

PROCEDURE FOR ESTIMATION OF LABELING EFFICIENCY  
IN TECHNETIUM Tc-99m DISOFENIN

MATERIALS

Chromatographic System: Chromatographic strips required for this procedure must be specially prepared.

This procedure requires Whatman #3mm chromatography paper treated with a 0.3m Carbonate-Bicarbonate Buffer.

Preparation of 0.3m Carbonate-Bicarbonate Buffer, pH 9.0: Weigh out 1.9g of sodium bicarbonate (anhydrous)  $\text{NaHCO}_3$  and 0.3g of sodium carbonate (anhydrous)  $\text{Na}_2\text{CO}_3$  then transfer both materials to the same dry 100ml volumetric flask. Add 50ml distilled water to the flask and agitate the flask until the contents are completely dissolved. Once the contents are dissolved, bring the flask to volume with distilled water and thoroughly mix.

Using a pH meter which has been standardized with two standard buffer solutions - one a pH 7.00 buffer (Phosphate buffer system) and the other a pH 10.00 buffer (Potassium Carbonate, Potassium Borate, and Potassium Hydroxide buffer system, Fisher Catalog No. So-B-115) measure the pH of the resulting buffer solution. When using the pH meter be sure to use a glass electrode. The pH of the buffer should be  $9.0 \pm 0.2$ .

Procedure for Treatment of Strips: Whatman #3mm chromatography paper is received from the manufacturer in 46 X 57cm sheets. Prior to treating the paper, cut these larger sheets into smaller 5 X 20cm sheets. Handling the 5 X 20cm strips with clean forceps, soak the paper strips for one (1) minute in a tray containing the 0.3m Carbonate - Bicarbonate Buffer. After one minute remove the strips with forceps, blot lightly with lab tissues, and dry the strips in an oven at  $85^\circ\text{C}$  for approximately 45 minutes. Once the strips are dried, each 5 X 20cm strip should be cut into 1/2" by 2" inch strips and stored in a clean-dry glass container.

Solvent: Methyl Ethyl Ketone, A.C.S. Reagent Grade.

NOTE: Use only a fresh container of Methyl Ethyl Ketone for each determination. The Methyl Ethyl Ketone must be stored and handled so as to minimize the possibility of any contamination, especially moisture. Substitution by any other material must not be made.

Chromatographic Chamber: 20ml liquid scintillation vial and screw cap or stopper.

Instrumentation: Capintec CRC-10 or CRC-5 Radioisotope Calibrator (or equivalent ion chamber), calibrated for Tc-99m activity with a suitable Cobalt Co-57 reference standard.

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### FINAL VIAL PREPARATION

The final vials are to be reconstituted with 3-5ml of Sodium Pertechnetate Tc-99m in 0.9% NaCl solution containing 75-100mCi. The vials must be vigorously swirled for at least 10 seconds to ensure proper labeling. The time of reconstitution must also be noted. Only 0.9% (w/v) NaCl solution which is additive free should be used during generator elution and eluate dilution. Any dilution of the eluate should be made only prior to reconstitution. NEN Eluant for Tc-99m Generator or Sodium Chloride Injection, U.S.P. is recommended.

### STRIP PREPARATION

Shortly prior to use, the strips must be "re-activated" by heating in an oven at 85°C for thirty minutes. Allow them to return to room temperature prior to spotting.

### PROCEDURE

Place an amount of Methyl Ethyl Ketone in the development chamber to a depth of about 1/8 inch (3-4mm).

Cap the chamber and allow to equilibrate for at least 5 minutes before strip insertion.

After 30 minutes has elapsed from the reconstitution time, withdraw 0.1ml of the reconstituted vial contents into a 1cc syringe with a small (e.g. - 25-26 gauge) needle. With the strip lying on a paper towel, place one or two small drops of sample onto the strip about 1/2 inch (10-13mm) from one end (do not saturate the strip at its edges).

Uncap the chamber, insert the strip, spotted-end down, into the chamber, and recap the chamber.

After the solvent front has migrated to the top of the strip, remove and hold the strip with forceps, allowing it to air dry (30-40 seconds).

The strip should be cut about 1/2 inch (10-13mm) from the top, and the two pieces placed into separate test tubes.

Assay the activity of both pieces using a calibrated (for Tc-99m) ionization chamber; use identical counting geometry for both tubes. Be sure to determine background activity level if ionization chamber does not automatically correct for it.

### CALCULATIONS

$$\% \text{ unbound species} = \frac{(SF - B)}{(C - B) + (SF - B)} \times 100$$

where SF = activity of top piece ( $\mu\text{Ci}$ )

C = activity of bottom piece ( $\mu\text{Ci}$ )

B = Background activity ( $\mu\text{Ci}$ )