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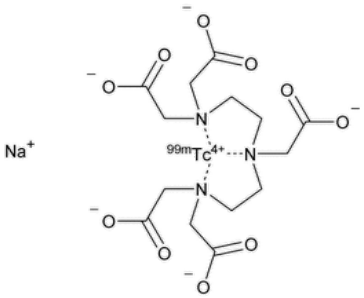
Technetium Tc 99m Pentetate Injection

Change to read:



$C_{14}H_{18}N_3NaO_{10}{}^{99m}Tc$ ▲510.21▲ (USP 1-Dec-2024)

Technetate(1-)^{99m}Tc, [*N*,*N*-bis[2-[bis(carboxymethyl)amino]ethyl]glycinato(5-)]-, sodium; Sodium [*N*,*N*-bis[2-[bis(carboxymethyl)amino]ethyl] glycinato(5-)]-technetate(1-)-^{99m}Tc CAS RN®: 65454-61-7; UNII: VW78417PU1.

Change to read:

DEFINITION

Technetium Tc 99m Pentetate Injection is a sterile solution of pentetic acid that is complexed with ^{99m}Tc in Sodium Chloride Injection. It is suitable for intravenous administration ▲or inhalation administration▲ (USP 1-Dec-2024) and may contain buffers. It contains NLT 90.0% and NMT 110.0% of the labeled amount of ^{99m}Tc as the pentetic acid complex expressed in megabecquerel (microcurie or millicurie) per milliliter at the time indicated in the labeling. Other chemical forms of radioactivity are NMT 10.0% of the total radioactivity.

IDENTIFICATION

• **A. Radionuclidic Identity**

(See *Radioactivity ⟨821⟩, Identification of Radionuclides*.)

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

Add the following:

▲• **B. Radiochemical Identity**

Analysis: Examine the radiochromatograms obtained in *Analysis A* and *Analysis B* of the *Radiochemical Purity* test.

Acceptance criteria: In *Analysis A*, the chromatogram shows the principal peak is at the solvent front (R_F 0.9–1.0). In *Analysis B*, the chromatogram shows the principal peak is at the origin (R_F 0–0.1).▲ (USP 1-Dec-2024)

ASSAY

• **Radioactive Concentration (Strength)**

(See *Radioactivity ⟨821⟩, Assay of Radionuclides*.)

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

Acceptance criteria: 90.0%–110.0% of the labeled amount of ^{99m}Tc at the 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 kilobecquerel per megabecquerel (microcurie 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 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.

Change to read:

• **Radiochemical Purity**

▲The determination of radiochemical purity for this Injection requires the use of two separate chromatographic systems.

Chromatographic system A

(See *Chromatography ⟨621⟩, General Procedures, Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: Glass fiber chromatographic strip impregnated with silica gel (1 cm × 10 cm)

Application volume: A volume of Injection providing a count rate of about 20,000 counts/min

Developing solvent system: Saline TS

Analysis A

Apply one small drop of the radioactive solution (about 20,000 counts/min) to the origin (1.5 cm from one end of the strip) of *Adsorbent*. Immediately develop the chromatographic strip in the *Developing solvent system*. Allow the solvent (about 1 mL in the chamber) front to move to 8 cm from the origin, and allow it to dry. Determine the radioactivity distribution by scanning the *Adsorbent* with a suitable radioactivity counting instrument. Hydrolyzed Tc 99m is located at the origin (R_F 0–0.1) and the free Pertechnetate and Technetium Tc 99m Pentetate are located at the solvent front (R_F 0.85–1.0). After completing the test for *Radiochemical Purity*, use the TLC strip (radiochromatogram) for the *Radiochemical Identity* test.

Calculate the percentage of radioactivity at the origin:

$$\text{Result}_A = (r_U/r_T) \times 100$$

r_U = response at the origin of the radiochromatogram

r_T = sum of all responses in the radiochromatogram

Chromatographic system B

(See *Chromatography ⟨621⟩, General Procedures, Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: Glass fiber chromatographic strip impregnated with silica gel (1 cm × 10 cm)

Application volume: A volume of Injection providing a count rate of about 20,000 counts/min

Developing solvent system: Acetone

Analysis B

Apply one small drop of the radioactive solution (about 20,000 counts/min) to the origin (1.5 cm from one end of the strip) of *Adsorbent*, and dry it under a stream of nitrogen. Develop the *Adsorbent* in the *Developing solvent system*. Allow the solvent front to move to 8 cm from the origin, and allow it to dry. Determine the radioactivity distribution by scanning the chromatogram with a suitable radioactivity counting instrument. Technetium Tc 99m pentetate and Hydrolyzed Technetium Tc 99m are located at the origin (R_F 0–0.1) and the free Pertechnetate (TcO_4-) is located at the solvent front (R_F 0.85–1.0). After completing the test for *Radiochemical Purity*, use the TLC strip for the *Radiochemical Identity* test.

Calculate the percentage of radioactivity at the solvent front:

$$\text{Result}_B = (r_U/r_T) \times 100$$

r_U = response at the solvent front of the radiochromatogram

r_T = sum of all responses in the radiochromatogram

Acceptance criteria: The sum of the percentage of radioactivity at the origin in *Analysis A* (Result_A) and the percentage of radioactivity at the solvent front in *Analysis B* (Result_B) is NMT 10.0%.▲ (USP 1-Dec-2024)

SPECIFIC TESTS

Delete the following:

▲• **Biological Distribution**▲ (USP 1-Dec-2024)

• **pH ⟨791⟩:** 3.8–7.5

Add the following:

▲• **Appearance:** Clear, free from visible particulates▲ (USP 1-Dec-2024)

Change to read:

• **Bacterial Endotoxins Test ⟨85⟩:** ▲Meets the requirements. The Injection may be distributed or dispensed prior to completion of the test.▲ (USP 1-Dec-2024)

Add the following:

▲• **Sterility Tests ⟨71⟩:** Meets the requirements. The Injection may be distributed or dispensed prior to completion of the test.▲ (USP 1-Dec-2024)

Delete the following:

▲• **Other Requirements**▲ (USP 1-Dec-2024)

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, at ▲25°; excursions permitted between 15° and 30°.▲ (USP 1-Dec-2024)

• **Labeling:** Label it to include the following, in addition to the information specified for *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*: the time and date of calibration; the amount of ^{99m}Tc as labeled pentetic acid complex expressed as total megabecquerel (microcurie or millicurie) and concentration as megabecquerel (microcurie or millicurie) per milliliter at the time of calibration; the expiration date; and the statement: [**Caution—**Radioactive Material]. The labeling indicates that in making dosage calculations, correction is to be made for radioactive decay and also indicates that the radioactive half-life of ^{99m}Tc is 6.0 h.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
TECHNETIUM TC 99M PENTETATE INJECTION	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 49(1)

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