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Technetium Tc 99m Tetrofosmin Injection

DEFINITION

Technetium Tc 99m Tetrofosmin Injection is a sterile, aqueous solution, suitable for intravenous injection, that contains ^{99m}Tc in the form of a complex of tetrofosmin. It contains NLT 90.0% and NMT 110.0% of the labeled amount of ^{99m}Tc as tetrofosmin complex expressed in megabecquerels (or millicuries) per milliliter at the date and time indicated in the labeling. Other chemical forms of radioactivity are NMT 10.0% of the total radioactivity. It may contain reducing agents, stabilizers, and buffers. It contains no antimicrobial agents.

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

Acceptance criteria: The retardation factor of the spot for Tc 99m tetrofosmin in the chromatogram of the Injection corresponds with that stated in the test for *Radiochemical Purity*.▲ (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 (microcuries) 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 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)

Radionuclidic Impurity	Most Prominent Photopeaks	Half-Life	Acceptance Criteria, NMT ^a
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.

• RADIOCHEMICAL PURITY

Chromatographic system

(See [Chromatography \(621\)](#), [General Procedures](#), [Thin-Layer Chromatography](#).)

Mode: TLC

Adsorbent: 2-cm × 20-cm instant thin-layer chromatographic silica gel strip

Application volume: 10–20 μL

Developing solvent system: [Acetone](#) and [dichloromethane](#) (35:65)

Analysis: Apply the Injection about 3.0 cm from the bottom of the *Adsorbent*. Immediately develop the chromatogram in the *Developing solvent system* by ascending chromatography to a height of 15 cm and allow to air-dry. Determine the radioactivity distribution of the chromatogram by scanning with a suitable radiation detector. The R_f value of the ^{99m}Tc tetrofosmin spot is approximately 0.5.

Acceptance criteria: The sum of radioactivity at the solvent front (unbound pertechnetate) and the origin (reduced hydrolyzed technetium and hydrophilic impurities) is NMT 10%.

SPECIFIC TESTS

Add the following:

▲ **APPEARANCE:** Clear, colorless solution, free from visible particulates ▲ (USP 1-Dec-2024)

• **pH (791):** 8.3–9.1

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

- **PACKAGING AND STORAGE:** Store in adequately shielded, single-dose or multiple-dose containers. Protect from light. Store at a temperature not exceeding 25°.
- **LABELING:** Label the Injection to include the following, in addition to the information specified under [Labeling \(7\), Labels and Labeling for Injectable Products](#): the time and date of calibration; the amount of ^{99m}Tc as labeled tetrofosmin expressed as total megabecquerels (or millicuries) and the concentration as megabecquerels per milliliter (or as millicuries per milliliter) on the date and time of calibration; the expiration date and time; 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 TETROFOSMIN 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](#)

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