

AUSTRALIAN RADIATION PROTECTION AND NUCLEAR SAFETY AGENCY

Results of the Quality Assurance Testing
Program for Radiopharmaceuticals 2001

by

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ABSTRACT

This report tabulates results obtained during 2001 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 in which 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. In other cases the specifications quoted have been adopted by this Agency and have no legal status. It should be noted that unless stated otherwise, the specifications listed apply at all times up to product expiry. Radionuclidic purity has been determined at the expiry time, except for Thallous^[201Tl] Chloride Injection where the impurity levels both at calibration and expiry are quoted.

Samples for testing were obtained through commercial channels. All technetium-99m cold kits were reconstituted according to the directions in the package insert using Sodium Pertechnetate^[99mTc] Injection. Pharmacopoeia methods are used for testing, together with some additional methods described in the report ARL/TR093*.

RESULTS

The results of testing during 2001 are summarised in the following tables. Overall, 69 batches of 20 different types of radiopharmaceuticals were tested. Failure to meet full specifications was observed in 10 of the 69 batches of radiopharmaceuticals tested (14%).

Non-compliance of the vial label was observed in four of the ten batches failing specification. The vial label non-compliance consisted of the absence of a statement as to the presence or absence of a microbiological preservative in four batches and the absence of the expiry time in two batches.

Other non-compliance was high radionuclidic content in two batches, low pH in two batches, low radiochemical purity in one batch and low microbiological preservative content in one batch. 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 proportion of non-compliance of radiopharmaceuticals is of the same order as that reported in previous years.

*ARL/TR093. "Quality Assurance of Radiopharmaceuticals - Specifications and Test Procedures" by J. Baldas, J. Bonnyman, S.F. Colmanet, Z. Ivanov and R.A. Lauder, Second Edition, 1990. Obtainable from The Librarian, ARPANSA, Lower Plenty Road, Yallambie, Victoria 3085, Australia.

ABBREVIATIONS

The following abbreviations are used in the tables -

| | | |
|---------|---|--|
| AMER | - | Nycomed Amersham plc, UK |
| ARI | - | Australian Radioisotopes, Lucas Heights, Sydney, Australia |
| MALL | - | Mallinckrodt Inc, St Louis, MO, USA |
| MALL(H) | - | Mallinckrodt Diagnostica (Holland) |
| RADPH | - | Radpharm Scientific, Belconnen, ACT, Australia |
| RC | - | Radiopharmacy Central, Tullamarine, VIC, Australia |
| N.D. | - | Not detected |
| N.A. | - | Not applicable |
| † | - | Not determined |
| LSC | - | Liquid scintillation counting |

SODIUM PHOSPHATE^[32P] INJECTION

| | | SUPPLIER | ARI | AMER | ARI | AMER |
|------------------------|---|---------------|----------|----------|----------|----------|
| | | LOT/BATCH No. | 10400 | 702 | 11472 | 726 |
| | | CALIB. DATE | 04/06/01 | 11/06/01 | 19/11/01 | 26/11/01 |
| SPECIFICATIONS | | EXPIRY DATE | 26/06/01 | 09/07/01 | 11/12/01 | 24/12/01 |
| Appearance | A clear, colourless solution | | Pass | Pass | Pass | Pass |
| Particulate matter | None visible | | Pass | Pass | Pass | Pass |
| Radionuclidic content | 90-110% of stated value | | 105 | 101 | 98 | 106 |
| Radionuclidic purity | i) Beta spectrum does not differ significantly from that of a standardised P-32 solution obtained under the same conditions | | Pass | Pass | Pass | Pass |
| | ii) decay rate should correspond to half-life of 14.3 d | | † | † | Pass | Pass |
| Radiochemical purity | ≥ 95% as orthophosphate | INIT. | 99.9 | 100 | 99.9 | 99.9 |
| | | EXP. | 99.9 | 100 | 99.9 | 99.8 |
| pH | 6.0 - 8.0 | | 6.5 | 7.5 | 6.5 | 7.0 |
| Specific radioactivity | ≥ 11.1 MBq of P-32/ mg of orthophosphate ion | | 129 | 65 | 132 | 61 |
| Label | Complies | | Complies | Complies | Complies | Complies |

CHROMIUM[⁵¹Cr] EDETATE INJECTION

| | | SUPPLIER | ARI | AMER | ARI | AMER |
|------------------------|--|---------------|----------|----------|----------|----------|
| | | LOT/BATCH No. | 09367 | 556 | 10100 | 570 |
| | | CALIB. DATE | 01/02/01 | 12/03/01 | 01/06/01 | 02/07/01 |
| SPECIFICATIONS | | EXPIRY DATE | 04/03/01 | 07/05/01 | 02/07/01 | 27/08/01 |
| Appearance | A clear, violet solution | | Pass | Pass | Pass | Pass |
| Particulate matter | None visible | | Pass | Pass | Pass | Pass |
| Radionuclidic content | 90-110% of stated value | | 111 | 105 | 104 | 104 |
| Radionuclidic purity | Gamma spectrum does not differ significantly from that of a standardised Cr-51 solution. No other radionuclide detected by gamma spectrometry. | | N.D. | N.D. | N.D. | N.D. |
| pH | 3.5 – 6.5 | | 5.0 | 4.0 | 5.0 | 4.0 |
| Chemical purity | | | | | | |
| 1) Total edetate | mg/mL | | | 2.2 | 9.7 | 2.2 |
| 2) Uncomplexed edetate | mg/mL | | | 1.4 | 7.8 | 1.4 |
| 3) Total chromium | ≤ 1mg/mL | | | 0.1 | 0.3 | 0.1 |
| Radiochemical purity | | | | | | |
| 1) Chromic ion | as % | | INIT. | | 0.4 | |

| | | | | | | |
|-----------------|-----------------------------------|------|----------|----------|----------|----------|
| 2) Chromate ion | as % | | | | 0.8 | |
| 3) Cr-edetate | ≥ 95% as ⁵¹ Cr-edetate | | | | 98.8 | |
| | | EXP. | 0.2 | 0.4 | 0.1 | 0.5 |
| | | | 0.7 | 0.7 | 0.4 | 2.1 |
| | | | 99.1 | 98.9 | 99.5 | 97.4 |
| Benzyl alcohol | 90 – 110 % of stated value | | N/A | 97 | N/A | 100 |
| Label | Complies | | Complies | Complies | Complies | Complies |

SODIUM CHROMATE[⁵¹Cr] SOLUTION

| | | SUPPLIER | ARI | AMER | ARI | AMER |
|-----------------------|--|--------------|----------|----------|----------|----------|
| | | LOT/BATCH No | 09368 | 686 | 10101 | 702 |
| SPECIFICATIONS | | CALIB. DATE | 01/02/01 | 21/02/01 | 01/06/01 | 13/06/01 |
| | | EXPIRY DATE | 04/03/01 | 18/04/01 | 02/07/01 | 08/08/01 |
| Appearance | A clear, colourless or slightly yellow solution | | Pass | Pass | Pass | Pass |
| Particulate matter | None visible | | Pass | Pass | Pass | Pass |
| Radionuclidic content | 90-110% of stated value | | 122 | 105 | 107 | 104 |
| Radionuclidic purity | Gamma spectrum does not differ significantly from that of a standardised 51-Cr solution. No other radionuclide detected by gamma spectrometry. | | Pass | Pass | Pass | Pass |
| pH | 6.0 - 8.5 | | 6.5 | 6.0 | 6.5 | 6.0 |
| Radiochemical purity | ≥ 90% as chromate ion | INIT. | 99.7 | 99.4 | 99.7 | 99.5 |
| | | EXP. | 99.8 | 98.5 | 99.7 | 99.5 |
| Total chromate | ≤ 2.7 µg of chromate ion/MBq at expiry | | 0.1 | 0.2 | 0.1 | 0.3 |
| Benzyl Alcohol | 90 – 110 % of stated value | | N/A | N/A | N/A | N/A |
| Label | Complies | | Complies | Complies | Complies | Complies |

GALLIUM[⁶⁷Ga] CITRATE INJECTION

| | | SUPPLIER | ARI | MALL(H) | ARI | MALL(H) | DuPont | ARI |
|-----------------------|---|---------------|----------|----------|----------|----------|----------|----------|
| | | LOT/BATCH No. | 19671 | 24929 | 10512 | 26656 | G17212S | 11728 |
| | | CALIB. DATE | 13/02/01 | 08/03/01 | 12/06/01 | 14/06/01 | 27/06/01 | 11/12/01 |
| SPECIFICATIONS | | EXPIRY DATE | 20/02/01 | 18/03/01 | 19/06/01 | 24/06/01 | 04/07/01 | 18/12/01 |
| Appearance | A clear, colourless solution | | Pass | Pass | Pass | Pass | Pass | Pass |
| Particulate matter | None visible | | Pass | Pass | Pass | Pass | Pass | Pass |
| Identification | | | | | | | | |
| 1) Gamma spectrum | Gamma spectrum does not differ significantly from that of a standardised Ga-67 solution | | Pass | Pass | Pass | Pass | Pass | Pass |
| 2) Citrate presence | Present | | † | † | † | † | † | † |
| Radionuclidic content | ≥ 90-110% of stated value | | 105 | 103 | 99 | 103 | 100 | 99 |
| Radionuclidic purity | ≤ 0.2% ⁶⁶ Ga | | N.D. | N.D. | N.D. | N.D. | N.D. | N.D. |
| pH | 5.0 - 8.0 | | 6.5 | 7.0 | 6.5 | 7.0 | 6.0 | 6.5 |
| Radiochemical purity | ≥ 97% as Ga citrate | INIT. | 99.4 | 97.0 | 99.1 | 98.7 | 98.9 | 99.4 |
| | | EXP. | 99.5 | 97.5 | 99.8 | 98.3 | 98.1 | 99.2 |
| Zinc limit test | ≤ 5 µg/mL Zn | | † | † | † | † | † | † |
| Benzyl alcohol | 90 – 110 % of stated value | | 95 | 95 | 94 | 94 | 89 | 99 |
| Label | Complies | | Complies | Fails | Complies | Fails | Complies | Complies |

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

| | | SUPPLIER | DuPont | DuPont |
|----------------------------------|--|---------------|----------|----------|
| | | LOT/BATCH No. | 0114A | 0121A |
| SPECIFICATIONS | | EXPIRY DATE | 01/02/02 | 01/11/02 |
| Appearance before reconstitution | Freeze dried solid | | Pass | Pass |
| Appearance after reconstitution | A clear, colourless solution | | Pass | Pass |
| Presence of vacuum | Complies | | N/A | N/A |
| pH | 6.3 - 7.6 after reconstitution | | 7.0 | 7.0 |
| Radiochemical purity | 1) ≥ 90.0 % as ^{99m} Tc-Bicisate 2) ≤ 10.0 % as impurities (colloidal, ^{99m} TcO ₄ ⁻ & ^{99m} Tc-EDTA) | INIT. | 96.5 | 97.1 |
| | | | 3.5 | 2.9 |
| | | EXP. | 98.6 | 97.9 |
| | | | 1.4 | 2.1 |
| Stannous tin content | 12 - 72 µg SnCl ₂ .2H ₂ O * | | † | † |
| Label | Complies | | Complies | Complies |

*Value given in label/product information

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

| | | SUPPLIER | RADPH |
|----------------------------------|---|---------------|----------|
| | | LOT/BATCH No. | 1701 |
| SPECIFICATIONS | | EXPIRY DATE | Feb 2002 |
| Appearance before reconstitution | Freeze-dried solid | | Pass |
| Appearance after reconstitution | A clear colourless solution | | Pass |
| pH | 4.0 - 6.0 after reconstitution | | 5.7 |
| Radiochemical purity | ≥ 95.0 % as ^{99m} Tc-Etifenin | INIT. | † |
| | | EXP. | 87.4 |
| Stannous tin content | 0.42 mg SnCl ₂ /vial * | | † |
| Biological distribution | ≥ 80% in the gall bladder + small and large intestines | | † |
| | ≤ 3% in the liver | | † |
| | ≤ 2% in the kidneys | | † |
| Label | Complies | | Complies |

*Value given in label/product information.

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

| | | SUPPLIER | AMER | AMER |
|----------------------------------|--|---------------|----------|----------|
| | | LOT/BATCH No. | 874 | 884 |
| SPECIFICATIONS | | EXPIRY DATE | 25/05/01 | 14/09/01 |
| Appearance before reconstitution | Freeze-dried solid | | Pass | Pass |
| Appearance after reconstitution | A clear colourless solution | | Pass | Pass |
| pH | 9.0 - 9.8 after reconstitution | | 9.3 | 9.3 |
| Radiochemical purity | ≥ 80.0 % as ^{99m} Tc-Exametazime | INT. | 88.0 | 87.9 |
| | % as free TcO ₄ ⁻ | | 3.0 | 0.5 |
| | % as hydrolysed reduced ^{99m} Tc | | 4.7 | 5.8 |
| | % as ^{99m} Tc secondary exametazime complex | | 4.3 | 5.8 |
| | | EXP. | 90.3 | 92.4 |
| | | | 0.5 | 1.0 |
| Stannous tin content | 7.6 µg SnCl ₂ .2H ₂ O/vial * | | 5.1 | 2.5 |
| | | | 4.1 | 4.1 |
| | | | † | † |
| | | | † | † |
| Biological distribution | ≥ 1.5 % in the brain | | † | † |
| | ≤ 20 % in the intestines | | † | † |
| | ≤ 15 % in the liver | | † | † |
| Label | Complies | | Complies | Complies |

*Value given in label/product information

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

| | | SUPPLIER | MALL | RADPH | MALL | MALL | RADPH |
|----------------------------------|---|---------------|----------|----------|----------|----------|----------|
| | | LOT/BATCH No. | 0939004 | 1681 | 0931013 | 0931020 | 1732 |
| SPECIFICATIONS | | EXPIRY DATE | 24/01/01 | Dec/01 | 14/02/02 | 21/03/02 | May/02 |
| Appearance before reconstitution | Freeze-dried solid | | Pass | Pass | Pass | Pass | Pass |
| Appearance after reconstitution | A white suspension which may separate on standing | | Pass | Pass | Pass | Pass | Pass |
| Presence of vacuum | Complies | | N/A | Complies | N/A | N/A | Complies |
| pH | 3.8 – 7.5 after reconstitution | | 4.5 | 6.5 | 5.0 | 4.0 | 6.5 |
| Radiochemical purity | 1) ≥ 90.0 % in aggregate | INIT. | 97.9 | 97.3 | 99.9 | 98.4 | 96.7 |
| | 2) % as soluble ^{99m} Tc-albumin | | 0.8 | 1.2 | 0.0 | 1.2 | 1.5 |
| | 3) % as free ^{99m} TcO ₄ ⁻ | | 1.3 | 1.5 | 0.1 | 0.4 | 1.8 |
| | 2) + 3) ≤ 10.0 % | EXP. | 96.0 | 94.0 | 99.8 | 99.1 | 98.0 |
| | | | 1.4 | 2.2 | 0.1 | 0.7 | 1.0 |
| | | | 2.6 | 3.8 | 0.1 | 0.2 | 1.0 |
| Particle size | For at least 5000 particles: ≤ 10 particles with maximum dimension >100 μm None with maximum dimension > 150 μm | | Pass | Pass | Pass | Pass | Pass |
| Non filterable radioactivity | ≥ 90 % of the total radioactivity remaining on the membrane | | 96 | 98 | 98 | 99 | 99 |
| Biological distribution | ≥ 80% in the lungs | | † | † | † | † | † |
| | ≤ 5% in the liver + spleen | | † | † | † | † | † |
| Label | Complies | | Complies | Complies | Complies | Complies | Complies |

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

| | | SUPPLIER | ARI | RADPH | ARI | RADPH | AMER | AMER |
|----------------------------------|--|---------------|----------|----------|----------|----------|----------|----------|
| | | LOT/BATCH No. | 1584 | 1622 | 1672 | 1683 | 490 | 492 |
| SPECIFICATIONS | | EXPIRY DATE | July/01 | Feb/01 | Sep/01 | Oct/01 | 28/01/02 | 04/02/02 |
| Appearance before reconstitution | Freeze dried solid | | Pass | Pass | Pass | Pass | Pass | Pass |
| Appearance after reconstitution | A clear, colourless solution | | Pass | Pass | Pass | Pass | Pass | Pass |
| Presence of vacuum | Complies | | Complies | N/A | Complies | Complies | N/A | N/A |
| pH | 3.5 – 7.5 after reconstitution | | 5.0 | 5.0 | 5.0 | 5.5 | 6.3 | 6.6 |
| Radiochemical purity | 1) ≥ 95.0 % as ^{99m} Tc-MDP | INIT. | 99.0 | 99.7 | 99.7 | 99.8 | 99.0 | 99.3 |
| | 2) ≤ 2.0 % as ^{99m} TcO ₄ ⁻ | | 0.8 | 0.1 | 0.1 | 0.1 | 0.1 | 0.2 |
| | 3) as colloidal ^{99m} Tc | | 0.2 | 0.2 | 0.2 | 0.1 | 0.9 | 0.5 |
| | 2) + 3) ≤ 5.0 % | EXP. | 99.8 | 99.8 | 99.6 | 99.7 | 97.7 | 99.3 |
| | | | | 0.1 | 0.1 | 0.2 | 0.0 | 1.7 |
| | | | 0.1 | 0.1 | 0.2 | 0.3 | 0.6 | 0.5 |
| Stannous tin content | 0.84 mg SnCl ₂ */vial | | † | | † | | | |
| | 1 mg SnCl ₂ /vial | | | † | | † | | |
| | 0.34 mg SnF ₂ /vial | | | | | | † | † |
| Biological distribution | ≥ 1.5% attached to femur | | † | † | † | † | † | † |
| | ≤ 1.0% in the liver | | † | † | † | † | † | † |
| | ≤ 0.05 %/g in the blood | | † | † | † | † | † | † |
| Label | Complies | | Complies | Complies | Complies | Complies | Complies | Complies |

*Value given in label/product information

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

| | | SUPPLIER | MALL | MALL | MALL |
|----------------------------------|--|---------------|----------|----------|----------|
| | | LOT/BATCH No. | 0969009A | 0961006 | 0960010B |
| SPECIFICATIONS | | EXPIRY DATE | 02/09/01 | 11/03/02 | 03/10/02 |
| Appearance before reconstitution | Freeze-dried solid | | Pass | Pass | Pass |
| Appearance after reconstitution | A clear, colourless solution free of particulate matter. | | Pass | Pass | Pass |
| pH | 5.0 - 7.5 after reconstitution | | 6.0 | 5.8 | 6.0 |
| Radiochemical purity* | 1) ≥ 94.0 % as ^{99m} Tc-MAG3 | INIT. | 99.2 | 99.7 | 99.5 |
| | 2) % as hydrophilic impurities | | 0.2 | 0.1 | 0.2 |
| | 3) % as non-elutable impurities | | 0.6 | 0.2 | 0.3 |
| | | EXP. | 99.8 | 99.5 | 99.8 |
| | | | 0.1 | 0.1 | 0.1 |
| | | | 0.1 | 0.4 | 0.1 |
| Stannous tin content | ≥ 50 µg SnCl ₂ .2H ₂ O/vial** | | † | † | † |
| Label | Complies | | 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)

| | | SUPPLIER | MALL | MALL |
|----------------------------------|--|---------------|----------|----------|
| | | LOT/BATCH No. | 0911002A | 0911005 |
| SPECIFICATIONS | | EXPIRY DATE | 01/08/01 | 04/09/01 |
| Appearance before reconstitution | Freeze-dried solid | | Pass | Pass |
| Appearance after reconstitution | A clear, colourless solution | | Pass | Pass |
| Presence of vacuum | Complies | | N/A | N/A |
| pH | 2.5 – 7.0 after reconstitution | | 5.5 | 4.5 |
| Radiochemical purity | 1) ≥ 90.0 % as ^{99m} Tc-HDP | INIT. | 99.8 | 98.7 |
| | 2) % as ^{99m} TcO ₄ ⁻ | | 0.1 | 0.1 |
| | 3) % as colloidal ^{99m} Tc | | 0.1 | 1.2 |
| | 2) + 3) ≤ 10.0 % | | | |
| | | EXP. | 98.7 | 99.1 |
| Stannous tin content | 0.258 mg SnCl ₂ .2H ₂ O* | | 0.1 | 0.1 |
| | | | 1.2 | 0.8 |
| | | | † | † |
| Biological distribution | ≥ 1.0% attached to one femur | | † | † |
| | ≤ 5.0% in the liver | | † | † |
| | ≤ 5.0% in the kidneys | | † | † |
| Label | Complies | | Complies | Complies |

*Value given in label/product information as minimum content.

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

| | | SUPPLIER | ARI | MALL(H) | RADPH | AMER | RADPH |
|----------------------------------|--|---------------|----------|----------|-----------|----------|----------|
| | | LOT/BATCH No. | 1602 | 86887 | 1616 | 252 | 1691 |
| SPECIFICATIONS | | EXPIRY DATE | March/01 | 28/04/01 | August/01 | 06/08/01 | Oct/01 |
| Appearance before reconstitution | Freeze-dried solid | | Pass | Pass | Pass | Pass | Pass |
| Appearance after reconstitution | A clear, colourless or slightly yellow solution | | Pass | Pass | Pass | Pass | Pass |
| Presence of vacuum | Complies | | Complies | N/A | Complies | Complies | Complies |
| pH | 4.0 - 7.5 after reconstitution | | 4.5 | 4.5 | 5.0 | 5.0 | 5.8 |
| Radiochemical purity | 1) $\geq 95.0\%$ as ^{99m} Tc-DTPA | INIT. | 99.6 | 99.9 | 99.6 | 99.9 | 99.6 |
| | 2) % as ^{99m} TcO ₄ ⁻ | | 0.2 | 0.0 | 0.1 | 0.1 | 0.1 |
| | 3) % as colloidal ^{99m} Tc | | 0.2 | 0.1 | 0.3 | 0.0 | 0.3 |
| | 2) + 3) $\leq 5.0\%$ | | | | | | |
| Stannous tin content | 1.05 mg SnCl ₂ */vial | | † | | | | |
| | 1 mg SnCl ₂ */vial | | | | † | | † |
| | 0.25 mg SnCl ₂ .2H ₂ O*/vial | | | | | † | |
| | 0.21 mg SnCl ₂ */vial | | | † | | | |
| Label | Complies | | Complies | Complies | Complies | Complies | Complies |

*Value given in label/product information

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

| | | SUPPLIER | MALL(H) | AMER | MALL(H) | ARI |
|----------------------------------|--|---------------|----------|----------|----------|----------|
| | | LOT/BATCH No. | 96615 | 254 | 98754 | 1695 |
| SPECIFICATIONS | | EXPIRY DATE | 06/10/01 | 09/10/01 | 31/10/01 | Nov/01 |
| Appearance before reconstitution | Freeze-dried solid | | Pass | Pass | Pass | Pass |
| Appearance after reconstitution | A clear, colourless or slightly yellow solution | | Pass | Pass | Pass | Pass |
| Presence of vacuum | Complies | | N/A | N/A | N/A | Complies |
| pH | 4.0 - 7.5 after reconstitution | | 5.0 | 4.5 | 4.5 | 4.5 |
| Radiochemical purity | 1) $\geq 95.0\%$ as ^{99m} Tc-DTPA | INIT. | 99.8 | 99.90 | 99.85 | 99.85 |
| | 2) % as ^{99m} TcO ₄ ⁻ | | 0.1 | 0.05 | 0.05 | 0.10 |
| | 3) % as colloidal ^{99m} Tc | | 0.1 | 0.05 | 0.10 | 0.05 |
| | 2) + 3) $\leq 5.0\%$ | | | | | |
| Stannous tin content | 1.05 mg SnCl ₂ */vial | | | | | † |
| | 1 mg SnCl ₂ */vial | | | | | |
| | 0.25 mg SnCl ₂ .2H ₂ O*/vial | | | † | | |
| | 0.21 mg SnCl ₂ */vial | | † | | † | |
| Label | Complies | | Complies | Complies | Complies | Complies |

*Value given in label/product information

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

| | | SUPPLIER | DuPont |
|----------------------------------|--|---------------|----------|
| | | LOT/BATCH No. | 3724 |
| SPECIFICATIONS | | EXPIRY DATE | 01/05/02 |
| Appearance before reconstitution | Freeze dried solid | | Pass |
| Appearance after reconstitution | A clear, colourless solution | | Pass |
| Presence of vacuum | Complies | | N/A |
| pH | 5.0 - 6.0 after reconstitution | | 5.2N/A |
| Radiochemical purity | 1) $\geq 90.0\%$ as ^{99m} Tc-Sestamibi | INIT. | 98.8 |
| | 2) $\leq 10.0\%$ ^{99m} Tc as impurities | | 1.2 |
| | | EXP | 95.5 |
| | | | 1.5 |
| Stannous tin content | 75 μg SnCl ₂ * | | † |
| Label | Complies | | Complies |

*Value given in label/product information

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

| | | SUPPLIER | RADPH | RADPH |
|----------------------------------|---|---------------|----------|----------|
| | | LOT/BATCH No. | 1673 | 1742 |
| SPECIFICATIONS | | EXPIRY DATE | April/01 | Feb/02 |
| Appearance before reconstitution | Freeze dried solid | | Pass | Pass |
| Appearance after reconstitution | A clear, colourless solution | | Pass | Pass |
| Presence of vacuum | Complies | | Complies | Complies |
| pH | 2.3 - 3.5 after reconstitution | | 3.5 | 3.1 |
| Radiochemical purity | ≥ 95.0 % as ^{99m} Tc-DMSA | INIT. | 99.8 | 99.8 |
| | ≤ 2.0 % as ^{99m} TcO ₄ ⁻ | | 0.2 | 0.2 |
| | | EXP. | 99.7 | 99.6 |
| | | | 0.3 | 0.4 |
| Stannous tin content | 0.4 mg SnCl ₂ * | | † | † |
| Biological distribution | ≥ 40% in the kidneys | | † | † |
| | ≤ 10% in the liver | | † | † |
| | ≤ 2% in the stomach | | † | † |
| | ≤ 5% in the lungs | | † | † |
| Label | Complies | | Complies | Complies |

*Value given in label/product information

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

| | | SUPPLIER | AMER | AMER |
|----------------------------------|--|---------------|----------|----------|
| | | LOT/BATCH No. | 552 | 590 |
| SPECIFICATIONS | | EXPIRY DATE | 19/04/01 | 08/09/01 |
| Appearance before reconstitution | Freeze-dried solid | | Pass | Pass |
| Appearance after reconstitution | A clear colourless solution | | Pass | Pass |
| Presence of vacuum | Complies | | N/A | N/A |
| pH | 7.5 - 9.0 after reconstitution | | 8.4 | 8.6 |
| Radiochemical purity | 1) ≥ 90.0 % as ^{99m} Tc-Tetrafosmin | INT. | 97.0 | 94.6 |
| | 2) as % reduced hydrolysed ^{99m} Tc and hydrophilic impurities | | 2.6 | 3.1 |
| | 3) as % unbound pertechnetate ^{99m} TcO ₄ ⁻ | | 0.4 | 2.3 |
| | 2 + 3) ≤ 10 % | EXP. | 95.4 | 96.9 |
| | | | 3.5 | 2.9 |
| Stannous tin content | 7.6 μ g SnCl ₂ .2H ₂ O/vial * | | † | † |
| Label | Complies | | Complies | Complies |

*Value given in label/product information.

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

| | | SUPPLIER | MALL | RADPH | MALL | MALL | RADPH |
|----------------------------------|--|---------------|----------|----------|----------|----------|----------|
| | | LOT/BATCH No. | 0940007B | 1610 | 0940010B | 0941003A | 1694 |
| SPECIFICATIONS | | EXPIRY DATE | 26/01/01 | June/01 | 23/04/01 | 28/09/02 | Nov/01 |
| Appearance before reconstitution | Freeze-dried solid | | Pass | Pass | Pass | Pass | Pass |
| Appearance after reconstitution | A clear, colourless solution | | Pass | Pass | Pass | Pass | Pass |
| Presence of vacuum | Complies | | N/A | Complies | N/A | N/A | Complies |
| pH | 6.0 – 7.0 after reconstitution | | | 5.5 | | | 5.7 |
| | 4.0 - 7.5 after reconstitution* | | 5.5 | | 5.5 | 5.0 | |
| Radiochemical purity | 1) ≥ 90.0 % as ^{99m} Tc-PYP | INIT. | 99.6 | 99.5 | 99.4 | 99.6 | 99.6 |
| | 2) as ^{99m} TcO ₄ ⁻ | | 0.2 | 0.3 | 0.4 | 0.1 | 0.2 |
| | 3) as colloidal ^{99m} Tc | | 0.2 | 0.2 | 0.2 | 0.3 | 0.2 |
| | 2) + 3) ≤ 10.0% | EXP. | 99.6 | 99.5 | 99.1 | 97.7 | 98.9 |
| | | | | 0.2 | 0.1 | 0.5 | 1.5 |
| | | | 0.2 | 0.4 | 0.4 | 0.8 | 1.0 |
| Sodium pyrophosphate content | 1-50 mg/mL sodium pyrophosphate on reconstitution | | Complies | Complies | Complies | Complies | Complies |
| Stannous tin content | 9.0 mg SnCl ₂ /vial ** | | | † | | | † |
| | 3.2 - 4.4 mg SnCl ₂ .2H ₂ O/vial * | | † | | † | † | |
| Label | Complies | | Complies | Complies | Complies | Complies | Complies |

*Value given in USP; ** Value given in label/product information

KIT FOR THE PREPARATION OF TECHNETIUM[^{99m}Tc] COLLOIDAL INJECTION

| | | SUPPLIER | RADPH** | RADPH** |
|----------------------------------|---------------------------------------|---------------|----------|----------|
| | | LOT/BATCH No. | 1620 | 1692 |
| SPECIFICATIONS | | EXPIRY DATE | June/01 | Nov / 01 |
| Appearance before reconstitution | Freeze-dried solid | | Pass | Pass |
| Appearance after reconstitution | A clear, colourless solution | | Pass | Pass |
| Presence of vacuum | Complies | | Complies | Complies |
| pH | 4.0 - 7.0 after reconstitution | | 5.0 | 4.8 |
| Radiochemical purity | ≥ 95.0 % as ^{99m} Tc-colloid | INIT. | 98.5 | 99.9 |
| | | EXP. | 96.9 | 97.6 |
| Stannous tin content | 1.0 mg SnCl ₂ * | | † | † |
| Biological distribution | ≥ 80% in the liver + spleen | | † | † |
| | ≤ 5% in the lungs | | † | † |
| Label | Complies | | Complies | Complies |

*Value given in label/product information.

**Technetium[^{99m}Tc] Calcium Phytate

SODIUM IODIDE¹³¹I CAPSULES

| | | SUPPLIER | ARI | ARI |
|-----------------------|---|---------------|----------|----------|
| | | LOT/BATCH No. | 10573 | 11800 |
| | | CALIB. DATE | 18/06/01 | 17/12/01 |
| SPECIFICATIONS | | EXPIRY DATE | 02/07/01 | 31/12/01 |
| Appearance | Gelatine capsule | | Pass | Pass |
| Gamma spectrum | Gamma spectrum does not differ significantly from that of a standardised I-131 solution | | Pass | Pass |
| Radionuclidic content | 90-110% of stated value | | 95.5 | 100 |
| Radionuclidic purity | ≤ 0.1% of the total radioactivity is due to ¹³³ I, ¹³⁵ I and other radionuclidic impurities | | N.D. | N.D. |
| Radiochemical purity | ≥ 95% of activity as iodide | INIT. | 96.3 | 99.4 |
| | | EXP. | 95.4 | 96.2 |
| Disintegration | The shell and its contents dissolve completely within 15 min. | | Complies | Complies |
| Label | Complies | | Complies | Complies |

SODIUM IODIDE[¹³¹I] INJECTION

| | | SUPPLIER | ARI | ARI |
|-----------------------|--|---------------|----------|----------|
| | | LOT/BATCH No. | 10597/01 | 11844 |
| | | CALIB. DATE | 20/06/01 | 19/12/01 |
| SPECIFICATIONS | | EXPIRY DATE | 04/07/01 | 02/01/02 |
| Appearance | A clear, colourless solution | | Pass | Pass |
| Particulate matter | None visible | | Pass | Pass |
| Gamma spectrum | Gamma spectrum does not differ significantly from that of a standardised I-131 solution | | Pass | Pass |
| pH | 7.0 – 8.5 | | 7.5 | 7.5 |
| Radionuclidic content | 90-110% of stated value | | 92 | 98 |
| Radionuclidic purity | ≤ 0.1 % of the total radioactivity is due to ¹³³ I, ¹³⁵ I and other radionuclidic impurities | | N.D. | N.D. |
| Radiochemical purity | ≥ 95% of activity as iodide | INIT. | 99.8 | 99.5 |
| | | EXP. | 99.7 | 100 |
| Label | Complies | | Complies | Complies |

THALLOUS[²⁰¹Tl] CHLORIDE INJECTION

| | | SUPPLIER | ARI | MALL(H) | ARI | MALL(H) | ARI |
|-----------------------|--|---------------|----------|----------|----------|----------|----------|
| | | LOT/BATCH No. | 19673 | 25102 | 10515 | 26721 | 11730 |
| | | CALIB. DATE | 12/02/01 | 07/03/01 | 13/06/01 | 13/06/01 | 10/12/01 |
| SPECIFICATIONS | | EXPIRY DATE | 17/02/01 | 14/03/01 | 18/06/01 | 20/06/01 | 15/12/01 |
| Appearance | A clear colourless solution | Pass | Pass | Pass | Pass | Pass | Pass |
| Particulate matter | None visible | Pass | Pass | Pass | Pass | Pass | Pass |
| Gamma spectrum | Gamma spectrum does not differ significantly from that of a standardised Tl-201 solution | Pass | Pass | Pass | Pass | Pass | Pass |
| pH | 4.5 – 7.0 | 5.0 | 6.0 | 5.5 | 5.5 | 5.0 | |
| Radiochemical content | 90-110% of stated value | 103 | 101 | 107 | 103 | 103 | |
| Radionuclidic purity | ≥ 97.0 % ²⁰¹ Tl at calibration | 99.5 | 99.6 | 99.3 | 99.6 | 99.5 | |
| | ≥ 97.0 % ²⁰¹ Tl at at expiry | 99.7 | 98.9 | 99.7 | 99.0 | 99.7 | |
| | ≤ 2.0% ²⁰² Tl at expiry | 0.3 | 1.1 | 0.2 | 1.0 | 0.3 | |
| | % ²⁰⁰ Tl at calibration | 0.4 | 0.05 | 0.6 | 0.05 | 0.4 | |
| | % ²⁰³ Pb at calibration | N.D. | N.D. | N.D. | N.D. | N.D. | |
| | % ²⁰¹ Pb at calibration | N.D. | N.D. | N.D. | N.D. | N.D. | |
| Radiochemical purity | ≥ 95.0 % as Tl(I) | INIT. | 99.7 | 98.0 | 99.6 | 99.5 | 99.8 |
| | | EXP. | 98.3 | 99.4 | 99.5 | 99.4 | 99.8 |
| Chemical purity | ≤ 10 µg/mL Tl | < 1 | < 1 | < 1 | < 1 | < 1 | |
| Benzyl alcohol | 90 – 110 % of stated value | 98.5 | - | 91 | - | 109 | |
| Label | Complies | Complies | Fails | Complies | Fails | Complies | |