

AUSTRALIAN RADIATION PROTECTION AND NUCLEAR SAFETY AGENCY

Results of the Quality Assurance Testing
Program for Radiopharmaceuticals 2000

by

J Baldas, Z Ivanov and I Bokor

Technical Report 133
ISSN 0157-1400
February 2002

LOWER PLENTY ROAD
YALLAMBIE VIC. 3085
TELEPHONE. +61 3 9433 2211
FAX: +61 3 9432 1835

Copyright Notice and Disclaimer

This work is copyright to the Commonwealth of Australia through the Australian Radiation Protection and Nuclear Safety Agency ('ARPANSA'). You may copy, reproduce, download, display, print and reproduce this material in unaltered form only (retaining this notice) for your personal, research or other non-commercial use or use within your organisation, but it must not be sold for commercial gain. All other rights are reserved, apart from any use as permitted under the *Copyright Act 1968*. Requests and inquiries concerning reproduction and rights should be addressed to the Information Officer, Australian Radiation Protection and Nuclear Safety Agency, Lower Plenty Road, Yallambie, Melbourne, Victoria. 3085.

All care has been taken in the preparation of this work and its conclusions. However, where the data or results presented are utilised by third parties outside of any intended purpose of this work, ARPANSA or the Commonwealth of Australia, shall not be liable for any special, indirect, consequential or other damages whatsoever resulting from such use. Nor will ARPANSA or the Commonwealth of Australia be liable for any damages arising from or in connection with any errors or omissions that have inadvertently occurred in this work.

ABSTRACT

This report tabulates results obtained during 2000 for the Radiopharmaceutical Quality Assurance Test Program conducted by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

CONTENTS

	<i>Page No.</i>
Introduction	1
Abbreviations	2
Results:	
<i>Sodium Phosphate</i> [³² P] <i>Injection</i>	3
<i>Chromium</i> [⁵¹ Cr] <i>Edetate Injection</i>	4
<i>Sodium Chromate</i> [⁵¹ Cr] <i>Solution</i>	5
<i>Gallium</i> [⁶⁷ Ga] <i>Citrate Injection</i>	6
<i>Sodium Pertechnetate</i> [^{99m} Tc] <i>Injection (Fission)</i>	7
Cold Kits for the Preparation of -	
<i>Technetium</i> [^{99m} Tc] <i>Etifenin Injection (DIDA)</i>	8
<i>Technetium</i> [^{99m} Tc] <i>Exametazime Injection (CERETEC)</i>	9
<i>Technetium</i> [^{99m} Tc] <i>Macrosalb Injection (MAA)</i>	10
<i>Technetium</i> [^{99m} Tc] <i>Medronate Injection (MDP)</i>	11
<i>Technetium</i> [^{99m} Tc] <i>Mertiatide Injection (MAG3)</i>	12
<i>Technetium</i> [^{99m} Tc] <i>Oxidronate Injection (HDP)</i>	13
<i>Technetium</i> [^{99m} Tc] <i>Pentetate Injection (DTPA)</i>	14
<i>Technetium</i> [^{99m} Tc] <i>Succimer Injection (DMSA)</i>	15
<i>Technetium</i> [^{99m} Tc] <i>Tin Pyrophosphate Injection (PYP)</i>	16
<i>Technetium</i> [^{99m} Tc] <i>Colloidal Injection</i>	17
<i>Sodium Iodide</i> [¹³¹ I] <i>Capsules</i>	18
<i>Sodium Iodide</i> [¹³¹ I] <i>Injection</i>	19
<i>Thallous</i> [²⁰¹ Tl] <i>Chloride Injection</i>	20

INTRODUCTION

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) 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 these Pharmacopoeias 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 Agency 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 expiry time, except for Thallous^[201Tl] Chloride Injection where the impurity levels both at calibration and expiry are 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^[99mTc] Injection. Pharmacopoeia methods are used for testing, together with some additional methods described in the report ARL/TR093*.

RESULTS

The results of testing during 2000 are summarised in the following tables. Overall, 37 batches of 18 different types of radiopharmaceuticals were tested. Failure to meet full specifications was observed in 3 of the 38 batches of radiopharmaceuticals tested (8 %).

Non-compliance of the vial label was observed in two of the three batches failing specification and was the only non-compliance for these batches. The vial label non-compliance consisted of the absence of a statement as to the presence or absence of a microbiological preservative.

Other non-compliance was slightly low pH in one batch. Regrettably, due to staff and resource reductions, ARPANSA is now no longer able to perform animal testing as part of the ARPANSA Quality Assurance Test Program. The Biological Distribution specifications have been retained in the Report for the sake of completeness only.

The proportion of non-compliance of radiopharmaceuticals is of the same order as that reported in previous years.

*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, ARPANSA, Lower Plenty Road, Yallambie, Victoria 3085, Australia.

ABBREVIATIONS

The following abbreviations are used in the tables -

AMER	-	Nycomed Amersham plc, UK
ARI	-	Australian Radioisotopes, Lucas Heights, Sydney, Australia
MALL	-	Mallinckrodt Inc, St Louis, MO, USA
MALL(H)	-	Mallinckrodt Diagnostica (Holland)
RADPH	-	Radpharm Scientific, Belconnen, ACT, Australia
RC	-	Radiopharmacy Central, Tullamarine, VIC, Australia
N.D.	-	Not detected
N.A.	-	Not applicable
†	-	Not determined
LSC	-	Liquid scintillation counting

SODIUM PHOSPHATE^[32P] INJECTION

		SUPPLIER	ARI	ARI
		LOT/BATCH No.	07375	09027
		CALIB. DATE	20/03/00	13/11/00
SPECIFICATIONS		EXPIRY DATE	11/04/00	05/12/00
Appearance	A clear, colourless solution		Pass	Pass
Particulate matter	None visible		Pass	Pass
Radionuclidic content	90-110% of stated value		109	101
Radionuclidic purity	i) Beta spectrum does not differ significantly from that of a standardised P-32 solution obtained under the same conditions		Pass	Pass
	ii) decay rate should correspond to half-life of 14.3 d		Pass	Pass
Radiochemical purity	≥ 95% as orthophosphate	INIT.	100	100
		EXP.	100	100
pH	6.0 - 8.0		6.5	6.0
Specific radioactivity	≥ 11.1 MBq of P-32/ mg of orthophosphate ion		122	129
Label	Complies		Complies	Complies

CHROMIUM[⁵¹Cr] EDETATE INJECTION

		SUPPLIER	ARI	ARI	AMER
		LOT/BATCH No.	06946	088559	0546
		CALIB. DATE	01/04/00	01/10/00	23/10/00
SPECIFICATIONS		EXPIRY DATE	02/05/00	01/11/00	18/12/00
Appearance	A clear, violet solution		Pass	Pass	Pass
Particulate matter	None visible		Pass	Pass	Pass
Radionuclidic content	90-110% of stated value		106	108	102
Radionuclidic purity	Gamma spectrum does not differ significantly from that of a standardised Cr-51 solution. No other radionuclide detected by gamma spectrometry.		Pass	Pass	Pass
pH	3.5 – 6.5		5.0	6.0	4.5
Chemical purity					
1) Total edetate	mg/mL		8.5	9.3	2.8
2) Uncomplexed edetate	mg/mL		6.3	8.5	1.8
3) Total chromium	≤ 1mg/mL		0.4	0.1	0.2
Radiochemical purity					
1) Chromic ion	as %	INIT.	0.1	0.1	0.1
2) Chromate ion	as %		2.2	1.0	0.3
3) Cr-edetate	≥ 95% as ⁵¹ Cr-edetate		97.7	99.0	99.6
		EXP.	0.3	0.1	0.3
			0.3	1.4	0.3
			99.4	98.5	99.4
Benzyl alcohol	90 – 110 % of stated value		N/A	N/A	94
Label	Complies		Complies	Complies	Complies

SODIUM CHROMATE[⁵¹Cr] SOLUTION

		SUPPLIER	ARI	AMER	ARI
		LOT/BATCH No.	07369	666	088560
		CALIB. DATE	01/04/00	04/10/00	01/10/00
SPECIFICATIONS		EXPIRY DATE	02/05/00	29/11/00	01/11/00
Appearance	A clear, colourless or slightly yellow solution		Pass	Pass	Pass
Particulate matter	None visible		Pass	Pass	Pass
Radionuclidic content	90-110% of stated value		105	104	110
Radionuclidic purity	Gamma spectrum does not differ significantly from that of a standardised 51-Cr solution. No other radionuclide detected by gamma spectrometry.		Pass	Pass	Pass
pH	6.0 - 8.5		6.0	6.0	6.0
Radiochemical purity	≥ 90% as chromate ion	INIT.	99.7	98.9	99.9
		EXP.	99.2	97.3	99.8
Total chromate	≤ 2.7 µg of chromate ion/MBq at expiry		0.1	0.1	0.1
Label	Complies		Complies	Complies	Complies

GALLIUM[⁶⁷Ga] CITRATE INJECTION

		SUPPLIER	ARI	MALL	ARI
		LOT/BATCH No.	07941	23048	09030
		CALIB. DATE	09/06/00	20/10/00	07/11/00
SPECIFICATIONS		EXPIRY DATE	16/06/00	29/10/00	14/11/00
Appearance	A clear, colourless solution		Pass	Pass	Pass
Particulate matter	None visible		Pass	Pass	Pass
Identification					
1) Gamma spectrum	Gamma spectrum does not differ significantly from that of a standardised Ga-67 solution		Pass	Pass	Pass
2) Citrate presence	Present		Pass	Pass	Pass
Radionuclidic content	≥ 90-110% of stated value		108	103	102
Radionuclidic purity	≤ 0.2% ⁶⁶ Ga		N.D.	N.D.	N.D.
pH	5.0 - 8.0		6.5	6.5	6.5
Radiochemical purity	≥ 97% as Ga citrate	INIT.	99.6	99.5	99.7
		EXP.	99.3	98.8	99.5
Zinc limit test	≤ 5 µg/mL Zn		Pass	Pass	Pass
Benzyl alcohol	90 – 110 %		94	Not stated	91
Label	Complies		Complies	Fail	Complies

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

		SUPPLIER	RC
		LOT/BATCH No.	231000
		CALIB. DATE	23/10/00
SPECIFICATIONS		EXPIRY TIME	0900 hrs.
Appearance	A clear, colourless solution		Pass
Particulate matter	None visible		Pass
Identification			
Gamma spectrum	Gamma spectrum does not differ significantly from that of a standardised Tc-99m solution		Pass
Radionuclidic content	90-110% of stated value		102
Radionuclidic purity	$\leq 0.1\% \text{ } ^{99}\text{Mo}$		N.D.
	$\leq 5 \times 10^{-3} \% \text{ } ^{131}\text{I}$		N.D.
	$\leq 5 \times 10^{-3} \% \text{ } ^{103}\text{Ru}$		N.D.
	$\leq 6 \times 10^{-5} \% \text{ } ^{89}\text{Sr}$		†
	$\leq 6 \times 10^{-6} \% \text{ } ^{90}\text{Sr}$		†
	$\leq 1 \times 10^{-7} \% \text{ alpha-emitting impurities}$		†
	$\leq 1 \times 10^{-2} \% \text{ all other gamma-emitting impurities}$		N.D.
pH	4.0 - 8.0		5.5
Radiochemical purity	$\geq 95\% \text{ as pertechnetate ion } (^{99m}\text{TcO}_4^-)$	INIT.	99.9
			0.1
		EXP.	99.9
	% as colloidal material		0.1
Chemical Purity			
Aluminium content	$\leq 5 \mu\text{g mL aluminium}$		Pass
Label	Complies		Complies

KIT FOR THE PREPARATION OF TECHNETIUM[^{99m}Tc] ETIFENIN INJECTION (DIDA)

		SUPPLIER	RADPH
		LOT/BATCH No.	16676
SPECIFICATIONS		EXPIRY DATE	July 2001
Appearance before reconstitution	Freeze-dried solid		Pass
Appearance after reconstitution	A clear colourless solution		Pass
pH	4.0 - 6.0 after reconstitution		5.5
Radiochemical purity	≥ 95.0 % as ^{99m} Tc-Etifenin	INIT.	97.5
		EXP.	98.0
Stannous tin content	0.42 mg SnCl ₂ /vial *		†
Biological distribution	≥ 80% in the gall bladder + small and large intestines		†
	≤ 3% in the liver		†
	≤ 2% in the kidneys		†
Label	Complies		Complies

*Value given in label/product information.

KIT FOR THE PREPARATION OF TECHNETIUM[^{99m}Tc] EXAMETAZIME INJECTION (CERETEC)

		SUPPLIER	AMER
		LOT/BATCH No.	A764
SPECIFICATIONS		EXPIRY DATE	03/06/00
Appearance before reconstitution	Freeze-dried solid		Pass
Appearance after reconstitution	A clear colourless solution		Pass
pH	9.0 - 9.8 after reconstitution		9.2
Radiochemical purity	≥ 80.0 % as ^{99m} Tc-Exametazime	EXP.	92.7
	% as hydrolysed ^{99m} Tc		1.5
	% as Hydrolysed ^{99m} Tc + ^{99m} TcO ₄ ⁻		1.9
Stannous tin content	7.6 µg SnCl ₂ .2H ₂ O/vial *		†
Biological distribution	≥ 1.5 % in the brain		†
	≤ 20 % in the intestines		†
	≤ 15 % in the liver		†
Label	Complies		Complies

*Value given in label/product information.

KIT FOR THE PREPARATION OF TECHNETIUM[^{99m}Tc]MACROSALB INJECTION (MAA)

		SUPPLIER	MALL	MALL	RADPH
		LOT/BATCH No.	0939003	0930004	1681
SPECIFICATIONS		EXPIRY DATE	25/01/00	24/01/01	Dec/01
Appearance before reconstitution	Freeze-dried solid		Pass	Pass	Pass
Appearance after reconstitution	A white suspension which may separate on standing		Pass	Pass	Pass
Presence of vacuum	Complies				
pH	3.8 – 7.5 after reconstitution		4.5	4.5	6.5
Radiochemical purity	1) % in aggregate	INIT.	96.8	97.9	†
	2) % as soluble ^{99m} Tc-albumin		1.4	0.8	†
	3) % as free ^{99m} TcO ₄ ⁻		1.8	1.3	†
		EXP.	94.1		
			1.9		
			4.0		
Particle size	For at least 5000 particles: ≤ 10 particles with maximum dimension >100 μm None with maximum dimension > 150 μm		Pass	Pass	Pass
Non filterable radioactivity	≥ 90 % of the total radioactivity remaining on the membrane		††	96	98
Biological distribution	≥ 80% in the lungs		†	†	†
	≤ 5% in the liver + spleen		†	†	†
Label	Complies		Complies	Complies	Complies

KIT FOR THE PREPARATION OF TECHNETIUM[^{99m}Tc] MEDRONATE INJECTION (MDP)

		SUPPLIER	ARI	RADPH
		LOT/BATCH No.	1584	1622
SPECIFICATIONS		EXPIRY DATE	Feb/01	July/01
Appearance before reconstitution	Freeze dried solid		Pass	Pass
Appearance after reconstitution	A clear, colourless solution		Pass	Pass
Presence of vacuum	Complies		N/A	Complies
pH	3.5 – 7.5 after reconstitution		5.0	5.0
Radiochemical purity	1) ≥ 95.0 % as ^{99m} Tc-MDP	INIT.	99.0	99.7
	2) ≤ 2.0 % as ^{99m} TcO ₄ ⁻		0.8	0.1
	3) as colloidal ^{99m} Tc		0.2	0.2
	2) + 3) ≤ 5.0 %			
Stannous tin content	0.84 mg SnCl ₂ */vial		†	
	1 mg SnCl ₂ .2H ₂ O (min.)*vial			†
Biological distribution	≥ 1.5 % attached to femur		†	†
	≤ 1.0 % in the liver		†	†
	≤ 0.05 %/g in the blood		†	†
Label	Complies		Complies	Complies

*Value given in label/product information

KIT FOR THE PREPARATION OF TECHNETIUM[^{99m}Tc] MERTIATIDE INJECTION (MAG3)

		SUPPLIER	MALL	MALL	MALL
		LOT/BATCH No.	0968006A	09688013A	0969009A
SPECIFICATIONS		EXPIRY DATE	24/06/00	15/10/00	02/09/01
Appearance before reconstitution	Freeze-dried solid		Pass	Pass	Pass
Appearance after reconstitution	A clear, colourless solution free of particulate matter.		Pass	Pass	Pass
pH	5.0 - 7.5 after reconstitution		5.5	5.0	6.0
Radiochemical purity*	1) ≥ 94.0 % as ^{99m} Tc-MAG3	INIT.	99.4	97.5	99.2
	2) % as hydrophilic impurities		0.2	0.0	0.2
	3) % as non-elutable impurities		0.4	2.5	0.6
		EXP.	99.0	99.0	
			0.4	0.3	
			0.6	0.7	
Stannous tin content	≥ 50 µg SnCl ₂ .2H ₂ O/vial**		†	†	†
Label	Complies		Complies	Complies	Complies

*Tested by the method recommended by the manufacturer

**Value given in label/product information

KIT FOR THE PREPARATION OF TECHNETIUM[^{99m}Tc] OXIDRONATE INJECTION (HDP)

		SUPPLIER	MALL	MALL
		LOT/BATCH No.	0999001B	0999003B
SPECIFICATIONS		EXPIRY DATE	07/01/00	17/08/00
Appearance before reconstitution	Freeze-dried solid		Pass	Pass
Appearance after reconstitution	A clear, colourless solution		Pass	Pass
Presence of vacuum	Complies		N/A	N/A
pH	2.5 – 7.0 after reconstitution		5.0	5.5
Radiochemical purity	1) ≥ 90.0 % as ^{99m} Tc-HDP 2) % as ^{99m} TcO ₄ ⁻ 3) % as colloidal ^{99m} Tc 2) + 3) ≤ 10.0 %	INIT.	99.3	99.0
			0.1	0.1
			0.6	0.9
		EXP.	99.8	99.0
			0.1	0.1
			0.1	0.9
Stannous tin content	0.16 mg SnCl ₂ *		†	†
Biological distribution	≥ 1.0% attached to one femur		†	†
	≤ 5.0% in the liver		†	†
	≤ 5.0% in the kidneys		†	†
Label	Complies		Complies	Complies

*Value given in label/product information

KIT FOR THE PREPARATION OF TECHNETIUM[^{99m}Tc] PENTETATE INJECTION (DTPA)

		SUPPLIER	ARI	MALL(H)	RADPH
		LOT/BATCH No.	1602	86887	1616
SPECIFICATIONS		EXPIRY DATE	March/01	28/04/01	August/01
Appearance before reconstitution	Freeze-dried solid		Pass	Pass	Pass
Appearance after reconstitution	A clear, colourless or slightly yellow solution		Pass	Pass	Pass
Presence of vacuum	Complies		Complies	N/A	Complies
pH	4.0 - 7.5 after reconstitution		4.5	4.5	5.0
Radiochemical purity	1) ≥ 95.0 % as ^{99m} Tc-DTPA	INIT.	99.6	99.9	99.6
	2) % as ^{99m} TcO ₄ ⁻		0.2	0.0	0.1
	3) % as colloidal ^{99m} Tc		0.2	0.1	0.3
	2) + 3) ≤ 5.0 %				
Stannous tin content	1.05 mg SnCl ₂ */vial		†	†	
	1 mg SnCl ₂ */vial				†
Label	Complies		Complies	Complies	Complies

*Value given in label/product information

KIT FOR THE PREPARATION OF TECHNETIUM[^{99m}Tc] SUCCIMER INJECTION (DMSA)

		SUPPLIER	RADPH
		LOT/BATCH No.	1673
		EXPIRY DATE	April/01
SPECIFICATIONS			
Appearance before reconstitution	Freeze dried solid		Pass
Appearance after reconstitution	A clear, colourless solution		Pass
Presence of vacuum	Complies		Complies
pH	2.3 - 3.5 after reconstitution		3.5
Radiochemical purity	≥ 95.0 % as ^{99m} Tc-DMSA	INIT.	99.8
	≤ 2.0 % as ^{99m} TcO ₄ ⁻		0.2
		EXP.	95.1
			0.3
Stannous tin content	0.4 mg SnCl ₂ *		†
Biological distribution	≥ 40% in the kidneys		†
	≤ 10% in the liver		†
	≤ 2% in the stomach		†
	≤ 5% in the lungs		†
Label	Complies		Complies

*Value given in label/product information

KIT FOR THE PREPARATION OF TECHNETIUM[^{99m}Tc] TIN PYROPHOSPHATE INJECTION (PYP)

		SUPPLIER	MALL	MALL	RADPH
		LOT/BATCH No.	0940003B	0940007B	1610
SPECIFICATIONS		EXPIRY DATE	07/09/00	26/01/01	June 2001
Appearance before reconstitution	Freeze-dried solid		Pass	Pass	Pass
Appearance after reconstitution	A clear, colourless solution		Pass	Pass	Pass
Presence of vacuum	Complies		N/A	N/A	Complies
pH	6.0 – 7.0 after reconstitution				5.5
	4.0 - 7.5 after reconstitution*		5.5	5.5	
Radiochemical purity	1) ≥ 90.0 % as ^{99m} Tc-PYP	INIT.	99.3	99.6	99.5
	2) as ^{99m} TcO ₄ ⁻		0.4	0.2	0.3
	3) ⁻ as colloidal ^{99m} Tc		0.3	0.2	0.2
	2) + 3) ≤ 10.0%				
		EXP.	99.4		
			0.4		
			0.2		
Sodium pyrophosphate content	1-50 mg/mL sodium pyrophosphate on reconstitution		Complies	Complies	Complies
Stannous tin content	9.0 mg SnCl ₂ /vial **				†
	3.2 - 4.4 mg SnCl ₂ .2H ₂ O/vial **		†	†	
Label	Complies		Complies	Complies	Complies

*Value given in USP; ** Value given in label/product information

KIT FOR THE PREPARATION OF TECHNETIUM[^{99m}Tc] COLLOIDAL INJECTION

SPECIFICATIONS		SUPPLIER	RADPH**
		LOT/BATCH No.	1620
		EXPIRY DATE	June 2001
Appearance before reconstitution	Freeze-dried solid		Pass
Appearance after reconstitution	A clear, colourless solution		Pass
Presence of vacuum	Complies		Complies
pH	4.0 - 7.0 after reconstitution		5.0
Radiochemical purity	≥ 95.0 % as ^{99m} Tc-colloid	INIT.	98.5
		EXP.	96.9
Stannous tin content	1.0 mg SnCl ₂ *		†
Biological distribution	≥ 80% in the liver + spleen		†
	≤ 5% in the lungs		†
Label	Complies		Complies

*Value given in label/product information.

**Technetium[^{99m}Tc] Calcium Phytate

SODIUM IODIDE [¹³¹I] CAPSULES

		SUPPLIER	ARI
		LOT/BATCH No.	09141
		CALIB. DATE	20/11/00
SPECIFICATIONS		EXPIRY DATE	10/12/00
Appearance	Gelatine capsule		Pass
Identification			
Gamma spectrum	Gamma spectrum does not differ significantly from that of a standardised I-131 solution		Pass
Radionuclidic content	90-110% of stated value		107
Radionuclidic purity	≤ 0.1% of the total radioactivity is due to ¹³³ I, ¹³⁵ I and other radionuclidic impurities		N.D.
Radiochemical purity	≥ 95% of activity as iodide	INIT.	97.5
		EXP.	96.0
Disintegration	The shell and its contents dissolve completely within 15 min.		Complies
Label	Complies		Complies

SODIUM IODIDE [¹³¹I] INJECTION

		SUPPLIER	ARI
		LOT/BATCH No.	09107
		CALIB. DATE	22/11/00
SPECIFICATIONS		EXPIRY DATE	06/12/00
Appearance	A clear, colourless solution		Pass
Particulate matter	None visible		Pass
Identification			
Gamma spectrum	Gamma spectrum does not differ significantly from that of a standardised I-131 solution		Pass
pH	7.0 – 8.5		7.0
Radionuclidic content	90-110% of stated value		103
Radionuclidic purity	≤ 0.1 % of the total radioactivity is due to ¹³³ I, ¹³⁵ I and other radionuclidic impurities		N.D.
Radiochemical purity	≥ 95% of activity as iodide	INIT.	99.8
		EXP.	99.7
Label	Complies		Complies

THALLOUS[²⁰¹Tl] CHLORIDE INJECTION

		SUPPLIER	ARI	MALL	ARI
		LOT/BATCH No.	07944	23092	09032
		CALIB. DATE	09/06/00	19/10/00	06/11/00
SPECIFICATIONS		EXPIRY DATE	14/06/00	26/10/00	11/11/00
Appearance	A clear colourless solution		Pass	Pass	Pass
Particulate matter	None visible		Pass	Pass	Pass
Identification Gamma spectrum	Gamma spectrum does not differ significantly from that of a standardised Tl-201 solution		Pass	Pass	Pass
pH	4.5 – 7.0		6.0	6.0	5.5
Radiochemical content	90-110% of stated value		106	99	109
Radionuclidic purity	≥ 97.0 % ²⁰¹ Tl at calibration		98.9	99.7	99.3
	≥ 97.0 % ²⁰¹ Tl at at expiry		99.7	99.1	99.7
	≤ 2.0% ²⁰² Tl at expiry		0.19	0.94	0.26
	% ²⁰⁰ Tl at calibration		1.05	0.06	0.55
	% ²⁰³ Pb at calibration		N.D.	N.D.	N.D.
	% ²⁰¹ Pb at calibration		N.D.	N.D.	N.D.
Radiochemical purity	≥ 95.0 % as Tl(I)	INIT.	99.9	99.7	99.5
		EXP.	99.7	99.5	99.6
Chemical purity	≤ 10 µg/mL Tl		Pass	Pass	Pass
Benzyl alcohol	90 – 110 % of stated value		91	Not stated	†
Label	Complies		Complies	Fail	Complies