TCK-39

KIT FOR THE PREPARATION OF $^{99m}$Tc-MEBROFENIN

(DIAGNOSTIC- FOR INTRAVENOUS USE)

The kit for the preparation of $^{99m}$Tc-Mebrofenin (3-bromo - 2,4,6 - trimethyl acetonilido iminodiacetic acid) is a single component kit. On reconstituting the kit as per specified recipe, $^{99m}$Tc-Mebrofenin solution formed is sterile, pyrogen free and suitable for i.v. administration.

$^{99m}$Tc- Mebrofenin exhibits rapid clearance from blood, rapid transit through hepatocytes, minimum renal excretion and effective competition with bilirubin compared to other IDA derivatives.

- $^{99m}$Tc- Mebrofenin is used as hepatobiliary function imaging agent for
  - Assessment of hepatobiliary patency.
  - Evaluation of intra as well as extra hepatic biliary obstruction.
  - Diagnosis of acute cholecystitis.
  - Diagnosis of biliary atresia in children with neonatal jaundice.
  - In conjunction with CCK (cholecystokinin) the contractibility of gall bladder is estimated quantitatively (Gall bladder ejection fraction).

DESCRIPTION OF THE KIT

Kit consists of a single vial.
Each vial contains 25 mg of mebrofenin and 0.2 mg of stannous chloride dihydrate in freeze-dried form.
**99mTc-Mebrofenin Formulation***

1. Allow the kit vial to attain ambient temperature.
2. Add 2-3 ml of sterile sodium pertechnetate (Na$^{99m}$TcO$_4$) in 0.9% sodium chloride solution containing the required activity of $^{99m}$Tc and mix well.
3. Keep the vial in boiling water bath for 5 min.
4. Remove the vial from the water bath and allow it to cool for 10 min.
5. The preparation is now ready for use.

(*For actual formulation, follow Product Recipe)

**DOSAGE AND ADMINISTRATION**

The suggested dose range per patient (fasted for 4 to 6 hours prior to administration of the agent) for i.v. administration of $^{99m}$Tc-Mebrofenin is 3-5 mCi (111 - 185 MBq). Higher dose may be needed for patients with elevated bilirubin levels.