Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-682D2DED-561A-46AC-9CBC-256EFEC9FD66_3_en-US
DOI: https://doi.org/10.31003/USPNF_M64730_03_01
DOI Ref: 70vwg

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 µL of USP Benzyl Alcohol RS and 1 µL 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 × 30-cm; packing L1

  Flow rate: 2 mL/min

  Injection volume: 10 µL

  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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 30(6)

Current DocID: GUID-682D2DED-561A-46AC-9CBC-256EFEC9FD66_3_en-US
Previous DocID: GUID-682D2DED-561A-46AC-9CBC-256EFEC9FD66_1_en-US
DOI: https://doi.org/10.31003/USPNF_M64730_03_01
DOI ref: 70vwg