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Physostigmine Salicylate Injection

DEFINITION

Physostigmine Salicylate Injection is a sterile solution of Physostigmine Salicylate in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of physostigmine salicylate ($C_{15}H_{21}N_3O_2 \cdot C_7H_6O_3$). It may contain an antimicrobial agent and an antioxidant.
 [NOTE—Do not use the Injection if it is more than slightly discolored.]

IDENTIFICATION

- **A.** ~~IDENTIFICATION—ORGANIC NITROGENOUS BASES (181).~~

Analysis: Use 1 g of sodium bicarbonate instead of 2 mL of 1 N sodium hydroxide.

Acceptance criteria: Meets the requirements

- **B.** ~~IDENTIFICATION TESTS—GENERAL, Salicylate(191):~~ Meets the requirements

ASSAY

PROCEDURE

Buffer: 3.85 g/L of ammonium acetate in water. Adjust, if necessary, with glacial acetic acid or ammonium hydroxide to a pH of 6 ± 0.1 .

Mobile phase: Acetonitrile and *Buffer* (50:50)

Solution A: 100 μ L of [USP Benzyl Alcohol RS](#) and 1 μ L of benzaldehyde in 400 mL of acetonitrile

Standard solution: 0.03 mg/mL of [USP Physostigmine Salicylate RS](#) in *Solution A*

Sample solution: Nominally 0.03 mg/mL from a suitable volume of Injection containing NLT 3 mg of physostigmine salicylate diluted with acetonitrile

Chromatographic system

(See [Chromatography \(621\), System Suitability.](#))

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm $\times$ 30-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 10 μ L

System suitability

Samples: *Solution A* and *Standard solution*

[NOTE—If the peaks due to benzyl alcohol and benzaldehyde co-elute when *Solution A* is injected, the *Standard solution* will exhibit only two peaks instead of three. In a suitable system, benzyl alcohol and benzaldehyde elute before physostigmine.]

Suitability requirements

Resolution: NLT 2.0 between the physostigmine peak and the adjacent peak (benzyl alcohol or benzaldehyde, or the combination of these), *Standard solution*

Column efficiency: NLT 1200 theoretical plates from the analyte peak, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of physostigmine salicylate ($C_{15}H_{21}N_3O_2 \cdot C_7H_6O_3$) in the portion of Injection 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 Physostigmine Salicylate RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of physostigmine salicylate in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **BACTERIAL ENDOTOXINS TEST (85):** NMT 83.4 USP Endotoxin Units/mg of physostigmine salicylate
- **pH (791):** 3.5–5.0
- **OTHER REQUIREMENTS:** It meets the requirements in [Injections and Implanted Drug Products \(1\)](#).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in single-dose containers, preferably of Type I glass, protected from light.
- **USP REFERENCE STANDARDS (11):**
[USP Benzyl Alcohol RS](#)
[USP Physostigmine Salicylate RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
PHYSOSTIGMINE SALICYLATE INJECTION	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

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