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Sodium Pertechnetate Tc 99m Injection

Pertechnetic acid ($H^{99m}TcO_4$), sodium salt.

Sodium pertechnetate ($Na^{99m}TcO_4$)

CAS RN®: 23288-60-0; UNII: A0730CX801.

» Sodium Pertechnetate Tc 99m Injection is a sterile solution, suitable for intravenous or oral administration, containing radioactive technetium (^{99m}Tc) in the form of sodium pertechnetate and sufficient Sodium Chloride to make the solution isotonic. Technetium 99m is a radioactive nuclide formed by the radioactive decay of molybdenum 99. Molybdenum 99 is a radioactive isotope of molybdenum and may be formed by the neutron bombardment of molybdenum 98 or as a product of uranium fission.

Sodium Pertechnetate Tc 99m Injection contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of ^{99m}Tc at the date and hour stated on the label. Other chemical forms of ^{99m}Tc do not exceed 5 percent of the total radioactivity.

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

Labeling—If intended for intravenous use, label it with the information specified for *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*. Label it also to include the following: the time and date of calibration; the amount of ^{99m}Tc as sodium pertechnetate expressed as total megabecquerels (millicuries) and as megabecquerels (millicuries) per mL on the date and at the time of calibration; a statement of the intended use, whether oral or intravenous; the expiration date; and the statement "Caution—Radioactive Material." If the Injection has been prepared from molybdenum 99 produced from uranium fission, the label so states. 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.

Radionuclide identification (see *Radioactivity ⟨821⟩*)—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.

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.

Radiochemical purity—Place a 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⟩*). Develop the chromatogram over a suitable period of time by ascending chromatography, using a mixture of acetone and 2 N hydrochloric acid (80:20). Allow the chromatogram to air-dry. Determine the radioactivity distribution by scanning the chromatogram with a suitable collimated radiation detector. The radioactivity of the pertechnetate band is not less than 95% of the total radioactivity in the test specimen. The R_F value for the pertechnetate band (approximately 0.9) falls within ±10.0% of the value found for a known sodium pertechnetate Tc 99m specimen when determined under identical conditions.

Radionuclidic purity—Using a suitable counting assembly , determine the radioactivity of each radionuclidic impurity, in kBq per MBq (µCi per mCi) of technetium 99m, in the Injection by use of a calibrated system as directed under *Radioactivity ⟨821⟩*.

For Injection prepared from technetium 99m derived from parent molybdenum 99 formed as a result of neutron bombardment of stable molybdenum—

MOLYBDENUM 99—The presence of molybdenum 99 in the Injection is shown by its characteristic gamma-ray spectrum. The most prominent photopeaks of this radioactive nuclide have energies of 0.181, 0.740, and 0.780 MeV. Molybdenum 99 decays with a radioactive half-life of 66.0 hours. The amount of molybdenum 99 is not greater than 0.15 kBq per MBq (0.15 µCi per mCi) of technetium 99m per administered dose in the Injection, at the time of administration.

OTHER GAMMA-EMITTING RADIONUCLIDIC IMPURITIES—The total amount of other gamma-emitting radionuclidic impurities does not exceed 0.5 kBq per MBq (0.5 µCi per mCi) of technetium 99m, and does not exceed 92 kBq (2.5 µCi) per administered dose of the Injection, at the time of administration.

For Injection prepared from technetium 99m derived from parent molybdenum 99 formed as a result of uranium fission—Gamma- and beta-emitting impurities—

MOLYBDENUM 99—The Injection meets the requirements set forth for the Injection prepared by neutron irradiation of stable molybdenum (see foregoing).

IODINE 131—The most prominent photopeak of this radioactive nuclide has an energy of 0.364 MeV. Iodine 131 decays with a radioactive half-life of 8.08 days. The concentration of iodine 131 is not more than 0.05 kBq per MBq (0.05 µCi per mCi) of technetium 99m, at the time of administration.

RUTHENIUM 103—The most prominent photopeak of this radioactive nuclide has an energy of 0.497 MeV. Ruthenium 103 decays with a radioactive half-life of 39.5 days. The concentration of ruthenium 103 is not more than 0.05 kBq per MBq (0.05 µCi per mCi) of technetium 99m, at the time of administration.

STRONTIUM 89—Determine the presence of strontium 89 in the Injection by a counting system appropriate for the detection of particulate radiations. Strontium 89 decays by a beta emission with a maximum energy of 1.463 MeV, and a radioactive half-life of 52.7 days. Strontium 89 may be present in a concentration of not more than 0.0006 kBq per MBq (0.0006 µCi per mCi) of technetium 99m, at the time of administration.

STRONTIUM 90—Determine the presence of strontium 90 in the Injection by a counting system appropriate for the detection of particulate radiations. Strontium 90 decays by a beta emission with a maximum energy of 0.546 MeV, and a radioactive half-life of 27.7 years. Strontium 90 may be present in a concentration of not more than 0.00006 kBq per MBq (0.00006 µCi per mCi) of technetium 99m, at the time of administration.

ALL OTHER RADIONUCLIDIC IMPURITIES—Not more than 0.01% of all other beta and gamma emitters is present at the time of administration. Not more than 0.001 Bq of gross alpha impurity per 1 MBq (or 0.001 nCi of gross alpha impurity per 1 mCi) of technetium 99m is present at the time of administration.

Chemical purity—

Aluminum (To be determined if separation is accomplished by an alumina column in the preparation of the Injection)—

ALUMINUM STANDARD SOLUTION—Dissolve 35.17 mg, accurately weighed, of aluminum potassium sulfate dodecahydrate in water to make 1000.0 mL. Each mL of this solution contains 2 µg of Al.

PROCEDURE—Pipet 10 mL of *Aluminum standard solution* into each of two 50-mL volumetric flasks. To each flask add 3 drops of methyl orange TS and 2 drops of 6 N ammonium hydroxide, then add 0.5 N hydrochloric acid, dropwise, until the solution turns red. To one flask add 25 mL of sodium thioglycolate TS, and to the other flask add 1 mL of edetate disodium TS. To each flask add 5 mL of eriochrome cyanine TS and 5 mL of acetate buffer TS, and add water to volume. Immediately determine the absorbance of the solution containing sodium thioglycolate TS at the wavelength of maximum absorbance at about 535 nm, with a suitable spectrophotometer, using the solution containing the edetate disodium TS as a blank. Repeat the procedure using two 1.0-mL aliquots of Injection. Calculate the quantity, in µg per mL, of aluminum in the Injection taken by the formula:

$$20(T_U/T_S)$$

in which T_U and T_S are the absorbances of the solution from the Injection and the solution containing the aluminum standard, respectively. The concentration of aluminum ion in the Injection is not greater than 10 µg per mL.

Methyl ethyl ketone (To be determined if separation is accomplished by liquid-liquid extraction in the preparation of the Injection)—Place 1.0 mL of the Injection in a suitable container, and dilute with water to 20.0 mL. Add 2.0 mL of 1 N sodium hydroxide, mix, then add 2.0 mL of 0.1 N iodine, dropwise, and again mix. At the same time, prepare a standard by placing 1.0 mL of a solution of methyl ethyl ketone (1 in 1000) in a similar container and diluting with water to 20.0 mL. Add 2.0 mL of 1 N sodium hydroxide, mix, then add 2.0 mL of 0.1 N iodine, dropwise, and again mix. After 2 minutes, the turbidity of the test specimen does not exceed that of the standard (0.1%).

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*, except that the Injection may be distributed or dispensed prior to the completion of the test for *Sterility*, the latter test being started on the day of 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 (mCi) per mL, in 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
SODIUM PERTECHNETATE TC 99M 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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