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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:

Pharmacopeial Forum: Volume No. Information currently unavailable

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