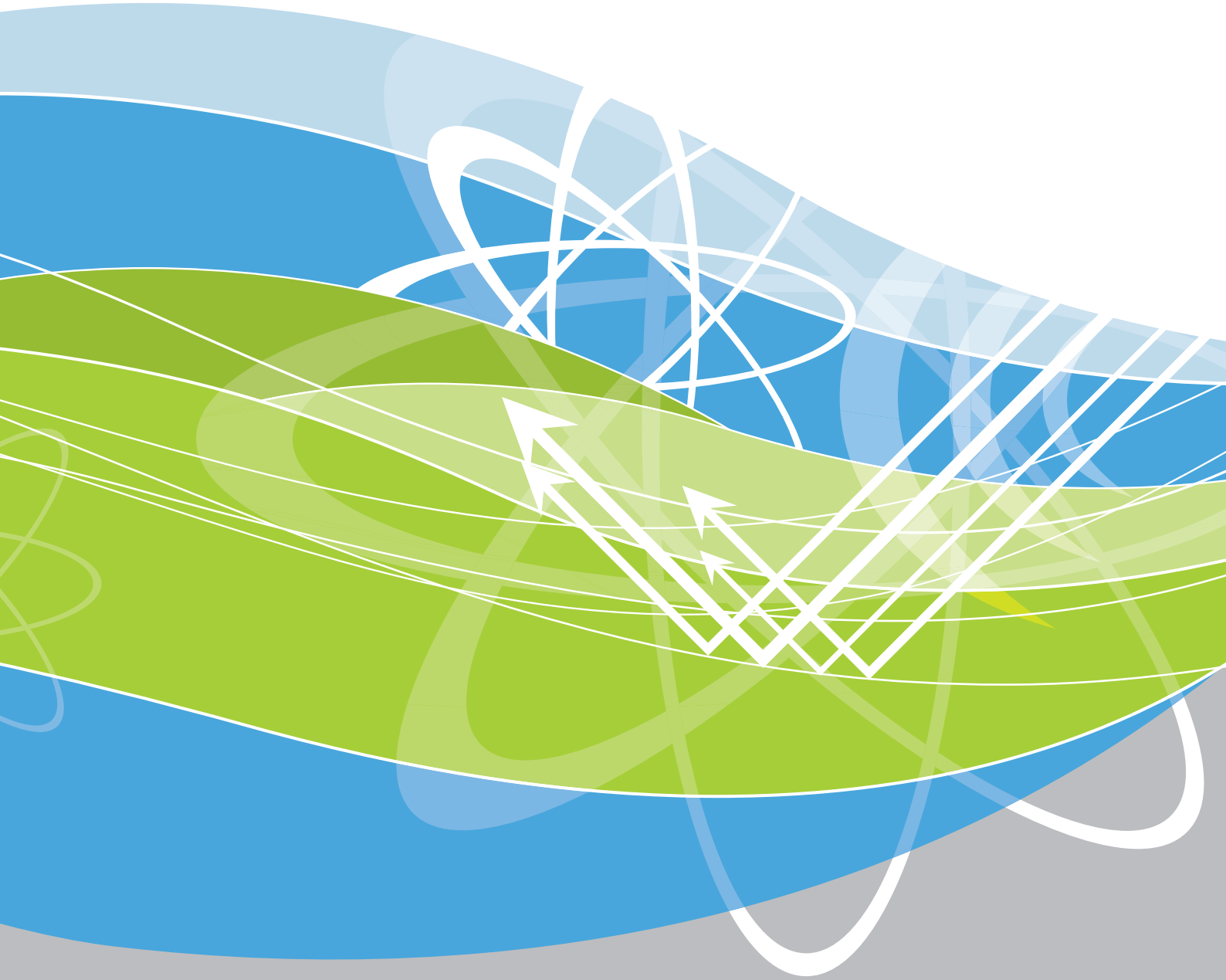
Australian Government
Australian Radiation Protection and Nuclear Safety Agency

Results of the Quality Assurance Testing Program for Radiopharmaceuticals (2011)

Z Ivanov



Technical Report Series No. 159

Australian Government

Australian Radiation Protection and Nuclear Safety Agency

Results of the Quality Assurance Testing Program for Radiopharmaceuticals 2011

Accredited for compliance with ISO/IEC 17025

Accreditation Number: 14442

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Technical Report 159
ISSN 0157-1400
July 2012

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Notice

Australian Radiation Protection and Nuclear Safety Agency 2012

ISSN: 0157-1400

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ABSTRACT

This report tabulates results obtained during 2011 for the Radiopharmaceutical Quality Assurance Test Program conducted by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

CONTENTS

INTRODUCTION

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) conducts a Radiopharmaceutical Quality Assurance (QA) 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 [^{99m}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 [^{99m}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 2011 are summarised in the following tables. Overall, 31 batches of 23 different types of radiopharmaceuticals were tested.

In the case of Iobenguane [^{123}I] Injection, the radionuclidic content could not be determined accurately. A certified reference standard for Iodine-123 is still not available and therefore the correction for the effect of the absorption of the abundant low energy X-ray emission by the container and the sample is unknown. Thus, measurement in the original sample glass vial (and using the dose calibrator manufacturer's setting for ^{123}I) gave an apparent 78 % of the stated radioactivity at the calibration date and time.

For Sodium Iodide [^{131}I] Capsules (Therapy) the BP does not require a "Uniformity of Content" test. The measurement of radioactivity content of 4 capsules of this batch showed that the radioactivity of no capsule differed by more than 7.4 % from the average value, with a relative standard deviation of 7.0 %.

The BP and USP do 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.

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), (c), 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.

In the case of one type of "cold kit" radiopharmaceutical, the kit from an overseas manufacturer, two batches met the value given in USP (pH = 4.0 – 7.5), which is outside the BP specification (pH = 6.0 – 7.0), but has been approved by the TGA.

Non-compliance of the vial/package label was observed in two batches of ready to use radiopharmaceuticals and one batch of a "cold kit" from an overseas manufacturer. Vial/label non-compliance consisted of the absence of the volume and only the names of the components were listed but not the quantities of each component.

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
ANSTO Health	-	ANSTO Australian Nuclear Science and Technology Organisation, Sydney, Australia
Austin Health	-	Heidelberg, VIC. Australia
CIS BIO	-	CIS Bio International, Gif Sur Yvette, France
Cyclotek	-	Bundoora, VIC. Australia
GE Healthcare	-	GE Healthcare Limited, UK
Lantheus (AUST)	-	Lantheus Medical Imaging, Tullamarine, VIC, Australia
Lantheus (USA)	-	Lantheus Medical Imaging, North Billerica, MA, USA
Mall/Covidien	-	Mallinckrodt Medical B.V., Petten, Netherlands, Covidien Pty. Ltd. Lane Cove, NSW, Australia
PHARMA	-	Pharmalucence Inc, Bedford, MA, USA
RADPH	-	Radpharm Scientific, Belconnen, ACT, Australia
RADPH/EDM	-	Edmonton Radiopharmaceutical Centre, Edmonton, Alberta
RADPH/Drax	-	Draxis Specialty Pharmaceuticals Inc., Quebec, Canada
TYCO/MALL	-	TYCO Healthcare, Lane Cove, NSW, Australia; Mallinckrodt Medical B.V., Petten, Netherlands
CALIB. DATE	-	Calibration Date
EXP.	-	Expiry testing
INT.	-	Initial testing
MAX	-	Maximum
MIN	-	Minimum
N.A.	-	Not applicable or not required by BP/USP
N.D.	-	Not detected
No.	-	Number
p	-	Page
reconst.	-	reconstituted
TBD	-	To be done
†	-	Not determined

FLUDEOXYGLUCOSE [^{18}F] INJECTION

Current edition of BP

		SUPPLIER	Austin Health	Cyclotek
		LOT/BATCH No.	FDG-111214-1	5328
		CALIB. DATE	14/12/11 @ 9:00h	14/12/11 @ 6:00h
	SPECIFICATIONS	EXPIRY DATE	14/12/11 @ 17:00h	14/12/11 @ 18:00h
Appearance	A clear, colourless or slightly yellow yellow solution		Pass	Pass
Particulate matter	None visible		Pass	Pass
Identification	The principal peak in the radiochromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with the reference solution.		Pass	Pass
	511 keV peak detected		Pass	Pass
Radionuclidic content	90-110% of stated value		105	99
Radionuclidic purity	The only gamma photons detected have an energy of 511 keV, a sum peak of 1022 keV may be observed		Pass	Pass
	The total radioactivity due to radionuclidic impurities is not more than 0.1 %		Pass	Pass
pH	4.5 – 8.5		6.5	6.3
Radiochemical purity (HPLC Method)	$\geq$ 95% of the total radioactivity is present as 2-[^{18}F] fluoro-2 deoxy-D-glucose and 2-[^{18}F] fluoro-2 deoxy-D-mannose	INT EXP	96.5 ± 0.1 96.5 ± 0.1	96.6 ± 0.04 96.4 ± 0.07
	2-[^{18}F] fluoro-2 deoxy-mannose: ≤ 10% of the total radioactivity of 2-[^{18}F] fluoro-2 deoxy-glucose and 2-[^{18}F] fluoro-2 deoxy-mannose	INT EXP	3.5 ± 0.1 4.0 ± 0.2	3.4 ± 0.04 3.7 ± 0.07
Vial/Package Label	Supplied		Yes	Yes

CHROMIUM [^{51}Cr] EDETATE INJECTION

Current edition of BP

		SUPPLIER	ARI	GE Healthcare
		LOT/BATCH No.	126352	1100
		CALIB. DATE	01/08/11	15/08/11
	SPECIFICATIONS	EXPIRY DATE	01/09/11	10/10/11
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	Vial 1	109.9 ± 0.04	103.3
		Vial 2	109.9 ± 0.05	103.7
Radionuclidic purity	Minimum 99.9 % of the total radioactivity as Chromium-51. The only gamma photons have an energy of 0.320 MeV		Pass	Pass
pH	3.5 – 6.5		5.5	4.0
Radiochemical purity				
1) Chromic ion	as %	INT. 1)	0.1 ± 0.03	0.2 ± 0.1
2) Chromate ion	as %	2)	0.9 ± 0.01	0.8 ± 0.2
3) Cr-edetate	≥ 95% as ^{51}Cr-edetate	3)	99.0 ± 0.03	99.0 ± 0.2
		EXP. 1)	0.2 ± 0.04	0.5 ± 0.1
		2)	0.4 ± 0.04	1.5 ± 0.3
		3)	99.4 ± 0.08	98.0 ± 0.3
Chromium (Cr)	≤ 1mg/mL		0.4	0.2
Benzyl Alcohol	90 – 110 % of stated value		N.A	101
Vial/Package Label	Complies		Complies	Complies

SODIUM CHROMATE [^{51}Cr] SOLUTION

Current edition of BP

		SUPPLIER	GE Healthcare
		LOT/BATCH No.	1234
		CALIB. DATE	10/08/11
	SPECIFICATIONS	EXPIRY DATE	05/10/11
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		105
Radionuclidic purity	Gamma spectrum does not differ significantly from that of a standardised chromium-51 solution		Pass
pH	6.0 - 8.5		6.5
Radiochemical purity	≥ 90% as sodium chromate	INT.	99.2 ± 0.03
	% as chromic ion		0.8 ± 0.03
		EXP.	99.1 ± 0.02
			0.9 ± 0.02
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

GALLIUM [^{67}Ga] CITRATE INJECTION

Current edition of BP

		SUPPLIER	ANSTO Health	Lantheus (USA)	Mall/Covidien
		LOT/BATCH No.	126509-002	G216111S	87346
		CALIB. DATE	09/08/11	12/08/11	12/08/11
	SPECIFICATIONS	EXPIRY DATE	14/08/11	19/08/11	22/08/11
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 gallium-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	99	100
Radionuclidic purity	≤ 0.2% ^{66}Ga		N.D.	N.D.	N.D.
pH	5.0 - 8.0		7.1	6.0	7.3
Radiochemical purity	≥ 97% as Ga Citrate	INT.	99.5 ± 0.2	99.1 ± 0.2	98.9 ± 0.2
		EXP.	99.6 ± 0.1	99.2 ± 0.02	99.2 ± 0.02
Zinc limit test	≤ 5 µg/mL		< 5	< 5	< 5
Benzyl Alcohol	90 – 110 % of stated value		103	96	†
Vial/Package Label	Complies		Complies	Complies	Fail

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

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

		SUPPLIER	ARI			
		LOT/BATCH No.	125693 - 027			
		CALIB. DATE	02/05/11 @ 09:00 h			
	SPECIFICATIONS	EXPIRY DATE	16/05/11@ 09:00 h			
Maximum surface radiation dose rate	< 2000 µSv/h		112 µSv/h			
Dose rate at 1 metre	< 100 µSv/h		3.5 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 technetium-99m solution		Pass			
			MIN		MAX	
			Elution	Expiry	Elution	Expiry
Radionuclidic purity	≤ 0. 1% ^{99}Mo		N.D.	N.D.	1E-4	3E-4
	≤ 5×10^{-3} % ^{131}I		N.D.	N.D.	N.D.	N.D.
	≤ 5×10^{-3} % ^{103}Ru		N.D.	N.D.	N.D.	N.D.
	≤ 6×10^{-5} % ^{89}Sr		†	†	†	†
	≤ 6×10^{-6} % ^{90}Sr		†	†	†	†
	≤ 1×10^{-7} % alpha-emitting impurities		†	†	†	†
	≤ 1×10^{-2} % all other gamma-emitting impurities		N.D.	N.D.	N.D.	N.D.
pH	4.0 - 8.0		5.0		5.0	
Radiochemical purity	≥ 95% as pertechnetate ion $(^{99m}TcO_4)^-$	INT.	99.8 ± 0.02		99.9 ± 0.01	
		EXP.	99.9 ± 0.01		99.9 ± 0.04	
Aluminium	≤ 5µg/mL		0.1 µg/mL		0.1 µg/mL	
Milking efficiency	None (for information only)		90.0 %		91.5 %	
Moly assay (^{99}Mo breakthrough)	≤ 0.1 % ^{99}Mo at expiry		N.D.		3 E-4	
Vial/Package Label	Supplied		Supplied			

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

Current edition of BP

		SUPPLIER	Lantheus (AUS)	
		LOT/BATCH No.	422757	
		CALIB. DATE	24/11/11 @ 09:00 h	
	SPECIFICATIONS	EXPIRY DATE	24/11/11 @ 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		100	
			INT.	EXP.
Radionuclidic purity	≤ 0. 1% ^{99}Mo		3E-4	7E-4
	≤ 5 x 10^{-3} % ^{131}I		2E-5	5E-5
	≤ 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		4.5	
Radiochemical purity	≥ 95% as pertechnetate ion ($^{99m}TcO_4^-$)		99.9 ± 0.01	99.9 ± 0.02
Aluminium (Al)	≤ 5 µg /mL		†*	
Vial/Package Label	Complies		N.A.	

*Insufficient sample size.

INDIUM OXINE [^{111}In] SOLUTION

Current edition of BP

		SUPPLIER	GE Healthcare
		LOT/BATCH No.	6178
		CALIB. DATE	12/10/11
	SPECIFICATIONS	EXPIRY DATE	17/10/11
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		N.D.
pH	6.0 – 7.5		7.0
Radiochemical purity	≥ 90% of activity as ^{111}In-Oxine	INT.	94.8 ± 1.2
		EXP.	93.7 ± 0.5
Vial/Package Label	Complies		Complies

IOBENGUANE [^{123}I] INJECTION

Current edition of BP

		SUPPLIER	ANSTO Health	
		LOT/BATCH No.	127093-012	
		CALIB. DATE	18/10/11 @ 09:00 h	
	SPECIFICATIONS	EXPIRY TIME	19/10/11 @ 01:00 h	
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, tellutium-121 and other radionuclidic impurities		Pass	
Radionuclidic content	90-110% of stated value		78*	
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		98.6 ± 0.02	98.84 ± 0.1
	≤ 4 % of activity as iodide		0.9 ± 0.1	0.83 ± 0.04
	≤ 1% of activity in other peaks		0.5 ± 0.1	0.33 ± 0.02
Vial/Package Label	Complies		Complies	

* Measurements performed in the glass vial supplied by the manufacturer.

Note: No reference standard is available and no adjustment was made to the Capintec setting. For details refer to p 5 of this report.

SODIUM IODIDE [^{131}I] CAPSULES (THERAPY)

Current edition of BP

		SUPPLIER	ANSTO Health
		LOT/BATCH No.	127070-026
		CALIB. DATE	24/10/11
	SPECIFICATIONS	EXPIRY DATE	07/11/11
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		101 ± 7*
Radionuclidic purity	≥ 99.9% as ^{131}I,		Pass
	≤ 0.1% of the total radioactivity is due to ^{130}I, ^{133}I, ^{135}I and other radionuclidic impurities		Pass
Radiochemical purity	≥ 95% of activity as iodide	INIT.	100
		EXP.	100
Disintegration	The shell and its contents dissolve completely within 15 min.		Pass
Vial/Package Label	Complies		Complies

* 4 capsules measured.

Note: The BP does not require a Uniformity of Content test for Sodium Iodide [131I] Capsules (Therapy). For details refer to p 6 of this report.

THALLOUS [^{201}Tl] CHLORIDE INJECTION

Current edition of BP

			SUPPLIER	ARI		Mall/Covidien	
			LOT/BATCH No.	125477-002		85731	
			CALIB. DATE	31/03/11		31/03/11	
	SPECIFICATIONS		EXPIRY DATE	05/04/11		07/04/11	
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 thallium-201 solution			Pass		Pass	
Radionuclidic content	90-110% of stated value			105 ± 0.06*		102 ± 0.01*	
Radionuclidic purity	At all times up to expiry			At calibration	At expiry	At calibration	At expiry
	^{201}Tl	≥ 97 %		99.6	99.1	99.6	98.9
	^{202}Tl	≤ 2.0 %		0.37	0.87	0.3	1.05
	^{200}Tl	%		0.04	0.005	0.08	0.004
	^{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			4.5		5.0	
Radiochemical purity	≥ 95% of the activity is present as Thallous ion		INT.	98.6 ± 0.3		99.5 ± 0.04	
			EXP.	99.1 ± 0.2		99.2 ± 0.03	
Thallium	≤ 10 µg/mL			< 2.5 µg/mL		< 1 µg/mL	
Benzyl Alcohol	90 – 120 % of stated value**			118		N.A.	
Vial/Package Label	Complies			Complies		Fail	

* Measurements performed in two different dose calibrators (Capintec ARC-120 and ARC-15R).

** Manufacturer's approved specification.

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

Current edition of USP/BP

	SPECIFICATIONS	SUPPLIER LOT/BATCH No. EXPIRY DATE	PHARMA 160038A 28/02/11		RADPH/EDM 9D399 Sept 2011	
			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 3.8 - 8.0**after reconstitution		6.0		5.0	
Radiochemical purity	1) ≥ 90.0 % in aggregated albumin (by chromatography)		99.9 ± 0.01	98.6 ± 0.1	99.2 ± 0.1	99.2 ± 0.1
	2) ≤ 10 % as soluble and dispersed radiochemical impurities (by centrifugation)		2.3 ± 0.05	6.5 ± 0.1	1.6 ± 0.04	0.8 ± 0.04
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%		97.8 ± 0.5	97.3 ± 0.4	98.5 ± 0.02	99.0 ± 0.2
Tin content*	≤ 3 mg/mL of Sn		< 3		< 3	
Biological distribution	≥ 80% in the lungs		†		†	
	≤ 5% in the liver + spleen		†		†	
Vial/Package Label	Complies		Complies		Complies	

* Current edition of BP.

** Current edition of USP

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

Current edition of USP/BP

	SPECIFICATIONS	SUPPLIER LOT/BATCH No. EXPIRY DATE	RADPH/Drax QC261 Sept.2012	
			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 3.8 - 8.0**after reconstitution		5.5	TBD
Radiochemical purity	1) ≥ 90.0 % in aggregated albumin (by chromatography)		99.3 ± 0.03	TBD
	2) ≤ 10 % as soluble and dispersed radiochemical impurities (by centrifugation)		1.0 ± 0.1	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%		99.2 ± 0.05	
Tin content*	≤ 3 mg/mL of Sn		TBD	
Biological distribution	≥ 80% in the lungs		†	
	≤ 5% in the liver + spleen		†	
Vial/Package Label	Complies		Complies	

* Current edition of BP.
** Current edition of USP

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

Current edition of BP/USP

		SUPPLIER	Lantheus (USA)	
		LOT/BATCH No.	0200A	
	SPECIFICATIONS	EXPIRY DATE	01/10/11	
			INT.	EXP.
Appearance before reconstitution	Freeze-dried solid		Pass	Pass
Appearance after reconstitution	A clear, colourless solution		Pass	Pass
pH	6.5 - 7.5* after reconstitution		7.0	7.0
Radiochemical purity	≥ 94.0 % as ^{99m}Tc-Bicisate* ≥ 90.0 % as ^{99m}Tc-Bicisate**		95.6 ± 0.1	97.2 ± 0.1
	≤ 6.0 % of the total radioactivity as sum of impurities* ≤ 10.0 % as impurities**		4.4 ± 0.1	2.8 ± 0.1
Tin content	12 - 72 µg $SnCl_2.2H_2O$***		N.A.	
Vial/Package Label	Complies		Complies	

* Current edition of BP specification.
** Current edition of USP specification.
***Value given in label/product information.

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

Current edition of BP (Technetium [^{99}mTc] Colloidal Tin Injection)

		SUPPLIER	RADPH			
		LOT/BATCH No.	2823/2879			
	SPECIFICATIONS	EXPIRY DATE	January 2012			
			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	4.0 - 7.0 after reconstitution		4.5		4.0	
			Pall ITLC-SG	Varian ITLC-SG	Pall ITLC-SG	Varian ITLC-SG
Radiochemical purity	≥ 95.0 % as ^{99m}Tc-colloid		97.1 ± 0.6	97.5 ± 0.2	98.9 ± 0.6	98.5 ± 0.2
Tin content	≤ 1.0 mg $SnCl_2$		0.4			
Vial/Package Label	Complies		Complies			

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

Current edition of USP

		SUPPLIER	PHARMA			
		LOT/BATCH No.	230027A			
	SPECIFICATIONS	EXPIRY DATE	30/09/12			
			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		4.4	
			Pall ITLC-SG	Varian ITLC-SG	Pall ITLC-SG	Varian ITLC-SG
Radiochemical purity	1) ≥ 90.0 % as ^{99m}Tc-disofenin	1)	99.4		99.3	
	2) hydrolysed ^{99m}Tc + tin colloid (chromatography system A)	2)	0.2 ± 0.07	0.4 ± 0.05	0.2 ± 0.02	0.3 ± 0.03
	3) free pertechnetate (chromatography system B)	3)	0.4 ± 0.2		0.5 ± 0.11	
	2) +3) ≤10%		0.6		0.7	
Tin content	0.24 - 0.6 mg $SnCl_2$*		N.A.		N.A.	
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 BP

		SUPPLIER	GE Healthcare	
		LOT/BATCH No.	1342	
	SPECIFICATIONS	EXPIRY	18/11/11	
			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		9.1	9.1
Radiochemical purity	≥ 80 % total radioactivity of: lipophilic ^{99m}Tc-Exametazime (X) and *meso* isomer of lipophilic ^{99m}Tc-Exametazime (A) (X+A)=100 – (C+B+D+E)		94.5	89.8
	≤ 10 % as free pertechnetate (C)		1.8 ± 0.2	6.0 ± 0.6
	% sum of: (B+D+E) ^{99m}Tc-colloidal (B), non lipophilic ^{99m}Tc-Exametazime complex (D) and *meso* isomer of non lipophilic ^{99m}Tc-Exametazime complex (E)		3.7 ± 0.2	4.2 ± 0.4
	≤ 5% of the radioactivity due to: meso isomer of lipophilic ^{99m}Tc-Exametazime (A)		0.1 ± 0.1	0.3 ± 0.1
Tin content	7.6 µg $SnCl_2.2H_2O$/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	ANSTO Health			
		LOT/BATCH No.	2920			
	SPECIFICATIONS	EXPIRY DATE	March 2012			
			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	3.5 – 7.5 after reconstitution		4.5		4.5	
			Pall ITLC-SG	Varian ITLC-SG	Pall ITLC-SG	Varian ITLC-SG
Radiochemical purity	1) ≥ 95.0 % as ^{99m}Tc-MDP		99.8	99.7		98.8
	2) ≤ 2.0 % as $^{99m}TcO_4^-$		0.1 ± 0.05	0.1 ± 0.03	†	0.2 ± 0.05
	3) as colloidal ^{99m}Tc		0.1 ± 0.01	0.2 ± 0.1	†	1.0 ± 0.3
	2) + 3) ≤ 5.0 %		0.2	0.3		1.2
Tin content	≤ 3 mg/mL					
	0.84 mg $SnCl_2$*		0.81 mg			
Biological distribution	≥ 1.5% attached to femur		†		†	
	≤ 1.0% in the liver		†		†	
	≤ 0.05 %/g in the blood		†		†	
Vial/Package Label	Complies		Complies		Complies	

* Value given in label/product information.

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

Current edition of BP

	SPECIFICATIONS	SUPPLIER LOT/BATCH No. EXPIRY DATE	TYCO/MALL 09690013 16/09/11			
			INT.		EXP.	
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture		Pass			
Appearance after reconstitution	A clear, colourless solution		Pass			
pH	5.0 - 7.5 after reconstitution		5.7		5.6	
Radiochemical purity	≥ 94.0 % as ^{99m}Tc-MAG3		97.9 ± 0.1*	99.2 ± 0.04**	98.3 ± 0.2*	99.3 ± 0.2**
	≤ 3.0 % as hydrophilic impurities including [^{99m}Tc] pertechnetate		1.7 ± 0.2*		1.5± 0.3*	
	≤ 4.0 % as lipophilic impurities		0.4 ± 0.03*		0.1 ± 0.07*	
	≤ 2% as reduced-hydrolysed technetium (by chromatography)		0.03 ± 0.005*		0.1 ± 0.01*	
Tin content	≥ 50 µg $SnCl_2.2H_2O$/vial***		N.A.			
Vial/Package Label	Complies		Complies			

* Tested by Current addition of BP

**Tested by the method recommended by the manufacturer (Sep-Pak C_{18} cartridge).

*** Value given in label/product information.

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

Current edition of USP

	SPECIFICATIONS	SUPPLIER LOT/BATCH No. EXPIRY DATE	TYCO/MALL 0911007 11/12/11	
			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		97.8	97.1
	2) % as free pertechnetate		1.9 ± 0.6	2.5 ± 0.2
	3) % as colloidal ^{99m}Tc		0.3 ± 0.04	0.4 ± 0.03
	2) + 3) ≤ 10 %		2.2	2.9
Tin content	0.258 - 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	

*Value given in label/product information.

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

Current edition of BP

		SUPPLIER	RADPH				ARI			
		LOT/BATCH No.	2800				2852			
	SPECIFICATIONS		July 2011				August 2011			
			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		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 – 7.5 after reconstitution		5.5		5.7		4.2		4.2	
			Pall ITLC-SG	Varian ITLC-SG	Pall ITLC-SG	Varian ITLC-SG	Pall ITLC-SG	Varian ITLC-SG	Pall ITLC-SG	Varian ITLC-SG
Radiochemical purity	1) ≥ 95.0 % as ^{99m}Tc-DTPA		99.9	99.8	99.6	99.6	99.9	99.3	99.8	99.7
	2) Colloidal ^{99m}Tc impurity (chromatography system A)		0.06 ± 0.02	0.1 ± 0.02	0.3 ± 0.01	0.3 ± 0.02	0.07 ± 0.01	0.4 ± 0.1	0.09 ± 0.01	0.11 ± 0.03
	3) Free pertechnetate ^{99m}Tc (chromatography system B)		0.04 ± 0.02	0.1 ± 0.07	0.1 ± 0.02	0.1 ± 0.01	0.06 ± 0.02	0.31 ± 0.06	0.08 ± 0.01	0.15 ± 0.02
	2) + 3) ≤ 5.0%		0.1	0.2	0.4	0.4	0.1	0.7	0.2	0.3
Tin content	≤ 1 mg/mL									
	0.21 mg $SnCl_2$ /vial*							0.18 ± 0.02mg		
	1 mg $SnCl_2$ /vial*				0.4 ± 0.01mg					
Vial/Package Label	Complies		Complies				Complies			

***** Value given in label/product information.

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

Current edition of BP

		SUPPLIER	Lantheus (USA)		Lantheus (USA)	
		LOT/BATCH No.	4009		4027	
	SPECIFICATIONS	EXPIRY DATE	01/03/12		01/06/12	
			INT.	EXP.	INT.	EXP.
Appearance before reconstitution	Freeze dried solid with no evidence of moisture		Pass	Pass	Pass	†
Appearance after reconstitution	A clear, colourless solution		Pass	Pass	Pass	†
pH	5.0 - 6.0 after reconstitution		5.2		5.2	
Radiochemical purity	≥ 94.0 % as ^{99m}Tc-Sestamibi		98.8 ± 0.01	98.7± 0.03	98.5 ± 0.09	†
			1.2 ± 0.01	1.3 ± 0.03	1.5 ± 0.09	†
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	CIS-BIO			
		LOT/BATCH No.	A004G			
	SPECIFICATIONS	EXPIRY DATE	30/07/11			
			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		2.8		2.9	
			Pall ITLC-SG	Varian ITLC-SG	Pall ITLC-SG	Varian ITLC-SG
Radiochemical purity	≥ 95.0 % as ^{99m}Tc-DMSA		99.93	99.95	99.9	99.9
	≤ 2.0 % as $^{99m}TcO_4^-$		0.07 ± 0.04	0.05 ± 0.01	0.1 ± 0.03	0.1 ± 0.04
Tin content	≤ 1 mg/mL		< 1			
Biological distribution	≥ 40% in the kidneys		†		†	
	≤ 10% in the liver		†		†	
	≤ 2% in the stomach		†		†	
	≤ 5% in the lungs		†		†	
Vial/Package Label	Complies		Fail			

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

Current edition of USP

		SUPPLIER	GE Healthcare			
		LOT/BATCH No.	1738			
	SPECIFICATIONS	EXPIRY DATE	11/11/11			
			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		8.3	
			Pall ITLC-SG	Varian ITLC-SG	Pall ITLC-SG	Varian ITLC-SG
Radiochemical purity	1) ≥ 90.0 % as ^{99m}Tc-Tetrofosmin		97.1 ± 0.1	97.5 ± 0.2	98.0 *	98.5 ± 0.05
	2) Reduced hydrolysed & hydrophilic impurities		2.3 ± 0.02	2.2 ± 0.1	1.6 *	1.3 ± 0.03
	3) Unbound pertechnetate		0.5 ± 0.1	0.3 ± 0.02	0.4 *	0.2 ± 0.02
	2) + 3) ≤ 10%		2.8	2.5	2.0	1.5
Tin content	0.03 mg/vial $SnCl_2.2H_2O$**		N.A.			
Vial/Package Label	Complies		Complies			

* Single strip only.

** Value given in label/product information.

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

Current edition of BP/USP

		SUPPLIER	Covidien/Mall				CIS BIO		
		LOT/BATCH No.	0941002				A006D		
	SPECIFICATIONS	EXPIRY DATE	07/09/11				28/10/11		
			INT.		EXP.		INT.		EXP.	
Appearance before reconstitution	Freeze-dried solid with no evidence of moisture		Pass				Pass		Pass	
Appearance after reconstitution	A clear, colourless or slightly yellow solution, free of any visible particulate matter		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.	
pH	6.0 – 7.0 after reconstitution*									
	4.0 - 7.5 after reconstitution**		5.0		4.5		5.0		5.0	
			Pall ITLC-SG	Varian ITLC-SG	Pall ITLC-SG	Varian ITLC-SG	Pall ITLC-SG	Varian ITLC-SG	Pall ITLC-SG	Varian ITLC-SG
Radiochemical purity	1) ≥ 90.0 % as ^{99m}Tc-PYP		98.8	95.0	98.6	93.8	99.0	91.3	98.9	93.0
	2) as free pertechnetate		0.4 ± 0.2	2.7 ± 0.9	0.8 ± 0.2	4.5 ± 0.8	0.3 ± 0.02	4.5 ± 0.7	0.3 ± 0.2	4.7 ± 0.5
	3) as colloidal [^{99m}Tc]		0.8 ± 0.1	2.3 ± 0.1	0.6 ± 0.2	1.6 ± 0.2	0.7 ± 0.2	4.7 ± 0.8	0.8 ± 0.1	2.3± 0.6
	2) + 3) ≤ 10 %		1.2	5.0	1.4	6.2	1.0	8.7	1.1	7.0
Sodium pyrophosphate	1-50 mg/mL sodium pyrophosphate on reconstitution		12 mg/mL				20 mg/mL			
Tin content	≤ 3 mg/mL		†				†			
Vial/Package Label	Complies		Complies				Complies			

* Current edition of BP.
** Value given in USP.