

1. NAME OF THE MEDICINAL PRODUCT

Pyroscint 60 mg powder for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains:

Active substance: Sodium pyrophosphate decahydrate 60.0 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Kit for radiopharmaceutical preparation.

The medicinal product is a sterile, non-pyrogenic, lyophilised powder sealed under a nitrogen atmosphere, ready for one-step radiolabelling with sterile sodium pertechnetate (^{99m}Tc) solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.

After radiolabelling with sterile sodium pertechnetate (^{99m}Tc) solution, the radiolabelled diagnostic preparation is indicated for the following diagnostic procedures:

- bone scintigraphy;
- cardiac scintigraphy for the diagnosis of acute myocardial infarction.

After reconstitution of the Pyroscint stannous pyrophosphate kit with physiological saline solution, it may be used for in vivo and in vitro red blood cell labelling for:

- determination of blood volume and spleen scintigraphy using in vivo and in vitro red blood cell labelling techniques.

4.2 Posology and method of administration

The recommended activity of technetium (^{99m}Tc) pertechnetate for radiolabelling one vial of lyophilisate is a maximum of 6 GBq in a volume of 2–5 mL.

- For bone scintigraphy, 185–555 MBq per patient is administered by slow intravenous injection over 10–20 seconds. Imaging may be started 3 hours after administration.
- For investigations of myocardial infarction, 370–555 MBq is administered by slow intravenous injection over 10–20 seconds. Scintigraphic imaging is performed 1–1.5 hours after injection.

- After reconstitution of the inactive lyophilisate with 6.0 mL of physiological, sterile, non-pyrogenic sodium chloride solution, the preparation is suitable for red blood cell labelling using the in vivo and in vitro methods.

The Paediatric Task Group of the EANM recommends calculating the activity to be administered according to body weight using the multiplication factors given in the following table:

3 kg = 0.10	22 kg = 0.50	42 kg = 0.78
4 kg = 0.14	24 kg = 0.53	44 kg = 0.80
6 kg = 0.19	26 kg = 0.56	46 kg = 0.82
8 kg = 0.23	28 kg = 0.58	48 kg = 0.85
10 kg = 0.27	30 kg = 0.62	50 kg = 0.88
12 kg = 0.32	32 kg = 0.65	52-54 kg = 0.90
14 kg = 0.36	34 kg = 0.68	56-58 kg = 0.92
16 kg = 0.40	36 kg = 0.71	60-62 kg = 0.96
18 kg = 0.44	38 kg = 0.73	64-66 kg = 0.98
20 kg = 0.46	40 kg = 0.76	68 kg = 0.99

For children under 1 year of age, the minimum dose is 80 MBq. For spleen scintigraphy, the minimum activity used is 20 MBq. It is not recommended to repeat the examination within 3 months.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients. Period of pregnancy and breast-feeding (see section 4.6).

4.4 Special warnings and precautions for use

This medicinal product is a radiopharmaceutical. The rules applicable to radioactive materials apply to the handling, transport and storage of this medicinal product. The medicinal product may only be administered by appropriately trained personnel in a designated clinical unit authorised to use radioisotopes.

Radiopharmaceuticals should be prepared by the user in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate precautions should be taken to ensure sterility, in accordance with the requirements of Good Manufacturing Practice (GMP) for medicinal products.

The use of this medicinal product in patients under 18 years of age is contraindicated unless the importance of obtaining the diagnostic information outweighs the risk arising from radiation exposure. In such cases, a reduced activity should be administered (see section 4.2).

The use of this medicinal product in pregnant or breast-feeding women is contraindicated unless the importance of obtaining the diagnostic information outweighs the risk arising from radiation exposure (see section 4.6).

For most diagnostic investigations using nuclear medicine procedures, the radiation dose delivered (effective dose/EDE) is less than 20 mSv. Higher doses may be justified in certain clinical circumstances.

4.5 Interaction with other medicinal products and other forms of interaction

The following reduce red blood cell labelling efficiency: heparin, high concentrations of tin, aluminium, prazosin, methyldopa, hydralazine, quinidine, β -adrenergic blockers, (verapamil, nifedipine), nitrates (nitroglycerin), iodine-containing contrast media and Teflon catheters (Sn^{2+} may react with the catheter).

4.6 Fertility, pregnancy and lactation

Investigations in women of childbearing potential When it is necessary to administer a radiopharmaceutical to women of childbearing potential, information should always be sought about possible pregnancy. Any woman who has missed a menstrual period should be assumed to be pregnant until proven otherwise. Where uncertainty exists, radiation exposure should be kept to the minimum necessary to obtain the required clinical information. Alternative examination methods which do not involve ionising radiation should always be considered in these women.

Pregnancy

Radionuclide diagnostic procedures carried out in pregnant women also involve a radiation dose to the foetus. Therefore, only urgent investigations should be carried out during pregnancy where the value of the information obtained from the examination outweighs the risk of harm to the mother and the foetus.

Breast-feeding

Before administering a radioactive medicinal product to a breast-feeding mother, consideration should be given as to whether the investigation could be delayed until after breast-feeding has ceased or whether the most appropriate radiopharmaceutical has been selected, bearing in mind that radioactive material is excreted into breast milk. If the use of the radioactive medicinal product is nevertheless considered necessary, breast-feeding should be interrupted for 24 hours and the expressed breast milk should be discarded. Breast-feeding may be resumed when the level of radioactivity in the breast milk will not result in a radiation dose to the child greater than 1 mSv.

4.7 Effects on ability to drive and use machines

The medicinal product does not directly affect the ability to drive and use machines.

4.8 Undesirable effects

Cardiac disorders Frequency not known (cannot be estimated from the available data)	Cardiac arrhythmia
Congenital, familial and genetic disorders Frequency not known (cannot be estimated from the available data)	Inherited deficiency
Nervous system disorders Frequency not known (cannot be estimated from the available data)	Headache, dizziness
Gastrointestinal disorders Frequency not known (cannot be estimated from the available data)	Nausea, vomiting
Skin and subcutaneous tissue disorders Frequency not known (cannot be estimated from the available data)	Rash
Musculoskeletal and connective tissue disorders Frequency not known (cannot be estimated from the available data)	Arthralgia
Neoplasms benign, malignant and unspecified (including cysts and polyps) Frequency not known (cannot be estimated from the available data)	Tumour induction
Vascular disorders Frequency not known (cannot be estimated from the available data)	Blood pressure decreased and symptoms of hypotension, subcutaneous vasodilatation
General disorders and administration site conditions Frequency not known (cannot be estimated from the available data)	Facial oedema, local reactions at the injection site
Immune system disorders Frequency not known (cannot be estimated from the available data)	Hypersensitivity reactions, allergic reactions

For each subject, the radiation dose resulting from exposure to ionising radiation must be justified by the useful information expected from the examination. The activity administered should be selected so that the desired diagnostic result can be obtained with the lowest possible radiation dose. Exposure to ionising radiation may induce cancer and may lead to the development of hereditary disorders. According to generally accepted evidence, these undesirable effects occur only rarely during radionuclide diagnostic investigations because of the low radiation doses used.

For most diagnostic investigations using nuclear medicine procedures, the radiation dose delivered (EDE) is less than 20 mSv.

4.9 Overdose

No cases of actual overdose have been reported. Should an overdose occur, measures should primarily be directed towards maintaining the patient's vital functions.

Administration of amounts of radioactivity higher than prescribed causes unnecessary radiation exposure to the patient and the patient's environment and should therefore be avoided. If this nevertheless occurs accidentally as a result of an error by the personnel, the actual activity of ^{99m}Tc administered, expressed in MBq, should be determined, and the absorbed doses to the individual organs and to the whole body should be calculated on the basis of the dosimetry table given in section 11. On the basis of the values obtained, a decision should be made as to whether the patient requires appropriate radiomedical intervention or treatment. The table gives the absorbed dose values, expressed in μGy , resulting from intravenous administration of 1 MBq of ^{99m}Tc -Pyroscint. These values should be multiplied by the administered activity, expressed in MBq, to obtain the absorbed dose values in μGy .

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Diagnostic radiopharmaceuticals, ATC code: V09BA03 At the chemical concentrations and levels of radioactivity used for diagnostic examinations, the medicinal product does not appear to have any pharmacodynamic activity.

5.2 Pharmacokinetic properties

Distribution:

For bone and cardiac imaging, 1–2 hours after intravenous injection, 40–50% of technetium (^{99m}Tc) pyrophosphate is taken up by the skeletal system and approximately 10% remains in the vascular system.

For blood pool studies, when the inactive lyophilisate is reconstituted with isotonic saline solution and injected 30 minutes before the intravenous administration of sodium pertechnetate (^{99m}Tc), approximately 75% of the activity remains in the circulation. The radiation doses absorbed by critical organs in healthy subjects following administration of labelled red blood cells are detailed in section 11.

Elimination:

In patients with normal renal function, during the first 24 hours following administration, 40–60% of the administered product is excreted unchanged in the urine, while less than 5% of the injected dose remains in the circulation.

Specific factors affecting pharmacokinetics:

Uptake of the product into bone depends primarily on the extent to which phosphate is taken up by the bone from its supplying blood vessels. Deposition in the skeletal system is bilaterally

symmetrical, with increased uptake in the axial skeleton compared with the appendicular skeleton. In children in whom the epiphyseal regions are still open, uptake of the product in the distal regions of the long bones is considerably higher than in adult patients in whom the epiphyseal regions are already closed. Localised areas of abnormal radiopharmaceutical uptake may be observed in primary malignant bone tumours, bone metastases from malignant disease, acute or chronic osteomyelitis, arthritis, recent bone fractures, areas of ectopic calcification in Paget's disease, areas of aseptic necrosis and, in general, in any process involving bone in which there is increased bone formation or locally increased bone perfusion. Localised areas of decreased radiopharmaceutical uptake may be observed in areas of bone that have been exposed to external irradiation.

5.3 Preclinical safety data

The medicinal product is not intended for regular or continuous use. The toxicity profile of sodium pyrophosphate is well known and does not represent a hazard to human health.

The LD50 of sodium pyrophosphate is 72.5 mg/kg in CFLP mice with an average body weight of 25 g.

Studies investigating the chronic toxicity, mutagenic potential, reproductive toxicity and carcinogenic potential of the product have not been performed because of the clinical use of the substance, which generally involves a single intravenous administration of a dose in the milligram range.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stannous chloride dihydrate, L-ascorbic acid

6.2 Incompatibilities

The Pyroscint radiopharmaceutical kit vials contain stannous chloride, which acts as a reducing agent and converts free pertechnetate, in which technetium is in oxidation state +7, into technetium in oxidation state +4, which is suitable for complex formation. The contents of the vials are therefore incompatible with moisture and with oxidising conditions (chemical oxidising agents, oxygen in the air, etc.). The product is likewise incompatible with alkalis, since an alkaline medium promotes oxidation of tin(II) before the radiolabelling procedure is carried out. Therefore, the protective cap of the sealed vials should only be removed immediately before radiolabelling, and radiolabelling should be performed in accordance with the instructions for use and handling of the medicinal product.

6.3 Shelf life

The shelf life of the Pyroscint radiopharmaceutical kit (lyophilised non-radioactive components in a vial closed with a rubber stopper and an aluminium cap) is 2 years from the date of manufacture. Each carton contains 6 vials. The individual vials may be radiolabelled at different times within the 2-year shelf life stated on the vial labels and on the carton label.

Pyroscint radiolabelled with the radionuclide ^{99m}Tc , i.e. ^{99m}Tc -pyrophosphate injection, should be used within 6 hours of radiolabelling.

6.4 Special precautions for storage

Do not store the Pyroscint radiopharmaceutical kit above 25°C.

Do not store ^{99m}Tc -pyrophosphate above 25°C. Store in accordance with radiation protection regulations.

6.5 Nature and contents of container

Sterile, clear, 8 mL Type I glass vial complying with the requirements of the European Pharmacopoeia, closed with a sterile siliconised chlorobutyl rubber stopper and a sterile tear-off cap.

The labelled vials are packed in a carton. An insert made of the same material as the carton holds the 6 vials in position and prevents movement during storage. Each carton contains 6 vials.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Note ☒ (one cross)

Classification: **Group II/3**

Medicinal product subject to restricted medical prescription, to be used under the conditions provided by healthcare service providers offering specialist outpatient care in an outpatient clinic or inpatient care, as defined in Section 3(ga) of Act CLIV of 1997 on Health (I).

7. MARKETING AUTHORISATION HOLDER

Name and address: MEDI-RADIOPHARMA Kft.

H-2030 Érd, Szamos u. 10-12.

Tel.: +36 23 521 261

Fax: +36 23 521 260

e-mail: mediradiopharma-kft@mediradiopharma.hu

8. MARKETING AUTHORISATION NUMBER(S)

OGYI-T-8817/01

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18 September 1996 / January 2005 / 15 October 2010

10. DATE OF REVISION OF THE TEXT

15 October 2010

11. DOSIMETRY

The radiation-physical characteristics of the radiolabelled product may be summarised as follows:

Physical half-life: 6 hours

Energy and abundance of emitted gamma photons: 140 keV, 100%

According to ICRP Publication 80 (International Commission on Radiological Protection), the absorbed radiation doses in healthy subjects following administration of radiolabelled red blood cells are given in the following table:

^{99m}Tc-labelled red blood cells (ICRP 80 – 1999)

Absorbed dose per unit activity administered (mGy/MBq)

Organ	Adult	15 years old	10 years old	5 years old	1 year old
Adrenals	9.9E-03	1.2E-02	2.0E-02	3.0E-02	5.6E-02
Urinary bladder	8.5E-03	1.1E-02	1.4E-02	1.7E-02	3.1E-02
Bone surfaces	7.4E-03	1.2E-02	1.9E-02	3.6E-02	7.4E-02
Brain	3.6E-03	4.6E-03	7.5E-03	1.2E-02	2.2E-02
Breasts	3.5E-03	4.1E-03	7.0E-03	1.1E-02	1.9E-02
Gall bladder	6.5E-03	8.1E-03	1.3E-02	2.0E-02	3.0E-02
Gastrointestinal tract					
Stomach	4.6E-03	5.9E-03	9.7E-03	1.4E-02	2.5E-02
Stomach wall	3.9E-03	4.9E-03	7.8E-03	1.2E-02	2.1E-02
Small intestine	3.7E-03	4.8E-03	7.5E-03	1.2E-02	2.0E-02
Upper large intestine	4.0E-03	5.1E-03	8.0E-03	1.3E-02	2.2E-02
Lower large intestine	3.4E-03	4.4E-03	6.9E-03	1.0E-02	1.8E-02
Heart	2.3E-02	2.9E-02	4.3E-02	6.6E-02	1.1E-01
Kidneys	1.8E-02	2.2E-03	3.6E-02	5.7E-02	1.1E-01
Liver	1.3E-02	1.7E-02	2.6E-02	4.0E-02	7.2E-02
Lungs	1.8E-02	2.2E-02	3.5E-02	5.6E-02	1.1E-01
Muscles	3.3E-03	4.0E-03	6.1E-03	9.4E-03	1.7E-02
Oesophagus	6.1E-03	7.0E-03	9.8E-03	1.5E-02	2.3E-02

Ovaries	3.7E-03	4.8E-03	7.0E-03	1.1E-02	1.9E-02
Pancreas	6.6E-03	8.1E-03	1.3E-02	1.9E-02	3.3E-02
Bone marrow	6.1E-03	7.6E-03	1.2E-02	2.0E-02	3.7E-02
Skin	2.0E-03	2.4E-03	3.8E-03	6.2E-03	1.2E-02
Spleen	1.4E-02	1.7E-02	2.7E-02	4.3E-02	8.1E-02
Testes	2.3E-03	3.0E-03	4.4E-03	6.9E-03	1.3E-02
Thymus	6.1E-03	7.0E-03	9.8E-03	1.5E-02	2.3E-02
Thyroid	5.7E-03	7.1E-03	1.2E-02	1.9E-02	3.6E-02
Uterus	3.9E-03	4.9E-03	7.4E-03	1.1E-02	1.9E-02
Other tissues	3.5E-03	4.5E-03	7.3E-03	1.3E-02	2.3E-02
Effective dose (mSv/MBq)	7.0E-03	8.9E-03	1.4E-02	2.1E-02	3.9E-02

Blood pool scintigraphy: For a healthy adult with a body weight of 70 kg, the effective dose equivalent following administration of an activity of 740 MBq is typically 6.3 mSv, and the typical radiation dose to the critical organ (heart) is 17 mGy.

Determination of blood volume: For a healthy adult with a body weight of 70 kg, the effective dose equivalent following administration of an activity of 5 MBq is typically 0.005 mSv.

^{99m}Tc-labelled denatured red blood cells (ICRP 53 – 1988)

Absorbed dose per unit activity administered (mGy/MBq)

Organ	Adult	15 years old	10 years old	5 years old	1 year old
Adrenals	1.3E-02	1.8E-02	2.7E-02	3.8E-02	6.3E-02
Urinary bladder wall	7.5E-04	1.1E-03	2.1E-03	3.8E-03	7.3E-03
Bone surfaces	3.1E-03	4.1E-03	6.1E-03	9.5E-03	1.9E-02
Breasts	2.1E-03	2.1E-03	4.1E-03	6.8E-03	1.0E-02
Gastrointestinal tract					
*Stomach wall	1.9E-02	2.1E-02	3.0E-02	4.0E-02	5.8E-02
Small intestine	3.7E-03	4.6E-03	7.7E-03	1.3E-02	2.2E-02
Upper large intestine	4.0E-03	4.9E-03	8.5E-03	1.4E-02	2.3E-02
Lower large intestine	1.7E-03	2.3E-03	4.3E-03	6.9E-03	1.3E-02
Heart	6.0E-03	7.3E-03	1.1E-02	1.6E-02	2.6E-02
*Kidneys	1.8E-02	2.2E-02	3.2E-02	4.6E-02	7.0E-02
*Liver	1.8E-02	2.3E-02	3.4E-02	4.9E-02	8.7E-02
Lungs	5.7E-03	7.5E-03	1.1E-02	1.7E-02	2.8E-02
Ovaries	1.4E-03	2.2E-03	3.9E-03	7.0E-03	1.2E-02
*Pancreas	3.6E-02	4.0E-02	5.7E-02	7.8E-02	1.2E-01
Bone marrow	4.3E-03	6.0E-03	8.4E-03	1.1E-02	1.7E-02
*Spleen	5.6E-01	7.8E-01	1.2E+00	1.8E-00	3.2E-00
Testes	4.7E-04	5.9E-04	1.1E-03	1.7E-03	4.1E-03
Thyroid	6.3E-04	1.0E-03	1.8E-03	3.2E-03	6.6E-03
Uterus	1.4E-03	1.8E-03	3.6E-03	5.9E-03	1.1E-02
Other tissues	3.3E-03	4.1E-03	5.8E-03	8.7E-03	1.5E-02
Effective dose equivalent (mSv/MBq)	4.1E-02	5.6E-02	8.4E-02	1.3E-01	2.2E-01

Effective dose (ICRP 80 – 1999): 1.9E-02

Spleen scintigraphy: For a healthy adult with a body weight of 70 kg, the effective dose equivalent following administration of an activity of 70 MBq is typically 2.9 mSv, and the typical radiation dose to the critical organ (spleen) is 39 mGy.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

The unlabelled Pyroscint in vivo kit must not be used directly for injection for bone, joint or myocardial infarction examinations. Only ^{99m}Tc -Pyroscint obtained after radiolabelling with the radionuclide may be administered to the patient. It should be borne in mind that ^{99m}Tc -Pyroscint is a solution containing a radioactive isotope; therefore, during its preparation and use, the regulations governing radioactive materials must be observed in addition to the applicable pharmaceutical requirements.

Aseptic technique must be used during radiolabelling. Pyroscint may be radiolabelled with ^{99m}Tc using eluate obtained from commercially available technetium generators.

LABELLING PROCEDURE:

1. For imaging of the skeletal system, joints and acute myocardial infarction

Place the vial containing the lyophilisate in a small lead shield with a wall thickness of 3 mm. Under aseptic conditions, using a sterile syringe, inject sterile ^{99m}Tc -pertechnetate of the required activity (maximum 6 GBq) through the rubber stopper into the vial (minimum volume 2 mL, maximum volume 5 mL). Before withdrawing the needle from the vial, draw 2–5 mL of the nitrogen gas from the vial into the syringe in order to equalise the pressure inside the vial. Do not use a venting needle. Shake the vial thoroughly and allow it to stand for 15 minutes at room temperature. Complete the enclosed label and affix it to the vial. The resulting radiolabelled compound, ^{99m}Tc -Pyroscint, may be administered by intravenous injection.

2. In vivo labelling of red blood cells with Pyroscint

Dissolve the contents of the Pyroscint vial in 6 mL of physiological saline solution. For an average-weight patient (70 kg), administer 2 mL intravenously, corresponding to 800 μg of Sn^{2+} ions, i.e. a dose of 11.43 $\mu\text{g}/\text{kg}$ body weight. (The ideal dose range for in vivo labelling of red blood cells is 10–20 $\mu\text{g}/\text{kg}$ body weight.) For in vivo labelling, 20–30 minutes after administration of the medicinal product, 550–740 MBq of ^{99m}Tc -pertechnetate, obtained aseptically from the generator and, if necessary, diluted with sterile physiological saline solution, should also be administered intravenously to the patient.

3. In vitro labelling

Place an ampoule containing 2–10 mL of anticoagulated blood taken from the patient into a lead container and add, for each mL of blood, 30 μL of Sn(II) -pyrophosphate solution containing 0.012 mg of Sn^{2+} ions. Incubate for 10 minutes. After centrifugation, remove the supernatant (plasma), add $^{99\text{m}}\text{TcO}_4^-$ solution of the required activity to the red blood cell mass and incubate for 5 minutes at room temperature. After incubation, wash the red blood cell mass with physiological saline solution. Resuspend the washed cell mass in autologous plasma and inject into the patient the radiolabelled red blood cell mass containing the activity appropriate for the purpose of the examination. The radiolabelled red blood cells may also be administered intravenously as a bolus injection.

4. Combined labelling

Withdraw 2–10 mL of blood from a patient who has previously received 2 mL of Pyroscint into a syringe containing anticoagulant, and add 550–740 MBq of $^{99\text{m}}\text{Tc}$ -pertechnetate. After incubation for 10 minutes, the radiolabelled blood may be reinjected.

The pH of the radiolabelled preparation is 6.0–7.0.

The radiolabelled preparation must be used within 6 hours of radiolabelling. Within this period, the total amount of radiochemical impurities must not exceed 10%.

The radiochemical purity of $^{99\text{m}}\text{Tc}$ -Pyroscint is determined on the basis of the results of paper chromatography and thin-layer chromatography.

QUALITY CONTROL OF THE MEDICINAL PRODUCT

Determination of free $^{99\text{m}}\text{TcO}_4^-$ by thin-layer chromatography

- Apply 5 μL of the radiolabelled product to the marked starting point of a 2×20 cm silica gel layer previously pretreated at 110°C for 10 minutes.
- Developing solvent: methyl ethyl ketone.
- Immediately before development, bubble nitrogen through the developing solvent in the chromatography chamber for 10 minutes.
- The development distance should be 10–15 cm.
- After air-drying, measure the radioactivity of the strips.

Indicative R_f values:

Free pertechnetate migrates with the solvent front ($R_f = 0.95\text{--}1.0$).

The $^{99\text{m}}\text{Tc}$ -stannous pyrophosphate complex remains at the starting point ($R_f = 0\text{--}0.1$).

Determination of radiocolloid impurity by thin-layer chromatography

- Apply 5 μL of the radiolabelled product to the marked starting point of a 2×20 cm silica gel layer previously pretreated at 110°C for 10 minutes.

- Developing solvent: 136 g/L sodium acetate.
- The development distance should be 10–15 cm.
- After air-drying, measure the radioactivity of the strips.

The ^{99m}Tc -stannous pyrophosphate complex and free pertechnetate migrate with the solvent front ($R_f = 0.9\text{--}1.0$).

The colloidal impurity remains at the starting point ($R_f = 0\text{--}0.1$).

The total amount of free pertechnetate and radiocolloid must not exceed 10%.



TECHNICAL TRANSLATION

Prepared by the Hungarian Office
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This translation shall in no way replace attested
translation.
