



Australian Government

**Australian Radiation Protection
and Nuclear Safety Agency**

**Results of the Quality Assurance Testing
Program for Radiopharmaceuticals 2003**

By

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ABSTRACT

This report tabulates results obtained during 2003 for the Radiopharmaceutical Quality Assurance Test Program conducted by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

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INTRODUCTION

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) conducts a Radiopharmaceutical Quality Assurance Test Program under a Memorandum of Understanding (MOU) between ARPANSA and the Therapeutic Goods Administration (TGA). As part of this MOU 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. 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[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[^{99m}Tc] Injection. Pharmacopoeia methods are used for testing, together with some additional methods described in the report ARL/TR093*.

RESULTS

The results of testing during 2003 are summarised in the following tables. Overall, 31 batches of 20 different types of radiopharmaceuticals were tested. Failure to meet full specifications was observed in 4 of the 31 batches of radiopharmaceuticals tested (13%). Radionuclidic content results (1 high and 2 low) caused 3 failures while a low pH value failed BP specification, but passed the USP specification.

Dates in this report appear as on the package label (i.e. no conversion to Melbourne time was made).

Due to staff and resource reductions, ARPANSA is 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.

ABBREVIATIONS

The following abbreviations are used in the tables -

AMER	- Amersham plc, UK
N.AMER	- Nycomed Amersham plc, UK
ARI	- Ansto Radiopharmaceuticals and Industrials, Lucas Heights, Sydney, Australia
MALL	- Mallinckrodt Inc, St Louis, MO, USA
MALL(H)	- Mallinckrodt Medical, Holland
RADPH	- Radpharm Scientific, Belconnen, ACT, Australia
RC	- Radiopharmacy Central, Tullamarine, VIC, Australia
BMS	- Bristol-Myers Squibb Australia Pty Ltd
BMS(USA)	- Bristol-Myers Squibb Medical Imaging, USA
N.D.	- Not detected
NA	- Not applicable
†	- Not determined
LSC	- Liquid scintillation counting
TBD	- To be determined
CALIB.	- Calibration

SODIUM PHOSPHATE^[32P] INJECTION

		SUPPLIER	AMER	ARI
		LOT/BATCH No.	794	34913009
		CALIB. DATE	17/03/03	24/03/03
SPECIFICATIONS		EXPIRY DATE	14/04/03	15/04/03
Appearance	A clear, colourless solution		Pass	Pass
Particulate matter	None visible		Pass	Pass
Identification	Beta spectrum does not differ significantly from that of a standardised P-32 solution obtained under the same conditions.		Pass	Pass
Radionuclidic content	90-110% of stated value		99	89, 87*
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 days		Pass	Pass
Radiochemical purity	≥ 95% as orthophosphate ion		INIT. 100	100
			EXP. 99.7	99.8
pH	6.0 - 8.0		7.0	6.5
Specific radioactivity	≥ 11.1 MBq of phosphorus-32 per mg of orthophosphate ion		66	135
Vial/Package Label	Complies		Complies	Complies

*two vials of the same batch

CHROMIUM[⁵¹Cr] EDETATE INJECTION

		SUPPLIER	AMER	ARI
		LOT/BATCH No.	696	35876
		CALIB. DATE	17/11/03	01/11/03
SPECIFICATIONS		EXPIRY DATE	12/01/04	02/12/03
Appearance	A clear, violet solution		Pass	Pass
Particulate matter	None visible		Pass	Pass
Identification	Gamma spectrum does not differ significantly from that of a standardised Cr-51 solution.		Pass	Pass
Radionuclidic content	90-110% of stated value		101	112
Radionuclidic purity	Gamma spectrum does not differ significantly from that of a standardised Cr-51 solution.		Pass	Pass
pH	3.5 – 6.5		3.5	4.5
Radiochemical purity, BP				
	% as Chromic ion	INIT.	1.3	0.5
	% as Chromate ion		0	0
	≥ 95% as ⁵¹ Cr-edetate		98.6	99
		EXP.	†	1.4
			†	0.3
			†	98.5
Chromium	≤ 1mg/mL total chromium		0.1	0.3
Benzyl alcohol	90 – 110 % of stated value		93%	NA
Vial/Package Label	Complies		Complies	Complies

SODIUM CHROMATE[⁵¹Cr] SOLUTION

		SUPPLIER	ARI	AMER
		LOT/BATCH No	35674	820
		CALIB. DATE	01/09/03	17/09/03
SPECIFICATIONS		EXPIRY DATE	02/10/03	12/11/03
Appearance	A clear, colourless or slightly yellow solution		Pass	Pass
Particulate matter	None visible		Pass	Pass
Identification	Gamma spectrum does not differ significantly from that of a standardised Cr-51 solution.		Pass	Pass
Radionuclidic content	90-110% of stated value		100,102*	105
Radionuclidic purity	Gamma spectrum does not differ significantly from that of a standardised Cr-51 solution.		Pass	Pass
pH	6.0 - 8.5		6.0	6.0
Radiochemical purity	≥ 90% as chromate ion % as Chromic ion	INIT.	98.3	98.8
			1.7	1.2
		EXP.	99.8	96.3
			0.2	3.7
Total chromate	≤ 2.7 µg of chromate ion (CrO ₄ ²⁻) per MBq		0.05	0.3
Vial/Package Label	Complies		Complies	Complies

*two vials of the same batch

GALLIUM[⁶⁷Ga] CITRATE INJECTION

		SUPPLIER	ARI	MALL(H)	BMS(USA)
		LOT/BATCH No.	34916	36321	G32432S
		CALIB. DATE	18/03/03	28/03/03	27/11/03
SPECIFICATIONS		EXPIRY DATE	25/03/03	07/04/03	04/12/03
Appearance	A clear, colourless solution		Pass	Pass	Pass
Particulate matter	None visible		Pass	Pass	Pass
Identification	Gamma spectrum does not differ significantly from that of a standardised Ga-67 solution		Pass	Pass	Pass
Citrate presence	A yellow colour develops in the test solution only		Pass	Pass	Pass
Radionuclidic content	90-110% of stated value		103	104	101
Radionuclidic purity	≤ 0.2% ⁶⁶ Ga		N.D.	N.D.	N.D.
pH	5.0 - 8.0		6.5	6.0	6.0
Radiochemical purity	≥ 97% as Ga Citrate	INIT.	99	99	99
		EXP.	99	98	99
Zinc limit test	≤ 5 µg/mL Zn		†	†	†
Benzyl alcohol	90 – 110 % of stated value		95	92	90
Vial/Package Label	Complies		Complies	Complies	Complies

⁹⁹Mo/^{99m}Tc CHROMATOGRAPHIC GENERATOR

		SUPPLIER	ARI		
		LOT/BATCH No.	36594/069		
		CALIB. DATE	17/11/03		
		EXPIRY DATE	1/12/03		
		SPECIFICATIONS			
Maximum Surface Radiation Dose	< 2 mGy/h		0.15	0.30	0.18
			bottom	side	top
Dose at 1 meter	<0.10 mGy/h		0.01		
Appearance (after milking)	A clear, colourless solution		Pass		
Particulate Matter	None visible		Pass		
Identification	Gamma spectrum does not differ significantly from that of a standardised ^{99m} Tc solution		Pass		
Radionuclidic purity	≤ 0.1% ⁹⁹ Mo	MAX	MIN	AVE	
		0.00006	0.000036	0.000046	
	≤ 5 x 10 ⁻³ % ¹³¹ I	N.D.	N.D.	N.D.	
	≤ 5 x 10 ⁻³ % ¹⁰³ Ru	N.D.	N.D.	N.D.	
	≤ 6 x 10 ⁻⁵ % ⁸⁹ Sr	†	†	†	
	≤ 6 x 10 ⁻⁶ % ⁹⁰ Sr	†	†	†	
	≤ 1 x 10 ⁻⁷ % alpha-emitting impurities	†	†	†	
	≤ 1 x 10 ⁻² % all other gamma-emitting impurities	Pass	Pass	Pass	
pH	4.0 – 8.0		5.5	5.0	5.25
Radiochemical Purity	≥ 95% as pertechnetate ion (^{99m} TcO ₄) ⁻		100	100	100
Aluminium	≤ 5µg/mL		1.4	1.1	1.25
Milking efficiency (%)			115	102	111
Vial/Package Label	Complies		Complies		

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

		SUPPLIER	RC	
		LOT/BATCH No.	22081	
		CALIB. DATE and TIME	04/02/03 09:00	
SPECIFICATIONS		EXPIRY DATE and TIME	04/02/03 17:00	
			INIT	EXP
Appearance	A clear, colourless solution		Pass	Pass
Particulate matter	None visible		Pass	Pass
Identification	Gamma spectrum does not differ significantly from that of a standardised Tc-99m solution		Pass	Pass
Radionuclidic content	90-110% of stated value		121	
Radionuclidic purity	≤ 0.1% ⁹⁹ Mo		0.001	0.0025
	≤ 5 x 10 ⁻³ % ¹³¹ I		9 x 10 ⁻⁶	2 x 10 ⁻⁵
	≤ 5 x 10 ⁻³ % ¹⁰³ Ru		N.D.	N.D.
	≤ 6 x 10 ⁻⁵ % ⁸⁹ Sr		†	†
	≤ 6 x 10 ⁻⁶ % ⁹⁰ Sr		†	†
	≤ 1 x 10 ⁻⁷ % alpha-emitting impurities		†	†
	≤ 1 x 10 ⁻² % all other gamma-emitting impurities		N.D.	N.D.
pH	4.0 - 8.0		5.5	
Radiochemical purity	≥ 95% as pertechnetate ion (^{99m} TcO ₄ ⁻)		99.7	99.8
Aluminium	≤ 5 µg/mL of aluminium		†	
Vial/Package Label	Complies		Complies	

KIT FOR THE PREPARATION OF TECHNETIUM[^{99m}Tc] BICISATE (NEUROLITE)

		SUPPLIER	BMS
		LOT/BATCH No.	01457
SPECIFICATIONS		EXPIRY DATE	01/12/04
		INIT.	EXP
Appearance before reconstitution	Freeze-dried solid	Pass	TBD
Appearance after reconstitution	A clear, colourless solution	Pass	TBD
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded.	NA	TBD
pH	6.3 - 7.6 *after reconstitution	6.9	TBD
Radiochemical purity	1) ≥ 90.0 % as ^{99m} Tc-Bicisate	98.4	TBD
	2) ≤ 10.0 % as impurities (colloidal, ^{99m} TcO ₄ ⁻ & ^{99m} Tc-EDTA)	1.6	TBD
Tin content	12 - 72 µg SnCl ₂ .2H ₂ O *	†	
Vial/Package Label	Complies	Complies	

*Value given in label/product information

KIT FOR THE PREPARATION OF TECHNETIUM[^{99m}Tc] CALCIUM PHYTATE INJECTION (COLLOID)

		SUPPLIER	RADPH
		LOT/BATCH No.	2005/2006
SPECIFICATIONS		EXPIRY DATE	Sep 2004
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture	INIT. Pass	EXP. TBD
Appearance after reconstitution	A clear, colourless or slightly yellow solution, free of any visible particulate matter	Pass	TBD
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded.	Yes	TBD
pH	4.0 - 7.0 after reconstitution	5.0	TBD
Radiochemical purity	≥ 95.0 % as ^{99m} Tc-colloid	98.1	TBD
Tin content	< 1.0 mg of Sn/mL	Pass	
Biological distribution	≥ 80% in the liver + spleen	†	
	≤ 5% in the lungs	†	
Label	Complies	Complies	

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

		SUPPLIER	N.AMER	
		LOT/BATCH No.	996	
SPECIFICATIONS		EXPIRY DATE	14/11/03	
			INIT.	EXP.
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture		Pass	Pass
Appearance after reconstitution	A clear, colourless solution, free of any visible particulate matter		Pass	Pass
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded.		NA	NA
pH	9.0 - 9.8 after reconstitution		9.1	†
Radiochemical purity	≥ 80.0 % as ^{99m} Tc-Exametazime	INT.	93.6	92.7
	% as free TcO ₄ ⁻		3.2	1.5
	% as hydrolysed reduced ^{99m} Tc		1.7	3.7
	% as ^{99m} Tc secondary exametazime complex		1.5	2.1
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		†	
Vial/Package Label	Complies		Complies	

*Value given in label/product information

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

		SUPPLIER	RADPH	
		LOT/BATCH No.	2013	
SPECIFICATIONS		EXPIRY DATE	Oct 2004	
			INIT.	EXP.
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture		Pass	TBD
Appearance after reconstitution	A white suspension which may separate on standing		Pass	TBD
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded.		Yes	TBD
pH	3.8 -7.5 after reconstitution		6.5	TBD
Radiochemical purity	≥ 90.0 % in aggregate		99.8	TBD
	% as soluble ^{99m} Tc-albumin		0.06	TBD
	% as free ^{99m} TcO ₄ ⁻		0.14	TBD
Particle size	For at least 5000 particles: ≤ 10 particles with maximum dimension >100 μm None with maximum dimension > 150 μm		Pass	TBD
Non filterable radioactivity	The radioactivity remaining on the membrane is ≥ 90%		99.8	TBD
Biological distribution	≥ 80% in the lungs			†
	≤ 5% in the liver + spleen			†
Vial/Package Label	Complies			Complies

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

		SUPPLIER	ARI	AMER	RADPH		
		LOT/BATCH No.	1930	556	1971		
SPECIFICATIONS		EXPIRY DATE	01/02/04	23/11/04	01/07/04		
		INT.	EXP.	INT.	EXP.	INT.	EXP.
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture	Pass	Pass	Pass	Pass	Pass	Pass
Appearance after reconstitution	A clear, colourless solution	Pass	Pass	Pass	Pass	Pass	Pass
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded.	NA	NA	NA	NA	Yes	Yes
pH	3.5 – 7.5 after reconstitution	4.5	5.3	6.0	6.1	5.0	4.5
Radiochemical purity	1) ≥ 95.0 % as ^{99m} Tc-MDP	99.6	99.8	99.4	98.9	99.3	99.7
	2) ≤ 2.0 % as ^{99m} TcO ₄ ⁻	0.07	0.05	0.16	0.44	0.2	0.1
	3) % as colloidal ^{99m} Tc	0.3	0.17	0.49	0.67	0.5	0.2
	2) + 3) ≤ 5.0 %						
Tin content	< 3mg of Sn/mL	Pass		Pass		Pass	
Biological distribution	≥ 1.5% attached to femur	†		†		†	
	≤ 1.0% in the liver	†		†		†	
	≤ 0.05 %/g in the blood	†		†		†	
Vial/Package Label	Complies	Complies		Complies		Complies	

*Value given in label/product information

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

SPECIFICATIONS		SUPPLIER	MALL
		LOT/BATCH No.	0963009
		EXPIRY DATE	13/8/04
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture	INIT. Pass	EXP. TBD
Appearance after reconstitution	A clear, colourless solution free of particulate matter. If not, the preparation should not be used	Pass	TBD
pH	5.0 - 7.5 after reconstitution	5.5	TBD
Radiochemical purity*	% as hydrophilic impurities	0.2	TBD
	≥ 94.0 % as ^{99m} Tc-MAG3	99.5	TBD
	% as non-elutable impurities	0.3	TBD
	≤ 2% as reduced-hydrolysed technetium	0.05	TBD
Tin content	≥ 50 µg SnCl ₂ .2H ₂ O/vial**	†	
Vial/Package Label	Complies	Complies	

*Tested by the method recommended by the manufacturer

**Value given in label/product information

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

SUPPLIER	ARI	MALL(H)	AMER
LOT/BATCH No	1928	288	1997
EXPIRY DATE	Feb 2004	06/04/04	01/07/04

SPECIFICATIONS

		INIT.	EXP.	INIT.	EXP.	INIT.	EXP.
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture	Pass	Pass	Pass	Pass	Pass	Pass
Appearance after reconstitution	A clear, colourless or slightly yellow solution, free of any visible particulate matter	Pass	Pass	Pass	Pass	Pass	Pass
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded.	Yes	Yes	NA	NA	Yes	Yes
pH	4.0 - 7.5 after reconstitution	4.7		4.5		5.3	
Radiochemical purity	≥ 95.0 % as ^{99m} Tc-DTPA	99.9	99.9	99.9	99.97	99.2	99.1
	% as free ^{99m} TcO ₄ ⁻	<0.1	<0.1	<0.1	0.02	0.2	0.2
	% as colloidal ^{99m} Tc	<0.1	<0.1	<0.1	0.02	0.6	0.7
Tin content	< 1mg of Sn/mL	Pass		Pass		Pass	
Vial/Package Label	Complies	Complies		Complies		Complies	

*Value given in label/product information

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

		SUPPLIER	BMS	
		LOT/BATCH No.	3770M	
SPECIFICATIONS		EXPIRY DATE	01/05/04	
			INIT.	EXP.
Appearance before reconstitution	Freeze dried solid		Pass	Pass
Appearance after reconstitution	A clear, colourless solution		Pass	Pass
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded		NA	NA
pH	5.0 - 6.0 after reconstitution		5.0	
Radiochemical purity	≥ 90.0 % as ^{99m} Tc-Sestamibi		98.3	97.0
	≤ 10.0 % ^{99m} Tc impurities		1.7	3.0
Tin content	0.075 mg SnCl ₂ *		†	
Vial/Package Label	Complies		Complies	

*Value given in label/product information

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

		SUPPLIER	RADPH	
		LOT/BATCH No.	1970	
SPECIFICATIONS		EXPIRY DATE	01/03/04	
Appearance before reconstitution	Freeze dried solid		INIT. Pass	EXP. Pass
Appearance after reconstitution	A clear, colourless solution		Pass	Pass
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded		Yes	Yes
pH	2.3 - 3.5 after reconstitution		2.85	
Radiochemical purity	≥ 95.0 % as ^{99m} Tc-DMSA	INIT.	99.6	99.8
	≤ 2.0 % as free ^{99m} TcO ₄ ⁻		0.4	0.2
Tin content	< 1mg of Sn/mL		Pass	
Biological distribution	≥ 40% in the kidneys		†	
	≤ 10% in the liver		†	
	≤ 2% in the stomach		†	
	≤ 5% in the lungs		†	
Vial/Package Label	Complies		Complies	

*Value given in label/product information

KIT FOR THE PREPARATION OF TECHNETIUM[^{99m}Tc] TETROFOSMIN (MYOVIEV)

		SUPPLIER	N.AMER	
		LOT/BATCH No.	942	
SPECIFICATIONS		EXPIRY DATE	01/01/04	
			INT.	EXP.
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture		Pass	Pass
Appearance after reconstitution	A clear, colourless solution, free of any visible particulate matter		Pass	Pass
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded		NA	NA
pH	8.3 - 9.1 after reconstitution		8.4	8.4
Radiochemical purity	1) $\geq 90.0\%$ as ^{99m} Tc-Tetrafosmin		96.6	96.3
	2) Reduced hydrolysed & hydrophilic impurities		2.9	2.4
	3) Unbound pertechnetate		0.5	1.2
	2 + 3) $\leq 10\%$		Complies	
Tin content	0.03 mg/vial SnCl ₂ .2H ₂ O*		†	
Vial/Package Label	Complies		Complies	

*Value given in label/product information.

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

		SUPPLIER	RADPH		MALL	
		LOT/BATCH No.	1993	0943006A		
SPECIFICATIONS		EXPIRY DATE	01/07/04	16/01/04		
			INIT.	EXP.	INIT.	EXP.
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture		Pass	Pass	Pass	Pass
Appearance after reconstitution	A clear, colourless or slightly yellow solution, free of any visible particulate matter		Pass	Pass	Pass	Pass
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded		NA	NA	Yes	Yes
pH	6.0 – 7.0 after reconstitution 4.0 - 7.5 after reconstitution*		5.0		5.0	
Radiochemical purity	1) ≥ 90.0 % as ^{99m} Tc-PYP		98.9	98.6	97.3	98.2
	2) % as free ^{99m} TcO ₄ ⁻		0.2	0.7	1.0	0.9
	3) % as colloidal ^{99m} Tc		0.9	0.7	1.7	0.9
Sodium pyrophosphate content	1-50 mg/mL sodium pyrophosphate on reconstitution		†		†	
Tin content	9.0 mg SnCl ₂ /vial **				†	
	3.2 - 4.4 mg SnCl ₂ .2H ₂ O/vial **		†			
Vial/Package Label	Complies		Complies		Complies	

*Value given in USP

**Value given in label/product information

m-IODOBENZYLGUANIDINE¹³¹I INJECTION (mIBG)

		SUPPLIER	ARI
		LOT/BATCH No.	36596
		CALIB. DATE	18/11/03
SPECIFICATIONS		EXPIRY DATE	23/11/03
Appearance	A clear, colourless or slightly yellow solution		Pass
Particulate matter	None visible		Pass
Identification	Gamma spectrum does not differ significantly from that of a standardised I-131 solution		Pass
Radionuclidic content	90-110% of stated value		98
Radionuclidic purity	≤ 0.1 % of the total radioactivity is due to ¹³³ I, ¹³⁵ I and other radionuclidic impurities		N.D.
pH	3.5 – 8.0		5.8
Radiochemical purity	≥ 94% as ¹³¹ I-mIBG ≤ 5% as iodide	INIT.	99.2
			0.8
		EXP.	98.9
			1.1
Vial/Package Label	Complies		Complies

SODIUM IODIDE[¹³¹I] INJECTION

		SUPPLIER	ARI
		LOT/BATCH No.	35147001
		CALIB. DATE	26/03/03
SPECIFICATIONS		EXPIRY DATE	09/04/03
Appearance	A clear, colourless solution		Pass
Particulate matter	None visible		Pass
Identification	Gamma spectrum does not differ significantly from that of a standardised I-131 solution		Pass
Radionuclidic content	90-110% of stated value		104
Radionuclidic purity	≤ 0.1 % of the total radioactivity is due to ¹³³ I, ¹³⁵ I and other radionuclidic impurities		N.D.
pH	7.0 – 8.5		7.0
Radiochemical purity	≥ 95% as iodide	INIT.	98
		EXP.	100
Vial/Package Label	Complies		Complies

THALLOUS[²⁰¹Tl] CHLORIDE INJECTION

	SUPPLIER	ARI	MALL(H)
	LOT/BATCH No.	34918 (026)	37064/000
	CALIB. DATE	17/03/03	26/03/03
	EXPIRY DATE	22/03/03	02/04/03
SPECIFICATIONS			
Appearance	A clear colourless solution	Pass	Pass
Particulate matter	None visible	Pass	Pass
Identification	Gamma spectrum does not differ significantly from that of a standardised Tl-201 solution	Pass	Pass
Radiochemical content	90-110% of stated value	109.5	100
Radionuclidic purity	At all times up till expiry	At calibration	At expiry
	²⁰¹ Tl ≥ 97 %	99.5	99.7
	²⁰² Tl ≤ 2.0 %	0.1	0.3
	²⁰⁰ Tl %	0.4	0.05
	²⁰¹ Pb %	N.D.	N.D.
	²⁰³ Pb %	N.D.	N.D.
pH	4.0 - 7.0	5.0	5
Radiochemical purity	≥ 95% as Thallous ion	INIT. 99.5	99.6
		EXP. 99.7	99.7
Thallium	≤ 10 µg/mL Thallium	< 2	< 2
Benzyl alcohol	90 – 110 % of stated value	92	NA
Vial/Package Label	Complies	Complies	Complies