

IODINE-131



► About us

CMR (Center of Molecular Research) was founded in 2001 by the group of professional scientist and specialists in nuclear medicine and international economic relations spheres firstly, focusing on production and distributing of Oxygen-18 water with Isotopic Enrichment $\geq 98\%$ and other medicine isotopes. After more than 20 years of development today CMR is a vertically constructed united group of companies having its representatives and offices in many countries of the world.

Nowadays CMR is not only one of the world's largest manufacturers of Oxygen-18 water but also the qualified supplier of a wide range of products including STABLE AND RADIOACTIVE ISOTOPES, PEPTIDES AND CHEMICAL KITS, which completely satisfy the needs of medicine centers and hospitals, scientist and technologists in isotopic fields.

Iodine-131



► **Intended use:** Sodium Iodide is used in brachytherapy of cancer (prostate and brain), to estimate the glomerular filtration rate and to diagnose deep vein thrombosis, and is also used extensively in the radioimmunoassay.

► **Half-Life:** 8.02 days.

► **Production methods:** there are 3 possible production methods of Iodine-131.

Fission (from Uranium-235)

In this case I-131 is a fission isotope, which emits with the production of Mo-99 from U-235. At the beginning, U-235 holds about a day in order the radioisotopes with a short half-life decay. After filtration nitric acid is added. While heating I-131 is distilled and accumulated, and the rest part of the mixture is additionally handled for receiving Mo-99.

Irradiation of natural Tellurium

The biggest quantity of I-131 is received by the neutron irradiation of the natural tellurium target in a nuclear reactor. The irradiation of natural tellurium helps to received practically pure I-131 as a singular isotope with a half-life of several days.

Irradiation of enriched Tellurium-130 $\text{Te-130}(n,\gamma)\text{Te-131} \rightarrow \text{I-131}$

I-131 is also produced in the neutron-capture reactions on the nucleus of Tellurium-130 nucleus with the formation of Te-131 and Te-131m which follows by beta-decays and appearance of I-131.



Our Iodine-131 is manufactured by irradiation of enriched Tellurium-130

► **Iodine-131 (nuclear reaction $^{130}\text{Te} (n,\gamma) \rightarrow ^{131}\text{Te} \rightarrow ^{131}\text{I}$)**

Specification

Solution of sodium iodide with Iodine-131, carrier free (Na I-131) in 0.05 M solution of sodium hydroxide	
CHEMICAL FORM	^{131}I , carrier free, in 0.05 mol/L NaOH solution containing 0.001mol/L $\text{Na}_2\text{S}_2\text{O}_3$ (as reducing agent)
Appearance	Transparent colorless liquid
Radioactive concentration, mCi/ml	not less than 2000.0
pH	7–12
Radiochemical purity, %	not less than 95.0
Radionuclide impurities tellurium content in the final product in the amount of not more than, %	0.01
Specific Activity, Ci/mg	not less than 6.5

► Qualitative and quantitative composition

Active substance: Radionuclide Iodine-131 (FS 42 Uz-0079-2017)	37.0–1110 MBq or at least 1850 MBq
Excipients: Sodium hydroxide (GOST 1277-75)	not more than 0.8 mg/ml
Water for injection (FS 42 Uz-0512-2017)	to 1 ml

► Trade name of the medicinal product:

Iodine-131 sodium iodide carrier free,
Radiopharmaceutical precursor, solution

► Colorless clear liquid.

► **pH:** from 7.0 to 12.0.

► **The main nuclear physical characteristics:** Iodine-131 has the most intense component of gamma radiation with an energy of 0.365 MeV (81.7%).

► **Volumetric activity of Iodine-131:** from 37 to 1100 MBq/ml at the date of manufacture.

► **Radionuclide impurities:** the relative content of tellurium impurities (^{121m}Te , ^{121}Te , ^{123m}Te , ^{125m}Te , ^{127m}Te , ^{129m}Te) and ^{75}Se should not exceed 0.01% of the activity of Iodine-131 at the date of manufacture.

► **Radiochemical purity:** not less than 95.0%.

► **Half-life $T_{1/2}$:** 8.02 days.

► **Packing:** 2000, 4000, 6000, 8000, 10000 MBq at the specified delivery date.

► **Application:** the radiopharmaceutical product is used to treat thyrotoxicosis, metastases of thyroid cancer.



► **Contraindications:** pregnancy, breast-feeding, hypersensitivity, individuals below 20 years of age. Blood diseases with inhibition of hematopoiesis (with impaired leukopoiesis and thrombocytopoiesis), severe hemorrhagic syndrome; peptic ulcer of the stomach and 12-intestine (in the acute stage); diffuse lesions of the kidneys.

► **The administered dose:** the value of a single therapeutic activity of Iodine-131 for adults is 37-56 MBq per kilogram of body weight. Before each re-appointment of the radiopharmaceutical product, Iodine-absorbing activity of metastases is studied by scintigraphy and radioisotopic scanning after administration of 37-74 MBq of the radiopharmaceutical product. For the treatment of thyrotoxicosis with diffuse and multinodular toxic goiter: from 111 to 555 MBq.

► **Radiation loads on the organs and tissues of the patient when using the radiopharmaceutical product "Sodium Iodide solution with Iodine-131, carrier free for oral administration"**

Body organs	Absorbed dose, mGy/MBq
Stomach	0.39
Red bone marrow	0.015
Lungs	0.02
Bladder	0.38
Liver	0.04
Pancreas	0.03
Kidneys	0.03
Spleen	0.03
Small intestine	0.05
Thyroid	25.0
Testicles	0.08
Ovaries	0.81
Body (effective equivalent dose), mSv/MBq	11.0

► **Shelf life:** 60 days from the date of manufacture.

► **Special precautions for storage:** In accordance with the current basic sanitary rules for working with radioactive substances and sources of ionizing radiation (SanPiN (Sanitary/Hygienic Standards and Regulations, Sanitary Rules and Standards) No. 0193-06 of the Ministry of Health of the Republic of Uzbekistan).

► **Type and contents of the primary packaging:** portions of 1000 and 2000 MBq for the specified date and time of delivery to medicine vials with a capacity of 5 or 10 ml (primary packaging), hermetically sealed with medical rubber stoppers of type AB and crimped with aluminum caps.

► **Labels** made of writing paper or label paper are stuck to the vials. Each vial is accompanied by a data sheet and instructions for use of the radiopharmaceutical product.

► **The vial, data sheet and instructions** for use of the radiopharmaceutical product are placed in a transport packaging kit for radioactive substances (secondary packaging).

► **Special safety measures when handling unused radiopharmaceutical product or radiopharmaceutical product waste:** In accordance with the current basic sanitary rules for working with radioactive substances and sources of ionizing radiation (SanPiN No. 0193-06 of the Ministry of Health of the Republic of Uzbekistan).

► **Owner of the registration certificate:** State Enterprise "Radiopreparat" of the Academy of Sciences of the Republic of Uzbekistan.

► **Registration certificate number:** 74/764/6, 20.02.2012.

► **Date of first registration or re-registration of a medicinal product:** 74/764/6, 01.03.2002.