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## INER TRODAT-1 KIT

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

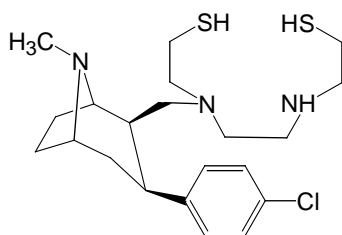
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### Description

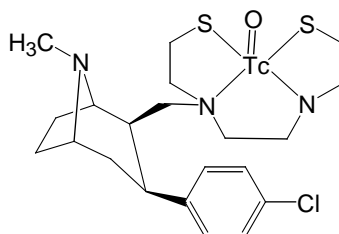
Each 10 mL vial contains a sterile, non-pyrogenic, lyophilized mixtures of:

TRODAT-1·3HCl	126 µg
Sodium glucoheptonate	320 µg
Disodium ethylenediaminetetraacetate dihydrate	930 µg
Stannous chloride dihydrate	32 µg
Mannitol	20 mg
Anhydrous sodium phosphate dibasic	4.1 mg
Sodium phosphate monobasic	460 µg

The contents of the vial are lyophilized and sealed under nitrogen. No bacteriostatic preservative is present. The preparation of Tc-99m-TRODAT-1 should follow the instructions description below. After reconstitution with sterile Sodium Pertechnetate Tc-99m injection, the Tc-99m-TRODAT-1 formed is suitable for intravenous injection. The pH of the reconstruction product is 6.5~8.5. The radiopharmaceutical should not be used without reconstitution or reconstitution with solvent other than Sodium Pertechnetate Tc-99m.



TRODAT-1



Tc-TRODAT-1

### Indications and Usage

Imaging of dopamine transporters located in the dopaminergic presynaptic

neuron terminals in the striatum.

## **Required Materials and Instrument for Preparation of Tc-99m-TRODAT-1**

Lead-shielding container, 5 mL sterile syringe, 0.9% saline solution injection, 75% alcohol, forceps, autoclave instrument.

## **Instructions for Preparation of Tc-99m-TRODAT-1**

(For ensuring the quality of Tc-99m-TRODAT-1 injection, use aseptic technique throughout)

1. Place one lyophilized TRODAT-1 kit vial in a suitable lead-shielding container and swab the rubber septum with an alcoholic sterile swab.
2. Using a 5 mL syringe, inject into the shielded vial 5 mL of Sodium Pertechnetate Tc-99m solution. Before withdrawing the syringe from the vial, withdraw 5 mL of gas from the space above the solution to maintain atmospheric the pressure within the vial.
3. Shake the shielded vial for 10 seconds to ensure complete dissolution of the contents.
4. Autoclave the shielded vial at 121°C for 30 min.
5. After cooling to room temperature, measure the total radioactivity.

### **Notes**

1. Use only Sodium Pertechnetate Tc-99m injection eluted less than 6 hours from a generator.
2. A  $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$  generator should be eluted within 24 hours prior to obtaining any elute for reconstitution with the lyophilized TRODAT-1 kit.
3. Use Sodium Pertechnetate Tc-99m injection complying with the specifications described in the USP and BP/EP monographs.
4. Use Sodium Pertechnetate Tc-99m injection with the specific radioactivity of 222~296MBq/mL (6~8 mCi/mL). And the total radioactivity should not exceed 1628 MBq (44 mCi). The Sodium Pertechnetate Tc-99m injection can be diluted with sodium chloride injection without bacteriostatic preservative.
5. Don't use the Sodium Pertechnetate Tc-99m injection with any oxidant, which may adversely affect the labeling efficiency.
6. For improving the diagnosis accuracy, it is recommended to combine the clinical observations from neurologist and the SPECT images evaluating with striatal/occipital uptake ratio or brain images score by ordinal scale.

## **Determination of Radiochemical Purity in Tc-99m-TRODAT-1**

The radiochemical purity of Tc-99m-TRODAT-1 can be determined by reversed-phase high-performance liquid chromatography analysis on a Gemini C-18, column (5  $\mu$ , 110A, 250  $\times$  4.6 mm) eluted with a mixture of acetonitrile- 5 mM dimethyl glutaric acid (DMGA) buffer (pH 7) in a ratio of 3:2 and at a flow rate of 1 mL/min. The retention time of Tc-99m-TRODAT-1 is about 19~31 min under these condition. The acceptable radiochemical purity has to be over 90% for administration.

## **Dosage and Administration**

The recommended dose for IV administration of Tc-99m-TRODAT-1 in a single dose to be employed in the average patient (70 kg) dose is 814~1036 MBq (22~28 mCi). SPECT imaging should take place around 4 hours post-administration.

## **Contraindications**

None known.

## **Adverse Reactions**

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

## **Storage**

INER TRODAT-1 kit should be stored in a refrigerator (2~8°C) upon receiving and protected from light until use. The reconstituted preparation should be stored at room temperature and must be used within 4 hours after preparation.

## **Precautions**

1. The contents of INER TRODAT-1 kit are not radioactive. However, after Sodium Pertechnetate Tc-99m is added, adequate shielding of the final preparation must be maintained.
2. The kit should not be used directly to the patient prior to reconstruction with Sodium Pertechnetate Tc-99m solution.
3. Tc-99m-TRODAT-1 should not be used more than 4 hours after preparation.
4. To minimize the radiation dose to the bladder, as well as other target organs, the patient should increase his or her fluid intake and void as often as possible after injection Tc-99m-TRODAT-1 and completing for 6 hours after the imaging procedure as often as possible.
5. Animal reproduction studies have not been conducted with 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. Tc-99m-TRODAT-1 should be given to a pregnant woman only if clearly needed.

6. Sodium Pertechnetate Tc-99m is excreted in human milk during lactation; therefore, formula feedings should be substituted for breast-feeding.

### **Expiry Date**

Six months (2~8°C).

### **Package**

Five vials/ box.



### **Manufacture:**

Radiopharmaceutical Production Center, Institute of Nuclear Energy Research, Atomic Energy Council.

1000, Wen-Hua Rd., Lung-Tan, Taiwan, Republic of China.