Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Aug-2024
Document Type: USP Monographs
DocId: GUID-77FE6A54-A65D-4626-8520-3B814358395D_4_en-US
DOI: https://doi.org/10.31003/USPNF_M80782_04_01
DOI Ref: z6jis

Technetium Tc 99m Red Blood Cells Injection

DEFINITION

Technetium Tc 99m Red Blood Cells Injection is a preparation of anticoagulated whole blood that is labeled with radioactive technetium (^{99m}Tc). The cells are prepared for labeling by collection of an autologous sample of whole blood, which is anticoagulated with Heparin Sodium or anticoagulant dextrose solution.

Technetium Tc 99m Red Blood Cells Injection contains NLT 90.0% and NMT 110.0% of the labeled concentration of ^{99m}Tc as labeled blood cells expressed in megabecquerels (or in millicuries or microcuries) per milliliter at the time indicated in the labeling. It may contain anticoagulants, such as heparin or anticoagulant citrate solution, chelating agents, stannous chloride, and sodium hypochlorite. Other chemical forms of radioactivity are NMT 10.0% of the total radioactivity. When derived from donor blood, its production and distribution are subject to federal regulations (see *Radioactivity ⟨821⟩* and *Biologics ⟨1041⟩*).

[**Caution—**A strict aseptic technique must be followed for collection of the blood sample, along with the processing steps required to label it with ^{99m}Tc. The blood samples must be labeled with the name of the patient and patient's identification code to prevent administration of the sample to other than the intended patient. In the event that donor blood is used, it must first be tested for viral contaminants and carefully typed and cross-matched to ensure compatibility with that of the recipient.]

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 distribution of the radioactivity found in the *Sample solution* for the *Radiochemical Purity* test.

Acceptance criteria: The distribution of the radioactivity contributes to the identification of the preparation.▲ (USP 1-Aug-2024)

ASSAY

• **Radioactive Concentration (Strength)**

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

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

Acceptance criteria: 90.0%–110.0% of the labeled concentration 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 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 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**

Sample solution: Transfer 0.2 mL of the Injection to a centrifuge tube containing 2 mL of 0.9% sodium chloride solution. Centrifuge for 5 min, and carefully withdraw the diluted plasma by pipet.

Analysis: Measure the radioactivity in the plasma and red blood cells of the *Sample solution* separately in a suitable counter.

Calculate ▲the percentage of ^{99m}Tc bound to the red blood cells in the portion of Injection taken:▲ (USP 1-Aug-2024)

$$\text{Result} = [A_{RBC}/(A_{RBC} + A_P)] \times 100$$

A_{RBC} = activity in the red blood cells

A_P = activity in the plasma

Acceptance criteria: NLT 90% of the ^{99m}Tc present in the Injection is bound to the red blood cells

SPECIFIC TESTS

• **Clarity and Color of Solution**

Analysis: Observe the appearance and color of the *Sample solution* obtained as directed in the *Radiochemical Purity* test.

Acceptance criteria: The diluted plasma is clear and has a colorless to a very slight pink or yellow appearance. Samples that produce a distinctive red coloration are not acceptable for administration.

• **pH ⟨791⟩:** 5.5–8.0

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-Aug-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-Aug-2024)

Delete the following:

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

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in adequately shielded single-dose or multiple-dose containers, at controlled room temperature.

• **Labeling:** Label the Injection to include the following, in addition to the information specified under *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*: the patient's name and identification number; the type of anticoagulant used; the time and date of calibration; the amount expressed as total megabecquerels (or microcuries or millicuries) and concentration as megabecquerels (or microcuries or millicuries) 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 RED BLOOD CELLS 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)

Current DocID: GUID-77FE6A54-A65D-4626-8520-3B814358395D_4_en-US

DOI: https://doi.org/10.31003/USPNF_M80782_04_01

DOI ref: z6jis