MEDI-RADIOPHARMA

Your Global Nuclear Medicine Supplier

CATALOGUE OF IN VIVO KITS FOR Tc-99m LABELLING

MRP
MEDI-RADIOPHARMA
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INTRODUCTION

MEDI-RADIOPHARMA Ltd. is a privately-owned company established in 1995. The company has more than 25 years of experience in developing, manufacturing and supplying radiopharmaceutical products to customers around the globe.

MEDI-RADIOPHARMA Ltd. specialises in the production and supply of generic in-vivo kits for Tc-99m labelling used in nuclear medicine. By potentially enabling accurate early diagnosis and treatment of cancer, as well as heart, brain and bone diseases, our world-class products empower our customers with effective treatment, and proven patient outcomes.

MEDI-RADIOPHARMA Ltd. holds a diverse portfolio of proven products registered in 67 countries world-wide. We pride ourselves on our ability to deliver a steady supply of quality diagnostic and therapy solutions, with the highest standards of quality and safety assured at every stage.

We develop, manufacture and distribute radiopharmaceutical products that meet industry standards in quality, safety, efficacy and innovation. The company holds valid Manufacturer's Authorization, Certificate of GMP Compliance of a Manufacturer, Wholesale Distribution Authorization, Certificate of GDP Compliance of a Wholesaler Distributor, Good Laboratory Practice (GLP) Certificate, ISO certificate and relevant authorization for the manufacture and wholesale distribution of radiopharmaceuticals.

MEDI-RADIOPHARMA Ltd., together with its partner company, Radiopharmacy Laboratory Ltd., is also involved in the development of therapeutic radiopharmaceuticals. The company is open for requests and suggestions on new research and development projects in the field of nuclear medicine. Our sterile injectables capabilities include formulation and process development and manufacturing of sterile injectable drug products at scales suitable for small clinical trials to global commercial supply. We will bring speed, flexibility, experience and a broad set of capabilities to your program.

At MEDI-RADIOPHARMA Ltd., we are committed to improving the lives of all those we serve. To us, this means striving to make a positive difference to our employees, partners, patients, and the local communities in which we operate.

The headquarter and the main manufacturing facilities of the company are located in Érd, south-west to Budapest. Additional laboratories are in Budaörs and Bátonyterenye.

WE ARE PROUD MEMBERS OF

NUCLEAR MEDICINE EUROPE
the industry association

EANM
EUROPEAN ASSOCIATION OF NUCLEAR MEDICINE

„At Medi-Radiopharma our purpose is to serve healthcare and improve patient outcomes through a wide portfolio of high-quality products. Our ambitious and passionate team makes me so inspired and proud every day – same goes for my father who established the foundations of our company and allowed us to become a key global player in our field.”

25 YEARS OF EXCELLENCE

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Nano-Scan (^{99m}Tc-HSA nanosized colloid)
Tc-MR-7

Active substance	Human Serum Albumin nano sized colloid 500 micrograms
Particle size	At least 95 % of human albumin colloidal particles have a diameter ≤ 80 nm.

Indications	**Intravenous administration:**
	• Bone marrow scanning (The product is not suitable to study the haematopoietic activity of the bone marrow)
	• Inflammation scanning in areas other than the abdomen
	Subcutaneous administration:
	• Conventional lymphoscintigraphy to demonstrate integrity of the lymphatic system and differentiation of venous from lymphatic obstruction
	• Sentinel node detection in:
	  • Melanoma malignum
	  • Breast cancer

Excipients	• Stannous(II) chloride dihydrate • Glucose monohydrate • Sodium dihydrogen phosphate dihydrate, di-Sodium hydrogen phosphate dihydrate • Nitrogen • Hydrochloric acid • Sodium hydroxide
Dose for adults	**Intravenous application:** • Bone marrow scanning: 185-500 MBq (i.v. injection) • Inflammation scanning: 370-500 MBq (i.v. injection) **Subcutaneous administration:** • Lymphoscintigraphy: 18.5-110 MBq per injection site **Sentinel node detection:** • Malignant melanoma: total activity applied 40-100 MBq • Breast cancer: total activity applied 100-200 MBq
Labelling activity	185 MBq - 5.5 GBq
Labelling volume	1-5 ml
Storage of cold kit	18 months from date of manufacturing, Do not store above 25°C
Storage of labelled compound	8 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Germany: 81340.00.00 Denmark: DK R 02248 Austria: 4-00046 Italy: 414/2012 Spain: 76905 Belgium: BE471911 The Netherlands: RVG 112760 Poland: 22470 Romania: 9353/2016/01-04 United Kingdom: PL 40129/0002
Marketing Authorization Holder	**Radiopharmacy Laboratory Ltd.** 2040 Budaörs, Gyár u. 2., Hungary

(for detailed actual information please read the current approved SmPC)

Senti-Scint (^{99m}Tc-HSA colloid)
Tc-MR-4

Active substance	Human Serum Albumin nano sized colloid (strength 1.0 mg)
Particle size	100-600 nm

Indications	Compound is suitable for
	• sentinel node lymphoscintigraphy in
	  • breast cancer and
	  • melanoma malignum

Excipients	• Stannous(II) chloride dihydrate • Glucose • Sodium phosphate monobasic & Sodium phosphate dibasic
Dose for adults	The recommended activity 60-100 MBq. 3-5 subcutaneous injections around the lesion. 20-20 MBq in volumes of 0.2-0.5 ml.
Labelling activity	maximum 5.5 GBq
Labelling volume	1-5 ml
Storage of cold kit	18 months from date of manufacturing, Do not store above 25°C Protect from light
Storage of labelled compound	maximum 6 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Hungary: OGYI-T-8665/01 Czech Republic: 88/100/01-C Slovak Republic: 88/0045/04-S Belarus: 9915/12/17 Croatia: UP/I-530-09/11-01/19 Turkey: 136/12
Marketing Authorization Holder	**Medi-Radiopharma Co., Ltd.** 2030 Érd, Szamos u. 10-12., Hungary

(for detailed actual information please read the current approved SmPC)

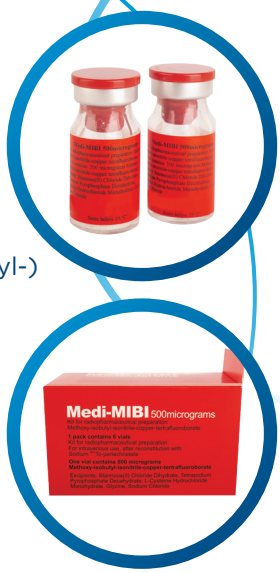
Nano-Albumon (^{99m}Tc-HSA nanosized colloid)

Tc-MR-3

Active substance	Human Serum Albumin nano sized colloid 1.0 mg
Particle size	More than 80% of the particles have a size maximum 100 nm
Indications	The labelled Nano-Albumon is suitable for • conventional lymphoscintigraphy • bone marrow scanning
Excipients	• Stannous(II) chloride dihydrate • Glucose • Sodium phosphate monobasic & Sodium phosphate dibasic
Dose for adults	Suggested dose ranges are different according to the type of investigation
Labelling activity	maximum 2.2 GBq
Labelling volume	1-3 ml
Storage of cold kit	18 months from date of manufacturing, Do not store above 25°C Protect from light
Storage of labelled compound	6 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Hungary: OGYI-T-8664/01 Czech Republic: 88/174/91-C Colombia: INVIMA 2018M-0018034
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 1012., Hungary

(for detailed actual information please read the current approved SmPC)

Medi-MIBI 500 micrograms (^{99m}Tc-MIBI)
Tc-MR-1



Active substance

Sestamibi [tetrakis (1 isocyanide-2-methoxy-2-methylpropyl-) copper(I)] tetrafluoroborate 0.5 mg

Indications

The Tc-99m labelled compound can be used for

- Myocardial perfusion scintigraphy for the detection and localisation of coronary artery disease (angina pectoris and myocardial infarction)
- Assessment of global ventricular function. First-pass technique for determination of ejection fraction and/or ECG-triggered, gated SPECT for evaluation of left ventricular ejection fraction, volumes and regional wall motion.
- Scintimammography for the detection of suspected breast cancer when mammography is equivocal, inadequate or indeterminate.
- Localisation of hyperfunctioning parathyroid tissue in patients with recurrent or persistent disease in both primary and secondary hyperparathyroidism, and in patients with primary hyperparathyroidism scheduled to undergo initial surgery of the parathyroid glands.

Excipients

- Stannous(II) chloride dihydrate
- Sodium chloride
- Tetrasodium pyrophosphate decahydrate
- L-cysteine hydrochloride monohydrate
- Glycine

Dose for adults

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

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

Labelling activity

Up to 15 GBq

Labelling volume

1-5 ml

Storage of cold kit

30 months from date of manufacturing,
Do not store above 25°C
Protect from light

Storage of labelled compound

8 hrs,
Do not store above 25°C

Package size

6 vials

Registration numbers

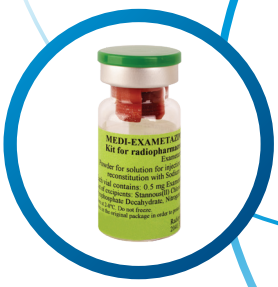
Denmark: DK.R.2236
Austria: 4-00035
Spain: 70755
Italy: 040312011
Croatia: HR-H-769142649
Republic of Belarus: 10057/12/18
Hong-Kong: HK-64680
Taiwan: R00098

Marketing Authorization Holder

Radiopharmacy Laboratory Ltd.
2040 Budaörs, Gyár u. 2., Hungary

(for detailed actual information please read the current approved SmPC)

Medi-Exametazime (^{99m}Tc-HM-PAO)
Tc-MR-14



Active substance	Exametazime 0.5 mg

Indications

Neurology:

- Evaluation of patients with cerebrovascular disease (specifically acute stroke, chronic ischemia, and transient ischemic attack)
- Presurgical lateralization and localization of epileptogenic foci.
- Evaluation of patients with suspected dementia (specifically Alzheimer's disease and frontotemporal dementia)
- Evaluation of patients with migraine
- Adjuvant technique in the diagnosis of brain death

Infectious or inflammatory diseases

- Localisation of abnormal foci guiding the aetiologic diagnosis in case of fever of unknown origin
- Diagnosis of infection in case of suspected osteomyelitis (with or without implants) and suspected hip or knee prosthesis infection.
- Detection of the extension of inflammation in case of inflammatory bowel disease.

Excipients	Stannous(II) chloride dihydrate Tetrasodium pyrophosphate decahydrate
Dose for adults	Brain perfusion SPECT: 350-500 MBq Labelled leucocyte scintigraphy: 200 MBq
Labelling activity	0.37-2.2 GBq
Labelling volume	5 ml
Storage of cold kit	12 months from date of manufacturing, Store at 2-8°C
Storage of labelled compound	1 hr, Do not store above 25°C Protect from light
Package size	6 vials

Registration numbers

Denmark: DK R 49482	Turkey: 135/53
Germany: 86253.00.00	Spain: 77468
Austria: 4-00051	Italy: AIC n 042496024
United Kingdom: PL40129/0001M	Hong-Kong: HK-64514

Marketing Authorization Holder

Radiopharmacy Laboratory Ltd.
2040 Budaörs, Gyár u. 2., Hungary

(for detailed actual information please read the current approved SmPC)

Brain-Spect (^{99m}Tc-HM-PAO)
Tc-MR-5

Active substance	Exametazime 0.3 mg
Indications	Diagnostic study of • Regional cerebral blood flow (stroke, carotid artery occlusion, transient ischaemic attack, migraine, tumours of the brain, dementia differential diagnosis, • BRAIN-SPECT kit can be applied for detection, localisation of cortical areas with decreased perfusion, and to estimate the extent of the damage. • Detection of affected cortical areas over 1-2 cm is feasible by planar gamma camera, the smaller areas can be detected by SPECT.
Excipients	Stannous(II) chloride dihydrate Tetrasodium pyrophosphate decahydrate
Dose for adults	370-740 MBq (i.v. injection)
Labelling activity	370-2200 MBq
Labelling volume	5 ml
Storage of cold kit	12 months from date of manufacturing, Store in a refrigerator (2-8°C) Protect from light
Storage of labelled compound	1 hr, Do not store above 25°C Protect from light
Package size	6 vials
Registration numbers	Hungary: OGYI-T-8733/01 Czech Republic: 88/418/92-C Belarus: 9904/12/17 Turkey: 135/53 Colombia: INVIMA 2015M-0015824
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 1012., Hungary

(for detailed actual information please read the current approved SmPC)

Stabilised Brain-Spect
(Technetium [^{99m}Tc] exametazim HMPAO)
Tc-MR-15

Active substance	Exametazime 0.5 mg
Indications	**Brain scintigraphy:** • Regional cerebral blood flow scintigraphy (Stroke, reduced cerebral blood flow, ischemic attack, epilepsy, migraine, trauma, tumours of the brain, differential diagnosis of dementia). • The stabilised Brain-Spect 0.5 mg kit is able to recognise, localize the altered cerebral cortical tissue perfusion and to estimate the size of the damaged area.
Excipients	**Lyophilizate:** Stannous(II) chloride dihydrate Sodium-pyrophosphate-decahydrate **Cobalt(II)-chloride solution:** Cobalt(II)-chloride-hexahydrate Water for injection
Dose for adults	350-500 MBq intravenously
Labelling activity	0.37-2.2 GBq
Labelling volume	5 ml
Storage of cold kit	12 months from date of manufacturing, Store in refrigerator (2°C – 8°C)
Storage of labelled compound	Stabilised labelled product 6 hrs, Do not store above 25°C
Package size	6 injection vial containing powder and 6 injection vial containing solution in a carton box
Registration numbers	Hungary: OGYI-T-8733/02
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 1012., Hungary

(for detailed actual information please read the current approved SmPC)

Leuco-Scint (^{99m}Tc-HM-PAO unit dose) for leucocytes labelling
Tc-MR-6

Active substance	Exametazime 0.18 mg
Indications	For in vitro labelling of leucocytes. Detection of inflammatory processes (based on white blood cell migration) in case of • bacterial infection • abscess • inflammatory lesions of the intestine, bones or joints
Excipients	Stannous(II) chloride dihydrate Tetrasodium pyrophosphate decahydrate
Additional reagents/dose	ACD-A anticoagulant buffer 10 ml 6% Hydroxyethyl starch (Plasmasterile) 15 ml
Dose for adults	200-250 MBq
Labelling activity	950-1000 MBq
Labelling volume	1.5 ml
Storage of cold kit	12 months from date of manufacturing Store in a refrigerator (2-8°C) Protect from light The labelled leucocytes must be re-injected in 30 minutes of reconstitution
Storage of labelled compound	0.5 hr, Do not store above 25°C Protect from light
Package size	Vials for 3 labellings
Registration numbers	Hungary: OGYI-T-8734/01 Czech Republic: 88/1121/94-C Colombia: INVIMA 2015M-0002589-R1
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 10-12., Hungary

Leuco-Scint accessories kit
Tc-MR-6/A

The kit contains sterile tubes and transfer pipettes for 3 complete leucocyte separations and labellings.
The one-patient-package contains:

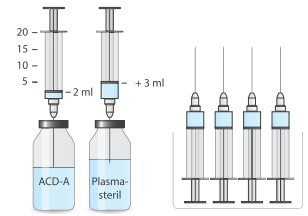
- 2 pcs 50 ml tube with screw cap
- 2 pcs 3 ml sterile Pasteur pipette
- 5 pcs 15 ml sterile tube with screw cap

(for detailed actual information please read the current approved SmPC)

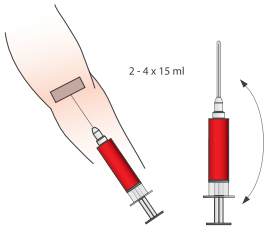
LEUCO-SCINT kit

SEPARATION AND LABELLING PROTOCOL

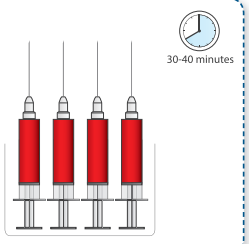
(Aseptic conditions should be kept throughout the separation and labelling process)



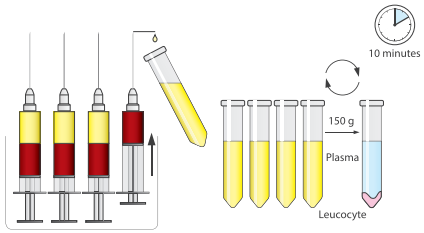
1. Draw 2 ml of ACD solution and 3 ml of Plasmasteril into each of the four 20 ml sterile plastic syringes.



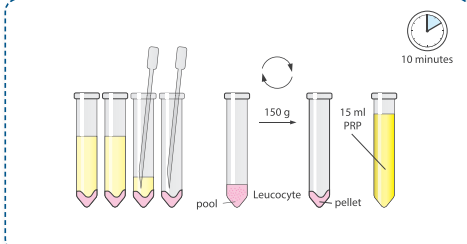
2. Withdraw 15 ml patient's blood into each syringe and mix gently by inversion.
Note: in case of infants the labelling can be managed with 2 x 15 ml



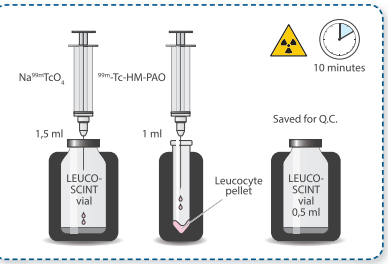
3. Leave to stand the syringes for 30-40 mins to allow red blood cells to sediment at room temperature.



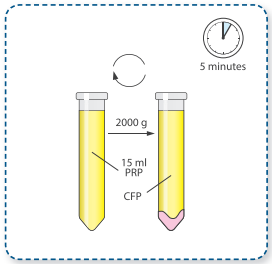
4. When the red cells are sedimented to about half of the original volume of the blood, carefully draw up the leucocyte platelet-rich plasma (LPRP) into sterile tubes and centrifuge 10 mins at 150 g.



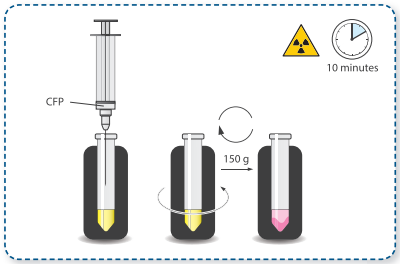
5. Remove and retain all the supernatant (platelet rich plasma, PRP). Pool the pellets of mixed leucocytes in one sterile tube. Centrifuge again for 10 mins at 150 g. Remove the remaining supernatant from the pellet of mixed leucocytes, leaving the pellet almost to dry
Note 1: During centrifugation please start labelling a Leuco-Scint kit vial with Tc-99m.
Note 2: only 15 ml PRP is needed to procedure described in step 7.



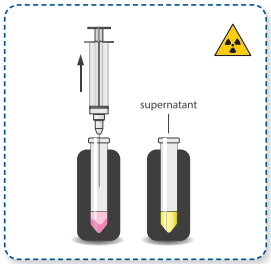
6. Reconstitute one vial of LEUCO-SCINT with 1.5 ml eluate of ^{99m}Tc-generator containing 700-750 MBq ^{99m}Tc-pertechnetate. Shake for 10 mins to dissolve the HM-PAO and add exactly 1 ml immediately ^{99m}Tc-HM-PAO to a tube of mixed leucocytes (the activity of ^{99m}Tc-HM-PAO is appr. 400-500 MBq). Mix gently and incubate the cells for 10 mins at room temperature.



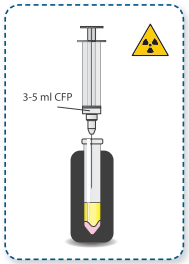
7. While incubating the leucocytes, centrifuge the PRP (step 5.) for 5 mins at 2000 g to produce cell-free plasma (CFP).



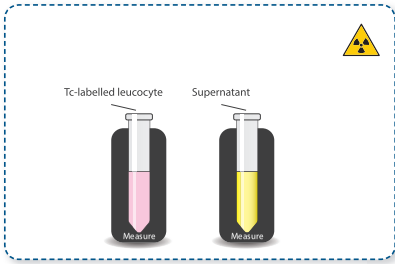
8. Add 3-5 ml CFP (obtained in step 7.) to the labelled cell suspension and gently mix. Centrifuge at 150g for 10 mins.



9. Transfer all supernatant to a tube.

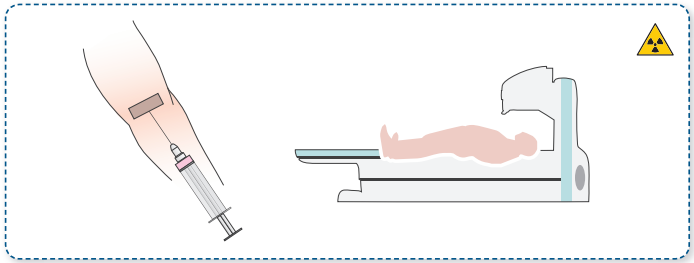


10. Add 3-5 ml of CFP to the pellet of leucocyte, gently swirl to mix.



11. Measure the radioactivity and calculate the cell labelling efficiency (%)=

$$\frac{\text{activity of labelled leucocytes}}{\text{activity of labelled leucocytes + activity of supernatant}} \cdot 100$$



12. The labelled leucocytes should be re-injected without delay. Imaging: at 30 mins, 2 hrs and 24 hrs after administration.

Renoscint MAG3 1 mg (Technetium (^{99m}Tc) tiatide)
Tc-MR-16

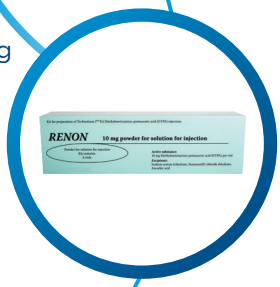
Active substance	Betiatide To be used with sodium (^{99m}Tc) pertechnetate for the preparation of the diagnostic agent: Technetium (^{99m}Tc) tiatide.
Indications	After reconstitution and labelling with sodium (^{99m}Tc) pertechnetate solution, the diagnostic agent technetium (^{99m}Tc) tiatide may be used intravenously for the evaluation of nephrological and urological disorders in particular for the study of morphology, perfusion, and function of the kidney and characterisation of urinary outflow.
Excipients	Disodium tartrate dihydrate Stannous (II) chloride dihydrate Hydrochloric acid for pH adjustment
Dose for adults	37-185 MBq, depending on the pathology to be studied and the method to be used. Studies of renal blood flow or transport through the ureters generally require a larger dose than studies of intra-renal transport, whereas renography requires smaller activities than sequential scintigraphy.
Labelling activity	maximum 2960 MBq
Labelling volume	10 ml
Storage of cold kit	18 months from date of manufacturing, Store in a refrigerator (2°C – 8°C)
Storage of labelled compound	8 hrs, Do not store above 25°C
Package size	1 pack contains 6 vials Sample package: 2 vials
Registration numbers	Hungary: OGYI-T-23275/01 (1x) OGYI-T-23275/02 (6x) Czech Republic: 88/832/16-C Denmark: DK R 58417 Italy: AIC 045669013 United Kingdom: PL 27151/0001 Austria: 438272 Germany: 98671.00.00 Spain: 82909 Poland: 24615
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 10-12., Hungary

Mercapton (^{99m}Tc-DMSA)
Tc-MR-13

Active substance	Meso-2-3-dimercapto succinic acid
Indications	The Tc-99m labelled compound can be used for static (planar or tomographic) renal imaging: • Kidney scintigraphy, static imaging of kidney location • Determination of functional kidney weight • Determine the relative function (%) of the right and left kidneys
Excipients	Stannous(II) chloride dihydrate Sodium acetate trihydrate Ascorbic acid
Dose for adults	Recommended dose ranges for i.v. administration to patient of average weight (70 kg) for adults: 50-140 MBq
Labelling activity	Up to 3.7 GBq
Labelling volume	2-5 ml
Storage of cold kit	12 months from date of manufacturing, Do not store above 25°C Protect from light
Storage of labelled compound	6 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Hungary: OGYI-T-9940/01
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 1012., Hungary

(for detailed actual information please read the current approved SmPC)

Renon (^{99m}Tc-DTPA)
Tc-MR-11



Active substance	Acidum diaethylentriamino-pentaaceticum (DTPA) 10.0 mg
Indications	The Tc-99m labelled compound can be used for: • After labeling with sterile 99mTc-pertechnetate solution, it is indicated for: • determination of glomerular filtration (GFR) • visualization of the kidney by sequential scintigraphy • renal perfusion studies • urinary tract studies • renal artery stenosis • estimation of transplanted kidney function • Vesico-urethral reflux • visualization of brain lesions (tumor, bleeding) • inhalation pulmonary scintigraphy (using a suitable nebulizer)
Excipients	Stannous(II) chloride dihydrate Sodium acetate trihydrate Ascorbic acid
Dose for adults	Suggested dose ranges are different according to the type of investigation: Glomerular filtration: 111-185 MBq Renal perfusion: 370-740 MBq Visualization of brain lesions: 370-740 MBq
Labelling activity	Up to 8 GBq
Labelling volume	1-5 ml
Storage of cold kit	24 months from date of manufacturing, Do not store above 25°C Protect from light
Storage of labelled compound	6 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Hungary: OGYI-T-8816/01
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 1012., Hungary

(for detailed actual information please read the current approved SmPC)

Makro-Albumon (^{99m}Tc-MAA)
Tc-MR-2

Active substance	Human Serum Albumin Macroaggregate 2.0 mg
Particle size	90% are between 10 and 100 µm (2-4x10^6 particles/vial)

Indications	The labelled MAA is suitable for
	• Pulmonary perfusion scintigraphy
	  • Pulmonary embolism and myocardial infarct
	  • Chronic circulatory failure
	  • Local respiratory distress
	  • Emphysema
	  • Tumour
	  • Inflammation
	• Visualisation of venous circulation
	  • Perfusion arterial scintigraphy of abdominal and retroperitoneal organs
	  • Detection of deep vein thrombosis in the lower extremities and pelvis
	  • Occlusion of the vena cava inferior

Excipients	Stannous(II) chloride dihydrate Glucose Ascorbic acid Sodium chloride
Dose for adults	Lung scintigraphy: 37-185 MBq
Labelling activity	Up to 3.7 GBq
Labelling volume	2-8 ml
Storage of cold kit	18 months from date of manufacturing, Store in a refrigerator (2°C -8°C) Protect from light
Storage of labelled compound	8 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Hungary: OGYI-T-8663-01 Czech Republic: 88/177/91-C Russia: ЛС-002157 Belarus: 10085/13/18 Turkey: 136/11 Croatia: UP/I-530-09/11-01/20
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 1012., Hungary

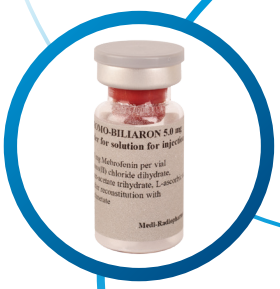
(for detailed actual information please read the current approved SmPC)

Skeleton (^{99m}Tc-MDP)
Tc-MR-10

Active substance	Methylene diphosphonic acid (MDP) 5.0 mg
Indications	• primary bone tumours imaging • bone metastases of other tumours (e.g. prostate, breast, lung cancer) • osteomyelitis • metabolic bone disease • Paget's disease • fractures • avascular necrosis • loosened/inflamed arthricular prosthesis • arthricular inflammations (rheumatoid arthritis)
Excipients	Stannous(II) chloride dihydrate Tetrasodium pyrophosphate decahydrate Ascorbic acid
Dose for adults	370-740 MBq
Labelling activity	Up to 10 GBq
Labelling volume	1-5 ml
Storage of cold kit	24 months from date of manufacturing, Do not store above 25°C Protect from light
Storage of labelled compound	8 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Hungary: OGYI-T-8815/01 Hong-Kong: HK-64681 Taiwan: R00095
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 1012., Hungary

(for detailed actual information please read the current approved SmPC)

Bromo-Biliaron (^{99m}Tc-Br-IDA)
Tc-MR-12



Active substance	Mebrofenin [N-(3-bromo-2,4,6-trimethylphenylcarba-moil-methyl)-iminodiacetic acid] 5.00 mg
Indications	Hepatobiliary imaging • Hepatobiliary function studies • Evaluation of bile flow, and diagnosis of extrahepatic biliary obstruction, malfunctioning gall-bladder, gall-bladder inflammation, biliary duct artresia, biliary cysts or similar pathologic alterations of the biliary duct.
Excipients	Stannous(II) chloride dihydrate Sodium acetate trihydrate Ascorbic acid
Dose	Adult doses: 150-300 MBq • Paediatric dose: to be adjusted to body weight. • 20 MBq is the minimal dose (also in babies) to obtain images of sufficient quality in kidney studies
Labelling activity	Up to 6.0 GBq
Labelling volume	2-5 ml
Storage of cold kit	12 months from date of manufacturing, Do not store above 25°C Protect from light
Storage of labelled compound	6 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Hungary: OGYI-T-9941/01
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 1012., Hungary

(for detailed actual information please read the current approved SmPC)

Pyroscint (^{99m}Tc-PYP)
Tc-MR-9

Active substance	Sodium Pyrophosphate Decahydrate 60.0 mg
Indications	After radiolabelling with sodium (99mTc) pertechnetate solution, the solution obtained is indicated for • Bone scintigraphy • Cardiac scintigraphy, diagnosis of acute myocardial infarction After reconstitution with physiological sodium chloride solution in vivo or in vivo/in vitro red blood cell labelling for determination of blood volume and spleen scintigraphy.
Excipients	Stannous(II) chloride dihydrate Ascorbic acid
Dose for adults	Suggested dose ranges are different according to the type of investigation
Labelling activity	maximum 6.0 GBq
Labelling volume	2-5 ml
Storage of cold kit	24 months from date of manufacturing, Do not store above 25°C Protect from light
Storage of labelled compound	6 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Hungary: OGYI-T-8817/01
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 1012., Hungary

(for detailed actual information please read the current approved SmPC)

ALBUMON (^{99m}Tc-Human Serum Albumin)
TC-MR-17

Active substance	Human serum albumin (HSA) 30 mg
Indications	Technetium (^{99m}Tc) human albumin is indicated for blood pool imaging, angiocardiography and ventriculography.
Excipients	Stannous(II) chloride dihydrate Sodium chloride
Dose for adults	• For static blood pool imaging the activity to be administered intravenously to varies between 111-185 MBq. Scintigraphy may start immediately after injection. • For radionuclidic angiocardiography a rapid intravenous bolus (1-2 ml) of 370-740 MBq should be administered intravenously. • For circulation and blood flow studies 18.5-185 MBq should be administered intravenously. Scintigraphy may start immediately after injection. • For ventriculography 185-925 MBq should be administered intravenously. Scintigraphy may start immediately after injection.
Labelling activity	maximum: 2.2 GBq
Labelling volume	2-5 ml
Storage of cold kit	12 months from the date of manufacturing, Store in refrigerator (2°C-8°C)
Storage of labelled compound	8 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Hungary: OGYI-T-23147/01
Marketing Authorization Holder	**Medi-Radiopharma Co., Ltd.** 2030 Érd, Szamos u. 10-12., Hungary

(for detailed actual information please read the current approved SmPC)

QUALITY CONTROL PRODUCTS

MediCheck QUALITY CONTROL KIT
MR-21

KIT FOR CHECKING THE QUALITY OF THE IN-HOUSE PREPARATION OF RADIOPHARMACEUTICALS

The kit is a complete compilation of reagents to check the Tc-99m generator and the labelling work in the hot lab of the nuclear medicine department and gives rapid and reliable results.

The ^{99}Mo/^{99m}Tc-99m sterile generator can be checked for

- radiochemical purity
- Al^{3+} content
- pH determination of the eluate.

The

- radiochemical purity
- Sn^{2+} content
- pH determination can be controlled right after the labelling in case of the following

^{99m}Tc labelled radiopharmaceuticals:

- Albumin colloid
- Colloidal tin
- Exametazime (HMPAO)
- Human albumin (HSA)
- Macrosalb (MAA)
- Mebrofenin (BrIDA)
- Medronate (MDP)
- Mertiatide (MAG3)
- Oxidronate (HDP)
- Pentetate (DTPA)
- Sestamibi (MIBI)
- Succimer (DMSA)
- Tetrofosmin
- Sn^{2+}-pyrophosphate (PYP)
- Sodium pertechnetate injection (TcO^{4-}) (fission and/or non-fission)

The kit is in complience with pharmacopeial methods and national regulations.

Mini Medi-Check QC kits for SmPC QC methods of ^{99m}Tc radiopharmaceuticals

- ready to use kit for QC methods according to SmPC
- easy to use for all Tc-99m independent from supplier of cold kit

Supply package available for refill and for individual demand.

(for detailed actual information please read the current approved SmPC)

MEDI-MEDIA FILL KIT & MEDI-MEDIA-FILL KIT SUPPLY PACKAGE

MR-25 & MR-25/S

ASEPTIC PROCEDURE SIMULATION TEST WITH PERSONNEL AND ENVIRONMENTAL MICROBIOLOGICAL MONITORING

Requirements for performing media-fill challenge tests (aseptic process simulation tests) are described and regulated as follows:

- The United States Pharmacopeia (USP) Chapter <797>
- European Pharmacopeia (Ph.Eur.)
- Current Good Manufacturing Practice (cGMP) in EudraLex Vol.4

Special requirements for aseptic preparations are also recommended by

- QuapoS4 a quality standard for oncology
- Current Good Radiopharmacy Practice (cGRPP) for radiopharmacy

MEDI-MEDIA-FILL KIT is suitable and applicable for all sterile medicinal products produced in situ in pharmacy and clinical laboratories including the simulation of sterile aseptic compounding and dispensing procedure of SPECT, PET and therapeutic radiopharmaceuticals, in addition non-radioactive parenteral medicines, oncology medicines. The kit provides also a useful tool for testing the personnel competency and environmental and personnel hygiene monitoring during the procedure.

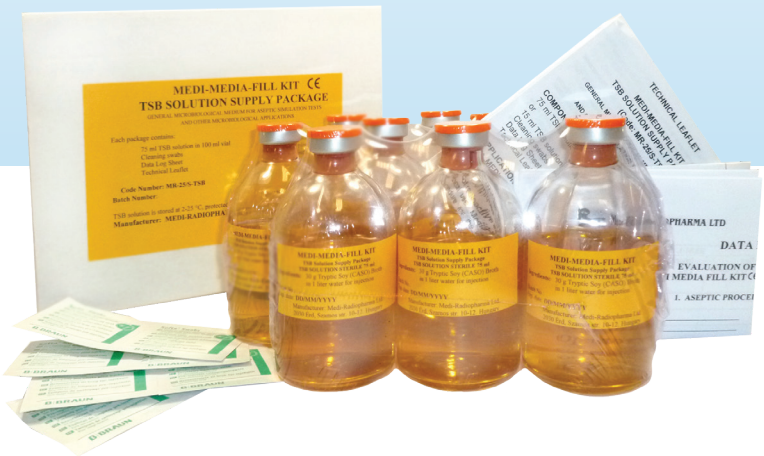
- SENSITIVE reagents for detecting microbial contaminations
- COMPLEX tools for performing aseptic simulation tests
- FLEXIBLE applications for laboratories dedicated to aseptic preparations
- QUALIFIED and CERTIFIED components produced under GMP regulation
- RELIABLE results are accepted by authorities
- EASY TO USE without any special instrumentation
- SUPPLEMENTABLE components - Supply kits are available.

KIT COMPONENTS

TSB-Solution 3 x 75 ml
Test Agar Plate 5
Sterile Test Vial 6 x 50 ml
Sterile Vacuum Test Vial 6 x 8 ml
Cleaning Swab 6
Label for vials 12
Data Log Sheet
Technical Leaflet

SUPPLY PACKAGE COMPONENTS

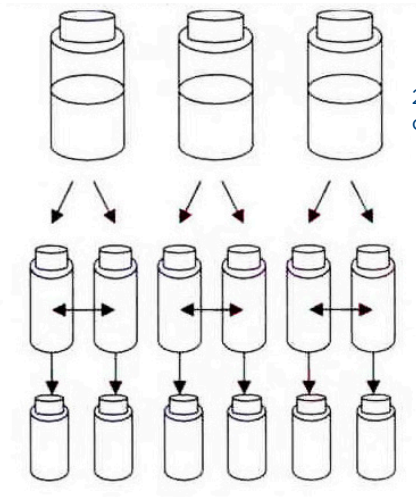
Available in 3 types of packaging:
TSB solution 3 x 15 ml/kit
TSB solution 4x 75 ml/kit
TSB solution 9x 75 ml/kit
Test-Agar Plates 5-20 pieces
Data Log Sheet, Technical Leaflet



Flowchart of MEDI-MEDIA-FILL KIT

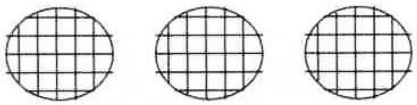
STEP 1
Aseptic Procedure Simulation

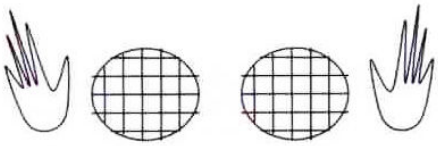
Dispensing, mixing and distribution of sterile TSB



STEP 2
Sampling for Personal and Enviromental Microbiological Monitoring

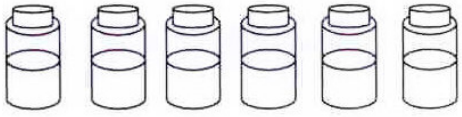
Sampling from surfaces of workbench and sterile clothes



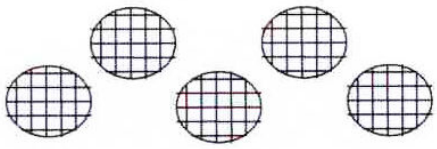


Sampling from right and left gloved hands

STEP 3
Sterility Test and Microbiological Enviromental Monitoring Test

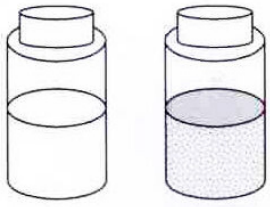


at 30-35°C for 7 days and at 20-25°C for 7 days
or at 30-35°C for 14 days

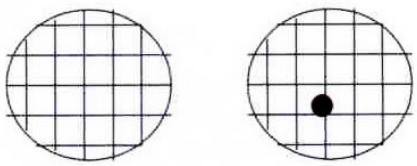


at 30-35°C for 48 hours
and at 20-25°C for 72 hours

STEP 2
Evaluation of Test Results



Visual check of TSB in Test Vials



Visual check of Counting of Colony Forming Unit (CFU) on RODAC Agar Plates

Clear, Amber fluid **Result: Negative (Pass)**	**Turbid or Cloudy fluid** **Result: Positive (Fail)**	**<1 CFU** **Result: Negtive (Pass)**	**1 CFU** **Result: Positive (Fail)**

STEP 5
Bacterial Endotoxin Test (LAL Test) should be performed on Negative Test Vials

Sterile and vacuum vials

Sterile and sterile/vacuum vials with stopper and caps for preparation of radiopharmaceuticals and use for eluting Tc-99m sterile generator:

Volume	D=mm	H=mm	code (sterile)	code (sterile/vacuum)
6	22±0.2	40±0.5	V-MR-6R	VV-MR-6R
8	23±0.4	46.8±0.5	V-MR-8H	VV-MR-8H
8	22±0.2	45±0.5	V-MR-8R	VV-MR-8R
10	23±0.2	55±0.5	V-MR-10	VV-MR-10
15	26.5±0.45	58.8±0.6	V-MR-15H	VV-MR-15H
15	24±0.2	60±0.5	V-MR-15R	VV-MR-15R
20	32±0.45	58±0.6	V-MR-20H	VV-MR-20H
50	42.5±0.8	73±0.8	V-MR-50H	VV-MR-50H
100	51.6±0.8	94.5±0.8	V-MR-100H	

Available colours of caps:

- white
- red
- grey
- yellow
- blue
- purple
- orange
- green
- brown

Certificates of quality is attached to the shipment.

BROAD EXPERIENCE, EXPERTISE & CAPABILITIES

MEDI-RADIOPHARMA Ltd. is open for requests for contract manufacturing of small volume sterile injectable products (cGMP aseptic manufacturing, lyophilised products).

MEDI-RADIOPHARMA Ltd. is also open for requests and suggestions on new research and development projects in the field of nuclear medicine. Our world-class sterile injectables capabilities include formulation and process development and manufacturing of sterile injectable drug products at scales suitable for small clinical trials to global commercial supply. We will bring speed, flexibility, experience and a broad set of capabilities to your program.

Our experts have the experience and capabilities to develop an optimal formulation and process with long-term commercial manufacturing in sight.

Offerings include:

- Formulation development
- Manufacturing process development
- Process Validation for Steriles
  - Freeze-thaw studies
  - Cleaning validation
  - Product contact part compatibility studies
  - Sterilization cycle development and validation
- Validation of analytical assays
- Release testing
- ICH stability studies
- Container shipment studies

(for detailed actual information please read the current approved SmPC)

MEDI-RADIOPHARMA

Your Global Nuclear Medicine Supplier

SERVICES

cGMP CONTRACT MANUFACTURING

- small volume sterile products according to **cGMP** for clinical trials and **R&D**
- investigational medicinal products
- synthetically prepared active pharmaceutical ingredients (API) for diagnostic kits

GLP CONTRACT RESEARCH SERVICES

- active and inactive analitical method development and validation
- **animal testing, biodistribution studies**
- **license for all isotopes** (including α-Emitters)

CONTRACT QUALITY CONTROL TESTING SERVICE

- physical
- chemical/radiochemical
- biological

DISTRIBUTION acc. to GDP

- pharmaceuticals
- radiopharmaceuticals
- isotope generators

MRP
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