

# **AUSTRALIAN RADIATION LABORATORY**

## **Results of the Quality Assurance Testing Program for Radiopharmaceuticals 1995**

by

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## **ABSTRACT**

This report tabulates results obtained during 1995 for the Radiopharmaceutical Quality Assurance Test Program conducted by the Australian Radiation Laboratory.

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## INTRODUCTION

The Australian Radiation Laboratory conducts a Radiopharmaceutical Quality Assurance Test Program in which radiopharmaceuticals used in nuclear medicine in Australia are tested for compliance with specifications. Where the radiopharmaceutical is the subject of a monograph in the British Pharmacopoeia or the European Pharmacopoeia, then the specifications given in that Pharmacopoeia are adopted. Where a monograph is only available in the US Pharmacopoeia, then this specification is generally adopted. In other cases the specifications quoted have been adopted by this Laboratory and have no legal status. It should be noted that unless stated otherwise, the specifications listed apply at all times up to product expiry. Radionuclidic purity has been determined at the calibration time, except for Thallous [ $^{201}\text{Tl}$ ] Chloride Injection where the highest impurity level up to product expiry is quoted.

Samples for testing were obtained through commercial channels. All technetium-99m cold kits were reconstituted according to the directions in the package insert using Sodium Pertechnetate [ $^{99\text{m}}\text{Tc}$ ] Injection. Methods used for testing are described in the report ARL/TR093\*.

## RESULTS

The results of testing during 1995 are summarised in the following tables. Overall, 111 batches of 27 different types of radiopharmaceuticals were tested in 1995. Failure to meet full specifications was observed in 10 of the 111 batches of radiopharmaceuticals tested (9.0%).

Non-compliance of the vial label was observed in one of the ten batches failing specification and was the sole cause of product failure for this batch. Vial label non-compliance consisted of, absence of volume in the vial.

Six batches failed the biodistribution test but in no case did this involve failure in the distribution for the target organ/s. One batch failed due to low femur/blood ratio only, four batches had higher than specified liver uptake and one batch had too high liver and kidney uptake.

Other non-compliance was pH out of range for one batch, higher than specified radionuclidic content for one batch and high benzyl alcohol content for one batch.

The failure rate is of the same order as that reported in previous years.

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\*ARL/TR093. "Quality Assurance of Radiopharmaceuticals - Specifications and Test Procedures" by J. Baldas, J. Bonnyman, S.F. Colmanet, Z. Ivanov and R.A. Lauder, Second Edition, 1990. Obtainable from The Librarian, Australian Radiation Laboratory, Lower Plenty Road, Yallambie, Victoria 3085, Australia.

The following abbreviations are used in the tables -

AMER	-	Amersham International plc, Buckinghamshire, UK
ARI	-	Australian Radioisotopes, Lucas Heights, Sydney, Australia
DuP	-	E. I. du Pont de Nemours and Co., Billerica, MA, USA
MALL	-	Mallinckrodt Inc, St Louis, MO, USA
MALL(H)	-	Mallinckrodt Diagnostica (Holland)
RADPH	-	Radpharm Scientific, Belconnen, ACT, Australia
MRI	-	Melbourne Radioisotopes, Bundoora, VIC, Australia
N.D.	-	Not detected
N.A.	-	Not applicable
†	-	Not determined
LSC	-	Liquid scintillation counting

## SODIUM PHOSPHATE<sup>[32P]</sup> INJECTION

SPECIFICATIONS		SUPPLIER	ARI	AMER	ARI	AMER
		LOT/BATCH No.	55262	400	56056	416
		CALIB. DATE	21/08/95	28/08/95	11/12/95	18/12/95
		EXPIRY DATE	12/09/95	28/09/95	01/01/96	18/01/96
Appearance	Clear, colourless solution		Pass	Pass	Pass	Pass
Particulate matter	None visible		N.D.	N.D.	N.D.	N.D.
Radionuclidic content	90-110% of stated		96	103	102	101
Radionuclidic purity	Beta spectrum complies with standard (LSC)		†	†	Pass	Pass
pH	6.0 - 8.0		6.5	7.0	6.0	7.0
Radiochemical purity	≥ 95% as orthophosphate	INIT	99.8	99.9	99.5	99.8
		EXP.	99.1	99.4	99.6	99.6
Specific activity	≥ 11 MBq/mg orthophosphate		167	77	152	70
Label	Complies		Complies	Complies	Complies	Complies

**CHROMIUM[<sup>51</sup>Cr] EDETATE INJECTION**

		SUPPLIER	ARI	AMER
		LOT/BATCH No.	55058	330
		CALIB. DATE	01/08/95	04/09/95
SPECIFICATION		EXPIRY DATE	01/09/95	04/11/95
Appearance	Clear solution with a purple tinge		Pass	Pass
Particulate matter	None visible		N.D.	N.D.
Identification	Gamma spectrum		Pass	Pass
Radionuclidic content	90-110% of stated		113	103
Radionuclidic purity	No other radionuclides detected. by gamma spectrometry		N.D.	N.D.
pH	3.5 - 6.5		5.5	4.0
Chemical purity (mg/mL)				
1) Total edetate			8.7	2.2
2) Uncomplexed edetate			7.0	1.6
3) Total chromium	≤ 1mg/mL		0.1	0.3
Radiochemical purity (%)				
1) Chromic ion		INIT.	0.6	0.3
2) Chromate ion			2.4	2.6
3) Cr-edetate	≥ 95% as <sup>51</sup> Cr-edetate		97.0	97.1
		EXP.	0.2	0.4
			2.8	2.7
			97.0	96.9
Benzyl alcohol	90-110%		N.A.	98
Label	Complies		Complies	Complies

**SODIUM CHROMATE[<sup>51</sup>Cr] SOLUTION**

SPECIFICATIONS		SUPPLIER	ARI	AMER
		LOT/BATCH No.	55059	400
		CALIB. DATE	01/08/95	30/08/95
		EXPIRY DATE	01/09/95	30/10/95
Appearance	Clear, colourless/faintly yellow solution		Pass	Pass
Particulate matter	None visible		N.D.	N.D.
Identification	Gamma spectrum		Pass	Pass
Radionuclidic content	90-110% of stated		109	110
Radionuclidic purity	No other radionuclides detected by gamma spectrometry		N.D.	N.D.
Radiochemical purity	≥ 90% as chromate	INIT.	99.8	99.9
		EXP.	99.7	99.8
pH	6.0 - 8.5		6.5	6.0
Specific activity	≥ 0.37 GBq/mg chromate ion		1.9	13.7
Label	Complies		Complies	Complies

**CYANOCOBALAMIN[<sup>57</sup>Co] CAPSULES**

SPECIFICATIONS		SUPPLIER	AMER
		LOT/BATCH No.	376
		CALIB. DATE	02/02/96
		EXPIRY DATE	02/04/96
Appearance	Gelatin capsule		Pass
Identification	Gamma spectrum		Pass
Radionuclidic content	85-115% of stated		94
Radionuclidic purity	≤ 0.1% total <sup>56</sup> Co+ <sup>58</sup> Co and all other radionuclides		N.D.
Radiochemical purity	≥ 90% as cyanocobalamin	INIT.	92.3
		EXP.	93.8
Dissolution test	≥ 70%		88
Label	Complies		Complies

**CYANOCOBALAMIN[<sup>58</sup>Co] SOLUTION**

SPECIFICATIONS		SUPPLIER	AMER
		LOT/BATCH No.	444
		CALIB. DATE	25/08/95
		EXPIRY DATE	28/10/95
Appearance	Clear , colourless solution		Pass
Identification	Gamma spectrum		Pass
Radionuclidic content	90-110% of stated		102
Radionuclidic purity	≤ 1% <sup>60</sup> Co ≤ 2% <sup>57</sup> Co+ <sup>60</sup> Co and all other radionuclides		N.D. N.D.
pH	4.0 - 6.0		4.5
Radiochemical purity	≥ 90% as cyanocobalamin	INIT. EXP.	92.2 91.6
Benzyl alcohol	90 - 110 % of stated		104
Label	Complies		Complies

## GALLIUM[<sup>67</sup>Ga] CITRATE INJECTION

		SUPPLIER	ARI	ARI	ARI	MALL(H)
		LOT/BATCH No.	54137	55468	55996	135
		CALIB. DATE	21/03/95	05/09/95	21/11/95	28/12/95
SPECIFICATIONS		EXPIRY DATE	28/03/95	12/09/95	28/11/95	07/01/96
Appearance	Clear, colourless solution		Pass	Pass	Pass	Pass
Identification						
1) Gamma spectrum	Complies		Pass	Pass	Pass	Pass
2) Citrate presence	Present		Pass	Pass	Pass	Pass
Particulate matter	None visible		N.D.	N.D.	N.D.	N.D.
Radionuclidic	90-110% of stated		104	103	104	104
Radionuclidic purity	≤ 0.2% <sup>66</sup> Ga ≤ 0.1% all other gamma radionuclidic impurities		N.D. N.D.	N.D. N.D.	N.D. N.D.	N.D. N.D.
pH	5.0 - 8.0		6.5	6.5	6.5	6.5
Radiochemical purity	≥ 97.0% as <sup>67</sup> Ga-citrate	INIT. EXP.	98.6 98.6	99.1 99.0	99.9 98.9	† 97.4
Zinc limit test	≤ 20 µg/mL Zn		Pass	Pass	Pass	Pass
Benzyl alcohol	90-110% of stated		103	104	102	99
Label	Complies		Complies	Complies	Complies	Fail

**SELENONORCHOLESTENOL<sup>[75Se]</sup> INJECTION**

SPECIFICATIONS		SUPPLIER	AMER
		LOT/BATCH No.	328
		CALIB. DATE	11/09/95
		EXPIRY DATE	11/10/95
Appearance	Clear, colourless/faintly yellow solution		Pass
Particulate matter	None visible		N.D.
Radionuclidic content	90-110% of stated		98
Radionuclidic purity	No other radionuclides detected by gamma spectrometry		N.D.
Radiochemical purity	≥ 70% as Selenonorcholestenol	INIT.	80
		EXP.	81
pH	2.5 - 3.5		3.0
Label	Complies		Complies

## TECHNETIUM[<sup>99m</sup>Tc] CHROMATOGRAPHIC GENERATOR

SPECIFICATIONS		SUPPLIER LOT/BATCH No. CALIB. DATE EXPIRY DATE	ARI 54193/074 27/03/95 10/04/95			ARI 554462/073 01/05/95 15/05/95			ARI 55130/075 24/07/95 07/08/95			ARI 56196/078 18/12/95 01/01/96		
Maximum surface radiation dose	< 2 mGy/hr		1.0			0.6			1.5			0.8		
Dose at 1 m	< 0.10 mGy/hr		0.05			0.04			0.09			0.04		
			MAX	MIN	AVG	MAX	MIN	AVG	MAX	MIN	AVG	MAX	MIN	AVG
pH	4.0 - 8.0		6.0	6.0	6.0	6.0	6.0	6.0	6.0	5.5	5.7	6.0	6.0	6.0
Radiochemical purity	≥ 95% <sup>99m</sup> TcO <sub>4</sub> <sup>-</sup>		100	100	100	100	100	100	100	100	100	100	100	100
Milking efficiency			81	72	79	99	94	96	89	81	88	96	93	95
Radionuclidic purity	≤ 0.1% <sup>99</sup> Mo		N.D.			N.D.			1.5E-6			N.D.		
	≤ 5E-3% <sup>131</sup> I		N.D.			N.D.			N.D.			N.D.		
	≤ 5E-3% <sup>103</sup> Ru		N.D.			N.D.			N.D.			N.D.		
	≤ 6E-5% <sup>89</sup> Sr		†			†			†			†		
	≤ 6E-6% <sup>90</sup> Sr		†			†			†			†		
	≤ 0.01% All other radionuclides		N.D.			N.D.			N.D.			N.D.		
	≤ 1E-7% Alpha emitters		†			†			†			†		
Aluminium content	≤ 20 µg/mL		3.1	2.6	2.9	2.7	2.3	2.5	2.8	2.0	2.4	†	†	†

**SODIUM PERTECHNETATE[<sup>99m</sup>Tc] INJECTION (FISSION)**

		SUPPLIER	MRI	MRI	MRI	MRI	MRI
		LOT/BATCH No.	170195	200495	230895	081195	051295
		CALIB. DATE	17/01/95	20/04/95	23/08/95	08/11/95	05/12/95
SPECIFICATIONS		CALIB. TIME	0900hrs	0900hrs	0900hrs	0900hrs	0900hrs
Appearance	Clear, colourless solution		Pass	Pass	Pass	Pass	Pass
Identity	Gamma spectrum		Pass	Pass	Pass	Pass	Pass
Particulate matter	None visible		N.D.	N.D.	N.D.	N.D.	N.D.
Radionuclidic content	90-110% of stated		105	103	107	107	105
pH	4.5 - 7.5		6.0	6.0	6.0	6.0	6.0
Chemical purity							
Aluminium content	≤ 20 µg/mL		2.6	2.9	3.0	2.8	†
Radionuclidic purity	≤ 0.1% <sup>99</sup> Mo		1.07E-6	N.D.	1.36E-4	N.D.	N.D.
	≤ 5E-3% <sup>131</sup> I		N.D.	N.D.	N.D.	N.D.	N.D.
	≤ 6E-5% <sup>89</sup> Sr		†	†	†	†	†
	≤ 6E-5% <sup>90</sup> Sr		†	†	†	†	†
	≤ 1E-7% Alpha emitters		†	†	†	†	†
	≤ 0.01% All other gamma emitters		N.D.	N.D.	<sup>103</sup> Ru 1.05E-4	N.D.	N.D.
Radiochemical purity	≥ 95% as <sup>99m</sup> TcO <sub>4</sub> <sup>-</sup>	INIT.	99.6	99.8	99.9	100	99.9
	≤ 2% as colloidal material		0.4	0.2	0.1	0.0	0.1
		EXP.	99.4	99.6	99.7	100	99.9
			0.6	0.4	0.3	0	0.1
Label	Complies		Complies	Complies	Complies	Complies	Complies

**KIT FOR THE PREPARATION OF TECHNETIUM[<sup>99m</sup>Tc] DISOFENIN INJECTION (PIPIDA)**

SPECIFICATIONS		SUPPLIER LOT/BATCH No. EXPIRY DATE	DuP 2587 01/05/96
Appearance before reconstitution	Freeze dried solid		Pass
Particulate matter	Free of any particulate matter after reconstitution		N.D.
pH	4.0 - 5.0 after reconstitution		4.5
Radiochemical purity	≥ 90.0% as <sup>99m</sup> Tc-Disofenin	INIT.	95.9
	≤ 10.0% as <sup>99m</sup> TcO <sub>4</sub> <sup>-</sup> + colloidal <sup>99m</sup> Tc	EXP.	4.1
Stannous tin content	≥ 0.24 mg SnCl <sub>2</sub> .2H <sub>2</sub> O/vial *		0.33
Biological distribution	≥ 70% gall bladder + small & large intestines	INIT.	71.4
	≤ 10% kidneys		2.7
	≤ 10% liver		3.8
	≤ 3% stomach		1.4
	≤ 3% blood		2.7
		EXP.	
Label	Complies		Complies

\*Value given in label/product information.

**KIT FOR THE PREPARATION OF TECHNETIUM[<sup>99m</sup>Tc] ETIFENIN INJECTION (DIDA)**

SPECIFICATIONS		SUPPLIER LOT/BATCH No. EXPIRY DATE	RADPH 1194 22/07/95	RADPH 1244 31/03/96
Appearance before re-constitution	Freeze dried solid		Pass	Pass
Particulate matter	Free of any particulate matter after reconstitution		N.D.	N.D.
pH	4.0 - 6.0 after reconstitution		5.5	5.5
Radiochemical purity	≥ 95.0% as <sup>99m</sup> Tc-Etifenin	INIT.	96.1	97.4
	≤ 5.0% as <sup>99m</sup> TcO <sub>4</sub> <sup>-</sup> + colloidal <sup>99m</sup> Tc		3.9	2.6
		EXP.	95.1 4.9	
Stannous tin content	0.42 mg SnCl <sub>2</sub> /vial *		0.30	0.40
Biological distribution	≥ 80% gall bladder + small & large intestines	INIT.	82.3	85.6
	≤ 3% liver		5.4	4.8
	≤ 2% kidneys		2.5	1.7
		EXP.	87.8 4.9 1.5	
Label	Complies		Complies	Complies

\*Value given in label/product information.

**KIT FOR THE PREPARATION OF TECHNETIUM[<sup>99m</sup>Tc] EXAMETAZIME INJECTION (CERETEC)**

SPECIFICATIONS		SUPPLIER LOT/BATCH No. EXPIRY DATE	AMER A520S 15/11/95	AMER A540S 01/03/96
Appearance before reconstitution	Freeze dried solid		Pass	Pass
Particulate matter	Free of any particulate matter after reconstitution		N.D.	N.D.
pH	9.0 - 9.8 after reconstitution		9.0	9.2
Radiochemical purity	≥ 80.0% as <sup>99m</sup> Tc-Exametazime	INIT .	†	85.4
	≤ 5.0% as hydrolysed <sup>99m</sup> Tc		†	0.4
	≤ 10.0% as hydrolysed <sup>99m</sup> Tc + <sup>99m</sup> TcO <sub>4</sub> <sup>-</sup>		†	2.2
		EXP.	94.8 3.8 5.2	
Stannous tin content	7.6 µg SnCl <sub>2</sub> .2H <sub>2</sub> O/vial *		7.4	8.8
Biological distribution	≥ 1.5% brain	INIT .	†	1.6
	≤ 20% intestines		†	12.4
	≤ 15% liver		†	10.8
		EXP.	1.8 10.1 7.6	
Label	Complies		Complies	Complies

\*Value given in label/product information.

**KIT FOR THE PREPARATION OF TECHNETIUM[<sup>99m</sup>Tc] GLUCONATE INJECTION**

SPECIFICATIONS		SUPPLIER LOT/BATCH No. EXPIRY DATE	ARI 1198 05/02/95
Appearance before re-constitution	Freeze dried solid		Pass
Particulate matter	Free of any particulate matter after reconstitution		N.D.
pH	4.0 - 8.0 after reconstitution		6.5
Radiochemical purity	1) ≥90% as <sup>99m</sup> Tc-Gluconate	INIT.	†
	2) as colloidal <sup>99m</sup> Tc		†
	3) as <sup>99m</sup> TcO <sub>4</sub> <sup>-</sup>		†
	2) + 3) ≤ 10%	EXP.	98.2 0.8 1.0
Stannous tin content	≥60% of stated		†
Biological distribution	≥ 15% kidneys	INIT.	†
	≤ 5% blood		†
	≤ 15% gastrointestinal tract		†
	≤ 5% liver		†
		EXP.	18.9 3.2 9.7 1.3
Label	Complies		Complies

**KIT FOR THE PREPARATION OF TECHNETIUM[<sup>99m</sup>Tc] LABELLED RED BLOOD CELLS (RBC)**

SPECIFICATIONS		SUPPLIER LOT/BATCH No. EXPIRY DATE	MALL 0683060 06/11/95	MALL 0685035 25/04/97
Appearance	i) Vial - freeze dried solid ii) Syringes I & II- clear solutions		Pass Pass	Pass Pass
Particulate matter	Free of any particulate matter		N.D.	N.D.
pH	11 - 13 Syringe I 4.5 - 5.5 Syringe II		12 5	12 5
pH	5.5 - 8.0 after reconstitution		6.3	5.9
Stannous tin content	≥ 50 µg as SnCl <sub>2</sub> .2H <sub>2</sub> O/vial*		120	124
Sodium hypochlorite	0.08 - 0.11 % w/v		0.10	0.10
Labelling efficiency	≥ 90% minimum labelling of rat blood at 20 - 30 min.	INIT. EXP.	† 98.0	98.0
Label	Complies		Complies	Complies

\*Value given in label/product information.

**KIT FOR THE PREPARATION OF TECHNETIUM[<sup>99m</sup>Tc] MACROSALB INJECTION (MAA)**

		SUPPLIER	MALL	MALL	MALL	MALL	DuP
		LOT/BATCH No.	0934018	0934027	0935023	0935041	7204
SPECIFICATIONS		EXPIRY DATE	08/06/95	08/08/95	22/05/96	14/08/96	01/01/97
Appearance before re-constitution	Freeze dried solid		Pass	Pass	Pass	Pass	Pass
Appearance after re-constitution	Suspension of white or faintly yellow particles which may settle on standing		Pass	Pass	Pass	Pass	Pass
pH	3.8 - 7.5		4.5	4.0	4.0	4.5	4.4
Radiochemical purity	1) ≥ 90% in aggregate 2) as soluble <sup>99m</sup> Tc-Albumin 3) as free pertechnetate 2) + 3) ≤ 10%	INIT.	97.9	98.3	98.9	99.5	98.7
			0.4	0.4	0.3	0.3	1.1
			1.7	1.3	0.8	0.2	0.2
		EXP.	99.3	98.9			
			0.3	0.9			
			0.4	0.2			
Particle size	None > 150 μm		Pass	Pass	Pass	Pass	Pass
Biological distribution	≥ 80% in lungs		84.2	89.5	89.4	95.5	94.8
	≤ 5% in liver + spleen		1.5	1.0	0.9	0.6	1.0
Label	Complies		Complies	Complies	Complies	Complies	Complies





**KIT FOR THE PREPARATION OF TECHNETIUM[<sup>99m</sup>Tc] MERTIATIDE INJECTION (MAG3)**

SPECIFICATIONS		SUPPLIER	MALL	MALL	MALL	MALL
		LOT/BATCH No.	0963003B	0964004B	0964009	0965007B
		EXPIRY DATE	05/05/95	22/04/96	21/07/96	10/08/97
Appearance before re-constitution	Freeze dried white fluffy solid		Pass	Pass	Pass	Pass
Particulate matter	Free of any particulate matter after reconstitution		N.D.	N.D.	N.D.	N.D.
pH	4.5 - 6.5 after reconstitution		6.0	6.0	6.0	5.5
Radiochemical purity	≥ 90% as <sup>99m</sup> Tc-MAG3 ≤ 2% as hydrolyzed + reduced <sup>99m</sup> Tc	INIT.	99.6	99.6	99.5	99.7
		EXP.	0.4	0.4	0.5	0.3
			98.9	99.7		
			1.1	0.3		
Stannous tin content	≥ 50 µg SnCl <sub>2</sub> .2H <sub>2</sub> O/vial *		62	58	82	70
Biological distribution			Pass	Pass	Pass	Pass
Label	Complies		Complies	Complies	Complies	Complies

\*Value given in label/product information.

**KIT FOR THE PREPARATION OF TECHNETIUM[<sup>99m</sup>Tc] OXIDRONATE INJECTION (HDP)**

SPECIFICATIONS		SUPPLIER	MALL	MALL	MALL	MALL
		LOT/BATCH No.	0994001A	0994011	0994023	0995021
		EXPIRY DATE	21/01/95	07/06/95	18/10/95	28/09/96
Appearance before re-constitution	Freeze dried solid		Pass	Pass	Pass	Pass
Particulate matter	Free of any particulate matter after reconstitution		N.D.	N.D.	N.D.	N.D.
pH	2.5 - 7.0 after reconstitution		5.5	5.5	5.0	5.0
Radiochemical purity	≥ 90.0% as <sup>99m</sup> Tc-HDP	INIT.	96.3	97.1	96.6	97.0
	≤ 10.0% as <sup>99m</sup> TcO <sub>4</sub> + colloidal <sup>99m</sup> Tc		3.7	2.9	3.4	3.0
		EXP.	98.8	99.6	94.2	
			1.2	0.4	5.8	
Stannous tin content	≥ 60% of stated		†	†	†	†
Biological distribution	≥ 1.0% attached to one femur		4.4	3.2	3.0	3.9
	≤ 5.0% in the liver		14.8	3.5	4.7	7.9
	≤ 5.0% in the kidneys		1.7	2.2	1.7	3.1
Label	Complies		Complies	Complies	Complies	Complies





**KIT FOR THE PREPARATION OF TECHNETIUM[<sup>99m</sup>Tc] SESTAMIBI INJECTION (CARDIOLITE)**

	SPECIFICATIONS	SUPPLIER LOT/BATCH No. EXPIRY DATE	DuP 3592MKA Jan 1995	DuP 3608WKA 01/05/96
Appearance	Freeze dried solid with no evidence of moisture		Pass	Pass
Particulate matter	Free of any particulate matter after reconstitution		N.D.	N.D.
pH	5.0 - 6.0 after reconstitution		5.0	5.5
Radiochemical Purity	1) $\geq 90\%$ as <sup>99m</sup> Tc-sestambi 2) as <sup>99m</sup> TcO <sub>4</sub> <sup>-</sup> 3) as colloidal <sup>99m</sup> Tc $2 + 3 \leq 10\%$	INIT.	97.5	97.1
		EXP.	1.6 0.9 96.5 0.6 2.8	0.6 2.3 98.1 0.7 1.2
Stannous tin content	75 $\mu\text{g}$ SnCl <sub>2</sub> .2H <sub>2</sub> O * (25 $\mu\text{g}$ minimum)		83	56
Label	Complies		Complies	Complies

\*Value given in label/product information.

**KIT FOR THE PREPARATION OF TECHNETIUM[<sup>99m</sup>Tc] SUCCIMER INJECTION (DMSA)**

SPECIFICATIONS		SUPPLIER LOT/BATCH No. EXPIRY DATE	RADPH 1215 20/07/95	RADPH 1237 23/10/95	RADPH 1275 30/06/96
Appearance before re constitution	Freeze dried white fluffy solid		Pass	Pass	Pass
Particulate matter	Free of any particulate matter after reconstitution		N.D.	N.D.	N.D.
pH	2.3 - 3.5 after reconstitution		3.0	3.5	3.5
Radiochemical purity	≥ 95.0% as <sup>99m</sup> Tc - DMSA ≤ 2.0% as <sup>99m</sup> TcO <sub>4</sub> <sup>-</sup>	INIT.	99.6 0.4	99.6 0.4	99.9 0.1
		EXP.	99.8 0.2	99.7 0.3	
Stannous tin content	≥ 60% as stated		†	†	†
Biological distribution	≥ 40% in kidneys ≤ 10.0% in liver ≤ 2.0% in stomach ≤ 5.0 % in lungs	INIT.	43.9 5.3 0.3 0.6	46.3 5.7 0.3 0.5	44.8 3.1 0.3 0.4
		EXP.	42.2 3.3 0.3 0.4	44.5 5.5 1.8 0.6	
Label	Complies		Complies	Complies	Complies

**KIT FOR THE PREPARATION OF TECHNETIUM[<sup>99m</sup>Tc] TIN PYROPHOSPHATE INJECTION (PYP)**

	SPECIFICATIONS	SUPPLIER LOT/BATCH No. EXPIRY DATE	RADPH 1160 24/03/95	RADPH 1193 08/07/95	MALL 0945008 13/09/95	MALL 0945013 31/01/96	RPHARM 1249 17/07/96
Appearance before re-constitution	Freeze dried solid		Pass	Pass	Pass	Pass	Pass
Particulate matter	Free of any particulate matter after reconstitution		N.D.	N.D.	N.D.	N.D.	N.D.
pH	6.0 - 7.0 after reconstitution		5.0	5.0	5.5	5.5	5.3
Radiochemical Purity	1) ≥ 90% as <sup>99m</sup> Tc-PYP 2) as <sup>99m</sup> TcO <sub>4</sub> <sup>-</sup> 3) as colloidal <sup>99m</sup> Tc 2 + 3 ≤ 10%	INIT.	97.4	95.8	93.8	95.3	98.3
			1.1	2.9	3.7	4.0	1.3
			1.5	1.3	2.5	0.7	0.4
		EXP.	97.8	98.3	95.6	94.6	
			1.5	1.3	3.9	2.3	
			0.7	0.4	0.5	3.1	
Pyrophosphate content	1-50 mg/mL pyrophosphate		30	26	12	12	18
Stannous tin content	9.0 mg SnCl <sub>2</sub> /vial *		8.0	6.2	-	-	10.4
	3.2 - 4.4 mg SnCl <sub>2</sub> .2H <sub>2</sub> O/vial *		-	-	4.1	3.8	-
Label	Complies		Complies	Complies	Complies	Complies	Complies

\*Value given in label/product information.

## KIT FOR THE PREPARATION OF TECHNETIUM[<sup>99m</sup>Tc] COLLOID INJECTION

SPECIFICATIONS		SUPPLIER	AMER*	AMER*	RADPH**	RADPH**	AMER*	AMER*	RADPH**
		LOT/BATCH No.	A112	A120	1162	1208	A136	A138	1270
		EXPIRY DATE	19/01/95	05/04/95	07/04/95	27/09/95	20/02/96	27/05/96	27/08/96
Appearance before re-constitution	All components are colourless and free from particulate matter		Pass	Pass	Pass	Pass	Pass	Pass	Pass
Appearance after re-constitution	Clear to slightly hazy colloid		Pass	Pass	Pass	Pass	Pass	Pass	Pass
pH	4.0 - 7.0		5.5	6.0	4.5	5.0	5.5	6.0	5.0
Radiochemical purity	≥ 95% as <sup>99m</sup> Tc colloid	INIT.	98.5	97.6	95.6	†	97.9	97.8	97.6
		EXP.	99.6	97.8	99.7	97.1	99.8		
Particle size	No flocculation		Pass	Pass	Pass	Pass	Pass	Pass	Pass
Biological distribution	≥ 80% in liver + spleen ≤ 5% in lungs	INIT.	†	90.4	93.7	†	92.8	97.7	97.6
			†	0.4	1.9	†	0.4	0.2	0.5
		EXP.	96.6	91.1	96.2	95.0	93.2		
			0.2	0.6	0.7	1.6	0.4		
Label	Complies		Complies	Complies	Complies	Complies	Complies	Complies	Complies

\* Technetium[<sup>99m</sup>Tc] Tin Colloid

\*\*Technetium[<sup>99m</sup>Tc] Calcium Phytate



**SODIUM IODIDE<sup>131</sup>I CAPSULES**

SPECIFICATIONS		SUPPLIER	ARI	ARI*	ARI*	ARI	ARI*	ARI	ARI*	ARI
		LOT/BATCH No.	54932	54891	55467	55550	55995	56038	56132	56174
		CALIB. DATE	26/06/95	26/06/95	04/09/95	13/09/95	20/11/95	27/11/95	11/12/95	18/12/95
		EXPIRY DATE	10/07/95	10/07/95	18/09/95	27/09/95	14/12/95	11/12/95	25/12/95	01/01/96
Appearance	Gelatine capsule		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Identification	Gamma spectrum		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Radionuclidic content	90-110% of stated		99.9	98.8	97.4	101.3	100.4	99.4	102.8	98.2
Radionuclidic purity	≤ 0.1% <sup>133</sup> I, <sup>135</sup> I and all other radionuclides		N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
Radiochemical purity	≥ 95% of activity as iodide	INIT.	98.1	99.7	98.9	98.9	99.2	97.8	99.2	97.6
		EXP.	98.6	99.2	99.9	98.5	99.4	97.9	99.3	97.3
Label	Complies		Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies

\* Therapy doses



**THALLOUS[<sup>201</sup>Tl] CHLORIDE INJECTION**

SPECIFICATIONS		SUPPLIER	ARI	ARI	ARI	MALL
		LOT/BATCH No.	54139	55471	55998	00100/001
		CALIB. DATE	20/03/95	04/09/95	20/11/95	27/12/95
		EXPIRY DATE	25/03/95	09/09/95	25/11/95	03/01/96
Appearance	Clear, colourless solution		Pass	Pass	Pass	Pass
Identification	Gamma spectrum		Pass	Pass	Pass	Pass
Particulate matter	None visible		N.D.	N.D.	N.D.	N.D.
Radionuclidic content	90-110% of stated		104	101	106	105
Radionuclidic purity	≤ 2.7% <sup>202</sup> Tl at expiry		0.2	0.3	0.2	0.9
	≤ 2.0% <sup>200</sup> Tl at calibration		N.D.	N.D.	N.D.	N.D.
	≤ 0.3% <sup>203</sup> Pb at calibration		N.D.	N.D.	N.D.	N.D.
pH	4.5 - 7.0		5.7	5.3	5.3	6.0
Radiochemical purity	≥ 95.0% Tl(I)	INIT.	100	100	99.9	†
		EXP.	99.8	100	99.9	99.2
Chemical purity	≤ 2 µg/mL Tl		0.04	0.36	0.3	0.24
Benzyl alcohol	90-110% of stated		108	116	100	N.A.
Label	Complies		Complies	Complies	Complies	Complies