

LEUCOCYTE Labelling Kit

Kit for the Preparation of Technetium[99mTc] Labelled Leucocytes

Product Data AUST R 14333

DESCRIPTION

This Kit comprises of sterile, pyrogen free ingredients which need reconstitution with sodium pertechnetate[99mTc] injection and mixing to produce technetium[99mTc] stannous colloid complex suitable for labelling white blood cells in whole blood. The precise structure of technetium[99mTc] stannous colloid is not known at this time.

Technetium [99mTc] stannous colloid when used to label white blood cells to form Technetium [99mTc] labelled leucocytes is a diagnostic pharmaceutical administered by intravenous injection.

CONTENTS AND PRESENTATION

This is a composite kit consisting of a Vial A (solution) and Vial B (lyophilised).

Vial A is supplied as a carton of 5 sterile, pyrogen free 10 mL vials containing a 6 mL solution of 1 mg/mL sodium fluoride in Water for Injection BP. Vial B is supplied as a carton of 5 sterile, pyrogen free, vacuum sealed 5 mL vials containing 640 g of stannous fluoride as a lyophilised powder.

This product contains no preservatives.

PHARMACOLOGY

Technetium[99mTc] labelled leucocytes radiolabels neutrophils and monocytes by phagocytic engulfment of the radiocolloid. The radiocolloid is administered to autologous whole blood, rotated and incubated at room temperature for 1 hour, with a resultant mean labelling efficiency of 85.2% (neutrophils 62.6% and monocytes 22.6%).

INDICATIONS

Technetium[99mTc] labelled leucocytes may be used to image acute inflammation or infection.

ADVERSE REACTIONS

For each patient, exposure to ionising radiation must be justifiable on the basis of likely benefit. The activity administered must be such that the resulting dose is as low as reasonably achievable bearing in mind the need to obtain the intended diagnostic or therapeutic result.

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. For diagnostic nuclear medicine

investigations the current evidence suggests that these adverse effects will occur with low frequency because of the low radiation doses incurred.

For most diagnostic investigations using a nuclear medicine procedure the radiation dose delivered (EDE) is less than 20 mSv. Higher doses may be justified in some clinical circumstances.

Hypersensitivity reactions have been reported with technetium [^{99m}Tc] preparations.

Any suspected adverse reaction should be reported to Adverse Drug Reactions Advisory Committee (ADRAC) TGA, PO Box 100 WODEN ACT 2606.

Tel: 06 289 8670 Fax: 06 289 7694.

DOSAGE AND ADMINISTRATION

Recommended intravenous dose for the normal adult is 400 to 600 MBq.

Heparin Preparation

Aseptically transfer 5 mL of heparin sodium (1000 units/mL) to 45 mL sodium chloride injection and mix. Final heparin sodium concentration is 100 units/mL.

PROCEDURE

Colloid Preparation

NOTE: If there is no vacuum in Vial B, discard and replace before delivering 5 mL from Vial A.

1. Draw 1.5 to 2 GBq sodium pertechnetate[^{99m}Tc] injection eluted from a technetium-99m generator into a 5 mL syringe and then draw sodium chloride injection to make volume of 2.5 mL.
2. Draw 5 mL from Vial A into a syringe and transfer to Vial B. Mix for 20 seconds to dissolve.
3. Aseptically withdraw 1 to 2 mL of this solution into a 2.5 mL syringe and then transfer 0.5 mL via a 0.22 µm membrane filter into the syringe containing 2.5 mL sodium pertechnetate[^{99m}Tc] injection (Step 1 Colloid Preparation).

NOTE: Filter has void volume of 0.5 mL.

4. Mix by slow rotation for 1 hour to produce ideal technetium[^{99m}Tc] stannous colloid integrity and size.

5. After mixing use within 1 hour.

SUMMARY

1.5 to 2 GBq sodium pertechnetate[99mTc] injection to 2.5 mL with sodium chloride injection.

5 mL from Vial A -----> Vial B.

Mix to reconstitute for 20 seconds.

0.22 m filter

0.5 mL from Vial B----->2.5mL sodium pertechnetate[99mTc] injection.

Mix by rotation for 1 hour.

After mixing use within 1 hour.

Leucocyte Labelling Procedure

1. Draw 20 mL blood into syringe containing 100 units of heparin sodium.

2. Transfer 1.5 mL technetium[99mTc] stannous colloid (Step 4 Colloid Preparation) to 20 mL blood. Mix by rotation for 1 hour.

3. Transfer to sterile 50 mL centrifuge tube.

4. Centrifuge at 400g (approx. 2000 rpm) for 5 minutes.

NOTE: The buffy coat between plasma and red blood cells must be observed.

5. Remove plasma to 1 cm of buffy coat making sure not to disturb cells.

6. Add sufficient sodium chloride injection to replace plasma, mix by inversion and reinject blood.

SUMMARY

20 mL blood -----> 100 units heparin (1 mL).

1.5 mL technetium[99mTc]stannous colloid -----> 20 mL blood.

Mix by slow rotation for 1 hour.

Transfer to centrifuge tube.

Centrifuge blood at 400g.

Remove plasma.

Add sodium chloride injection to replace plasma. Mix.

Reinject patient's blood.

Stability after Reconstitution with Technetium-99m

After slow rotation for 1 hour (step 4 in Colloid preparation) the technetium[99mTc] stannous colloid is stable at room temperature for 1 hour.

STORAGE AND EXPIRY

Vial A and Vial B must be stored at 2 C to 8 C (Refrigerate. Do not freeze).

Expiry is 12 months from the date of manufacture. The expiry date is stated on the vial and carton.

MANUFACTURER

This product is manufactured by Radpharm Scientific, Unit 3 Oatley Lane
Belconnen, 2617 ACT