

AUSTRALIAN RADIATION PROTECTION AND NUCLEAR SAFETY AGENCY

Results of the Quality Assurance Testing
Program for Radiopharmaceuticals 1998 & 1999

by

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Technical Report 130
ISSN 0157-1400
May 2000

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ABSTRACT

This report tabulates results obtained during 1998 & 1999 for the Radiopharmaceutical Quality Assurance Test Program conducted by the Australian Radiation Protection and Nuclear Safety Agency.

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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. 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 [^{201}Tl] 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 [$^{99\text{m}}\text{Tc}$] Injection. Methods used for testing are described in the report ARL/TR093*.

RESULTS

The results of testing during 1998 & 1999 are summarised in the following tables. Overall, 77 batches of 25 different types of radiopharmaceuticals were tested. Failure to meet full specifications was observed in 13 of the 77 batches of radiopharmaceuticals tested (16.9%).

Non-compliance of the vial label was observed in seven of the thirteen batches failing specification and was the only non-compliance for these batches. Vial label non-compliance consisted of, absence of a statement as to the presence or absence of a microbiological preservative, the absence of an expiry date and absence of stannous tin content.

Other non-compliance was high radionuclidic content in three batches, slightly low pH in three batches and one batch failed due to the presence of radionuclidic impurity. 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.

The following abbreviations are used in the tables -

AMER	-	Amersham International plc, Buckinghamshire, UK
ARI	-	Australian Radioisotopes, Lucas Heights, Sydney, Australia
DuP	-	DuPont Pharma Radiopharmaceuticals, North Billerica (Boston) , MA, USA
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
H	-	Not determined
LSC	-	Liquid scintillation counting

SODIUM PHOSPHATE[³²P] INJECTION

SPECIFICATIONS		SUPPLIER	AMER	ARI
		LOT/BATCH No.	530	83418
		CALIB. DATE	23/02/98	21/09/98
		EXPIRY DATE	23/03/98	13 /10/98
Appearance	Clear, colourless solution		Pass	Pass
Particulate matter	None visible		N.D.	N.D.
Radionuclidic content	90-110% of stated		93	102
Radionuclidic purity	Beta spectrum complies with standard (LSC)		Pass	Pass
pH	6.0 - 8.0		7.0	5.7
Radiochemical purity	∃ 95% as orthophosphate	INIT: EXP.	99.7 99.7	99.4 99.4
Specific activity	∃11 MBq/mg orthophosphate		54.4	†
Label	Complies		Complies	Complies

CHROMIUM[⁵¹Cr] EDETATE INJECTION

		SUPPLIER	AMER	AMER	ARI
		LOT/BATCH No.	448	472	83288
		CALIB. DATE	16/02/98	03/08/98	01/09/98
	SPECIFICATION	EXPIRY DATE	13/04/98	28/09/98	01/10/98
Appearance	Clear purple solution		Pass	Pass	Pass
Particulate matter	None visible		N.D.	N.D.	N.D.
Identification	Gamma spectrum		Pass	Pass	
Radionuclidic content	90-110% of stated		104	102	116
Radionuclidic purity	No other radionuclides detected by gamma spectrometry		N.D.	N.D.	Fail*
pH	3.5 - 6.5		4.0	4.0	4.5
Chemical purity (mg/mL)					
1) Total edetate			1.7	2.5	8.6
2) Uncomplexed edetate			0.8	1.4	6.2
3) Total chromium	# 1mg/mL		0.16	0.19	0.45
Radiochemical purity					
1) Chromic ion		INIT.	0.5	0.1	0.2
2) Chromate ion			1.4	3.5	2.8
3) Cr-edetate	∃ 95% as ⁵¹ Cr-edetate		98.1	96.4	97.0
		EXP.	0.2	0.2	0.2
			0.7	4.3	4.8
			99.1	95.5	95.0
Benzyl alcohol	90-110%		104	94	N.A.
Label	Complies		Complies	Complies	Complies

* ¹²⁴Sb content 0.3% at calibration, 0.44% at expiry. The batch was recalled by the manufacturer.

SODIUM CHROMATE[⁵¹Cr] SOLUTION

SPECIFICATIONS		SUPPLIER	AMER	AMER	ARI
		LOT/BATCH No.	530	554	83289
		CALIB. DATE	25/02/98	12/08/98	01/09/98
		EXPIRY DATE	22/04/98	07/10/98	01/10/98
Appearance	Clear, colourless/faintly yellow solution		Pass	Pass	Pass
Particulate matter	None visible		N.D.	N.D.	N.D.
Identification	Gamma spectrum		Pass	Pass	Pass
Radionuclidic content	90-110% of stated		110	108	102
Radionuclidic purity	No other radionuclides detected by gamma		N.D.	N.D.	N.D.
Radiochemical purity	∃ 90% as chromate	INIT.	99.8	99.5	98.9
		EXP.	99.5	99.3	99.4
pH	6.0 - 8.5		6.0	6.6	6.0
Specific activity	∃ 0.37 GBq/mg of chromate ion		11.0	15.3	4.7
Label	Complies		Complies	Complies	Complies

CYANOCOBALAMIN[⁵⁷Co] CAPSULES

SPECIFICATIONS		SUPPLIER	AMER
		LOT/BATCH No.	430
		CALIB. DATE	17/04/98
		EXPIRY DATE	12/06/98
Appearance	Gelatin capsule		Pass
Identification	Gamma spectrum		Pass
Radionuclidic content	90-110% of stated		90
Radionuclidic purity	# 0.1% total ⁵⁶ Co+ ⁵⁸ Co and all other radionuclides		N.D.
Radiochemical purity	∃ 90% as cyanocobalamin	INIT.	96.0
		EXP.	96.4
Dissolution test	> 70%		99
Label	Complies		Complies

SELENONORCHOLESTENOL^[75Se] INJECTION

SPECIFICATIONS		SUPPLIER	AMER
		LOT/BATCH No.	394
		CALIB. DATE	23/02/98
		EXPIRY DATE	23/03/98
Appearance	Clear, colourless/faintly yellow solution		Pass
Particulate matter	None visible		N.D.
Radionuclidic content	90-110% of stated		101
Radionuclidic purity	No other radionuclides detected by gamma spectrometry		N.D.
Radiochemical purity	> 70% as Selenonorcholestenol	INIT. EXP.	77 H
pH	2.5 - 3.5		3.0
Absorption on closure	# 10% of the radioactivity in the vial		5.3
Benzyl alcohol	90-110% of stated		N.A.
Label	Complies		Complies

TECHNETIUM[^{99m}Tc] CHROMATOGRAPHIC GENERATOR

		SUPPLIER	ARI		
		LOT/BATCH No.	83542073		
		CALIB. DATE	28/09/98		
SPECIFICATIONS		EXPIRY DATE	12/10/98		
Maximum surface radiation dose	< 2 mGy/hr		0.7		
Dose at 1 m	< 0.10 mGy/hr		0.03		
			MAX	MIN	AVG
pH	4.0 - 8.0		6.0	6.0	6.0
Radiochemical purity	∃ 95% ^{99m} TcO ₄ ⁻¹		100	100	100
Milking efficiency			105	96	100
Radionuclidic purity	# 0.1% ⁹⁹ Mo		N.D.		
	# 5E-3% ¹³¹ I	N.D.			
	# 5E-3% ¹⁰³ Ru		N.D.		
	# 6E-5% ⁸⁹ Sr		H		
	# 6E-6% ⁹⁰ Sr		H		
	# 0.01% all other radionuclides		N.D.		
	# 1E-7% alpha emitters		H		
Aluminium content	# 20 µg/mL		H		

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

SPECIFICATIONS		SUPPLIER	RC	RC
		LOT/BATCH No.	230798	081299
		CALIB. DATE	23/07/98	08/12/99
		CALIB. TIME	0900hrs	0900hrs
Appearance	Clear, colourless solution		Pass	Pass
Identity	Gamma spectrum		Pass	Pass
Particulate	None visible		N.D.	N.D.
Radionuclidic content	90-110% of stated		104	98
pH	4.5 - 7.5		5.0	5.0
Chemical purity				
Aluminium cont.	# 20 $\mu\text{g/mL}$		H	H
Radionuclidic purity	# 1E-1% ^{99}Mo		1.2 E3	N.D.
	# 5E-3% ^{103}Ru		1.3 E5	N.D.
	# 5E-3% ^{131}I		N.D.	N.D.
	# 6E-5% ^{89}Sr		H	H
	# 6E-6% ^{90}Sr		H	H
	# 1E-2% all other gamma emitters		N.D.	N.D.
	# 1E-7% alpha-emitting impurities		H	H
Radiochemical purity	\exists 95% as $^{99m}\text{TcO}_4^-$	INIT.	100	99.9
	# 2% as colloidal material			0.1
		EXP.	99.9	99.9
			0.1	0.1
Label	Complies		Complies	Complies

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

	SPECIFICATIONS	SUPPLIER LOT/BATCH No. EXPIRY DATE	DuP 2596 KA 01/02/99
Appearance	Freeze dried solid before reconstitution		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 ^{99m} Tc-Disofenin # 10.0% as ^{99m} TcO ₄ ⁻¹ + colloidal ^{99m} Tc	INIT.	97.0
		EXP.	3.0 95.3 4.7
Stannous tin content	0.24 - 0.6 mg SnCl ₂ .2H ₂ O/vial *		H
Biological distribution	∃ 70% gall bladder + small & large intestines	INIT.	H
	# 10% kidneys		H
	# 10% liver		H
	# 3% stomach		H
	# 3% blood		H
Label	Complies		Complies

*Value given in label/product information.

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

	SPECIFICATIONS	SUPPLIER LOT/BATCH No. EXPIRY DATE	RADPH 1450 April 99
Appearance before reconstitution	Freeze dried solid		Pass
Particulate matter	Free of any particulate matter after reconstitution		N.D.
pH	4.0 - 6.0 after reconstitution		5.5
Radiochemical purity	∃ 95.0% as ^{99m} Tc-Etifenin	INIT.	96.3
	# 5.0% as ^{99m} TcO ₄ ⁻¹ + colloidal ^{99m} Tc		3.7
		EXP.	96.3 3.7
Stannous tin content	0.42 mg SnCl ₂ /vial *		H
Biological distribution	∃ 80% gall bladder + small & large intestines	INIT.	H
	# 3% liver		H
	# 2% kidneys		H
Label	Complies		Complies

*Value given in label/product information.

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

	SPECIFICATIONS	SUPPLIER LOT/BATCH No. EXPIRY DATE	AMER A60S 21/04/98	AMER A764 03/-6/00
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		9.1	9.2
Radiochemical purity	∃ 80.0% as ^{99m} Tc-Exametazime	INIT.	90.0	H
	# 5.0% as hydrolysed ^{99m} Tc		2.3	H
	# 10.0% as hydrolysed ^{99m} Tc + ^{99m} TcO ₄ ⁻¹		4.0	H
		EXP.	90.1 3.1 4.2	92.7 1.5 1.9
Stannous tin content	7.6 µg SnCl ₂ .2H ₂ O/vial * (min 0.6 µg as stannous ion / 1.14 µg SnCl ₂ .2H ₂ O)		H	H
Biological distribution	∃ 1.5% brain		H	H
	# 20% intestines		H	H
	# 15% liver		H	H
Label	Complies		Complies	Complies

*Value given in label/product information.

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

		SUPPLIER	RADPH	DuP	MALL	RADPH	MALL
		LOT/BATCH No.	1324	7225KA	0938020	1462	0939003
SPECIFICATIONS		EXPIRY DATE	Feb/98	01/09/98	27/04/99	Aug/99	25/01/00
Appearance before reconstitution	Freeze dried solid		Pass	Pass	Pass	Pass	Pass
Appearance after reconstitution	Suspension of white or faintly yellow particles which may settle on standing		Pass	Pass	Pass	Pass	Pass
pH	3.8 - 7.5		6.0	6.0	4.0	6.0	4.5
Radiochemical purity	1) ∃ 90% in aggregate 2) as soluble ^{99m} Tc-Albumin 3) as free pertechnetate 2) + 3) # 10%	INIT.	98.3	98.2	97.6	98.6	96.8
			1.0	0.2	1.0	0.8	1.4
			0.7	0.9	1.4	0.6	1.8
		EXP.	98.4	97.5	97.7	98.5	
			0.4	1.1	1.1	0.5	
			0.2	1.4	1.2	1.0	
Particle size	None > 150 μm		Pass	Pass	Pass	Pass	Pass
Biological distribution	∃ 80% in lungs		H	H	H	H	H
	# 5% in liver + spleen		H	H	H	H	H
Label	Complies		Complies	Complies	Complies	Complies	Complies

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

SPECIFICATIONS	SUPPLIER	DuP	AMER	AMER	AMER	DuP	ARI	RPHAR	AMER	
	BATCH No.	6134	400	408	418	6/38	1454	1459	432	
	EXPIRY DATE	01/04/98	15/06/98	19/10/98	22/01/99	01/04/99	May/99	June/99	14/10/99	
Appearance before re-constitution	Freeze dried solid	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	
Particulate matter	Free of any particulate matter after reconstitution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	
pH	3.5 - 7.5 after reconstitution	6.0	6.0	6.0	6.0	7.0	4.5	4.5	5.5	
Radiochemical purity	1) \geq 95.0% as ^{99m} Tc-MDP 2) # 2.0% as ^{99m} TcO ₄ ⁻ 3) as colloidal ^{99m} Tc 2) + 3) # 5.0%	INIT.	98.2	99.6	98.7	99.8	98.7	99.3	99.5	99.5
			1.3	0.2	1.1	0.1	0.8	0.1	0.1	0.3
			0.5	0.2	0.2	0.1	0.5	0.6	0.4	0.2
		EXP.	98.1	99.0	99.0	99.5	98.6	99.8	99.6	99.8
		1.5	0.2	0.2	0.3	1.2	0.1	0.1	0.1	
		0.4	0.8	0.8	0.2	0.2	0.1	0.3	0.1	
Stannous tin content	0.34 mg SnF ₂		0.46	0.57	H	-	-	-	H	
	0.84 mg SnCl ₂ *	H	-	-	-	-	H	-	-	
	0.6 mg SnCl ₂ .2H ₂ O (min.)*	-	-	-	-	H	-	H	-	
Biological distribution	\geq 2.5% attached to two femurs	H	H	H	H	H	H	H	H	
	# 1.0% in the liver	H	H	H	H	H	H	H	H	
	\geq 100 femurs : muscle	H	H	H	H	H	H	H	H	
	\geq 40 femurs : blood	H	H	H	H	H	H	H	H	
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)

SPECIFICATIONS		SUPPLIER	MALL	MALL	MALL
		LOT/BATCH No.	0966009A	0968006A	0968013A
		EXPIRY DATE	11/09/98	24/06/00	15/10/00
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	4.5 - 6.5 after reconstitution		5.5	5.5	5.0
Radiochemical purity	\geq 90% as ^{99m} Tc-MAG3 as % hydrophilic impurities as % non-elutable impurities	INIT.	99.0	99.4	97.5
			0.4	0.2	0.0
			0.6	0.4	2.5
		EXP.	99.0		
			0.7		
			0.3		
Stannous tin content	\geq 50 μ g SnCl ₂ .2H ₂ O/vial *		H	H	H
Biological distribution			H	H	H
Label	Complies		Complies	Complies	Complies

*Value given in label/product information.

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

SPECIFICATIONS		SUPPLIER LOT/BATCH No. EXPIRY DATE	MALL 0998001 13/01/99	MALL 0999001B 07/01/00
Appearance before reconstitution	Freeze dried solid		Pass	Pass
Particulate matter	Free of any particulate matter after reconstitution		N.D.	N.D.
pH	2.5 - 7.0 after reconstitution		5.0	5.0
Radiochemical purity	1) \exists 90.0% as ^{99m} Tc-HDP 2) as ^{99m} TcO ₄ ⁻ + 3) as colloidal ^{99m} Tc 2)+3)# 10.0%	INIT.	99.0 0.1 0.9	99.3 0.1 0.6
		EXP.	98.7 0.1 1.3	
Stannous tin content	0.16 mg SnCl ₂ *		H	H
Biological distribution	\exists 1.0% attached to one femur		H	H
	# 5.0% in the liver		H	H
	# 5.0% in the kidneys		H	H
Label	Complies		Complies	Complies

* Value given in label/product information.

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

		SUPPLIER	AMER	AMER	ARI	MALL(H)	AMER	MALL(H)	AMER	RADPH	
SPECIFICATIONS		LOT/BATCH No.	A202	A206	1445	79192	A218	72715	A222	1465	
		EXPIRY DATE	18/03/98	20/07/98	Mar/99	11/04/99	12/04/99	24//07/99	26/07/99	Aug/99	
Appearance before re-constitution	Freeze dried solid		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	
Particulate matter	Free of any particulate matter after reconstitution		N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	
pH	4.0 - 7.5 after reconstitution		4.5	4.5	4.5	4.5	4.5	4.5	4.5	5.0	
Radiochemical purity 3) as colloidal ^{99m} Tc	1) ∃ 95.0% as ^{99m} Tc-DTPA 2) as ^{99m} TcO ₄ ⁻	INIT.	99.8	99.8	99.8	99.8	99.8	99.6	99.7	99.3	
			0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	
			0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.1	0.5
		EXP.	99.8	99.8	99.8	99.8	99.7	99.8	97.2	99.2	
			0.1	0.1	0.1	0.1	0.2	0.1	1.0	0.4	
			0.1	0.1	0.1	0.1	0.1	0.1	1.8	0.4	
Stannous tin content	∃ 60% of stated		H	H	H	H	H	H	H	H	
Label	Complies		Complies	Complies	Fail	Complies	Complies	Complies	Complies	Complies	

* Value given in label/product information.

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

		SUPPLIER	DuP	DuP	DuP
		LOT/BATCH No.	3642	3665	3674
SPECIFICATIONS		EXPIRY DATE	01/01/98	01/03/99	01/07/990
Appearance	Freeze dried solid with no evidence of moisture		Pass	Pass	Pass
Particulate matter	Free of any particulate matter after reconstitution		N.D.	N.D.	N.D.
pH	5.0 - 6.0 after reconstitution		5.0	5.5	5.0
Radiochemical Purity	1) \exists 90% as ^{99m} Tc-sestambi	INIT.	97.8	93.7	98.3
	2) as ^{99m} TcO ₄ ⁻		0.9	3.7	0.8
	3) as colloidal ^{99m} Tc		1.3	2.6	0.9
	2) + 3) # 10%				
		EXP.	98.1	93.7	98.5
			1.1	3.7	0.5
			0.8	2.6	1.0
Stannous tin content	75 μ g SnCl ₂ .2H ₂ O * (25 μ g minimum)		131	H	H
Label	Complies		Complies	Complies	Complies

*Value given in label/product information.

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

SPECIFICATIONS		SUPPLIER LOT/BATCH No. EXPIRY DATE	RADPH 1446 Dec./98
Appearance before reconstitution	Freeze dried white fluffy solid		Pass
Particulate matter	Free of any particulate matter after reconstitution		N.D.
pH	2.3 - 3.5 after reconstitution		3.5
Radiochemical purity	∃ 95.0% as ^{99m} Tc - DMSA # 2.0% as ^{99m} TcO ₄ ⁻	INIT.	99.7 0.3
		EXP.	99.7 0.3
Stannous tin content	0.4 mg SnCl ₂ *		H
Biological distribution	∃ 40% in kidneys	INIT.	H
	# 10.0% in liver		H
	# 2.0% in stomach		H
	# 5.0 % in lungs		H
Label	Complies		Complies

* Value given in label/product information.

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

		SUPPLIER	AMER	AMER	AMER
		LOT/BATCH No.	256	302	372
SPECIFICATIONS		EXPIRY DATE	09/01/98	23/10/98	07/09/99
Appearance before reconstitution	Freeze dried solid		Pass	Pass	Pass
Particulate matter	Free of any particulate matter after reconstitution		N.D.	N.D.	N.D.
pH	8.3 - 9.1 after reconstitution		H	8.3	8.4
Radiochemical purity	∃ 90.0% as ^{99m} Tc - Tetrofosmin # 10.0% as ^{99m} Tc hydrophilic # 5.0% (Hydrolysed ^{99m} Tc + ^{99m} TcO ₄ ⁻)	INIT.	96.7	97.1	H
			3.2	2.3	H
			0.1	0.6	H
		EXP.	98.0	97.1	96.1
			1.9	2.3	2.9
		0.1	1.6	1.0	
Stannous tin content	∃ 7.0 - 15.8 µg as stannous ion*		H	H	H
Biological distribution	# 0.4% in blood		H	H	H
	# 4.0% in liver		H	H	H
	# 3.0% in stomach		H	H	H
	# 1.0 % in lungs		H	H	H
	∃ 2.8 Heart:whole body		H	H	H
Label	Complies		Fail	Fail	Fail

* 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.	1360	0948004	1460	0948009
SPECIFICATIONS		EXPIRY DATE	Jan/98	01/01/99	June/99	16/06/99
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	6.0 - 7.0 after reconstitution		5.0	-	5.0	
	4.0 - 7.5 after reconstitution **		-	5.0	-	5.0
Radiochemical Purity 3) as colloidal ^{99m} Tc 2) + 3) # 10%	1) ∃ 90% as ^{99m} Tc-PYP	INIT.	98.4	99.4	99.4	99.1
			1.0	0.4	0.3	0.6
	2) as ^{99m} TcO ₄ ⁻		0.6	0.2	0.3	0.3
		EXP.	97.3	99.6	99.5	99.6
			2.1	0.3	0.3	0.3
		0.6	0.1	0.2	0.1	
Pyrophosphate content	1-50 mg/mL pyrophosphate		H	H	H	H
Stannous tin content	9.0 mg SnCl ₂ /vial *		10.4	-	H	-
	3.2 - 4.4 mg SnCl ₂ .2H ₂ O/vial *		-	H	-	H
Label	Complies		Complies	Complies	Complies	Complies

*Value given in label/product information.

** Value given in USP

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

SPECIFICATIONS	SUPPLIER		AMER*	AMER*	RADPH**	AMER*
	LOT/BATCH No.	AMER*	A158	A160	1467	A164
	EXPIRY DATE	AMER*	19/08/98	12/01/99	July/99	10/09/99
Appearance before re-constitution	All components are colourless and free from particulate matter		Pass	Pass	Pass	Pass
Appearance after re-constitution	Clear to slightly hazy colloid		Pass	Pass	Pass	Pass
pH	4.0 - 7.0		5.5	6.0	5.0	5.5
Radiochemical purity	∃ 95% as ^{99m} Tc colloid	INIT.	98.2	99.6	99.9	99.3
		EXP.	97.7	99.7	99.8	98.4
Stannous Tin content	1 mg SnCl ₂ ***		-	-	-	H
	0.125 mg SnF ₂ ***		0.23	H	H	-
Biological distribution	∃ 80% in liver + spleen		H	H	H	H
	# 5% in lungs		H	H	H	H
Label	Complies		Complies	Complies	Complies	Complies

* Technetium[^{99m}Tc] Tin Colloid

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

*** Value given in label/product information.

META-IODOBENZYLGUANIDINE[¹³¹I] INJECTION (mIBG)

SPECIFICATIONS		SUPPLIER	AMER	ARI
		LOT/BATCH No.	432199000	83544
		CALIB. DATE	15/02/98	29/09/98
		EXPIRY DATE	18/02/98	04/10/98
Appearance	Clear, colourless solution		Pass	Pass
Identification	Gamma spectrum		Pass	Pass
Particulate matter	None visible		N.D.	N.D.
Radionuclidic content	90-110% of stated		103	101
Radionuclidic purity	# 0.1% ¹³³ I, ¹³⁵ I and all other radionuclides		N.D.	N.D.
pH	4.0 - 7.0		5.5	5.5
Radiochemical purity	∃ 95.0% of activity as mIBG sulphate	INIT. EXP.	99.4 99.4	98.6 99.0
Benzyl alcohol	90-110% of stated		102	N.A.
Label	Complies		Complies	Complies

SODIUM IODIDE[¹³¹I] CAPSULES

SPECIFICATIONS		SUPPLIER	AMER
		LOT/BATCH No.	408738000/001
		CALIB. DATE	13/02/98
		EXPIRY DATE	Not stated
Appearance	Gelatine capsule		Pass
Identification	Gamma spectrum		Pass
Radionuclidic content	90-110% of stated		104
Radionuclidic purity	# 0.1% ¹³³ I, ¹³⁵ I and all other radionuclides		N.D.
Radiochemical purity	∃ 95% of activity as iodide	INIT.	99.4
		EXP.	99.8
Label	Complies		Fail

* Therapy dose

SODIUM IODIDE[¹³¹I] INJECTION

SPECIFICATIONS		SUPPLIER	AMER	ARI
		LOT/BATCH No.	414394000	83571/01
		CALIB. DATE	17/02/98	30/09/98
		EXPIRY DATE	17/03/98	14/10/98
Appearance	Clear, colourless solution		Pass	Pass
Identification	Gamma spectrum		Pass	Pass
Particulate matter	None visible		N.D.	N.D.
Radionuclidic content	90-110% of stated		107	97
Radionuclidic purity	# 0.1% ¹³³ I, ¹³⁵ I and all other radionuclides		N.D.	N.D.
pH	7.0 - 8.5		8.0	7.0
Radiochemical purity	≧ 95.0% of activity as iodide	INIT. EXP.	99.9 99.7	99.4 99.9
Label	Complies		Complies	Complies

THALLOUS[²⁰¹Tl] CHLORIDE INJECTION

		SUPPLIER	AMER	ARI	MALL(H)	DuP	AMER	ARI	MALL(H)
		LOT/BATCH No.	2151	81999	08058	T037845	2366	83538	11318
		CALIB. DATE	27/01/98	28/01/98	28/01/98	11/02/98	04/08/98	28/09/98	30/09/98
SPECIFICATIONS		EXPIRY DATE	30/01/98	02/02/98	04/02/98	15/02/98	07/08/98	03/10/98	07/10/98
Appearance	Clear, colourless solution			Pass	Pass	Pass	Pass	Pass	PassPass
Identification	Gamma spectrum		Pass	Pass	Pass	Pass	Pass	Pass	Pass
Particulate matter	None visible		N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
Radionuclidic content	90-110% of stated		106	107	103	114	108	101	98
Radionuclidic purity	∃97.0% ²⁰¹ Tl at calibration		99.7	99.5	99.6	99.8	99.7	99.7	99.6
	∃97.0% ²⁰¹ Tl at expiry		99.6	99.7	99.7	99.6	99.5	99.5	99.0
	# 2.0% ²⁰² Tl at expiry		0.36	0.28	1.11	0.45	0.51	0.46	1.01
	# 2.0% ²⁰⁰ Tl at calibration		0.04	0.34	0.05	0.03	0.04	0.11	0.06
	# 0.3% ²⁰³ Pb at calibration		N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
pH	4.5 - 7.0		6.0	6.0	6.0	6.0	6.0	5.5	5.5
Radiochemical purity	∃ 95.0% Tl(I)	INIT.	99.8	99.4	99.6	99.9	100	99.1	99.9
		EXP.	99.5	99.3	99.7	99.9	99.9	99.9	97.7
Chemical purity	# 2 µg/mL Tl		<1	<1	<1	<1	<1	<1	<1
Benzyl alcohol	90-110% of stated		103	99	Not Stated	99	100	98	Not Stated
Label	Complies		Complies	Complies	Fail	Complies	Complies	Complies	Fail