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Sodium Iodide I 131 Solution

Sodium iodide ($Na^{131}I$).

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CAS RN®: 7790-26-3; UNII: 29VCO8ACHH.

» Sodium Iodide I 131 Solution is a solution suitable for either oral or intravenous administration, containing radioactive iodine (^{131}I) processed in the form of Sodium Iodide from the products of uranium fission or the neutron bombardment of tellurium in such a manner that it is essentially carrier-free and contains only minute amounts of naturally occurring iodine 127.

Sodium Iodide I 131 Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of ^{131}I as iodide expressed in megabecquerels (microcuries or in millicuries) per mL at the time indicated in the labeling. Other chemical forms of radioactivity do not exceed 5 percent of the total radioactivity. The Solution may contain a preservative or stabilizer.

Packaging and storage—Preserve in single-dose or multiple-dose containers that previously have been treated to prevent adsorption.

Labeling—Label it to include the following: the time and date of calibration; the amount of ^{131}I as iodide expressed as total megabecquerels (microcuries or millicuries) and as megabecquerels (microcuries or millicuries) per mL at the time of calibration; the name and quantity of any added preservative or stabilizer; a statement of the intended use, whether oral or intravenous; a statement of whether the contents are intended for diagnostic or therapeutic use; the expiration date; 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 ^{131}I is 8.08 days.

Radionuclide identification (see *Radioactivity* ⟨821⟩)—Its gamma-ray spectrum is identical to that of a specimen of iodine 131 of known purity that exhibits a major photopeak having an energy of 0.364 MeV.

Bacterial Endotoxins Test ⟨85⟩—Solution intended for intravenous use meets the requirements of the *Bacterial Endotoxins Test* ⟨85⟩, the limit of endotoxin content being not more than 175/*V* USP Endotoxin Unit per mL of the Solution, when compared with the USP Endotoxin RS, in which *V* is the maximum recommended total dose, in mL, at the expiration date or time.

pH ⟨791⟩**:** between 7.5 and 9.0 for solutions intended for intravenous administration; between 7.5 and 10.0 for solutions intended for oral administration.

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 appropriately diluted Solution such that it provides a count rate of about 20,000 counts per minute, and allow to dry. Develop the chromatogram over a period of about 4 hours by ascending chromatography, using dilute methanol (7.0 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 ^{131}I band is not less than 95% of the total radioactivity, and its R_F value falls within ±5% of the value found for sodium iodide when determined under parallel 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 presence of iodide.

Other requirements—Solution intended for intravenous use meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩, except that the Solution may be distributed or dispensed prior to completion of the test for *Sterility*, the latter test being started on the day of final manufacture, and except that it is not subject to the recommendation on *Container Content*.

Assay for radioactivity—Using a suitable counting assembly, determine the radioactivity, in MBq (μCi) per mL, of Solution by use of a calibrated system as directed under *Radioactivity* ⟨821⟩.

Topic/Question	Contact	Expert Committee
SODIUM IODIDE I 131 SOLUTION	Documentary Standards Support	SM42020 Small Molecules 4

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