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Povidone–Iodine Topical Solution

DEFINITION
Povidone–Iodine Topical Solution is a solution of Povidone–Iodine. It contains NLT 85.0% and NMT 120.0% of the labeled amount of iodine (I).
It may contain a small amount of alcohol.

IDENTIFICATION

- A.**
Sample solution 1: Dilution containing 0.05% of iodine
Analysis 1: Add 1 mL of *Sample solution 1* to a mixture of 1 mL of starch TS and 9 mL of water.
Acceptance criteria 1: A deep blue color is produced.
Sample solution 2: 10 mL
Analysis 2: Transfer *Sample solution 2* to a 50-mL conical flask, avoiding contact with the neck of the flask. Cover the mouth of the flask with a small disk of filter paper, and wet it with 1 drop of starch TS.
Acceptance criteria 2: No blue color appears within 60 s.

ASSAY

- PROCEDURE**
Sample solution: Nominally 50 mg of iodine from an accurately measured volume of Topical Solution
Titrimetric system
Mode: Direct titration
Titrant: 0.02 N sodium thiosulfate VS
Endpoint detection: Potentiometric
Analysis: Transfer the *Sample solution* to a 100-mL beaker, and add water to make a total volume of NLT 30 mL. 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

OTHER COMPONENTS

- ALCOHOL DETERMINATION (611)**(if present): 90.0%–110.0% of the labeled amount of alcohol (C₂H₅OH)

SPECIFIC TESTS

- pH (791):** 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 TOPICAL SOLUTION | Documentary Standards Support | SM12020 Small Molecules 1 |
| REFERENCE STANDARD SUPPORT | RS Technical Services RSTECH@usp.org | SM12020 Small Molecules 1 |

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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