



Australian Government

**Australian Radiation Protection
and Nuclear Safety Agency**

TECHNICAL REPORT

**Results of the Quality
Assurance Testing Program
for Radiopharmaceuticals
(2006)**

Z Ivanov

TECHNICAL REPORT SERIES No. 146



Australian Government

**Australian Radiation Protection
and Nuclear Safety Agency**

Results of the Quality Assurance Testing Program for Radiopharmaceuticals 2006



This document is issued in
accordance with NATA's
accreditation requirements.

Accredited for compliance
with ISO/IEC 17025
Version: 3
Issue Date: May 2007

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ABSTRACT

This report tabulates results obtained during 2006 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 up to the expiry time, except for Thallous [^{201}Tl] Chloride Injection and Sodium Pertechnetate [$^{99\text{m}}\text{Tc}$] 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 [$^{99\text{m}}\text{Tc}$] 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 2006 are summarised in the following tables. Overall, 40 batches of 22 different types of radiopharmaceuticals were tested.

Non-compliance of the vial/package label was observed in one batch. Vial/package label non-compliance consisted of absence of a statement as to the presence or absence of a microbiological preservative. The measurement of the radionuclidic content of Thallous [^{201}Tl] Chloride Injection presents an additional uncertainty due to the contribution of the ^{200}Tl and ^{202}Tl impurities present in the sample. The ARPANSA Capintec dose calibrator has been calibrated for ^{201}Tl by the use of ARI/ANSTO certified ^{201}Tl standard solutions for which the content of ^{200}Tl and ^{202}Tl impurity was not stated, and for which the correction for the presence of these impurities has not been determined as pure samples of ^{200}Tl and ^{202}Tl are not available. Results quoted on p.16 are for measurements made using

the ARI/ANSTO calibration value and the equipment manufacturer's calibration setting.

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 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's manufacturer setting for ^{123}I) gave an apparent 74 and 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 138 and 139% 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.

In the case of one type of "cold kit" radiopharmaceutical, two kits from an Australian manufacturer met the manufacturer's specification for pH after reconstitution, but did not meet the BP specification. The manufacturer has since obtained approval to retain their specification. For the two batches of the same 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.

Kits from an US manufacturer met the USP (and the manufacturer's specification) for pH after reconstitution for the two kits tested, but did not meet the BP specification for one 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 and Z Ivanov.

ABBREVIATIONS

The following abbreviations are used in the tables –

GE	- 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 [⁵¹Cr] EDETATE INJECTION

Current edition of BP

		SUPPLIER	ARI	GE
		LOT/BATCH No.	108292-001	816
		CALIB. DATE	01/03/06	06/03/06
SPECIFICATIONS		EXPIRY DATE	01/04/06	01/05/06
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		106.1, 106.8*	101
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.	0.01 ± 0.002	0.01 ± 0.01
2) Chromate ion	as %		0.01 ± 0.002	0.03 ± 0.04
3) Cr-edetate	≥ 95% as ⁵¹ Cr-edetate		99.98 ± 0.005	99.96 ± 0.01
		EXP.	0.07 ± 0.03	0.2 ± 0.06
			0.08 ± 0.02	0.1 ± 0.03
			99.85 ± 0.05	99.7 ± 0.1
Chromium	≤ 1mg/mL		Pass	Pass
Benzyl Alcohol	90 – 110 % of stated value		N/A	95
Vial/Package Label	Complies		Complies	Complies

* Two vials from the same batch.

SODIUM CHROMATE [⁵¹Cr] SOLUTION

Current edition of BP

		SUPPLIER	GE
		LOT/BATCH No.	990
		CALIB. DATE	20/12/06
SPECIFICATIONS		EXPIRY DATE	14/02/07
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		106
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.	99.4 ± 0.2
	% as chromic ion		0.6 ± 0.2
		EXP.	99.0 ± 0.07
			1.0 ± 0.07
Total chromate	≤ 2.7 µg of chromate ion (CrO ₄ ²⁻) per MBq		0.4
Benzyl Alcohol	90 – 110 % of stated value		N/A
Vial/Package Label	Complies		Complies

CYANOCOBALAMIN [⁵⁷Co] CAPSULES

Current edition of BP

		SUPPLIER	GE
		LOT/BATCH No.	608
		CALIB. DATE	20/10/06
		EXPIRY DATE	15/12/06
SPECIFICATIONS			
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		104
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.	95.7 ± 0.4
		EXP.	95.6 ± 0.1
Uniformity of content	The radioactivity of no capsule differs by more than 10 % from the average		Pass
	The relative standard deviation is < 3.5 %		1.8
Vial/Package Label	Complies		Complies

GALLIUM [⁶⁷Ga] CITRATE INJECTION

Current edition of BP

		SUPPLIER	ARI	BMS (US)	TYCO/MALL
		LOT/BATCH No.	108593-002	G061611S	54357
		CALIB. DATE	10/03/06	10/03/06	10/03/06
SPECIFICATIONS		EXPIRY DATE	15/03/06	17/03/06	20/03/06
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 Ga-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	104	100	99	
Radionuclidic purity	≤ 0.2% ⁶⁶ Ga	N.D.	N.D.	N.D.	N.D.
pH	5.0 - 8.0	6.5	6.5	6.0	
Radiochemical purity	≥ 97% as Ga Citrate	INT. EXP.	99.62 ± 0.31 99.52 ± 0.11	99.55 ± 0.15 99.52 ± 0.06	99.46 ± 0.04 99.50 ± 0.20
Zinc limit test	≤ 5 µg/mL	†	†	†	†
Benzyl Alcohol	90 – 110 % of stated value	97	92	96	
Vial/Package Label	Complies	Complies	Complies	Fails	

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.	111096-040				
		CALIB. DATE	20/11/06				
SPECIFICATIONS		EXPIRY DATE	04/12/06				
Maximum surface radiation dose rate	< 2000 µSv/h		233				
Dose rate at 1 metre	< 100µSv/h		4.4				
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				
Radionuclidic purity	≤ 0.1% ⁹⁹ Mo	MIN	Elution	Expiry	MAX	Elution	Expiry
	≤ 5 x 10 ⁻³ % ¹³¹ I	2.4E-4	1.5E-4	5.4E-4	3.6E-4		
	≤ 5 x 10 ⁻³ % ¹⁰³ Ru	1.8E-6	3.4E-6	3.2E-6	8.4E-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		4.5		4.5		
Radiochemical purity	≥ 95% as pertechnetate ion (^{99m} TcO ₄) ⁻	INT.	99.74 ± 0.015		99.85 ± 0.011		
		EXP.	99.84 ± 0.017		99.90 ± 0.002		
Aluminium	≤ 5µg/mL		Pass		Pass		
Milking efficiency	None (for information only)		109.8 %		110.8 %		
Moly assay (⁹⁹ Mo breakthrough)	≤ 0.1 % ⁹⁹ Mo at expiry		0.0000		0.0004		
Vial/Package Label	Complies		Complies				

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

Current edition of BP

		SUPPLIER	BMS	
		LOT/BATCH No.	162205	
		CALIB. DATE	30/10/06 @ 09:00 h	
SPECIFICATIONS		EXPIRY TIME	30/10/06 @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		102 ± 1%	
Radionuclidic purity	≤ 0.1% ⁹⁹ Mo		INT.	EXP.
	≤ 5 x 10 ⁻³ % ¹³¹ I		8E-4	1.9E-3
	≤ 5 x 10 ⁻³ % ¹⁰³ Ru		7E-6	1.9 E-5
	≤ 6 x 10 ⁻⁵ % ⁸⁹ Sr		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.
pH	4.0 - 8.0		6.0	
Radiochemical purity	≥ 95% as pertechnetate ion (^{99m} TcO ₄ ⁻)		99.75 ± 0.013	99.92 ± 0.004
Aluminium	≤ 5 µg /mL		Pass	
Vial/Package Label	Complies		Complies	

INDIUM OXINE [¹¹¹In] SOLUTION

Current edition of BP

SPECIFICATIONS		SUPPLIER	GE
		LOT/BATCH No.	4608
		CALIB. DATE	11/10/06
		EXPIRY TIME	16/10/06
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		106
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	6.0 – 7.5		7.0
Radiochemical purity	≥ 90% of activity as ¹¹¹ In-Oxine	INT.	95.3 ± 1.0
		EXP.	96.4 ± 0.2
Vial/Package Label	Complies		Complies

IOBENGUANE [¹²³I] INJECTION (m-IBG)

Current edition of BP

SPECIFICATIONS		SUPPLIER	ARI	
		LOT/BATCH No.	111197-004	
		CALIB. DATE	28/11/06	
		EXPIRY DATE	29/11/06	
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-131 solution		Pass	
Radionuclidic content	90-110% of stated value		* 74, 75 **138, 139	
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		97.4 ± 0.3	97.3 ± 0.1
	≤ 4 % of activity as iodide		2.3 ± 0.1	2.6 ± 0.1
	≤ 1% of activity in other peaks		0.3 ± 0.3	0.1 ± 0.1
Vial/Package Label	Complies		Complies	

* Measurements performed in a glass vial, as supplied by the manufacturer in two different dose calibrators.

** 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 5 and 6 of this report.

THALLOUS [²⁰¹Tl] CHLORIDE INJECTION

Current edition of BP

		SUPPLIER	ARI	MALL		
		LOT/BATCH No.	109252-002	56602/000		
		CALIB. DATE	16/05/06	18/05/06		
SPECIFICATIONS		EXPIRY DATE	21/05/06	24/05/06		
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		
Radionuclidic content	90-110% of stated value		*110.4 **118	*93.6 **100		
Radionuclidic purity	At all times up to expiry		At calibration	At expiry	At calibration	At expiry
	²⁰¹ Tl ≥ 97 %		99.3	99.70	99.59	98.95
	²⁰² Tl ≤ 2.0 %		0.09	0.22	0.35	1.15
	²⁰⁰ Tl %		0.61	0.08	0.06	0.00
	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		5.5		5.5	
Radiochemical purity	≥ 95% of the activity is present as Thallous ion	INT.	99.5 ± 0.1		99.6 ± 0.02	
		EXP.	99.7 ± 0.1		99.54 ± 0.03	
Thallium	≤ 10 µg/mL		< 2 µg/mL		< 2 µg/mL	
Benzyl Alcohol	90 – 100 % of stated value		104		N/A	
Vial/Package Label	Complies		Complies		Fail	

Note:

ARI (#109252-002) Outside surface of lead pot contaminated with ¹³¹I (swab counted using Ge detector).

*Result obtained by measurement in Capintec calibrated for ²⁰¹Tl by the use of an ARI/ANSTO certified ²⁰¹Tl standard solution. No reference standards are available to determine the contribution of ²⁰⁰Tl and ²⁰²Tl impurities to the measurement reading at the ²⁰¹Tl setting.

** Results obtained using Capintec manufacturer's calibration.

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

Current edition of USP

		SUPPLIER	Cis-US
		LOT/BATCH No.	127275
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 white suspension which may separate on standing	Pass	Pass
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded.	N/A	N/A
pH	3.8 -7.5 after reconstitution	6.0	6.0
Radiochemical purity	1) ≥ 90.0 % in aggregated albumin (by chromatography)	97.8 ± 0.4	98.7 ± 0.3
	2) ≤ 10 % as soluble and dispersed radiochemical impurities (by centrifugation)	2.7 ± 0.07	1.9 ± 0.03
Particle size	$\geq 90\%$ of the observed aggregated particles (not less than 100) have a diameter between 10 μm and 90 μm	Pass	Pass
	No particle having a maximum diameter $> 150 \mu\text{m}$ is present	Pass	Pass
Non filterable radioactivity*	The radioactivity remaining on the membrane is $\geq 90\%$	98.0	97.0
Biological distribution	$\geq 80\%$ in the lungs		†
	$\leq 5\%$ 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

		SUPPLIER	BMS (US)	
		LOT/BATCH No.	0162	
SPECIFICATIONS		EXPIRY DATE	01/05/07	
			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		7.0	6.9
Radiochemical purity	≥ 90.0 % as ^{99m} Tc-Bicisate (chromatography system A)		98.6 ± 0.03	98.3 ± 0.1
	≤ 10.0 % as impurities (colloidal, ^{99m} TcO ₄ ⁻ & ^{99m} Tc-EDTA) (chromatography system B)		1.4 ± 0.03	1.7 ± 0.1
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.	2226	2347/2348		
SPECIFICATIONS	EXPIRY DATE	April 2006	30/06/07			
		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.	Yes	Yes	Yes	TBD	
pH	4.0 - 7.0 after reconstitution	4.5	4.5	5.0	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.	142623A	
SPECIFICATIONS		EXPIRY DATE	01/04/06	
		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	N/A	N/A	
pH	4.0 - 7.0 after reconstitution	4.5	4.5	
Radiochemical purity	1) $\geq 90.0\%$ as ^{99m} Tc-disofenin	98.6	94.9	
	2) hydrolysed + tin colloid (chromatography system A)	0.1 ± 0.07	0.35 ± 0.02	
	3) free pertechnetate (chromatography system B)	1.3 ± 0.15	4.76 ± 0.15	
	4) $\leq 10\%$ as impurities 2+3	1.4	5.1	
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	AMER	
		LOT/BATCH No.	1178	
SPECIFICATIONS		EXPIRY DATE	05/01/07	
			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	9.0 - 9.8 after reconstitution		9.15	9.02
Radiochemical purity	≥ 80.0 % as ^{99m} Tc-Exametazime		92.7	92.4
	% as free pertechnetate		1.1 ± 0.04	1.0 ± 0.03
	% as hydrolysed reduced ^{99m} Tc		4.5 ± 0.43	3.5 ± 0.2
	% as ^{99m} Tc secondary exametazime complex		1.8 ± 0.55	3.1 ± 0.2
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	AMER/GE Healthcare		ARI		RADPH	
		LOT/BATCH No.	584		2216		2227	
SPECIFICATIONS		EXPIRY DATE	09/01/06		April 2006		May 2006	
			@ 15 min after reconstitution	@ 8 h after reconstitution	INT.	EXP.	INT.	EXP.
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Appearance after reconstitution	A clear, colourless solution	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	Yes	Yes	Yes
pH	3.5 – 7.5 after reconstitution	5.9		5.0	4.5	5.5	5.5	
Radiochemical purity	1) ≥ 95.0 % as ^{99m} Tc-MDP	99.4	99.4	99.7	99.8	99.8	99.8	99.8
	2) ≤ 2.0 % as ^{99m} TcO ₄ ⁻	0.56 ± 0.27	0.55 ± 0.08	0.05 ± 0.01	0.10 ± 0.02	0.05±0.01	0.1 ± 0.05	
	3) as colloidal ^{99m} Tc	0.06 ± 0.02	0.05 ± 0.01	0.22 ± 0.04	0.06 ± 0.00	0.18±0.06	0.1 ± 0.02	
	4) ≤ 5.0 % as impurities 2+3	0.62	0.60	0.27	0.16	0.23	0.20	
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 [^{99m}Tc] MEDRONATE INJECTION (MDP)

Current edition of BP

		SUPPLIER	RADPH		ARI			
		LOT/BATCH No.	2320		2328			
SPECIFICATIONS		EXPIRY DATE	Proficiency Test sample		30/06/06			
			@ 15 min after reconstitution	@ 5 h after reconstitution	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	Yes	TBD	N/A	TBD	
pH	3.5 – 7.5 after reconstitution	5.0	5.5	5.5	TBD	5.0	TBD	
Radiochemical purity	1) ≥ 95.0 % as ^{99m} Tc-MDP	99.9	99.96	99.8	TBD	99.8	TBD	
	2) ≤ 2.0 % as ^{99m} TcO ₄ ⁻	0.02 ± 0.01	0.02 ± 0.01	0.05 ± 0.03	TBD	0.08 ± 0.02	TBD	
	3) as colloidal ^{99m} Tc	0.04 ± .01	0.02 ± 0.01	0.11 ± 0.03	TBD	0.12 ± 0.02	TBD	
	4) ≤ 5.0 % as impurities 2+3	0.06	0.04	0.16		0.20		
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	Not supplied	Complies	Complies		Complies		

KIT FOR THE PREPARATION OF TECHNETIUM [^{99m}Tc] MERTIATIDE INJECTION (MAG3)**Current edition of BP**

SPECIFICATIONS		SUPPLIER	MALL
		LOT/BATCH No.	0966001
		EXPIRY DATE	20/01/07
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture	INT. Pass	EXP. Pass
Appearance after reconstitution	A clear, colourless solution free of particulate matter. If not, the preparation should not be used	Pass	Pass
pH	5.0 - 7.5 after reconstitution	5.7	6.0
Radiochemical purity	≥ 94.0 % as ^{99m} Tc-MAG3*	99.8 ± 0.1	99.8 ± 0.1
	% as hydrophilic impurities*	0.12 ± 0.01	0.06 ± 0.01
	% as non-elutable impurities*	0.05 ± 0.02	0.09 ± 0.08
	≤ 2% as reduced-hydrolysed technetium (by chromatography)	0.02 ± 0.02	0.04 ± 0.00
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.	0916006	
SPECIFICATIONS		EXPIRY DATE	05/11/06	
			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		99.8	99.7
	2) % as free pertechnetate		0.10 ± 0.02	0.20 ± 0.08
	3) % as colloidal ^{99m} Tc		0.08 ± 0.05	0.15 ± 0.11
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	RADPH		ARI	
		LOT/BATCH No.	2276		2252	
SPECIFICATIONS		EXPIRY DATE	October 2006		October 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	Vacuum present. If no vacuum is found, the vial should be discarded.		Yes	Yes	N/A	N/A
pH	4.0 - 7.5 after reconstitution		5.5	5.5	4.5	5.0
Radiochemical purity	1) $\geq 95.0\%$ as ^{99m} Tc-DTPA		99.69	99.48	99.84	99.87
	2) Colloidal ^{99m} Tc impurity (chromatography system A)		0.11 ± 0.01	0.06 ± 0.02	0.07 ± 0.01	0.06 ± 0.01
	3) Free pertechnetate ^{99m} Tc (chromatography system B)		0.2 ± 0.02	0.46 ± 0.42	0.09 ± 0.01	0.07 ± 0.01
	4) $\leq 5.0\%$ as impurities 2+3		0.31	0.52	0.16	0.13
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

SPECIFICATIONS		SUPPLIER	BMS	BMS		
		LOT/BATCH No.	3843	3869		
		EXPIRY DATE	01/09/06	01/04/07		
			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
Check for vacuum	Vacuum present. If no vacuum is found, the vial should be discarded		N/A	N/A	N/A	N/A
pH	5.0 - 6.0 after reconstitution		5.25	5.09	5.14	5.19
Radiochemical purity	≥ 90.0 % as ^{99m} Tc-Sestamibi		98.3 ± 0.3	98.5 ± 0.1	97.0 ± 2.4	98.6 ± 0.2
	≤ 10.0 % ^{99m} Tc impurities		1.7 ± 0.3	1.5 ± 0.1	3.0 ± 2.4	1.4 ± 0.2
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. 2277		
SPECIFICATIONS		EXPIRY DATE	July 2006	
		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	3.26	3.18	
Radiochemical purity	≥ 95.0 % as ^{99m} Tc-DMSA	99.3 ± 0.1	99.5 ± 0.3	
	≤ 2.0 % as ^{99m} TcO ₄ ⁻	0.26 ± 0.06	0.21 ± 0.07	
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 (MYOVIEV)

Current edition of USP

		SUPPLIER	GE Healthcare		GE Healthcare	
		LOT/BATCH No.	1274	1366		
SPECIFICATIONS		EXPIRY DATE	01/03/06	22/11/06		
		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 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	8.3 - 9.1 after reconstitution	8.40	8.42	8.38	8.23	
Radiochemical purity	1) ≥ 90.0 % as ^{99m} Tc-Tetrofosmin	97.9 ± 0.1	97.2 ± 0.1	96.5 ± 0.1	97.3 ± 0.03	
	2) Reduced hydrolysed & hydrophilic impurities	1.9 ± 0.07	2.5 ± 0.1	3.1 ± 0.11	2.5 ± 0.1	
	3) Unbound pertechnetate	0.2 ± 0.04	0.3 ± 0.02	0.4 ± 0.04	0.2 ± 0.1	
	4) ≤ 10% as impurities 2+3	2.1	2.8	3.5	2.7	
Tin content	0.03 mg/vial SnCl ₂ .2H ₂ O*	N.A.		N.A.		
Vial/Package Label	Complies	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					
		LOT/BATCH No.	221419	2202	0946007	2315					
SPECIFICATIONS		EXPIRY DATE	08/01/06	March 2006	27/11/06	March 2007					
			@ 30min. after reconst.	@ 4 h after reconst.	INT.	EXP.	INT.	EXP. @ 10min. after recon:	@ 5 h after recon:	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	N/A	N/A	Yes	Yes	N/A	N/A	N/A	Yes	Yes	
pH	6.0 – 7.0 after reconstitution* 4.5 – 6.0 after reconstitution** 4.0 - 7.5 after reconstitution***	6.2		5.5	5.5		5.0	5.0		5.5	5.0
Radiochemical purity	1) ≥ 90.0 % as ^{99m} Tc-PYP	98.4	93.7	99.8	99.2	99.7	99.6	99.6	99.8	99.7	
	2) as free pertechnetate (chromatography system A)	0.99±0.21	4.9±1.87	0.12±0.04	0.4±0.06	0.27±0.04	0.1±0.04	0.2±0.06	0.1±0.03	0.1±0.04	
	3) as colloidal [^{99m} Tc] (chromatography system B)	0.57±0.01	1.4±0.11	0.13±0.01	0.4±0.10	0.05±0.04	0.3±0.1	0.2±0.08	0.1±0.02	0.2±0.12	
	≤ 10 % as impurities 2+3	1.6	6.3	0.25	0.8	0.3	0.4	0.4	0.2	0.3	
Sodium pyrophosphate	1-50 mg/mL sodium pyrophosphate on reconstitution	Pass		Pass		Pass		Pass		Pass	
Tin content	≤ 3 mg/mL	Pass		Pass		Pass		Pass		Pass	
Vial/Package Label	Complies	Complies		Complies		Complies		Complies		Complies	

* Value given in BP

** Manufacturer specification

*** Value given in USP