

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

TechneScan LyoMAA, Powder for suspension for injection/kit for radiopharmaceutical preparation

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains 2.0 mg macrosalb (macroaggregates from human serum albumin)

The radioisotope is not part of the kit.

The number of particles per vial is 4.5×10^6 .

Excipients:

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for suspension for injection. Kit for radiopharmaceutical preparation.

White powder for reconstitution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

This product is for diagnostic use only.

TechneScan LyoMAA is used after labelling with a sodium pertechnetate [^{99m}Tc] solution (Ph. Eur.) obtained from an authorised radionuclide generator in the following indications:

Pulmonary perfusion scintigraphy

- For the diagnosis or exclusion of pulmonary embolism in patients with symptoms of pulmonary embolism; and for monitoring the evolution of a pulmonary embolism
- For examinations concomitant to therapies that result in a significant reduction in the regional lung perfusion, as preoperative investigation of local pulmonary perfusion prior to (partial) lung resection, preoperative examination and progress monitoring of lung transplants and for pre therapeutic examinations for assisting radiation therapy planning
- In combination with ventilation scintigraphy for the initial evaluation and the follow-up of patients with severe obstructive and/or restrictive pulmonary diseases
- For the diagnosis and quantification of pulmonary right-to-left shunts

Radionuclide venography

As an alternative to Doppler ultrasound, for radionuclide venography of the lower limbs, in combination with pulmonary perfusion scintigraphy in patients with both suspected lower limb deep vein thrombosis and pulmonary embolism.

4.2 Posology and method of administration

Dosage instructions for pulmonary perfusion scintigraphy and venoscintigraphy:

Adult and elderly patients

The recommended radioactivity intravenously administered is between 40 and 150 MBq, with a middle value of 100 MBq for planar pulmonary perfusion scintigraphy and up to 200 MBq for SPECT pulmonary perfusion scintigraphy. The average recommended number of particles for adults should fall within the range of 100,000 and 300,000. The maximum number of

particles of 700,000 per administration must not be exceeded. The minimum number of particles per dosage administered should be 100,000 in order to obtain optimal image quality.

Adult and elderly patients with severe cardiovascular disease, with pulmonary hypertension accompanied by respiratory insufficiency or with a right-to-left shunt

The number of particles should be reduced to 100,000 to 200,000.

Paediatric patients

The Paediatric Task Group of the EANM recommends calculation of the activity administered to children on the basis of body weight in accordance with the following table:

Fraction of the adult dosage:

| | | |
|--------------|--------------|-----------------|
| 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 |

To ensure a sufficient image quality in small children, the administered activity should not be below 10 MBq.

Newborns: The number of particles is to be restricted to a maximum of 50,000.

One-year-old children: The number of particles is to be restricted to a maximum of 150,000.

Paediatric patients where a right-to-left shunt is present

Newborns: The number of particles should be limited to 1,000 – 5,000.

One-year-old children: The number of particles should be limited to 5,000 – 15,000.

5-10 year-old children: The number of particles should be limited to 20,000 – 30,000.

15-year-old adolescents: The number of particles should be limited to 20,000 – 70,000.

Method of administration and scintigraphic examination

This medicinal product must be reconstituted before use. Any unused suspension should be discarded 12 hours after reconstitution. Information on the preparation of the reconstituted product is provided in Section 12. After reconstitution and labelling the technetium [^{99m}Tc] macrosalb injection is a white, aqueous suspension of particles which may precipitate on standing.

This medicinal product must be administered exclusively by authorised personnel (see section "General warnings" in section 4.4).

The contents of the syringe must be carefully swirled once again prior to the injection, in order to achieve a uniform distribution of the particles and in order to avoid the formation of larger-sized aggregates. A thin cannula should be used in order to disperse any complexes of aggregates present. Additional information on precautions regarding administration of the suspension may be found in section 4.4.

For the same reason, blood should never be drawn up into the syringe because that induces the formation of small clots, which are presented in the scintigram as false positive defects because of the occlusion of the bigger arterioles. If possible, the product should not be injected via an implanted venous access device, as this can result in inadequate mixing of the radioactivity in the pulmonary artery.

Patient Preparation

A thyroid blockade prior to application of the technetium [^{99m}Tc] macrosalb injection suspension can help to reduce the radiation exposure of the thyroid by reducing the thyroid-uptake of technetium [^{99m}Tc] pertechnetate which develops in lesser amounts by the metabolism.

After the patient has coughed and taken several deep breaths, the medicinal product is slowly injected intravenously over 3 to 5 respiratory cycles or for at least 30 seconds, if possible however, not via an implanted venous catheter. Great care must be taken to see that the radioactive product does not enter the surrounding tissues and that no blood is aspirated, as otherwise there is a danger that larger complexes of aggregates will form. The patient should lie on his back during the injection or as close to this position as possible for patients with orthopnea. The pulmonary investigation can begin immediately after the injection.

The intravenous injection is carried out on official recommendation in the supine position, the craniocaudal difference being thus evened out. On the other hand there are sources that advise carrying out the injection in the same position in which inhalation of the radioactive inert gas or of aerosols is undertaken, i.e. preferably in the sitting position, this position being taken up at least 5 minutes beforehand. In this way, as a consequence of the better ventilation of the lungs in the sitting position, the danger of false positive results in a staggered investigation of ventilation and perfusion is avoided.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients.
- Severe pulmonary hypertension.

4.4 Special warnings and precautions for usePotential 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.

Paediatric population

Particular caution is required when administering technetium [^{99m}Tc] Macrosalb, as the effective dose per MBq is higher than in adults.

Special care should be exercised when administering technetium [^{99m}Tc] macrosalb injection to patients with significant right to left cardiac shunt, patients with pulmonary hypertension, or respiratory insufficiency. The number of particles must be kept as low as possible. In adults the number of particles can be reduced to between 100,000 and 200,000 particles without meaning that image quality for the detection of perfusion defects need suffer as a result. Non-homogenous distribution of activity can occur if the number of particles is reduced to less than 100,000 for an adult. If indications exist of the illnesses listed above, then Technescan LyoMAA may not be administered except after a careful benefit/risk analysis has been performed. In order to minimise the possibility of microembolism to the cerebral and renal circulations Technetium [^{99m}Tc] macrosalb injection should be given by slow intravenous injection and the number of particles reduced by up to 50%. Such precautions are also advised in patients with respiratory failure complicating pulmonary hypertension.

Contents of the vial are intended only for use in the preparation of technetium [^{99m}Tc] macrosalb injection and are not to be administered directly to the patient without first undergoing the preparative procedure.

The syringe should be gently swirled immediately prior to injection to homogenise the injectate. Blood should never be drawn into the syringe because that induces the formation of small clots.

The medicinal product should not come into contact with air.

In order not to restrict the stability of the radioactively labelled medicinal product, technetium [^{99m}Tc] macrosalb aggregates are not permitted to be mixed with other medicinal products or components nor be administered together with them

Viral safety

Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.

There are no reports of virus transmissions with albumin manufactured to European Pharmacopoeia specifications by established processes.

It is strongly recommended that every time that Technescan LyoMAA is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

Excipients:

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

4.5 Interaction with other medicinal products and other forms of interactions

Changes in the biological distribution of [^{99m}Tc]-MAA may be induced by different drugs.

- Pharmacologic interactions may be caused by chemotherapeutic agents, heparin, bronchodilators.
- Toxicologic interactions may be caused by heroin, nitrofurantoin, busulfan, cyclophosphamide, bleomycin, methotrexate, methysergide.
- Pharmaceutic interactions may be caused by magnesium sulphate.

4.6 Fertility, pregnancy and lactation

There is no experience from the use of technetium [^{99m}Tc] macrosalb injection in pregnant women.

Pregnancy:

Radionuclide procedures carried out on pregnant women also involve radiation doses to the fetus. Only imperative investigations should therefore be carried out during pregnancy, when the likely benefit exceeds the risk incurred by the mother and the foetus.

Women of childbearing potential

When it is necessary to administer radioactive medicinal products to women of childbearing potential, information should always be sought about pregnancy. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. Where uncertainty exists it is important that radiation exposure should be the minimum consistent with achieving the desired clinical information.

Alternative techniques which do not involve ionising radiation should be considered.

Breast feeding:

Before administering a radioactive medicinal product to a mother who is breast-feeding consideration should be given as to whether the investigation could be reasonably delayed until the mother has ceased breast feeding and as to whether the most appropriate choice of radiopharmaceutical has been made, bearing in mind the secretion of activity in breast milk. If the administration is considered necessary, breast feeding should be interrupted for 12 hours and the expressed feeds discarded. Breastfeeding can be restarted when the level in the milk will not result in a radiation dose to a child greater than 1 mSv.

4.7 Effects on ability to drive and use machines

No studies on the effects on ability to drive and use machines have been performed.

4.8 Undesirable effects

For safety with respect to transmissible agents see section 4.4.

The frequencies of undesirable effects are defined as follows:

Very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/10,000$) and not known (cannot be estimated from the available data)

Very rare: after intravenous administration of technetium [^{99m}Tc] macrosalb aggregates, hypersensitivity reactions appear such as urticaria, shivering fits, fever, nausea, reddening of the face and sweating as well as impairments of cardiac and circulatory functions in the form of changes in respiration, pulse, blood pressure and collapse which may be related to vascular occlusion.

Serious anaphylactoid reactions including shock with possible fatal outcome have been reported, but are very rare. The appearance of these reactions may also not be immediate. Local allergic reactions at the injection site have been observed.

If symptoms such as redness, itching, sneezing, coughing, sweating or feeling cold, difficulty breathing, nausea, vomiting, oedema, urticaria or other sensitivity reactions occur during injection, administration of the medicinal product must be interrupted immediately. Emergency equipment including the medicinal products necessary for treatment must be ready at hand.

Ionized radiation can cause cancer and genetic changes. As most nuclear medicine investigations are carried out with low effective doses of radiation of less than 20 mSv, the probability of these effects occurring should be regarded as being very slight. The effective dose after administration of the maximum recommended activity of this medicinal product is 2.2 mSv.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

The number of MAA particles per adult patient must not exceed 1.5×10^6 . (see section 12).

The dangers to be expected relating to inadvertent administration of excess radioactivity may be reduced by promoting a diuresis and frequent voiding of urine.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Diagnostic radiopharmaceuticals for the respiratory system.
ATC code: V09E B01.

When administered in usual doses, technetium [^{99m}Tc] macrosalb injection shows no pharmacodynamic effects detectable clinically or/and analytically.

5.2 Pharmacokinetic properties

Following intravenous injection of technetium [^{99m}Tc] macrosalb injection, temporary occlusion of pulmonary capillaries and arterioles occurs, which is proportional to the regional pulmonary blood flow at the time.

The principle of perfusion scintigraphy is capillary blockade. After intravenous injection most of the macrosalb aggregates are retained in the arterioles and capillaries of the lung at the time of first passage through the lungs. The diameter of most of the macroaggregates is between 10 and 90 micrometer. Depending on the distribution of particle sizes, roughly every 1,000,000th capillary (diameter < 20 micrometer) and every 1,000th arteriole (diameter > 20 micrometer) is temporarily occluded. The extent of the regional blockade with micro embolisms is thus directly proportional to the regional lung perfusion at the time. Larger particles can lead to occlusion of larger vessels and therefore cause artificial perfusion disturbances. Hemodynamic changes are directly linked to the particle size of the macrosalb aggregates.

The elimination of the macroaggregate particles from the lungs takes place by mechanical fragmentation through the systolic-diastolic pressure pulses within the capillaries and by enzymatic breakdown with subsequent phagocytosis by macrophages of the reticuloendothelial system. In the context of elimination, activity accumulates in the liver and kidneys. Liver accumulation is extremely variable; it increases over time and can become as high as approximately 25%. With regard to elimination from the lungs, great differences exist between individuals. The particles are eliminated from the lungs with a biological half-life of about 7-20 hours. 30-45% of the injected radioactivity is excreted through the urine within 24 hours.

If a right-to-left shunt is present, a proportion of the macroaggregates moves into the general circulation system and becomes trapped there in the capillary bed. If this happens, the formation of a cerebral or renal microembolism is, for example, possible.

5.3 Preclinical safety data

Correlation exists between the size of the MAA and their toxic effects.

The pathophysiologic mechanism responsible for toxicity is shown to be the increase of the pulmonary blood pressure. With particulars from 10-50 micrometer in diameter the first pulmonary signs of toxicity in dogs (*e.g.* tachypnea) appear after injection of 20 to 25 mg per kg of body weight.

A sharp increase of the pulmonary blood pressure is noticed when 20 mg of less than 80 micrometer sized macrosalb particles are injected, where no significant pressure changes are recorded with 40 mg of less than 35 micrometer macrosalb particles. With suspension of macrosalb particles up to 150 micrometer diameter, no blood pressure changes appear below 10 mg/kg, while larger diameter suspensions (up to 300 micrometer) typical blood pressure changes in pulmonary artery appear when the doses exceed 5 mg/kg.

Doses of 20-50 mg/kg cause sudden death from failure. A safety factor of 100 is found after injection in dogs of 14,000 particles of technetium [^{99m}Tc] macrosalb (size: 30 -50 micrometer).

The repeated-dose toxicity studies performed in dogs show no detectable variations in the general behaviour of the animals.

No evidence of pathological changes in the main organs has been detected.

There is no evidence in the literature of teratogenic, mutagenic or carcinogenic effect of the unlabelled product.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Sodium acetate
Stannous chloride dihydrate
Human serum albumin
Hydrochloric acid

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6 or 12.

6.3 Shelf life

18 months

After reconstitution: 12 hours

6.4 Special precautions for storage

Lyophilized product: Store at 2 - 8°C.

Labelled product: Store at 2 - 8°C.

Storage should be in accordance with national regulations for radioactive material.

6.5 Nature and contents of container

10 ml Type I (Ph. Eur.) glass vial closed with a bromobutyl rubber stopper.

Technescan LyoMAA is supplied as five vials in one carton.

6.6 Special precautions for disposal

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 by the user in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

The content of the kit before extemporary preparation is not radioactive. However, after sodium pertechnetate [^{99m}Tc] solution (Ph. Eur.) 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 spill 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.

7 MARKETING AUTHORISATION HOLDER

Curium Netherlands B.V.
Westerduinweg 3
1755 LE Petten
The Netherlands

8 MARKETING AUTHORISATION NUMBER

PA0690/012/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First date of authorisation: 05 April 2002

Last date of authorisation: 05 April 2007

10 DATE OF REVISION OF THE TEXT

11 DOSIMETRY

Technetium [^{99m}Tc] decays with the emission of gamma radiation with energy of 140 keV and a half-life of 6 hours to technetium [⁹⁹Tc] which can be regarded as quasi stable.

Data on radiation exposure come from the ICRP publication 80.

| Organ | Absorbed dose per activity administered (mGy/MBq) | | | | |
|---|---|--------------|--------------|--------------|--------------|
| | Adult | 15 years | 10 years | 5 years | 1 year |
| Adrenal glands | 0.0068 | 0.0088 | 0.013 | 0.019 | 0.031 |
| Bladder | 0.0087 | 0.011 | 0.014 | 0.016 | 0.030 |
| Bone surface | 0.0051 | 0.0064 | 0.0091 | 0.014 | 0.026 |
| Brain | 0.00092 | 0.0012 | 0.0020 | 0.0032 | 0.0055 |
| Mammary gland | 0.0050 | 0.0056 | 0.0099 | 0.014 | 0.021 |
| Gall bladder | 0.0056 | 0.0070 | 0.010 | 0.016 | 0.024 |
| Gastrointestinal tract | | | | | |
| Stomach | 0.0037 | 0.0052 | 0.0080 | 0.012 | 0.020 |
| Small intestine | 0.0020 | 0.0026 | 0.0043 | 0.0068 | 0.012 |
| Colon | 0.0019 | 0.0026 | 0.0043 | 0.0069 | 0.012 |
| Upper large intestine | 0.0022 | 0.0029 | 0.0050 | 0.0083 | 0.014 |
| Lower large intestine | 0.0016 | 0.0021 | 0.0033 | 0.0050 | 0.0095 |
| Heart | 0.0096 | 0.013 | 0.018 | 0.025 | 0.038 |
| Kidneys | 0.0037 | 0.0048 | 0.0072 | 0.011 | 0.018 |
| Liver | 0.016 | 0.021 | 0.030 | 0.042 | 0.074 |
| Lung | 0.066 | 0.097 | 0.13 | 0.20 | 0.39 |
| Muscles | 0.0028 | 0.0037 | 0.0052 | 0.0077 | 0.014 |
| Esophagus | 0.0061 | 0.0077 | 0.011 | 0.015 | 0.022 |
| Ovaries | 0.0018 | 0.0023 | 0.0035 | 0.0054 | 0.010 |
| Pancreas | 0.0056 | 0.0075 | 0.011 | 0.017 | 0.029 |
| Red bone marrow | 0.0032 | 0.0038 | 0.0053 | 0.0072 | 0.012 |
| Skin | 0.0015 | 0.0017 | 0.0027 | 0.0043 | 0.0078 |
| Spleen | 0.0041 | 0.0055 | 0.0083 | 0.013 | 0.022 |
| Testes | 0.0011 | 0.0014 | 0.0022 | 0.0033 | 0.0062 |
| Thymus | 0.0061 | 0.0077 | 0.011 | 0.015 | 0.022 |
| Thyroid | 0.0025 | 0.0033 | 0.0057 | 0.0090 | 0.016 |
| Uterus | 0.0022 | 0.0028 | 0.0042 | 0.0060 | 0.011 |
| Effective dose per administered activity (mSv/MBq) | 0.011 | 0.016 | 0.023 | 0.034 | 0.063 |

The effective dose among adults for administration of 150 MBq of activity (maximum recommended dose for planar perfusion scintigraphy) is approximately 1.7 mSv and 2.2 mSv for 200 MBq (maximum recommended dosage for SPECT scintigraphy). The absorbed dose in the target organ, the lungs, is thus approximately 10 mGy, and in the critical organs – adrenal glands, bladder wall, liver, pancreas and spleen – is 1.0, 1.3, 2.4, 0.8 and 0.6 mGy, respectively.

When a dosage of 200 MBq is administered, the administered dosage in the lungs as target organ is around 13 mGy; in the critical organs – adrenal glands, bladder wall, liver, pancreas and spleen, the figures are 1.4, 1.7, 3.2, 1.1 and 0.8 mGy respectively.

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.

Estimation of volume and pertechnetate activity in connection with the number of macrosalb particles

Step 1: Estimation of the labelling volume of the vial in dependence of the volume and number of the macrosalb particles per dose to be injected.

Table 1 gives examples for injection volumes of 0.3 to 1 ml which were calculated with the following formula.

Labelling volume = $\frac{\text{Number of macrosalb-particles per vial} \times \text{volume to inject}}{\text{Number of macrosalb-particles per dose to be injected}}$

Number of macrosalb-particles per dose to be injected

Table 1: Calculation of volume (in ml) needed for reconstitution and labelling

(Calculations are based on 4,500,000 particles/vial)

| Desired number of macrosalb particles to be injected per dose | Volume needed for reconstitution and labelling (ml) | | | |
|---|---|------|------|------|
| | 0.3* | 0.5* | 0.8* | 1.0* |
| 700,000 | 1.9 | 3.3 | 5.1 | 6.5 |
| 600,000 | 2.3 | 3.8 | 6.0 | 7.5 |
| 500,000 | 2.7 | 4.5 | 7.2 | 9.0 |
| 400,000 | 3.4 | 5.6 | 9.0 | -- |
| 300,000 | 4.5 | 7.5 | -- | -- |
| 250,000 | 5.4 | 9.0 | -- | -- |
| 200,000 | 6.8 | -- | -- | -- |
| 150,000 | 9.0 | -- | -- | -- |

* Injection Volume

Step 2: Calculation of the radioactivity to be added to the vial. Here the following formula is used:

Total activity of the vial = $\frac{\text{Activity to be injected} \times \text{Labelled volume}}{\text{Volume to inject}}$

Table 2: Calculation of the number of macrosalb particles to be injected

(Calculations are based on 4,500,000 particles/vial)

| Volume used for reconstitution and labelling (ml) | Volume to be administered (ml) | | | |
|---|--------------------------------|---------|---------|---------|
| | 0.3 | 0.5 | 0.8 | 1.0 |
| 3 | 450,000 | 750,000 | -- | -- |
| 4 | 330,000 | 560,000 | -- | -- |
| 5 | 270,000 | 450,000 | 720,000 | -- |
| 6 | 225,000 | 375,000 | 600,000 | 750,000 |
| 7 | 190,000 | 320,000 | 515,000 | 640,000 |
| 8 | 170,000 | 280,000 | 450,000 | 560,000 |
| 9 | 150,000 | 250,000 | 400,000 | 500,000 |
| 10 | 135,000 | 225,000 | 360,000 | 450,000 |

Method of preparation

- Aseptically add – as required – 1 to 10 ml of sodium pertechnetate [^{99m}Tc] solution (Ph. Eur.) with an activity between 370 MBq and 3.7 GBq to a vial Technescan LyoMAA.

Do not use a venting needle, but relieve the excess of pressure in the vial by withdrawing a volume of gas equal to the introduced volume of eluate.

- Swirl the vial carefully a few times to suspend the freeze-dried albumin macroaggregates.
- Incubate for 5 minutes at room temperature.
- Swirl the vial again before withdrawing the desired dose.

Under no circumstances the preparation should come into direct contact with air.

Quality control

Properties of the medicinal product after reconstitution and labelling:

Technetium [^{99m}Tc] macrosalb injection is a white, aqueous suspension that may precipitate upon standing.

- Labelling yield : ≥ 90 %
- Free pertechnetate : ≤ 5 %
- pH : 5.0 to 7.0

.Determination of free [^{99m}Tc] by membrane filtration 5 minutes after labelling:

(For particulars consult the Ph. Eur. monograph 0296)

- Use a polycarbonate membrane filter with circular 3 micrometre pores in a suitable holder. Bring 0.2 ml of the technetium [^{99m}Tc] macrosalb injection onto the filter membrane.
- Wash the filter with 20 ml saline solution.
- The radioactivity remaining in the membrane must be $\geq 90\%$ of the total radioactivity.