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Sodium Iodide I 123 Capsules

Sodium iodide ($Na^{123}I$).

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CAS RN®: 41927-88-2.

» Sodium Iodide I 123 Capsules contain radioactive iodine (^{123}I) processed in the form of Sodium Iodide obtained from the bombardment of enriched tellurium 124 with protons or of enriched tellurium 122 with deuterons, or by proton irradiation of enriched xenon 124, or by the decay of xenon 123 in such manner that it is carrier-free. Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of ^{123}I as iodide expressed in megabecquerels (microcuries or millicuries) at the time indicated in the labeling. Other chemical forms of radioactivity do not exceed 5 percent of the total radioactivity. The Capsules may contain a stabilizer.

Packaging and storage—Preserve in well-closed containers that are adequately shielded.

Labeling—Label the Capsules to include the following: the name of the Capsules; the name, address, and batch or lot number of the manufacturer; the time and date of calibration; the amount of ^{123}I as iodide expressed in megabecquerels (microcuries or millicuries) per Capsule at the time of calibration; the name and quantity of any added preservative or stabilizer; a statement indicating that the Capsules are for oral use only; the expiration date and time; and the statement "Caution—Radioactive Material." The labeling indicates that in making dosage calculations, correction is to be made for radioactive decay, and also indicates that the radioactive half-life of ^{123}I is 13.2 hours.

Change to read:

Radionuclide identification ▲(see *Radioactivity* ⟨821⟩)—

The gamma-ray spectrum of a solution or suspension of 1 or more Capsules in water is identical to that of a specimen of ^{123}I of known purity that exhibits a major photoelectric peak having an energy of 0.159 MeV.▲ (ERR 1-Sep-2020)

Uniformity of dosage units ⟨905⟩: meet the requirements.

Procedure for content uniformity—Determine the instrument response of each of 20 Capsules by measurement in a suitable counting assembly and under identical geometric conditions. Calculate the mean radioactivity value per Capsule: the requirements of the test are met if not less than 19 of the Capsules are within the limits of 96.5% and 103.5% of the mean radioactivity value.

Change to read:

Radionuclidic purity ▲(see *Radioactivity* ⟨821⟩)—

Using a suitable counting assembly, determine the radionuclidic purity of a solution or suspension of 1 or more Capsules in water: not less than 90% of the total radioactivity is present as I 123.▲ (ERR 1-Sep-2020)

Change to read:

Radiochemical purity—▲Place a measured volume of a solution, containing 100 mg of potassium iodide, 200 mg of potassium iodate, and 1 g of sodium bicarbonate in each 100 mL, 25 mm from one end of a 25- × 300-mm strip of chromatographic paper (see *Chromatography* ⟨621⟩), and allow to dry. To the same area add a similar volume of the sample solution prepared as follows: homogenize the content from 1 Capsule in 3 mL of water and 3 mL of methanol and centrifuge. The supernatant should be diluted so that it provides a count rate of about 20,000 counts per minute. Allow the spots to dry. Develop the chromatogram over a period of about 4 hours by ascending chromatography, using dilute methanol (7 in 10). Dry the chromatogram in air, and determine the radioactivity distribution by scanning with a suitable collimated radiation detector: the radioactivity of the iodide ^{123}I band is not less than 95.0% of the total radioactivity, and its R_F value falls within ±5.0% of the value found for sodium iodide when determined under similar conditions. Confirmation of the identity of the iodide band is made by the addition to the suspected iodide band of 6 drops of acidified hydrogen peroxide solution (prepared by adding 6 drops of 1 N hydrochloric acid to 10 mL of hydrogen peroxide solution) followed by the dropwise addition of starch TS: the development of a blue color indicates the presence of iodide.▲ (ERR 1-Sep-2020)

Change to read:

▲**Assay for radioactivity**—Prepare a solution or suspension▲ (ERR 1-Sep-2020) by homogenizing 1 or more Capsules in water to yield a concentration of not less than 1 MBq (25 µCi) per mL. ▲Determine the radioactivity of the resulting solution using a suitable counting assembly, by use of a calibrated system as directed under *Radioactivity* ⟨821⟩.▲ (ERR 1-Sep-2020)

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

Topic/Question	Contact	Expert Committee
SODIUM IODIDE I 123 CAPSULES	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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