Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

TechneScan HDP 3mg, kit for radiopharmaceutical preparation

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains:
Sodium oxidronate (or sodium hydroxymethylene diphosphonate=HDP) 3.0 mg
The radionuclide is not part of the kit.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Kit for radiopharmaceutical preparation.
Off-white to slightly yellow lyophilisate.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.

After radiolabelling with sodium pertechnetate (^{99m}Tc) solution, the solution of technetium (^{99m}Tc) oxidronate obtained is indicated in adults and children for bone scintigraphy, where it delineates areas of altered osteogenesis.

4.2 Posology and method of administration

Posology

Adults
The recommended activity of technetium (^{99m}Tc) oxidronate is 500 MBq (300-740 MBq) for an adult of average weight (70 kg). Other activities may be justifiable. It should be noted that in each country physicians should follow the national Diagnostic Reference Levels and the rules set out by local law.

Elderly population
There is no special dosage regimen for elderly patients.

Renal impairment
Careful consideration of the activity to be administered is required since an increased radiation exposure is possible in these patients.

Paediatric population
The use in children and adolescents has to be considered carefully, based upon clinical needs and assessing the risk/benefit ratio in this patient group. The activities to be administered to children and to adolescents may be calculated according to the EANM (European Association of Nuclear Medicine) paediatric dosage card (2016) by using the following formula:
A[MBq]Administered = Baseline Activity x Multiple (with a baseline activity of 35.0)

The resulting activities to be administered may be found in the following table:

Weight (kg)	Activity (MBq)	Weight (kg)	Activity (MBq)	Weight (kg)	Activity (MBq)
3	40	22	185	42	320
4	40	24	200	44	335
6	60	26	215	46	350
8	75	28	225	48	360
10	95	30	240	50	375

12	110	32	255	52–54	395
14	125	34	270	56–58	420
16	140	36	280	60–62	445
18	155	38	295	64–66	470
20	170	40	310	68	490

In very young children (up to 1 year) a minimum activity of 40 MBq is recommended in order to obtain images of sufficient quality.

Method of administration
Multidose vials.
This medicinal product should be reconstituted before administration to the patient.
The reconstituted solution should be administered by slow intravenous injection.

For instructions on reconstitution of the medicinal product before administration, see section 12.

For patient preparation, see section 4.4.

Image acquisition
The patient should void before scanning.

Acquisition parameters and protocols may vary depending on the indication and type of equipment.
No specific studies have been carried out on the optimum time between injection and camera exposure.
Images can be obtained shortly after injection (e.g. in the so-called "3-phase bone scan" procedure) to detect an abnormal blood supply in a region of the skeleton (*phase 1 images*), then a few minutes later to highlight a possible rapid distribution of the tracer in certain areas of the bone (*phase 2 images*).
Late phase static scintigraphy (*phase 3 images*) is usually performed from 2 to 5 hours after injection of technetium (^{99m}Tc) oxidronate.

Late images (6 to 24 hours) give a better signal-to-noise ratio and better visualisation of the pelvis if the images from 2 to 5 hours have been poor due to bladder retention.
Late images (6 to 24 hours) may also be particularly helpful in patients with renal insufficiency or peripheral circulatory disorders, as well as those suffering from urinary retention.

Depending on the indication and the results of the planar images, one or more tomoscintigraphic acquisitions may be useful to improve the sensitivity of the examination and clarify the topography of the fixation sites.

Image acquisition should be performed according to clinical needs and/or current international guidelines.

4.3 Contraindications

Hypersensitivity to the active substance, to any of the excipients listed in section 6.1 or to any of the components of the labelled radiopharmaceutical.

4.4 Special warnings and precautions for use

Potential for hypersensitivity or anaphylactic reactions

If hypersensitivity or anaphylactic reactions occur, 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, the radiation exposure must be justifiable by the likely benefit. The activity administered should in every case be as low as reasonably achievable to obtain the required diagnostic information.

Renal impairment
Careful consideration of the benefit risk ratio in these patients is required since an increased radiation exposure is possible (see section 4.2).

Generalised increased soft tissue uptake can be due to renal failure.

Paediatric population
For information on the use in paediatric population, see section 4.2.
In infants and children, particular attention should be paid to the relatively higher radiation exposure of the epiphyses in growing bone. 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 before the images acquisition and as often as possible during the first hours after the procedure in order to reduce radiation exposure to the bladder wall.

Interpretation of images
In patients with hypercalcaemia, soft-tissue uptake of bone-seeking radiopharmaceuticals may be observed.
Abnormal accumulation is also possible in the liver (e.g. in case of liver metastases), spleen, adrenal glands, or heart (e.g. infarction, pericarditis) resulting in image defect (see also section 4.5).

After the procedure
Close contact with infants and pregnant women should be restricted during 1 hour.

Specific warnings
Inadvertent or accidental subcutaneous administration of technetium (^{99m}Tc) oxidronate should be avoided as perivascular inflammation has been described (see section 4.8). In the event of paravenous injection, the injection should be immediately stopped.

In order to avoid accumulation of the radioisotope in the musculature, strenuous exercise immediately after the injection is discouraged until a satisfactory bone scan is obtained.

This medicinal product contains less than 1 mmol sodium (23 mg) per vial, i.e. essentially "sodium- free".

Precautions with respect to environmental hazard see section 6.6.

4.5 Interaction with other medicinal products and other forms of interaction

The captation of technetium (^{99m}Tc) oxidronate in the skeleton may be decreased with an extraosseous uptake of the radioisotope after:

- chelates (iron or aluminium-containing medicinal drugs),
- diphosphonates,
- various cytostatics (vincristine, cyclophosphamide, doxorubicin, methotrexate),
- immunosuppressive medicinal products (e.g. cortisone) and,
- antibiotics (gentamicin, amphotericin, tetracycline).

Regular medication with aluminium-containing medicinal drugs (notably antacids) may lead to abnormally high uptake of technetium (^{99m}Tc) in the liver, presumably caused by the formation of labelled colloids.

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 be carried out during pregnancy, when likely benefit exceeds the risk incurred by the mother and foetus.
Administration of 740 MBq technetium (^{99m}Tc) oxidronate to a patient with normal bone uptake results in an absorbed dose to

the uterus of 4.6 mGy. The dose decreases to 2.1 mGy in patients with high bone uptake and/or severely impaired kidney function.
Doses above 5 mGy would be regarded as a potential risk for the foetus.

Breast-feeding
Technetium(^{99m}Tc) is excreted into breast milk.
Before administering radiopharmaceuticals to a mother who is breast-feeding, consideration should be given to the possibility of delaying the administration of radionuclide until the mother has ceased breast-feeding, and to what is the most appropriate choice of radiopharmaceuticals, bearing in mind the secretion of activity in breast milk. If the administration is considered necessary, breast-feeding should be interrupted for 4 hours and the expressed feeds discarded.
Close contact with infants should be restricted during 1 hour.

Fertility
The effect of the administration of technetium (^{99m}Tc) oxidronate on fertility is unknown.

4.7 Effects on ability to drive and use machines

Technescan HDP has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Information on adverse reactions is available from spontaneous reporting. The reported adverse reactions are anaphylactic or anaphylactoid reactions, vegetative reactions, as well as different types of injection site reactions and other general disorders. Onset of symptoms may be delayed 4 to 24 hours after administration.

Tabulated list of adverse reactions
The following table includes the adverse reactions sorted by system organ classes according to MedDRA. The frequencies are defined as follows: very common ≥ 1/10; common from ≥ 1/100 to < 1/10; uncommon from ≥ 1/1 000 to < 1/100, rare from ≥ 1/10 000 to < 1/1 000; very rare < 1/10 000; frequency not known (cannot be estimated from the available data).

Adverse Reactions sorted by System Organ Class

System Organ Class (SOCs)	***Adverse reactions***	***Frequency***
Immune system disorders	Anaphylactic and anaphylactoid reactions (e.g. anaphylactic shock, loss of consciousness, cardio-respiratory arrest, hypersensitivity, angioedema, tachycardia, hypertension, dyspnoea, conjunctivitis, rhinitis and nasal congestion, dermatitis, generalised pruritus, face oedema, laryngeal oedema, tongue oedema, and other types of oedema, urticaria, erythema, rash, dysgeusia, paraesthesia, hyperhidrosis)	Not known*
Nervous system disorders	Vasovagal reactions (e.g. syncope, circulatory collapse, dizziness, headache, tachycardia, bradycardia, hypotension, tremor, blurred vision, flushing)	Not known*
Gastrointestinal disorders	Vomiting, nausea, diarrhoea, abdominal pain	Not known*
Musculoskeletal and connective tissue disorders	Arthralgia	Not known*
General disorders and administration site conditions	Injection site reactions (e.g. cellulitis, dermatitis, inflammation, pain, erythema, swelling), Chest pain, Chills.	Not known*

* Frequency cannot be estimated from spontaneous reporting

Anaphylactic or anaphylactoid reactions
Anaphylactic or anaphylactoid reactions were reported with a wide array of symptoms ranging from mild skin reactions to anaphylactic shock (see section 4.4).

Vegetative reactions (nervous system and gastrointestinal disorders)

Severe vegetative reactions like circulatory collapse or syncope have been reported, however most of the reported vegetative effects include gastrointestinal reactions like nausea or vomiting. Other reports include vasovagal reactions like headache or dizziness. Vegetative effects are rather considered to be related to the procedure itself, especially in anxious patients, but a contribution of the product cannot be excluded.

General disorders and administration site conditions
Injection site reactions are related to extravasation of the radioactive material during the injection, and the reported reactions rank from local swelling up to cellulitis.

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 3.6 mSv in adult with normal bone uptake (or 3.2 mSv with high bone uptake and/or renal failure) when the maximal recommended activity of 740 MBq is administered, these adverse reactions are expected to occur with a low probability.

Paediatric population
Frequency, type and severity of adverse reactions in children are expected to be the same as in adults.

Reporting of 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
HPRA Pharmacovigilance
Website: www.hpra.ie

4.9 Overdose

In the event of administration of a radiation overdose with technetium (^{99m}Tc) oxidronate, the absorbed dose to the patient should be reduced where possible by increasing the elimination of the radionuclide from the body by forced diuresis and frequent bladder voiding. It might be helpful to estimate the effective dose that was applied.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Diagnostic radiopharmaceuticals skeleton, ATC code: V09BA01.

Pharmacodynamic effects:
At chemical concentrations used for diagnostic examinations, technetium (^{99m}Tc) oxidronate does not appear to have any pharmacodynamic activity.

5.2 Pharmacokinetic properties

Distribution
After intravenous injection, technetium (^{99m}Tc) oxidronate is rapidly distributed throughout the extracellular space.

Organ uptake
Skeletal uptake begins almost immediately and proceeds rapidly. 30 minutes post-injection, 10 % of the initial dose is still present in whole blood. At 1 hour, 2 hours, 3 hours and 4 hours after injection, these values are respectively 5 %, 3 %, 1.5 % and 1 %.

Elimination
Clearance from the body takes place via the kidneys. Of the administered activity, approximately 30 % is excreted within the first hour, 48 % within two hours and 60 % within six hours.

5.3 Preclinical safety data

Minimal liver abnormalities are seen at the level of 30 mg/kg in rats. In subacute toxicity studies rats do not react to the administration of 10 mg/kg/day for 14 days, dogs show histological changes in the liver (microgranuloma) after 3 and 10 mg/kg/day for 14 days. In dogs, which were treated for 14 consecutive days, long-lasting indurations at the site of injection

were observed.
This medicinal product is not intended for regular or continuous administration.
Reproduction, mutagenicity studies and long-term carcinogenicity studies have not been carried out.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stannous chloride dihydrate
Gentisic acid
Sodium chloride
Hydrochloric acid (for pH adjustment)
Sodium hydroxide (for pH adjustment)

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 12. In order to avoid compromising the stability of technetium (^{99m}Tc) oxidronate, the radiolabelled solution, if dilution is required, should be diluted with sodium chloride 0.9 % solution and should not be administered at the same time as other intravenous drugs and/or parenteral nutrition.

6.3 Shelf life

2 years.

After reconstitution and labelling, chemical and physical in-use stability has been demonstrated for 8 hours below 25 °C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

6.4 Special precautions for storage

Store below 25 °C. Store in the original container in order to protect from light.

For storage conditions after radiolabelling of the medicinal product, see section 6.3.
Storage of radiopharmaceuticals should be in accordance with national regulation on radioactive materials.

6.5 Nature and contents of container

10 ml glass vial (type I) closed with a bromobutyl rubber stopper sealed with an aluminium crimp cap.
Pack size: five vials in a carton box.

6.6 Special precautions for disposal and other handling

General warning
Radiopharmaceuticals should be received, used and administered only by authorised persons in designated clinical settings. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licences of the competent official organisation.

Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

Content of the vial is intended only for use in the preparation of the technetium (^{99m}Tc) oxidronate solution and is not to be administered directly to the patient without first undergoing the preparative procedure.

For instructions on extemporary preparation of the medicinal product before administration, see section 12.

If at any time in the preparation of this product the integrity of this vial is compromised it should not be used.

Administration procedures should be carried out in a way to minimise risk of contamination of the medicinal product and irradiation of the operators. Adequate shielding is mandatory.

The content of the kit before extemporary preparation is not radioactive. However, after sodium pertechnetate (^{99m}Tc) is added, adequate shielding of the final preparation must be maintained.

The administration of radiopharmaceuticals creates risks for other persons from external radiation or contamination from spills of urine, vomit, etc. Radiation protection precautions in accordance with national regulations must therefore be taken.

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

7 MARKETING AUTHORISATION HOLDER

Curium Netherlands B.V.
Westerduinweg 3
1755 ZG Petten
Netherlands

8 MARKETING AUTHORISATION NUMBER

PA0690/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 November 1993

Date of last renewal: 19 November 2008

10 DATE OF REVISION OF THE TEXT

November 2025

11 DOSIMETRY

Technetium (^{99m}Tc) is produced by means of a (^{99}Mo/^{99m}Tc) generator and decays with the emission of gamma radiation with an energy of 140 keV and a half-life of 6.02 hours to technetium (^{99}Tc) which, in view of its long half-life of 2.13 x 10^5 years, can be regarded as quasi stable.
The dosimetry data listed below are from International Commission on Radiological Protection (ICRP publication 128) and are calculated according to the following assumptions:

- Main absorption occurs in the bone, with minor further absorption in the kidney, and excretion occurs through the renal system. A fraction equal to 0.5 of the injected activity is assumed to be absorbed by the bone with a half-time of 15 min, and retained there with half-times of 2 hours (0.3) and 3 days (0.7). In children, uptake is predominantly in the metaphyseal growth zones. Kidney uptake is set at 0.02 with retention identical to that of the total body, having half-times (with fractional retention) of 0.5 hours (0.3), 2 hours (0.3) and 3 days (0.4).
- In pathological cases, there may be higher uptake and/or longer retention in bone, especially in renal diseases. The 24-h total body retention, which normally amounts to 30 %, has been reported to be 40 % in osteomalacia, 50 % in primary hyperparathyroidism, 60 % in Paget's disease, and 90 % in renal osteodystrophy. For the calculation of the absorbed dose in pathological cases, an average bone uptake of 70 % is assumed, without excretion.

Radiation exposure with normal bone uptake and excretion

Absorbed doses for ^{99m}Tc-labelled phosphonates

Organ	**Absorbed dose per unit activity administered (mGy/MBq)**				
	Adult	**15 years**	**10 years**	**5 years**	**1 year**
Adrenals	0.0021	0.0026	0.0038	0.0058	0.011

Bone surfaces	0.034	0.015	0.023	0.038	0.082
Brain	0.0017	0.0020	0.0028	0.0042	0.0059
Breast	0.00069	0.00086	0.0013	0.0021	0.0040
Gallbladder wall	0.0014	0.0018	0.0033	0.0043	0.0065
Gastrointestinal tract					
Stomach wall	0.0012	0.0014	0.0024	0.0036	0.0064
Small intestine wall	0.0022	0.0028	0.0043	0.0061	0.0093
Colon wall	0.0027	0.0034	0.0052	0.0072	0.010
Upper large intestine wall	0.0019	0.0024	0.0038	0.0057	0.0087
Lower large intestine wall	0.0038	0.0047	0.0071	0.0092	0.013
Heart wall	0.0012	0.0015	0.0022	0.0033	0.0059
Kidneys	0.0072	0.0087	0.012	0.018	0.031
Liver	0.0012	0.0016	0.0024	0.0036	0.0064
Lungs	0.0012	0.0016	0.0023	0.0035	0.0067
Muscles	0.0018	0.0022	0.0033	0.0047	0.0077
Oesophagus	0.0010	0.0013	0.0019	0.0029	0.0051
Ovaries	0.0036	0.0045	0.0065	0.0086	0.012
Pancreas	0.0016	0.0020	0.0030	0.0045	0.0079
Red marrow	0.0059	0.0054	0.0088	0.017	0.036
Skin	0.00099	0.0013	0.0019	0.0030	0.0053
Spleen	0.0014	0.0018	0.0027	0.0044	0.0077
Testes	0.0024	0.0033	0.0054	0.0075	0.010
Thymus	0.0010	0.0013	0.0019	0.0029	0.0051
Thyroid	0.0013	0.0015	0.0022	0.0034	0.0054
Urinary bladder wall	0.047	0.059	0.087	0.11	0.13
Uterus	0.0062	0.0075	0.011	0.014	0.018
Remaining organs	0.0019	0.0023	0.0034	0.0050	0.0077
Effective dose[mSv/MBq]	**0.0049**	**0.0057**	**0.0086**	**0.012**	**0.018**

Radiation exposure with high bone uptake and/or severely impaired kidney function:

Absorbed doses for ^{99m}Tc-labelled phosphonates

Organ	**Absorbed dose per unit activity administered (mGy/MBq)**				
	Adult	**15 years**	**10 years**	**5 years**	**1 year**
Adrenals	0.0040	0.0050	0.0072	0.011	0.021
Bone surfaces	0.065	0.030	0.045	0.074	0.16
Brain	0.0037	0.0045	0.0063	0.0096	0.014
Breast	0.0017	0.0021	0.0032	0.0050	0.0096
Gallbladder wall	0.0028	0.0036	0.0059	0.0085	0.013
Gastrointestinal tract					
Stomach wall	0.0025	0.0032	0.0051	0.0073	0.014
Small intestine wall	0.0030	0.0038	0.0056	0.0085	0.015
Colon wall	0.0030	0.0038	0.0058	0.0091	0.016
Upper large intestine wall	0.0028	0.0036	0.0053	0.0086	0.015
Lower large intestine wall	0.0033	0.0042	0.0065	0.0098	0.018
Heart wall	0.0029	0.0036	0.0052	0.0077	0.014
Kidneys	0.0029	0.0037	0.0056	0.0087	0.016
Liver	0.0026	0.0033	0.0049	0.0074	0.014
Lungs	0.0029	0.0037	0.0054	0.0081	0.015
Muscles	0.0029	0.0036	0.0053	0.0080	0.015
Oesophagus	0.0025	0.0031	0.0045	0.0070	0.012
Ovaries	0.0032	0.0041	0.0058	0.0088	0.016
Pancreas	0.0032	0.0040	0.0058	0.0088	0.016
Red marrow	0.011	0.010	0.017	0.032	0.071
Skin	0.0019	0.0024	0.0037	0.0060	0.011

Spleen	0.0026	0.0034	0.0051	0.0084	0.015
Testes	0.0022	0.0027	0.0038	0.0060	0.011
Thymus	0.0025	0.0031	0.0045	0.0070	0.012
Thyroid	0.0031	0.0037	0.0053	0.0082	0.014
Urinary bladder wall	0.0026	0.0035	0.0054	0.0073	0.015
Uterus	0.0029	0.0037	0.0053	0.0081	0.015
Remaining organs	0.0030	0.0037	0.0055	0.0086	0.015
Effective dose [mSv/MBq]	**0.0043**	**0.0045**	**0.0068**	**0.011**	**0.022**

The effective dose resulting from the administration of a (maximal recommended) activity of 740 MBq technetium (^{99m}Tc) oxidronate for an adult weighing 70 kg is about 3.6 mSv. For an administered activity of 740 MBq the typical radiation dose to the target organ (bone) is 25.2 mGy and the typical radiation dose to the critical organ (bladder wall) is 34.8 mGy.

In cases of high bone uptake and/or renal insufficiency, the effective dose resulting from the administration of 740 MBq activity of technetium (^{99m}Tc) oxidronate is 3 mSv. The radiation dose absorbed by the target organ (bone) is 48.1 mGy and the radiation dose absorbed by the critical organ (red marrow) is 8.1 mGy.

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

As with any pharmaceutical product, if at any time in the preparation of this product the integrity of this vial is compromised it should not be used.

Method of preparation

Preparation for multi-dose application
Aseptically add the required amount of sodium pertechnetate (^{99m}Tc) Injection (Fission or Non-Fission) with a maximum activity of 14 GBq, in a volume of 3-10 ml to one vial Technescan HDP.
Shake for 30 seconds to dissolve the contents. The preparation is then ready for injection.
Dilution should preferably be done with Sodium Chloride 0.9 % solution.

For a single patient at most 1 mg of HDP (1/3 of a vial) may be injected

Properties after labelling
After labelling the solution is colourless and clear to slightly opalescent.

Quality control
Examined by means of two paper chromatography methods. One method for impurity A, (^{99m}Tc) technetium in colloidal form, and one method for impurity B, (^{99m}Tc) pertechnetate ion according to the European Pharmacopoeia (Monograph 2376).

1. Impurity A: Ascending paper chromatography using 9 g/L solution of sodium chloride R as mobile phase:
Apply about 5 µl over a path of approximately 15 cm. Use a suitable detector to determine the distribution of radioactivity.
Technetium oxidronate and pertechnetate ion migrate near the solvent front, technetium in colloidal form remains at the start.
2. Impurity B: Ascending paper chromatography (2.2.26) using water R, methanol R (15:85) as mobile phase:
Apply 5 to 10 µl over a path of approximately 15 cm. Use a suitable detector to determine the distribution of radioactivity.
Pertechnetate ion migrates near the solvent front, technetium oxidronate and technetium in colloidal form remain at the start.

Calculate the percentage of radioactivity due to technetium oxidronate using the following expression:
(^{99m}Tc) Technetium oxidronate = 100% – (A+B)

A = percentage of radioactivity due to impurity A
B = percentage of radioactivity due to impurity B

(^{99m}Tc) technetium oxidronate: minimum 95 per cent of the total radioactivity due to technetium-99m.