

Radiopharmaceuticals

Radiochemical purity tests of the radiopharmaceuticals should be performed on the first of each batch before patient administration. Chromatography tests are generally acceptable for routine radiochemical purity (RCP) tests. The results of radiochemical purity tests are in accordance with the European Pharmacopoeia or with the recommendations of the manufacturer.

Radiopharmaceutical	Stationary phase	Mobile phase	Rf RHCs	Rf TcO ₄	Rf Tc-bound
99mTc-pertechnetate	ITLC-SG	0.9% NaCl	0.0	1.0	—
99mTc-MDP	No. 1	Acetone 1M sodium acetate or 0.9% NaCl	0.0	1.0	0.0
	ITLC-SG		0.0	1.0	1.0
99mTc-DTPA	No. 1 ITLC-SG	Acetone 0.9% NaCl	0.0	1.0	0.0
			0.0	1.0	1.0
99mTc-DMSA	No. 1	Acetone	0.0	1.0	0.0
99mTc-HIDA/DISIDA	ITLC-SG	0.9% NaCl	0.0	1.0	1.0
	ITLC-SA	20% NaCl	0.0	1.0	0.0
99mTc-MAA	ITLC-SG	0.9% NaCl	0.0	1.0	1.0
99mTc-MAG	No. 1 ITLC-SG	Acetonitrile 0.1M HCl	0.0	1.0	1.0
			0.0	1.0	0.0
99mTc-tetrofosmin	No. 1	Ethyl acetate	0.0	0.0	1.0
99mTc-sestamibi	No. 1	Ethyl acetate	0.0	0.0	1.0

Note:

Stationary phases:

ITLC-SG: Instant Thin-layer Chromatography, silica gel, Pal Gelman Laboratory.

ITLC-SA: Instant Thin-layer Chromatography, silica acid (poysilicic acid).

No. 1: Whatman No. 1 chromatography paper.

Mobile phases:

0.1 M HCl: 0.1 M hydrochloric acid.

0.9% NaCl: 0.9% sodium chloride solution (normal saline).

1 M sodium acetate can be prepared with 82 mg/mL anhydrous sodium acetate or 136 mg/mL sodium acetate trihydrate.

Terminology:

Rf: relative front.

1.0: front.

0.0: origin.

RHC: reduced hydrolysed colloids.

Al³⁺ ion is measured calorimetrically. A drop of the eluate is placed on one end of a special test paper; a drop of a standard solution of Al³⁺, concentration 10 ppm, is placed on the other end of the test strip. If the colour at the centre of the drop of eluate is less red than that of the standard solution, the eluate has passed the Aluminium Ion Breakthrough Test. Units may be expressed as ug/ml.

Upon each preparation, the radiopharmaceutical should also be **visually inspected**. **pH should also be tested** on the first of each batch received. **Particle size determination** is also important for preparation and dispensing of colloids and aggregates: the first vial in each batch should be examined. **Sensitive kits should be tested** each time they are made, e.g. MAG3, HMPAO. Periodic testing is recommended to ensure the consistency of a product. These tests provide an assessment of the stability of kits under local conditions. **A sterility test** programme for prepared kits should be implemented.

Radiochemical purity tests

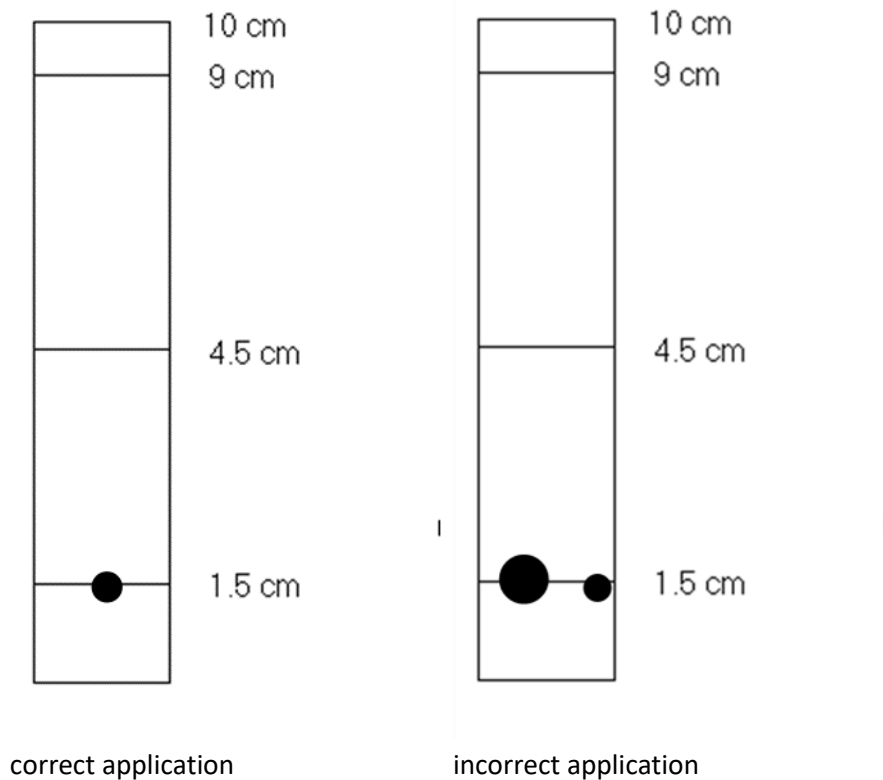


What we need to perform Planar Chromatography:

- Scissors
- Tweezers
- Pencil
- Ruler
- Gloves
- Mobile phase
- Glass container in which we give mobile phase???
- Stationary phase
- Radioactivity meter
- Radiochromatogram reader
- Calibrator of radioactive doses

The most common problems:

- Uneven application of the sample
- Embossing the stationary phase at the touch of your fingers
- Contact with the edge of the stationary phase to the surface of the tubs
- Inadequate mobile phase
- Evaporation of mobile phase components (ethyl acetate)
- Unladen components of the mobile phase
- Insufficient amount of mobile phase
- Polluted mobile phase
- Contaminated tweezers or scissors



In the test tube or the appropriate chromatography container, fill a mobile phase up to a height of 3-4 mm and the test tube is covered with a paraffin or a suitable lid.

On the chromatographic paper with pencil we mark the old line; 1.5 cm from the lower edge of the chromatographic paper and the final line; depending on the test

Apply a drop of sample to the starting line. The sample diameter must not exceed 10 mm.

The drop of sample dried slightly.

Chromatograph paper with tweezers or with gloves transferred in the measuring cylinder and allow the mobile phase to travel to the final line.

When the mobile phase enters the final line, take the chromatogram from the roller or the appropriate chromatography container with a tweezer, dry it a little and paste it with a Micropore adhesive tape

Chromatogram with tweezers applied to the scanner or cut into several pieces and move each piece in the correct order on the dose calibrator.

Calculation of radiochemical purity:

$$\text{Radiochemical purity} = \frac{\text{radioactivity of component}}{\text{total radioactivity}} * 100$$

Assignment:

Do you perform radiochemical purity of the first eluate?

Do you use gloves and tweezers in when carrying out tests of?

Do you perform Aluminium Ion breakthrough test of the first eluate?

Do you perform pH test of the first eluate?

Do you perform radiochemical tests on the purity of radiopharmaceuticals?

How often and which radiopharmaceuticals you test?

Do you use gloves and tweezers in when carrying out tests of?

Do you perform pH test of radiopharmaceuticals?

Do you perform pH test of radiopharmaceuticals?

Do you perform visual inspection of radiopharmaceuticals?

Do you perform test for determination particle size of colloids?

Do you all results stored properly?

Links:

https://pharmacyce.unm.edu/nuclear_program/freelessonfiles/Vol15Lesson3.pdf (Page 20-25)

https://www.bnms.org.uk/images/stories/UKRG/2015/Information_Resources_Radiochemical_Purity_Testing_05Jan2015.pdf

https://www.eanm.org/content-eanm/uploads/2016/11/tech_radiopharmacy.pdf (Page 27-32)