

Status: Currently Official on 16-Feb-2025
 Official Date: Official Prior to 2013
 Document Type: USP Monographs
 DocId: GUID-9FA6703B-FC46-402F-8FCF-5D2C834395FB_1_en-US
 DOI: https://doi.org/10.31003/USPNF_M68150_01_01
 DOI Ref: 6mm4I

© 2025 USPC
 Do not distribute

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_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 CLEANSING SOLUTION	Documentary Standards Support	SM12020 Small Molecules 1

Topic/Question	Contact	Expert Committee
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

Current DocID: [GUID-9FA6703B-FC46-402F-8FCF-5D2C834395FB_1_en-US](#)

DOI: https://doi.org/10.31003/USPNF_M68150_01_01

DOI ref: [6mm4l](#)

OFFICIAL