⟩**

For Oral Solution packaged in single-unit containers

Acceptance criteria: Meets the requirements

• **DELIVERABLE VOLUME ⟨698⟩**

For Oral Solution packaged in multiple-unit containers

Acceptance criteria: Meets the requirements

IMPURITIES

Add the following:

▲• **ORGANIC IMPURITIES**

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

Standard stock solution: Prepare as directed for the *Standard solution* in the *Assay*.

Standard solution: 0.6 µg/mL each of USP Pseudoephedrine Hydrochloride RS and USP Sodium Benzoate RS in water from the *Standard stock solution*

Sensitivity solution: 0.3 µg/mL each of USP Pseudoephedrine Hydrochloride RS and USP Sodium Benzoate RS in water from the *Standard stock solution*

System suitability

Samples: *Standard solution* and *Sensitivity solution*

Suitability requirements

Resolution: NLT 2.0 between sodium benzoate and pseudoephedrine, *Standard solution*

Relative standard deviation: NMT 6.0% for sodium benzoate, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any unspecified degradation product in the portion of Oral Solution taken:

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

r_U = peak response of any unspecified degradation product from the *Sample solution*

r_S = peak response of sodium benzoate from the *Standard solution*

C_S = concentration of USP Sodium Benzoate RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of pseudoephedrine hydrochloride in the *Sample solution* (mg/mL)

F = relative response factor for sodium benzoate, 0.12

Acceptance criteria: See *Table 2*.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Pseudoephedrine	1.0	—
Any unspecified degradation product	—	0.2
Total degradation products	—	3.0▲ (USP 1-Dec-2020)

SPECIFIC TESTS

Change to read:

• **Reaction**

▲**Sample:** Oral Solution▲ (USP 1-Dec-2020)

Acceptance criteria: It is acid to litmus.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

Change to read:

• **USP Reference Standards** ⟨11⟩

USP Pseudoephedrine Hydrochloride RS

▲ USP Sodium Benzoate RS▲ (USP 1-Dec-2020)

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

Topic/Question	Contact	Expert Committee
PSEUDOEPHEDRINE HYDROCHLORIDE ORAL 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:
Pharmacopeial Forum: Volume No. 45(1)

Current DocID: GUID-E68E3468-294D-40BF-A0E9-CD4A6367EBC9_2_en-US

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