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Povidone–Iodine Ointment

DEFINITION

Povidone–Iodine Ointment is an emulsion, solution, or suspension of Povidone–Iodine in a suitable water-soluble ointment base. It contains NLT 85.0% and NMT 120.0% of the labeled amount of iodine (I).

IDENTIFICATION

- A.

Sample solution: Alcohol dilution containing 0.05% of iodine

Analysis: Add 1 mL of the *Sample solution* to a mixture of 1 mL of starch TS and 9 mL of water.

Acceptance criteria: A deep blue color is produced.

- B.

Sample: 10 g

Analysis: Place the *Sample* in a 50-mL beaker, avoiding contact with the walls of the beaker. Cover the mouth of the beaker with a disk of filter paper, and wet it with 1 drop of starch TS.

Acceptance criteria: No blue color appears within 60 s.

ASSAY

- PROCEDURE

Sample: Nominally 50 mg of iodine from an accurately weighed quantity of Ointment

Titrimetric system

Mode: Direct titration

Titrant: 0.02 N sodium thiosulfate VS

Endpoint detection: Potentiometric

Analysis: Transfer the *Sample* to a 100-mL beaker, add water to make a total volume of NLT 30 mL, and stir until the Ointment is dissolved.

Titrate immediately with *Titrant* to the endpoint, using a platinum–calomel electrode system. Perform a blank determination, and make any necessary correction. Each mL of 0.02 N sodium thiosulfate is equivalent to 2.538 mg of iodine.

Acceptance criteria: 85.0%–120.0% of the labeled amount of iodine

PERFORMANCE TESTS

- [MINIMUM FILL \(755\)](#): Meets the requirements

SPECIFIC TESTS

- [pH \(791\)](#):

Sample solution: 50 mg/mL

Acceptance criteria: 1.5–6.5

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.

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

Topic/Question	Contact	Expert Committee
POVIDONE-IODINE OINTMENT	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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