

COMMONWEALTH DEPARTMENT OF HEALTH



Australian Radiation Laboratory

Quality Assurance of Radiopharmaceuticals —
Specifications and Test Procedures

by

J. Baldas, J. Bonnyman and P. M. Pojer

PART 2

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LOWER PLENTY ROAD
YALLAMBIE VICTORIA 3085
TELEPHONE: 433 2211

COLD KIT FOR THE PREPARATION OF TECHNETIUM (^{99m}Tc) TIN PYROPHOSPHATEDESCRIPTION

A freeze-dried preparation of sodium pyrophosphate and stannous chloride dispensed in vials which are sealed either, under vacuum or under an atmosphere of nitrogen. The radiopharmaceutical is prepared by reconstitution of the vial with Sodium Pertechnetate (^{99m}Tc) Injection.

TEST PROCEDURES

The kit should be reconstituted with Sodium Pertechnetate (^{99m}Tc) Injection according to the manufacturer's instructions.

For kits stored under vacuum, the pertechnetate should be drawn from the syringe immediately the septum is punctured. Report any absence of vacuum observed during reconstitution.

Appearance

1. Examine the vial containing the lyophilised mixture. Report any evidence of stickiness or if the material has a glassy appearance.
2. Examine the reconstituted injection and report any particulate matter or any evidence of undissolved material or cloudiness.

Identity

Prepare a KBr disc of the freeze-dried solid and record the infra-red spectrum. The infra-red spectrum should be identical to the reference spectrum.

pH

Measure the pH of the reconstituted solution using the standard procedure.

Radiochemical Purity

Activate four instant thin layer chromatography sheets (consisting of glass fibre coated with silica gel) by heating at $110\text{ }^{\circ}\text{C}$ for 10 minutes. The sheets should be such that during development the mobile phase will migrate a distance of 10 to 15 cm in about 10 minutes.

- a. Apply 2 μ l of the injection to two of the sheets and dry in a stream of nitrogen. Develop the sheets for 10 minutes in a chromatography tank containing methyl ethyl ketone through which nitrogen has been bubbled for 10 minutes prior to the chromatography. Remove the plates and dry. Determine the distribution of radioactivity using the radiochromatogram scanner.

Cut the sheets midway between the origin and solvent front and count the two sections in the gamma counter.

R_f values

Pertechnetate	0.9 - 1.0
Colloidal Tc + Tc-Pyrophosphate	0.0

Calculate the per cent of free pertechnetate.

- b. Apply 2 μ l of the injection to the other two sheets and develop for 10 minutes using a 13.6% sodium acetate as eluent. Allow the sheets to dry and measure the distribution of radioactivity using the radiochromatogram scanner.

Cut the sheets midway between the origin and the solvent front and count the two sections in the gamma counter.

R_f values

Colloidal Tc	0.0
Pertechnetate + Tc-Pyrophosphate	0.9 - 1.0.

Calculate the per cent of colloidal technetium and add to this the per cent of free pertechnetate ion.

Biological Distribution

Inject 0.1 ml of the injection into the tail vein of three mice and measure the total injected activity by placing each mouse into an ionisation chamber. After two hours sacrifice the mice and decapitate and collect and weigh the blood of two mice. Measure the activity retained in the mice and scan the mouse which has not been decapitated. Report on the quality of the scan.

Remove and measure the activity in the bladder, liver and femurs of all mice and calculate the average per cent of the injected dose in the

- (i) femurs
- (ii) liver
- (iii) urine and bladder.

Calculate the average per cent of the dose remaining in the blood.

Sodium Pyrophosphate Content

Test Solutions:

- (i) Iron standard solution: Dissolve 0.56 g ferrous ammonium sulphate (AR grade) in 50 ml of 6M hydrochloric and made up to 1 l with distilled water in a volumetric flask. Immediately before use dilute 100 ml of this solution to 1 l with distilled water. The iron standard solution contains 8 ppm Fe.
- (ii) Test solution: Use a suitable amount of the Injection or of a non-radioactive solution prepared by reconstituting with saline. Dilute to 1 ml with water.
- (iii) Reference solutions: Prepare a solution containing sodium pyrophosphate and stannous chloride in the same proportions as that stated in the lyophilised vial. Prepare a range of solutions containing from twice to one half the concentration of sodium pyrophosphate expected to be present in the test solutions.

To the test solution and to 1 ml of each of the reference solutions add successively -

- (i) 10 ml of a 0.1⁰/o w/v disodium hydrogen phosphate.
- (ii) 10 ml of the iron standard solution.
- (iii) 5 ml of glacial acetic acid.
- (iv) 5 ml of a 0.1⁰/o w/v hydroxylamine hydrochloride.

Also prepare a reagent blank containing 10 ml of 0.03M hydrochloric acid in place of the iron standard solution.

Dilute each of the solutions to 40 ml with distilled water and heat on a water-bath at 40 °C for 1 hour. To each solution the add 4 ml of a 0.1% w/v phenanthroline hydrochloride and dilute to 50.0 ml with distilled water. Measure the absorbance of each solution at 515 nm against the reagent blank. Using the absorbances of the reference solutions, draw a calibration curve and determine the concentration of sodium pyrophosphate in the test solution. Calculate the amount of sodium pyrophosphate present in the lyophilised vial.

Stannous Tin Content

Determine the stannous tin content by iodine titration (see General Test Procedures S 8).

Labelling

Report on product labelling.

INDIUM (¹¹¹In) DTPA INJECTIONDESCRIPTION

Indium (¹¹¹In) DTPA Injection is a clear, colourless solution of indium (¹¹¹In) diethylenetriaminepentaacetate and calcium-DTPA containing sufficient sodium chloride to make the Injection isotonic with blood. The Injection is sterile and pyrogen free.

TEST PROCEDURESAppearance

Examine the sample for the presence of particulate matter.

Radionuclide Content

Measure the radioactive content in a calibrated ionisation chamber and calculate the activity in the date and hour stated on the label.

Radionuclide Concentration

Using an automatic dispenser, dispense a 500 µl aliquot of the Injection and measure the indium-111 content in a calibrated ionisation chamber.

Identity

Place a drop of 0.008^o/o w/v nickel sulphate solution into two adjacent depressions of a white spot plate. To one add a drop of the reconstituted solution and to the other a drop of water to act as a reagent blank. To each add a drop of 10^o/o v/v ammonium hydroxide solution followed by a drop of dimethylglyoxime solution (1^o/o w/v in ethanol).

A distinct red precipitate should appear immediately in the reagent blank. If no precipitate occurs the test should be repeated. No red colour or precipitate should develop in the spot prepared with the reconstituted solution.

pH

Measure the pH of the sample using the standard procedure.

Radionuclidic Purity

Remove a small sample of the product (5-10 µCi indium-111) and determine the level of gamma emitting impurities by gamma spectrometry.

Radiochemical Purity

Measure the radiochemical purity of the labelled product immediately on arrival and at expiry in the following chromatographic system.

(i) Whatman No. 1	-	Saline
R_f values	-	
Hydrolysed In		0.0
In-DTPA		0.9-1.0

Biological Clearance

Inject approximately 0.1 ml of the solution onto a tail vein of at least 3 mice. Measure the total activity injected into each animal in an ionisation chamber. Place the mice into a suitable cage and allow free access to food and water.

After 24 hours sacrifice the mice and measure the activity remaining in the carcasses with tails removed. Correct all measurements for decay and calculate the activity in the carcass as a percentage of the injected activity. If significant activity is present in the tail the result should be discarded.

Product Labelling

Report on product labelling.

IODINATED (¹²⁵I) HUMAN ALBUMIN INJECTIONDESCRIPTION

Iodinated (¹²⁵I) Human Albumin Injection is a sterile, isotonic solution of human serum albumin which has been radioactively labelled with iodine-125. The Injection contains a bactericide.

TEST PROCEDURESAppearance

Examine the Injection for the presence of visible particulate matter.

Radionuclide Identification

Compare the gamma spectrum of a suitable amount of the injection with the iodine-125 reference spectrum.

Radionuclidic Content

Determine the iodine-125 content of the Injection at the date stated on the label using the method described in General Test Procedures S 4.2.

Radionuclidic Purity

Remove a sample (5 - 10 μ Ci) of the product and determine the radionuclidic purity by gamma spectroscopy using a Ge(Li) detector.

pH

Measure the pH of the injection using the standard procedure.

Radiochemical Purity

Place a volume of the Injection containing about 0.5 mg of human serum albumin onto two strips of Whatman No. 1 paper (5 cm width). Submit the paper strips to electrophoresis with 0.05M barbital buffer pH 8.6 at 500V for 30 minutes. Dry the papers and determine the distribution of radioactivity with the chromatogram scanner.

Under these electrophoretic conditions iodine-125 labelled human serum albumin migrates about 1.5 cm towards the cathode and iodide ion migrates about 12 cm towards the anode.

Count the regions of ^{125}I - labelled human serum albumin activity and the remainders of the paper strips in the gamma counter and calculate the per cent of iodine-125 activity attached to human serum albumin.

Total Protein

Test Solutions

(i) Biuret Reagent

- (a) Dissolve 1.73 g $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$ in 10 ml hot water.
- (b) Dissolve 17.3 g sodium citrate and 10 g anhydrous sodium carbonate by heating in 80 ml water.

When both solutions are cool, pour solution (a) into solution (b) while stirring and dilute to 100 ml.

Prepare human serum albumin standards containing 2, 1.5, 1.0, 0.75 and 0.5 times the amount of human serum albumin stated to be present in the Injection.

Into a series of test tubes, dispense in duplicate 5.0 ml of 0.75M sodium hydroxide solution and 0.1 ml of the ^{125}I - human albumin or human serum albumin standard. Immediately add 1.0 ml of biuret reagent to each tube and mix well. Prepare a reagent blank with 0.1 ml of water in place of serum.

After 15 minutes measure the absorbance of the standards and the ^{125}I - human serum albumin tubes at 545 nm against the reagent blank. Plot the calibration curve and determine the total protein content of the Injection.

Nature of Protein

Apply 2 μl of the Injection and 2 μl of a human serum albumin standard of the same concentration separately to two 5 x 30 cm cellulose acetate strips. Subject the strips to electrophoresis in 0.05M barbital buffer pH 8.6 at 400V for 1 hour. Remove excess buffer from the strips with blotting paper and then stain the strips for 7 minutes with 0.2% Ponceau S in 0.5M acetic acid. Wash the strips in 5% v/v acetic acid until the background is white (3 washings each for 3 minutes should be sufficient). Dry the strips by washing in 95% ethanol for 1 minute and then remove excess ethanol with blotting paper.

The Injection should give essentially one band of stained protein corresponding to the major band from the human serum albumin standard.

Benzyl Alcohol Content

Activate a 5 x 20 cm silica gel plate by heating at 80 °C for 1 hour. Mark the origin lightly with pencil and apply separate spots of

- a. 5 µl ^{125}I - human serum albumin
- b. 5 µl of 1% benzyl alcohol in methanol.

Allow the spots to dry and develop the plate in 15% v/v methanol in toluene. Allow the solvent front to migrate about 10 cm from the origin and then remove and dry the plate. Spray the plate with a freshly prepared solution of 5% w/v phosphomolybdic acid in ethanol and then heat the plate at 120 °C for 10-15 minutes.

Benzyl alcohol appears as a blue-green spot on a yellow background at R_f about 0.4. Report the R_f values and the intensity comparison of the spots produced by the Injection and the benzyl alcohol standard.

Labelling

Report on product labelling.

IODINATED (¹²⁵I) HUMAN FIBRINOGEN INJECTIONDESCRIPTION

A freeze-dried preparation of human fibrinogen uniformly labelled with iodine-125 to an average iodine content of 0.5 atom per molecule of fibrinogen. The product contains human albumin together with sodium chloride and sodium citrate which yield an isotonic solution when reconstituted.

TEST PROCEDURESAppearance

Report on the appearance of the freeze-dried product. Reconstitute the product according to the manufacturer's instructions and examine the solution for total solubility and particulate matter.

Radionuclide Content

Measure the iodine-125 content of the reconstituted vial using the methods described for the assay of iodine-125 in General Test Procedures S 4.2. Calculate the activity present at the date stated on the label.

Radionuclidic Purity

Remove a small sample of the reconstituted product (5 - 10 μ Ci iodine-125) and determine the levels of gamma emitting impurities by gamma spectrometry.

pH

Measure the pH using the standard procedure.

Radiochemical Puritya. Activity Coagulated by Thrombin

Measure the activity of a 0.3 ml sample of the reconstituted Injection in a polystyrene test tube and then add 0.1 ml of bovine thrombin solution (500 U strength). Shake vigorously and allow to stand for 20 minutes for the fibrin clot to form. Using a Pasteur pipette carefully transfer the supernate to another polystyrene test tube. Wash the fibrin clot twice with 0.5 ml aliquots of distilled water and add the washings to supernate. Measure the activities of the clot and the supernate plus washings and calculate the percent of the total iodine-125 activity present in the clot.

b. Free Iodide Activity

Submit 5 μ l of the Injection to paper electrophoresis on Whatman No. 1 chromatography paper at 500 V for 30 minutes with 0.05M barbital buffer pH 8.60. Under these conditions the mobilities are approximately

Iodinated fibrinogen	4cm	towards	the	anode
Iodide ion	12cm	"	"	"

Calculate the percent of the iodine-125 activity present as iodide ion.

Labelling

Report on the product labelling.

SODIUM IODIDE (¹²⁵I) SOLUTIONDESCRIPTION

A clear, colourless solution containing sodium iodide (¹²⁵I) and suitable for oral administration. The solution contains sodium thiosulphate or other suitable reducing agent.

TEST PROCEDURESAppearance

Examine the Solution and report the colour, clarity and the presence of visible particulate matter.

Radionuclide Identification

Compare the gamma spectrum of a suitable amount of the Sodium Iodide (¹²⁵I) Solution with the iodine-125 reference spectrum.

Radionuclidic Content

Determine the iodine-125 content of the Solution using the method described in General Test Procedures S 4.2. Calculate the activity present at the date stated on the label.

Radionuclidic Purity

Remove a small sample of the product (5-10 µCi iodine-125) and determine the levels of gamma emitting impurities by gamma spectrometry.

pH

Measure the pH of the solution using the standard procedure.

Radiochemical Purity

Determine the radiochemical purity of the Sodium Iodide (¹²⁵I) Solution using the procedure described for Sodium Iodide (¹³¹I) Injection.

Labelling

Report on product labelling.

SODIUM IODOHIPPURATE (¹²⁵I) INJECTIONDESCRIPTION

A clear, colourless aqueous solution containing sodium o-iodohippurate (¹²⁵I) and may contain a bactericide. The injection is sterile and pyrogen free. If labelled "for ERPF", the injection is suitable for use to measure effective renal plasma flow.

TEST PROCEDURESAppearance

Examine the Injection for the presence of particulate matter.

Radionuclidic Identification

Compare the gamma spectrum of a sample of the Injection with the iodine-125 reference spectrum.

Radionuclidic Purity

Remove a small sample of the product (5-10 μ Ci iodine-125) and determine the levels of gamma emitting impurities by gamma spectrometry.

Radionuclidic Content

Determine the iodine-125 content of the Injection using the method described in General Test Procedures S 4.2. Calculate the activity present at the date stated on the label.

pH

Measure the pH of the Injection using the standard procedure.

Radiochemical Purity

As for Sodium Iodohippurate (¹³¹I) Injection.

Benzy] Alcohol Content

As for Sodium Iodohippurate (¹³¹I) Injection.

Labelling

Report on product labelling.

SODIUM IODIDE (^{131}I) INJECTIONDESCRIPTION

A clear, colourless, sterile solution containing sodium iodide (^{131}I) stabilised by the addition of sodium thiosulphate or other suitable reducing agents.

TEST PROCEDURESAppearance

Examine the Injection for the presence of particulate matter.

Other Tests

Perform the tests described for Sodium Iodide (^{131}I) Solution.

SODIUM IODIDE (¹³¹I) SOLUTIONDESCRIPTION

A clear, colourless solution containing sodium iodide (¹³¹I) and suitable for oral administration. The solution contains sodium thiosulphate or other suitable reducing agent.

TEST PROCEDURESRadionuclide Identification

Compare the gamma spectrum of a suitable amount of the Solution with the iodine-131 reference spectrum.

Radionuclidic Content

Measure the iodine-131 content of the Solution in a calibrated ionisation chamber and calculate the activity at the date and hour stated on the label.

Radionuclidic Purity

Remove a small sample of the Solution (5-10 µCi iodine-131) and determine the levels of gamma emitting impurities by gamma spectrometry.

pH

Measure the pH of the Solution using the standard procedure.

Radiochemical Purity

Prepare a carrier solution by dissolving in 100 ml of distilled water -

- (i) 100 mg potassium iodide.
- (ii) 200 mg potassium iodate.
- (iii) 1 g sodium hydrogen carbonate.

Also prepare a solution containing 1 g of potassium iodide and 2 g of potassium iodate in 100 ml of distilled water but without any sodium hydrogen carbonate. This solution will slowly turn brown due to the liberation of iodine and should be freshly prepared as required.

a. Paper Chromatography

Spot two 5 cm wide strips of Whatman No. 1 paper with the carrier solution and on the same spots place 2 µl of the Sodium Iodide

(^{131}I) Solution. On two other strips place 2 μl of the potassium iodide/iodate solution. Develop the papers by ascending (or descending) chromatography using 75% v/v methanol as the eluent. Remove and dry the papers.

Determine the R_f of iodide and iodate using the two papers not containing iodine-131:

- (i) Gently dab one of the chromatograms with filter paper impregnated with a solution of 1% w/v potassium iodate in 1M acetic acid. A brown colouration indicates the position of iodide on the chromatogram. Calculate the R_f of iodide ion.
- (ii) Repeat the procedure on the other chromatogram but using 1% w/v potassium iodide in 1M acetic acid. A brown colouration indicates the position of iodate on the chromatogram.

Determine the distribution of radioactivity on the two chromatograms containing iodine-131 with the radiochromatogram scanner. The activity should be at the R_f determined for iodide ion.

Cut the chromatograms at a position between the R_f of iodide and iodate ions and count the two sections in a gamma counter. Calculate the per cent of non-iodide activity.

R_f values

Iodide	0.8
Iodate	0.6

b. Low Voltage Electrophoresis.

Proceed as for paper chromatography but perform the separation by use of electrophoresis in 0.05M barbital buffer pH 8.6 for 35 minutes at 400V. Under these conditions iodate moves about 3.5 cm and iodide about 9 cm towards the anode.

Labelling

Report on product labelling.

SODIUM IODOHIPPURATE (131I) INJECTIONDESCRIPTION

A clear, colourless, aqueous solution containing sodium o-iodohippurate (¹³¹I) and which may contain a bactericide. The Injection is sterile and pyrogen free. If labelled 'for ERPF', the Injection is suitable for use to measure effective renal plasma flow.

TEST PROCEDURESAppearance

Examine the Injection for the presence of particulate matter.

Radionuclidic Identification

Compare the gamma spectrum with the reference iodine-131 spectrum.

Radionuclidic Purity

Remove a small sample of the Injection (5-10 μ Ci iodine-131) and determine the levels of gamma emitting impurities by gamma spectrometry.

Radionuclidic Content

Measure the iodine-131 content of the sample in a calibrated ionisation chamber. Calculate the iodine-131 content at the date and hour stated on the label.

Identity

Identify the presence of o-iodohippurate by high performance liquid chromatography.

Column	μ Bondapak C18.
Solvent	0.1% phosphoric acid in water.
Detection	Ultraviolet absorbance at 254 nm.

Dilute the radioactive sample to 1:10 with distilled and then inject 10 μ l onto the column. Elute at 1 ml/min and measure the retention time of the o-iodohippurate peak. Repeat using 0.5 mg/ml solution of sodium o-iodohippurate. Compare the retention times - they should agree to within 0.5 minute.

pH

Measure the pH of the Injection using the standard procedure.

Radiochemical Purity

a. Paper Chromatography

Solvent: Prepare a mixture of

benzene	2 parts
acetic acid	2 parts
water	1 part.

Shake well and allow to separate. Remove the upper benzene phase by use of a separating funnel.

Dissolve 5 mg of o-iodohippuric acid in 1 ml of ether and place a 2 μ l spot onto each of two 5 cm wide strips of Whatman No. 1 chromatography paper. Separately, on the same strips place 2 μ l of the Injection under test alongside the o-iodohippuric acid spot. Develop the chromatograms for 1 hour by descending chromatography using the upper benzene phase as eluent. Remove and dry the papers. Locate the spot due to o-iodohippuric acid by examining the chromatogram under an ultraviolet lamp having maximum output at about 366 nm. Locate the areas of radioactivity with the radiochromatogram scanner.

R_f values

<u>o</u> -Iodohippurate	0.8
Iodide	0.0

Cut the papers into segments containing the o-iodohippurate and iodide activity and count in a gamma counter. Determine the per cent of the activity present as o-iodohippurate. If the injection is intended for ERPF studies, determine the per cent activity present as iodide ion.

b. Low Voltage Electrophoresis

Place 2 μ l of the Injection onto the centre of two 5 cm wide strips of Whatman No. 1 paper and subject to electrophoresis for 40 min at 400 V in 0.05M barbital buffer pH 8.6. Dry the strips and determine the radioactivity distribution with the radiochromatogram scanner.

Under these conditions the o-iodohippurate ion moves about 6 cm and the iodide ion 12-13 cm towards the anode. Determine the per cent of the activity present as o-iodohippurate and iodide.

Benzyl Alcohol Content

Measure the benzyl alcohol content by high performance liquid chromatography (see General Test Procedures S 9).

Labelling

Report on product labelling.

XENON (^{133}Xe) INJECTIONDESCRIPTION

Xenon (^{133}Xe) Injection is a sterile solution of xenon-133 made isotonic with blood by the addition of sodium chloride.

TEST PROCEDURESAppearance

Examine the Injection for the presence of any particulate matter.

Radionuclide Content

Measure the radionuclide content in a calibrated ionisation chamber and calculate the activity at the date and hour stated on the label.

Radionuclide Identity

Compare the gamma spectrum of a suitable amount of the Injection with the xenon-133 reference spectrum.

Radionuclidic Purity

Remove a sample of the Injection (5-10 μCi xenon-133) and determine the levels of gamma emitting impurities by gamma spectrometry.

pH

Measure the pH of the Injection using the standard procedure.

Labelling

Report on product labelling.

THALLIUM (²⁰¹Tl) CHLORIDE INJECTIONDESCRIPTION

A clear, colourless, sterile, apyrogenic solution of thallos (²⁰¹Tl) chloride. The solution may contain a bactericide.

TEST PROCEDURESAppearance

Examine the Injection for the presence of any particulate matter.

Radionuclidic Content

Measure the thallium-201 content of the Injection in a calibrated ionisation chamber and calculate the activity at the date and hour stated on the label.

Radionuclidic Identity

Compare the gamma spectrum of the Injection to that of the standard thallium-201 spectrum.

Radionuclidic Purity

Remove a small sample of the Injection (5 - 10 µCi) and determine the levels of gamma emitting impurities by gamma spectrometry.

pH

Measure the pH of the sample using the standard procedure.

Radiochemical Purity

Determine the radiochemical of the Injection using the following systems.

(a) Paper Chromatography

Whatman 3MM - 0.1M Na₂HPO₄: Acetone (1:9)

R_f values

Thallos ion 0.0

Thallic ion 1.0

(b) High Voltage Electrophoresis

Place 2 µl spots of the Injection onto the centre of Whatman No. 1 paper strips and subject these to HVE at 1500V for 15 minutes using 0.1M Na H₂PO₄ as the buffer. Dry the papers and determine the distribution of radioactivity with a radiochromatogram scanner.

Under these conditions thallic ion remains at the point of application while thallos ion moves about 14 cm towards the cathode.

Chemical Purity

Thallium Content

Standard Solutions - Dissolve 98.8 mg of thallos sulphate (Tl_2SO_4) in 100 ml of distilled water and then make up to 1 l in a volumetric flask. This stock solution contains 80 ppm of thallium. Prepare 4, 6, and 8 ppm thallium standards by diluting the stock solution to 1:20, 1:15, and 1:10 respectively.

Test procedure

Add 0.5 ml of the Injection to be tested and 0.5 ml of each of the thallium standards separately into four test tubes. Add 0.5 ml of 5M hydrochloric acid and 1 drop of bromine water to each tube and mix well. If the colour of the bromine water is discharged, continue adding bromine water dropwise until a permanent yellow colour persists. Decolourise the solutions by adding 1 drop of 3% (w/v) sulphosalicylic acid in water. Add 1 ml of rhodamine B solution (0.1% in water) and 1.0 ml of benzene. Stopper the tubes and shake well for one minute. Allow the layers to separate and measure the absorbance of the upper (benzene) layers at 550 nm against a reagent blank (prepared by substituting water for the test solutions) using micro 10 mm cells. Plot a calibration curve from the measured absorbances of the standard thallium solutions and determine the thallium content of the injection.

Iron Content

Determine the iron content of the solution by u.v. spectrophotometry (see General Test Procedures S 7.1).

Copper Content:

Determine the copper content of the solution by u.v. spectrophotometry (see General Test Procedures S 7.6).

Benzyl Alcohol Content

Determine the benzyl alcohol content of the Injection by high performance liquid chromatography (see General Test Procedures S 9).

Labelling

Report on product labelling.

SODIUM PHOSPHATE (32P) INJECTION - SPECIFICATIONSAppearance

Clear, colourless solution free of visible particulate matter.

pH

6.0 - 8.0

Radionuclide Purity

The beta spectrum does not differ significantly from that of a standardised phosphorus - 32 solution under identical conditions.

Radiochemical Purity

Greater than 95 per cent of phosphorus-32 activity is present in the form of orthophosphate ion.

Radionuclide Content

The content of phosphorus-32 is not less than 90.0 per cent and not more than 110.0 per cent of the content of phosphorus-32 stated on the label at the date and hour stated on the label.

Specific Radioactivity

Greater than 0.3 millicuries phosphorus-32 per mg of orthophosphate ion.

Sterility

Complies with the test for sterility.

Labelling

The label on the container states -

1. The product name.
2. The content of phosphorus-32 at a given date and hour.
3. That the Injection is radioactive.
4. Either it does not contain a bactericide or the name and proportion of any added bactericide.
5. The manufacturer's name.

6. The batch number.
7. The expiry date and hour.

The label on the package also states -

1. The total volume in the container(s).
2. The content of total phosphate.
3. Recommended storage conditions.

CHROMIC CHLORIDE (⁵¹Cr) INJECTION - SPECIFICATIONSAppearance

A clear, colourless or very faintly yellow solution free of visible particulate matter.

Radionuclide Content

The content of chromium-51 is not less than 90.0 per cent and not greater than 110.0 per cent of the content of chromium-51 stated on the label at the date and hour stated on the label.

Radionuclidic Purity

No other radioisotopes detectable by gamma spectroscopy.

pH

1.0 - 4.0.

Radiochemical Purity

Greater than 95 per cent of the chromium-51 activity is present in the form of the chromic ion.

Sterility

Complies with the test for sterility.

Pyrogens

Complies with the test for pyrogens.

Labelling

The label on the container states

1. The product name.
2. The content of chromium-51 at the date and hour stated on the label.
3. That the Injection is radioactive.
4. Either that the Injection does not contain a bactericide or the name and proportion of any added bactericide.
5. The manufacturer's name.
6. The batch number.
7. The expiry date and hour.

The label on the package also states -

1. The total volume in the container(s).
2. Recommended storage condition.

CHROMIUM (51Cr) - EDTA INJECTION - SPECIFICATIONSAppearance

A violet coloured solution free of any particulate matter.

Radionuclide Content

The content of chromium-51 is not less than 90.0 per cent and not more than 110.0 per cent of the content of chromium-51 stated on the label at the date and hour stated on the label.

Radionuclidic Purity

No other gamma emitting radionuclides detectable by gamma spectrometry.

pH

6.0 - 8.0.

Radiochemical Purity

Greater than 95.0 per cent of the total chromium-51 radioactivity is in the form of chromic - EDTA complex.

Total EDTA and Uncomplexed EDTA

Refer to manufacturer's specifications.

Benzyl Alcohol Content

90 - 110 per cent of that stated on the label.

Sterility

Complies with the test for sterility.

Pyrogens

Complies with the test for pyrogens.

Labelling

The label on the container states -

1. The product name.
2. The content of chromium-51 at the date and hour stated on the label.
3. That the Injection is radioactive.

4. The volume of the Injection.
5. Either that the Injection does not contain a bactericide, or the name and proportion of any added bactericide.
6. The batch number.
7. The expiry date and hour.

The label on the container also states -

1. The content of chromium-EDTA.

SODIUM CHROMATE (^{51}Cr) STERILE SOLUTION - SPECIFICATIONS

Appearance

A clear, colourless or faintly yellow solution free of visible particulate matter.

Radionuclidic Purity

No other radionuclides detectable by gamma spectrometry.

Specific Activity

Not less than 20 mCi per milligram of total chromium at the date and hour stated on the label.

Radiochemical Purity

Greater than 90 per cent of the chromium-51 activity is in the form of chromate ion.

Radionuclide Content

The content of chromium-51 is not less than 90.0 per cent and not more than 110.0 per cent of the content of chromium-51 stated on the label at the date and hour stated on the label.

pH

5.0 - 8.0.

Sterility

Complies with the test for sterility.

Labelling

The label on the container states -

1. The product name.
2. The content of chromium-51 at the date and hour stated on the label.
3. That the Solution is radioactive.
4. That the Solution does not contain a bactericide.
5. The manufacturer's name.
6. The batch number.
7. The expiry date and hour.

The label on the package also states -

1. The total volume of solution in the container(s).
2. The content of total chromium expressed in milligrams per millilitre of solution.
3. Recommended storage conditions.

CYANOCOBALAMIN (^{57}Co) ORAL SOLUTION OR CAPSULES – SPECIFICATIONS

Appearance

A freeze-dried solid or an aqueous solution.

Radionuclide Content

The content of cobalt-57 is not less than 85.0 per cent and not more than 115.0 per cent of the content of cobalt-57 stated on the label at the date stated on the label.

Radionuclidic Purity

Not more than 1.0 per cent of the total radioactivity is due to cobalt-60 at the date stated on the label.

pH

The pH of the oral solution is in the range 5.0 – 7.0.

Radiochemical Purity

Not less than 90.0 per cent of the cobalt-57 activity is in the form of cyanocobalamin.

Labelling

The label on the container states –

1. The name and form of the product.
2. The content of cobalt-57 at the date stated on the label.
3. That the product is radioactive.

The label on the package also states –

1. Recommended storage conditions.
2. The expiry date of the product.
3. The total quantity in the container.
4. The name and amount of any added stabilising agent.

CYANOCOBALAMIN (^{58}Co) ORAL SOLUTION OR CAPSULES - SPECIFICATIONS

The specifications are as for cyanocobalamin (^{57}Co) oral solution or capsule with ^{57}Co being replaced by ^{58}Co , excepting for -

Radionuclide Content

The content of cobalt-58 is not less than 90.0 per cent and not greater than 110.0 per cent of the content of cobalt-58 stated on the label at the date stated on the label.

FERRIC CITRATE (⁵⁹Fe) INJECTION - SPECIFICATIONSAppearance

A clear, colourless or faintly orange-brown solution free of visible particulate matter.

Radionuclide

Iron-59, prepared by the neutron irradiation of iron-58 sufficiently low in iron-54 to ensure that the final content of iron-55 is not more than 2 per cent of the total activity.

Radionuclidic Purity

The content of iron-55 is not more than 2 per cent of the total activity at the date stated on the label.

Specific Activity

Not less than 1 mCi per mg of total iron at the date stated on the label.

Radionuclidic Content

The content of iron-59 is not less than 90.0 per cent and not more than 110.0 per cent of the content of iron-59 stated on the label at the date stated on the label.

pH

6.0 - 8.0.

Sterility

Complies with the test for sterility.

Pyrogens

Complies with the test for pyrogens.

Labelling

The label on the container states -

1. The product name.
2. The content of iron-59 at a given date.
3. That the Injection is radioactive.
4. That the Injection does not contain a bactericide.

The label on the package also states -

1. The total volume in the container(s).
2. The content of total iron.
3. The calculated content of iron-55 at the date stated on the container.
4. Recommended storage conditions.
5. The manufacturer's name.
6. The batch number.
7. The expiry date.

GALLIUM CITRATE (⁶⁷Ga) INJECTION - SPECIFICATIONSAppearance

Clear, colourless solution containing no particulate matter.

Radionuclide Content

The content of gallium-67 is not less than 90.0 per cent and not more than 110.0 per cent of the content of gallium-67 at the date and hour stated on the label.

pH

4.5 - 7.5.

Radionuclidic Purity

All other gamma emitters should be less than 0.1% at the time of calibration.

Radiochemical Purity

Greater than 95 per cent of the gallium-67 activity is in the form of gallium citrate.

Benzyl Alcohol

90-110% of the concentration stated on the package label.

Zinc

Less than 20 ppm.

Sterility

Complies with the test for sterility.

Pyrogens

Complies with the test for pyrogens.

Labelling

The label on the container states -

1. The product name.
2. The content of the gallium-67 at the date and hour stated on the label.

3. That the Injection is radioactive.
4. Either that it does not contain a bactericide or the name and proportion of any added bactericide.
5. The manufacturer's name.
6. The batch number.
7. The expiry date.

The label on the package also states -

1. The total volume in the container(s).
2. Recommended storage conditions.

L-SELENOMETHIONINE (⁷⁵Se) INJECTION - SPECIFICATIONSAppearance

A clear, colourless or faintly yellow solution free of visible particulate matter.

Radionuclide Content

The content of selenium-75 is not less than 90.0 per cent and not more than 110.0 per cent of the content of selenium-75 stated on the label at the date stated on the label.

Radionuclidic Purity

No other radionuclides detectable by gamma spectrometry.

pH

6.0 - 8.0.

Radiochemical Purity

Not less than 90 per cent of the selenium-75 activity is present in the form of selenomethionine at the date stated on the label.

Sterility

Complies with the test for sterility.

Pyrogens

Complies with the test for pyrogens.

Labelling

The label on the container states -

1. The product name.
2. The content of selenium-75 at the date and hour stated on the label.
3. That the Injection is radioactive.
4. The volume of the Injection.
5. Either that the Injection does not contain a bactericide, or the name and proportion of any added bactericide.
6. The batch number.
7. The expiry date.

The label on the package also states -

1. Recommended storage conditions.

SODIUM PERTECHNETATE (^{99m}Tc) INJECTION - SPECIFICATIONSDescription

Clear, colourless solution containing no particulate matter.

pH

4.5 - 7.5.

Radionuclide Content

The content of technetium-99m is not less than 90.0 per cent and not more than 110.0 per cent of the content of technetium-99m stated on the label at the date and hour stated on the label.

Radionuclidic Purity

Sodium Pertechnetate (^{99m}Tc) Injection meets the following specifications at the time of administration.

- (i) Technetium-99m derived from molybdenum-99 produced by neutron irradiation of stable molybdenum.

^{99}Mo	< 1 μCi per mCi ^{99m}Tc
All other gamma emitters	< 0.1 μCi per mCi ^{99m}Tc .

- (ii) Technetium-99m derived from molybdenum-99 produced by uranium fission.

^{99}Mo	< 1 μCi per mCi ^{99m}Tc
^{103}Ru	< 0.05 μCi per mCi ^{99m}Tc
^{131}I	< 0.05 μCi per mCi ^{99m}Tc
^{132}I	< 0.75 μCi per mCi ^{99m}Tc
^{89}Sr	< 0.0006 μCi per mCi ^{99m}Tc
^{90}Sr	< 0.00006 μCi per mCi ^{99m}Tc
All other beta or gamma emitters	< 0.1 μCi per mCi ^{99m}Tc
Alpha emitters	< 0.001 nCi per mCi ^{99m}Tc .

Radiochemical Purity

Greater than 95 per cent of the technetium-99m activity is in the form of pertechnetate ion.

Chemical Purity

Aluminium	< 10 ppm
Chromium	< 0.1 ppm as dichromate
Methyl Ethyl Ketone	< 0.1 ⁰ /o

Note

- (A) Chromium is only determined in generator eluates containing added dichromate.
- (B) Methyl ethyl ketone is only determined in the Injection prepared using the solvent extraction process.

Sterility

Complies with the test for sterility.

Labelling

The labels on the container and the package state -

1. The product name.
2. The content of technetium-99m at the date and hour stated on the label.
3. The volume in the container.
4. That the Injection is radioactive.
5. The expiry date and hour of the Injection.
6. The manufacturer's name.
7. The batch number.

COLD KIT FOR THE PREPARATION OF TECHNETIUM
(^{99m}Tc) COLLOIDAL ANTIMONY SULPHIDE INJECTION - SPECIFICATIONS

Appearance

- (i) Antimony Sulphide Pre-Colloid
Clear, orange solution free of visible particulate matter.

- (ii) Buffer Solution
A clear, colourless solution free of any particulate matter.

- (iii) Reconstituted Product
A clear, orange solution with no evidence of any flocculent precipitate.

pH

- (i) Citrate buffer 11.5 - 12.1 after 1:20 dilution
- (ii) Reconstituted product 5.2 - 5.4

Radiochemical purity

Less than 5 per cent of the technetium-99m activity in the reconstituted product is in the form of pertechnetate ion.

Biological Distribution

Twenty minutes after injection of the reconstituted product into mice, the distribution of technetium-99m is as follows

Liver and spleen	> 80 ⁰ /o
Lungs	< 5 ⁰ /o.

Sterility

Complies with the test for sterility.

Pyrogens

Complies with the test for pyrogens.

Chemical Purity

Sb content (Pre-Colloid) 0.43 - 0.51 mg Sb/ml

Labelling

The label on each vial states -

1. The component name.
2. The volume of each solution.
3. That the contents of each vial are not to be injected without reconstitution according to the manufacturer's directions.
4. That the contents of each vial are sterile and pyrogen free.
5. The batch number.
6. The expiry date.

The label on the package also states -

1. The composition of each vial.
2. Directions for reconstituting each vial.
3. Recommended storage conditions.

TECHNETIUM (^{99m}Tc) COLLOIDAL RHENIUM SULPHIDE INJECTION - SPECIFICATIONSAppearance

Clear to slightly hazy colloid containing no flocculent precipitate.

pH

4.0 - 7.0.

Radionuclide Content

The content of technetium-99m is not less than 90.0 per cent and not more than 110.0 per cent of the content of technetium-99m stated on the label at the date and hour stated on the label.

Radionuclidic Purity

At the time of administration, the product meets the specification for Sodium Pertechnetate (^{99m}Tc) Injection.

Radiochemical Purity

Greater than 92 per cent of the technetium-99m activity is in the form of colloid.

Biological Distribution

Twenty minutes after injection into mice, the distribution of technetium-99m is as follows

Liver plus spleen	> 80%
Lung	< 5%.

Sterility

Complies with the test for sterility.

Rhenium Content

Re < 0.22 mg per millilitre.

Labelling

The label on the container states -

1. The product name.
2. The content of technetium-99m at the date and hour stated on the label.

3. That the Injection is radioactive.
4. The expiry date and hour of the Injection.
5. The total volume in the container.
6. The manufacturer's name.
7. The batch number.

The label on the package also states -

1. The rhenium content of the preparation.
2. Recommended storage conditions.

TECHNETIUM (^{99m}Tc) COLLOIDAL SULPHUR INJECTION - SPECIFICATIONSAppearance

Clear to slightly hazy colloid containing no flocculent precipitate.

pH

4.0 - 7.0.

Radionuclide Content

The content of technetium-99m is not less than 90.0 per cent and not more than 110.0 per cent of the content of technetium-99m stated on label at the date and hour stated on the label.

Radionuclidic Purity

At the time of administration, the product meets the specification for Sodium Pertechnetate (^{99m}Tc) Injection.

Radiochemical Purity

Greater than 92 per cent of the technetium-99m activity is in the form of colloid.

Biological Distribution

Twenty minutes after injection into mice, the distribution of technetium-99m is as follows

Liver plus spleen	> 80 per cent
Lung	< 5 per cent.

Sterility

Complies with the test for sterility.

Labelling

The label on the container states -

1. The product name.
2. The content of technetium-99m at the date and hour stated on the label.
3. That the Injection is radioactive.

4. The expiry date and hour of the Injection.
5. The total volume in the container.
6. The manufacturer's name.
7. The batch number.

The label on the package also states -

1. Recommended storage conditions.

COLD KIT FOR THE PREPARATION OF TECHNETIUM (^{99m}Tc)
COLLOIDAL SULPHUR INJECTION - SPECIFICATIONS

Appearance

All component solutions are colourless and free of particulate matter.

pH

The reconstituted product meets the requirements for Technetium (^{99m}Tc) Colloidal Sulphur Injection.

Radiochemical Purity

The reconstituted product meets the requirements for Technetium (^{99m}Tc) Colloidal Sulphur Injection.

Biological Distribution

The reconstituted product meets the requirements for Technetium (^{99m}Tc) Colloidal Sulphur Injection.

Sterility

Complies with the test for sterility.

Pyrogens

Complies with the test for pyrogens.

Labelling

The label on each container states -

1. The component name.
2. The volume of each solution.
3. That the contents of each vial are not to be injected without reconstitution according to the manufacturer's directions.
4. That the contents of each vial are sterile and pyrogen free.
5. The batch number.
6. The expiry date.

The label on the package also states -

1. The composition of each container.
2. Directions for reconstitution.
3. Recommended storage conditions.
4. The expiry time of the Injection after reconstitution.

COLD KITS FOR THE PREPARATION OF ^{99m}Tc -MAA AND
 ^{99m}Tc -MICROSPHERES - SPECIFICATIONS

Appearance

A freeze-dried plug with no evidence of any moisture. Reconstitution with Sodium Pertechnetate (^{99m}Tc) Injection produces a whitish suspension of macroaggregates or microspheres which slowly settle on standing.

pH

4.0 - 7.0 after reconstitution.

Radiochemical Purity

After reconstitution, greater than 90 per cent of the technetium-99m activity is attached to the albumin aggregates or microspheres.

Particle Size

After reconstitution no clumps of particles are present and most of the particles are in the 10 - 100 μm size range.

No particle is larger than 150 μm .

Biological Distribution

Fifteen minutes after injection into mice, the distribution of technetium-99m activity is

Liver plus spleen	< 5 per cent
Lung	> 90 per cent.

Sterility

Complies with the test for sterility.

Pyrogens

Complies with the test for pyrogens.

Labelling

The label on the container states -

1. The product name.
2. The manufacturer's name.

3. The expiry date.
4. The batch number.

The label on the package also states -

1. The composition of the vial.
2. Directions for reconstituting the product.
3. Recommended storage conditions.
4. The expiry time of the product after reconstitution.

TECHNETIUM (^{99m}Tc) - LABELLED MACROAGGREGATED FERROUS
HYDROXIDE INJECTION - SPECIFICATIONS

Appearance

White to pale green coloured particles suspended in a pale straw coloured vehicle.

Radionuclide Content

The Injection contains not less than 90.0 per cent and not more than 110.0 per cent of the stated technetium-99m activity at the date and hour stated on the label.

Radionuclidic Purity

At the time of administration, the product meets the specification for Sodium Pertechnetate (^{99m}Tc) Injection.

pH

6.0 - 7.5.

Radiochemical Purity

Not more than 5 per cent of the radioactivity is present in the form of pertechnetate.

Particle Size

The sample contains no clumps or particles and most of the particles are in the 20 - 50 μm size range.

No particle is greater than 150 μm .

Biological Distribution

Twenty minutes after injection into mice, the distribution of technetium-99m is as follows

Liver plus spleen	< 10 per cent
Lung	> 90 per cent.

Sterility

Complies with the test for sterility.

Labelling

The label on the container states:

1. The product name.
2. The content of technetium-99m at the date and hour stated on the label.
3. The volume in the container.
4. That the Injection is radioactive.
5. The expiry date and time of the Injection.
6. The manufacturer's name.
7. The batch number.

COLD KIT FOR THE PREPARATION OF
TECHNETIUM (^{99m}Tc) GLUCONATE INJECTION - SPECIFICATIONS

Appearance

A freeze-dried plug with no evidence of any moisture. Reconstitution with Sodium Pertechnetate (^{99m}Tc) Injection produces a clear, colourless solution free of any particulate matter.

pH

5.0 - 7.0 after reconstitution.

Radiochemical Purity

After reconstitution, greater than 95 per cent of the technetium-99m activity is in the form of a technetium - gluconate complex.

Biological Clearance

10-16% of injected activity remains in the body 6 hours after injection of the reconstituted Injection into mice.

Biological Distribution

Two hours after injection of the reconstituted Injection into mice, greater than 50 per cent of the total activity remaining in the body is located in the kidneys.

Sterility

Complies with the test for sterility.

Pyrogens

Complies with the test for pyrogens.

Stannous Tin

Greater than 60% of the stated quantity of stannous tin.

Labelling

The label on the container states -

1. The product name.
2. The manufacturer's name.
3. The expiry date.
4. The batch number.

The label on the package also states -

1. The composition of the vial.
2. Directions for reconstituting the product.
3. Recommended storage conditions.
4. The expiry time of the Injection after reconstitution.

COLD KIT FOR THE PREPARATION OF
TECHNETIUM (^{99m}Tc) DTPA INJECTION - SPECIFICATIONS

Appearance

Freeze-dried plug with no evidence of any moisture. Reconstitution with Sodium Pertechnetate (^{99m}Tc) Injection produces a clear, colourless solution free of any particulate matter.

pH

4.0 - 7.0 after reconstitution.

Sterility

Complies with the test for sterility.

Pyrogens

Complies with the test for pyrogens.

Radiochemical Purity

After reconstitution, greater than 95 per cent of the technetium- 99m activity is in the form of a technetium-DTPA complex.

Biological Clearance

5⁰/o of the injected activity remains in the carcass 6 hours after injection of the reconstituted Injection into mice.

Stannous Tin

Greater than 60⁰/o of the stated quantity of stannous tin.

Labelling

The label on the container states -

1. The product name.
2. The manufacturer's name.
3. The expiry date.
4. The batch number.

The label on the package also states -

1. The composition of the vial.
2. Directions for reconstituting the product.
3. Recommended storage conditions.
4. The expiry time of the Injection after reconstitution.

COLD KIT FOR THE PREPARATION OF TECHNETIUM (^{99m}Tc)
METHYLENEDIPHOSPHONATE INJECTION - SPECIFICATIONS

Appearance

A freeze-dried plug with no evidence of any moisture. Reconstitution with Sodium Pertechnetate (^{99m}Tc) Injection produces a clear, colourless solution free of any particulate matter.

pH

5.5 - 7.5 after reconstitution.

Radiochemical Purity

After reconstitution,

^{99m}Tc as pertechnetate	< 5 ⁰ /o
^{99m}Tc as colloidal Tc	< 5 ⁰ /o
^{99m}Tc as Tc-MDP	> 90 ⁰ /o.

Biological Distribution

At 2 hours after intravenous injection into mice the distribution of the injected radioactivity of the reconstituted Injection is

1. Not less than 30 per cent attached to the skeleton.
2. Not greater than 3 per cent retained in the liver.
3. Not greater than 3 per cent remaining in the blood.

Stannous Tin Content

Greater than 60⁰/o of the stated quantity of stannous tin.

Sterility

Complies with the test for sterility.

Pyrogens

Complies with the test for pyrogens.

Labelling

The label on the vial states -

1. The product name.
2. The content of methylenediphosphonic acid.

3. The name and content of the stannous salt.
4. The manufacturer's name.
5. The lot or batch number and the expiry date of the product.

The label on the package also states -

1. That the product is intended for use after the addition of Sodium Pertechnetate (^{99m}Tc) Injection.
2. Recommended storage conditions.
3. The expiry time of the Injection after reconstitution.

COLD KIT FOR THE PREPARATION OF
TECHNETIUM (^{99m}Tc) TIN PYROPHOSPHATE INJECTION - SPECIFICATIONS

Appearance

A freeze-dried plug with no evidence of any moisture. Reconstitution with Sodium Pertechnetate (^{99m}Tc) Injection produces a clear, colourless solution free of any particulate matter.

Pyrophosphate Content

The pyrophosphate content is not less than 80 per cent or more than 120 per cent of that stated on the label.

Radiochemical Purity

Not less than 90 per cent of the radioactivity of the reconstituted Injection is present as a technetium-pyrophosphate complex.

pH

6.0 - 7.0 after reconstitution.

Biological Distribution

At 2 hours after intravenous injection of the reconstituted Injection into mice -

1. Not less than 30 per cent of the activity is attached to the skeleton.
2. Not greater than 3 per cent of the activity is retained in the liver.
3. Not greater than 2 per cent of the activity remains in the blood.

Stannous Tin

Greater than 60 per cent of the stated quantity of stannous tin.

Sterility

Complies with the test for sterility.

Pyrogens

Complies with the test for pyrogens.

Labelling

The label on the container states -

1. The product name.
2. The manufacturer's name.
3. The expiry date.
4. The batch number.

The label on the package also states -

1. The composition of the vial.
2. Directions for reconstituting the product.
3. Recommended storage conditions.
4. The expiry time of the Injection after reconstitution.

INDIUM (^{111}In) DTPA INJECTION - SPECIFICATIONSAppearance

Clear, colourless solution containing no particulate matter.

Radionuclide Content

The content of indium-111 is not less than 90.0 per cent and not more than 110.0 per cent of the content of indium-111 stated on the label at the date and hour stated on the label.

Radionuclide Concentration

The concentration of indium-111 is not less than 90.0 per cent and not more than 110.0 per cent of the concentration of indium-111 stated on the label at the date and hour stated on the label.

pH

7.0 - 8.0.

Radionuclidic Purity

At the time of injection,

$^{114\text{m}}\text{In}$	<	6 $\mu\text{Ci/mCi}$	^{111}In
^{65}Zn	<	6 $\mu\text{Ci/mCi}$	^{111}In .

Radiochemical Purity

Greater than 90 per cent of the indium-111 is in the form of indium-DTPA.

Biological Clearance

Less than 5⁰/o of the injected activity remains in the carcass 24 hours after injection into mice.

Sterility

Complies with the test for sterility.

Pyrogens

Complies with the test for pyrogens.

Labelling

The label on the container states -

1. The product name.
2. The content of indium-111 at the date and hour stated on the label.
3. That the Injection is radioactive.
4. Either that it does not contain a bactericide or the name and proportion of any added bactericide.
5. The manufacturer's name.
6. The batch number.
7. The expiry date.

The label on the package also states -

1. The total volume in the container(s).
2. Recommended storage conditions.

IODINATED (¹²⁵I) HUMAN ALBUMIN INJECTION - SPECIFICATIONSAppearance

A clear, colourless solution, free of visible particulate matter.

Radionuclide Content

The content of iodine-125 is not less than 85.0 per cent and not more than 115.0 per cent of the iodine-125 content stated on the label at the date stated on the label.

pH

6.5 - 8.5.

Radiochemical Purity

Not less than 95 per cent of the iodine activity is attached to the human serum albumin.

Radionuclidic Purity

Not more than 1.0 per cent of the total activity at the time of calibration is due to iodine-126.

Total Protein

The protein content of the injection is not less than 10 mg/ml and is between 80.0 and 120.0 per cent of the value stated on the label.

Nature of Protein

The human serum albumin contains not more than 5 per cent of globulins.

Sterility

Complies with the test for sterility.

Pyrogens

Complies with the test for pyrogens.

Sterility

Complies with the test for sterility.

Pyrogens

Complies with the test for pyrogens.

Labelling

The label on the container states -

1. The product name.
2. The content of iodine-125 at the date stated on the label.
3. That the Injection is radioactive.
4. The weight of human albumin in the container.
5. The manufacturer's name
6. The batch number.
7. The expiry date of the Injection.

The package label also states -

1. The total volume in the container(s).
2. Recommended storage conditions.
3. The name and proportion of salts and bactericides present.
4. That the Injection is not necessarily suitable for use in metabolic studies.

IODINATED (¹²⁵I) HUMAN FIBRINOGEN INJECTION – SPECIFICATIONSAppearance

A white or greyish freeze-dried solid, totally soluble on reconstitution.

Radionuclide Content

The content of iodine-125 is not less than 85 per cent and not greater than 115 per cent of the content of iodine-125 stated on the label of the date and hour stated on the label.

Radionuclidic Purity

Not more than 1.0 per cent of the total activity at the time of calibration is due to iodine-126.

pH

5.0 – 7.0 after reconstitution.

Radiochemical Purity

Not less than 80 per cent of the iodine-125 activity is coagulated by bovine thrombin in the presence of human plasma.

Not greater than 5 per cent of the iodine-125 activity is present as iodide ion.

Labelling

The label on the container states –

1. The name of the product.
2. The iodine-125 content at the date stated on the label.
3. That the product is radioactive.
4. The content of human fibrinogen and human albumin in the vial.

The package label also states –

1. Recommended storage conditions.
2. The expiry date of the product.

SODIUM IODIDE (¹²⁵I) SOLUTION - SPECIFICATIONSAppearance

A clear, colourless solution.

Radionuclidic Content

The content of iodine-125 is not less than 85.0 per cent and not more than 115.0 per cent of the content of iodine-125 stated on the label at the date stated on the label.

Radionuclidic Purity

Not more than 1.0 per cent of the total activity at the time of calibration is due to iodine-126.

Specific Activity

Not less than 2 mCi iodine-125 per microgram of iodine at the date stated on the label.

pH

7.0 - 10.0.

Radiochemical Purity

Not less than 99 per cent of the iodine-125 activity is in the form of iodide ion.

Labelling

The label on the container states -

1. The product name.
2. The content of iodine-125 at the date stated on the label.
3. That the Solution is radioactive.
4. That the Solution is not be used for parenteral injection.
5. The manufacturer's name.
6. The batch number.
7. The expiry date of the Solution.

The label on the package also states -

1. The total volume in the container(s).

SODIUM IODOHIPPURATE (^{125}I) INJECTION - SPECIFICATIONSAppearance

A clear, colourless solution free of visible particulate matter.

Radionuclide Content

The content of iodine-125 is not less than 85% and not greater than 115% of the content of iodine-125 stated on the label at the date stated on the label.

Radionuclidic Purity

Not more than 1.0 per cent of the total activity at the time of calibration is due to iodine-126.

pH

7.0 - 8.5.

Radiochemical Purity

Not less than 95% of the iodine-125 activity is in the form of *o*-iodohippurate and not more than 2% as iodide ion up to the time of expiry.

Bactericide Content

90 - 110 per cent of the stated concentration.

Sterility

Complies with the test for sterility.

Pyrogens

Complies with the test for pyrogens.

Labelling

The label on the container states -

1. The product name.
2. The content of iodine-125 at the date stated on the label.
3. That the Injection is radioactive.
4. Either that it does not contain a bactericide or the name and proportion of any added bactericide.

5. The manufacturer's name
6. The batch number.
7. The expiry date.

The label on the package also states -

1. The total volume in the container(s).
2. The total content of sodium o-iodohippurate.

SODIUM IODIDE (¹³¹I) INJECTION - SPECIFICATIONSSPECIFICATIONS

The specifications for Sodium Iodide (¹³¹I) Injection are as for Sodium Iodide (¹³¹I) Solution excepting for -

pH

7.0 - 8.0.

Sterility

Complies with the test for sterility.

Labelling

The label on the container states -

1. The product name.
2. The content of iodine-131 at the date and hour stated on the label.
3. That the Injection is radioactive.
4. The manufacturer's name.
5. The batch number.
6. The expiry date of the Injection.

The package label states in addition.

1. The total volume in the container(s).
2. Recommended storage conditions.

SODIUM IODIDE (¹³¹I) SOLUTION - SPECIFICATIONSAppearance

A clear, colourless solution, free of visible particulate matter.

Radionuclide Content

The content of iodine-131 is not less than 90.0 per cent and not more than 110.0 per cent of the content of iodine-131 stated on the label at the date and hour stated on the label.

Radionuclidic Purity

No other radionuclide detectable by gamma spectrometry.

Specific Activity

Not less than 5 mCi per microgram of iodine at the date and hour stated on the label.

pH

7.0 - 10.0.

Radiochemical Purity

Not less than 99 per cent of the iodine-131 activity is in the form of the iodide ion.

Labelling

The label on the container states -

1. The product name.
2. That the Solution is not to be used for parenteral injection.
3. The content of iodine-131 at the date and hour stated on the label.
4. That the Solution is radioactive.
5. The manufacturer's name.
6. The batch number.
7. The expiry date.

The label on the package states in addition.

1. The total volume in the container(s).
2. Recommended storage conditions.

SODIUM IODOHIPPURATE (^{131}I) INJECTION - SPECIFICATIONSAppearance

A clear, colourless solution free from visible particulate matter. The solution may become slightly brown.

Radionuclide Content

The content of iodine-131 is not less than 90.0 per cent and not greater than 110.0 per cent of the content of iodine-131 stated on the label at the hour and date stated on the label.

Radionuclidic Purity

No other radioisotopes to be detectable by gamma spectrometry.

pH

7.0 - 8.5.

Radiochemical Purity

Not less than 95% of the iodine-131 activity is in the form of o-iodohippurate. If the injection is intended for ERPF studies the iodine-131 activity present as iodide ion is less than 0.5 per cent of the total activity.

Bactericide Content

Between 90 and 110 per cent of the stated concentration.

Sterility

Complies with the test for sterility.

Pyrogens

Complies with the test for pyrogens.

Labelling

The label on the container states -

1. The product name.
2. The content of iodine-131 at the date and hour stated on the label.
3. That the Injection is radioactive.
4. Either that it does not contain a bactericide or the name and proportion of any added bactericide.

5. The manufacturer's name.
6. The batch number.
7. The expiry date of the Injection.

The label on the package also states -

1. The total volume in the container(s).
2. Recommended storage conditions.
3. The total content of sodium o-iodohippurate.

XENON (^{133}Xe) INJECTION - SPECIFICATIONSAppearance

A clear, colourless solution containing no particulate matter.

Radionuclide Content

The total content of xenon-133 in the container is not less than 80.0 per cent and not more than 120.0 per cent of the content of xenon-133 stated on the label at the date and hour stated on the label.

Radionuclidic Purity

No other gamma emitting radionuclides detected by gamma spectrometry.

pH

5.0 - 8.0.

Labelling

The label on the container states -

1. The product name.
2. The content of xenon-133 at the date and hour stated on the label.
3. That the Injection is radioactive.
4. The volume of the Injection.
5. Either that the Injection does not contain a bactericide, or the name and proportion of any added bactericide.
6. The batch number.
7. The expiry date and hour.

THALLIUM (^{201}Tl) CHLORIDE INJECTION - SPECIFICATIONSAppearance

A clear, colourless solution containing no visible particulate matter.

Radionuclide Content

The content of thallium-201 is not less than 90 per cent and not more than 110 per cent of the content of thallium-201 stated on the label at the date and hour stated on the label.

Radionuclidic Purity

At the time of administration

Tl-202	< 5.0 ⁰ /o	of total radioactivity
Tl-200	< 0.75 ⁰ /o	" " "
Pb-203	< 0.25 ⁰ /o	" " "
All other gamma emitters	< 0.01 ⁰ /o	" " "

Radiochemical Purity

Greater than 95⁰/o of the thallium-201 activity is present as thallos ion.

pH

4.5 - 6.5

Chemical Purity

Thallium	less than	6 ppm
Iron	" "	25 ppm
Copper	" "	6 ppm.

Bactericide Content

90 - 110 per cent of the stated concentration.

Sterility

Complies with the test for sterility.

Pyrogens

Complies with the test for pyrogens.

Labelling

The label on the container states -

1. The product name.
2. The content of thallium-201 at the date and hour stated on the label.
3. That the Injection is radioactive.
4. Either that it does not contain a bactericide or the name and proportion of any added bactericide.
5. The manufacturer's name.
6. The batch number.
7. The expiry date.

The label on the package also states -

1. The total volume in the container(s).
2. Recommended storage conditions.