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Iodine Topical Solution

DEFINITION

Iodine Topical Solution contains NLT 1.8 g and NMT 2.2 g of iodine (I) and NLT 2.1 g and NMT 2.6 g of sodium iodide (NaI) in each 100 mL.

Iodine	20 g
Sodium Iodide	24 g
Purified Water, a sufficient quantity to make	1000 mL

Dissolve *Iodine* and *Sodium Iodide* in 50 mL of *Purified Water*, then add sufficient *Purified Water* to bring to final volume.

IDENTIFICATION

- A.**
Analysis: Add 1 drop to a mixture of 1 mL of starch TS and 9 mL of water.
Acceptance criteria: A deep blue color is produced.
- B. ~~IDENTIFICATION TESTS—GENERAL~~ (191), *Iodide***
Sample: Evaporate a few milliliters on a steam bath to dryness.
Acceptance criteria: The residue meets the requirements of the test for *Iodide*.
- C. Sodium:** The *Sample* obtained in *Identification B* imparts an intense yellow color to a nonluminous flame.

ASSAY

- IODINE**
Sample: 10.0 mL
Titrimetric system
Mode: Direct titration
Titrant: 0.1 N sodium thiosulfate VS
Endpoint detection: Visual
Analysis: Transfer the *Sample* into a glass-stoppered 500-mL flask, and dilute with 10 mL of water. Titrate with *Titrant*, adding 3 mL of starch TS as the endpoint is approached. Each milliliter of *Titrant* is equivalent to 12.69 mg of iodine (I).
Acceptance criteria: 1.8–2.2 g in 100 mL of Topical Solution
- SODIUM IODIDE**
Sample: 10.0 mL
Titrimetric system
Mode: Direct titration
Titrant: 0.05 M potassium iodate VS
Endpoint detection: Visual
Analysis: Transfer the *Sample* into a glass-stoppered 500-mL flask, add 30 mL of water and 50 mL of hydrochloric acid, cool to room temperature, and titrate with *Titrant* until the dark brown solution that is produced becomes pale brown. Add 1 mL of amaranth TS, and continue the titration slowly until the red color just changes to yellow. The difference in volume, in milliliters, between the *Titrant* used and half the volume of 0.1 N sodium thiosulfate VS used in the Assay for *Iodine*, multiplied by 14.99, represents the number of milligrams of sodium iodide (NaI) in the portion of Topical Solution taken.
Acceptance criteria: 2.1–2.6 g in 100 mL of Topical Solution

ADDITIONAL REQUIREMENTS

- PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store at a temperature not exceeding 35°.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
IODINE TOPICAL SOLUTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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