GMS TRODAT-1 KIT

For the Preparation of Technetium Tc-99m TRODAT-1 for Injection

DESCRIPTION: The kit consists of reaction vials which contain the sterile, nonpyrogenic, non-radioactive ingredients necessary to produce Technetium Tc-99m TRODAT-1 for diagnostic use by intravenous injection.

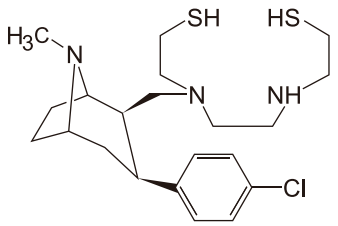
Each 10 mL reaction vial contains:

TRODAT-1•3HCl	0.126 mg
Sodium glucoheptonate	0.32 mg
Disodium ethylenediaminetetraacetate dihydrate	0.93 mg
Stannous chloride dihydrate	0.032 mg
Mannitol	20 mg
Anhydrous sodium phosphate dibasic	4.1 mg
Sodium phosphate monobasic	0.46 mg

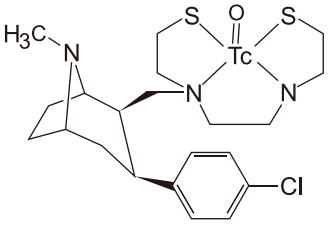
The contents are in a lyophilized form under an atmosphere of nitrogen. No bacteriostatic preservative is present.

Technetium Tc-99m TRODAT-1 for Injection is in its final dosage form when sterile sodium pertechnetate Tc-99m solution is added to each vial. The pH of the reconstructed product is 6.5-8.5. No less than 90% of the sodium pertechnetate Tc-99m added to a reaction vial is bound to TRODAT-1 at preparation time and remains bound throughout the 4 hour lifetime of the preparation.

NOTE: The reaction vial should not be reconstituted with any solvent other than sodium pertechnetate Tc-99m injection.



TRODAT-1



Tc-TRODAT-1

INDICATIONS AND USAGE: Technetium Tc-99m TRODAT-1 for Injection is for imaging of dopamine transporters located in the dopaminergic presynaptic neuron terminals in the striatum.

INSTRUCTIONS FOR PREPARATION OF Technetium Tc-99m TRODAT-1

Use aseptic procedures throughout and take precautions to minimize exposure by use of suitable shielding. Waterproof gloves should be worn during the preparation procedure.

To prepare Technetium Tc-99m TRODAT-1 for Injection:

1. Remove the protective plastic disc from a reaction vial and swab the rubber septum with either an alcohol swab or a suitable bacteriostatic agent to sanitize the surface.
2. Place the vial in a suitable lead vial shield.
3. Using a shielded syringe, obtain 5 ml of a sterile sodium pertechnetate Tc-99m injection with radioactivity of 1480 MBq (40 mCi). Add the sodium pertechnetate Tc-99m injection to the reaction vial aseptically. Remove an equal volume of headspace to maintain atmospheric pressure within the vial before withdrawing the syringe.
4. Swirl the contents of the vial for 10 seconds.
5. Heat the contents of the vial in an autoclave at 121°C for 30 minutes.
6. Remove the vial from the autoclave and cool to room temperature.
7. Assay the product in a suitable calibrator.

NOTE

1. **Sodium pertechnetate Tc-99m injection is used no later than 6 hours from the time of generator elution.**
2. **The ^{99}Mo/^{99m}Tc generator should be eluted within 24 hours from the previous elution.**
3. The sodium pertechnetate Tc-99m injection used in the reconstitution of the reaction vial should be in compliance with the Pharmacopoeia.
4. The specific activity of sodium pertechnetate Tc-99m injection used in the preparation of Technetium Tc-99m TRODAT-1 for Injection is 222-296 MBq/mL (6-8 mCi/mL). Total radioactivity should not exceed 1628 MBq (44 mCi). The sodium pertechnetate Tc-99m injection can be diluted with a sterile preservative-free saline.
5. Oxidant-free sodium pertechnetate Tc-99m injection is used; otherwise labeling efficiency will be adversely affected.
6. To increase the accuracy of diagnosis, it is recommended to evaluate theSPECT imaging with striatal/occipital uptake ratio, combining brain images score by ordinal scale or clinical observations.

DETERMINATION OF RADIOCHEMICAL PURITY (RCP) IN PRPERATION

1. Obtain two plastic iTLC-SG plates, pre-cut to 15 mm × 130 mm.
2. Prepare two types of mobile phase: (1) 0.9% sodium chloride solution and (2) acetone. Pour adequate amount of each mobile phase into two distinct developing tanks, respectively, to a depth of <2 cm. Cover the tank and let the solvent equilibrate for 10 minutes.
3. Apply one drop of Technetium Tc-99m TRODAT-1 at the center of the place 2 cm from the bottom of each plate.
   - **System 1:** develop the plate with 0.9% sodium chloride solution in the covered TLC tank for a distance of 12 cm from the bottom of the plate.
   - **System 2:** develop the plate with acetone in the covered TLC tank for a distance of 12 cm from the bottom of the plate. After drying, develop the plate again with 0.9% sodium chloride solution.
4. Measure the distribution of Tc-99m activity by an appropriate radiation detector.
5. Calculate the %RCP of Technetium Tc-99m TRODAT-1 as:
   %RCP of Technetium Tc-99m TRODAT-1 = 100 - [(% radioactivity in the SOLVENT FRONT of System 1) + (% radioactivity in the ORIGIN of System 2)]

DOSAGE AND ADMINISTRATION: The recommended dose range for intravenous administration of Technetium Tc-99m TRODAT-1 for a 70 kg patient is 814-1036 MBq (22-28 mCi). SPECT imaging should be performed 4 hours post-administration.

CONTRAINDICATIONS: None known.

ADVERSE REACTIONS: Dizziness, back pain, hypertension and paresthesia have been reported occasionally.

STORAGE

Store the unreconstructed reaction vials below 25°C and protected from light. After labeling with Technetium Tc-99m, store the solution at room temperature in a suitable lead shield, and discard after 4 hours.

PRECAUTIONS

1. Contents of the reaction vial before preparation are nonradioactive. However, after the sodium pertechnetate Tc-99m injection is added, adequate shielding must be maintained.
2. Contents of the reaction vial are intended only for use in the preparation of Technetium Tc-99m TRODAT-1 and are not to be administered directly to the patient without reconstruction.
3. Technetium Tc-99m TRODAT-1 should not be used more than 4 hours after preparation.
4. To minimize radiation dose to the bladder and other target organs, the patient is encouraged to drink fluids and to void frequently during the 6 hours after injection.
5. **Pregnancy:** Animal reproduction studies have not been conducted with Technetium Tc-99m TRODAT-1. It is also not known whether this drug can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, Technetium Tc-99m TRODAT-1 should be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus.
6. **Nursing Mothers:** Technetium Tc-99m TRODAT-1 can be excreted in human milk. Therefore, formula feedings should be substituted for breast-feeding.

PACKAGE: Five 10 ml reaction vials in one carton box.

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Distributed By:

Global Medical Solutions Taiwan

11F, 237, Section 1, Fu-Shing S. Road, Taipei 10666, Taiwan
+886-2-2707-9900

Manufactured By:

Shinlin Sinseng Pharmaceutical Co., Ltd.
237, Tien-Hu 1 Road, Longtan District, Taoyuan City 235, Taiwan