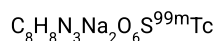
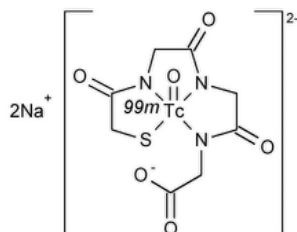


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Technetium Tc 99m Mertiatide Injection



Technetate(2-)- $^{99\text{mTc}}$, [N-[N-[N-(mercaptoacetyl)-glycyl]glycyl]glycinato(5-)-N,N',N'',S]-oxo-, disodium, (SP-5-25)-;

Disodium [N-[N-[N-(mercaptoacetyl)glycyl]glycyl]glycinato (5-)-N,N',N'',S]-oxo[$^{99\text{mTc}}$]technetate(V)

CAS RN[®]: 125224-05-7.

DEFINITION

Technetium Tc 99m Mertiatide Injection is a sterile, aqueous solution, suitable for intravenous injection, that contains radioactive technetium ($^{99\text{mTc}}$) in the form of a chelate of mertiatide. It contains NLT 90.0% and NMT 110.0% of the labeled amount of $^{99\text{mTc}}$ as mertiatide complex expressed in megabecquerels (millicuries or microcuries) per milliliter at the date and time indicated in the labeling. It contains uncomplexed betiatide, a suitable $^{99\text{mTc}}$ reducing agent, a transfer ligand, and stabilizers.

IDENTIFICATION

• A. RADIONUCLIDIC IDENTITY

(See [Radioactivity \(821\)](#), [Identification of Radionuclides](#).)

Acceptance criteria: Its gamma-ray spectrum is identical to that of a specimen of $^{99\text{mTc}}$ that exhibits a major photopeak having an energy of 0.140 MeV.

Add the following:

▲ • B. RADIOCHEMICAL IDENTITY

Analysis: After completing the *Analysis for Procedure 2 (Simultaneous determination of free pertechnetate and $^{99\text{mTc}}$ mertiatide)* in the *Radiochemical Purity* test, examine the radiochromatograms obtained.

Acceptance criteria: The chromatogram shows the retention time of the major peak obtained with the *Sample solution* is between 10 and 14 min. ▲ (USP 1-Dec-2024)

ASSAY

• RADIOACTIVE CONCENTRATION (STRENGTH)

(See [Radioactivity \(821\)](#), [Assay of Radionuclides](#).)

Analysis: Using a suitable counting assembly, determine the radioactivity, in megabecquerels (or millicuries) per milliliter, of the Injection by use of a calibrated system.

Acceptance criteria: 90.0%–110.0% of the labeled amount of $^{99\text{mTc}}$ at the date and time indicated in the labeling

PURITY

• RADIONUCLIDIC PURITY

(See [Radioactivity \(821\)](#).)

Analysis: Using a suitable counting assembly, determine the radioactivity of each radionuclidic impurity, in kilobecquerels per megabecquerel (microcuries per millicurie) of technetium 99m, in the Injection by use of a calibrated system.

Acceptance criteria

For Injection prepared from technetium 99m derived from parent molybdenum 99 formed as a result of neutron bombardment of stable molybdenum: See [Table 1](#).

For Injection prepared from technetium 99m derived from parent molybdenum 99 formed as a result of uranium fission—gamma- and beta-emitting impurities: See [Table 2](#).

Table 1

Radionuclidic Impurity	Most Prominent Photopeaks	Half-Life	Acceptance Criteria, NMT ^a
Molybdenum 99	0.181 MeV gamma 0.740 MeV gamma 0.780 MeV gamma	66.0 h	0.15 kBq/MBq (μCi/mCi)
Total of all other gamma-emitting radionuclidic impurities	—	—	0.5 kBq/MBq (μCi/mCi) ^b

^a Radioactivity of radionuclidic impurity/radioactivity of Tc 99m per administered dose of the Injection at the time of administration.

^b Does not exceed 92 kBq (2.5 μCi) per administered dose of the Injection at the time of administration.

Table 2

Radionuclidic Impurity	Most Prominent/Maximum Photopeaks	Half-Life	Acceptance Criteria, NMT ^a
Molybdenum 99	0.181 MeV gamma 0.740 MeV gamma 0.780 MeV gamma	66.0 h	0.15 kBq/MBq (μCi/mCi)
Iodine 131	0.364 MeV	8.08 d	0.05 kBq/MBq (μCi/mCi)
Ruthenium 103	0.497 MeV	39.5 d	0.05 kBq/MBq (μCi/mCi)
Strontium 89 ^b	1.463 MeV beta	52.7 d	0.0006 kBq/MBq (μCi/mCi)
Strontium 90 ^b	0.546 MeV beta	27.7 y	0.00006 kBq/MBq (μCi/mCi)
Gross alpha impurity	—	—	0.001 Bq/MBq (nCi/mCi)
All other beta- and gamma-emitting radionuclidic impurities	—	—	0.01%

^a Radioactivity of radionuclidic impurity/radioactivity of Tc 99m present at the time of administration.

^b Use a counting system appropriate for the detection of particulate radiations.

• RADIOCHEMICAL PURITY

Procedure 1 (Determination of hydrolyzed reduced technetium)

Chromatographic system

(See [Chromatography \(621\)](#), [General Procedures](#), [Paper Chromatography](#).)

Mode: Paper chromatography

Adsorbent: 25-mm × 20-cm strip of chromatographic paper

Application volume: About 5–10 μL (100–250 μCi)

Developing solvent system: [Acetonitrile](#) and [water](#) (60:40)