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Potassium Iodide Delayed-Release Tablets

DEFINITION

Potassium Iodide Delayed-Release Tablets contain NLT 94.0% and NMT 106.0% of the labeled amount of potassium iodide (KI) for Tablets of 300 mg or more, and NLT 92.5% and NMT 107.5% for Tablets of less than 300 mg.

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL, [Potassium\(191\)](#) and [Iodide\(191\)](#):** A filtered solution of powdered Tablets meets the requirements.

ASSAY

PROCEDURE

Sample solution: Transfer an equivalent to 1.2 g of potassium iodide, from finely powdered Tablets (NLT 20), to a 250-mL volumetric flask.

Add 100 mL of water, shake for 20 min, and dilute with water to volume. Filter through paper, discarding the first 20 mL of the filtrate.

Transfer 100.0 mL of the filtrate, 25 mL of alcohol, and 1.0 mL of 1 N nitric acid to a 200-mL beaker.

Analysis: Transfer 100.0 mL of the filtrate, 25 mL of alcohol, and 1.0 mL of 1 N nitric acid to a 200-mL beaker. Titrate with 0.1 N silver nitrate VS, using a silver indicator electrode and an appropriate reference electrode. Perform a blank determination (see [Titrimetry\(541\)](#)). Each mL of 0.1 N silver nitrate is equivalent to 16.60 mg of KI.

Acceptance criteria: 94.0%–106.0% of the labeled amount of potassium iodide (KI) for Tablets of 300 mg or more, and 92.5%–107.5% for Tablets of less than 300 mg

PERFORMANCE TESTS

DISINTEGRATION (701)

Analysis: Proceed as directed for *Delayed-Release (Enteric-Coated) Tablets*.

Acceptance criteria: The Tablets do not disintegrate after 1 h of agitation in simulated gastric fluid TS, but they disintegrate within 90 min in simulated intestinal fluid TS.

- **UNIFORMITY OF DOSAGE UNITS (905):** Meet the requirements

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
POTASSIUM IODIDE DELAYED-RELEASE TABLETS	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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