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and Nuclear Safety Agency

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Results of the Quality Assurance Testing Program for Radiopharmaceuticals (2008)

Z Ivanov

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**Australian Radiation Protection
and Nuclear Safety Agency**

Results of the Quality Assurance Testing Program for Radiopharmaceuticals 2008



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ABSTRACT

This report tabulates results obtained during 2008 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. Unless stated otherwise, these specifications listed apply at all times up to the date of product expiry. Radionuclidic purity has been determined up to the expiry time.

For Thallous [^{201}Tl] Chloride Injection and Sodium Pertechnetate [$^{99\text{m}}\text{Tc}$] Injection, radionuclidic purity is determined and the impurity levels at both the time of 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 as described in *Quality Assurance of Radiopharmaceuticals including Cold Kits: MR-RPQA-SOP-0000*. All technetium-99m cold kits were reconstituted using Sodium Pertechnetate [$^{99\text{m}}\text{Tc}$] Injection according to the directions supplied in the package insert. 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 2008 are summarised in the following tables. Overall, 29 batches of 20 different types of radiopharmaceuticals were tested.

In 2008, ARPANSA participated in the Radionuclide Dose Calibration Survey conducted by Lantheus Medical Imaging. The calibration standards were obtained from ANSTO Radiopharmaceuticals and Industrials (ANSTO/ARI).

^{201}Tl radionuclidic content measurements on the two ARPANSA dose calibrators (Capintec) showed good agreement with each other. Results quoted on p.17 for ^{201}Tl are for:

- (i) measurement's made using Capintec manufacturer's calibration setting;
- (ii) the results obtained by the use of a calibration factor determined from a National Institute of Standards and Technology (NIST), USA, certified ^{201}Tl standard solution; and
- (iii) the results obtained by the use of a calibration factor determined from an ANSTO/ARI verified ^{201}Tl calibration source (solution).

Whilst the ARPANSA results were within 93 – 111 % (specification 90 – 110%) of the activity stated on the label there was a 10% difference between the ANSTO/ARI and NIST calibration standards. The difference in the two standards appears to be due to varying levels of radionuclidic impurities, in particular the longer lived ^{202}Tl ($t_{1/2} = 12.23$ days).

In the case of Iobenguane [^{123}I] Injection, the radionuclidic content could not be determined accurately due to the unavailability of a certified reference standard for Iodine-123 and the uncertain correction for the effect of the absorption of the abundant low energy X-ray emission by the container. Thus, measurement in the original sample glass vial (and using the dose calibrator manufacturer's setting for ^{123}I) gave an apparent 70 % of the stated radioactivity at the calibration date and time when measured using two different dose calibrators. Measurements with the Iobenguane [^{123}I] Injection in Terumo^R and Livingstone plastic 1 mL syringes gave the value of 134 % of the stated radioactivity at the calibration date and time on the basis of the MBq/mL activity concentration. The manufacturers of dose calibrators advise that for the measurement of ^{123}I a 10 - 20% syringe correction may be required.

For Sodium Iodide [^{131}I] Capsules (Therapy) the BP does not require a "Uniformity of Content" test. The measurement of radioactivity content of 3 capsules of this batch showed that the radioactivity of no capsule differed by more than 8.9 % from the average value, with a relative standard deviation of 7.74 %.

According to the current BP, labelling of the radiopharmaceutical preparations complies with the relevant national and European legislation. In accordance with the "*General Requirements for Labels for Medicines*" of the Therapeutic Goods Act 1989, TGA Order No. 69, 3(2) (b), the label or labels must include the name(s) and quantity or proportion of all active ingredients in the goods. For small volume injections the label on the primary pack must include the name and quantity of each excipient.

The BP/USP does not require a test for benzyl alcohol used as an antimicrobial preservative in some "ready to use" radiopharmaceuticals. ARPANSA, however performs this test using an in-house method.

In the case of one type of “cold kit” radiopharmaceutical, the kit from an overseas manufacturer met the USP specification for pH after reconstitution (pH = 4.0 – 7.5), which is outside the BP specification (pH = 6.0 – 7.0).

Non-compliance of the vial/package label was observed in two batches. Vial/label non-compliance consisted of absence of a statement as to the presence or absence of a microbiological preservative and the absence of expiry time. Both parameters were stated in the delivery note.

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.

ACKNOWLEDGEMENTS

The testing of the radiopharmaceuticals and cold kits was performed by Ilonka Bokor and Zlata Ivanov.

ABBREVIATIONS

The following abbreviations are used in the tables –

ARI	- ANSTO Radiopharmaceuticals and Industrials, Lucas Heights, Sydney, Australia
BMS/Lantheus	- Bristol-Myers Squibb Medical Imaging, Tullamarine, VIC, Australia
BMS (US)	- Bristol-Myers Squibb Medical Imaging, North Billerica, MA, USA
GE Healthcare	- GE Healthcare Limited, formerly Amersham Health Pty. Ltd., UK
RADPH	- Radpharm Scientific, Belconnen, ACT, Australia
TYCO/MALL	- TYCO Healthcare, Lane Cove, NSW Australia; Mallinckrodt Medical B.V., Petten, Netherlands
CALIB. DATE	- Calibration Date
CIS-US	- CIS-US Inc., Bedford, MA, USA
EXP.	- Expiry testing
INT.	- Initial testing
MAX	- Maximum
MIN	- Minimum
N.A.	- Not applicable (not required by BP/USP)
N.D.	- Not detected
No.	- Number
p	- Page
reconst.	- reconstitute
TBD	- To be done
†	- Not determined

CHROMIUM [⁵¹Cr] EDETATE INJECTION

Current edition of BP

SPECIFICATIONS		SUPPLIER	ARI
		LOT/BATCH No.	115784-001
		CALIB. DATE	01/06/08
		EXPIRY DATE	02/07/08
Appearance	A clear, violet 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		106.3 ± 0.5*
Radionuclidic purity	Gamma spectrum does not differ significantly from that of a standardised chromium-51 solution		Pass
pH	3.5 – 6.5		4.8 4.0
Radiochemical purity			
1) Chromic ion	as %	INT.	0.2 ± 0.09
2) Chromate ion	as %		2.0 ± 0.1
3) Cr-edetate	≥ 95% as ⁵¹ Cr-edetate		97.8 ± 0.2
		EXP.	0.5 ± 0.1
			1.5 ± 0.2
			98.0 ± 0.3
Chromium (Cr)	≤ 1mg/mL		Complies
Benzyl Alcohol	90 – 110 % of stated value		N.A.
Vial/Package Label	Complies		Complies

* Two vials from the same batch.

SODIUM CHROMATE [⁵¹Cr] SOLUTION

Current edition of BP

SPECIFICATIONS		SUPPLIER	GE Healthcare
		LOT/BATCH No.	1080
		CALIB. DATE	10/09/08
		EXPIRY DATE	05/11/08
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		103
Radionuclidic purity	Gamma spectrum does not differ significantly from that of a standardised chromium-51 solution		Pass
pH	6.0 - 8.5		6.0
Radiochemical purity	≥ 90% as chromate ion	INT.	98.6 ± 0.1
	% as chromic ion		0.2 ± 0.04
		EXP.	98.1 ± 0.2
			1.0 ± 0.08
Total chromate	≤ 2.7 µg of chromate ion (CrO ₄ ²⁻) per MBq		0.33
Benzyl Alcohol	90 – 110 % of stated value		N.A.
Vial/Package Label	Complies		Complies

GALLIUM [⁶⁷Ga] CITRATE INJECTION

Current edition of BP

		SUPPLIER	ARI	BMS (US)	TYCO/MALL
		LOT/BATCH No.	115680-004	G136811S	69152
		CALIB. DATE	23/05/08	23/05/08	30/05/08
SPECIFICATIONS		EXPIRY DATE	28/05/08	30/05/08	09/06/08
Appearance	A clear, colourless solution	Pass	Pass	Pass	Pass
Particulate matter	None visible	Pass	Pass	Pass	Pass
Identification	Gamma spectrum does not differ significantly from that of a standardised gallium-67 solution	Pass	Pass	Pass	Pass
Citrate presence	A yellow colour develops in the test solution only	Pass	Pass	Pass	Pass
Radionuclidic content	90-110% of stated value	103	98	99	
Radionuclidic purity	≤ 0.2% ⁶⁶ Ga	N.D.	N.D.	N.D.	N.D.
pH	5.0 - 8.0	6.5	6.0	6.5	
Radiochemical purity	≥ 97% as Ga Citrate	INT. 99.7 ± 0.01 EXP. 99.7 ± 0.02	99.6 ± 0.1 99.6 ± 0.1	99.7 ± 0.01 99.6 ± 0.1	99.7 ± 0.01 99.6 ± 0.1
Zinc limit test	≤ 5 µg/mL	Pass	Pass	Pass	Pass
Benzyl Alcohol	90 – 110 % of stated value	108	96	97	
Vial/Package Label	Complies	Complies	Complies	Complies	Fails

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

		SUPPLIER	ARI		
		LOT/BATCH No.	116531-066		
		CALIB. DATE	01/09/08		
SPECIFICATIONS		EXPIRY DATE	15/09/08		
Maximum surface radiation dose rate	< 2000 µSv/h		320 µSv/h		
Dose rate at 1 metre	< 100 µSv/h		7.2 µSv/h		
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 technetium-99m solution		Pass		
Radionuclidic purity	≤ 0.1% ⁹⁹ Mo	MIN	MAX		
		Elution	Expiry	Elution	Expiry
	≤ 5 x 10 ⁻³ % ¹³¹ I	1.6E-4	3.7E-4	3.6E-4	8.3E-4
	≤ 5 x 10 ⁻³ % ¹⁰³ Ru	1.2E-6	3.0E-6	3.9E-6	9.5E-6
	≤ 6 x 10 ⁻⁵ % ⁸⁹ Sr	N.D.	N.D.	N.D.	N.D.
	≤ 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.	
pH	4.0 - 8.0		5.5	5.5	
Radiochemical purity	≥ 95% as pertechnetate ion (^{99m} TcO ₄) ⁻	INT.	99.8 ± 0.02	99.8 ± 0.03	
		EXP.	99.7 ± 0.01	99.8 ± 0.03	
Aluminium	≤ 5µg/mL		0.6 µg/mL	1.9 µg/mL	
Milking efficiency	None (for information only)		111 %	117 %	
Moly assay (⁹⁹ Mo breakthrough)	≤ 0.1 % ⁹⁹ Mo at expiry		N.D.	0.0004	
Vial/Package Label	Complies		Complies		

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

Current edition of BP

SPECIFICATIONS		SUPPLIER	BMS/Lantheus	
		LOT/BATCH No.	241912	
		CALIB. DATE	26/6/08 @ 09:00 h	
		EXPIRY DATE	26/6/08 @ 17:00 h	
Appearance	A clear, colourless solution		Pass	
Particulate matter	None visible		Pass	
Identification	Gamma spectrum does not differ significantly from that of a standardised technetium-99m solution		Pass	
Radionuclidic content	90-110% of stated value		105	
Radionuclidic purity	≤ 0.1% ⁹⁹ Mo		INT.	EXP.
	≤ 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	
Radiochemical purity	≥ 95% as pertechnetate ion (^{99m} TcO ₄ ⁻)		99.8 ± 0.02	99.9 ± 0.01
Aluminium (Al)	≤ 5 µg /mL		< 1 µg/mL	
Vial/Package Label	Complies		Complies	

INDIUM OXINE [¹¹¹In] SOLUTION

Current edition of BP

		SUPPLIER	GE Healthcare
		LOT/BATCH No.	5238
		CALIB. DATE	15/10/08
SPECIFICATIONS		EXPIRY DATE	20/10/08
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		108
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		Pass
	≤ 0.25% of the total radioactivity is due to radionuclides other than indium-111 at all times up to expiry		0.22
pH	6.0 – 7.5		7.0
Radiochemical purity	≥ 90% of activity as ¹¹¹ In-Oxine	INT.	91.4 ± 0.9
		EXP.	90.6 ± 0.4
Vial/Package Label	Complies		Complies

IOBENGUANE [¹²³I] INJECTION

Current edition of BP

		SUPPLIER	ARI	
		LOT/BATCH No.	115285-006	
		CALIB. DATE	27/03/08 @ 09:00 h	
SPECIFICATIONS		EXPIRY TIME	16:00 h after calibration	
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 iodine-123 solution apart from any differences attributed to the presence of iodine-125, tellurium-121 and other radionuclidic impurities		Pass	
Radionuclidic content	90-110% of stated value		69.8* 133.9** 134.2***	
Radionuclidic purity	≤ 0.35 % of the total radioactivity is due to radionuclides other than iodine-123		Pass	
pH	3.5 – 8.0		5.0	
			INT.	EXP.
Radiochemical purity	≥95% of activity as iobenguane		97.9 ± 0.2	97.2 ± 0.3
	≤ 4 % of activity as iodide		1.7 ± 0.2	2.2 ± 0.2
	≤ 1% of activity in other peaks		0.4 ± 0.02	0.5 ± 0.05
Vial/Package Label	Complies		Complies	

* Measurements performed in the glass vial, supplied by the manufacturer in two different dose calibrators (Capintec).

** Measurements performed in a Terumo^R plastic 1 mL syringe.

*** Measurements performed in a Livingstone plastic 1 mL syringe

Note: No reference standard is available and no adjustment was made to the Capintec setting. For details refer to p 6 of this report.

SODIUM IODIDE [¹³¹I] CAPSULES (THERAPY)

Current edition of BP

SPECIFICATIONS		SUPPLIER	ARI
		LOT/BATCH No.	117597-025
		CALIB. DATE	22/12/08
		EXPIRY DATE	05/01/09
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		97 ± 7.5*
Radionuclidic purity	≥ 99.9% as ¹³¹ I, ≤ 0.1% of the total radioactivity is due to ¹³⁰ I, ¹³³ I, ¹³⁵ I and other radionuclidic impurities		Pass N.D.
Radiochemical purity	≥ 95% of activity as iodide	INIT.	98.9 ± 0.2
		EXP.	98.1 ± 0.05
Disintegration	The shell and its contents dissolve completely within 15 min.		Pass
Vial/Package Label	Complies		Complies

* 3 capsules measured.

Note: The BP does not require a Uniformity of Content test for Sodium Iodide [¹³¹I] Capsules (Therapy). The measurement of radioactivity content of 3 capsules of this batch showed that the radioactivity of no capsule differed by more than 8.9% from the average value, with a relative standard deviation of 7.74%.

THALLOUS [²⁰¹Tl] CHLORIDE INJECTION

Current edition of BP

		SUPPLIER	ARI	BMS (US)		TYCO/MALL		
		LOT/BATCH No.	115357-003	T096811S		68202		
		CALIB. DATE	10/04/08	11/04/08		10/04/08		
SPECIFICATIONS		EXPIRY DATE	15/04/08	15/04/08		17/04/08		
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 thallium-201 solution		Pass		Pass		Pass	
Radionuclidic content	90-110% of stated value		104.0, 103.4* 110.8, 110.4** 99.7, 100.5***		100.5, 99.4* 107.1, 105.8** 96.4, 96.5***		97.2, 96.7* 103.5, 103.0** 93.2, 93.8***	
Radionuclidic purity	At all times up to expiry		At calibration	At expiry	At calibration	At expiry	At calibration	At expiry
	²⁰¹ Tl ≥ 97 %		99.55	99.65	99.7	99.4	99.7	99.0
	²⁰² Tl ≤ 2.0 %		0.13	0.3	0.3	0.6	0.3	0.95
	²⁰⁰ Tl %		0.32	0.04	N.D.	N.D.	N.D.	N.D.
	²⁰¹ Pb %		N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
	²⁰³ Pb %		N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
pH	4.0 - 7.0		5.5		5.5		5.5	
Radiochemical purity	≥ 95% of the activity is present as Thallous ion		INT. 99.6 ± 0.2		99.5 ± 0.2		98.9 ± 0.1	
			EXP. 99.9 ± 0.02		99.9 ± 0.01		99.4 ± 0.05	
Thallium	≤ 10 µg/mL		Complies		Complies		Complies	
Benzyl Alcohol	90 – 100 % of stated value		96		110		N.A.	
Vial/Package Label	Complies		Complies		Complies		Fails	

* Results obtained using Capintec manufacturer's calibration.

** Result obtained by measurement in Capintec calibrated for ²⁰¹Tl by the use of a calibration factor determined from a NIST certified ²⁰¹Tl standard solution.

***Result obtained by measurement in Capintec calibrated for ²⁰¹Tl by the use of a calibration factor determined from an ANSTO/ARI verified ²⁰¹Tl calibration source (solution).

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

Current edition of USP

		SUPPLIER	BMS (US)		BMS (US)	
		LOT/BATCH No.	0167A		0182A	
SPECIFICATIONS		EXPIRY DATE	01/03/08		01/05/09	
			INT.	EXP.	INT.	EXP.
Appearance	before reconstitution	Freeze-dried solid	Pass	Pass	Pass	Pass
Appearance	after reconstitution	A clear, colourless solution	Pass	Pass	Pass	Pass
pH		6.3 - 7.6* after reconstitution 6.5 - 7.5** after reconstitution	7.1	7.0	7.0	7.1
Radiochemical purity		≥ 90.0 % as ^{99m} Tc-Bicisate (chromatography system A) ≤ 10.0 % as impurities (colloidal, ^{99m} TcO ₄ ⁻ & ^{99m} Tc-EDTA) (chromatography system B)	98.3 ± 0.03 1.7 ± 0.03	98.4 ± 0.02 1.6 ± 0.02	94.0 ± 0.2 6.0 ± 0.2	95.7 ± 0.1 4.3 ± 0.1
Tin content		12 - 72 µg SnCl ₂ .2H ₂ O*	N.A.		N.A.	
Vial/Package Label		Complies	Complies		Complies	

* Manufacturer's approved specification.

** Current addition of BP 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.	2472		2547	
SPECIFICATIONS		EXPIRY DATE	31/05/08		31/05/09	
			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		Pass	Pass	Pass	Pass
pH	4.0 - 7.0 after reconstitution		4.7		5.0	
Radiochemical purity	≥ 95.0 % as ^{99m} Tc-colloid		96.4 ± 2.3	94.6 ± 0.1	96.3 ± 1.5	97.3 ± 0.4
Tin content	≤ 1.0 mg SnCl ₂		Pass		Pass	
Vial/Package Label	Complies		Complies		Complies	

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

Current edition of USP

SPECIFICATIONS		SUPPLIER	RADPH	
		LOT/BATCH No.	230011A	
		EXPIRY DATE	31/08/08	
			INT.	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
pH	4.0 - 5.0 after reconstitution		4.5	4.5
Radiochemical purity	1) $\geq 90.0\%$ as ^{99m} Tc-disofenin		96.7	96.9
	2) hydrolysed + tin colloid (chromatography system A)		0.1 ± 0.01	0.2 ± 0.01
	3) free pertechnetate (chromatography system B)		3.2 ± 0.17	2.9 ± 0.2
	2) + 3) $\leq 10\%$		3.3	3.1
Tin content	0.24 - 0.6 mg SnCl ₂ *		N.A.	
Biological distribution	$\geq 70\%$ in gallbladder + intestines		†	
	$\leq 10\%$ in the liver		†	
	$\leq 10\%$ in the kidneys		†	
	$\leq 3\%$ in the stomach		†	
	$\leq 3\%$ in the blood		†	
Vial/Package Label	Complies		Complies	

* Value given in label/product information.

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

Current edition of USP

		SUPPLIER	GE Healthcare		
		LOT/BATCH No.	1238		
SPECIFICATIONS	EXPIRY DATE	22/10/08			
		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		
pH	9.0 – 9.8 after reconstitution	9.2	9.4		
Radiochemical purity	≥ 80.0 % as ^{99m} Tc-Exametazime	93.6	95.2		
	% as free pertechnetate	1.6 ± 0.4	1.3 ± 0.1		
	% as hydrolysed reduced ^{99m} Tc	1.2 ± 0.1	2.3 ± 0.1		
	% as ^{99m} Tc secondary exametazime complex	3.6	1.2		
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	ARI	RADPH	
		LOT/BATCH No.	2491	2608	
SPECIFICATIONS		EXPIRY DATE	31/08/08	October 2009	
		INT.	EXP.	INT.	EXP.
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture	Pass	Pass	Pass	TBD
Appearance after reconstitution	A clear, colourless solution	Pass	Pass	Pass	TBD
pH	3.5 – 7.5 after reconstitution	5.0	5.1	5.0	TBD
Radiochemical purity	1) ≥ 95.0 % as ^{99m} Tc-MDP	99.6	99.7	99.8	TBD
	2) ≤ 2.0 % as ^{99m} TcO ₄ ⁻	0.07 ± 0.02	0.06 ± 0.01	0.06 ± 0.02	TBD
	3) as colloidal ^{99m} Tc	0.35 ± 0.11	0.22 ± 0.004	0.17 ± 0.01	TBD
	2) + 3) ≤ 5.0 %	0.4	0.3	0.2	TBD
Tin content	≤ 3 mg/mL	Complies		TBD	
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

SPECIFICATIONS		SUPPLIER	TYCO/MALL	
		LOT/BATCH No.	0948004	
		EXPIRY DATE	01/02/09	
			INT.	EXP.
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture		Pass	Pass
Appearance after reconstitution	A clear, colourless solution		Pass	Pass
pH	5.0 - 7.5 after reconstitution		5.5	5.5
Radiochemical purity	≥ 94.0 % as ^{99m} Tc-MAG3*		99.7 ± 0.1	99.7 ± 0.01
	% as hydrophilic impurities*		0.14 ± 0.01	0.16 ± 0.02
	% as non-elutable impurities*		0.12 ± 0.01	0.13 ± 0.02
	≤ 2% as reduced-hydrolysed technetium (by chromatography)		0.06 ± 0.003	0.06 ± 0.001
Tin content	≥ 50 µg SnCl ₂ .2H ₂ O/vial**		N.A.	
Vial/Package Label	Complies		Complies	

* Tested by the method recommended by the manufacturer.

** Value given in label/product information.

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

Current edition of USP

		SUPPLIER	TYCO/MALL	
		LOT/BATCH No.	0918007	
SPECIFICATIONS		EXPIRY DATE	24/12/08	
			INT.	EXP.
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture		Pass	Pass
Appearance after reconstitution	A clear, colourless solution		Pass	Pass
pH	2.5 – 7.0 after reconstitution		4.5	4.5
Radiochemical purity*	1) ≥ 90.0 % as ^{99m} Tc-oxidronate		99.4	99.7
	2) % as free pertechnetate		0.4 ± 0.14	0.12 ± 0.04
	3) % as colloidal ^{99m} Tc		0.2 ± 0.05	0.23 ± 0.04
	2) + 3) ≤ 10 %			
Tin content	0.258 - 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 for [^{99m}Tc] Pyrophosphate Injection.

** Value given in label/product information.

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

Current edition of BP

SPECIFICATIONS		SUPPLIER	ARI
		LOT/BATCH No.	2562
		EXPIRY DATE	31/03/2009
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	Pass	Pass
Check for vacuum	If a vacuum is not observed when the vial is pierced, the vial should be discarded	Pass	Pass
pH	4.0 – 7.5 after reconstitution	5.0	4.7
Radiochemical purity	1) $\geq 95.0\%$ as ^{99m} Tc-DTPA	99.7	99.5
	2) Colloidal ^{99m} Tc impurity (chromatography system A)	0.13 ± 0.03	0.17 ± 0.01
	3) Free pertechnetate ^{99m} Tc (chromatography system B) 2) + 3) $\leq 5.0\%$	0.17 ± 0.06	0.34 ± 0.02
Tin content	≤ 1 mg/mL	Pass	
Vial/Package Label	Complies	Complies	

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

Current edition of USP

SPECIFICATIONS		SUPPLIER	BMS (US)		BMS (US)	
		LOT/BATCH No.	3914 KA	3945 KA		
		EXPIRY DATE	01/06/08	01/08/09		
		INT.	EXP.	INT.	EXP.	
Appearance before reconstitution	Freeze dried solid with no evidence of moisture	Pass	Pass	Pass	TBD	
Appearance after reconstitution	A clear, colourless solution	Pass	Pass	Pass	TBD	
pH	5.0 - 6.0 after reconstitution	5.2	5.3	5.1	TBD	
Radiochemical purity	≥ 90.0 % as ^{99m} Tc-Sestamibi	98.4± 0.04	98.4± 0.1	98.6± 0.06	TBD	
	≤ 10.0 % ^{99m} Tc impurities	3.0 ± 0.04	1.4± 0.2	1.4 ± 0.06	TBD	
Tin content	0.075 mg SnCl ₂ *	N.A.		N.A.		
Vial/Package Label	Complies	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	
		LOT/BATCH No.	2568	
SPECIFICATIONS		EXPIRY DATE	30/04/09	
		INT.	EXP.	
Appearance before reconstitution	Freeze dried solid	Pass	Pass	
Appearance after reconstitution	A clear, colourless solution	Pass	Pass	
Check for vacuum	If a vacuum is not observed when the vial is pierced, the vial should be discarded	Pass	Pass	
pH	2.3 - 3.5 after reconstitution	2.7	3.0	
Radiochemical purity	≥ 95.0 % as ^{99m} Tc-DMSA	99.5 ± 0.11	99.51 ± 0.08	
	≤ 2.0 % as ^{99m} TcO ₄ ⁻	0.2 ± 0.14	0.5 ± 0.08	
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 [^{99m}Tc] TETROFOSMIN (MYOVIEW)

Current edition of USP

		SUPPLIER	GE Healthcare	
		LOT/BATCH No.	1586	
SPECIFICATIONS		EXPIRY DATE	12/11/08	
			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
pH	8.3 - 9.1 after reconstitution		8.3	8.4
Radiochemical purity	1) $\geq 90.0\%$ as ^{99m} Tc-Tetrofosmin		96.2 ± 0.2	98.4 ± 0.1
	2) Reduced hydrolysed & hydrophilic impurities		3.2 ± 0.2	1.5 ± 0.1
	3) Unbound pertechnetate		0.55 ± 0.13	0.14 ± 0.1
	2) + 3) $\leq 10\%$		3.8	1.6
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 USP

		SUPPLIER	TYCO/MALL	
		LOT/BATCH No.	0948004	
SPECIFICATIONS		EXPIRY DATE	01/02/09	
			INT.	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		Pass	Pass
pH	6.0 – 7.0 after reconstitution* 4.5 – 6.0 after reconstitution** 4.0 - 7.5 after reconstitution***		5.5	5.0
Radiochemical purity	1) ≥ 90.0 % as ^{99m} Tc-PYP 2) as free pertechnetate (chromatography system A) 3) as colloidal [^{99m} Tc] (chromatography system B) 2) + 3) ≤ 10 %		98.6 0.6 ± 0.07 0.8 ± 0.2 1.4	98.1 0.4 ± 0.12 1.5 ± 0.3 1.9
Sodium pyrophosphate	1-50 mg/mL sodium pyrophosphate on reconstitution		Complies	
Tin content	≤ 3 mg/mL		2	
Vial/Package Label	Complies		Complies	

* Value given in BP.

** Manufacturer specification.

*** Value given in USP.