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Technetium Tc 99m Succimer Injection

meso-2,3-Dimercaptosuccinic acid, ^{99m}Tc complex.

» Technetium Tc 99m Succimer Injection is a sterile, clear, colorless, aqueous solution of succimer complexed with ^{99m}Tc. It is suitable for intravenous administration. It contains not less than 85.0 percent of the labeled amount of ^{99m}Tc as the succimer complex expressed in megabecquerels (microcuries or millicuries) per mL at the time indicated in the labeling. It may contain reducing agents. Other chemical forms of radioactivity do not exceed 15.0 percent of the total radioactivity.

Packaging and storage—Preserve in single-dose containers, at a temperature between 15° and 30°. Do not freeze or store above 30°. Protect from light.

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 succimer 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 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 hours. In addition, the labeling states that it is not to be used if discoloration or particulate matter is observed. [Note—A beyond-use time of 30 minutes shall be stated on the label upon constitution with 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 2.0 and 3.0.

Radiochemical purity—Activate a 65- × 95-mm silicic acid thin-layer chromatographic plate by heating at 100-110° for 30 minutes. Cool over silica gel and immediately apply 1 µL of Injection, appropriately diluted, if necessary, to a radioactive concentration of 18.5 to 370 MBq (0.5 to 10 mCi) per mL, about 17 mm from one end of the chromatographic plate, and allow to dry. Develop the chromatogram over a period of about 30 to 45 minutes by ascending chromatography, using *n*-butanol saturated with 0.3 N hydrochloric acid, and air-dry. Determine the radioactive distribution by scanning the chromatogram with a suitable collimated radiation detector. Not less than 85% of the total radioactivity is found as succimer at an R_F between 0.45 and 0.70. Hydrolyzed ^{99m}Tc is located at the origin (R_F 0 to 0.15) and the unbound ^{99m}Tc is located at the solvent front (R_F 1.0).

Biological distribution—Inject intravenously between 3.7 MBq and 92.5 MBq (100 µCi and 2500 µCi) of Injection, in a volume of 0.2 to 0.25 mL, into the caudal vein of each of three 125-g to 225-g anesthetized Sprague-Dawley female rats. Clamp the opening of the urethra with a hemostat. Sacrifice the animals 1 hour after the injection, and carefully remove the kidneys, bladder, and liver and spleen of each as *three* separate organs by dissections. Place each organ and the remaining carcass (excluding the tail) in separate, suitable counting containers, and determine the radioactivity, in counts per minute, in each container with an appropriate detector, using the same counting geometry. Determine the percentage of administered radioactive dose in each organ: not less than 40% of the administered radioactive dose is found in the kidneys and a ratio of not less than 6:1 of the administered dose is found in the ratio kidneys/(liver and spleen), in not fewer than two of the animals.

Other requirements—It meets the requirements of the tests for *Radionuclide identification* and *Radionuclidic purity* under *Sodium Pertechnetate Tc 99m Injection.* It meets also the requirements under *Injections and Implanted Drug Products ⟨1⟩*, except that it 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.

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

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