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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 (C_2H_5OH)

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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