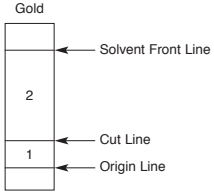
INTRODUCTION

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



With these chromatography strips, radiochemical impurities, namely free Tc-99m pertechnetate and hydrolyzed reduced Tc-99m, remain at the origin while the specific radiopharmaceutical migrates with the solvent front. For Tc-99m Ceretec™, to identify specific radiochemical impurities, the conventional three-strip chromatography system should be utilized. The single-strip chromatography procedure outlined is rapid, taking less than one minute to develop.

Each gold-colored chromatography strip has three distinct lines: an origin line, a cut line, and a solvent front line. 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. After cutting the strip at the cutting line, the strip is then divided into sections one and two.

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
800-888-9160 / 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 10 microliters)
3. Immediately place the gold-colored strip in the developing vial containing solvent, and develop until solvent migrates to the solvent front line. It is imperative that the strip be placed in the solvent immediately after spotting. Even a 15-second delay between strip spotting and developing can cause significant errors.
4. Remove the chromatography strip and cut strip at cut line, producing sections one and two.
5. Using a gamma scintillation counter peaked for Tc-99m, individually count each strip section for a specific period of time (i.e. 10 seconds).
6. 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 radiochemical purity of a Tc-99m Ceretec™ or a Tc-99m Neurolite™ preparation.

PREPARATION QUALITY

The percent lipophilic complex in Tc-99m Ceretec™ preparations should be greater or equal to 80%. The radiochemical purity of Tc-99m Neurolite™ should be greater than 90%.

CALCULATIONS

Percent Lipophilic Exametazine Complex or Percent Radiolabeled Neurolite™

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

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Emergo Europe
Molenstraat 15
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EC REP

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Certified Quality Management System

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TEC-CONTROL

CHROMATOGRAPHY STRIPS

For Bicisate (Neurolite™) and Exametazine (Ceretec™)

OPERATION MANUAL
150-130

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