

Status: Currently Official on 15-Feb-2025
 Official Date: Official Prior to 2013
 Document Type: USP Monographs
 DocID: GUID-76D42657-7567-48A9-A1C5-68AB86DDA75B_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M41670_02_01
 DOI Ref: wuk1u

© 2025 USPC
 Do not distribute

Sodium Iodide I 131 Capsules

Sodium iodide (Na^{131}I).

Sodium iodide (Na^{131}I)

CAS RN®: 7790-26-3.

» Sodium Iodide I 131 Capsules contain radioactive iodine (^{131}I) processed in the form of Sodium Iodide from 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. Capsules contain 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 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 stabilizing agent.

Packaging and storage—Preserve in well-closed containers.

Labeling—Label the Capsules to include the following: the date of calibration; the amount of ^{131}I as iodide expressed in megabecquerels (microcuries or millicuries) per Capsule at the time of calibration; 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—A solution or suspension of 1 or more Capsules in water responds to the test for [Radionuclide identification](#) under [Sodium Iodide I 131 Solution](#).

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 are met if not fewer than 19 of the Capsules are within the limits of 96.5% and 103.5% of the mean radioactivity value.

Radiochemical purity—Homogenize 1 Capsule in 3 mL of water, add 3 mL of methanol, and centrifuge. The supernatant meets the requirements of the test for *Radiochemical purity* under [Sodium Iodide I 131 Solution](#).

Other requirements—A solution or suspension prepared by homogenizing 1 or more Capsules in sufficient water to yield a concentration of not less than 1 MBq (25 μCi) per mL meets the requirements of the [Assay for radioactivity](#) under [Sodium Iodide I 131 Solution](#).

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-76D42657-7567-48A9-A1C5-68AB86DDA75B_2_en-US

Previous DocID: GUID-76D42657-7567-48A9-A1C5-68AB86DDA75B_1_en-US

DOI: https://doi.org/10.31003/USPNF_M41670_02_01

DOI ref: wuk1u