SUMMARY OF PRODUCT CHARACTERISTICS
for
Renoscan MAG3, kit for radiopharmaceutical preparation

1. NAME OF THE MEDICINAL PRODUCT
Renoscan MAG3 1 mg kit for radiopharmaceutical preparation

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
One vial contains Betiatide, 1 mg
To be used with sodium (^{99m}Tc) pertechnetate (not included in this kit) for the preparation of the diagnostic agent: Technetium (^{99m}Tc) tiatide.
Excipient with known effect:
Each vial contains 4 mg sodium ions.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Kit for radiopharmaceutical preparation

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
This medicinal product is for diagnostic use only.
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.
4.2 Posology and method of administration
Posology
Adults and the elderly
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.
Pediatric population
Although Renoscan MAG3 may be used in paediatric patients, formal studies have not been performed. Clinical experience indicates that for pediatric use the activity should be reduced. Because of the variable relationship between the size and body weight of patients it is sometimes more satisfactory to adjust activities to body surface area.
The activity to be administered in children and adolescents is determined according to the EANM dosage card (2016) using the following formula:
The activity to be administered A[MBq] = Baseline activity (of 11.9 MBq) x Multiple

The activities to be applied are listed in the following table:

Weight (kg)	Activity (MBq)	Weight (kg)	Activity (MBq)	Weight (kg)	Activity (MBq)
3	15	22	36	42	52
4	15	24	38	44	54
6	18	26	40	46	55
8	20	28	41	48	57
10	23	30	43	50	58
12	26	32	45	52-54	60
14	28	34	46	56-58	62
16	30	36	48	60-62	65
18	32	38	50	64-66	67
20	34	40	51	68	69

In very young children, a minimum dose of 15 MBq is necessary in order to obtain images of sufficient quality.

The administration of a diuretic or an ACE inhibitor during the diagnostic procedure is sometimes used for differential diagnosis of nephrological and urological disorders. The scintigraphic investigation is usually performed immediately after administration
Method of administration
This medicinal product should be reconstituted before administration to the patient.
For intravenous use. For multidose use. The scintigraphic investigation is usually performed immediately after administration.
For instructions on reconstitution and labelling of the medicinal product before administration, see section 12. For patient preparation, see section 4.4.
4.3 Contraindications
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
4.4 Special warnings and precautions for use
Potential for hypersensitivity or anaphylactic reaction
If hypersensitivity or anaphylactic reactions occurs, the administration of the medicinal product must be discontinued immediately and intravenous treatment initiated, if necessary. To enable immediate action in emergencies, the necessary medicinal products and equipment such as endotracheal tube and ventilator must be immediately available.
Individual benefit/risk justification
For each patient, exposure to ionising radiation must be justifiable on the basis of likely benefit. The activity administered must be such that the resulting radiation dose is as low as reasonably achievable **bearing** in mind the need to obtain the intended diagnostic information.
Pediatric population
The use in children has to be considered carefully, based upon clinical needs and assessing the risk/benefit ratio in this patient group.
For information on the use in the pediatric population, see section 4.2.
Careful consideration of the indication is required since the effective dose per MBq is higher than in adults (see section 11).
Patient preparation
The patient should be well hydrated before the start of the examination and urged to void as often as possible during the first hours after the examination in order to reduce radiation.
Specific warnings
The agent is not suited for exact monitoring of effective renal plasma flow respectively blood flow in patients with seriously impaired renal function.
Small amounts of ^{99m}Tc-labelled impurities may be present and/or are formed during the labelling process. As some of these impurities are distributed to the liver and excreted via the gall bladder they may influence the late phase (after 30 minutes) of a dynamic renal study due to the overlap of kidney and liver in the region of interest.
Inadvertent or accidental subcutaneous administration of technetium (^{99m}Tc) tiatide should be avoided as perivascular inflammation has been described.
Excipients
This medicinal product contains less than 1 mmol sodium (23mg) per dose, i.e. essentially 'sodium free'.
Depending on the time when you administer the injection, the content of the sodium given to the patient may in some cases be greater than 1 mmol. This should be taken into account in patient on low sodium diet.
4.5 Interaction with other medicinal products and other forms of interaction
Technetium (^{99m}Tc) tiatide has not been described to interfere with agents commonly prescribed to or given to patients requiring investigations with Technetium (^{99m}Tc) tiatide (e.g. antihypertensives and medicinal products used to treat or prevent organ transplant rejection).
However, the single administration of a diuretic or ACE inhibitor is sometimes used in the differential diagnosis of nephrological and urological disorders.
Administered contrast media may impair tubular renal excretion and thereby influence the technetium (^{99m}Tc) tiatide clearance.
4.6 Fertility, pregnancy and lactation
Women of childbearing potential
When an administration of radiopharmaceuticals to a woman of childbearing potential is intended, it is important to determine whether or not she is pregnant. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. If in doubt about her potential pregnancy (if the woman has missed a period, if the period is very irregular, etc.), alternative techniques not using ionising radiation (if there are any) should be offered to the patient.
Pregnancy
Radionuclide procedures carried out on pregnant women also involve radiation doses to the foetus. Only essential investigations should therefore be carried out during pregnancy, when the likely benefit far exceeds the risk incurred by the mother and the foetus.
Breast-feeding
Before administering radiopharmaceuticals to a mother who is breastfeeding, consideration should be given to the possibility of delaying the administration of radionuclide until the mother has ceased breastfeeding and to what is the most appropriate choice of radiopharmaceutical, bearing in mind the secretion of activity in breast milk.
If the administration is considered necessary, breastfeeding should be interrupted for 4 hours and the expressed feeds discarded.
4.7 Effects on ability to drive and use machines
No studies on the effects on the ability to drive and use machines have been performed.
4.8 Undesirable effects
The frequencies of undesirable effects are defined as follows:
Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) and not known (cannot be estimated from the available data)

Nervous system disorders Not known (cannot be estimated from the available data)	Cerebral convulsion[1].
Immune system disorders Very rare (<1/10,000)	Anaphylactoid reactions such as urticarial rash, swelling of eyelids and coughing.

[1] Seen in a 15 days old child. Causal relationship not established.

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. For diagnostic nuclear medicine investigations the current evidence suggests that these adverse effects will occur with low frequency because of the low radiation doses incurred.
For most diagnostic investigations using nuclear medicine procedures the radiation dose delivered (Effective Dose Equivalent, EDE) is less than 20 mSv. Higher doses might be justified in some clinical circumstances
Reporting suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
4.9 Overdose
The risk of an excessive technetium (^{99m}Tc) tiatide dose is largely theoretical and most likely to be due to excessive radiation exposure. In such circumstances the radiation to the body (kidney, bladder and gall bladder) can be reduced by forced diuresis and frequent bladder voiding.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Diagnostic radiopharmaceuticals, renal system, technetium (^{99m}Tc) compounds.
ATC Code: V 09 CA 03
At the chemical doses envisaged technetium (^{99m}Tc) tiatide Injection has no known pharmacodynamic action.
Measuring the activity over the kidneys allows renal blood flow, intrarenal tubular transit times and excretion via the outflow tracts to be recorded separately for both kidneys.
5.2 Pharmacokinetic properties
Distribution
After intravenous injection technetium (^{99m}Tc) tiatide is rapidly cleared from the blood by the kidneys.
Organ uptake
Technetium (^{99m}Tc) tiatide has a relatively high binding to plasma proteins. In normal renal function 70 % of the administered dose has been excreted after 30 minutes and more than 95 % after 3 hours. These latter percentages are dependent on the pathology of the kidneys and the urogenital system.
Elimination
The mechanism of excretion is predominantly based on tubular secretion. Glomerular filtration accounts for 11 % of total clearance.
5.3 Preclinical safety data
Acute, subacute (8 days) and chronic (13 weeks) toxicity studies as well as mutagenicity studies were performed. At the studied dose levels, up to 1000 times the maximal human dose, no toxicological effects were observed. Similarly, mutagenic effects have not been observed.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
- Disodium tartrate dihydrate
- Stannous (II) chloride dihydrate
- Hydrochloric acid for pH adjustment

6.2 Incompatibilities
Major incompatibilities are not known. However, in order not to compromise the stability of ^{99m}Tc-tiatide, preparations should not be administered together with other drugs.
This medicinal product must not be mixed with other medicinal products except those mentioned in section 12.
6.3 Shelf life
18 months.
The expiry date is stated on the label of the immediate packaging vial and on the carton.
After radiolabelling: 8 hours. Store below 25 °C.
6.4 Special precautions for storage
Store in a refrigerator (2-8 °C).
Store in the outer carton in order to protect from light.
For storage conditions after radiolabelling of the medicinal product, see section 6.3.
Storage should be in accordance with national regulations for radioactive materials.
6.5 Nature and contents of container
10 ml Type 1 Ph.Eur glass vial closed with a chlorobutyl rubber stopper Ph.Eur and sealed with an aluminium flip-cap.
Renoscan MAG3 is supplied as six or two vials in a carton.
Pack sizes
1 pack contains 6 vials.
Sample package: 2 vials.
6.6 Special precautions for disposal and other handling
General warning
This radiopharmaceutical should be received, used and administered only by authorised persons in designated clinical settings. Its receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licences of the local competent official organisations.
Radiopharmaceuticals should be prepared by the user in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.
The contents of the vial are to be labelled with Sodium Pertechnetate (^{99m}Tc) Injection. After reconstitution with the sodium (^{99m}Tc) pertechnetate solution, the diagnostic agent technetium (^{99m}Tc) tiatide is obtained upon boiling.
The administration of radiopharmaceuticals creates risks for other persons from external radiation or contamination from spills of urine, vomiting etc. Radiation protection precautions in accordance with national regulations must therefore be taken. Any unused product or waste material should be disposed of in accordance with local requirements.
Only eluates obtained from a ^{99m}Tc-generator, which has been eluted within the preceding 24 hours, should be used. Dilution of the preparation should be done with saline.
After reconstitution and labelling the solution may be used for one or more administrations.
The vial does not contain a preservative agent.
Properties of the medicinal product after labelling:
Clear to slightly opalescent, colourless, aqueous solution.
pH 5.0-7.5 Osmolality: slightly hypertonic.

7. MARKETING AUTHORISATION HOLDER
Medi-Radiopharma Ltd. 2030 Érd, Szamos st. 10-12 Hungary

8. MARKETING AUTHORISATION NUMBER(S)
PL 27151/0001

9. DATE OF FIRST AUTHORISATIO
24/10/2017

10. DATE OF REVISION OF THE TEXT
24/10/2017

11. DOSIMETRY
The following radiation dosimetry is calculated according to the MIRD system. The data are given in ICRP publication 80 in 1998.
The following assumptions have been made in this model:

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– In the normal case following intravenous administration of MAG3, the substance is rapidly distributed in the extracellular fluid and excreted entirely by the renal system according to the kidney-bladder model. Total body retention is described by a three-exponential function. The renal transit time is assumed to be 4 minutes as for Hippuran.
– When renal function is bilaterally impaired, it is assumed that the clearance rate of the substance is one tenth of that of the normal case, that the renal transit time is increased to 20 minutes, and that a fraction of 0.04 is taken up in the liver.
– As an example of acute unilateral renal blockage, it is assumed that a fraction of 0.5 of the administered radiopharmaceutical is taken up by one kidney and slowly released to the blood with a half-time of 5 days and subsequently excreted by the other kidney, which is assumed to function normally.

Normal renal function:

Absorbed doses ^{99m}Tc MAG3, ^{99m}Tc 6.02 h

Absorbed dose per unit activity administered (mGy/MBq)

Organ	Adult	15 years	10 years	5 years	1 year
Adrenals	0.00039	0.00051	0.00082	0.0012	0.0025
Bladder	0.11	0.14	0.17	0.18	0.32
Bone surfaces	0.0013	0.0016	0.0021	0.0024	0.0043
Brain	0.0001	0.00013	0.00022	0.00035	0.00061
Breast	0.00010	0.00014	0.00024	0.00039	0.00082
Gall bladder	0.00057	0.00087	0.0020	0.0017	0.0028
GI-tract					
Stomach	0.00039	0.00049	0.00097	0.0013	0.0025
SI	0.0023	0.0030	0.0042	0.0046	0.0078
Colon	0.0034	0.0043	0.0059	0.0060	0.0098
ULI	0.0017	0.0023	0.0034	0.0040	0.0067)
LLI	0.0057	0.0070	0.0092	0.0087	0.014)
Heart	0.00018	0.00024	0.00037	0.00057	0.0012
Kidneys	0.0034	0.0042	0.0059	0.0084	0.015
Liver	0.00031	0.00043	0.00075	0.0011	0.0021
Lungs	0.00015	0.00021	0.00033	0.00050	0.0010
Muscles	0.0014	0.0017	0.0022	0.0024	0.0041
Oesophagus	0.00013	0.00018	0.00028	0.00044	0.00082
Ovaries	0.0054	0.0069	0.0087	0.0087	0.014
Pancreas	0.0004	0.0005	0.00093	0.0013	0.0025
Red marrow	0.00093	0.0012	0.0016	0.0015	0.0021
Skin	0.00046	0.00057	0.00083	0.00097	0.0018
Spleen	0.00036	0.00049	0.00079	0.0012	0.0023
Testes	0.0037	0.0053	0.0081	0.0087	0.016
Thymus	0.00013	0.00018	0.00028	0.00044	0.00082
Thyroid	0.00013	0.00016	0.00027	0.00044	0.00082
Uterus	0.012	0.014	0.019	0.019	0.031
Remaining Organs	0.0013	0.0016	0.0021	0.0022	0.0036
Effective dose (mSv/MBq)	**0.007**	**0.0090**	**0.012**	**0.012**	**0.022**

The bladder wall contributes up to 80 % of the effective dose.
Effective dose if bladder is emptied 1 or 0,5 hours after administration:

1 hour	0.0025	0.0031	0.0045	0.0064	0.0064
30 min.	0.0017	0.0021	0.0029	0.0039	0.0068

For an administered activity of 185 MBq (Maximal dose) the effective dose is 1.3 mSv.
The absorbed dose in the target organ (kidney) is 0.63 mGy and the typical radiation dose to the critical organ (bladder wall) is 20 mGy.

Abnormal renal function:

Absorbed doses ^{99m}Tc MAG3, ^{99m}Tc 6.02 h

Absorbed dose per unit activity administered (mGy/MBq)

Organ	Adult	15 years	10 years	5 years	1 year
Adrenals	0.0016	0.0021	0.0032	0.0048	0.0086
Bladder	0.083	0.11	0.13	0.13	0.23
Bone surfaces	0.0022	0.0027	0.0038	0.0050	0.0091
Brain	0.00061	0.00077	0.0013	0.0020	0.0036
Breast	0.00054	0.00070	0.0011	0.0017	0.0032
Gall bladder	0.0016	0.0022	0.0038	0.0046	0.0064
GI-tract					
Stomach	0.0012	0.0015	0.0026	0.0035	0.0061
SI	0.0027	0.0035	0.0050	0.0060	0.010
Colon	0.0035	0.0044	0.0061	0.0069	0.011
ULI	0.0022	0.0030	0.0043	0.0056	0.0093)
LLI	0.0051	0.0063	0.0085	0.0085	0.014)
Heart	0.00091	0.0012	0.0018	0.0027	0.0048
Kidneys	0.014	0.017	0.024	0.034	0.059
Liver	0.0014	0.0018	0.0027	0.0038	0.0066
Lungs	0.00079	0.0011	0.0016	0.0024	0.0045
Muscles	0.0017	0.0021	0.0029	0.0036	0.0064
Oesophagus	0.00074	0.00097	0.0015	0.0023	0.0041
Ovaries	0.0049	0.0063	0.0081	0.0087	0.014
Pancreas	0.0015	0.0019	0.0029	0.0043	0.0074
Red marrow	0.0015	0.0019	0.0026	0.0031	0.0050
Skin	0.00078	0.00096	0.0015	0.0020	0.0038
Spleen	0.0015	0.0019	0.0029	0.0043	0.0074
Testes	0.0034	0.0047	0.0071	0.0078	0.014
Thymus	0.00074	0.00097	0.0015	0.0023	0.0041
Thyroid	0.00073	0.00095	0.0015	0.0024	0.0044
Uterus	0.010	0.012	0.016	0.016	0.027
Remaining Organs	0.0017	0.0021	0.0028	0.0034	0.0060
Effective dose (mSv/MBq)	0.0061	0.0078	0.010	0.011	0.019

For an administered activity of 185 MBq (Maximal dose) the effective dose is 1.1 mSv.
The absorbed dose in the target organ (kidney) is 2.6 mGy and the typical radiation dose to the critical organ (bladder wall) is 15 mGy.

Acute unilateral renal function:

Absorbed doses ^{99m}Tc MAG3, ^{99m}Tc 6.02 h

Absorbed dose per unit activity administered (mGy/MBq)

Organ	Adult	15 years	10 years	5 years	1 year
Adrenals	0.011	0.014	0.022	0.032	0.055
Bladder	0.056	0.071	0.091	0.093	0.17
Bone surfaces	0.0031	0.0040	0.0058	0.0084	0.017
Brain	0.00011	0.00014	0.00023	0.00039	0.00075
Breast	0.00038	0.00051	0.0010	0.0016	0.0030
Gall bladder	0.0062	0.0073	0.010	0.016	0.023
GI-tract					
Stomach	0.0039	0.0044	0.0070	0.0093	0.012
SI	0.0043	0.0055	0.0085	0.012	0.019
Colon	0.0039	0.0050	0.0072	0.0092	0.0015
ULI	0.0040	0.0051	0.0076	0.010	0.016)
LLI	0.0038	0.0048	0.0067	0.0082	0.013)
Heart	0.0013	0.0016	0.0027	0.0040	0.0061
Kidneys	0.20	0.24	0.33	0.47	0.81
Liver	0.0044	0.0054	0.0081	0.011	0.017
Lungs	0.0011	0.0016	0.0025	0.0039	0.0072
Muscles	0.0022	0.0027	0.0037	0.0051	0.0089
Oesophagus	0.00038	0.00054	0.00085	0.0015	0.0023
Ovaries	0.0038	0.0051	0.0071	0.0092	0.015
Pancreas	0.0074	0.0090	0.013	0.018	0.029
Red marrow	0.0030	0.0036	0.0050	0.0060	0.0083
Skin	0.00082	0.0010	0.0015	0.0022	0.0042
Spleen	0.0098	0.012	0.018	0.026	0.040
Testes	0.0020	0.0029	0.0045	0.0050	0.0098
Thymus	0.00038	0.00054	0.00085	0.0015	0.0023
Thyroid	0.00017	0.00023	0.00045	0.00092	0.00160
Uterus	0.0072	0.0087	0.012	0.013	0.022
Remaining Organs	0.0021	0.0026	0.0036	0.0047	0.0080
Effective dose (mSv/MBq)	0.010	0.012	0.017	0.022	0.038

For an administered activity of 185 MBq (Maximal dose) the effective dose is 1.85 mSv.
The absorbed dose in the target organ (kidney) is 37 mGy and the typical radiation dose to the critical organ (bladder wall) is 10 mGy.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Method of preparation

Elute a ^{99m}Tc generator in a 5 ml volume, according to the fractionated elution technique and follow the directions for use for the generator. The desired amount of ^{99m}Tc, with a maximum of 2960 MBq (80 mCi) must be diluted to a volume of 10 ml with a sterile saline solution (0.9 %). Add this volume to a vial of Renoscan MAG3.
For this a thin needle must be used (G20 or higher) so that the puncture hole closes again. This prevents the water from entering the vial during the heating and cooling steps that follow.
Heat immediately during 10 minutes in a heating block previously heated to 120°C or boiling water bath. During heating the vial should be standing upright in order to prevent traces of metal coming off the rubber stopper, so influencing the labelling procedure unfavourably. Cool down the vial to room temperature in cold water. The preparation is ready for administration. If needed, a dilution with 0.9 % saline solution is possible.
This ^{99m}Tc labelled preparation having a concentration of 2960 MBq per 10 ml can be used until 8 hours after completion of the heating step.
Preferably use eluates obtained by fractionated elution. Follow the pertinent directions for use of the generator.

Precaution during the labelling procedure

To indicate that during the heating and the cooling step no contamination of the contents of the vial has occurred, the user is advised to add a suitable dyestuff to the heating bath and to the cooling bath (e.g. methylene blue to make a concentration of 1 % or sodium fluorescein to make a concentration of 0.1 %).
The radiolabelled product vial should be examined for contamination (taking appropriate radiological protective measures) prior to use.

Quality control

The following methods may be used:

1. HPLC method:

The radiochemical purity of the labelled substance is examined by high performance liquid chromatography (HPLC) using a suitable detector of radioactivity, on a 25 cm RP18 column, flow rate 1.0 ml/min. Mobile phase A is a 93:7 mixture of phosphate solution (1.36 g KH_2PO_4, adjusted with 0.1 M NaOH to pH 6) and ethanol. Mobile phase B is a 1:9 mixture of water and methanol.
Use an elution program with the following parameters:

Time (min.):	Flow (ml/min.):	% A	% B
10	1	100	0
15	1	0	100

The technetium (^{99m}Tc) tiatide peak appears at the end of the passage of mobile phase A.
The injection volume is 20 µl and the total count rate per channel must not exceed 30.000.

Requirement:

	t = 0	after 8 hours
Tiatide	≥ 95.0 %	≥94.0 %
Total front fractions	≤ 3.0 %	≤ 3.0 %
Methanol fraction	≤ 4.0 %	≤ 4.0 %

2. TLC method

Method: thin layer chromatography, Hydrophilic impurities
Requirement:location of radioactive impurities: in the front Rf=0.8-1.0, quantity: max.: 5 %
Method:
Sample solution: drop 2 µl labelled product on the layer
Reference solution: drop 2 µl eluate on the layer (pertechnetate ion)
Test parameters:
• Layer: ITLC-SG
• application: 2 cm from the bottom edge of the plate
• start of developing: right after application of the sample
• Front distance: 6 cm
• Developing solution: ethyl acetate: methyl ethyl ketone = 60:40
• Jar: saturated
• Saturation time: 30 minutes
• Drying: allowed to dry at room temperature after development
• Time of application: 20 minutes after labeling
Detection: radioactivity measuring detector.
Evaluation:
The radioactive impurities migrate in the front Rf=0.8-1.0, reading of the corresponding quantity (in percentage of the total radioactivity in %) from the chromatogram.

3 Paperchromatographic method

Radioactive impurities (method: paperchromatography)
Impurity A: (^{99m}Tc) Technetium in colloidal form
Requirement:location of radioactive impurities: on the start point Rf=0.0-0.1 quantity: max.: 2 %
Method:
Sample solution: drop 2 µl labelled product on the paper
Reference solution: drop 2 µl eluate on the layer (pertechnetate ion)
Test parameters:
- Layer: chromatography paper
- application: 2 cm from the bottom edge of the plate
- start of developing: right after application of the sample
- Front distance: 15 cm
- Developing solution: water: acetonitril=40:60
- Jar: saturated
- Saturation time: 30 minutes
- Paper drying: allowed to dry at room temperature after development
- Time of application: 20 minutes after labeling

Detection: radioactivity measuring detector.
Evaluation:
The radioactive impurities remain in the start point Rf=0.0-0.1, reading of the corresponding quantity (in percentage of the total radioactivity in %) from the chromatogram.
Calculate the percentage of radioactivity due to ^{99m}Tc technetium mertiatide using the following expression:100-(A+B) Where
A = percentage of radioactivity due to impurity A, (^{99m}Tc) Technetium in colloidal form resulting from paper chromatographic method
B= percentage of radioactivity due to hydrophilic impurities, including impurity B resulting from TLC method
A radiochemical purity of at least 94 % may be expected provided the test samples have been taken and analysed within 8 hours of reconstitution.

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