# Radiopharmaceuticals and Radiochemicals

IZOTOP
INSTITUTE OF ISOTOPES CO. LTD.

# Radiopharmaceutical Business Unit

**'NUCLEAR MEDICINE is not just a pair of well-sounding and promising words: it is an advanced method of using radioactive isotopes to revolutionize therapy'**

The Radiopharmaceutical Business Unit of the Institute of Isotopes Co. Ltd. is dedicated to supplying high-quality radiopharmaceutical products to nuclear medicine professionals worldwide, supporting early diagnosis and contributing to improved patient outcomes.

Our effective Quality Management System complies with both customer standards as well as applicable regulatory standards including GMP and relevant ISO standards, ensuring consistent product quality and reliability.

Our R&D team supports the development and manufacturing of radiopharmaceuticals with strong technical expertise and a practical, solution-oriented approach, aligned with the needs of the nuclear medicine community.

We are proud to be involved in various co-operations and partnerships benefiting from our specific expertise, technological background and well-equipped facility.

I-131 ISOTOPE DECAY FACTORS

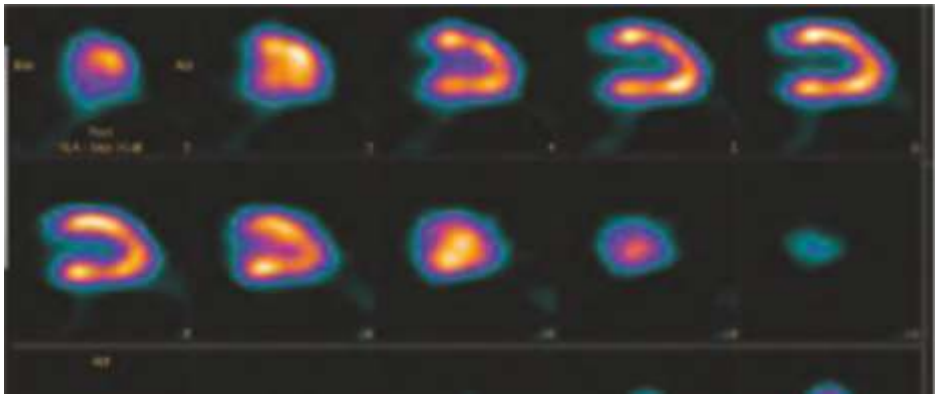
| day | hours | 0.0 | 1.0 | 2.0 | 3.0 | 4.0 | 5.0 | 6.0 | 7.0 | 8.0 | 9.0 | 10.0 | 11.0 | 12.0 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 1.0000 | 0.9964 | 0.9928 | 0.9893 | 0.9857 | 0.9822 | 0.9787 | 0.9752 | 0.9717 | 0.9682 | 0.9647 | 0.9613 | 0.9578 |
| | 12 | 0.9578 | 0.9544 | 0.9510 | 0.9475 | 0.9441 | 0.9408 | 0.9374 | 0.9340 | 0.9307 | 0.9273 | 0.9240 | 0.9207 | 0.9174 |
| 1 | 24 | 0.9174 | 0.9141 | 0.9108 | 0.9076 | 0.9043 | 0.9011 | 0.8978 | 0.8946 | 0.8914 | 0.8882 | 0.8850 | 0.8819 | 0.8787 |
| | 36 | 0.8787 | 0.8755 | 0.8724 | 0.8693 | 0.8662 | 0.8631 | 0.8600 | 0.8569 | 0.8538 | 0.8507 | 0.8477 | 0.8447 | 0.8416 |
| 2 | 48 | 0.8416 | 0.8386 | 0.8356 | 0.8326 | 0.8296 | 0.8266 | 0.8237 | 0.8207 | 0.8178 | 0.8148 | 0.8119 | 0.8090 | 0.8061 |
| | 60 | 0.8061 | 0.8032 | 0.8003 | 0.7975 | 0.7946 | 0.7918 | 0.7889 | 0.7861 | 0.7833 | 0.7805 | 0.7777 | 0.7749 | 0.7721 |
| 3 | 72 | 0.7721 | 0.7693 | 0.7666 | 0.7638 | 0.7611 | 0.7584 | 0.7556 | 0.7529 | 0.7502 | 0.7475 | 0.7449 | 0.7422 | 0.7395 |
| | 84 | 0.7395 | 0.7369 | 0.7342 | 0.7316 | 0.7290 | 0.7264 | 0.7238 | 0.7212 | 0.7186 | 0.7160 | 0.7134 | 0.7109 | 0.7083 |
| 4 | 96 | 0.7083 | 0.7058 | 0.7033 | 0.7007 | 0.6982 | 0.6957 | 0.6932 | 0.6907 | 0.6883 | 0.6858 | 0.6833 | 0.6809 | 0.6784 |
| | 108 | 0.6784 | 0.6760 | 0.6736 | 0.6712 | 0.6688 | 0.6664 | 0.6640 | 0.6616 | 0.6592 | 0.6569 | 0.6545 | 0.6522 | 0.6498 |
| 5 | 120 | 0.6498 | 0.6475 | 0.6452 | 0.6429 | 0.6405 | 0.6383 | 0.6360 | 0.6337 | 0.6314 | 0.6291 | 0.6269 | 0.6246 | 0.6224 |
| | 132 | 0.6224 | 0.6202 | 0.6179 | 0.6157 | 0.6135 | 0.6113 | 0.6091 | 0.6069 | 0.6048 | 0.6026 | 0.6004 | 0.5983 | 0.5961 |
| 6 | 144 | 0.5961 | 0.5940 | 0.5919 | 0.5898 | 0.5876 | 0.5855 | 0.5834 | 0.5813 | 0.5793 | 0.5772 | 0.5751 | 0.5730 | 0.5710 |
| | 156 | 0.5710 | 0.5689 | 0.5669 | 0.5649 | 0.5628 | 0.5608 | 0.5588 | 0.5568 | 0.5548 | 0.5528 | 0.5508 | 0.5489 | 0.5469 |
| 7 | 168 | 0.5469 | 0.5449 | 0.5430 | 0.5410 | 0.5391 | 0.5372 | 0.5352 | 0.5333 | 0.5314 | 0.5295 | 0.5276 | 0.5257 | 0.5238 |
| | 180 | 0.5238 | 0.5219 | 0.5201 | 0.5182 | 0.5164 | 0.5145 | 0.5127 | 0.5108 | 0.5090 | 0.5072 | 0.5053 | 0.5035 | 0.5017 |

# OVERVIEW OF RADIOPHARMACEUTICALS AND RADIOCHEMICALS

# COLD KITS (SPECT) FOR DIAGNOSIS

## **MIBITop 1 mg kit** for radiopharmaceutical preparation

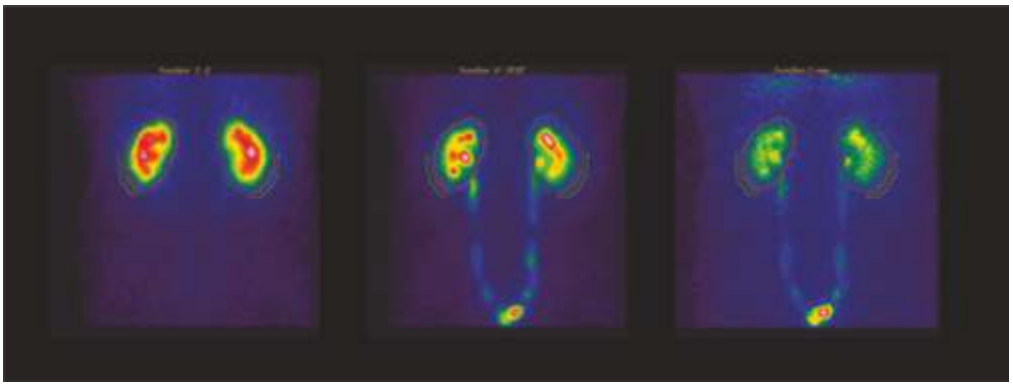
| | |
|---|---|
| **Product code:** | **Tc-IK-81** |
| **ATC code:** | V09GA01, Reg.No. OGYI-T-23814/01, MA1372/00101 |
| **Active substance:** | 1 mg [tetrakis(1-isocyanide-2-methoxy-2-methylpropy)copper(I)] tetrafluoroborate |
| **Indications/Posology:** | Diagnosis of reduced coronary perfusion and myocardial infarction:<br>400 – 900 MBq |
| | Diagnosis of ischaemic heart disease:<br>- Two-day protocol: 600 – 900 MBq/study<br>- One-day protocol: 400 – 500 MBq for the 1st injection,<br>3 times more for the 2nd injection |
| | Assessment of global ventricular function: 600 – 800 MBq injected as a bolus |
| | Scintimammography: 700 – 1000 MBq injected as a bolus |
| | Localisation of hyperfunctioning parathyroid tissue: 200 – 700 MBq injected as a bolus |
| **Activity of sodium pertechnetate ($^{99m}$Tc ) to use for reconstitution:** | Maximum 15 GBq |
| **Volume of sodium pertechnetate ($^{99m}$Tc) to use for reconstitution:** | 1-3 mL |
| **Shelf life and storage of MIBITop kit:** | 24 months in refrigerator (2°C - 8°C) |
| **Shelf life and storage of $^{99m}$Tc-MIBITop, the radiolabelled injection:** | After radiolabelling 16 hours, do not store above 25°C |
| **Pack size:** | 6 vials/kit |

# COLD KITS (SPECT) FOR DIAGNOSIS

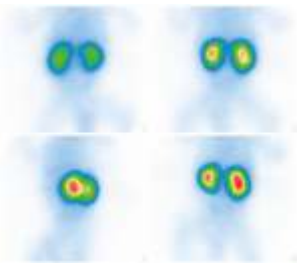
## **EC 2 mg kit** for radiopharmaceutical preparation

| | |
|---|---|
| **Product code:** | **Tc-IK-25** |
| **ATC code:** | V09CA, Reg. No. OGYI-T-9141/01 |
| **Active substance:** | 2.0 mg EC (Ethylene-dicysteine) |
| **Three-vial formulation:** | $^{99m}$Tc-EC injection can be prepared „in situ" at the site of the use by mixing the contents of vial-A, vial-B, vial-C and the ($^{99m}$Tc) pertechnetate eluate. |
| **Indications/Posology:** | The $^{99m}$Tc-EC injection is indicated for renal tubular functional imaging, dynamic kidney tests by imaging technique, camera renography. |
| | 90 – 120 MBq of $^{99m}$Tc-EC injection for intravenous administration (for an average body weight of 70 kg). |
| | In case of children and adolescents can use also, the administered activity is according to the SPC. |
| **Activity of sodium pertechnetate ($^{99m}$Tc ) to use for reconstitution:** | 0.8 – 1.6 GBq |
| **Volume of sodium pertechnetate ($^{99m}$Tc) to use for reconstitution:** | 2 mL |
| **Shelf life and storage of EC kit:** | 24 months in refrigerator (2°C – 8°C). |
| **Shelf life and storage of $^{99m}$Tc-EC, the radiolabelled injection:** | After radiolabelling 8 hours, do not store above 25 °C. [labelling procedure: at room temperature, not need preheated boiling water bath] |
| **Pack size:** | One box contains vials for 4 individual labelling, i.e. 4 pieces of vial-A. 4 pieces of vial-B and 4 pieces of vial-C |



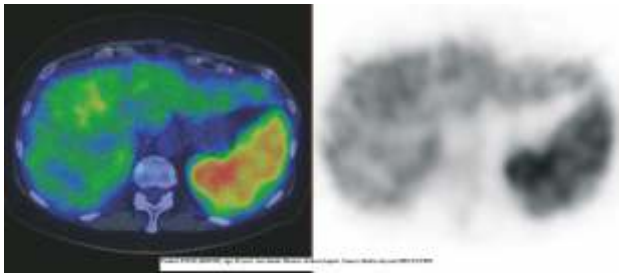
# COLD KITS (SPECT) FOR DIAGNOSIS

| | FOR RENAL STUDIES | | FOR BLOOD-POOL SCINTIGRAPHY |
|---|---|---|---|
| **Isotope:** | **Tc-99m** | | |
| **In vivo kit:** | **DMSA 1.5 mg** | **DTPA 9 mg** | **PYRON 25 mg** |
| **Product code:** | **Tc-IK-7** | **Tc-IK-8** | **Tc-IK-5** |
| **ATC code:** | V09CA02 | V09CA01 | V09BA03 |
| **Marketing Authorisation Number:** | OGYI-T-9245/01 | OGYI-T-9244/01 | OGYI-T-9246/01 |
| **Active ingredient:** | Dimercaptosuccinic acid | Diethylene-triamino pentaacetic acid | Sodium pyrophosphate |
| **Content/vial:** | 1.5 mg | 9.0 mg | 25.0 mg |
| **Indications:** | » Kidney scintigraphy, static kidney imaging, localisation of the kidneys with imaging<br>» Determination of the functional mass of the kidney<br>» Determination of the relative function ratio (percentage) of the left and right kidneys | » Dynamic studies of kidney,<br>» Determination of kidney per-fusion, glomerular filtration rate, total and partial kidney function<br>» Examination of the cerebral blood circulation<br>» Examination of the gastrointestinal tract by using labelled foodstuff or drink<br>» Examination of liquor circulation | » Bone and acute myocardial infarct scintigraphy<br>» Blood pool scintigraphy<br>» Spleen scintigraphy |
| **Activity for labelling 1 vial:** | 1.0 – 1.8 GBq<br>no more than 3 ml | 0.8 – 2.4 GBq<br>no more than 3 ml | 1.3 – 3.0 GBq<br>no more than 2-5 ml |
| **Vials per kit:** | 6 injection vials | 6 injection vials | 6 injection vials |
| **Shelf life:** | 24 months<br>after radiolabelling: 8 h | 12 months<br>after radiolabelling: 8 h | 12 months<br>after radiolabelling: 3 h |
| **Storage:** | 2-8 °C<br>after radiolabelling: ≤ 25°C | ≤ 25 °C<br>after radiolabelling: ≤ 25°C | ≤ 25 °C<br>after radiolabelling: ≤ 25°C |



# COLD KITS (SPECT) FOR DIAGNOSIS

| | FOR EXAMINATION OF THE LIVER- AND HEPATOBILIARY SYSTEM | | FOR BONE SCINTIGRAPHY |
|---|---|---|---|
| **Isotope:** | **Tc-99m** | | |
| **In vivo kit:** | **FYTON 15 mg** | **TECHIDA 30 mg** | **MDP 5 mg** |
| **Product code:** | **Tc-IK-2** | **Tc-IK-6** | **Tc-IK-10** |
| **ATC code:** | V09DB07 | V09DA02 | V09BA02 |
| **Marketing Authorisation Number:** | OGYI-T-9288/01 | OGYI-T-9210/01 | OGYI-T-9702/01 |
| **Active ingredient:** | Sodium phytate | Diethyl-acetanilid-iminodiacetic acid | Medronic acid |
| **Content/vial:** | 15.0 mg | 30.0 mg | 5.0 mg |
| **Indications:** | » Morphological examination of the liver by imaging technique<br>» Diagnosis of benign and malignant liver tumours and monitoring of the therapy | » Dynamic examination of the function of the hepatocytes<br>» Liver transplant evaluation<br>» Dynamic examination of flow disorders in the hepatobiliary system (blockage in the biliary duct, etc.)<br>» Examination of the acute cholecystitis<br>» Verification of focal nodular hyperplasia | » For bone scintigraphy (diagnostic skeletal imaging)<br>» Use of the preparation is highly recommended for:<br>• Primer bone tumours<br>• Metastases of other tumours, for example prostate / breast / lung cancer<br>• Osteomyelitis<br>• Metabolic bone diseases<br>• Paget's disease |
| **Activity for labelling 1 vial:** | 0.8 – 1.6 GBq<br>no more than 3 ml | 0.8 – 1.6 GBq<br>in 2-5 ml | 3.0 – 6.0 GBq<br>in 2-5 ml |
| **Vials per kit:** | 6 injection vials | 6 injection vials | 6 injection vials |
| **Shelf life:** | 12 months<br>after radiolabelling: 3 h | 24 months<br>after radiolabelling: 6 h | 12 months<br>after radiolabelling: 6 h |
| **Storage:** | ≤ 25 °C<br>after radiolabelling: ≤ 25°C | 2-8 °C<br>after radiolabelling: 2-8°C | 2-8 °C<br>after radiolabelling: ≤ 25°C |



# I-131 PHARMACEUTICALS
# THYROTOP – FOR DIAGNOSIS

| | |
|---|---|
| **Name:** | **ThyroTop D 0.5-37 MBq hard capsule** |
| **Product code:** | **I-RA-7/D** |
| **ATC code:** | V09F |
| **Marketing Authorisation Number:** | OGYI-T-9681/05 |
| **Compliance with monograph:** | European Pharmacopoeia 0938 |
| **Pharmaceutical form and description:** | Hard capsule, Size „0", colourless, transparent, CONI-SNAP type gelatine capsule, containing I-131 labelled sodium iodide, for oral administration |
| **Activity per capsule:** | 0.5 – 37 MBq |
| **Radionuclidic purity:** | I-131 ≥ 99.9 % |
| **Radiochemical purity:** | ≥ 95 % |
| **Expiry time:** | 21 days from the manufacturing date |
| **Indications:** | **Thyroid diagnostics**<br>» 0.2 – 0.5 MBq capsule for radioiodine uptake of thyroid in case no accurate dosimetry is needed.<br>» 2 – 4 MBq capsule can be used for calculation of personalised dose for the radionuclide therapy and thyroid scintigraphy for the establishment of the size of the hyperfunctioning tissue in thyroid nodules.<br>» For whole body radioiodine scintigraphy in differentiated thyroid cancer 37 – 185 MBq (usually 74 – 111 MBq) I-131 is needed. 2 – 3 capsules should be administered per os. |
| **Storage:** | Do not store above 25°C. Store in the original packaging.<br>Comply with the regulations for radiation safety. |
| **Packaging:** | 1 - 10 capsules in Type „I" injection vial (closed with brombutyl stopper and green aluminium cap) in lead container. Transported in a Type A package. |

# I-131 PHARMACEUTICALS
# THYROTOP – FOR THERAPY

| | |
|---|---|
| **Name:** | **I-131-sodium-iodide ThyroTop 38-7400 MBq hard capsules** |
| **Product code:** | **I-RA-7/K** |
| **ATC code:** | V10XA01 |
| **Marketing Authorisation Number:** | OGYI-T-9681/01 |
| **Compliance with monograph:** | European Pharmacopoeia 2116 |
| **Pharmaceutical form and description:** | Hard capsule, Size „0", colourless, transparent, CONI-SNAP type gelatine capsule, containing I-131 labelled sodium iodide, for oral administration |
| **Activity per capsule:** | 38 – 7400 MBq |
| **Radionuclidic purity:** | I-131 ≥ 99.9 % |
| **Radiochemical purity:** | ≥ 95 % |
| **Expiry time:** | 21 days from the manufacturing date |
| **Indications:** | **Radioiodide thyroid therapy is indicated in adults and children for:**<br>» Hyperthyroidism: Treatment of Graves'disease, toxic multinodular goitre or autonomous nodules<br>» Treatment of papillary and follicular thyroid carcinoma including metastatic disease:<br>• Ablation of residual thyroid tissues following thyroid cancer surgery.<br>• Treatment of recidivations and metastases. |
| **Storage:** | Do not store above 25°C. Store in the original packaging.<br>Comply with the regulations for radiation safety. |
| **Packaging:** | 1 capsule in plastic tube with screw cap in lead contanier.<br>Transported in a Type A package. |

# I-131 PHARMACEUTICALS
# MIBG – FOR DIAGNOSIS

| | |
|---|---|
| **Name:** | **I-131 MIBG 20 MBq/ml injection for diagnostic use** |
| **Product code:** | **I-RAO-1** |
| **ATC code:** | V09IX02 |
| **Marketing Authorisation Number:** | 20 MBq, OGYI-T-9205/01; 40 MBq, OGYI-T-9205/02; 80 MBq, OGYI-T-9205/03 |
| **Pharmaceutical form and description:** | Radioactive sterile injection solution.<br>The active ingredient of the radioactive solution for injection for intravenous use is I-131 radioisotope labelled meta-iodobenzyl guanidine (MIBG). |
| **Activity per vial:** | 20 MBq, 40 MBq or 80 MBq at activity reference date and time. |
| **Specific activity:** | ≥ 26.7 GBq/g MIBG at activity reference date and time. |
| **Radioactive concentration:** | 20 MBq/ml at activity reference date and time. |
| **Radionuclid impurities:** | ≤ 0.1 % |
| **Radiochemical purity:** | ≥ 95 % |
| **pH:** | 5 – 7 |
| **Expiry time:** | 5 days from manufacturing date. |
| **Indications:** | Indication field: radioisotope diagnostic<br>Localisation and imaging of neuro-endocrine tumours, especially: phaeochromocytoma, neuroblastoma. |
| **Recommended dose:** | The recommended individual patient dose is 20 – 40 MBq $^{131}$I-MIBG.<br>To prevent the uptake of the free radioiodine evolving in vivo, thyroid blockade is recommended before the examination.<br>The injection should be administered slowly.<br>Time of administration is 2-4 minutes.<br>Rapid administration of MIBG can result in blood pressure increase, allergic symptoms, flush or asthmatic spasms. |
| **Storage:** | Store in refrigerator at 2-8 °C. Comply with the regulations for radiation safety. |
| **Packaging:** | I-131 MIBG in Type „I" glass (6R) injection vial, closed with rubber stopper and green aluminium cap placed in a lead container.<br>Transported in a Type A package. |

# I-131 PHARMACEUTICALS
# MIBG – FOR THERAPY

| | |
|---|---|
| **Name:** | **I-131 MIBG 370 MBq/ml injection for therapy** |
| **Product code:** | **I-RAO-2** |
| **ATC code:** | V10XA02 |
| **Marketing Authorisation Number:** | OGYI-T-9197/01 |
| **Pharmaceutical form and description:** | Radioactive, sterile solution for injection.<br>For intravenous use. The active ingredient of the radioactive solution is I-131 radioisotope labelled meta-iodobenzylguanidine (MIBG). |
| **Activity per vial:** | 3700 ± 10% MBq at activity reference date and time |
| **Specific activity:** | ≥ 555 GBq/g MIBG at activity reference date and time |
| **Radioactive concentration:** | 370 ± 10% MBq/mL at activity reference date and time |
| **Radionuclid impurities:** | ≤ 0.1 % |
| **Radiochemical purity:** | ≥ 90 % |
| **pH:** | 5 – 5.5 |
| **Expiry time:** | 5 days from manufacturing date. |
| **Indications:** | RADIOISOTOPE THERAPY<br>Local, lesion-specific treatment of neuro-endocrine tumours, especially: phaeochromocytoma, neuroblastoma, paraganglioma, medullar thyroid carcinoma, carcinoid |
| **Recommended dose:** | The recommended individual dose is 3.3 – 4.1 GBq.<br>To prevent the uptake of the free radioiodine evolving in vivo, thyroid blockade is recommended before the examination.<br>Do not administer the injection directly.<br>10 ml of the MIBG solution for injection must be mixed with 90 ml of 5% glucose injection. The obtained solution which has a total volume of 100 ml should be administered to the patient slowly. Time of administration is 2-4 hours.<br>Rapid administration of MIBG can result in blood pressure increase, allergic symptoms, flush or asthmatic spasms. |
| **Storage:** | Store in a freezer, below -18°C.<br>Storage of radiopharmaceuticals should be in accordance with national regulation on radioactive materials.<br>To ensure the low temperature during shipping dry-ice is used to cool the container. |
| **Packaging:** | I-131 MIBG in Type „I" glass (10R) injection vial, closed with rubber stopper and green aluminium cap placed in a lead container.<br>Transported in a Type A package |

# API

| | |
|---|---|
| **Name:** | **I-131 sodium iodide sterile solution, drug substance** |
| **Product code:** | **I-RA-7** |
| **Compliance with monograph:** | European Pharmacopoeia 0281 |
| **Description:** | Clear, colourless solution of I-31 sodium iodide containing iodine-131 in the form of sodium iodide in $NaHCO_3$ /$Na_2CO_3$ /NaOH buffer.<br>Non-carrier and sodium thiosulfate 0.5-2.0 mg/mL reducing agent added. |
| **Volume:** | 0.2 – 10 mL |
| **Radioactive concentration:** | 0.1 – 55.5 GBq/mL |
| **Radionuclidic impurities:** | ≤ 0.1 % |
| **Radiochemical purity:** | ≥ 95 % |
| **pH:** | 7 – 10 |
| **Expiry time:** | 21 days from manufacturing date. |
| **Storage:** | Store at room temperature in its own container, in accordance with the regulations on radioactive materials. |
| **Packaging:** | In Type „I" injection vial (6R or 10R), closed with brombutyl stopper and green aluminium cap in lead container (Type A packaging).<br>6R vial in KT1-KT6 and 10R vial in KT6B lead container. |
| **Pack size:** | ≤ 111 GBq ± 10% (at the indicated calibration date)/vial |

## Description

The largescale production of I-131 based on the neutron irradiation of $TeO_2$ target followed by the separation of I-131 using dry distillation technique. I-131 sterile drug substance solution is manufactured from the I-131 sodium iodide base solution (175 GBq/mL, active substance specified according to the current edition of the European Pharmacopoeia Monograph 0281) by dilution with 50 mg/mL sodium hydrogen carbonate solution (Diluting agent 'A') and 20 mg/mL sodium thiosulphate solution (Diluting agent 'B') according to the customer specified active concentration. The drug substance is supported with ASMF.

## Composition

| Components | Quantity | Quantity | Quantity | Quantity |
|---|---|---|---|---|
| I-131 sodium iodide | 55.5 GBq/mL ± 10% (at the day of production) | 37 GBq/mL ± 10% (at the day of production) | 55.5 GBq/mL ± 10% (at the day of production) | 1 GBq/mL ± 10% (at the day of production) |
| Sodium bicarbonate | 16.72 mg/mL | 14.48 mg/mL | 10.67 mg/mL | 10.12 mg/mL |
| Sodium carbonate | 1.33 mg/mL | 0.88 mg/mL | 0.13 mg/mL | 0.02 mg/mL |
| Sodium thiosulfate | 0.5 mg/mL | 0.5 mg/mL | 2.0 mg/mL | 2.0 mg/mL |
| Sodium hydroxide | 0.63 µg/mL | 0.42 µg/mL | 0.06 µg/mL | 0.01 µg/mL |
| Water for injection | 1.0 g/mL | 1.0 g/mL | 1.0 g/mL | 1.0 g/mL |

# API

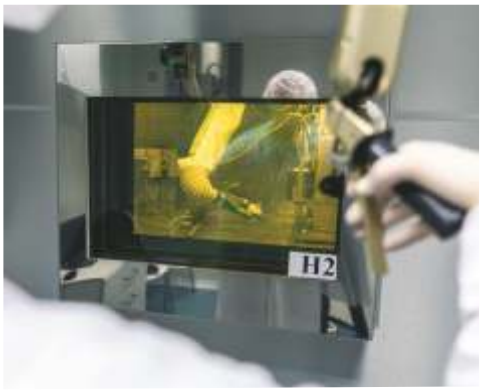
| | |
|---|---|
| **Name:** | **I-131 sodium iodide non-sterile solution, drug substance [low carbonate content and without thiosulfate]** |
| **Product code:** | **I-RA-5** |
| **Compliance with monograph:** | European Pharmacopoeia 2121 |
| **Description:** | Clear, colourless solution of I-31 sodium iodide containing iodine-131 in the form of sodium iodide in $NaHCO_3$ /$Na_2CO_3$ /NaOH buffer.<br>Non-carrier and no reducing agents added. |
| **Volume:** | 0.2 – 10 mL |
| **Radioactive concentration:** | 0.1 – 74 GBq/mL |
| **Radionuclidic impurities:** | ≤ 0.1 % |
| **Radiochemical purity:** | ≥ 95 % |
| **pH:** | 8 – 11 |
| **Expiry time:** | 21 days from manufacturing date. |
| **Storage:** | Store at room temperature in its own container, in accordance with the regulations on radioactive materials. |
| **Packaging:** | In Type „I" injection vial (6R or 10R), closed with brombutyl stopper and green aluminium cap in lead container (Type A packaging).<br>6R vial in KT1-KT6 and 10R vial in KT6B lead container. |
| **Pack size:** | ≤ 111 GBq ± 10% (at the indicated calibration date)/vial |

## Description

The largescale production of I-131 based on the neutron irradiation of $TeO_2$ target followed by the separation of I- 131 using dry distillation technique.
I-131 non-sterile drug substance solution is manufactured from the I-131 sodium iodide base solution, 175 GBq/mL active substance by dilution with 0.0001M NaOH according to the customer specified active concentration. It is specified according to the current edition of the European Pharmacopoeia Monograph 2121. The drug substance is supported with ASMF.

## Composition

| Components | Quantity | Quantity | Quantity | Quantity |
|---|---|---|---|---|
| I-131 sodium iodide | 74 GBq/mL ± 10% (at the day of production) | 55.5 GBq/mL ± 10% (at the day of production) | 37 GBq/mL ± 10% (at the day of production) | 1 GBq/mL ± 10% (at the day of production) |
| Sodium bicarbonate | 8.96 mg/mL | 6.72 mg/mL | 4.48 mg/mL | 0.12 mg/mL |
| Sodium carbonate | 1.78 mg/mL | 1.33 mg/mL | 0.89 mg/mL | 0.02 mg/mL |
| Sodium hydroxide | 3.15 µg/mL | 3.36 µg/mL | 3.58 µg/mL | 3.9 µg/mL |
| Water for injection | 1.0 g/mL | 1.0 g/mL | 1.0 g/mL | 1.0 g/mL |



# API

| | |
|---|---|
| **Name:** | **I-131 sodium iodide solution (175 - 500 GBq/mL, active substance)** |
| **Product code:** | **I-RA-5s** |
| **Compliance with monograph:** | European Pharmacopoeia 2121 |
| **Description:** | I-131 non-sterile drug substance solution is prepared from the I-131 sodium iodide solution, 175 - 500 GBq/mL. (supported with ASMF)<br>Clear, colourless solution of I-31 sodium iodide containing iodine-131 in the form of sodium iodide in $NaHCO_3$ /$Na_2CO_3$ /NaOH buffer.<br>Non-carrier and no reducing agents added. |
| **Radioactive concentration:** | 175 – 500 GBq/mL at the day of production |
| **Radionuclidic impurities:** | ≤ 0.1 % |
| **Radiochemical purity:** | ≥ 95 % |
| **pH:** | ≥ 8 |
| **Expiry time:** | 14 days from manufacturing date. |
| **Storage:** | Store at room temperature in its own container, in accordance with the regulations on radioactive materials. |
| **Packaging:** | In Type „I" injection vial (6R or 10R), closed with brombutyl stopper and green aluminium cap in lead container (Type A packaging). |
| **Pack size:** | ≤ 111 GBq ± 10% (at the indicated calibration date)/vial<br>≤ 333 GBq ± 10% (at the indicated calibration date)/vial |


## Composition

| Components | Quantity | Quantity |
|---|---|---|
| I-131 sodium iodide | 175 - 350 GBq/mL ± 10% (at the day of production) | 350 - 500 GBq/mL ± 10% (at the day of production) |
| Sodium carbonate | 21.2 - 42.4 mg/mL | 42.4 mg/mL |
| Sodium bicarbonate | 4.2 - 8.4 mg/mL | 8.4 mg/mL |
| Sodium hydroxide | 0 - 2.0 µg/mL | – |
| Water for injection | 1.0 g/mL | 1.0 g/mL |

| | | |
|---|---|---|
| **Name:** | **High purity I-125 sodium iodide solution for labelling** | |
| **Product code:** | **I-RB-4**<br>**with radioactive concentration ≥ 3700 MBq/ml** | **I-RB-41**<br>**with radioactive concentration < 3700 MBq/ml** |
| **Description:** | Clear, colourless solution containing I-125 sodium iodide in NaOH.<br>Non-carrier and no reducing agents added. | |
| **Specific activity:** | ≥ 600 GBq/mg | |
| **Radionuclidic impurities:** | I-126 < 0.005% | |
| **Radiochemical purity:** | ≥ 95 % | |
| **pH:** | 8 – 11 | |
| **Calibration date:** | 13 days | |
| **Expiry time:** | 60 days from dispatch | |
| **Storage:** | Store at room temperature in its own container, in accordance with the regulations on radioactive materials. | |
| **Packaging:** | Supplied in plastic vial placed in a lead container (KT 1-3).<br>The lead container is packed in a labelled easy-open metal can, which contains plastic insert.<br>Transported in a Type A packaging in accordance with IATA regulation. | |

I-125 ISOTOPE DECAY FACTORS

| day | hours | 0.0 | 8.0 | 16.0 | 24.0 | 32.0 | 40.0 | 48.0 | 56.0 | 64.0 | 72.0 | 80.0 | 88.0 | 96.0 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 1.0000 | 0.9961 | 0.9923 | 0.9884 | 0.9846 | 0.9807 | 0.9769 | 0.9731 | 0.9694 | 0.9656 | 0.9619 | 0.9581 | 0.9544 |
| 4 | 96 | 0.9544 | 0.9507 | 0.9470 | 0.9433 | 0.9397 | 0.9360 | 0.9324 | 0.9288 | 0.9252 | 0.9216 | 0.9180 | 0.9144 | 0.9109 |
| 8 | 192 | 0.9109 | 0.9073 | 0.9038 | 0.9003 | 0.8968 | 0.8933 | 0.8899 | 0.8864 | 0.8830 | 0.8796 | 0.8761 | 0.8727 | 0.8694 |
| 12 | 288 | 0.8694 | 0.8660 | 0.8626 | 0.8593 | 0.8559 | 0.8526 | 0.8493 | 0.8460 | 0.8427 | 0.8394 | 0.8362 | 0.8329 | 0.8297 |
| 16 | 384 | 0.8297 | 0.8265 | 0.8233 | 0.8201 | 0.8169 | 0.8137 | 0.8106 | 0.8074 | 0.8043 | 0.8012 | 0.7981 | 0.7950 | 0.7919 |
| 20 | 480 | 0.7919 | 0.7888 | 0.7857 | 0.7827 | 0.7797 | 0.7766 | 0.7736 | 0.7706 | 0.7676 | 0.7646 | 0.7617 | 0.7587 | 0.7558 |
| 24 | 576 | 0.7558 | 0.7528 | 0.7499 | 0.7470 | 0.7441 | 0.7412 | 0.7383 | 0.7355 | 0.7326 | 0.7298 | 0.7269 | 0.7241 | 0.7213 |
| 28 | 672 | 0.7213 | 0.7185 | 0.7157 | 0.7129 | 0.7102 | 0.7074 | 0.7047 | 0.7019 | 0.6992 | 0.6965 | 0.6938 | 0.6911 | 0.6884 |
| 32 | 768 | 0.6884 | 0.6857 | 0.6831 | 0.6804 | 0.6778 | 0.6752 | 0.6725 | 0.6699 | 0.6673 | 0.6647 | 0.6622 | 0.6596 | 0.6570 |
| 36 | 864 | 0.6570 | 0.6545 | 0.6519 | 0.6494 | 0.6469 | 0.6444 | 0.6419 | 0.6394 | 0.6369 | 0.6344 | 0.6320 | 0.6295 | 0.6271 |
| 40 | 960 | 0.6271 | 0.6246 | 0.6222 | 0.6198 | 0.6174 | 0.6150 | 0.6126 | 0.6102 | 0.6079 | 0.6055 | 0.6032 | 0.6008 | 0.5985 |
| 44 | 1056 | 0.5985 | 0.5962 | 0.5938 | 0.5915 | 0.5892 | 0.5870 | 0.5847 | 0.5824 | 0.5801 | 0.5779 | 0.5756 | 0.5734 | 0.5712 |
| 48 | 1152 | 0.5712 | 0.5690 | 0.5668 | 0.5646 | 0.5624 | 0.5602 | 0.5580 | 0.5558 | 0.5537 | 0.5515 | 0.5494 | 0.5473 | 0.5451 |
| 52 | 1248 | 0.5451 | 0.5430 | 0.5409 | 0.5388 | 0.5367 | 0.5346 | 0.5326 | 0.5305 | 0.5284 | 0.5264 | 0.5244 | 0.5223 | 0.5203 |
| 56 | 1344 | 0.5203 | 0.5183 | 0.5163 | 0.5143 | 0.5123 | 0.5103 | 0.5083 | 0.5063 | 0.5043 | 0.5024 | 0.5004 | 0.4985 | 0.4966 |
| 60 | 1440 | 0.4966 | 0.4946 | 0.4927 | 0.4908 | 0.4889 | 0.4870 | 0.4851 | 0.4832 | 0.4814 | 0.4795 | 0.4776 | 0.4758 | 0.4739 |

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