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Technetium Tc 99m Sulfur Colloid Injection

Sulfur, colloidal, metastable technetium-99 labeled

CAS RN®: 7704-34-9.

» Technetium Tc 99m Sulfur Colloid Injection is a sterile, colloidal dispersion of sulfur labeled with radioactive ^{99m}Tc, suitable for intravenous administration.

Technetium Tc 99m Sulfur Colloid Injection contains not less than 90.0 percent and not more than 110.0 percent of the labeled concentration of ^{99m}Tc as sulfur colloid expressed in megabecquerels (microcuries or millicuries) per mL at the time indicated in the labeling. It may contain chelating agents, buffers, and stabilizing agents. Other chemical forms of radioactivity do not exceed 8 percent of the total radioactivity.

[Note—Agitate the container before withdrawing the Injection into a syringe.]

Packaging and storage—Store in single-dose or multiple-dose containers.

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 sulfur colloid expressed as total megabecquerels (microcuries or millicuries) and concentration as megabecquerels (microcuries or millicuries) per mL 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 hours; in addition, the labeling states that it is not to be used if flocculent material is visible and directs that the container be agitated before the Injection is withdrawn into a syringe.

Radionuclide identification (see *Radioactivity ⟨821⟩*)—It meets the requirements of the test for *Radionuclide identification* under *Sodium Pertechnetate Tc 99m Injection*.

Bacterial Endotoxins Test ⟨85⟩—The limit of endotoxin content is not more than 175/*V* USP Endotoxin Unit per mL of the Injection, when compared with the USP Endotoxin RS, in which *V* is the maximum recommended total dose, in mL, at the expiration date or time.

pH ⟨791⟩: between 4.5 and 7.5.

Radionuclidic purity—It meets the requirements of the test for *Radionuclidic purity* under *Sodium Pertechnetate Tc 99m Injection*.

Radiochemical purity—Place a measured volume of Injection, appropriately diluted, such that it provides a count rate of about 20,000 counts per minute, about 25 mm from one end of a 25- × 300-mm strip of chromatographic paper (see *Chromatography ⟨621⟩*), and allow to dry. Develop the chromatogram over a suitable period by ascending chromatography, using dilute methanol (8.5 in 10), and air-dry. Determine the radioactivity distribution by scanning the chromatogram with a suitable collimated radiation detector. Not less than 92% of the total radioactivity is found as sulfur colloid (at the point of application).

Biological distribution—Inject intravenously between 0.075 MBq and 0.75 MBq (2 µCi and 20 µCi) of the Injection in a volume not exceeding 0.2 mL into the caudal vein of each of three 20-g to 25-g mice. Ten to 30 minutes after the injection, sacrifice the animals, and carefully remove the liver and lungs of each by dissection. Place each organ and remaining carcass in separate, suitable counting containers, and determine the radioactivity, in counts per minute, in each container in an appropriate scintillation well counter, using the same counting geometry. Determine the percentage of radioactivity in the liver and the lungs taken by the formula:

$$100(A/B)$$

in which *A* is the net radioactivity, in counts per minute, in the organ, and *B* is the total radioactivity, in counts per minute, in the lungs, liver, and carcass. Not less than 80% of the radioactivity is found in the liver and not more than 5% of the radioactivity is found in the lungs, in two of the mice.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*, except that the Injection may be distributed or dispensed prior to completion of the test for *Sterility*, the latter test being started on the day of final manufacture, and except that it is not subject to the recommendation on *Container Content*.

Assay for radioactivity (see *Radioactivity ⟨821⟩*)—Using a suitable counting assembly, determine the radioactivity, in MBq (µCi) per mL, of Injection by use of a calibrated system.

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

Topic/Question	Contact	Expert Committee
TECHNETIUM TC 99M SULFUR COLLOID 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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