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Strong Iodine Tincture

DEFINITION
Strong Iodine Tincture contains NLT 6.8 g and NMT 7.5 g of iodine (I) and NLT 4.7 g and NMT 5.5 g of potassium iodide (KI) in each 100 mL.
Prepare Strong Iodine Tincture as follows.

Potassium Iodide	50 g
Iodine	70 g
Purified Water	50 mL
Alcohol, a sufficient quantity to make	1000 mL

Dissolve *Potassium Iodide* in *Purified Water*. Add *Iodine* and agitate until the solution is effected. Add *Alcohol* 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*
Analysis: Evaporate a few milliliters on a steam bath to dryness.
Acceptance criteria: The residue meets the requirements of the test for *Iodide*.
• **C. Potassium:** The *Sample* obtained in *Identification B* imparts a violet color to a nonluminous flame. The presence of small quantities of sodium masks the color unless the yellow color produced by sodium is screened out by viewing through a blue filter that blocks the emission at 589 nm (sodium). It is transparent to the emission at 404 nm (potassium).[Note—Traditionally, cobalt glass has been used, but other suitable filters are commercially available.]

ASSAY
• **Iodine**
Sample: 10 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 add 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: 6.8–7.5 g of iodine (I) in 100 mL
• **Potassium Iodide**
Sample: 10 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 between the volume of *Titrant* used and half the

volume of 0.1 N sodium thiosulfate used in the *Assay* for *Iodine*, in milliliters, multiplied by 16.60, represents the number of milligrams of potassium iodide (KI) in the portion of Tincture taken.

Acceptance criteria: 4.7–5.5 g of potassium iodide (KI) in 100 mL

OTHER COMPONENTS

• **Alcohol Determination ⟨611⟩:** 82.5%–88.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
STRONG IODINE TINCTURE	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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