Radiopharmaceuticals & radiochemicals

IZOTOP

Product catalogue

INSTITUTE OF ISOTOPES CO. LTD.

OVERVIEW OF RADIOPHARMACEUTICALS AND RADIOCHEMICALS

^{131}I products

ThyroTop ^{131}I sodium iodide hard capsule	^{131}I sodium iodide sterile solution, drug substance	^{131}I sodium iodide oral solution	^{131}I sodium iodide non-sterile solution, drug substance	^{131}I-MIBG injection for diagnostic use	^{131}I-MIBG injection for therapy
I-RA-7/D and I-RA-7/K	**I-RA-7**	**I-RA-6**	**I-RA-5**	**I-RAO-1**	**I-RAO-2**
0.5 - 7400 MBq	0.1 - 55.5 GBq/ml	20 MBq/ml	≥ 740 MBq/ml	20 MBq/ml	333 - 410 MBq/ml
for determination of thyroid uptake curve and for therapy of hyperthyreosis and thyroid carcinoma	for preparing oral radio-pharmaceuticals by dilution with water or by capsule preparation containing reductant	for determination of thyroid uptake curve	for preparing oral radio-pharmaceuticals by dilution with water or by capsule preparation or starting material for radiolabelling **without reductant**	for diagnosis of neuroendocrine tumours	for treatment of neuroendocrine tumours
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PHYSICAL PROPERTIES AND DECAY FACTORS

Isotope	^{131}I	
Physical half life	**8.04 days**	
Energy and intensity of the emitted gamma photons	80 keV 164 keV 177 keV 284 keV 325 keV 364 keV 503 keV 636 keV 722 keV	2.6 % 0.6 % 0.26 % 6.14 % 0.274 % 81.7 % 0.36 % 7.2 % 1.8 %
Energy and intensity of the emitted beta particles	250 keV 304 keV 330 keV 608 keV 810 keV	2.1 % 0.6 % 7.27 % 89.9 % 0.48 %

^{131}I 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

^{131}I

ThyroTop D 0.5-37 MBq hard capsule
^{131}I-sodium-iodide ThyroTop 38-7400 MBq hard capsules

Product code:	**I-RA-7/D**	**I-RA-7/K**
ATC code:	V09F	V10XA01
Marketing Authorisation Number:	OGYI-T-9681/05	OGYI-T-9681/01
Pharmaceutical form and description:	Hard capsule, Size "0", colourless, transparent, CONI-SNAP type gelatine capsule, containing ^{131}I-labelled sodium iodide, for oral administration.	
Activity per capsule:	**0.5-37 MBq**	**38-7400 MBq**
Radionuclidic impurities:	≤ 0.1 %	≤ 0.1 %
Radiochemical purity:	≥ 95 %	≥ 95 %
Expiry time:	21 days from the manufacturing date	
Indications and phosology:	**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.	**Radionuclid therapy** *Treatment of hyperthyreosis* Graves disease. Hyperfunctioning adenoma. Non immunogenic diffuse goiter. *Treatment of thyroid carcinoma* Ablation of residual thyroid tissues following thyroid cancer surgery and treatment of recidivations and metastases. Required amount of activity is administered per os in one or maximum two capsules.
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 with paper insert.	1 capsule in a plastic insert with screwed cap placed into a lead container with wall thickness of 15-38 mm.

^{131}I

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

Product code:	**I-RA-7**
Description:	Clear, colourless and sterile solution of ^{131}I sodium iodide containing 10 mg/ml sodium hydrogencarbonate and 0.25-2 mg/ml sodium thiosulphate. Non-carrier added.
Volume:	0.2 - 10.0 ml
Radioactive concentration:	0.1 - 55.5 GBq/ml
Radionuclidic impurities:	≤ 0.1 %
Radiochemical purity:	≥ 95 %
pH	8 - 10
Expiry time:	21 days from manufacturing date
Other information:	Active pharmaceutical ingredient for manufacture of radiopharmaceuticals by dilution with water or by capsule preparation, for oral administration.
Indication:	Therapy of hyperthyreosis and thyroid carcinoma
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 with paper insert. (Type A packaging). Pack size: ≤ 29.6 GBq (at the indicated calibration date)/vial.

^{131}I | ^{131}I sodium iodide 20 MBq/ml oral solution

Product code:	**I-RA-6**
ATC code:	V09FX03
Marketing Authorisation Number:	OGYI-T-9680/01
Pharmaceutical form and description:	Sterile aqueous solution. Non-carrier added, aqueous solution of ^{131}I sodium iodide containing 10 mg/ml sodium hydrogencarbonate and 2 mg/ml sodium thiosulphate. For oral administration.
Radioactive concentration:	20 MBq/ml
Activity per vial:	200 MBq
Volume:	10 ml
Radionuclidic impurities:	≤ 0.1 %
Radiochemical purity:	≥ 95 %
pH:	8 - 10
Expiry time:	21 days from manufacturing date
Indications:	Sodium (^{131}I) iodide 20 MBq/ml solution for diagnostic use. Measurement of iodine uptake and function of the thyroid by nuclear imaging. Localisation of the thyroid. Determination of the size and morphological deviations of the thyroid and regional function of the thyroid. Diagnosis of hyperthyreosis or hypothyreosis, toxic adenoma, autonomous adenoma, thyroid carcinoma and its metastases by whole body imaging.
Storage:	Store at room temperature in its own container, in accordance with the regulations on radioactive materials.
Packaging:	In type I injection vial (10R), closed with brombutyl stopper and green aluminium cap in lead container with paper insert. (Type A packaging).

^{131}I | ^{131}I sodium iodide non-sterile solution, drug substance

Product code:	**I-RA-5**
Description:	Clear, colourless and sterile solution of ^{131}I sodium iodide containing iodine-131 in the form of sodium iodide in $NaHCO_3$/NaOH buffer. Non-carrier added. No reducing agents added.
Radioactive concentration:	≥ 100 MBq/ml
Radionuclidic impurities:	≤ 0.1 %
Radiochemical purity:	≥ 95 %
pH	8 - 10
Expiry time:	21 days from manufacturing date
Other information:	Active ingredient for manufacture of radiopharmaceuticals by dilution with water or by capsule preparation, for oral administration. Starting material for labelling purposes.
Indication:	Therapy of hyperthyreosis and thyroid carcinoma
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 with paper insert. (Type A packaging). Pack size: ≤ 111 GBq (at the indicated calibration date)/vial

^{131}I | ^{131}I-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 The active ingredient of the radioactive solution for injection for intravenous use is ^{131}I radioisotope labelled meta-iodobenzylguanidine (MIBG).
Activity per vial:	20 MBq; 40 MBq; 80 MBq
Specific activity:	>26.7 MBq/mg MIBG
Radioactive concentration:	20 MBq/ml
Radionuclidic impurities:	≤ 0.1 %
Radiochemical purity:	≥ 95 %
pH	5 - 7
Expiry time:	5 days from manufacture
Indications and posology:	Indication field: radioisotope diagnostics Localisation and imaging of neuro-endocrine tumours, especially: • phaeochromocytoma • neuroblastoma 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:	In type I injection vial (6R), closed with brombutyl stopper and green aluminium cap in lead container with paper insert. (Type A packaging). Pack size: 20 MBq, 40 MBq or 80 MBq (at the indicated calibration date)/vial

^{131}I-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. For intravenous use. The active ingredient of the radioactive solution is ^{131}I radioisotope labelled meta-iodobenzylguanidine (MIBG).
Activity per vial:	3300 - 4100 MBq (at indicated calibration date)
Specific activity:	>555 MBq/mg MIBG
Radioactive concentration:	333 - 410 MBq/ml
Radionuclidic impurities:	≤ 0.1 %
Radiochemical purity:	≥ 90 %
pH	5 - 5.5
Expiry time:	5 days from manufacturing date
Indications and posology:	**Radioisotope therapy** Local, lesion-specific treatment of neuro-endocrine tumours, especially: • phaeochromocytoma • neuroblastoma • paraganglioma • medullar thyroid carcinoma • carcinoid The recommended individual dose is 3.3 - 4.1 GBq.
Storage:	Store in a freezer, below -18°C. Storage of radiopharmaceuticals should be in accordance with national regulation on radioactive materials. To ensure the low temperature during shipping dry-ice is used to cool the container.
Packaging:	In type I injection vial (10R), closed with brombutyl stopper and green aluminium cap in lead container with paper insert. (Type A packaging). Pack size: 3300-4100 MBq (at indicated calibration date)/vial.

In VIVO diagnostic KITS

	FOR RENAL STUDIES			FOR BLOOD-POOL SCINTIGRAPHY
ISOTOPE	^{99m}Tc			
IN VIVO KIT	**DMSA**	**DTPA**	**EC**	**PYRON**
PRODUCT CODE	Tc-IK-7	Tc-IK-8	Tc-IK-25	Tc-IK-5
ATC CODE	V09CA02	V09CA01	V09CA	V09BA03
MARKETING AUTHORISATION NUMBER	OGYI-T-9245/01	OGYI-T-9244/01	OGYI-T-9141/01	OGYI-T-9246/01
FOR PREPARATION OF	Technetium (^{99m}Tc) succimer injection	Technetium (^{99m}Tc) pentetate injection	Technetium (^{99m}Tc) EC injection	Technetium (^{99m}Tc) tin pyrophosphate injection
ACTIVE INGREDIENT CONTENT/VIAL	Meso-dimercaptosuccinic acid 1.5 mg	Diethylene-triamino pentaacetic acid 9.0 mg	L-Ethylene-dicysteine 2.0 mg	Sodium pyrophosphate 25.0 mg
EXCIPIENTS	- Stannous chloride dihydrate - Ascorbic acid - Calcium gluconate	- Stannous chloride dihydrate - Ascorbic acid - Sodium chloride	**VIAL A** - Disodium hydrogen phosphate dihydrate - Mannitol - Ascorbic acid - Sodium edetate **VIAL B** - Stannous chloride dihydrate - Tartaric acid - Ascorbic acid **VIAL C** - Potassium dihydrogen phosphate - Ascorbic acid	- Stannous chloride dihydrate - Sodium chloride
INDICATIONS	-Renal scintigraphy, of static kidney imaging -Determination of the functional mass of the kidney -Determination of the relative function ratio (percentage) of the left and right kidneys	-Examination of the glomerular function of the kidney -Examination of the cerebral blood circulation -Examination of the gastrointestinal tract by using labelled foodstuff or drink -Examination of liquor circulation	-Examination of the tubular function of the kidney, camera renography	-Bone and acute myocardial infarct scintigraphy -Blood pool scintigraphy -Spleen scintigraphy
ACTIVITY FOR LABELLING 1 VIAL	1.0 - 1.8 GBq	0.8 - 2.4 GBq	0.8 - 1.6 GBq	1.3 - 3.0 GBq
VIALS PER KIT	6 vials	6 vials	3 x 4 vials	6 vials
RECOMMENDED DOSES	see in the Summary of Product Characteristics			
SHELF LIFE	12 months after radiolabelling: 3h (8h under extention procedure)	12 months after radiolabelling: 8 hours	12 months after radiolabelling: 3h (8 hours under extention procedure)	12 months after radiolabelling: 3h (6 hours under extention procedure)
STORAGE	2 - 8 °C after radiolabelling: ≤ 25 °C	≤ 25 °C after radiolabelling: ≤ 25 °C	2 - 8 °C after radiolabelling: ≤ 25 °C	≤ 25 °C after radiolabelling: ≤ 25 °C

In VIVO diagnostic KITS

	FOR EXAMINATION OF THE LIVER- AND HEPATOBILIARY SYSTEM		FOR BONE SCINTIGRAPHY
ISOTOPE	^{99m}TC		
IN VIVO KIT	**FYTON**	**TECHIDA**	**MDP**
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
FOR PREPARATION OF	Technetium (^{99m}Tc) phytate injection	Technetium (^{99m}Tc) etifenin injection	Technetium (^{99m}Tc) medronate injection
ACTIVE INGREDIENT CONTENT/VIAL	Sodium phytate 15.0 mg	N-(2,6-diethyl-acetanilid)-imino diacetic acid 30.0 mg	Methylene-diphosphonic acid 5.0 mg
EXCIPIENTS	- Stannous chloride dihydrate - Sodium chloride	- Stannous chloride dihydrate - Ascorbic acid - Sodium chloride	- Stannous chloride dihydrate - Ascorbic acid - Urea
INDICATIONS	-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 -Diagnosis of focalis nodular hyperplasia	-For bone scintigraphy (diagnostic skeletal imaging). -Primer bone tumours -Metastases of other tumours, for example prostate, breast and lung cancer -Osteomyelitis, -Metabolic bone diseases, -Paget's disease.
ACTIVITY FOR LABELLING 1 VIAL	0.8 - 1.6 GBq	0.8 - 1.6 GBq	3.0 - 6.0 GBq
VIALS PER KIT	6 vials	6 vials	6 vials
RECOMMENDED DOSES	see in the Summary of Product Characteristics		
SHELF LIFE	12 months after radiolabelling: 3h (6h under extention procedure)	24 months after radiolabelling: 6h	12 months after radiolabelling: 6h
STORAGE	≤ 25 °C after radiolabelling: ≤ 25 °C	2 - 8 °C after radiolabelling: 2 - 8 °C	2 - 8 °C after radiolabelling: ≤ 25°C

Kit for labelling with ^{153}Sm precursor

^{153}Sm-MULTIBONE

(ethylenediamine tetramethylene phosponate, EDTMP)

kit for pharmaceutical preparation

Product code:	**Sm – IK- 26**
ATC code:	V10BX02
Marketing Authorisation Number:	OGYI-T-9192/01
Composition (per vial):	Ethylenediamine tetramethylene phosphonate 25.0 mg Stannous chloride dihydrate 1.0 mg Ascorbic acid 5.0 mg Glucose, anhydrous 10.0 mg
Indications:	**RADIONUCLIDE THERAPY** Palliative, analgesic treatment of previously localised bone metastases. Use of the product is highly recommended in the case of the indications listed below: • palliative treatment of painful bone metastases of breast cancer • palliative treatment of bone metastases of prostate cancer • palliative treatment of bone metastases of other tumours
Administration:	Intravenous injection
pH	5 - 8
Labelling efficiency:	≥ 95 %
Method of administration:	^{153}Sm-Multibone prepared in one labelling reaction represents the dose for one patient.
Posology:	Labelling should be performed by using 2500-5000 MBq of ^{153}Sm. The individual patient dose is 37 MBq of ^{153}Sm-Multibone /kg bodyweight. ^{153}Sm-Multibone should be administered slowly, intravenously to the patient.

Contraindications:

• The use of the product is relatively contraindicated at the age below 18 years, except when the necessity and importance of the therapy prevails the risk originating from the radiation exposure.

• in case of patient with seriously impaired bone marrow, since the risk of the therapy would be higher than the advantageous effect expected. The contraindication is especially valid if the following quantitative parameters of the patient are above/below the limits given below:

- o White cell count $< 3 \times 10^9$
- o Platelet count $< 120 \times 10^9$
- o Serum creatinine > 120 µmol/litre
- o Karnofsky index < 60 %

• in case of pregnant or breast-feeding women,

• if the patient does not provide an oral or written consent of being treated with the radionuclide.

• if the quantitative parameters of the patient are above/below the limits given above.

Storage:

Multibone kit is to be stored in a fridge at 2-8 °C in its original paper box protected from light and oxidising agents.

^{153}**Sm-EDTMP injection** is to be stored at room temperature (15 - 25 °C) in accordance with the regulations on radioactive materials.

Expiry time: 12 months from manufacturing date

Packaging:

Primary packaging material of the sterile, bacterial endotoxin-free, freeze-dried powder for solution for injection is glass vial closed with rubber stopper and aluminium cap.
The labelled vials are supplied in a white carton box, which contains:

• 6 glass vials for 6 labelling procedures
• 1 Summary of Product Characteristics
• 6 empty, self-adhesive labels with radiation symbol

^{153}Sm	^{153}Sm samarium chloride radioactive precursor for labelling MULTIBONE kit

Product code: **Sm-RA-26**

ATC code: V10BX02

Marketing Authorisation Number: OGYI-T-9192/01

Description: Clear, colourless, sterile solution of ^{153}Sm-samarium chloride in physiological saline (0.9 % sodium chloride solution)

Activity per vial: 2500 MBq (-5000 MBq under variation process)

Specific activity: > 5 GBq/mg

Radioactive concentration: 2500 MBq/ml

Radionuclidic impurities: ≤ 0.2 %

Radiochemical purity: ≥ 95 %

pH 5 - 6

Expiry time: 5 days from manufacturing date

Other information: ^{153}Sm samarium chloride precursor must not be administered directly to the patients. It is for labelling MULTIBONE kit.
Only ^{153}Sm- MULTIBONE injection can be administered.

Physical properties:

Physical half life:	46.27 hrs
Energy of beta particles:	705 keV (17.5 %), 808 keV (49.6 %)
Energy of gamma photons:	103 keV (29.8 %), 635 keV (32.2 %)

Storage: Store at room temperature in its own container, in accordance with the regulations on radioactive materials.

Packaging: Supplied in 6 ml injection vial closed with rubber stopper and tear-off aluminium cap. The labelled vial is placed in a lead container, which contains a paper insert (KT 2-3). The lead container is packed in a labelled tear-off metal can, which contains plastic insert (Type A packaging).

^{153}Sm ISOTOPE DECAY FACTORS

min.	0	20	40	60	80	100	120	140	160	180	200	220	240
hours	0.0	0.3	0.7	1.0	1.3	1.7	2.0	2.3	2.7	3.0	3.3	3.7	4.0
0	1.0000	0.9950	0.9901	0.9851	0.9802	0.9753	0.9705	0.9656	0.9608	0.9561	0.9513	0.9466	0.9418
4	0.9418	0.9371	0.9325	0.9278	0.9232	0.9186	0.9140	0.9095	0.9050	0.9004	0.8960	0.8915	0.8871
8	0.8871	0.8826	0.8782	0.8739	0.8695	0.8652	0.8609	0.8566	0.8523	0.8481	0.8439	0.8396	0.8355
12	0.8355	0.8313	0.8272	0.8230	0.8189	0.8149	0.8108	0.8068	0.8027	0.7987	0.7948	0.7908	0.7869
16	0.7869	0.7830	0.7791	0.7752	0.7713	0.7675	0.7636	0.7598	0.7561	0.7523	0.7485	0.7448	0.7411
20	0.7411	0.7374	0.7337	0.7301	0.7265	0.7228	0.7192	0.7156	0.7121	0.7085	0.7050	0.7015	0.6980
24	0.6980	0.6945	0.6911	0.6876	0.6842	0.6808	0.6774	0.6740	0.6707	0.6673	0.6640	0.6607	0.6574
28	0.6574	0.6541	0.6509	0.6476	0.6444	0.6412	0.6380	0.6348	0.6317	0.6285	0.6254	0.6223	0.6192
32	0.6192	0.6161	0.6130	0.6100	0.6069	0.6039	0.6009	0.5979	0.5949	0.5920	0.5890	0.5861	0.5832
36	0.5832	0.5803	0.5774	0.5745	0.5716	0.5688	0.5659	0.5631	0.5603	0.5575	0.5548	0.5520	0.5492
40	0.5492	0.5465	0.5438	0.5411	0.5384	0.5357	0.5330	0.5304	0.5277	0.5251	0.5225	0.5199	0.5173
44	0.5173	0.5147	0.5122	0.5096	0.5071	0.5045	0.5020	0.4995	0.4970	0.4946	0.4921	0.4896	0.4872
48	0.4872	0.4848	0.4824	0.4800	0.4776	0.4752	0.4728	0.4705	0.4681	0.4658	0.4635	0.4612	0.4589
52	0.4589	0.4566	0.4543	0.4520	0.4498	0.4476	0.4453	0.4431	0.4409	0.4387	0.4365	0.4343	0.4322
56	0.4322	0.4300	0.4279	0.4258	0.4236	0.4215	0.4194	0.4173	0.4153	0.4132	0.4111	0.4091	0.4070
60	0.4070	0.4050	0.4030	0.4010	0.3990	0.3970	0.3950	0.3931	0.3911	0.3892	0.3872	0.3853	0.3834

^{125}I PRODUCTS

RADIOCHEMICALS FOR LABELLING PURPOSES

Physical half life: 59.4 days
Energy of the emitted X photons: 27.47 keV (74%)
Energy of the emitted gamma photons: 35.49 keV (6.68 %)

^{125}I 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

125I	^{125}I sodium iodide solution for labelling

Product code:	**I-RB-4**
Description:	Clear, colourless solution containing ^{125}I sodium iodide in NaOH. Non-carrier added. No reducing agents added.
Specific activity:	≥ 600 GBq/mg
Radioactive concentration:	≥ 3700 MBq/ml
Radionuclidic impurities:	^{126}I ≤ 0.005 %
Radiochemical purity:	≥ 95 %
pH:	8 - 11
Expiry time:	60 days from dispatch
Other information:	For labelling purposes.
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 tear-off metal can, which contains plastic insert (Type A packaging).

125I	^{125}I sodium iodide solution for labelling

Product code:	**I-RB-41**
Description:	Clear, colourless solution containing ^{125}I sodium iodide in NaOH. Non-carrier added. No reducing agents added.
Specific activity:	≥ 600 GBq/mg
Radioactive concentration:	< 3700 MBq/ml
Radionuclidic impurities:	^{126}I ≤ 0.005 %
Radiochemical purity:	≥ 95 %
pH	8 - 11
Expiry time:	60 days from dispatch
Other information:	For labelling purposes.
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 tear-off metal can, which contains plastic insert (Type A packaging).

GENERAL CONDITIONS OF SALE AND DELIVERY

effective from 1st September, 2017

1. GENERAL
All our offers, sales and deliveries are subject exclusively to the following conditions, unless anything to the contrary has been confirmed by us in writing. Business conditions of the Buyer which conflict with present conditions will become the part of the current contract only if they are accepted expressly and in writing by us.

2. ACCEPTANCE OF ORDER
All offers issued by us are open for acceptance for the period stated in the offer, or if none is stated, for thirty days. Orders are considered accepted by us, if we have submitted to the Buyer a written confirmation, or executed the delivery implicitly.

Any amendments, cancellations or other modifications of orders by the Buyer are subject to their acceptance by the manufacturer.

3. PRICES
Our prices are to be understood net, in the currency agreed upon.

4. DESPATCH
The goods are shipped for account and risk of Buyer, even if transport charges are being borne by us, or delivered free of charge. We shall not be liable for any loss occurred during transportation. All forwarding instructions are to be given with the order. However, we have the right to choose the route and the means of transportation, unless otherwise agreed. Any warranty for the quickest and cheapest transportation are explicitly excluded. Special fees for express deliveries, effected on the Buyer's request, shall be at the Buyer's expense. International Commercial Terms such as FOB., CIF., C and F. etc. are to be interpreted according to the INCOTERMS, 2010.

5. DELIVERY
Delivery dates are indicated in good faith, however we reserve the right to alter the delivery date notifying the Buyer as soon as possible. We do not accept liability for any direct or indirect loss or damage due to the eventual delay in delivery howsoever caused.

6. PACKAGING
Where the goods are supplied by us in returnable containers they must be returned to us at the Buyer's expense in good condition within the period specified by us in writing.

Containers are hired out - unless otherwise agreed - for 30 days free of charge, after this period a specified charge - subject to the type of the container - is to be paid.

7. RESERVATION OF TITLE
We retain ownership of the goods until such time as the Buyer has completely fulfilled all his obligations from the current business transaction toward us, such ownership is retained notwithstanding delivery to the Buyer. If under the law of the country in which the goods are located reservation of title is not permitted, we are entitled to demand an equivalent security from the Buyer.

8. COMPLAINTS
Complaints arising out of material defects or inadequate quantities so far as this can be discovered by a reasonable examination, must be submitted together with the evidences in writing immediately and in the case of apparent defect within 15 days after receipt of the consignment at the latest. If the complaint is justified, shortages will be rectified by further delivery, or the goods will be replaced. If the rectification or replacement would be either impossible or also defective, we shall, at our choice, either take back the goods, repay the purchase price or grant an appropriate rebate. Further claims are explicitly excluded. In case of hidden defects, which cannot be detected upon receipt of the goods complaints must be submitted within the expiry period stated in the analytical certificate or on the label, and where no expiry period is stated, within 30 days from the receipt of the consignment.

In case the order refers to products for which the unit is the activity the order is fulfilled in case the delivered amount is 100 + / - 10 % of the ordered amount; in case of radiopharmaceuticals and radioactive drug substances it corresponds to the European Pharmacopoeia.

9. FORCE MAJEURE
We do not assume any responsibility for non-deliveries, delays or losses in general caused by any circumstances beyond our reasonable control including but not limited to any strike, lock-out, shortage of energy or raw materials, war, unavoidable breakdown, authorities' orders or regulations, including but not limited to any economic sanction imposed under a resolution approved by the Security Council of the United Nations, the US or the EU, which render the execution of a particular contract in part or in full impossible. All the aforementioned occurrences entitle us to withdraw from the contract wholly or in part without the Buyer having any right to compensation.

10. SPECIAL CONDITIONS FOR CUSTOM SYNTHESIS
We retain the right to revise the quoted price and/or deadline based on the preliminary synthesis experiments not later than the half-time of the expected synthesis duration counted from the confirmation of the firm order till the quoted delivery date. The Buyer has the right either to accept the amendment or to withdraw the order.
In case of delayed shipment due to unexpected, unavoidable technical problems during the synthesis procedure we agree to compensate the Buyer with 0.8 % weekly but totally not more than 10% of the net value of the ordered compound.
We retain the right to terminate the contract in case we are not able to fulfil it due to unexpected, unavoidable technical problems during the synthesis procedure. In case we do it later than the half-time of the expected synthesis duration counted from the confirmation of the firm order till the quoted delivery date we agree to compensate the Buyer with 10% of the net value of the ordered compound.
Any kind of compensation for delayed delivery and non-performance other than determined as above is expressly and explicitly excluded.
The elaborated synthesis route is the intellectual property of the Institute of Isotopes Co., Ltd. unless otherwise agreed in written form.
In case Buyer doesn't instruct us to dispatch the goods within 2 weeks after finishing the synthesis of the compound Buyer has to pay in advance the total price of the compound (i.e. in case 40% was paid in advance the remaining 60% is due). We are ready to store the goods, the fee and the duration of the storage is to be agreed separately. We can't guarantee that the material keeps its quality during the storage.
Cost of the repeated analysis - if it is requested by the Customer - before the delivery (if it is later, than 2 weeks from finishing the synthesis) and cost of the purification (if it is needed) is to be agreed separately.

11. SAFETY DATA EXCHANGE CLAUSE FOR PHARMACEUTICALS
We shall be informed by the Buyer promptly at any complaint, including any quality, safety, efficacy or performance related complaint, or after sales enquiry concerning the products, or any other issue which could be relevant to Seller's pharmacovigilance obligations in relation to the products, of which the Buyer receives notice or otherwise becomes aware, either within or outside the territory, concerning for the below listed cases: adverse events, overdose, off label use, misuse and abuse.
We ensure detailed guideline and background information, legal frame and relevant contact for pharmacovigilance on company website, via regular email.

12. PAYMENT
Unless otherwise agreed in writing, payment of all invoices shall be made to us net and in full amount without any bank deduction in the currency invoiced through remittance in advance. If agreed in writing by both side previously remittance within 30 days from the date of the invoice is acceptable. Depending on the value of the goods delivered irrevocable, confirmed L/C might be required. In case of delay in payment on part of the Buyer, we reserve the right either

a) to demand an adequate security for payment, or
b) to levy interest for default on the unpaid amounts at the usual international rate or
c) to suspend the deliveries and/or cancel any of our outstanding obligations.

All bank charges, expenses, exchange commissions and other costs arising at foreign banks are to be borne by the Buyer. We cover only those bank charges expenses and other costs which - according to the type of contract - are to be borne by the Seller, or which are expressly and explicitly undertaken by him.

13. LIABILITY
Many of the products sold can be hazardous by nature. No liability is taken by us in case the products are not used according to the instructions supplied to them, and / or to relevant applicable regulations, practices and procedures concerning safety, storage, handling, use and disposal. The Buyer shall pass on to his users all relevant information received.

14. PATENT SITUATION
By the offer or the sale of merchandise we do not assume guarantee in respect of the patent situation of the product involved in the country of the Buyer unless otherwise agreed in writing.

15. DISPUTES
All disputes arising out of or in relation to this agreement shall be discussed by the parties in a friendly manner. Place of performance and jurisdiction for both parties shall be Budapest. Both parties accept the competency of the Arbitration Court of the Hungarian Chamber of Commerce in Budapest. However, we retain the right to assert our claims at the Buyer's legal domicile. The claims or disputes arising out of particular contract have to be settled on the basis of the Hungarian Substantive Law.

16. REEXPORT PROHIBITION
Reexport is not allowed unless previously agreed in written form.

17. RETURN DELIVERIES
Return deliveries require our previous consent.

RADIOPHARMACEUTICALS

RADIOPHARMACEUTICALS AND RADIOCHEMICALS

^{131}I products

ThyroTop sodium iodide capsules for diagnostic and therapeutic purposes
Sodium iodide solutions
MIBG for diagnostic and therapeutic purposes

In vivo diagnostic kits (for labelling with ^{99m}Tc)

DMSA • DTPA • EC • PYRON • FYTON • TECHIDA • MDP

MULTIBONE kit and ^{153}Sm precursor

^{125}I products

Sodium iodide solutions for labelling purposes

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