Radiopharmaceuticals and Radiochemicals

IZOTOP
INSTITUTE OF ISOTOPES CO. LTD.

Radiopharmaceutical Business Unit

The Radiopharmaceutical Business Unit has been exclusively focused on supplying radiopharmaceutical products to nuclear medicine professionals serving the recovery of patients worldwide and supporting early diagnosis.

Our effective Quality Management System is compliant with customer standards and regulatory requirements and ensures the high-quality of our products. Our R&D group provides exceptional service in the development and manufacture of radiopharmaceuticals.

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

Diagnosis and Therapy

API

GMP

Active substance master file

Quality

Pharmacovigilance

World wide delivery

COLD KITS (SPECT) FOR DIAGNOSIS

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 No.	OGYI-T-9245/01	OGYI-T-9244/01	OGYI-T-9246/01
Active ingredient	Dimercaptosuccinic acid	Diethylenetriamino pentaacetic acid	Sodium pyrophosphate
Content/vial	1.5 mg	9.0 mg	25.0 mg
Activity for labelling 1 vial	1.0–1.8 GBq no more than 3 ml	0.8–2.4 GBq no more than 3 ml	1.3–3.0 GBq in 2-5 ml
Vials per kit	6 injection vials	6 injection vials	6 injection vials
Shelf life	24 months after radiolabelling: 8 h	12 months after radiolabelling: 8 h	12 months after radiolabelling: 3 h
Storage	2-8°C after radiolabelling: ≤ 25°C	≤ 25°C after radiolabelling: ≤ 25°C	≤ 25°C after radiolabelling: ≤ 25°C
Indications	» Kidney scintigraphy, static kidney imaging, localisation of the kidneys with imaging » Determination of the functional mass of the kidney » Determination of the relative function ratio (percentage) of the left and right kidneys	» Dynamic studies of kidney, determination of kidney perfusion, glomerular filtration rate, total and partial kidney function » Examination of the cerebral blood circulation » Examination of the gastrointestinal tract by using labelled foodstuff or drink » Examination of liquor circulation	» Bone and acute myocardial infarct scintigraphy » Blood pool scintigraphy » Spleen scintigraphy

COLD KITS (SPECT) FOR DIAGNOSIS

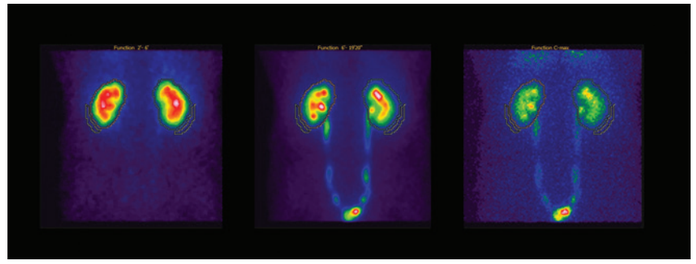
In vivo kit	MDP 5 mg	FYTON 15 mg	TECHIDA 30 mg
Product code	Tc-IK-10	Tc-IK-2	Tc-IK-6
ATC code	V09BA02	V09DB07	V09DA02
Marketing Authorisation No.	OGYI-T-9702/01	OGYI-T-9288/01	OGYI-T-9210/01
Active ingredient	Medronic acid	Sodium phytate	Diethyl-acetanilid-imino diacetic acid
Content/vial	5.0 mg	15.0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

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 „A", „B" and „C" injection vial 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:** 12 months in refrigerator (2°C - 8°C).
  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



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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:**

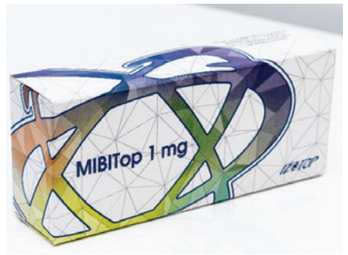
  Diagnosis of reduced coronary perfusion and myocardial infarction: 400 - 900 MBq

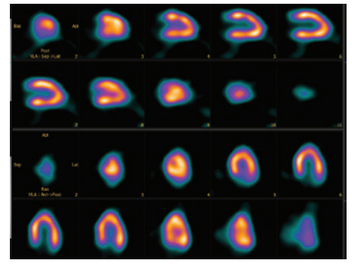
  Diagnosis of ischaemic heart disease: – Two-day protocol: 600 - 900 MBq /study
  – One-day protocol: 400 - 500 MBq for the first injection, three times more for the second injection

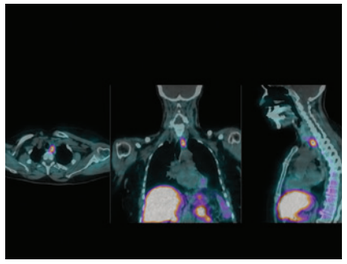
  Assessment of global ventricular function: 600 - 800 MBq injected as a bolus

  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







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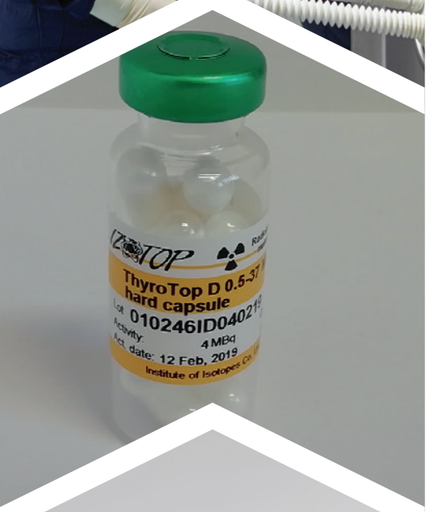
I-131 PHARMACEUTICALS THYROTOP – FOR DIAGNOSIS



Name	**ThyroTop D 0.5-37 MBq hard capsule** complies with the European Pharmacopoeia 0938 monograph
Product code	I-RA-7/D
ATC code	V09F
Marketing Auth. No.	OGYI-T-9681/05
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	$^{131}I \geq 99.9$ %
Radiochemical purity	≥ 95 %
Expiry time	21 days from the manufacturing date
Indications	**Thyroid diagnostics** » 0.2-0.5 MBq capsule for radioiodine uptake of thyroid in case no accurate dosimetry is needed. » 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. » 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. 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

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I-131 PHARMACEUTICALS THYROTOP – FOR THERAPY

Name	**I-131-sodium-iodide ThyroTop 38-7400 MBq hard capsules** complies with the European Pharmacopoeia 2116 monograph
Product code	I-RA-7/K
ATC code	V10XA01
Marketing Auth. No.	OGYI-T-9681/01
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	$^{131}I \geq 99.9$ %
Radiochemical purity	≥ 95 %
Expiry time	21 days from the manufacturing date
Indications	**Radioiodide thyroid therapy is indicated in adults and children for:** » Hyperthyroidism: Treatment of Graves' disease, toxic multinodular goitre or autonomous nodules. » Treatment of papillary and follicular thyroid carcinoma including metastatic disease: » Ablation of residual thyroid tissues following thyroid cancer surgery. » Treatment of recidivations and metastases.
Storage	Do not store above 25 ºC. Store in the original packaging. Comply with the regulations for radiation safety.
Packaging	1 capsule in plastic tube with screw cap in lead container. Transported in a Type A package.

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I-131 PHARMACEUTICALS
MIBG – FOR DIAGNOSIS

Product code	I-RAO-1
Pharmaceutical form and description	Radioactive sterile injection solution. 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 date	5 days from manufacturing date
Indications	Indication field: radioisotope diagnostics Localisation and imaging of neuroendocrine tumours, especially phaeochromocytoma, neuroblastoma
Recommended dose	The recommended individual patient dose is 20–40 MBq ^{131}I-MIBG
	To prevent the uptake of the free radioiodine evolving in vivo, thyroid blockade is recommended before the examination. The injection should be administered slowly; time of administration is 2-4 minutes. 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	^{131}I-MIBG in type I glass, (6R) injection vial, closed with rubber stopper and green aluminium cap placed in a lead container. Transported in a Type A package.

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I-131 PHARMACEUTICALS
MIBG – FOR THERAPY

Product code	I-RAO-2
Pharmaceutical form and description	Radioactive sterile solution for injection. For intravenous use. The active ingredient of the radioactive solution for injection for intravenous use is I-131 radioisotope labelled meta-iodobenzyl guanidine (MIBG).
Activity per vial	3700 ± 10% MBq MBq at activity reference date and time
Specific activity	≥ 555 GBq/g 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 date	5 days from manufacturing date
Indication	RADIOISOTOPE THERAPY 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.
	To prevent the uptake of the free radioiodine evolving in vivo, thyroid blockade is recommended before the examination. Do not administer the injection directly. 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. Rapid administration of MIBG can result in blood pressure increase, allergic symptoms, flush or asthmatic spasms.
Storage	Store in a freezer, below -18°C. Storage of radiopharmaceuticals should be in accordance with national regulation on radioactive material. To ensure the low temperature during shipping dry-ice is used to cool the container.
Packaging	^{131}I-MIBG in type I glass, (10R) injection vial, closed with rubber stopper and green aluminium cap placed in a lead container. Transported in a Type A package

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High purity I-125 sodium iodide solution for labelling

We offer two product variations:

Product code: **I-RB-4** with Radioactive concentration ≥ 3700 MBq/mL

Product code: **I-RB-41** with Radioactive concentration < 3700 MBq/mL

Description	Clear, colourless solution containing I-125 sodium iodide in NaOH. Non-carrier added. No reducing agents added
Specific activity	≥ 600 GBq/mg
Radionuclid impurities	I-126 ≥ 0.005%
Radiochemical purity	≥ 95%
pH	8 – 11
Calibration date	13 days
Expiry date	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).
	The lead container is packed in a labelled easy-open metal can, which contains plastic insert.
	Transported in a Type A packaging in accordance with IATA regulation.

Specification of ^{131}I sodium iodide solution, sterile drug substance

Name:	**^{131}I sodium iodide sterile solution, drug substance**
Product code:	**I-RA-7**
Description:	Clear, colourless solution of ^{131}I sodium iodide containing iodine-131 in the form of sodium iodide in $NaHCO_3$/Na_2CO_3/NaOH buffer. Non-carrier and sodium thiosulfate 0.5-2.0 mg/mL reducing agent added.
Radioactive concentration:	1.0-55.5 GBq/mL
Volume:	0.2-10 mL
Radionuclidic impurities:	≤ 0.1 %
Radiochemical purity:	≥ 95 %
pH:	7-10
Expiry date:	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). 6R vial in KT1-KT6 and 10R vial in KT6B lead container.
Pack size:	≤ 29.6 GBq ± 10% (at the indicated calibration date)/vial.

Description

The largescale production of ^{131}I based on the neutron irradiation of TeO_2 target followed by the separation of ^{131}I 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
^{131}I sodium iodide	55.5 GBq/mL ± 10% (at the day of production)	37 GBq/mL ± 10% (at the day of production)	5.55 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

Specification of I-RA-5s ^{131}I sodium iodide solution (175-500 GBq/mL active substance) complies with Ph. Eur. 2121 and supported with ASMF

Name:	**^{131}I sodium iodide solution (175-500 GBq/mL, active substance)**
Product code:	**I-RA-5s**
Description:	I-131 non sterile drug substance solution is prepared from the ^{131}I sodium iodide solution, 175-500 GBq/mL. Clear, colourless solution of ^{131}I sodium iodide containing iodine-131 in the form of sodium iodide in $NaHCO_3$/Na_2CO_3/ NaOH buffer. 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 date:	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 bromobutyl rubber stopper and green aluminium cap in lead container (Type A packaging).
Pack size:	≤ 111 GBq ± 10% (at the indicated calibration date)/vial ≤ 333 GBq ± 10% (at the indicated calibration date)/vial

Composition

Components	Quantity	Quantity
^{131}I sodium iodide	175 - 350 GBq/ml GBq/mL ± 10% (at the day of production)	350 - 500 GBq/ml 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

Specification of ^{131}I sodium iodide solution, non-sterile drug substance [low carbonate content and without thiosulfate]

Name:	**^{131}I sodium iodide non-sterile solution, drug substance**
Product code:	**I-RA-5**
Description:	Clear, colourless solution of ^{131}I sodium iodide containing iodine-131 in the form of sodium iodide in $NaHCO_3$/Na_2CO_3/ NaOH buffer. Non-carrier and no reducing agents added.
Radioactive concentration:	≥ 0.1-74 GBq/mL
Volume:	0.2-10 mL
Radionuclidic impurities:	≤ 0.1 %
Radiochemical purity:	≥ 95 %
pH:	8-11
Expiry date:	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). 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 ^{131}I based on the neutron irradiation of TeO_2 target followed by the separation of ^{131}I using dry distillation technique. I-131 non-sterile drug substance solution is manufactured from the ^{131}I 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
^{131}I 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

Our R&D group provides exceptional service in the development and manufacture of our radiopharmaceuticals.

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

In addition to our products, we are looking forward to new possibilities to widen our portfolio and meet our growing customer demands. If you are looking for an experienced and licenced distributor do not hesitate to contact our Sales Team

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