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**Australian Radiation Protection
and Nuclear Safety Agency**

TECHNICAL REPORT

**Results of the Quality
Assurance Testing Program
for Radiopharmaceuticals
(2005)**

Z Ivanov

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Australian Government

**Australian Radiation Protection
and Nuclear Safety Agency**

Results of the Quality Assurance Testing Program for Radiopharmaceuticals 2005



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ABSTRACT

This report tabulates results obtained during 2005 for the Radiopharmaceutical Quality Assurance Test Program conducted by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

CONTENTS

	<i>Page No.</i>
Copyright Notice and Disclaimer	2
Abstract	3
Contents	4
Introduction	5
Abbreviations	6
Results:	
<i>Ready to use radiopharmaceuticals</i>	
<i>Sodium Phosphate [³²P] Injection</i>	7
<i>Chromium [⁵¹Cr] Edetate Injection</i>	8
<i>Sodium Chromate [⁵¹Cr] Solution</i>	9
<i>Cyanocobalamin [⁵⁷Co]Capsules</i>	10
<i>Gallium [⁶⁷Ga] Citrate Injection</i>	11
<i>⁹⁹Mo/^{99m}Tc Chromatographic Generator</i>	12
<i>Sodium Pertechnetate [^{99m}Tc] Injection (Fission)</i>	13
<i>Indium Oxine [¹¹¹In]Solution</i>	28
<i>Sodium Iodide [¹³¹I] Capsules (Diagnostics)</i>	29
<i>Sodium Iodide [¹³¹I] Injection</i>	30
<i>Thallous [²⁰¹Tl] Chloride Injection</i>	31
 <i>Kit for the Preparation of -</i>	
<i>Technetium [^{99m}Tc] Albumin Aggregated Injection (PULMOLITE)</i>	14
<i>Technetium [^{99m}Tc] Bicisate Injection (NEUROLITE)</i>	15
<i>Technetium [^{99m}Tc]Calcium Phytate Injection (Colloid)</i>	16
<i>Technetium [^{99m}Tc]Disofenin Injection (HEPATOLITE)</i>	17
<i>Technetium [^{99m}Tc] Exametazime Injection (CERETEC)</i>	18
<i>Technetium [^{99m}Tc] Medronate Injection (MDP)</i>	19
<i>Technetium [^{99m}Tc] Mertiatide Injection (MAG3)</i>	21
<i>Technetium [^{99m}Tc] Oxidronate Injection (HDP)</i>	22
<i>Technetium [^{99m}Tc] Pentetate Injection (DTPA)</i>	23
<i>Technetium [^{99m}Tc] Sestamibi Injection (CARDIOLITE)</i>	24
<i>Technetium [^{99m}Tc] Succimer Injection (DMSA)</i>	25
<i>Technetium [^{99m}Tc] Tetrofosmin Injection (MYOVIEW)</i>	26
<i>Technetium [^{99m}Tc] Tin Pyrophosphate Injection (PYP)</i>	27

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}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 2005 are summarised in the following tables. Overall, 46 batches of 24 different types of radiopharmaceuticals were tested. Failure to meet full specifications was observed in 1 of the 46 batches of radiopharmaceuticals tested (2 %). This batch was found to have benzyl alcohol content lower than specified by the manufacturer.

In the case of one type of “cold kit” radiopharmaceutical, kits from an Australian manufacturer met the manufacturer’s specification for pH after reconstitution, but did not meet the BP specification. Kits from an US manufacturer met the USP (and the manufacturer’s) specification for pH after reconstitution for the three kits tested, but did not meet the BP specification for two of the kits.

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, J McLeish and Z Ivanov

ABBREVIATIONS

The following abbreviations are used in the tables –

AMER	- Amersham Health Pty. Ltd., UK
ARI	- ANSTO Radiopharmaceuticals and Industrials, Lucas Heights, Sydney, Australia
BMS	- Bristol-Myers Squibb Medical Imaging , Tullamarine, VIC, Australia
BMS (US)	- Bristol-Myers Squibb Medical Imaging , North Billerica, MA, USA
CALIB. DATE	- Calibration Date
Cis-US	- Cis-US Inc., Bedford, MA, USA
EXP.	- Expiry testing
INT.	- Initial testing
MALL	- Mallinckrodt Medical B.V., Petten, Netherlands
MAX	- Maximum
MIN	- Minimum
N.A.	- Not applicable
N.D.	- Not detected
No.	- Number
RADPH	- Radpharm Scientific, Belconnen, ACT, Australia
reconst.	- reconstitute
TBD	- To be done
†	- Not determined

SODIUM PHOSPHATE [³²P] INJECTION

Current edition of BP

		SUPPLIER	ARI
		LOT/BATCH No.	104582-001
		CALIB. DATE	21/03/05
SPECIFICATIONS		EXPIRY DATE	12/04/05
Appearance	A clear, colourless solution		Pass
Particulate matter	None visible		Pass
Identification	Beta spectrum does not differ significantly from that of a standardised phosphorus-32 solution obtained under the same conditions		Pass
Radionuclidic content	90-110% of stated value		100, 98*
Radionuclidic purity	i) Beta spectrum does not differ significantly from that of a standardised phosphorus-32 solution obtained under the same conditions		Pass
	ii) decay rate should correspond to half-life of 14.3 d		Pass
Radiochemical purity	≥ 95% as orthophosphate ion	INIT.	99.55±0.15
		EXP.	99.96±0.02
pH	6.0 - 8.0		6.5
Specific radioactivity	≥ 11.1 MBq of phosphorus-32 per mg of orthophosphate ion		Pass
Vial/Package Label	Complies		Complies

* Two vials from the same batch.

CHROMIUM [⁵¹Cr] EDETATE INJECTION

Current edition of BP

		SUPPLIER	ARI	AMER
		LOT/BATCH No.	104317-001	768
		CALIB. DATE	01/03/05	04/04/05
SPECIFICATIONS		EXPIRY DATE	31/03/05	30/05/05
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, 109.6*	101
Radionuclidic purity	Gamma spectrum does not differ significantly from that of a standardised chromium-51 solution		Pass	Pass
pH	3.5 – 6.5		6.0	4.0
Radiochemical purity				
1) Chromic ion	as %	INT.	0.15±0.04	0.1±0.04
2) Chromate ion	as %		0.8±0.3	0.6±0.04
3) Cr-edetate	≥ 95% as ⁵¹ Cr-edetate		99.07	99.25
		EXP.	0.19±0.02	0.2±0.05
			0.76±0.12	1.4±0.7
			99.05	98.3
Chromium	≤ 1mg/mL		Pass	Pass
Benzyl Alcohol	90 – 110 % of stated value		N/A	101.4
Vial/Package Label	Complies		Complies	Complies

* Two vials from the same batch.

SODIUM CHROMATE [⁵¹Cr] SOLUTION

Current edition of BP

		SUPPLIER	AMER
		LOT/BATCH No.	900
		CALIB. DATE	30/03/05
SPECIFICATIONS		EXPIRY DATE	15/05/05
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 chromium-51 solution.		Pass
Radionuclidic content	90-110% of stated value		107
Radionuclidic purity	Gamma spectrum does not differ significantly from that of a standardised chromium-51 solution.		Pass
pH	6.0 - 8.5		6.6
Radiochemical purity	≥ 90% as chromate ion	INT.	99.35
	% as chromic ion		0.65±0.05
		EXP.	99.42
			0.58±0.025
Total chromate	≤ 2.7 µg of chromate ion (CrO ₄ ²⁻) per MBq		Pass
Vial/Package Label	Complies		Complies

CYANOCOBALAMIN [⁵⁷Co] CAPSULES

Current edition of BP

		SUPPLIER	AMER
		LOT/BATCH No.	582
		CALIB. DATE	23/09/05
SPECIFICATIONS		EXPIRY DATE	18/11/05
Appearance	Gelatin capsule		Pass
Particulate matter	None visible		Pass
Identification	Gamma spectrum does not differ significantly from that of a standardised cobalt-57 solution		Pass
Radionuclidic content	90-110% of stated value		92.5
Radionuclidic purity	≤ 0.1% of the total radioactivity is due to ⁵⁶ Co, ⁵⁸ Co, and other radionuclidic impurities present		N.D.
Radiochemical purity	≥ 90% of activity as ⁵⁷ Co-cyanocobalamin	INT.	97.4 ± 0.6
		EXP.	97.6 ± 0.05
Uniformity of content	The radioactivity of no capsule differs by more than 10 % from the average		Pass
	The relative standard deviation is < 3.5 %		2.6
Vial/Package Label	Complies		Complies

GALLIUM [⁶⁷Ga] CITRATE INJECTION

Current edition of BP

		SUPPLIER	ARI	BMS (US)
		LOT/BATCH No.	105144-002	G132511S
		CALIB. DATE	06/05/05	20/05/05
SPECIFICATIONS		EXPIRY DATE	11/05/05	26/05/05
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 Ga-67 solution		Pass	Pass
Citrate presence	A yellow colour develops in the test solution only		Pass	Pass
Radionuclidic content	90-110% of stated value		107	102
Radionuclidic purity	≤ 0.2% ⁶⁶ Ga		N.D.	N.D.
pH	5.0 - 8.0		6.5	6.0
Radiochemical purity	≥ 97% as Ga Citrate	INT.	99.6±0.05	99.6±0.1
		EXP.	99.7±0.07	99.3±0.2
Zinc limit test	≤ 5 µg/mL		Pass	Pass
Benzyl Alcohol	90 – 110 % of stated value		101.6	83.2
Vial/Package Label	Complies		Complies	Complies

⁹⁹Mo/^{99m}Tc CHROMATOGRAPHIC GENERATOR

MR-RPQA-WI-0060A and Current edition of BP (Sodium Pertechnetate [^{99m}Tc] Injection (Fission))

		SUPPLIER	ARI	
		LOT/BATCH No.	107263-030	
		CALIB. DATE	07/11/05	
SPECIFICATIONS		EXPIRY DATE	21/11/05	
Maximum surface radiation dose rate	< 2 mGy/h		0.16	
Dose rate at 1 metre	<0.10 mGy/h		0.02	
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 Expiry
Radionuclidic purity	≤ 0.1% ⁹⁹ Mo	2.6E-5		5.9E-5
	≤ 5 x 10 ⁻³ % ¹³¹ I	N.D.	N.D.	N.D. N.D.
	≤ 5 x 10 ⁻³ % ¹⁰³ Ru	N.D.	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	N.D.	N.D.	N.D. N.D.
		MAX		MIN
pH	4.0 -8.0	5.2		5.2
Radiochemical purity	≥ 95% as pertechnetate ion (^{99m} TcO ₄) ⁻	99.88±0.01		97.04±0.18
Aluminium	≤ 5µg/mL	< 1		< 1
Milking efficiency	None (for information only)	106.2		85.3
Moly assay (⁹⁹ Mo breakthrough)	≤ 0.1 % ⁹⁹ Mo at expiry	0.003		0.000
Vial/Package Label	Complies			Complies

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

Current edition of BP

		SUPPLIER	BMS	
		LOT/BATCH No.	99901	
		CALIB. DATE	11/05/05 @ 0900 h	
SPECIFICATIONS		EXPIRY TIME	11/05/05 @ 1700 h	
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		106	
			INT.	EXP.
Radionuclidic purity	≤ 0.1% ⁹⁹ Mo		3.9E-4	9.8E-4
	≤ 5 x 10 ⁻³ % ¹³¹ I		2.0E-6	5.1E-6
	≤ 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 ⁻)	INT.	99.8 ± 0.01	
		EXP.	99.9 ± 0.01	
Aluminium	≤ 5 µg mL		Pass	
Vial/Package Label	Complies		Complies	

KIT FOR THE PREPARATION OF TECHNETIUM [^{99m}Tc] ALBUMIN AGGREGATED INJECTION (PULMOLITE)

Current edition of USP

		SUPPLIER	Cis-US	Cis-US	
		LOT/BATCH No.	127271	127275	
SPECIFICATIONS		EXPIRY DATE	01/08/05	01/03/06	
		INT.	EXP.	INT.	EXP.
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture	Pass	Pass	Pass	Pass
Appearance after reconstitution	A white suspension which may separate on standing	Pass	Pass	Pass	Pass
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded.	N/A	N/A	N/A	N/A
pH	3.8 -7.5 after reconstitution	6.5	6.0	6.0	6.0
Radiochemical purity	1) ≥ 90.0 % in aggregated albumin (by chromatography)	98.5	97.3	97.8	98.7
	2) ≤ 10 % as soluble and dispersed radiochemical impurities (by centrifugation)	1.5±0.01	2.8±0.05	2.7±0.07	1.9±0.03
Particle size	≥ 90% of the observed aggregated particles (not less than 100) have a diameter between 10 µm and 90 µm	Pass	Pass	Pass	Pass
	No particle having a maximum diameter > 150 µm is present	Pass	Pass	Pass	Pass
Non filterable radioactivity*	The radioactivity remaining on the membrane is ≥ 90%		98.0	98.0	97.0
Biological distribution	≥ 80% in the lungs		†		†
	≤ 5% in the liver + spleen		†		†
Vial/Package Label	Complies		Complies	Complies	

* Current edition of BP

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

Current edition of USP

		SUPPLIER	BMS (US)	
		LOT/BATCH No.	101293	
SPECIFICATIONS		EXPIRY DATE	01/11/05	
			INT.	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		7.1	7.2
Radiochemical purity	≥ 90.0 % as ^{99m} Tc-Bicisate (chromatography system A)		98.9	98.4
	≤ 10.0 % as impurities (colloidal, ^{99m} TcO ₄ ⁻ & ^{99m} Tc-EDTA) (chromatography system B)		1.61± 0.05	1.56±0.08
Tin content	12 - 72 µg SnCl ₂ .2H ₂ O *			N/A
Vial/Package Label	Complies		Complies	

* Manufacturer's specification

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

Current edition of BP(Technetium [^{99m}Tc] Colloidal Tin Injection

		SUPPLIER	RADPH		RADPH	
		LOT/BATCH No.	2051		2226	
SPECIFICATIONS		EXPIRY DATE	January 2005		April 2006	
			INT.	EXP.	INT.	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	4.5	4.5
Radiochemical purity	≥ 95.0 % as ^{99m} Tc-colloid		96.7	96.4	*	*
Tin content	≤ 1.0 mg SnCl ₂ **		Pass		Pass	
Biological distribution	≥ 80% in the liver + spleen ≤ 5% in the lungs			†		†
Vial/Package Label	Complies		Complies		Complies	

* Could not be determined due to the insufficient chromatographic separation.

**Value given in label/product information.

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

Current edition of USP

		SUPPLIER	RADPH		RADPH	
		LOT/BATCH No.	142617		142623	
SPECIFICATIONS		EXPIRY DATE	01/03/05		01/04/06	
		INT.	EXP.	INT.	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	N/A	N/A	N/A	N/A	
pH	4.0 - 7.0 after reconstitution	4.5	4.5	4.5	4.5	
Radiochemical purity	1) ≥ 90.0 % as ^{99m} Tc-disofenin	96.1	98.6	98.6	94.9	
	2) hydrolysed + tin colloid (chromatography system A)	0.15±0.01	0.17±0.1	0.1±0.07	0.35±0.02	
	3) free pertechnetate (chromatography system B)	3.74±0.91	1.22±0.07	1.3±0.15	4.76±0.15	
	≤10% as impurities 2+3	3.9	1.4	1.4	5.1	
Biological distribution	≥ 70% in gallbladder + intestines		†		†	
	≤ 10% in the liver		†		†	
	≤ 10% in the kidneys		†		†	
	≤ 3 % in the stomach		†		†	
	≤ 3 % in the blood		†		†	
Vial/Package Label	Complies	Complies		Complies		

* Value given in label/product information.

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

Current edition of USP

		SUPPLIER	AMER	
		LOT/BATCH No.	1118	
SPECIFICATIONS		EXPIRY DATE	02/12/05	
			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	9.0 - 9.8 after reconstitution		9.14	9.35
Radiochemical purity	≥ 80.0 % as ^{99m} Tc-Exametazime		92.2	90.4
	% as free pertechnetate		1.51±0.07	1.05±0.14
	% as hydrolysed reduced ^{99m} Tc		1.62±0.09	1.65±0.18
	% as ^{99m} Tc secondary exametazime complex		4.67±0.56	6.92±0.41
Tin content	7.6 µg SnCl ₂ .2H ₂ O/vial*			N/A
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] MEDRONATE INJECTION (MDP)

Current edition of BP

		SUPPLIER	RADPH		AMER		ARI		AMER	
		LOT/BATCH No.	2078		564		2142		578	
SPECIFICATIONS		EXPIRY DATE	February 2005		16/05/05		Sept. 2005		03/11/05	
		INT.	EXP.	INT.	EXP.	INT.	EXP.	INT.	EXP.	
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	
Appearance after reconstitution	A clear, colourless solution	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
pH	3.5 – 7.5 after reconstitution	4.5	5.0	6.1	6.0	5.2	5.2	6.5	6.0	
Radiochemical purity	1) ≥ 95.0 % as ^{99m} Tc-MDP	99.7	99.96	97.7	98.7	98.3	99.69	99.6	99.67	
	2) ≤ 2.0 % as ^{99m} TcO ₄ ⁻	0.1±0.01	0.01±0.01	0.7±0.13	0.7±0.2	0.1±0.01	0.17±0.05	0.2±0.06	0.24±0.02	
	3) as colloidal ^{99m} Tc	0.2±0.01	0.03±0.01	1.6±0.08	0.6±0.1	1.6±0.2	0.14±0.06	0.2±0.00	0.08±0.02	
	≤ 5.0 % as impurities 2+3	0.3	0.04	2.3	1.3	1.7	0.3	0.4	0.3	
Tin content	≤ 3 mg/mL	Pass		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		Complies		

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

Current edition of BP

		SUPPLIER	ARI	RADPH		AMER	
		LOT/BATCH No.	2216	2227		584	
SPECIFICATIONS		EXPIRY DATE	April 2006	May 2006		09/01/06	
		INT.	EXP.	INT.	EXP.	@ 15 min after reconstitution	@ 8 h after reconstitution
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture	Pass		Pass		Pass	Pass
Appearance after reconstitution	A clear, colourless solution	Pass		Pass		Pass	Pass
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded.	N/A		Yes		N/A	N/A
pH	3.5 – 7.5 after reconstitution	5.0		5.5		5.9	
Radiochemical purity	1) ≥ 95.0 % as ^{99m} Tc-MDP 2) ≤ 2.0 % as ^{99m} TcO ₄ ⁻ 3) as colloidal ^{99m} Tc ≤ 5.0 % as impurities 2+3	99.74 0.05±0.01 0.22±0.04 0.27		99.77 0.05±0.01 0.18±0.06 0.23		99.38 0.56±0.27 0.06±0.02 0.62	99.4 0.55±0.08 0.05±0.01 0.6
Tin content	≤ 3 mg/mL	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		-	

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

Current edition of BP

		SUPPLIER	MALL	MALL		
		LOT/BATCH No.	0964006	0964017		
SPECIFICATIONS		EXPIRY DATE	27/05/05	19/09/05		
		INT.	EXP.	INT.	EXP.	
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture	Pass	Pass	Pass	Pass	
Appearance after reconstitution	A clear, colourless solution free of particulate matter. If not, the preparation should not be used	Pass	Pass	Pass	Pass	
pH	5.0 - 7.5 after reconstitution	5.8	5.5	5.5	5.5	
Radiochemical purity	≥ 94.0 % as ^{99m} Tc-MAG3*	99.4	99.6	99.8	99.67	
	% as hydrophilic impurities*	0.5±0.02	0.2±0.01	0.1±0.01	0.09±0.01	
	% as non-elutable impurities*	0.1±0.01	0.2±0.04	0.06±0.01	0.23±0.09	
	≤ 2% as reduced-hydrolysed technetium (by chromatography)	0.1±0.02	0.05±0.01	0.05±0.01	0.01±0.02	
Tin content	≥ 50 µg SnCl ₂ .2H ₂ O/vial**	N.A.		N.A.		
Vial/Package Label	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)

Current edition of USP

		SUPPLIER	MALL
		LOT/BATCH No.	0915008
SPECIFICATIONS		EXPIRY DATE	06/09/05
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture	INT. 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	4.7
Radiochemical purity*	1) ≥ 90.0 % as ^{99m} Tc-oxidronate	99.5	99.7
	2) % as free pertechnetate	0.31±0.16	0.23±0.11
	3) % as colloidal ^{99m} Tc	0.21±0.08	0.04±0.02
Tin content	0.342 mg SnCl ₂ .2H ₂ O**		N/A
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 [^{99m}Tc] PENTETATE INJECTION (DTPA)

Current edition of BP

		SUPPLIER	ARI	AMER	AMER	RADPH	ARI					
		LOT/BATCH No.	2038	304	314	2159	2166					
SPECIFICATIONS		EXPIRY DATE	January 2005	22/02/05	25/07/05	October 2005	November 2005					
			INT.	EXP.	INT.	EXP.	INT.	EXP.	INT.	EXP.	INT.	EXP.
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture		Pass	Pass	Pass	Pass	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	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	N/A	N/A	Yes	Yes	Yes	Yes
pH	4.0 - 7.5 after reconstitution		4.7	4.7	4.7	4.7	4.7	4.5	5.5	5.5	4.5	4.7
Radiochemical purity	1) ≥ 95.0 % as ^{99m} Tc-DTPA		99.7	99.8	99.7	99.8	99.9	99.96	99.8	99.8	99.9	99.8
	2) Colloidal ^{99m} Tc impurity (chromatography system A)		0.1±0.00	0.1±0.01	0.1±0.01	0.07±0.01	0.02±0.01	0.00	0.1±0.02	0.11±0.04	0.08±0.01	0.10±0.04
	3) Free pertechnetate ^{99m} Tc (chromatography system B)		0.19±0.04	0.1±0.01	0.2±0.06	0.08±0.03	0.05±0.03	0.04±0.02	0.1±0.06	0.11±0.09	0.07±0.02	0.06±0.01
	≤ 5.0% as impurities 2+3		0.3	0.2	0.3	0.2	0.07	0.04	0.2	0.22	0.15	0.16
Tin content	≤ 1 mg/mL		Pass		Pass		Pass		Pass		Pass	
Vial/Package Label	Complies		Complies		Complies		Complies		Complies		Complies	

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

Current edition of USP

SPECIFICATIONS		SUPPLIER	BMS (US)
		LOT/BATCH No.	3843A
		EXPIRY DATE	01/09/06
Appearance before reconstitution	Freeze dried solid	INT. Pass	EXP. 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	N/A	TBD
pH	5.0 - 6.0 after reconstitution	5.25	TBD
Radiochemical purity	≥ 90.0 % as ^{99m} Tc-Sestamibi	98.3	TBD
	≤ 10.0 % ^{99m} Tc impurities	1.7±0.3	TBD
Tin content	0.075 mg SnCl ₂ *		N/A
Vial/Package Label	Complies	Complies	

*Value given in label/product information

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

Current edition of BP

		SUPPLIER	RADPH		RADPH	
		LOT/BATCH No.	2203		2277*	
SPECIFICATIONS		EXPIRY DATE	December 2005		July 2006	
			INT.	EXP.	INT.	EXP.
Appearance before reconstitution	Freeze dried solid		Pass	Pass	Pass	TBD
Appearance after reconstitution	A clear, colourless solution		Pass	Pass	Pass	TBD
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded		Yes	Yes	Yes	TBD
pH	2.3 - 3.5 after reconstitution		3.05		3.09	TBD
Radiochemical purity	≥ 95.0 % as ^{99m} Tc-DMSA		99.9		99.9	TBD
	≤ 2.0 % as ^{99m} TcO ₄ ⁻		0.1±0.04		0.08±0.02	TBD
Tin content	≤ 1 mg/mL		Pass		Pass	
Biological distribution	≥ 40% in the kidneys		†		†	
	≤ 10% in the liver		†		†	
	≤ 2% in the stomach		†		†	
	≤ 5% in the lungs		†		†	
Vial/Package Label	Complies		Complies		Complies	

* Batch was recalled by the manufacturer due to poor labelling. Only the initial testing completed.

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

Current edition of USP

		SUPPLIER	AMER	
		LOT/BATCH No.	1274	
SPECIFICATIONS		EXPIRY DATE	01/03/06	
			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		8.40	8.42
Radiochemical purity	1) ≥ 90.0 % as ^{99m} Tc-Tetrofosmin		97.9	97.2
	2) Reduced hydrolysed & hydrophilic impurities		1.9±0.07	2.5±0.1
	3) Unbound pertechnetate		0.2±0.04	0.3±0.02
	≤ 10% as impurities 2+3		2.1	2.8
Tin content	0.03 mg/vial SnCl ₂ .2H ₂ O*		N/A	
Vial/Package Label	Complies		Complies	

* Value given in label/product information.

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

Current edition of BP

		SUPPLIER	MALL	RADPH	MALL	RADPH	MALL	RADPH	MALL		
		LOT/BATCH No.	0944009	2062	0945003	2202	221419				
SPECIFICATIONS		EXPIRY DATE	10/01/05	February 2005	20/08/05	March 2006	08/01/06				
		INT.	EXP.	INT.	EXP.	INT.	EXP.	INT.	EXP.	@30 min. after reconst.	@ 4 h after reconst.
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture	Pass	Pass	Pass	Pass	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	Pass	Pass	Pass	Pass
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded	N/A	N/A	Yes	Yes	N/A	N/A	Yes	Yes	N/A	N/A
pH	6.0 – 7.0 after reconstitution* 4.5 – 6.0 after reconstitution** 4.0 - 7.5 after reconstitution***	5.0	5.0	5.0	5.3	4.5	4.7	5.5	5.5		6.2
Radiochemical purity	1) ≥ 90.0 % as ^{99m} Tc-PYP	98.1	98.7	98.3	99.2	98.3	99.2	99.75	99.2	98.4	93.7
	2) as free pertechnetate (chromatography system A)	1.1±0.12	0.8±0.11	0.9±0.27	0.2±0.11	0.6±0.33	0.08±0.06	0.12±0.04	0.4±0.06	0.99±0.21	4.92±1.87
	3) as colloidal [^{99m} Tc] (chromatography system B)	0.8±0.06	0.5±0.11	0.85±0.28	0.6±0.4	1.12±0.13	0.73±0.37	0.13±0.01	0.41±0.10	0.57±0.01	1.41±0.11
	≤ 10 % as impurities 2+3	1.9	1.3	1.7	0.8	1.7	0.8	0.25	0.8	1.6	6.3
Sodium pyrophosphate	1-50 mg/mL sodium pyrophosphate on reconstitution	1.3-1.5		5.8		Pass		Pass		†	
Tin content	≤ 3 mg/mL	Pass		Pass		Pass		Pass		†	
Vial/Package Label	Complies	Complies		Complies		Complies		Complies		Complies	

* Value given in BP

** Manufacturer specification

*** Value given in USP

INDIUM OXINE [¹¹¹In] Solution**Current edition of BP**

		SUPPLIER	AMER
		LOT/BATCH No.	4232
		CALIB. DATE	27/07/05
SPECIFICATIONS		EXPIRY DATE	01/08/05
Appearance	A clear, colourless solution		Pass
Particulate matter	None visible		Pass
Identification	Gamma spectrum does not differ significantly from that of a standardised indium-111 solution, apart from any difference due to the presence of indium-114m		Pass
Radionuclidic content	90-110% of stated value		102
Radionuclidic purity	Gamma spectrum does not differ significantly from that of a standardised indium-111 solution, apart from any difference due to the presence of indium-114m. ≤ 0.25 % of the total radioactivity is due to radionuclides other than indium-111 at all times up to expiry.		Pass
pH	3.5 – 8.0		7.0
Radiochemical purity	≥ 90% of activity as ¹¹¹ In-Oxine	INT.	92.0±1.9
		EXP.	92.7±1.0
Vial/Package Label	Complies		Complies

SODIUM IODIDE [¹³¹I] CAPSULES (DIAGNOSTIC)

Current edition of BP

		SUPPLIER	ARI
		LOT/BATCH No.	107043
		CALIB. DATE	17/10/05
SPECIFICATIONS		EXPIRY DATE	31/10/05
Appearance	Gelatin 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		97
Radionuclidic purity	≤ 0.1% of the total radioactivity is due to ¹³³ I, ¹³⁵ I and other radionuclidic impurities		N.D.
Radiochemical purity	≥ 95% of activity as iodide	INT.	99.6±0.1
		EXP.	98.6±0.4
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.		Pass
	The relative standard deviation is ≤ 3.5%		1.3
Vial/Package Label	Complies		Complies

SODIUM IODIDE [¹³¹I] INJECTION

Current edition of BP

		SUPPLIER	ARI
		LOT/BATCH No.	107034
		CALIB. DATE	19/10/05
SPECIFICATIONS		EXPIRY DATE	02/11/05
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 ¹³³ I, ¹³⁵ I and other radionuclidic impurities		N.D.
pH	7.0 – 8.5		7.0
Radiochemical purity	≥ 95% of activity as iodide	INT.	99.7±0.1
		EXP.	98.6±0.4
Vial/Package Label	Complies		Complies

THALLOUS [²⁰¹Tl] CHLORIDE INJECTION

Current edition of BP

		SUPPLIER	MALL	ARI		
		LOT/BATCH No.	49244/000	105073/002		
		CALIB. DATE	28/04/05	29/04/05		
SPECIFICATIONS		EXPIRY DATE	04/05/05	04/05/05		
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		94	100		
Radionuclidic purity	At all times up to expiry		At calibration	At expiry	At calibration	At expiry
	²⁰¹ Tl ≥ 97 %		99.7	99.1	99.5	99.7
	²⁰² Tl ≤ 2.0 %		0.3	0.9	0.1	0.3
	²⁰⁰ Tl %		0.07	0.004	0.4	0.05
	²⁰¹ Pb %		N.D.	N.D.	N.D.	N.D.
	²⁰³ Pb %		N.D.	N.D.	N.D.	N.D.
pH	4.0 - 7.0		5.3		5.3	
Radiochemical purity	≥ 95% of the activity is present as Thallous ion	INT.	99.1±0.06		99.4±0.06	
		EXP.	98.9±0.03		99.6±0.1	
Thallium	≤ 10 µg/mL		Pass		Pass	
Benzyl Alcohol	90 – 100 % of stated value		N/A		96.9	
Vial/Package Label	Complies		Complies		Complies	