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Physostigmine Salicylate

$C_{15}H_{21}N_3O_2 \cdot C_7H_6O_3$ 413.47

Pyrrolo[2,3-*b*]indol-5-ol, 1,2,3,3a,8,8a-hexahydro-1,3a,8-trimethyl-, methylcarbamate (ester), (3*aS*-*cis*)-, mono(2-hydroxybenzoate);

Physostigmine monosalicylate CAS RN®: 57-64-7; UNII: 2046ZRO9VU.

DEFINITION

Physostigmine Salicylate contains NLT 97.0% and NMT 102.0% of physostigmine salicylate ($C_{15}H_{21}N_3O_2 \cdot C_7H_6O_3$), calculated on the dried basis.

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**

Sample: 250 mg of Physostigmine Salicylate

Analysis: Dissolve the *Sample* in 25 mL of chloroform, and add 25 mL of glacial acetic acid. Titrate with 0.02 N perchloric acid in dioxane VS, determining the endpoint potentiometrically. Perform a blank determination, and make any necessary correction. Each mL of 0.02 N perchloric acid is equivalent to 8.270 mg of physostigmine salicylate ($C_{15}H_{21}N_3O_2 \cdot C_7H_6O_3$).

Acceptance criteria: 97.0%–102.0% on the dried basis

IMPURITIES

- **[RESIDUE ON IGNITION \(281\)](#).**

Sample: 100 mg

Acceptance criteria: Negligible

- **SULFATE**

Sample solution: Precipitate the salicylic acid from 10 mL of a cold, saturated solution of Physostigmine Salicylate with a slight excess of 3 N hydrochloric acid, and filter.

Analysis: Add 5 drops of barium chloride TS to the *Sample solution*.

Acceptance criteria: No turbidity is produced immediately.

SPECIFIC TESTS

- **[OPTICAL ROTATION, *Specific Rotation* \(781S\)](#).**

Sample solution: 10 mg/mL in water

Acceptance criteria: -91° to -94°

- **[LOSS ON DRYING \(731\)](#).**

Analysis: Dry over silica gel for 24 h.

Acceptance criteria NMT 1.0%

- **[READILY CARBONIZABLE SUBSTANCES TEST \(271\)](#).**

Sample solution: Dissolve 100 mg in 5 mL of sulfuric acid.

Acceptance criteria: At the end of 5 min, the *Sample solution* has no more color than *Matching Fluid I*.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers. Store at 25° , excursions permitted between 15° and 30° .
- **[USP REFERENCE STANDARDS \(11\)](#).**

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

Topic/Question	Contact	Expert Committee
PHYSOSTIGMINE SALICYLATE	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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