TCK 5

KIT FOR THE PREPARATION OF $^{99mTc}$-SULPHUR COLLOID
(DIAGNOSTIC- FOR INTRAVENOUS USE)

The kit for the preparation of $^{99mTc}$-Sulphur colloid is a three-component kit. On reconstitution, as per specified recipe, the colloid formed is sterile, pyrogen free and suitable for i.v. administration. The particle size of colloid formed is in the range of 0.1-1µm (80%). In normal subjects 80-85% of injected dose localizes in the liver. $^{99mTc}$-Sulphur colloid is entrapped in the Reticulo Endothelial System (RES) by phagocytic cell, and is retained for a long time.

- $^{99mTc}$- Sulphur colloid is used as liver and spleen imaging agent for:
  - Evaluation of functional morphology of reticulo endothelial system.
  - Quantitative assessment of parenchymal liver disease such as cirrhosis.
  - Delineation of space occupying lesions in liver.
  - Differentiation of fatty infiltration in liver in conjunction with sonography.

- $^{99mTc}$- Sulphur colloid is also used:
  - In post renal transplant to distinguish acute tubular necrosis (ATN) from early rejection.
  - Orally for estimation of esophageal transit and gastro esophageal reflux (quantitative).

DESCRIPTION OF THE KIT

Each kit consists of three components (vials).

Component - A : 0.5 ml solution of 0.3N HCl.
Component - B : 1 ml solution of 3% gelatin/haemaccel, 10 mg of sodium thiosulphate and perrhenate (equivalent to 1 mg of Re).
Component-C : 1 ml solution of 0.8M phosphate buffer, pH 7.4
**99mTc-Sulphur Colloid Formulation***

1. Add 2 to 3 ml of sterile sodium pertechnetate (Na\(^{99m}\)TcO\(_4\)) in 0.9% sodium chloride solution containing the required activity of \(^{99m}\)Tc to the vial labelled Component-A (hereafter termed as reaction vial). Withdraw equal volume of air from the vial.

2. Transfer 0.5 ml of component-B vial to the reaction vial and withdraw equal volume of air from the vial.

3. Keep the reaction vial in boiling water bath for 3 to 5 min.

4. Remove the reaction vial from water bath and allow it to cool.

5. Transfer 0.5 ml of Component-C to the reaction vial.

6. Shake the contents of the vial.

7. The preparation is now ready for use.

(*For actual formulation, follow Product Recipe)

**DOSAGE AND ADMINISTRATION**

The suggested dose range per patient for i.v. administration of \(^{99m}\)Tc-Sulphur colloid is 2 - 3 mCi (74 - 111 MBq).