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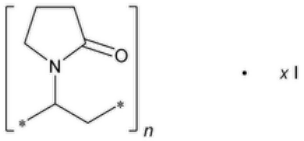
Povidone–Iodine



$(C_6H_9NO)_n \cdot xI$

2-Pyrrolidinone, 1-ethenyl-, homopolymer, compound with iodine;
1-Vinyl-2-pyrrolidinone polymer, compound with iodine

CAS RN®: 25655-41-8; UNII: 85H0HZU99M.

DEFINITION

Povidone–Iodine is a complex of Iodine with Povidone. It contains NLT 9.0% and NMT 12.0% of available iodine (I), calculated on the dried basis.

IDENTIFICATION

• **A.**

Sample solution: 100 mg/mL

Analysis: Add 1 drop of the *Sample solution* to a mixture of 1 mL of starch TS and 9 mL of water.

Acceptance criteria: A deep blue color is produced.

• **B.**

Sample solution: 100 mg/mL

Analysis: Spread 1 mL of the *Sample solution* over an area of 20 cm × 20 cm on a glass plate, and allow to air-dry at room temperature in an atmosphere of low humidity overnight.

Acceptance criteria: A brown, dry, non-smearing film is formed, and it dissolves readily in water.

ASSAY

• **Available Iodine**

Sample solution: Place 5 g of Povidone–Iodine in a 400-mL beaker, and add 200 mL of water. Cover the beaker, and stir by mechanical means at room temperature for NMT 1 h to dissolve as completely as possible.

Titrimetric system

Mode: Direct titration

Titrant: 0.1 N sodium thiosulfate VS

Analysis: Titrate the *Sample solution* immediately with *Titrant*, adding 3 mL of starch TS as the endpoint is approached. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N sodium thiosulfate is equivalent to 12.69 mg of iodine (I).

Acceptance criteria: 9.0%–12.0% of available iodine (I) on the dried basis

OTHER COMPONENTS

• **Iodide Ion**

Determination of total iodine

Sample: 500 mg of Povidone–Iodine

Titrimetric system

(See *Titrimetry ⟨541⟩, Residual Titrations*.)

Mode: Residual titration

Titrant: 0.1 N silver nitrate VS

Back-titrant 0.1 N ammonium thiocyanate VS

Endpoint detection: Visual

Analysis: Dissolve the *Sample* in 100 mL of water in a 250-mL conical flask. Add sodium bisulfite TS until the color of iodine has disappeared. Add 25.0 mL of *Titrant* and 10 mL of nitric acid.

Titrate the excess silver nitrate with *Back-titrant*, using ferric ammonium sulfate TS as the indicator. Perform a blank determination. Each mL of 0.1 N silver nitrate is equivalent to 12.69 mg of iodine (I). From the percentage of total iodine, calculated on the dried basis, subtract the percentage of available iodine (see *Assay* for available iodine), to obtain the percentage of iodide ion.

Acceptance criteria: NMT 6.6% on the dried basis

• **Nitrogen Determination,** *Method II*⟨461⟩**:** 9.5%–11.5% of nitrogen (N) is found, calculated on the dried basis

IMPURITIES

• **Residue on Ignition** ⟨281⟩

Sample: 2 g

Acceptance criteria: NMT 0.025%

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩

Sample: 5.0 g

Analysis: Dry the *Sample* at 105° until the difference between two successive weighings at 1-h intervals is NMT 5.0 mg.

Acceptance criteria: NMT 8.0%

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	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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