



Australian Government

**Australian Radiation Protection
and Nuclear Safety Agency**

**Results of the Quality Assurance Testing
Program for Radiopharmaceuticals 2002**

By

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ABSTRACT

This report tabulates results obtained during 2002 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 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. 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[^{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 2002 are summarised in the following tables. Overall, 89 batches of 22 different types of radiopharmaceuticals were tested. Failure to meet full specifications was observed in 18 of the 89 batches of radiopharmaceuticals tested (20%).

Non-compliance of the vial label was observed in 9 of the 89 batches failing specification. The vial label non-compliance consisted of the absence of the expiry date and time in two batches, the absence of the expiry time in four batches and the absence of the vial volume in three batches.

Other non-compliance was high radionuclidic content in two batches and lower than specified in one batch, low pH in two batches, low radiochemical purity in one batch at the initial testing and two batches at expiry testing. 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.

The proportion of non-compliance of radiopharmaceuticals is higher than 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	AMER	AMER	ARI
		LOT/BATCH No.	22951	756	770	23672
		CALIB. DATE	24/06/02	24/06/02	30/09/02	23/09/02
SPECIFICATIONS		EXPIRY DATE	16/07/02	28/10/02	15/10/02	15/10/02
Appearance	A clear, colourless solution		Pass	Pass	Pass	Pass
Particulate matter	None visible		Pass	Pass	Pass	Pass
Radionuclidic content	90-110% of stated value		89.4, 84.8*	105.5, 104.2*	105.2, 105.2*	92.9, 92.6*
Radionuclidic purity	i) Beta spectrum does not differ significantly from that of a standardised P-32 solution obtained under the same conditions		Pass	Pass	Pass	Pass
	ii) decay rate should correspond to half-life of 14.3 d		Pass	Pass	Pass	Pass
Radiochemical purity	≥ 95% as orthophosphate	INIT.	100	99.9	99.1	99.7
		EXP.	99.6	99.7	99.9	99.9
pH	6.0 - 8.0		6.5	7.0	7.5	6.5
Specific radioactivity	≥ 11.1 MBq of P-32/ mg of orthophosphate ion		137	62	61	135
Label	Complies		Complies	Complies	Complies	Complies

* two vials of same batch

CHROMIUM[⁵¹Cr] EDETATE INJECTION

		SUPPLIER	ARI	AMER	ARI	AMER
		LOT/BATCH No.	11749	604	22868	0626
SPECIFICATIONS		CALIB. DATE	01/02/02	11/02/02	01/07/02	29/07/02
		EXPIRY DATE	04/03/02	08/04/02	01/08/02	23/09/02
Appearance	A clear, violet solution		Pass	Pass	Pass	Pass
Particulate matter	None visible		Pass	Pass	Pass	Pass
Identification	Gamma spectrum does not differ significantly from that standardised Cr-51 solution.		Pass	Pass	Pass	Pass
Radionuclidic content	90-110% of stated value		108.7, 107.6*	102.7	109.7	106
Radionuclidic purity	Gamma spectrum does not differ significantly from that of a standardised Cr-51 solution.		N.D.	N.D.	N.D.	N.D.
pH	3.5 – 6.5		5.0	4.4	5.8	3.5
Chemical purity						
1) Total edetate	mg/mL		8.7	2.1	9.2	2.3
2) Uncomplexed edetate	mg/mL		6.8	1.3	7.3	1.5
3) Total chromium	≤ 1mg/mL		0.3	0.2	0.4	0.1
Radiochemical purity						
1) Chromic ion	as %	INIT.	0.1	0.1	0.1	0.05
2) Chromate ion	as %		1.3	0.7	0.4	0.01
3) Cr-edetate	≥ 95% as ⁵¹ Cr-edetate		98.6	99.2	99.5	99.9
		EXP.	0.1	0.1	0.0	†
			1.7	0.8	0.6	†
			98.2	99.1	99.4	†
Benzyl alcohol	90 – 110 % of stated value		N/A	†	N/A	94
Label	Complies		Complies	Complies	Complies	Complies

* two vials of same batch

SODIUM CHROMATE[⁵¹Cr] SOLUTION

		SUPPLIER	ARI	AMER	ARI	AMER
		LOT/BATCH No	11858	736	22869	758
		CALIB. DATE	01/02/02	06/02/02	01/07/02	10/07/02
SPECIFICATIONS		EXPIRY DATE	04/03/02	03/04/02	01/08/02	04/09/02
Appearance	A clear, colourless or slightly yellow solution		Pass	Pass	Pass	Pass
Particulate matter	None visible		Pass	Pass	Pass	Pass
Identity	Gamma spectrum does not differ significantly from that of a standardised 51-Cr solution		Pass	Pass	Pass	Pass
Radionuclidic content	90-110% of stated value		112.1, 113.7*	106.2	105.5	105.5
Radionuclidic purity	Gamma spectrum does not differ significantly from that of a standardised 51-Cr solution.		Pass	Pass	Pass	Pass
pH	6.0 - 8.5		6.0	6.0	6.0	6.0
Radiochemical purity	≥ 90% as chromate ion	INIT.	98.8	99.3	95.7	99.5
		EXP.	98.7	98.4	97.4	99.6
Total chromate	≤ 2.7 µg of chromate ion/MBq at expiry		0.3	0.2	0.2	0.2
Label	Complies		Complies	Complies	Complies	Complies

* two vials of same batch

GALLIUM[⁶⁷Ga] CITRATE INJECTION

		SUPPLIER	ARI	MALL	ARI	MALL	ARI	MALL	ARI	ARI
		LOT/BATCH No.	21970	30109	23028	32689	23248	32699	23675	24001
		CALIB. DATE	29/01/02	31/01/02	25/06/02	27/06/02	30/07/02	01/08/02	24/09/02	15/11/02
SPECIFICATIONS		EXPIRY DATE	05/02/02	10/02/02	02/07/02	07/07/02	06/08/02	11/08/02	01/10/02	22/11/02
Appearance	A clear, colourless solution		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Particulate matter	None visible		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Identification										
1) Gamma spectrum	Gamma spectrum does not differ significantly from that of a standardised Ga-67 solution		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
2) Citrate presence	Present		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Radionuclidic content	≥ 90-110% of stated value		103.9	102.9	101.8	102.5	106	103.2	106.6	103.6
Radionuclidic purity	≤ 0.2% ⁶⁶ Ga		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	6.0	6.5	6.0	7.0	6.5
Radiochemical purity*	≥ 97% as Ga citrate	INIT.	98.6	97.2	99.3	†	99.6	99.3	99.0	98.7
		EXP.	96.7	96.3	99.1	99.0	99.4	99.2	99.2	99.3
Zinc limit test	≤ 5 µg/mL Zn		†	†	†	†	†	†	†	†
Benzyl alcohol	90 – 110 % of stated value		92	91	90	90	92	92	95	93
Label	Complies		Complies	Fail	Complies	Fail	Complies	Fail	Complies	Complies

*USP test method

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

		SUPPLIER	RC	RC
		LOT/BATCH No.	10252	17546
		CALIB. DATE	18/9/02	09/12/02
SPECIFICATIONS		EXPIRY TIME	18/09/02	09/12/02
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		104.9	114.7
Radionuclidic purity	≤ 0.1% ⁹⁹ Mo		N.D.	N.D.
	≤ 5 x 10 ⁻³ % ¹³¹ I		N.D.	N.D.
	≤ 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	5.5
Radiochemical purity	≥ 95% as pertechnetate ion (^{99m} TcO ₄ ⁻)	INIT.	99.9	99.7
		EXP.	99.9	99.5
Aluminium	≤ 5 µg mL /aluminium		0.35	†
Vial/Package Label	Complies		Complies	Complies

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

		SUPPLIER	DuPont	DuPont	DuPont	DuPont
		LOT/BATCH No.	0114A	0121A	0128A	0136A
SPECIFICATIONS		EXPIRY DATE	01/02/02	01/11/02	01/02/03	01/11/03
Appearance before reconstitution	Freeze dried solid		Pass	Pass	Pass	Pass
Appearance after reconstitution	A clear, colourless solution		Pass	Pass	Pass	Pass
Presence of vacuum	Complies		N/A	N/A	N/A	N/A
pH	6.3 - 7.6 after reconstitution		7.0	7.0	7.0	7.0
Radiochemical purity	1) ≥ 90.0 % as ^{99m} Tc-Bicisate 2) ≤ 10.0 % as impurities (colloidal, ^{99m} TcO ₄ ⁻ & ^{99m} Tc-EDTA)	INIT.	96.5	97.1	98.3	97.8
			3.5	2.9	1.7	2.2
		EXP.	98.6	97.9	98.8	98.3
			1.4	2.1	1.2	1.7
Stannous tin content	12 - 72 µg SnCl ₂ .2H ₂ O *		†	†	†	†
Label	Complies		Complies	Complies	Complies	Complies

*Value given in label/product information

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

		SUPPLIER	RADPH	RADPH	RADPH
		LOT/BATCH No.	1701	1815	1828
SPECIFICATIONS		EXPIRY DATE	February 2002	November 2002	February 2003
Appearance before reconstitution	Freeze-dried solid		Pass	Pass	Pass
Appearance after reconstitution	A clear colourless solution		Pass	Pass	Pass
pH	4.0 - 6.0 after reconstitution		5.7	5.8	5.9
Radiochemical purity	≥ 95.0 % as ^{99m} Tc-Etifenin	INIT.	†	90.3	†
		EXP.	87.4	†	80.2
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	Complies	Complies

*Value given in label/product information.

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

		SUPPLIER	AMER	AMER
		LOT/BATCH No.	930	958
SPECIFICATIONS		EXPIRY DATE	19/04/02	14/02/03
Appearance before reconstitution	Freeze-dried solid		Pass	Pass
Appearance after reconstitution	A clear colourless solution		Pass	Pass
pH	9.0 - 9.8 after reconstitution		9.1	9.1
Radiochemical purity	≥ 80.0 % as ^{99m} Tc-Exametazime	INT.	90.6	94.6
	% as free TcO ₄ ⁻		0.7	1.5
	% as hydrolysed reduced ^{99m} Tc		3.3	2.3
	% as ^{99m} Tc secondary exametazime complex		5.4	1.6
		EXP.	94.1	91.1
			0.6	2.7
			3.5	3.9
			1.8	2.3
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	Complies

*Value given in label/product information

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

		SUPPLIER	AMER	AMER	ARI	RADPH	AMER	RADPH	ARI	AMER
		LOT/BATCH No.	490	492	1773	1806	518	1827	1868	538
SPECIFICATIONS		EXPIRY DATE	28/01/02	04/02/02	01/09/02	01/10/02	07/04/02	Feb/02	July/03	10/02/04
Appearance before reconstitution	Freeze dried solid		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Appearance after reconstitution	A clear, colourless solution		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Presence of vacuum	Complies		N/A	N/A	N/A	Complies	N/A	Complies	N/A	N/A
pH	3.5 – 7.5 after reconstitution		6.3	6.6	4.5	5.0	6.1	5.0	5.0	6.1
Radiochemical purity	1) ≥ 95.0 % as ^{99m} Tc-MDP	INIT.	99.0	99.3	99.6	99.6	97.6	99.7	99.3	98.9
	2) ≤ 2.0 % as ^{99m} TcO ₄ ⁻		0.1	0.2	0.1	0.1	0.6	0.1	0.1	0.1
	3) as colloidal ^{99m} Tc		0.9	0.5	0.3	0.3	1.8	0.2	0.6	1.0
	2) + 3) ≤ 5.0 %	EXP.	97.7	99.3	99.5	99.6	99.6	98.7	99.3	99.4
				1.7	0.2	0.1	0.1	0.1	0.2	0.1
			0.6	0.5	0.4	0.3	0.3	1.1	0.6	0.3
Stannous tin content	0.84 mg SnCl ₂ /vial*				†				†	
	1 mg SnCl ₂ /vial*					†		†		
	0.34 mg SnF ₂ /vial*		†	†			†			†
Tin	<3mg/ml of Sn		†	†	Pass	Pass	Pass	Pass	Pass	Pass
Biological distribution	≥ 1.5% attached to femur		†	†	†	†	†	†	†	†
	≤ 1.0% in the liver		†	†	†	†	†	†	†	†
	≤ 0.05 %/g in the blood		†	†	†	†	†	†	†	†
Label	Complies		Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies

*Value given in label/product information

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

		SUPPLIER	MALL	MALL	MALL	MALL
		LOT/BATCH No.	0961006	0960010B	0961013A	0962002A
SPECIFICATIONS		EXPIRY DATE	11/03/02	03/10/02	28/8/02	16/2/03
Appearance before reconstitution	Freeze-dried solid		Pass	Pass	Pass	Pass
Appearance after reconstitution	A clear, colourless solution free of particulate matter.		Pass	Pass	Pass	Pass
pH	5.0 - 7.5 after reconstitution		5.8	6.0	5.5	5.5
Radiochemical purity*	1) ≥ 94.0 % as ^{99m} Tc-MAG3	INIT.	99.7	99.5	99.6	99.8
	2) % as hydrophilic impurities		0.1	0.2	0.2	0.1
	3) % as non-elutable impurities		0.2	0.3	0.2	0.1
		EXP.	99.5	99.8	99.6	99.8
			0.1	0.1	0.25	0.1
			0.4	0.1	0.15	0.1
Stannous tin content	≥ 50 µg SnCl ₂ .2H ₂ O/vial**		N/A	N/A	N/A	N/A
Label	Complies		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.	0912010B	0912015B
SPECIFICATIONS		EXPIRY DATE	29/11/02	22/02/03
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	5.0
Radiochemical purity	1) ≥ 90.0 % as ^{99m} Tc-HDP	INIT.	98.9	99.8
	2) % as ^{99m} TcO ₄ ⁻		0.6	0.1
	3) % as colloidal ^{99m} Tc		0.5	0.1
	2) + 3) ≤ 10.0 %			
		EXP.	99.4	99.7
Stannous tin content	0.258 mg SnCl ₂ .2H ₂ O*		†	†
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 as minimum content.

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

		SUPPLIER	ARI	RADPH	AMER	RADPH	ARI	AMER
		LOT/BATCH No.	1774	1804	262	1831	1848	274
SPECIFICATIONS		EXPIRY DATE	01/11/02	01/10/02	12/06/02	Feb/03	May/03	07/05/03
Appearance before reconstitution	Freeze-dried solid		Pass	Pass	Pass	Pass	Pass	Pass
Appearance after reconstitution	A clear, colourless or slightly yellow solution		Pass	Pass	Pass	Pass	Pass	Pass
Presence of vacuum	Complies		Complies	Complies	N/A	Complies	Complies	N/A
pH	4.0 - 7.5 after reconstitution		4.4	5.5	4.5	5.5	4.7	4.7
Radiochemical purity	1) ≥ 95.0 % as ^{99m} Tc-DTPA	INIT.	99.8	99.1	99.8	99.3	99.9	99.9
	2) % as ^{99m} TcO ₄ ⁻		0.1	0.2	0.1	0.2	0.1	0.1
	3) % as colloidal ^{99m} Tc		0.1	0.7	0.1	0.5	0	0
	2) + 3) ≤ 5.0%	EXP.	99.8	99.3	99.8	99.2	99.8	99.6
				0.1	0.2	0.2	0.3	0.1
Stannous tin content	1.05 mg SnCl ₂ */vial		†				†	
	1 mg SnCl ₂ */vial			†		†		
	0.25 mg SnCl ₂ .2H ₂ O*/vial				†			†
	0.21 mg SnCl ₂ */vial							
Tin	<1mg/ml of Sn		Pass	Pass	Pass	Pass	Pass	Pass
Label	Complies		Complies	Complies	Complies	Complies	Complies	Complies

*Value given in label/product information.

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

		SUPPLIER	DuPont	Dupont	Dupont
		LOT/BATCH No.	3724	3729A	3762MA
SPECIFICATIONS		EXPIRY DATE	01/05/02	01/08/02	01/10/03
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	N/A
pH	5.0 - 6.0 after reconstitution		5.2	5.3	5.1
Radiochemical purity	1) ≥ 90.0 % as ^{99m} Tc-Sestamibi	INIT.	98.8	98.5	97.9
			1.2	1.5	2.1
	2) ≤ 10.0 % ^{99m} Tc as impurities	EXP	95.5	93.1	98.0
			1.5	6.9	2.0
Stannous tin content	75 μ g SnCl ₂ *		N/A	N/A	N/A
Label	Complies		Complies	Complies	Complies

*Value given in label/product information.

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

		SUPPLIER	RADPH	RADPH	RADPH
		LOT/BATCH No.	1742	1805	1824
SPECIFICATIONS		EXPIRY DATE	Feb/02	1/07/02	Nov/02
Appearance before reconstitution	Freeze dried solid		Pass	Pass	Pass
Appearance after reconstitution	A clear, colourless solution		Pass	Pass	Pass
Presence of vacuum	Complies		Complies	Complies	Complies
pH	2.3 - 3.5 after reconstitution		3.1	3.0	2.9
Radiochemical purity	≥ 95.0 % as ^{99m} Tc-DMSA ≤ 2.0 % as ^{99m} TcO ₄ ⁻	INIT.	99.8	99.7	99.5
		EXP.	0.2	0.3	0.5
			99.6	99.7	99.2
			0.4	0.3	0.8
Stannous tin content	0.4 mg SnCl ₂ *		†	†	†
Tin	<1mg/ml of Sn		†	Pass	Pass
Biological distribution	$\geq 40\%$ in the kidneys		†	†	†
	$\leq 10\%$ in the liver		†	†	†
	$\leq 2\%$ in the stomach		†	†	†
	$\leq 5\%$ in the lungs		†	†	†
Label	Complies		Complies	Complies	Complies

*Value given in label/product information

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

		SUPPLIER	AMER	AMER
		LOT/BATCH No.	704	828
SPECIFICATIONS		EXPIRY DATE	04/05/02	28/03/03
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	7.5 - 9.0 after reconstitution		8.4	8.3
Radiochemical purity	1) ≥ 90.0 % as ^{99m} Tc-Tetrofosmin	INT.	†	97.0
	2) as % reduced hydrolysed ^{99m} Tc and hydrophilic impurities		†	2.8
	3) as % unbound pertechnetate ^{99m} TcO ₄ ⁻		†	0.2
	2 + 3) ≤ 10 %	EXP.	97.6	97.4
			2.3	2.2
			0.1	0.4
Stannous tin content	7.6 μ g SnCl ₂ .2H ₂ O/vial *		†	†
Label	Complies		Complies	Complies

*Value given in label/product information.

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

		SUPPLIER	RADPH	MALL	RADPH	MALL
		LOT/BATCH No.	1776	0941014B	1846	0942002B
SPECIFICATIONS		EXPIRY DATE	01/08/02	05/05/02	05/03	13/08/02
Appearance before reconstitution	Freeze-dried solid		Pass	Pass	Pass	Pass
Appearance after reconstitution	A clear, colourless solution		Pass	Pass	Pass	Pass
Presence of vacuum	Complies		Complies	N/A	Complies	N/A
pH	6.0 – 7.0 after reconstitution		5.3		5.0	
	4.0 - 7.5 after reconstitution*			5.0		5.0
Radionuclidic purity	1) ≥ 90.0 % as ^{99m} Tc-PYP	INIT.	98.8	97.6	98.7	†
	2) as ^{99m} TcO ₄ ⁻		0.2	0.9	0.3	†
	3) as colloidal ^{99m} Tc		1.1	1.4	1.0	†
	2) + 3) ≤ 10.0%	EXP.	98.5	97.6	94.4	98.9
			0.4	1.5	0.3	0.3
			1.1	0.9	5.3	0.8
Sodium pyrophosphate content	1-50 mg/mL sodium pyrophosphate on reconstitution		31	12	32	11
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	Complies

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

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

SPECIFICATIONS		SUPPLIER	RADPH**	RADPH**
		LOT/BATCH No.	1788	1829
		EXPIRY DATE	01/10/02	03/03
Appearance before reconstitution	Freeze-dried solid		Pass	Pass
Appearance after reconstitution	A clear, colourless solution		Pass	Pass
Presence of vacuum	Complies		Complies	Complies
pH	4.0 - 7.0 after reconstitution		4.7	5.0
Radiochemical purity	≥ 95.0 % as ^{99m} Tc-colloid	INIT.	99.2	99.6
		EXP.	95.7	97.7
Stannous tin content	1.0 mg SnCl ₂ *		†	†
Tin	<1mg/ml of Sn		Pass	Pass
Biological distribution	≥ 80% in the liver + spleen		†	†
	≤ 5% in the lungs		†	†
Label	Complies		Complies	Complies

*Value given in label/product information.

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

SODIUM IODIDE¹³¹I CAPSULES

		SUPPLIER	AMER	ARI	AMER	ARI
		LOT/BATCH No.	516220000170	23117	523180000210	24069
		CALIB. DATE	21/06/02	08/07/02	15/11/02	18/11/02
SPECIFICATIONS		EXPIRY DATE	Not stated	22/7/02	Not stated	02/12/02
Appearance	Gelatine capsule		Pass	Pass	Pass	Pass
Gamma spectrum	Gamma spectrum does not differ significantly from that of a standardised I-131 solution		Pass	Pass	Pass	Pass
Radionuclidic content	90-110% of stated value		105.3	100.3	106.1	100.1
Radionuclidic purity	≤ 0.1% of the total radioactivity is due to ¹³³ I, ¹³⁵ I and other radionuclidic impurities		N.D.	N.D.	N.D.	N.D.
Radiochemical purity	≥ 95% of activity as iodide	INIT.	99.1	99.3	98.8	98.4
		EXP.	97.5	†	96.7	98.5
Disintegration	The shell and its contents dissolve completely within 15 min.		Complies	Complies	Complies	Complies
Label	Complies		Fail	Complies	Fail	Complies

m-IODOBENZYLGUANIDINE[¹³¹I] INJECTION (mIBG)

		SUPPLIER	ARI	ARI
		LOT/BATCH No.	23683	24066
		CALIB. DATE	24/09/02	19/11/02
SPECIFICATIONS		EXPIRY DATE	29/09/02	24/11/02
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 I-131 solution		Pass	Pass
Radionuclidic content	90-110% of stated value		96.1	100.0
Radionuclidic purity	≤ 0.1 % of the total radioactivity is due to ¹³³ I, ¹³⁵ I and other radionuclidic impurities		N.D.	N.D.
pH	3.5 – 8.0		5.8	5.5
Radiochemical purity	≥ 94% of activity as ¹³¹ I-mIBG ≤ 5% of activity as iodide	INIT.	99.2	98.8
			0.8	1.2
		EXP.	98.7	98.4
			1.3	1.6
Vial/Package Label	Complies		Complies	Complies

SODIUM IODIDE¹³¹I INJECTION

		SUPPLIER	ARI	ARI	ARI
		LOT/BATCH No.	23185	23768	24249
		CALIB. DATE	05/07/02	25/09/02	20/11/02
SPECIFICATIONS		EXPIRY DATE	19/07/02	09/10/02	04/12/02
Appearance	A clear, colourless solution		Pass	Pass	Pass
Particulate matter	None visible		Pass	Pass	Pass
Gamma spectrum	Gamma spectrum does not differ significantly from that of a standardised I-131 solution		Pass	Pass	Pass
pH	7.0 – 8.5		7.0	7.0	7.5
Radionuclidic content	90-110% of stated value		99.6	99.8	96.3
Radionuclidic purity	≤ 0.1 % of the total radioactivity is due to ¹³³ I, ¹³⁵ I and other radionuclidic impurities		Pass	Pass	Pass
Radiochemical purity	≥ 95% of activity as iodide	INIT.	99.7	99.9	100
		EXP.	†	99.8	100
Label	Complies		Complies	Complies	Complies

THALLOUS[²⁰¹Tl] CHLORIDE INJECTION

		SUPPLIER	ARI	MALL	ARI	MALL	ARI	MALL	MALL	ARI
		LOT/BATCH No.	21973	30566	23031	32661	23678	34087	34992	24004
		CALIB. DATE	30/1/02	1/2/02	26/06/02	26/06/02	25/09/02	25/09/02	14/11/02	15/11/02
SPECIFICATIONS		EXPIRY DATE	4/2/02	7/2/02	01/07/02	03/07/02	30/09/02	02/10/02	21/11/02	20/11/02
Appearance	A clear colourless solution		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Particulate matter	None visible		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Gamma spectrum	Gamma spectrum does not differ significantly from that of a standardised Tl-201 solution		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
pH	4.5 – 7.0		5.0	5.0	5.0	5.3	5.5	5.5	5.5	5.5
Radiochemical content	90-110% of stated value		106.6	97.2	106.4	99.7	107.7	99.7	99.5	108.2
Radionuclidic purity	≥ 97.0 % ²⁰¹ Tl at calibration		99.5	99.6	99.3	99.6	99.8	99.7	99.7	99.3
	≥ 97.0 % ²⁰¹ Tl at at expiry		99.7	99.1	99.7	98.9	99.6	98.9	99.3	99.7
	≤ 2.0% ²⁰² Tl at expiry		0.3	0.9	0.2	1.1	0.4	1.1	0.7	0.3
	% ²⁰⁰ Tl at calibration		0.4	0.1	0.6	0.1	N.D.	N.D.	0.1	0.6
	% ²⁰³ Pb at calibration		N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
	% ²⁰¹ Pb at calibration		N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
Radiochemical purity	≥ 95.0 % as Tl(I)	INIT.	99.8	99.8	99.6	99.4	99.5	99.1	99.3	99.4
		EXP.	99.8	99.7	99.9	99.9	99.9	99.9	99.8	99.7
Chemical purity	≤ 10 µg/mL Tl		†	< 2	< 2	< 2	< 2	< 2	< 2	< 2
Benzyl alcohol	90 – 110 % of stated value		†	N/A	95	N/A	91	N/A	N/A	97
Label	Complies		Complies	Fails	Complies	Fails	Complies	Fails	Fails	Complies