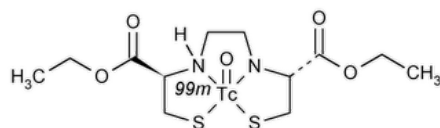


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Technetium Tc 99m Bicisate Injection



DEFINITION

Technetium Tc 99m Bicisate Injection is a sterile, clear, colorless solution, suitable for intravenous administration, of bicisate dihydrochloride complexed to radioactive technetium (^{99m}Tc). It contains NLT 90.0% and NMT 110.0% of the labeled amount of ^{99m}Tc as a complex with bicisate, expressed in megabecquerels (or in millicuries) per milliliter at the time indicated in the labeling. Other chemical forms of radioactivity are NMT 10% 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

Acceptance criteria: The retardation factors of the spots for Tc 99m bicisate and/or Tc(IV) 99m bicisate in the chromatogram of the *Sample* correspond with the ranges stated in the test for *Radiochemical Impurities*. ▲ (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 ^{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: Prepare four vials of Injection and perform the test on each vial.

Chromatographic system

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

Mode: TLC

Adsorbent: 2.5-cm × 7.5-cm chromatographic silica gel sheet

Application volume: About 5 μL

Developing solvent system: [Ethyl acetate](#)

Analysis

Sample: ▲The *Sample solution* used to perform this test is also used to perform the test for *Radiochemical Impurities*. Perform the tests in parallel with a minimal delay in spotting of the chromatographic media following the 30-min Injection incubation period.▲ (USP 1-Dec-2024)

Place the *Sample solution* about 2 cm from the bottom of the *Adsorbent* and allow to dry for 5–10 min. Position the plate in a pre-equilibrated chromatographic chamber containing the *Developing solvent system*, and develop the chromatogram until the solvent front has moved 5 cm from the origin. Remove the plate from the chamber, and allow to dry. Cut the chromatographic sheet 4.5 cm from the