Australian Government

Australian Radiation Protection and Nuclear Safety Agency

Results of the Quality Assurance Testing Program for Radiopharmaceuticals 2007

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ABSTRACT

This report tabulates results obtained during 2007 for the Radiopharmaceutical Quality Assurance Test Program conducted by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

CONTENTS

Page No.

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 up to the expiry time, except for Thallous [^{201}Tl] Chloride Injection and Sodium Pertechnetate [^{99m}Tc] where the impurity levels at both 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 [^{99m}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 2007 are summarised in the following tables. Overall, 37 batches of 23 different types of radiopharmaceuticals were tested.

Non-compliance of the vial/package label was observed in two batches. Vial/package label non-compliance consisted of absence of a statement as to the presence or absence of a microbiological preservative.

In 2007, ARPANSA participated in the National Radionuclide Dose Calibration Survey conducted by Dr Richard Smart, St George Hospital, Kogarah, NSW on behalf of the Australian and New Zealand Society of Nuclear Medicine. The calibration standards were obtained from ANSTO Radiopharmaceuticals and Industrials (ANSTO/ARI). In addition, a Thallium-201 calibration standard from the National Institute of Standards and Technology (NIST) Gaithersburg, Maryland, USA (an internationally recognised standards Agency) was used to survey dose calibrators. Results quoted on p.17 for ^{201}Tl are for the measurements made using (i) Capintec manufacturer's calibration setting, (ii) an ANSTO/ARI verified calibration source and (iii)

NIST certified ^{201}Tl standard solutions. Whilst the ARPANSA results were within 96 – 110% (specification 90 – 110%) of the activity stated on the label it is noted that there was a 10% difference between the ANSTO/ARI and NIST calibration standards.

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 effect of the container due to the variability in the absorption of the abundant low energy X-ray emission. Thus, measurement in the original sample glass vial (and using the dose calibrator manufacturer's setting for ^{123}I) gave an apparent 75 % of the stated radioactivity at the calibration date and time when measured using two different dose calibrators. Measurements with the sample in Terumo^{R} plastic 1 mL syringes gave the values of 137 and 138 % of the stated radioactivity at the calibration date and time on the basis of the MBq/mL activity concentration. It is noted that 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 5 capsules of this batch showed that the radioactivity of no capsule differed by more than 5.7% from the average value, with a relative standard deviation of 4.07%.

In the case of one type of "cold kit" radiopharmaceutical, the kit from an Australian manufacturer met the TGA approved manufacturer's specification for pH after reconstitution (pH = 4.5 – 6.0), which is outside the BP specification (pH = 6.0 – 7.0).

For another type of "cold kit" radiopharmaceutical, from an Australian manufacturer, radiochemical purity could not be accurately determined due to the insufficient chromatographic separation when using the test method of the current edition of the BP monograph.

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 Health Pty. Ltd., UK
MALL	- Mallinckrodt Medical B.V., Petten, Netherlands
GE Healthcare	- GE Healthcare Limited, formerly 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
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
RADPH	- Radpharm Scientific, Belconnen, ACT, Australia
EXP.	- Expiry testing
INT.	- Initial testing
MAX	- Maximum
MIN	- Minimum
N.A.	- Not applicable
N.D.	- Not detected
No.	- Number
p	- Page
reconst.	- reconstitute
TBD	- To be done
†	- Not determined

CHROMIUM [^{51}Cr] EDETATE INJECTION

Current edition of BP

		SUPPLIER	ARI	GE Healthcare
		LOT/BATCH No.	111980-001	868
		CALIB. DATE	01/03/07	05/03/07
	SPECIFICATIONS	EXPIRY DATE	01/04/07	30/04/07
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		104.7 ± 0.2*	101.5
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	4.0
Radiochemical purity				
1) Chromic ion	as %	INT.	0.2 ± 0.04	0.17 ± 0.003
2) Chromate ion	as %		1.1 ± 0.2	1.3 ± 0.35
3) Cr-edetate	≥ 95% as ^{51}Cr-edetate		98.7 ± 0.2	98.6 ± 0.35
		EXP.	0.06 ± 0.01	0.2 ± 0.04
			1.4 ± 0.17	0.7 ± 0.07
			98.5 ± 0.17	99.1 ± 0.1
Chromium	≤ 1mg/mL		Pass	Pass
Benzyl Alcohol	90 – 110 % of stated value		N.A.	94
Vial/Package Label	Complies		Complies	Complies

* Two vials from the same batch.

SODIUM CHROMATE [^{51}Cr] SOLUTION

Current edition of BP

		SUPPLIER	GE Healthcare
		LOT/BATCH No.	1002
		CALIB. DATE	14/03/07
	SPECIFICATIONS	EXPIRY DATE	09/05/07
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		104
Radionuclidic purity	Gamma spectrum does not differ significantly from that of a standardised chromium-51 solution.		Pass
pH	6.0 - 8.5		6.2
Radiochemical purity	≥ 90% as chromate ion	INT.	99.0 ± 0.06
	% as chromic ion		1.0 ± 0.06
		EXP.	98.0 ± 0.1
			2.0 ± 0.1
Total chromate	≤ 2.7 µg of chromate ion (CrO_4^{2-}) per MBq		0.3
Benzyl Alcohol	90 – 110 % of stated value		N.A.
Vial/Package Label	Complies		Complies

CYANOCOBALAMIN [^{57}Co] CAPSULES

Current edition of BP

		SUPPLIER	GE Healthcare
		LOT/BATCH No.	626/3
		CALIB. DATE	19/10/07
	SPECIFICATIONS	EXPIRY DATE	14/12/07
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		103 ± 1.5*
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.	91.2 ± 0.6
		EXP.	91.1 ± 0.2
Uniformity of content	The radioactivity of no capsule differs by more than 10 % from the average		Pass
	The relative standard deviation is < 3.5 %		1.5
Vial/Package Label	Complies		Complies

*****12 capsules measured.

GALLIUM [^{67}Ga] CITRATE INJECTION

Current edition of BP

		SUPPLIER	ARI	BMS (US)	TYCO/MALL
		LOT/BATCH No.	112646-002	G137711S	62999
		CALIB. DATE	22/05/07	24/05/07	24/05/07
	SPECIFICATIONS	EXPIRY DATE	27/05/07	31/05/07	03/06/07
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		102	98	99
Radionuclidic purity	≤ 0.2% ^{66}Ga		N.D.	N.D.	N.D.
pH	5.0 - 8.0		6.5	5.5	6.5
Radiochemical purity	≥ 97% as Ga Citrate	INT.	99.6 ± 0.1	99.6 ± 0.1	99.6 ± 0.1
		EXP.	99.7 ± 0.1	99.8 ± 0.1	99.8 ± 0.04
Zinc limit test	≤ 5 μg/mL		Pass	Pass	Pass
Benzyl Alcohol	90 – 110 % of stated value		108	94	Not stated
Vial/Package Label	Complies		Complies	Complies	Fails

^{99}Mo/ ^{99m}Tc CHROMATOGRAPHIC GENERATOR

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

		SUPPLIER	ARI			
		LOT/BATCH No.	114256-034			
		CALIB. DATE	03/12/07			
	SPECIFICATIONS	EXPIRY DATE	17/12/07			
Maximum surface radiation dose rate	< 2000 µSv/h		220 µSv/h			
Dose rate at 1 metre	< 100 µSv/h		5 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 Tc-99m solution		Pass			
			MIN Elution	MIN Expiry	MAX Elution	MAX Expiry
Radionuclidic purity	≤ 0. 1% ^{99}Mo		4.2E-5	9.7E-5	9.3E-5	2.4E-4
	≤ 5 x 10^{-3} % ^{131}I		5.7E-7	1.4E-6	5.7E-7	1.4E-6
	≤ 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.
pH	4.0 - 8.0		5.0		5.5	
Radiochemical purity	≥ 95% as pertechnetate ion ($^{99m}TcO_4$)$^-$	INT.	99.1 ± 0.6		99.98 ± 0.00	
		EXP.	99.8 ± 0.2		99.97 ± 0.02	
Aluminium	≤ 5µg/mL		<1 µg/mL		<1 µg/mL	
Milking efficiency	None (for information only)		113 %		115 %	
Moly assay (^{99}Mo breakthrough)	≤ 0.1 % ^{99}Mo at expiry		N.D.		0.0002	
Vial/Package Label	Complies		Complies			

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

Current edition of BP

		SUPPLIER	BMS	
		LOT/BATCH No.	191872	
		CALIB. DATE	14/06/07 @ 09:00 h	
	SPECIFICATIONS	EXPIRY TIME	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 Tc-99m solution		Pass	
Radionuclidic content	90-110% of stated value		108	
			INT.	EXP.
Radionuclidic purity	≤0. 1% ^{99}Mo		5.2E-4	1.2E-3
	≤ 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 ± 0.01	99.5 ± 0.7
Aluminium	≤ 5 µg /mL		< 1 µg/mL	
Vial/Package Label	Complies		Complies	

INDIUM OXINE [^{111}In] SOLUTION

Current edition of BP

		SUPPLIER	GE Healthcare
		LOT/BATCH No.	4866
		CALIB. DATE	08/08/07
	SPECIFICATIONS	EXPIRY DATE	13/08/07
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		110
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.		0.07
pH	6.0 – 7.5		7.0
Radiochemical purity	≥ 90% of activity as ^{111}In-Oxine	INT.	92.2 ± 0.7
		EXP.	95.9 ± 0.9
Vial/Package Label	Complies		Complies

IOBENGUANE [^{123}I] INJECTION (m-IBG)

Current edition of BP

		SUPPLIER	ARI	
		LOT/BATCH No.	113864-022	
		CALIB. DATE	09/10/07 @ 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		Pass	
Radionuclidic content	90-110% of stated value		* 74.6 ± 0.1 **137.5 ± 0.9	
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		97.3 ± 0.2	96.9 ± 0.1
	≤ 4 % of activity as iodide		2.3 ± 0.1	2.6 ± 0.1
	≤ 1% of activity in other peaks		0.4 ± 0.1	0.6 ± 0.1
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.

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[^{131}I] CAPSULES (THERAPY)

Current edition of BP

	SPECIFICATIONS	SUPPLIER LOT/BATCH No. CALIB. DATE EXPIRY DATE	ARI 114206-062 26/11/07 10/12/07
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		98.5 ± 4.0*
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. EXP.	99.5 ± 0.2 99.6 ± 0.04
Disintegration	The shell and its contents dissolve completely within 15 min.		Pass
Vial/Package Label	Complies		Complies

* 5 capsules measured.

Note: The BP does not require a Uniformity of Content test for Sodium Iodide [^{131}I] Capsules (Therapy). The measurement of radioactivity content of 5 capsules of this batch showed that the radioactivity of no capsule differed by more than 5.7% from the average value, with a relative standard deviation of 4.07%.

THALLOUS [^{201}Tl] CHLORIDE INJECTION

Current edition of BP

		SUPPLIER	MALL		ARI		BMS (US)	
		LOT/BATCH No.	61251/000		111933/002		T055711S	
		CALIB. DATE	01/03/07		01/03/07		02/03/07	
	SPECIFICATIONS	EXPIRY DATE	08/03//07		06/03/07		06/03/07	
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 Tl-201 solution		Pass		Pass		Pass	
Radionuclidic content	90-110% of stated value		99* 106** 96***		103* 110** 100***		101* 108** 98***	
Radionuclidic purity	At all times up to expiry		At calibration	At expiry	At calibration	At expiry	At calibration	At expiry
	^{201}Tl ≥ 97 %		99.6	99.0	99.3	99.6	99.7	99.5
	^{202}Tl ≤ 2.0 %		0.3	1.0	0.1	0.3	0.3	0.5
	^{200}Tl %		0.1	0.004	0.5	0.1	0.03	0.01
	^{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		5.0		5.0		5.0	
Radiochemical purity	≥ 95% of the activity is present as Thallous ion	INT.	99.3 ± 0.2		99.9 ± 0.1		99.9 ± 0.04	
		EXP.	99.0 ± 0.1		99.9 ± 0.04		99.9 ± 0.04	
Thallium	≤ 10 µg/mL		< 2 µg/mL		< 2 µg/mL		< 2 µg/mL	
Benzyl Alcohol	90 – 100 % of stated value		Not stated		103		94	
Vial/Package Label	Complies		Fails		Complies		Complies	

Note: * Results obtained using Capintec manufacturer's calibration. ** Result obtained by measurement in Capintec calibrated for ^{201}Tl by the use of an NIST certified ^{201}Tl standard solution ***Result obtained by measurement in Capintec calibrated for ^{201}Tl by the use of an ANSTO/ARI verified ^{201}Tl standard solution.

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

Current edition of USP/BP

		SUPPLIER	CIS-US	
		LOT/BATCH No.	160017A	
	SPECIFICATIONS	EXPIRY DATE	31/07/08	
			INT.	EXP.
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture		Pass	TBD
Appearance after reconstitution	A white suspension which may separate on standing		Pass	TBD
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded.		N.A.	TBD
pH	3.8 -7.5 after reconstitution		5.5	TBD
Radiochemical purity	1) ≥ 90.0 % in aggregated albumin (by chromatography)		98.5 ± 0.3	TBD
	2) ≤ 10 % as soluble and dispersed radiochemical impurities (by centrifugation)		3.7 ± 0.15	TBD
Particle size	≥ 90% of the observed aggregated particles (not less than 100) have a diameter between 10 μm and 90 μm		Pass	TBD
	No particle having a maximum diameter > 150 μm is present		Pass	TBD
Non filterable radioactivity*	The radioactivity remaining on the membrane is ≥ 90%		98	TBD
Biological distribution	≥ 80% in the lungs		†	
	≤ 5% in the liver + spleen		†	
Vial/Package Label	Complies		Complies	

* Current edition of BP.

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

Current edition of USP

	SPECIFICATIONS	SUPPLIER LOT/BATCH No. EXPIRY DATE	BMS (US) 0162 01/05/07		BMS (US) 0167A 01/03/08	
			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		N.A.	N.A.	N.A.	TBD
pH	6.3 - 7.6* after reconstitution		7.0	6.9	7.1	TBD
Radiochemical purity	≥ 90.0 % as ^{99m}Tc-Bicisate (chromatography system A)		98.6 ± 0.03	98.3 ± 0.1	98.3 ± 0.03	TBD
	≤ 10.0 % as impurities (colloidal, $^{99m}TcO_4^-$ & ^{99m}Tc-EDTA) (chromatography system B)		1.4 ± 0.03	1.7 ± 0.1	1.7 ± 0.03	TBD
Tin content	12 - 72 µg $SnCl_2.2H_2O$ *		N.A.		N.A.	
Vial/Package Label	Complies		Complies		Complies	

* Manufacturer's approved 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.	2347/2348		2472	
	SPECIFICATIONS	EXPIRY DATE	30/06/07		31/05/08	
			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 or slightly yellow solution, free of any visible particulate matter		Pass	Pass	Pass	TBD
Check for vacuum	If a vacuum is not observed when the vial is pierced, the vial should be discarded.		Pass	Pass	Pass	TBD
pH	4.0 - 7.0 after reconstitution		5.0	5.0	4.7	TBD
Radiochemical purity	≥ 95.0 % as ^{99m}Tc-colloid		*	*	*	TBD
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. Manufacturer uses different solvent system (which does not separate impurities from ^{99m}Tc-colloid) from that recommended in the current edition of BP (Technetium [^{99m}Tc] Colloidal Tin Injection).
**Value given in label/product information.

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

Current edition of USP

		SUPPLIER	RADPH	
		LOT/BATCH No.	230011A	
	SPECIFICATIONS	EXPIRY DATE	31/08/08	
			INT.	EXP.
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture		Pass	TBD
Appearance after reconstitution	A clear, colourless or slightly yellow solution, free of any visible particulate matter		Pass	TBD
Check for vacuum	If a vacuum is not observed when the vial is pierced, the vial should be discarded		N.A.	TBD
pH	4.0 - 7.0 after reconstitution		4.5	TBD
Radiochemical purity	1) ≥ 90.0 % as ^{99m}Tc-disofenin		96.7	TBD
	2) hydrolysed + tin colloid (chromatography system A)		0.1 ± 0.01	TBD
	3) free pertechnetate (chromatography system B)		3.2 ± 0.17	TBD
	2) +3) ≤10%		3.3	TBD
Tin content	0.24 - 0.6 mg $SnCl_2$*			TBD
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	

* Value given in label/product information.

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

Current edition of USP

		SUPPLIER	AMER		AMER	
		LOT/BATCH No.	1178		1206	
	SPECIFICATIONS	EXPIRY DATE	05/01/07		27/10/07	
			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 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.	N.A.	N.A.
pH	9.0 – 9.8 after reconstitution		9.15	9.02	9.35	9.10
Radiochemical purity	≥ 80.0 % as ^{99m}Tc-Exametazime		92.7	92.4	94.1	95.4
	% as free pertechnetate		1.1 ± 0.04	1.0 ± 0.03	1.4 ± 0.1	1.2 ± 0.1
	% as hydrolysed reduced ^{99m}Tc		4.5 ± 0.43	3.5 ± 0.2	2.0 ± 0.1	2.0 ± 0.1
	% as ^{99m}Tc secondary exametazime complex		1.8 ± 0.43	3.1 ± 0.2	2.5 ± 0.1	1.5 ± 0.1
Tin content	7.6 µg $SnCl_2.2H_2O$/vial*		N.A.		N.A.	
Biological distribution	≥ 1.5 % in the brain		†		†	
	≤ 20 % in the intestines		†		†	
	≤ 15 % in the liver		†		†	
Vial/Package Label	Complies		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		ARI		RADPH		ARI	
		LOT/BATCH No.	2328		2353		2406		2491	
	SPECIFICATIONS	EXPIRY DATE	30/06/07		30/06/07		30/11/07		31/08/08	
			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	TBD
Appearance after reconstitution	A clear, colourless solution		Pass	Pass	Pass	Pass	Pass	Pass	Pass	TBD
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded.		Pass	Pass	N.A.	N.A.	N.A.	Pass	Pass	TBD
pH	3.5 – 7.5 after reconstitution		5.5	5.3	5.0	5.3	5.0	4.5	5.0	TBD
Radiochemical purity	1) ≥ 95.0 % as ^{99m}Tc-MDP		99.8	99.7	99.8	99.7	99.8	99.6	99.6	TBD
	2) ≤ 2.0 % as $^{99m}TcO_4^-$		0.05 ± 0.03	0.1 ± 0.1	0.1 ± 0.02	0.1 ± 0.03	0.03 ± 0.004	0.08 ± 0.02	0.07 ± 0.02	TBD
	3) as colloidal ^{99m}Tc		0.11 ± 0.03	0.2 ± 0.01	0.1 ± 0.02	0.2 ± 0.04	0.13 ± 0.09	0.3 ± 0.07	0.35 ± 0.11	TBD
	2) + 3) ≤ 5.0 %		0.2	0.3	0.2	0.3	0.2	0.4	0.4	
Tin content	≤ 3 mg/mL		Pass		Pass		Pass			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		Complies		Complies	

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

Current edition of BP

		SUPPLIER	TYCO/MALL		TYCO/MALL	
		LOT/BATCH No.	0966001		0966015	
	SPECIFICATIONS	EXPIRY DATE	20/01/07		14/12/07	
			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		5.7	6.0	5.5	5.5
Radiochemical purity	≥ 94.0 % as ^{99m}Tc-MAG3*		99.8 ± 0.1	99.8 ± 0.1	99.9 ± 0.1	99.0 ± 0.28
	% as hydrophilic impurities*		0.12 ± 0.01	0.06 ± 0.01	N.D.	0.51 ± 0.02
	% as non-elutable impurities*		0.05 ± 0.02	0.09 ± 0.08	0.08 ± 0.07	0.47 ± 0.26
	≤ 2% as reduced-hydrolysed technetium (by chromatography)		0.02 ± 0.02	0.04 ± 0.00	0.03 ± 0.007	0.06 ± 0.002
Tin content	≥ 50 µg $SnCl_2.2H_2O$/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	TYCO/MALL	
		LOT/BATCH No.	0917008	
	SPECIFICATIONS	EXPIRY DATE	04/11/07	
			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	Vacuum present. If no vacuum is found, the vial should be discarded		N.A.	N.A.
pH	2.5 – 7.0 after reconstitution		4.5	4.5
Radiochemical purity*	1) ≥ 90.0 % as ^{99m}Tc-oxidronate		99.3	99.5
	2) % as free pertechnetate		0.1 ± 0.03	0.07 ± 0.02
	3) % as colloidal ^{99m}Tc		0.6 ± 0.1	0.46 ± 0.01
Tin content	0.342 mg $SnCl_2.2H_2O$****		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 as minimum content.

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

Current edition of BP

		SUPPLIER	AR I		RADPH	
		LOT/BATCH No.	2397		2405	
	SPECIFICATIONS	EXPIRY DATE	September 2007		October 2007	
			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	Vacuum present. If no vacuum is found, the vial should be discarded.		Pass	Pass	N.A.	N.A.
pH	4.0 - 7.5 after reconstitution		5.5	5.5	5.5	5.0
Radiochemical purity	1) ≥ 95.0 % as ^{99m}Tc-DTPA		99.9	99.4	99.7	99.4
	2) Colloidal ^{99m}Tc impurity (chromatography system A)		0.07 ± 0.01	0.29 ± 0.06	0.15 ± 0.003	0.12 ± 0.03
	3) Free pertechnetate ^{99m}Tc (chromatography system B)		0.05 ± 0.01	0.33 ± 0.003	0.17 ± 0.02	0.44 ± 0.01
	2) + 3) ≤ 5.0%		0.1	0.6	0.3	0.6
Tin content	≤ 1 mg/mL		Pass		Pass	
Vial/Package Label	Complies		Complies		Complies	

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

Current edition of USP

		SUPPLIER	BMS (US)		BMS (US)	
		LOT/BATCH No.	3869		3914	
	SPECIFICATIONS	EXPIRY DATE	01/04/07		01/06/08	
			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		N.A.	N.A.	N.A.	TBD
pH	5.0 - 6.0 after reconstitution		5.14	5.19	5.20	TBD
Radiochemical purity	≥ 90.0 % as ^{99m}Tc-Sestamibi		97.0 ± 2.4	98.6 ± 0.2	98.4 ± 0.04	TBD
	≤ 10.0 % ^{99m}Tc impurities		3.0 ± 2.4	1.4 ± 0.2	1.6 ± 0.04	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.	2407	
	SPECIFICATIONS	EXPIRY DATE	August 2007	
			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		Yes	Yes
pH	2.3 - 3.5 after reconstitution		2.81	2.83
Radiochemical purity	≥ 95.0 % as ^{99m}Tc-DMSA		97.6 ± 1.13	97.7 ± 0.7
	≤ 2.0 % as $^{99m}TcO_4^-$		0.1 ± 0.04	0.08 ± 0.03
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	1464	
	SPECIFICATIONS	EXPIRY DATE	19/09/07	
			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) ≥ 90.0 % as ^{99m}Tc-Tetrofosmin		97.6 ± 0.07	98.0 ± 0.4
	2) Reduced hydrolysed & hydrophilic impurities		2.3 ± 0.06	1.8 ± 0.4
	3) Unbound pertechnetate		0.1 ± 0.03	0.14 ± 0.1
	2) + 3) ≤ 10%		2.4	2.0
Tin content	0.03 mg/vial $SnCl_2.2H_2O$*		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	RADPH	
		LOT/BATCH No.	2315	
	SPECIFICATIONS	EXPIRY DATE	March 2007	
			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	Vacuum present. If no vacuum is found, 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		99.8	99.7
	2) as free pertechnetate (chromatography system A)		0.1 ± 0.03	0.1 ± 0.04
	3) as colloidal [^{99m}Tc] (chromatography system B)		0.1 ± 0.02	0.2 ± 0.12
	2) + 3) ≤ 10 %		0.2	0.3
Sodium pyrophosphate	1-50 mg/mL sodium pyrophosphate on reconstitution		Pass	
Tin content	≤ 3 mg/mL		Pass	
Vial/Package Label	Complies		Complies	

* Value given in BP.
** Manufacturer specification.
*** Value given in USP.