

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pulmocis

Kit for the preparation of technetium [^{99m}Tc] Human albumin macroaggregates injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Human albumin as macroaggregates : 2.0 mg/vial.

The product contains no antimicrobial preservative.

The particles number per vial is ranging between 2 and 4 millions, No macroaggregates has a size higher than 150 μm . Not more than 10 of them have a size higher than 100 μm .

For a full list of excipients, *see section 6.1*

3 PHARMACEUTICAL FORM

Powder for suspension for injection (Powder for injection).

Kit for radiopharmaceutical preparation.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

This medical product is for diagnostic use only.

- Pulmonary perfusion scintigraphy.
- As secondary indication ^{99m}Tc -albumin macroaggregates may be used for venoscintigraphy

4.2 Posology and method of administration

Recommended activities to be administered intravenously to an adult weighing 70 kg varies between 37 - 185 MBq (1-5 mCi). The number of particles per administered dose must be in a range of 60×10^3 - 700×10^3 . The lung test may start immediately after injection.

The activity to be administered in children should be a fraction of the adult activity and should be calculated according to the following equation:

$$\text{Paediatric dose (MBq)} = \frac{\text{Adult dose (MBq)} \times \text{child weight (kg)}}{70 \text{ (kg)}}$$

Although body weight is the more used factor on which to base the adjustment of the activity administered, in a limited number of cases the body surface area may be considered to be more appropriate.

$$\text{Paediatric dose (MBq)} = \frac{\text{Adult dose (MBq)} \times \text{child surface (m}^2\text{)}}{1.73}$$

4.3 Contraindications

Hypersensitivity to the active substance, to any of the excipients or to any of the components of the labelled radiopharmaceutical.

4.4 Special warnings and precautions for use

The possibility of hypersensitivity including serious, life-threatening, fatal anaphylactic/anaphylactoid reactions should always be considered. Advanced life support facilities should be readily available. 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.

Special care should be exercised when administering ^{99m}Tc albumin macroaggregates (MAA) to patients with significant right to left cardiac shunt. In order to minimise the possibility of microembolism to the cerebral and renal circulations ^{99m}Tc -MAA 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.

General warnings

Radiopharmaceuticals should be received, used and administered only by authorised persons in designated clinical settings. Their receipt, use, transfer and disposal are subject to national licensing regulations. Radiopharmaceuticals should be prepared by the user in a manner which satisfies both radiological safety and pharmaceutical requirements. Appropriate aseptic precautions should be taken.

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

Specific warnings

Pulmocis contains human albumin.

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 PULMOCIS 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.

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.

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 interaction

Changes in the biological distribution of ^{99m}Tc -MAA are induced by different drugs.

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

4.6 Fertility, pregnancy and lactation

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 always be considered.

Pregnancy

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

Breastfeeding

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.

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)

Due to the fact that only spontaneous reports could be analysed, no frequency indications could be provided.

Adverse Reactions sorted by System Organ Class

Immune system disorders

Frequency unknown: Anaphylactic reaction, hypersensitivity-type reactions, including life-threatening anaphylaxis. Application site hypersensitivity.

Vascular disorders

Frequency unknown: Circulatory collapse

General disorders and administration site conditions

Frequency unknown: Chest pain, chills

Single or repeated injections of ^{99m}Tc -albumin macroaggregates may be associated with hypersensitive-type reactions, including very rare life-threatening anaphylaxis; chest pain, rigor and collapse may occur. Local allergic reactions have been seen at the injection site.

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. For diagnostic nuclear medicine investigations with current evidence suggests that these adverse effects will occur with low frequency because of the low radiation doses incurred.

As the effective dose equivalent is 2.2 mSv when the maximal recommended activity of 185 MBq is administered these adverse events are expected to occur with a low probability.

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

^{99m}Tc -MAA, when administered at the recommended doses, shows no pharmacodynamic effects detectable clinically or/and analytically.

5.2 Pharmacokinetic properties

Following injection into a superficial vein of the systemic venous circulation, the macroaggregates are carried at the speed of this circulation to the first capillary filter, i.e. the capillary tree of the pulmonary artery system.

The albumin macroaggregates particles do not penetrate the lung parenchyma (interstitial or alveolar) but remain in a temporary occlusive position in the lumen of the capillary. When pulmonary flow distribution is normal, the compound distributes over the entire pulmonary area following physiologic gradients; when district flow is altered the areas of reduced flow are reached by a proportionally smaller amount of particles. The technetium labelled macroaggregates remain in the lungs for variable periods of time, depending of the structure, size and number of particles.

The disappearance of activity from the particles in the lungs is governed by an exponential law: the larger aggregates have a longer biological half-life, whereas particles between 5 and 90 μm in diameter have a half-life ranging from 2 to 8 hours.

The decrease in pulmonary concentration is caused by the mechanical break-down of the particles occluding the capillaries, stemming from the systo-diastolic pressure pulsations within the capillary itself.

The products of macroaggregate break-down, once recirculated as albumin microcolloid, are quickly removed by the macrophages of the reticuloendothelial system, i.e. essentially the liver and the spleen.

The microcolloid is metabolized with introduction of the radioactive label (^{99m}Tc) into the systemic circulation from which it is removed and excreted in urine.

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 particles from 10 to 50 μm in a 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 μm sized MAA are injected, while not significant pressure changes are recorded with 40 mg of less than 35 μm MAA particles.

With suspension of MAA up to 150 μm diameter, no blood pressure changes appear below 10 mg/kg, while larger diameter suspensions (up to 300 μm) typical blood pressure changes in pulmonary artery appear when the doses exceeds 5 mg/kg.

Doses of 20-50 mg/kg cause sudden death for respiratory failure. a safety factor of 100 is found after injection in dogs of 14,000 ^{99m}Tc -MAA (size: 30-50 μm).

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

Human albumin
Stannous chloride dihydrate
Sodium chloride
Sodium caprylate
Under nitrogen atmosphere

6.2 Incompatibilities

In the absence of compatability studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

The expiry date for this kit is 12 months from the day of manufacture.
The expiry date is indicated on the outer packaging and on each vial.
The expiry date for the labelled product is 8 hours after labelling.

6.4 Special precautions for storage

Store the kit and the labelled product in a refrigerator (2°C - 8°C).

Storage of the labelled product must be in accordance with national regulations for radiopharmaceuticals.

6.5 Nature and contents of container

15 ml, colourless, Ph. Eur. type I, drawn glass vials, closed with rubber stoppers and aluminium capsules.

Pack size: kit of 5 multidose vials.

6.6 Special precautions for disposal and other handling

The administration of radiopharmaceuticals creates risks for other persons from external radiation or contamination from spill or urine, vomiting, etc.

Radiation protection precautions in accordance with national regulations must therefore be taken.

The residues may be put in an ordinary waste bin insofar as the activity of vials and syringes does not exceed that of background when measured with a low level radiation detector. Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

CIS bio international
BP 32
91192 Gif Sur Yvette Cedex
France

8 MARKETING AUTHORISATION NUMBER

PA 0677/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 October 2001

Date of last renewal: 19 October 2006

10 DATE OF REVISION OF THE TEXT

June 2016

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 [^{99m}Tc] which can be regarded as quasi stable.

For this product the effective dose equivalent resulting from an administered activity of 185 MBq is typically 2.2 mSv (per 70 kg individual).

According to ICRP 53 (1988) the radiation doses absorbed by the patients are the following:

Organ	Absorbed dose per unit activity administered (mGy/MBq)				
	Adult	15 years	10 years	5 years	1 year

*Adrenals	5.8E-03	8.7E-03	1.3E-02	1.9E-02	3.1E-02
*Bladder wall	1.0E-02	1.3E-02	1.9E-02	2.8E-02	5.1E-02
Bone surface	3.5E-03	4.4E-03	6.4E-03	9.7E-03	1.9E-02
Breast	5.6E-03	5.5E-03	1.0E-02	1.4E-02	2.2E-02
Gastro-Intestinal tract					
Stomach wall	4.0E-03	5.2E-03	7.8E-03	1.2E-02	2.0E-02
Small intest	2.1E-03	2.6E-03	4.3E-03	7.0E-03	1.3E-02
ULI wall	2.2E-03	2.9E-03	5.0E-03	8.4E-03	1.5E-02
LLI wall	1.6E-03	2.1E-03	3.5E-03	5.4E-03	1.0E-02
Kidneys	3.7E-03	4.8E-03	7.2E-03	1.1E-02	1.8E-02
*Liver	1.6E-02	2.1E-02	3.0E-02	4.3E-02	7.5E-02
Lungs	6.7E-02	9.9E-02	1.4E-01	2.1E-01	4.0E-01
Ovaries	1.8E-03	2.3E-03	3.7E-03	5.9E-03	1.1E-02
*Pancreas	5.8E-03	7.5E-03	1.1E-02	1.7E-02	2.9E-02
Red marrow	4.4E-03	6.2E-03	8.3E-03	1.1E-02	1.7E-02
*Spleen	4.4E-03	5.6E-03	8.3E-03	1.3E-02	2.2E-02
Testes	1.1E-03	1.4E-03	2.3E-03	3.7E-03	7.1E-03
Thyroid	2.0E-03	3.3E-03	5.5E-03	9.0E-03	1.6E-02
Uterus	2.4E-03	2.9E-03	4.6E-03	7.1E-03	1.3E-02
Other tissue	2.9E-03	3.6E-03	5.2E-03	7.8E-03	1.4E-02
Effective dose equivalent (mSv/MBq)	1.2E-03	1.8E-02	2.5E-02	3.8E-03	6.9E-02

For an administered activity of 185 MBq the typical radiation dose to the target organ, lungs, is 12.3 mGy and the typical radiation dose to the critical organs*, adrenals, bladder wall, liver pancreas, spleen, are 1.07, 1.85, 2.96, 1.07 and 0.81 mGy respectively.

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

The product is to be used after labelling by the addition of sterile, pyrogen free isotonic sodium pertechnetate [^{99m}Tc] injection, allowing the preparation of Technetium [^{99m}Tc] human albumin macroaggregates injection.

Method of preparation

Usual precautions regarding sterility and radioprotection should be respected.

Take a vial from the kit and put it in an appropriate lead shielding.

Using a hypodermic syringe, introduce through the rubber stopper 2.5 to 10 ml of sterile and pyrogen-free sodium pertechnetate [^{99m}Tc] injection, radioactivity varying as a function of the volume from 92.5 to maximum 3700 MBq.

Sodium pertechnetate [^{99m}Tc] injection should comply with European Pharmacopoeia specifications.

Do not use a breather needle as the contents is under nitrogen: after introduction of the colume of sodium pertechnetate [^{99m}Tc] injection, without removing the needle, withdraw an equivalent volume of nitrogen in order to avoid excess pressure in the vial.

Shake for about 2 minutes and wait for 15 minutes before use.

The vial should be shaken before each withdrawal in order to homogenise suspension.

The syringe should be swirled immediately prior to injection to homogenise the suspension.

The homogeneousness of the suspension after preparation, pH, radioactivity and gamma spectrum should be checked before use.

The vial should never be opened and must be kept inside its lead shielding. The suspension should be removed aseptically through the stopper with a sterile lead protected syringe.

Determination of volume and activity of pertechnetate in relation with the number of MAA particles per dose.

In order to take into account the number of MAA particles per dose in the determination of volume and radioactivity of pertechnetate to prepare the radiopharmaceutical, charts have been performed and are described hereafter.

The proposed figures in the following tables are calculated from a mean value of 3 millions of MAA particles per vial.

-The first step allows to determine the volume of labelling of the vial as a function of the volume and the number of MAA particles to inject per dose.

The used formula is as follows:

Number of labelling = $\frac{\text{Number of MAA particles per vial} \times \text{Volume to inject}}{\text{Number of MAA particles to inject per dose.}}$

The tables 1 and 2 show examples for volumes to inject of 0.5, 0.8 and 1 ml.

- The second step allows to know the radioactivity to add in the vial for the labelling as a function of the radioactivity to inject and the previously set parameters. The used formula is as follows:

Total radioactivity of the vial= $\frac{\text{Radioactivity to inject} \times \text{Volume of labelling}}{\text{Volume to inject}}$

The total radioactivity of the vial is calculated for radioactivities to inject of 37, 74, 111 and 148 MBq. *See tables 3,4,5 and 6.*

- The third step will describe the decrease calculation taking into account the time of labelling and the time of injection. The decay table of ^{99m}Tc is presented in table 7.

TABLE 1

DETERMINATION OF THE LABELLING VOLUME
FROM VOLUME AND NUMBER OF MAA PARTICLES TO INJECT
AND CONSIDERING A VIAL CONTAINING 3 MILLIONS MAA PARTICLES

NUMBER OF MAA PARTICLES TO INJECT PER DOSE	VOLUME TO INJECT (ml)		
	0.5	0.8	1
600 000	2.5	4	5
500 000	3	4.8	6
480 000	3.1	5	6.3
428 000	3.5	5.6	7
400 000	3.75	6	7.5
375 000	4	6.4	8
343 000	4.4	7	8.7
330 000	4.5	7.3	9
300 000	5	8	10
267 000	5.6	9	
250 000	6	9.6	
240 000	6.25	10	
215 000	7		
188 000	8		
167 000	9		
150 000	10		

TABLE 1

- Labelling volume (ml)
- Injected volume (ml)
- Number of MAA particles to inject / dose

TABLE 2

DETERMINATION OF THE NUMBER OF INJECTED MAA PARTICLES AS A FUNCTION OF THE LABELLING VOLUME OF THE VIAL AND THE VOLUME TO INJECT AND CONSIDERING A VIAL CONTAINING 3 MILLIONS MAA PARTICLES

VOLUME OF LABELLING (ml)	VOLUME TO INJECT (ml)		
	0.5	0.8	1
3	500 000		
4	375 000	600 000	
5	300 000	480 000	600 000
6	250 000	400 000	500 000
7	215 000	343 000	428 000
8	188 000	300 000	375 000
9	167 000	267 000	330 000
10	150 000	240 000	300 000

□

□ Labelling volume (ml)

■ Injected volume (ml)

■ Number of MAA particles to inject/dose

TABLES 3, 4, 5 and 6

DETERMINATION OF THE RADIOACTIVITY TO ADD TO THE VIAL AS A FUNCTION OF THE LABELLING VOLUME, THE VOLUME AND THE RADIOACTIVITY TO INJECT AND CONSIDERING A VIAL CONTAINING 3 MILLIONS MAA PARTICLES

37 MBq				74 MBq				111 MBq				148 MBq			
	0.5	0.8	1		0.5	0.8	1		0.5	0.8	1		0.5	0.8	1
3	222	139	111		444				666				888		
4	296	185	148		592	370			888	555			1184	740	
5	370	231	185		740	462	370		1110	694	555		1480	925	740
6	444	277	222		888	555	444		1332	832	666		1776	1110	888
7	518	324	259		1036	647	518		1554	980	777		2072	1295	1036
8	592	370	296		1184	740	592		1776	1110	888		2368	1480	1184
9	666	416	333		1332	832	666		1998	1249	999		2664	1665	1332
10	740	462	370		1480	925	740		2220	1387	1110		2960	1850	1480

Injected activity (MBq)		Injected volume (ml)	
Total activity (MBq)		Labelling volume (ml)	

TABLE 7

99mTc (HALF-LIFE : 6.02 hours) DECAY TABLE											
H Min	%	H Min	%	H Min	%	H Min	%	H Min	%	H Min	%
0 05	99.05	2 05	78.67	4 05	62.49	6 05	49.64	8 05	39.43	10 05	31.32
0 10	98.10	2 10	77.92	4 10	61.89	6 10	49.16	8 10	39.05	10 10	31.02
0 15	97.16	2 15	77.18	4 15	61.30	6 15	48.69	8 15	38.68	10 15	30.72
0 20	96.23	2 20	76.44	4 20	60.72	6 20	48.23	8 20	38.61	10 20	30.43
0 25	95.32	2 25	75.71	4 25	60.14	6 25	47.77	8 25	37.94	10 25	30.14
0 30	94.41	2 30	74.99	4 30	59.56	6 30	47.31	8 30	37.58	10 30	29.85
0 35	93.50	2 35	74.27	4 35	58.99	6 35	46.86	8 35	37.22	10 35	29.57
0 40	92.61	2 40	73.56	4 40	58.43	6 40	46.41	8 40	36.87	10 40	29.28
0 45	91.73	2 45	72.86	4 45	57.87	6 45	45.97	8 45	36.51	10 45	29.00
0 50	90.85	2 50	72.16	4 50	57.32	6 50	45.53	8 50	36.17	10 50	28.73
0 55	89.98	2 55	71.47	4 55	56.77	6 55	45.10	8 55	35.82	10 55	28.45
1 00	89.12	3 00	70.79	5 00	56.23	7 00	44.66	9 00	35.48	11 00	28.18

TABLE 7

99mTc (HALF-LIFE : 6.02 hours) DECAY
TABLE

H %	H %	H %	H %	H %	H %
Min	Min	Min	Min	Min	Min
1 05 88.27	3 05 70.12	5 05 55.69	7 05 44.24	9 05 35.14	11 05 27.91
1 10 87.43	3 10 69.45	5 10 55.16	7 10 43.82	9 10 34.80	11 10 27.64
1 15 86.60	3 15 68.78	5 15 54.64	7 15 43.40	9 15 34.47	11 15 27.38
1 20 85.77	3 20 68.13	5 20 54.11	7 20 42.98	9 20 34.14	11 20 27.12
1 25 84.95	3 25 67.48	5 25 53.60	7 25 42.57	9 25 33.82	11 25 26.86
1 30 84.14	3 30 66.83	5 30 53.09	7 30 42.17	9 30 33.49	11 30 26.60
1 35 83.33	3 35 66.19	5 35 52.58	7 35 41.76	9 35 33.17	11 35 26.35
1 40 82.54	3 40 65.56	5 40 52.08	7 40 41.36	9 40 32.86	11 40 26.10

1 45 81.75	3 45 64.94	5 45 51.58	7 45 40.97	9 45 32.54	11 45 25.85
1 50 80.97	3 50 64.32	5 50 51.09	7 50 40.58	9 50 32.23	11 50 25.60
1 55 80.20	3 55 63.70	5 55 50.60	7 55 40.19	9 55 31.92	11 55 25.36
2 00 79.43	4 00 63.09	6 00 50.12	8 00 39.81	10 00 31.62	12 00 25.12

EXAMPLE FOR AN INJECTED VOLUME OF 1mL

The following table and curve allow to determine the number of MAA particles injected when volumes of labelling are 5 to 10 mL and when the volume to inject is 1 mL.

The proposed figures in the following tables are calculated from a mean value of 3 millions of MAA particles per vial.

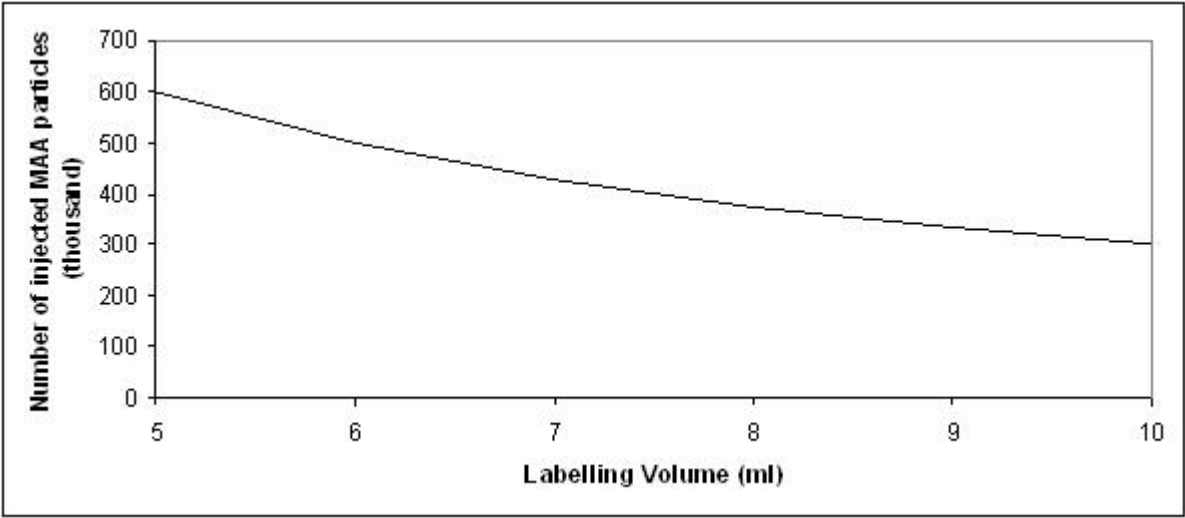
The formula used is:

Number of injected MAA particles =

Total number of MAA particles x Injected volume

Labelling Volume

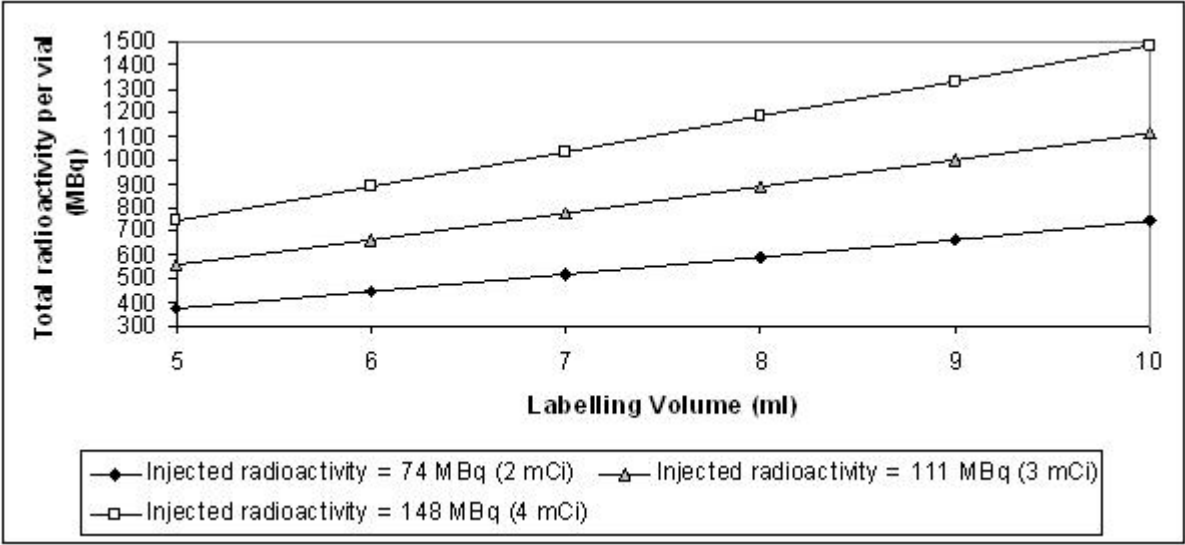
Volume of labelling (mL)	Number of injected MAA particles
5	600 000
6	500 000
7	428 600
8	375 000
9	333 300
10	300 000



The following table and graph allow to deduce **the total radioactivity to add to the vial** when the radioactivities to inject

are 74, 111 or 148 MBq with an injected volume of 1 mL and considering a vial containing 3 millions particles.

Volume of labelling (mL)	Total radioactivity per vial (MBq) with a radioactivity to inject of		
	74 MBq	111 MBq	148 MBq
5	370	555	740
6	444	666	888
7	518	777	1036
8	592	888	1184
9	666	999	1332
10	740	1110	1480



Quality control

The quality of labelling (radiochemical purity) could be checked according to the following procedure:

Method

Non-filterable radioactivity.

Materials and methods

- 1. Polycarbonate membrane filter 13 mm to 25 mm in diameter, 10 µm thick and with circular pores 3 µm in diameter.
- 2. 0.9% sodium chloride solution.
- 3. Miscellaneous: syringes, needles, 15 ml glass vials, appropriate counting assembly.

Procedure

1. Fit the membrane into a suitable holder.
2. Place 1 ml of the injection on the membrane, filter and collect in a vial (A).
3. Rinse the membrane with 2 ml of 0.9% sodium chloride solution and collect in the vial (A)
4. Measure the radioactivity of the filter (X) and the radioactivity of the vial A (Y), using an appropriate detection apparatus.
5. Calculations:
Calculate the percentage of technetium [^{99m}Tc] human albumin macroaggregates as follows:

$$\frac{X}{X+Y} \times 100$$

The radioactivity remaining on the membrane should be not less than 90.0% of the total radioactivity of the injection.

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