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# Povidone–Iodine Cleansing Solution

## DEFINITION

Povidone–Iodine Cleansing Solution is a solution of Povidone–Iodine with one or more suitable surface-active agents. 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.

### • B.

**Sample solution:** 2 mL

**Analysis:** To the *Sample solution*, in a glass-stoppered test tube, add 1 mL of peanut oil and 4 mL of water, and shake vigorously for 10 s. Allow to stand for 3 min.

**Acceptance criteria:** A stable emulsion is formed.

## ASSAY

### • PROCEDURE

**Sample solution:** Nominally 50 mg of iodine from an accurately measured volume of 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<sub>2</sub>H<sub>5</sub>OH)

## 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 CLEANSING SOLUTION	<a href="#">Documentary Standards Support</a>	SM12020 Small Molecules 1

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM12020 Small Molecules 1

**Chromatographic Database Information:** [Chromatographic Database](#)

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