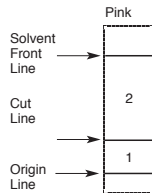


INTRODUCTION

These chromatography strips are designed to determine the radiochemical purity of Tc-99m labeled Cardiolite™ and Miraluma™ using a single strip method. With these



chromatography strips, radiochemical impurities, namely free Tc-99m pertechnetate, hydrolyzed reduced Tc-99m and other polar radiochemical impurities are separated for Tc-99m Sestamibi. The single-

strip chromatography procedure outlined is rapid, taking less than one minute to develop.

Each pink-colored chromatography strip has three distinct lines: an origin line, a cut line, and a solvent front line. For user convenience the back of each strip is marked with a soluble dye, located close to the solvent front line, that will migrate with the solvent front. The technologist can easily see the solvent front via the movement of the dye. Use a 5ml Serum Vial (approximate height 40 mm) as a developing vial.

NOTE: The 99.5% Ethyl Acetate ACS Reagent solvent (Sigma-Aldrich part # 31990-2) required to complete this procedure must be purchased separately.

*Tec-Control Solvent Vendor:
Sigma-Aldrich Chemical Company
800-558-9160 / www.sigmaaldrich.com*

Customers outside the USA should visit the Sigma-Aldrich web site to locate a regional office.

TEST PROCEDURE

1. Place approximately 0.5 to 0.8 ml of ethyl acetate in a developing vial.
2. Spot approximately one drop of radiopharmaceutical on the origin line of the chromatography strip. (Using a 26G needle and syringe, one drop equals a volume of approximately 10 microliters)
3. Place the strip in the developing vial containing solvent, and develop until solvent migrates to the solvent front line.

4. Remove the chromatography strip and cut strip at cut line, producing sections one and two.
5. Count background and calculate the net counts by subtracting the background counts from the number of counts registered for each strip section.

NOTE: The strip should be placed on top or away from the well detector depending on count rate. If the strip is placed in the well, the dead time of the detector will give erroneous results.

DATA ANALYSIS

The object of the test is to determine the percentage of Tc-99m Sestamibi.

PREPARATION QUALITY

A value of at least 90% radiochemical purity should be obtained in a satisfactory preparation.

CALCULATIONS

Percent Tc-99m Cardiolite™ or Miraluma™ (Sestamibi)

$$= \left[\frac{\text{(Net Counts Section 2)}}{\text{(Net Counts Section 1 + 2)}} \right] \times 100$$

Authorized European Community Representative:



*Emergo Europe
Prinsessegracht 20
2514 AP, The Hague
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TEC-CONTROL CHROMATOGRAPHY STRIPS

For Sestamibi
(Cardiolite™ and Miraluma™)

OPERATION MANUAL
150-991

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