AUSTRALIAN PRODUCT INFORMATION

GENTECH (SODIUM PERTECHNETATE [^{99m}Tc]) INJECTION

1 NAME OF THE MEDICINE

Molybdenum [^{99}Mo]/Technetium [^{99m}Tc] Sterile Generator
For Production of sodium pertechnetate [^{99m}Tc] Injection Multidose Vial.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Description
ANSTO's Gentech® Generator provides a means of obtaining a sterile, isotonic, additive and pyrogen free solution of sodium pertechnetate [^{99m}Tc] Injection (fission) BP. The generator contains fission-product molybdenum-99 [^{99}Mo] from which ^{99m}Tc is separated by elution into evacuated vials.

The generator consists of a sealed glass vessel containing aluminium oxide. The ^{99}Mo is firmly bound to the alumina and as a result, the eluted ^{99m}Tc contains negligible amounts of ^{99}Mo. Over the life of the generator, an elution will provide a yield of approximately 90% of the theoretical amount of ^{99m}Tc available from the ^{99}Mo contained within the generator vessel.

Active Ingredient:
Each vial of eluted solution contains active ^{99m}Tc in 0.9% sodium chloride solution for injections BP.

Quantity: 10 to 370 GBq at calibration

Physical Characteristics
Technetium-99m [^{99m}Tc], with a physical half-life of 6.02 hours, decays by isometric transition to ^{99}Tc. Photons associated with this transition which are useful for detection and imaging studies are listed in Table 1.

Table-1

Principal Radiation	Mean % per Disintegration	Mean Energy (keV)
Gamma-2	89.1	140.5

Reference: "D A Weber, K F Eckerman, LT Dillman and JC Ryman.MIRD: Radionuclide and Decay Schemes." The Society of Nuclear Medicine Inc., New York, 1989.

External Radiation
The specific gamma ray constant for ^{99m}Tc is 0.19mGy per MBq^{-h-1} at 1cm. The first half value thickness of lead for ^{99m}Tc is 0.2mm. Attenuation by lead is given in the following table.

Table-2

Shield Thicknesses mm Pb	Coefficient of Attenuation (approx.)
0.2	0.5
0.95	10^{-1}
1.8	10^{-2}
2.7	10^{-3}
3.6	10^{-4}

Elution Behaviour

Molybdenum-99, with a half-life of 2.75 days, decays to ^{99m}Tc. The physical decay characteristics of ^{99}Mo are such that 87.5% of its disintegrations form ^{99m}Tc. The decay of ^{99}Mo to ^{99m}Tc occurs until a transient equilibrium is reached when the ^{99m}Tc decay rate equals the rate of its generation, which in turn is proportional to the decay rate of ^{99}Mo, a period of approximately 23 hours. Hence, the activity of ^{99m}Tc available for elution from the generator will depend upon the time interval from the last elution. Table 3 shows the ^{99m}Tc activity for a given growth period following complete elution, relative to the ^{99}Mo activity contained in the generator at the end of the growth period.

Table-3

Growth Periods (hours)	^{99m}Tc:^{99}Mo
1	0.096
2	0.182
4	0.329
8	0.546
24	0.885
48	0.957

Table-4
Physical Decay Chart ^{99}Mo (half-life: 2.75 days)

Days	Fraction Remaining	Days	Fraction Remaining
0	1.000	8	0.1333
1	0.777	9	0.103
2	0.604	10	0.080
3	0.469	11	0.063
4	0.365	12	0.049
5	0.284	13	0.038
6	0.220	14	0.030
7	0.171		

Table-5
Physical Decay Chart ^{99m}Tc (half-life: 6.02 hours)

Hours	Fraction Remaining	Hours	Fraction Remaining
0	1.000	6	0.501
1	0.891	7	0.447
2	0.794	8	0.398
3	0.708	9	0.355
4	0.631	10	0.316
5	0.562		

Excipient(s) with known effect:
Each mL of sodium pertechnetate (^{99m}Tc) solution contains 3.5 mg of sodium.
For full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Clear and colourless sodium pertechnetate [^{99m}Tc] solution for I.V. injection eluted from the radionuclide generator.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Sodium pertechnetate [^{99m}Tc] is used for scintigraphy, principally of the brain and thyroid. It can also be used to prepare various technetium-99m labelled injections for selective organ imaging especially of the liver, lung, bone and kidney.

4.2 DOSE AND METHOD OF ADMINISTRATION

Sodium pertechnetate [^{99m}Tc] injection is administered by intravenous injection. The dosage employed varies for each diagnostic procedure with due allowances being made for patient body weight. The suggested intravenous dose range employed in the average adult (70kg) for the various diagnostic procedures is as follows:

Table-6

Brain Scan	370-740 MBq (10-20 mCi)
Thyroid Gland Scan	37-185 MBq (1-5 mCi)
Salivary Gland Scan	37-185 MBq (1-5 mCi)
Blood Pool Imaging	370-740 MBq (10-20 mCi)

In order to reduce radiation dose to the bladder the patient should be encouraged to drink fluids and to void as frequently as possible after the administration of the radiopharmaceutical for a period of four to six hours.

RADIATION DOSIMETRY
Absorbed dose per unit activity administered (mGy MBq-1) for various body organs is given in Tables 7 and 8 below. Table 7 contains absorbed dose from an Intravenous administration of ^{99m}Tc, when no blocking agent is given. Table 8 contains absorbed dose from an Intravenous administration of ^{99m}Tc, when a blocking agent is given. The data presented in Tables 7 and 8 has been taken from "ICRP publication 128, Radiation Dose to Patients from Radiopharmaceuticals: a Compendium of Current Information Related to Frequently Used Substances"

Table 7
Absorbed dose per unit activity administered (mGy MBq^{-1})

Intravenous administration, no blocking agent given					
Organ	Adult	15 years	10 years	5 years	1 year
Adrenals	3.7E-03	4.6E-03	7.1E-03	1.1E-02	1.9E-02
Bone surfaces	5.4E-03	6.5E-03	9.6E-03	1.4E-02	2.5E-02
Brain	2.0E-03	2.5E-03	4.1E-03	6.5E-03	1.1E-02
Breast	1.8E-03	2.3E-03	3.4E-03	5.6E-03	1.1E-02
Gallbladder wall	7.4E-03	9.8E-03	1.6E-02	2.3E-02	3.5E-02
Gastrointestinal tract -					
Stomach wall	2.6E-02	3.4E-02	4.8E-02	7.8E-02	1.6E-01
Small intestine wall	1.6E-02	2.0E-02	3.1E-02	4.7E-02	8.2E-02
Colon wall	4.1E-02	5.3E-02	8.9E-02	1.4E-01	2.7E-01
Upper large intestine wall	5.6E-02	7.3E-02	1.2E-01	2.0E-01	3.7E-01
Lower large intestine wall	2.1E-02	2.7E-02	4.5E-02	7.1E-02	1.3E-01
Heart wall	3.1E-03	4.0E-03	6.0E-03	9.1E-03	1.6E-02
Kidneys	5.0E-03	6.0E-03	8.6E-03	1.3E-02	2.1E-02
Liver	3.8E-03	4.8E-03	8.0E-03	1.2E-02	2.2E-02
Lungs	2.6E-03	3.4E-03	5.1E-03	7.9E-03	1.4E-02
Muscles	3.2E-03	4.0E-03	6.0E-03	9.1E-03	1.6E-02
Oesophagus	2.5E-03	3.2E-03	4.8E-03	7.5E-03	1.4E-02
Ovaries	9.9E-03	1.3E-02	1.8E-02	2.7E-02	4.4E-02
Pancreas	5.6E-03	7.2E-03	1.1E-02	1.6E-02	2.7E-02
Red marrow	3.7E-03	4.4E-03	6.5E-03	9.0E-03	1.5E-02
Salivary glands	8.5E-03	1.0E-02	1.4E-02	1.8E-02	2.6E-02
Skin	1.8E-03	2.2E-03	3.5E-03	5.6E-03	1.0E-02
Spleen	4.3E-03	5.3E-03	8.0E-03	1.2E-02	2.0E-02
Testes	2.8E-03	3.7E-03	5.9E-03	9.1E-03	1.6E-02
Thymus	2.5E-03	3.2E-03	4.8E-03	7.5E-03	1.4E-02
Thyroid	2.2E-02	3.6E-02	5.4E-02	1.2E-01	2.2E-01
Urinary bladder wall	1.8E-02	2.3E-02	3.4E-02	4.5E-02	6.6E-02
Uterus	8.1E-03	1.0E-02	1.6E-02	2.3E-02	3.7E-02
Remaining organs	3.7E-03	4.7E-03	7.1E-03	1.1E-02	1.9E-02
Effective dose (mSv MBq^{-1})	**1.3E-02**	**1.7E-02**	**2.6E-02**	**4.2E-02**	**7.9E-02**

ICRP publication 128, Radiation Dose to Patients from Radiopharmaceuticals: a Compendium of Current Information Related to Frequently Used Substances

Table 8
Absorbed dose per unit activity administered (mGy MBq^{-1})

Intravenous administration, blocking agent given					
Organ	Adult	15 years	10 years	5 years	1 year
Adrenals	3.3E-03	4.1E-03	6.2E-03	9.3E-03	1.7E-02
Bone surfaces	5.1E-03	6.1E-03	9.0E-03	1.3E-02	2.3E-02
Brain	2.3E-03	2.9E-03	4.7E-03	7.6E-03	1.3E-02
Breast	1.9E-03	2.5E-03	3.5E-03	5.6E-03	1.1E-02
Gallbladder wall	3.5E-03	4.7E-03	7.8E-03	1.1E-02	1.4E-02
Gastrointestinal tract -					
Stomach wall	3.1E-03	4.1E-03	6.6E-03	9.3E-03	1.6E-02
Small intestine wall	3.9E-03	4.9E-03	7.5E-03	1.1E-02	1.9E-02
Colon wall	4.1E-03	5.3E-03	8.0E-03	1.2E-02	1.9E-02
Upper large intestine wall	3.7E-03	4.8E-03	7.1E-03	1.1E-02	1.8E-02
Lower large intestine wall	4.7E-03	5.9E-03	9.1E-03	1.2E-02	2.1E-02
Heart wall	3.1E-03	3.9E-03	5.8E-03	8.6E-03	1.5E-02
Kidneys	4.6E-03	5.6E-03	8.3E-03	1.3E-02	2.2E-02
Liver	3.0E-03	3.8E-03	5.9E-03	8.8E-03	1.6E-02
Lungs	2.7E-03	3.5E-03	5.2E-03	7.9E-03	1.4E-02
Muscles	2.8E-03	3.5E-03	5.3E-03	7.9E-03	1.4E-02
Oesophagus	2.7E-03	3.5E-03	5.2E-03	8.0E-03	1.5E-02
Ovaries	4.8E-03	5.9E-03	8.7E-03	1.3E-02	2.0E-02
Pancreas	3.5E-03	4.4E-03	6.6E-03	1.0E-02	1.8E-02
Red marrow	2.9E-03	3.6E-03	5.4E-03	7.9E-03	1.4E-02
Skin	1.9E-03	2.2E-03	3.6E-03	5.6E-03	1.0E-02
Spleen	3.1E-03	3.9E-03	6.0E-03	8.9E-03	1.6E-02
Testes	3.4E-03	4.3E-03	6.8E-03	1.0E-02	1.6E-02
Thymus	2.7E-03	3.5E-03	5.2E-03	8.0E-03	1.5E-02
Thyroid	2.8E-03	3.5E-03	5.6E-03	9.0E-03	1.6E-02
Urinary bladder wall	3.0E-02	3.8E-02	5.5E-02	7.1E-02	9.1E-02
Uterus	6.4E-03	7.8E-03	1.2E-02	1.6E-02	2.4E-02
Remaining organs	2.9E-03	3.6E-03	5.4E-03	8.2E-03	1.4E-02
Effective dose (mSv MBq^{-1})	**4.6E-03**	**5.8E-03**	**8.7E-03**	**1.2E-02**	**2.0E-02**

ICRP publication 128, Radiation Dose to Patients from Radiopharmaceuticals: a Compendium of Current Information Related to Frequently Used Substances

GENTECH: DIRECTIONS FOR USE

Molybdenum [^{99}Mo]/Technetium [^{99m}Tc] Sterile Generator

The Gentech® generator is supplied with the following procedure packs -1) saline vials pack containing 0.9% sodium chloride injection BP (saline) vials and sterile wet wipes, and 2) evacuated vials pack containing evacuated elution vials, sterile wet wipes and needles.

The generators are sterile and pyrogen free when they leave ANSTO. To ensure the sterility of the eluate, aseptic techniques must be followed during elution of the Gentech®. Compliance to appropriate radiation safety regulations is required for handling generator eluate.

First Elution

1. Remove the Gentech® generator and its accessories from the transport packaging. Install in the Gentech Garage or in the user shielding.
2. Lift Gentech® handle. Rotate the cover until the yellow saline spike cover and elution outlet filter are exposed. Push down handle to lock the lid in the operating position.
3. Remove flip off seal from saline vial (5 or 10 mL). The minimum elution volume is 5 mL. For elution volume between 5 and 10 mL, aseptically remove the unwanted saline from the vial with a hypodermic needle and discard.
4. Place Gentech® saline vial into the **new** Gentech® saline vial holder, provided in the foam insert of the transport package with every generator. Swab the exposed part of the saline vial's silicone septum with a sterile swab provided. **Ensure to allow to dry.**
5. Remove the yellow protective cap from the Gentech® saline spike.
6. Align the lugs of the Gentech® saline vial holder with grooves in the saline port of the Gentech®generator and push down firmly. When vial is fully depressed, turn clockwise in direction of arrows to engage the vial on the saline spike and lock the saline vial holder in place.
7. Remove white plastic lid from the elution vial shield. Unscrew metal top. Remove the red flip-off seal from the 30 mL evacuated elution vial. Place the de-capped vial in the elution vial shield and screw on the metal cap to hold the vial in place. Swab the top of the evacuated elution vial shield and the exposed part of the septum of the evacuated elution vial, with a sterile swab provided. **Ensure to allow to dry.**
8. Grip the red protective cap (male luer closure), turn it anticlockwise through 90° and remove from the outlet filter. With the sterile needle cover in place, attach a sterile needle (screw clockwise). **Caution: do not over-tighten.** Remove the sterile needle cover.
9. Invert the prepared elution vial shield on to the sterile needle. Lower the elution vial shield until the evacuated vial is fully penetrated by the sterile needle. **Allow at least 3 minutes to complete the elution**.
10. Observe emptying of the saline vial and filling of the evacuated elution vial, indicated by the sight and sound of air bubbles in the elution vial.
11. Visibly check the saline vial is empty and through the elution vial shield window that the elution occurred. If elution did not occur, repeat steps 3 and 4 and 6 to 10 with a fresh saline and evacuated elution vials.
12. Remove the elution vial shield from the sterile needle. Cover the elution vial shield with white plastic lid.
13. Place the needle cover back on to the sterile needle and leave it in place until the next elution. (Replace with a fresh sterile needle before each elution).

14. **Do not remove saline vial assembly until the next elution**.

15. Record the appropriate information on the elution vial in accordance with your facility procedures, such as date, time and the contents being radioactive.

16. Assay the contents of the vial, for its 99mTc contents using a previously calibrated 99mTc dose calibrator (or other suitable measuring instrument). Calculate the total 99mTc content of the vial. Record the results.

17. Perform a gamma spectroscopy test to determine extent of 99Mo breakthrough. Alternate method described by *Richards and O'Brien may be used.

Subsequent Elutions

1. Remove the used saline vial (by twisting anti-clockwise), then repeat steps 3, 4, and 6, 7.

2. Remove used elution needle (by twisting anti-clockwise) and replace with a fresh sterile elution needle.

3. Repeat steps 9 through to 17.

Troubleshooting tips when the Generator is not eluting

1. Check that the elution needle is not loose (see step 8).

2. Try another evacuated vial.

3. If you inadvertently remove the elution vial before it finishes eluting, the column will have become wet and will need to be dried. Attach a fresh evacuated vial but do not replace the saline vial unless it still contains some saline. In this case replace it with an empty saline vial. This process will allow air and not saline, to pass through and this will dry off the column. This process using an empty saline vial and a new evacuated elution vial can be repeated to ensure the column is dry.

4. Call ANSTO on 1800 251 572 or email: health@ansto.gov.au.

To Prevent Damaging the Spike

1. Use a new Gentech® saline vial holder, provided with every new generator in the foam insert of the packaging of every new Gentech® generator.

2. Ensure the protective flip off seal is removed from the saline vial.

3. Ensure the lid of the Gentech® generator garage is fully open, to allow clear access to the Gentech® generator.

4. Ensure the yellow protective cap is removed from the saline spike.

5. Ensure the saline vial is placed on the spike vertically and not at an angle.

6. Following swabbing of the silicon septum of the saline vial, ensure to allow to dry.

*Reference: *Richards, P. and O'Brien, M.J., Rapid determination of ^{99}Mo in separated ^{99m}Tc. J. Nucl. Med., 10:517, 1969.*

4.3 CONTRAINDICATIONS

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Since sodium pertechnetate [^{99m}Tc] is excreted through the kidneys and the gastrointestinal tract, its use in patients suffering obstructive pathology may give rise, to a higher level of radiation exposure.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

General

Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides produced by a nuclear reactor or particle accelerator and whose experience and training have been approved by the appropriate government agency authorised to license the use of radionuclides.

Care should be taken to minimise radiation exposure to patients consistent with proper patient management. As with other radioactive drugs, sodium pertechnetate [^{99m}Tc] must be handled with care and appropriate safety measures should be used to minimise radiation exposure to clinical personnel.

Disposal of all radioactive wastes should be carried out in accordance with the ARPANSA's "Code for the Disposal of Radioactive Waste by the User - Radiation Protection Series, C-6, September 2018".

Use with caution in the following circumstances

Because the pertechnetate ion is concentrated in the thyroid gland, choroid plexus and salivary glands, a blocking dose of up to 1 gram of reagent grade potassium perchlorate in a suitable base of capsule may be given orally prior to the administration of sodium pertechnetate [^{99m}Tc] injection for brain scanning.

Patients who have had scans performed on them in the previous 6 weeks with agents containing tin may show distribution artefacts and/or poor quality images in a subsequent sodium pertechnetate [^{99m}Tc] brain scan as a result of uptake of pertechnetate by the red blood cells. The physician should give special consideration in such cases to an alternative agent, e.g. ^{99m}Tc:DTPA.

Check the following before use

Verification of the dose to be administered and patient identification is necessary prior to administration. Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration whenever solution or container permits.

At the time of administration the solution should be crystal clear and should not be used if it is cloudy or if it contains particulate matter.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the foetus.

Use in the elderly

No data available.

Paediatric use

No data available.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Drug interactions have been reported in brain scintigraphy where there can be increased uptake of [^{99m}Tc] pertechnetate in the walls of cerebral ventricles as a result of methotrexate induced ventriculitis.

In abdominal imaging, drugs such as atropine, isoprenaline and analgesics can result in a delay in gastric emptying and redistribution of pertechnetate.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy - Pregnancy Category C

Direct administration of 800 MBq sodium pertechnetate [^{99m}Tc] to a patient results in an absorbed dose to the uterus of 6.5mGy. Following pre-treatment of patients with a blocking agent, administration of 800 MBq Sodium pertechnetate [^{99m}Tc] results in an absorbed dose to the uterus of 5.3 mGy.

Administration of 925 MBq ^{99m}Tc-labelled red blood cells results in an absorbed dose to the uterus of 4.3mGy. Doses above 0.5mGy should be regarded as a potential risk to the foetus.

Use in lactation

As a general rule, breast-feeding should not be undertaken when a patient is administered radioactive material.

If the administration is considered necessary, breast-feeding should be interrupted and the expressed feeds discarded.

Breast-feeding can be restarted when the activity level in the milk will not result in a radiation dose to the child greater than 1mSv.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Adverse Reactions

The following adverse reactions have been reported following intravenous injection of sodium pertechnetate [^{99m}Tc]:

Hypersensitivity and Skin	urticaria, pruritus
Cardiovascular	arrhythmia, vasodilation
Body as a whole	facial oedema, coma

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

In the event of an administration of a radiation overdose with sodium pertechnetate [^{99m}Tc], increasing the elimination of the radionuclide from the body should reduce the absorbed dose. Measures to reduce possible harmful effects include frequent voiding of urine and promotion of diuresis and faecal excretion. Very little treatment can be undertaken in the event of an overdose of [^{99m}Tc] labelled red blood cells since elimination is dependent on the normal haemolytic process.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

At diagnostic doses sodium pertechnetate [^{99m}Tc] does not exhibit clinically and/or analytically noticeable pharmacodynamic effects.

Mechanism of action

Not applicable.

Clinical trials

Not applicable.

5.2 PHARMACOKINETIC PROPERTIES

The pertechnetate ion [^{99m}Tc] has similar biological distribution to iodide and perchlorate ions, concentrating temporarily in salivary glands, choroid plexus, stomach (gastric mucosa) and in the thyroid gland, from which it is released unchanged. The pertechnetate ion also
tends to concentrate in areas with increased vascularisation or with abnormal vascular permeability, particularly when pre-treatment with blocking agents inhibits uptake in glandular structures.
Technetium - 99m is selectively excluded from the cerebrospinal fluid. Following intravenous administration, pertechnetate [^{99m}Tc] is distributed throughout the vascular system from which it is cleared by three main mechanisms:

- rapid removal, depending on the diffusion equilibrium with interstitial fluid;
- intermediate rate of removal, depending on the concentration of the pertechnetate in glandular tissue, mainly thyroid, salivary and gastric fundus glands which have an ionic pump mechanism;
- slow removal, by glomerular filtration by the kidneys, dependent on rate of urinary excretion.

Plasma clearance has a half-life of approximately 3 hours. Excretion during the first 24 hours following administration is mainly urinary (~25%) with faecal excretion occurring over the next 48 hours. Approximately 50% of the administration activity is excreted within the first 50 hours.

When selective uptake of pertechnetate [^{99m}Tc] in glandular structures in inhibited by the pre-administration of blocking agents, excretion follows the same pathways but there is a higher rate of renal clearance.

When pertechnetate [^{99m}Tc] is administered in association with pre-treatment with reducing agents such as stannous/medronate which cause a "stannous leading" of red blood cells, up to approximately 95% of the administered activity is taken up by the red blood cells where it becomes bound within the cells. Any unbound pertechnetate [^{99m}Tc] is cleared by the kidneys. Radioactivity in the plasma normally constitutes less than 5% of the intravascular activity.

The fate of ^{99m}Tc follows that of the labelled erythrocyte themselves and the activity is cleared very slowly. A small level of elution of activity from the circulating red cells is thought to occur.

Sodium pertechnetate [^{99m}Tc] injection may be reacted with a range of reagents (cold kits) to provide diagnostic agents for the imaging of specific organs.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity:

No data available.
Carcinogenicity:
No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Sodium Chloride, BP
Water for Injections, BP

Refer to Section 2 - Qualitative and Quantitative composition.

6.2 INCOMPATIBILITIES

This medicinal product must not be mixed with other medicinal products except with those as required to achieve therapeutic indications given in Section 4 of this Product Information document.

Interaction of this medicine with others is also given in Section 4.5 of this Product Information document.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the ARTG. The expiry date can be found on the packaging.

Note:
(i) Generator has an expiration time of 14 days from the date of calibration (shown on the generator label).

(ii) Eluate from generators, Sodium Pertechnetate [^{99m}Tc] Injection does not contain an antimicrobial preservative, hence should only be used within 8 hours after elution.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Storage
The generator is designed to operate at normal room temperature (below 30°C). The yield of Sodium pertechnetate [^{99m}Tc] may be affected if the generator and the 0.9% sodium chloride solution are stored below room temperature.

6.5 NATURE AND CONTENTS OF CONTAINER

Borosilicate glass column contains alumina on which molybdic [^{99}Mo] acid is bound and decays to sodium pertechnetate [^{99m}Tc]. The glass column is housed in a lead shield contained within a plastic chassis.

Sodium pertechnetate [^{99m}Tc] injection is eluted into a 30mL brown tinted evacuated vial housed within a shield.

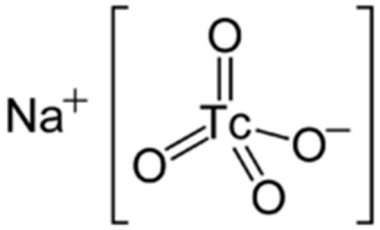
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

Disposal of the Generator
The generator (and packaging) should be kept and not disposed of as normal waste within 70 days of the calibration date. Users are encouraged to return their generators to ANSTO for recycling. A special set of instructions and labels are included with each generator.

Refer to Section 4.4 - Special warnings and precautions for use.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure:



CAS number:
23288-60-0

7 MEDICINE SCHEDULE (POISONS STANDARD)

Unscheduled.

8 SPONSOR

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9 DATE OF FIRST APPROVAL

24th January 1994.

10 DATE OF REVISION

31 July 2020.

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
2	- Physical half-life of "Technetium-99m [^{99m}Tc]" updated from 6 to 6.02 hours
6.3	- Generator and eluate shelf-life included.
8	- Sponsor details updated.

Australian Government

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