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**Australian Radiation Protection  
and Nuclear Safety Agency**

TECHNICAL REPORT

**Results of the Quality  
Assurance Testing Program  
for Radiopharmaceuticals  
(2004)**

*Z Ivanov*

TECHNICAL REPORT SERIES No. 140

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## **ABSTRACT**

This report tabulates results obtained during 2004 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 expiry time, except for Thallous [ $^{201}\text{Tl}$ ] Chloride Injection where the impurity levels both at calibration and expiry are quoted.

Samples for testing were obtained through commercial channels according to the schedule set at the beginning of the test period and described in *Quality Assurance of Radiopharmaceuticals including Cold Kits: MR-RPQA-SOP-0000*. All technetium-99m cold kits were reconstituted according to the directions in the package insert using Sodium Pertechnetate [ $^{99\text{m}}\text{Tc}$ ] Injection. Pharmacopoeia methods are used for testing, together with some additional methods described in the ARPANSA Quality System: Radiopharmaceuticals Quality Assurance Testing Program (MR-RPQA-WI-0060A).

## RESULTS

The results of testing during 2004 are summarised in the following tables. Overall, 38 batches of 24 different types of radiopharmaceuticals were tested. Failure to meet full specifications was observed in 2 of the 38 batches of radiopharmaceuticals tested (5 %). One batch was found to have slightly higher than specified benzyl alcohol content, while a low pH value failed BP specification, but passed the USP specification.

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 testing of the radiopharmaceuticals and cold kits was performed by I Bokor and Z Ivanov.

## ABBREVIATIONS

The following abbreviations are used in the tables -

AMER	- Amersham Healty Pty. Ltd., UK
ARI	- ANSTO Radiopharmaceuticals and Industrials, Lucas Heights, Sydney, Australia
MALL	- Mallinckrodt Inc, St Louis, MO, USA
MALL(H)	- Mallinckrodt Diagnostica (Holland)
RADPH	- Radpharm Scientific, Belconnen, ACT, Australia
BMS	- Bristol-Myers Squibb Medical Imaging , Tullamarine, VIC, Australia
BMS (US)	- Bristol-Myers Squibb Medical Imaging , North Billerica, Massachusetts, USA
N.D.	- Not detected
N.A.	- Not applicable
†	- Not determined
LSC	- Liquid scintillation counting
TBD	- To be done

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

### Current edition of BP

		SUPPLIER	ARI	AMER
		LOT/BATCH No.	101259-001	858
		CALIB. DATE	07/06/04	07/06/04
SPECIFICATIONS		EXPIRY DATE	29/06/04	05/07/04
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 phosphorus-32 solution obtained under the same conditions.		Pass	Pass
Radionuclidic content	90-110% of stated value		93, 94	105, 106
Radionuclidic purity	i) Beta spectrum does not differ significantly from that of a standardised phosphorus-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 ion		INIT. 100	100
			EXP. 100	100
pH	6.0 - 8.0		6.0	7.0
Specific radioactivity	≥ 11.1 MBq of phosphorus-32 per mg of orthophosphate ion		Pass	Pass
Vial/Package Label	Complies		Complies	Complies

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

Current edition of BP

		SUPPLIER	ARI	AMER
		LOT/BATCH No.	102175-001	740
		CALIB. DATE	01/09/04	20/09/04
SPECIFICATIONS		EXPIRY DATE	01/10/04	15/11/04
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 chromium-51 solution.		Pass	Pass
Radionuclidic content	90-110% of stated value		106	103
Radionuclidic purity	Gamma spectrum does not differ significantly from that of a standardised chromium-51 solution.		Pass	Pass
pH	3.5 – 6.5		5.5	3.9
Radiochemical purity				
1) Chromic ion	as %	INIT.	N.D.	N.D.
2) Chromate ion	as %		N.D.	N.D.
3) Cr-edetate	≥ 95% as <sup>51</sup> Cr-edetate		100	100
		EXP.	N.D.	0.1
			N.D.	0.1
			100	99.8
Chromium	≤ 1mg/mL		Pass	Pass
Benzyl Alcohol	90 – 100 % of stated value		N/A	105
Vial/Package Label	Complies		Complies	Complies

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

### Current edition of BP

		SUPPLIER	ARI	AMER
		LOT/BATCH No	102193-001	874
		CALIB. DATE	01/09/04	29/09/04
SPECIFICATIONS		EXPIRY DATE	01/10/04	24/11/04
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 chromium-51 solution.		Pass	Pass
Radionuclidic content	90-110% of stated value		98, 102	106
Radionuclidic purity	Gamma spectrum does not differ significantly from that of a standardised chromium-51 solution.		Pass	Pass
pH	6.0 - 8.5		6.0	6.0
Radiochemical purity	≥ 90% as chromate ion as chromic ion	INIT.	98.4	98.7
			1.6	1.3
		EXP.	98.3	98.9
			1.7	1.1
Total chromate	≤ 2.7 µg of chromate ion (CrO <sub>4</sub> <sup>2-</sup> ) per MBq		Pass	Pass
Vial/Package Label	Complies		Complies	Complies

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

### Current edition of BP

		SUPPLIER	ARI	MALL(H)	BMS (US)
		LOT/BATCH No.	101254-002	43376	G162411S
		CALIB. DATE	04/06/04	04/06/04	18/06/04
SPECIFICATIONS		EXPIRY DATE	11/06/04	14/06/04	25/06/04
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	106	100
Radionuclidic purity	≤ 0.2% <sup>66</sup> Ga		N.D.	N.D.	N.D.
pH	5.0 - 8.0		6.5	6.0	5.5
Radiochemical purity	≥ 97% as Ga Citrate	INIT.	99.3	99.2	98.7
		EXP.	99.0	98.8	98.4
Zinc limit test	≤ 5 µg/mL		Pass	Pass	Pass
Benzyl Alcohol	90 – 100 % of stated value		114	98	98
Vial/Package Label	Complies		Complies	Complies	Complies

**<sup>99</sup>Mo/<sup>99m</sup>Tc CHROMATOGRAPHIC GENERATOR**

**MR-RPQA-WI-0060A and Current edition of BP (Sodium Pertechnetate [<sup>99m</sup>Tc] Injection (Fission))**

		SUPPLIER	ARI	
		LOT/BATCH No.	103427-030	
		CALIB. DATE	06/12/04	
SPECIFICATIONS		EXPIRY DATE	20/12/04	
Maximum Surface Radiation Dose Rate	< 2 mGy/h		0.5	
Dose Rate at 1 metre	<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 Tc-99m solution		Pass	
		MAX Elution	MIN	MAX MIN Expiry
Radionuclidic purity	≤ 0.1% <sup>99</sup> Mo	9.5E-5	2.9E-5	2.2E-4 6.7E-5
	≤ 5 x 10 <sup>-3</sup> % <sup>131</sup> I	1E-5	3.8E-6	2.5E-5 9.3E-6
	≤ 5 x 10 <sup>-3</sup> % <sup>103</sup> Ru	N.D.	N.D.	N.D. N.D.
	≤ 6 x 10 <sup>-5</sup> % <sup>89</sup> Sr	†	†	† †
	≤ 6 x 10 <sup>-6</sup> % <sup>90</sup> Sr	†	†	† †
	≤ 1 x 10 <sup>-7</sup> % alpha-emitting impurities	†	†	† †
	≤ 1 x 10 <sup>-2</sup> % all other gamma-emitting impurities	N.D.	N.D.	N.D. N.D.
pH	4.0 -8.0	MAX 5.5		MIN 5.5
Radiochemical Purity	≥ 95% as pertechnetate ion ( <sup>99m</sup> TcO <sub>4</sub> ) <sup>-</sup>	99.9		99.7
Aluminium	≤ 5µg/mL	Pass		Pass
Milking efficiency	None (for information only)	105		96
Moly assay ( <sup>99</sup> Mo breakthrough)	≤ 0.1 % <sup>99</sup> Mo at expiry	7.0E-04		N.D.
Vial/Package Label	Complies			Complies

## SODIUM PERTECHNETATE [ $^{99m}\text{Tc}$ ] INJECTION (FISSION)

### Current edition of BP

		SUPPLIER	BMS	
		LOT/BATCH No.	76222	
		CALIB. DATE	14/09/04	
SPECIFICATIONS		EXPIRY TIME	1700 hr	
Appearance	A clear, colourless solution		Pass	
Particulate matter	None visible		Pass	
Identification	Gamma spectrum does not differ significantly from that of a standardised Tc-99m solution		Pass	
Radionuclidic content	90-110% of stated value		104	
			INT.	EXP.
Radionuclidic purity	$\leq 0.1\% \text{ } ^{99}\text{Mo}$		1.2E-3	2.8E-3
	$\leq 5 \times 10^{-3}\% \text{ } ^{131}\text{I}$		6.7E-6	1.6E-5
	$\leq 5 \times 10^{-3}\% \text{ } ^{103}\text{Ru}$		N.D.	N.D.
	$\leq 6 \times 10^{-5}\% \text{ } ^{89}\text{Sr}$		†	†
	$\leq 6 \times 10^{-6}\% \text{ } ^{90}\text{Sr}$		†	†
	$\leq 1 \times 10^{-7}\%$ alpha-emitting impurities		†	†
	$\leq 1 \times 10^{-2}\%$ all other gamma-emitting impurities		N.D.	N.D.
pH	4.0 - 8.0		5.3	
Radiochemical purity	$\geq 95\%$ as pertechnetate ion ( $^{99m}\text{TcO}_4^-$ )	INIT.	99.8	
		EXP.	99.8	
Aluminium	$\leq 5 \mu\text{g mL}$			†
Vial/Package Label	Complies		Complies	

**KIT FOR THE PREPARATION OF TECHNETIUM[<sup>99m</sup>Tc] ALBUMIN AGGREGATED INJECTION (PULMOLITE)**

**Current edition of USP**

		SUPPLIER	RADPH		RADPH	
		LOT/BATCH No.	2013		127271	
SPECIFICATIONS		EXPIRY DATE	October 2004		01/08/05	
			INT.	EXP.	INT.	EXP.
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture		Pass	Pass	Pass	TBD
Appearance after reconstitution	A white suspension which may separate on standing		Pass	Pass	Pass	TBD
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded.		Pass	Pass	N/A	TBD
pH	3.8 -7.5 after reconstitution		6.5	6.5	6.5	TBD
Radiochemical purity	≥ 90.0 % in aggregated albumin		99.8	99.7	98.5	TBD
	≤ 10 % as soluble and dispersed radiochemical impurities		0.2	0.3	1.5	TBD
Particle size	≥ 90% of the observed aggregated particles (not less than 100) have a diameter between 10 µm and 90 µm		Pass	Pass	Pass	TBD
	No particle having a maximum diameter > 150 µm is present		Pass	Pass	Pass	TBD
Non filterable radioactivity*	The radioactivity remaining on the membrane is ≥ 90%		99.8	99.7	98.0	TBD
Biological distribution	≥ 80% in the lungs			†		†
	≤ 5% in the liver + spleen			†		†
Tin content	0.21 mg SnCl <sub>2</sub> /vial**			†		†
Vial/Package Label	Complies		Complies		Complies	

\*Current edition of BP

\*\*Value given in label/product information

**KIT FOR THE PREPARATION OF TECHNETIUM[<sup>99m</sup>Tc]-ARCITUMOMAB INJECTION(CEA-SCAN)**

**Current edition of USP**

SPECIFICATIONS		SUPPLIER	ARI
		LOT/BATCH No.	IMR020DA
		EXPIRY DATE	April 2004
			INT. EXP.
Appearance before reconstitution	Freeze-dried solid	†	Pass
Appearance after reconstitution	A clear, colourless solution	†	Pass
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded.	†	N/A
pH	5.0 – 7.0 after reconstitution	†	5.5
Radiochemical purity	≥ 90.0 % <sup>99m</sup> Tc-Arcitumomab	†	99.6
	≤ 10.0 % as unbound pertechnetate	†	0.4
Vial/Package Label	Complies		Complies

Note: only one vial received

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

**Current edition of USP**

		SUPPLIER	BMS	
		LOT/BATCH No.	0145A	
		EXPIRY DATE	01/12/04	
SPECIFICATIONS			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.		N/A	N/A
pH	6.3 - 7.6 *after reconstitution		6.9	7.1
Radiochemical purity	≥ 90.0 % as <sup>99m</sup> Tc-Bicisate		98.4	98.8
	≤ 10.0 % as impurities (colloidal, <sup>99m</sup> TcO <sub>4</sub> <sup>-</sup> & <sup>99m</sup> Tc-EDTA)		1.6	1.2
Tin content	12 - 72 µg SnCl <sub>2</sub> .2H <sub>2</sub> O **			†
Vial/Package Label	Complies			Complies

\*Approved manufacturer's specification

\*\*Manufacturer's specifications

**KIT FOR THE PREPARATION OF TECHNETIUM[<sup>99m</sup>Tc] CALCIUM PHYTATE INJECTION (COLLOID)**

**Current edition of BP(Technetium[<sup>99m</sup>Tc] Calcium Phytate Injection (Colloid))**

SPECIFICATIONS		SUPPLIER	RADPH	RADPH		
		LOT/BATCH No.	2006	2051		
		EXPIRY DATE	Sept. 2004	January 2005		
			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	If a vacuum is not observed when the vial is pierced, the vial should be discarded.		Yes	Yes	Yes	Yes
pH	4.0 - 7.0 after reconstitution		5.0	5.0	5.0	5.0
Radiochemical purity	≥ 95.0 % as <sup>99m</sup> Tc-colloid		98.1	98.6	96.7	96.4
Tin content	≤ 1.0 mg SnCl <sub>2</sub> *		Pass	Pass	Pass	Pass
Biological distribution	≥ 80% in the liver + spleen ≤ 5% in the lungs		†		†	†
Vial/Package Label	Complies		Complies		Complies	

\*Value given in label/product information.

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

**Current edition of USP**

		SUPPLIER	RADPH	
		LOT/BATCH No.	142617	
SPECIFICATIONS		EXPIRY DATE	01/03/05	
			INIT.	EXP.
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture		Pass	Pass
Appearance after reconstitution	A clear, colourless or slightly yellow solution, free of any visible particulate matter		Pass	Pass
Check for vacuum	If a vacuum is not observed when the vial is pierced, the vial should be discarded.		N/A	N/A
pH	4.0 - 7.0 after reconstitution		4.5	4.5
Radiochemical purity	≥ 90.0 % as <sup>99m</sup> Tc-disofenin ≤10% as other impurities		96.1 3.9	98.6 1.4
Tin content	0.24 – 0.6 mg SnCl <sub>2</sub> .H <sub>2</sub> O/vial*			†
Biological distribution	≥ 70% in gallbladder + intestines			†
	≤ 10% in the liver			†
	≤ 10% in the kidneys			†
	≤ 3 % in the stomach			†
	≤ 3 % in the blood			†
Label	Complies		Complies	

\*Value given in label/product information.

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

**Current edition of USP**

		SUPPLIER	AMER
		LOT/BATCH No.	1056
SPECIFICATIONS		EXPIRY DATE	12/11/04
		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.	N/A	N/A
pH	9.0 - 9.8 after reconstitution	9.15	9.3
Radiochemical purity	≥ 80.0 % as <sup>99m</sup> Tc-Exametazime	92.4	90.8
	% as free pertechnetate	1.3	1.4
	% as hydrolysed reduced [ <sup>99m</sup> Tc]	2.3	3.3
	% as <sup>99m</sup> Tc secondary exametazime complex	4.0	4.5
Tin content	7.6 µg SnCl <sub>2</sub> .2H <sub>2</sub> 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[<sup>99m</sup>Tc] MEDRONATE INJECTION (MDP)

### Current edition of BP

SPECIFICATIONS		SUPPLIER	RADPH	AMER	ARI		
		LOT/BATCH No.	2078	564	2142		
		EXPIRY DATE	March 2005	16/05/05	Sept. 2005		
		INT.	EXP.	INT.	EXP.	INT.	EXP.
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture	Pass	Pass	Pass	TBD	Pass	TBD
Appearance after reconstitution	A clear, colourless solution	Pass	Pass	Pass	TBD	Pass	TBD
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded.	Yes	Yes	N/A	TBD	N/A	TBD
pH	3.5 – 7.5 after reconstitution	4.5	5.0	6.1	TBD	5.2	TBD
Radiochemical purity	1) ≥ 95.0 % as <sup>99m</sup> Tc-MDP	99.7	99.96	97.7	TBD	98.3	TBD
	2) ≤ 2.0 % as <sup>99m</sup> TcO <sub>4</sub> <sup>-</sup>	0.1	0.01	0.7	TBD	0.1	TBD
	3) as colloidal <sup>99m</sup> Tc	0.2	0.04	1.6	TBD	1.6	TBD
	2) + 3) ≤ 5.0 %						
Tin content	≤ 3 mg/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	

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

## Current edition of BP

SPECIFICATIONS		SUPPLIER	MALL	MALL	
		LOT/BATCH No.	0963009	0964006	
		EXPIRY DATE	13/08/04	27/05/05	
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture	INIT. Pass	EXP. XX	INIT. Pass	EXP. TBD
Appearance after reconstitution	A clear, colourless solution free of particulate matter. If not, the preparation should not be used	Pass	XX	Pass	TBD
pH	5.0 - 7.5 after reconstitution	5.5	XX	5.8	TBD
Radiochemical purity*	≥ 94.0 % as <sup>99m</sup> Tc-MAG3	99.5	XX	99.4	TBD
	% as hydrophilic impurities	0.2	XX	0.5	TBD
	% as non-elutable impurities	0.3	XX	0.1	TBD
	≤ 2% as reduced-hydrolysed technetium	0.05	XX	0.1	TBD
Tin content	≥ 50 µg SnCl <sub>2</sub> .2H <sub>2</sub> O/vial**		†		†
Vial/Package Label	Complies	Complies		Complies	

\*Tested by the method recommended by the manufacturer

\*\*Value given in label/product information

XX - Product was recalled by the manufacturer

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

**Current edition of USP**

SPECIFICATIONS		SUPPLIER	MALL
		LOT/BATCH No.	0914005
		EXPIRY DATE	09/09/04
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture	INIT. Pass	EXP. Pass
Appearance after reconstitution	A clear, colourless or slightly yellow solution, free of any visible particulate matter	Pass	Pass
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded	N/A	N/A
pH	2.5 – 7.0 after reconstitution	5.0	5.0
Radiochemical purity*	1) ≥ 90.0 % as <sup>99m</sup> Tc-oxidronate	99.5	99.1
	2) % as free pertechnetate	0.2	0.1
	3) % as colloidal [ <sup>99m</sup> Tc]	0.3	0.8
Tin content	0.342 mg SnCl <sub>2</sub> .2H <sub>2</sub> O**		†
Biological distribution	≥ 1.0% attached to one femur		†
	≤ 5.0% in the liver		†
	≤ 5.0% in the kidneys		†
Vial/Package Label	Complies		Complies

\*Current edition of BP

\*\*Value given in label/product information as minimum content

## KIT FOR THE PREPARATION OF TECHNETIUM[<sup>99m</sup>Tc] PENTETATE INJECTION (DTPA)

Current edition of BP

SPECIFICATIONS		SUPPLIER	RADPHAR	ARI	AMER		
		LOT/BATCH N	2042	2038	304		
		EXPIRY DATE	Dec. 2004	Jan. 2005	22/02/05		
		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 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	N/A	N/A	Yes	Yes
pH	4.0 - 7.5 after reconstitution	5.0	5.3	4.7	4.7	4.7	4.7
Radiochemical purity	≥ 95.0 % as <sup>99m</sup> Tc-DTPA	99.1	99.0	99.7	99.8	99.7	99.94
	Free pertechnetate [ <sup>99m</sup> Tc]	0.1	0.2	0.2	0.1	0.2	0.04
	Colloidal [ <sup>99m</sup> Tc] impurity	0.8	0.8	0.1	0.1	0.1	0.02
Tin content	≤ 1 mg/mL	Pass		Pass		Pass	
Vial/Package Label	Complies	Complies		Complies		Complies	

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

**Current edition of USP**

SPECIFICATIONS		SUPPLIER	BMS
		LOT/BATCH No.	3770MA
		EXPIRY DATE	01/05/04
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	N/A	N/A
pH	5.0 - 6.0 after reconstitution	5.0	5.0
Radiochemical purity	≥ 90.0 % as <sup>99m</sup> Tc-Sestamibi	98.3	97.0
	≤ 10.0 % <sup>99m</sup> Tc impurities	1.7	3.0
Tin content	0.075 mg SnCl <sub>2</sub> *		†
Vial/Package Label	Complies	Complies	

\*Value given in label/product information

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

**Current edition of BP**

SPECIFICATIONS		SUPPLIER	RADPH	
		LOT/BATCH No.	2063	
		EXPIRY DATE	Nov 2004	
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		3.1	3.1
Radiochemical purity	≥ 95.0 % as <sup>99m</sup> Tc-DMSA		99.8	99.7
	≤ 2.0 % as <sup>99m</sup> TcO <sub>4</sub> <sup>-</sup>		0.2	0.3
Tin content	≤ 1 mg/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	

**KIT FOR THE PREPARATION OF TECHNETIUM[<sup>99m</sup>Tc] TETROFOSMIN (MYOVIEW)**

**Current edition of USP**

		SUPPLIER	AMER
		LOT/BATCH No.	1078
SPECIFICATIONS		EXPIRY DATE	05/10/04
		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	N/A	N/A
pH	8.3 - 9.1 after reconstitution	8.4	8.5
Radiochemical purity	1) $\geq 90.0\%$ as <sup>99m</sup> Tc-Tetrafosmin	96.5	96.9
	2) Reduced hydrolysed & hydrophilic impurities	2.9	2.6
	3) Unbound pertechnetate	0.6	0.5
	$2 + 3 \leq 10\%$		
Tin content	0.03 mg/vial SnCl <sub>2</sub> .2H <sub>2</sub> O*		†
Vial/Package Label	Complies		Complies

\*Value given in label/product information.

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

**Current edition of BP**

		SUPPLIER	MALL	RADPH	
		LOT/BATCH No.	0944009	2062	
SPECIFICATIONS		EXPIRY DATE	10/01/05	Feb.2005	
		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	N/A	N/A	Pass	Pass
pH	6.0 – 7.0 after reconstitution			5.0	5.3
	4.0 - 7.5 after reconstitution*	5.0	5.0		
Radiochemical purity	1) ≥ 90.0 % as <sup>99m</sup> Tc-PYP	98.1	98.7	98.3	99.2
	2) as free pertechnetate	1.1	0.8	0.9	0.2
	3) as colloidal [ <sup>99m</sup> Tc]	0.8	0.5	0.8	0.6
Sodium pyrophosphate	1-50 mg/mL sodium pyrophosphate on reconstitution	1.3 - 13		5.8	
Tin content	≤ 3 mg/mL	0.15 – 1.5		1.1	
Vial/Package Label	Complies	Complies		Complies	

\*Value given in USP

## m-IODOBENZYLGUANIDINE<sup>131</sup>I INJECTION (mIBG)

Current edition of BP

		SUPPLIER	ARI
		LOT/BATCH No.	01274-002
		CALIB. DATE	08/06/04
SPECIFICATIONS		EXPIRY DATE	13/06/04
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		98.6
Radionuclidic purity	≤ 0.1 % of the total radioactivity is due to <sup>133</sup> I, <sup>135</sup> I and other radionuclidic impurities		N.D.
pH	3.5 – 8.0		5.8
Radiochemical purity	≥ 94% of activity as <sup>131</sup> I-mIBG	INIT.	98.8
	≤ 5% of activity as iodide		1.2
		EXP.	98.5
			1.5
Vial/Package Label	Complies		Complies

## SODIUM IODIDE[<sup>131</sup>I] CAPSULES (DIAGNOSTICS)

Current edition of BP

SPECIFICATIONS		SUPPLIER	ARI
		LOT/BATCH No.	103425-003
		CALIB. DATE	06/12/04
		EXPIRY DATE	20/12/04
Appearance	Gelatine capsule		Pass
Identification	Gamma spectrum does not differ significantly from that of a standardised iodine-131 solution		Pass
Radionuclidic content	90-110% of stated value		98
Radionuclidic purity	≤ 0.1% of the total radioactivity is due to <sup>133</sup> I, <sup>135</sup> I and other radionuclidic impurities		N.D.
Radiochemical purity	≥ 95% of activity as iodide	INIT.	97.3
		EXP.	†
Disintegration	The shell and its contents dissolve completely within 15 min.		Pass
Uniformity of content	Radioactivity of no capsule differs by more than 10% from the average.		0.2 – 1.3
	The relative standard deviation is ≤ 3.5%		0.8
Vial/Package Label	Complies		Complies

## SODIUM IODIDE[<sup>131</sup>I] INJECTION

Current edition of BP

		SUPPLIER	ARI
		LOT/BATCH No.	103443-002
		CALIB. DATE	08/12/04
SPECIFICATIONS		EXPIRY DATE	22/12/04
Appearance	A clear, colourless solution		Pass
Particulate matter	None visible		Pass
Identification	Gamma spectrum does not differ significantly from that of a standardised iodine-131 solution		Pass
Radionuclidic content	90-110% of stated value		101
Radionuclidic purity	≤ 0.1 % of the total radioactivity is due to <sup>133</sup> I, <sup>135</sup> I and other radionuclidic impurities		Pass
pH	7.0 – 8.5		7.5
Radiochemical purity	≥ 95% of activity as iodide	INIT.	99.7
		EXP.	99.7
Vial/Package Label	Complies		Complies

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

## Current edition of BP

		SUPPLIER	ARI	MALL(H)		
		LOT/BATCH No.	102466-002	45514/000		
		CALIB. DATE	15/09/04	22/09/04		
SPECIFICATIONS		EXPIRY DATE	20/09/04	29/09/04		
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		110	95		
Radionuclidic purity	At all times up till expiry		At calibration	At expiry	At calibration	At expiry
	<sup>201</sup> Tl	≥ 97 %	99.3	99.7	99.8	99.52
	<sup>202</sup> Tl	≤ 2.0 %	0.1	0.2	0.1	0.47
	<sup>200</sup> Tl	%	0.6	0.1	0.1	0.01
	<sup>201</sup> Pb	%	N.D.	N.D.	N.D.	N.D.
	<sup>203</sup> Pb	%	N.D.	N.D.	N.D.	N.D.
pH	4.0 - 7.0		5.3	5.0		
Radiochemical purity	≥ 95% of the activity is present as Thallous ion	INIT.	99.9	99.7		
		EXP.	99.7	99.8		
Thallium	≤ 10 µg/mL		Pass	Pass		
Benzyl Alcohol	90 – 100 % of stated value		104	N/A		
Vial/Package Label	Complies		Complies	Complies		