Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-20C56809-CB33-4332-A180-DC29C7E4D48D_3_en-US
DOI: https://doi.org/10.31003/USPNF_M80770_03_01
DOI Ref: nd490

Technetium Tc 99m Pyrophosphate Injection

» Technetium Tc 99m Pyrophosphate Injection is a sterile, aqueous solution, suitable for intravenous administration, of pyrophosphate that is labeled with ^{99m}Tc. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of ^{99m}Tc as pyrophosphate expressed in megabecquerels (microcuries or millicuries) per mL at the time indicated in the labeling. It may contain antimicrobial agents, buffers, reducing agents, and stabilizers. Other chemical forms of radioactivity do not exceed 10.0 percent of the total radioactivity.

Packaging and storage—Preserve in single-dose or multiple-dose containers, at a temperature between 2° and 8°.

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 tetrasodium pyrophosphate 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.

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 4.0 and 7.5.

Radiochemical purity—The determination of radiochemical purity for this product requires the use of two separate chromatography systems.

System A—Under an atmosphere of nitrogen, place a measured volume of Injection, appropriately diluted, such that it provides a count rate of about 20,000 counts per minute, about 20 mm from one end of a thin-layer chromatographic strip impregnated with silica gel (see *Chromatography ⟨621⟩*), and allow to dry. Develop the chromatogram over a suitable period by ascending chromatography, using saline TS, and dry it under nitrogen. Determine the radioactivity distribution by scanning the chromatogram with a suitable collimated radiation detector. Hydrolyzed Tc 99m and technetium-tin colloid are located at the origin (R_F 0 to 0.1).

System B—Proceed as directed for *System A*, except to develop the chromatogram in a mixture of methanol and acetone (1:1). Free pertechnetate is located at the solvent front. The sum of the percentage of radioactivity at the origin in *System A* plus the percentage of radioactivity at the solvent front in *System B* is not greater than 10.0%.

Biological distribution—Inject intravenously between 0.075 MBq and 75 MBq (2 µCi and 2 mCi) of Injection, in a volume not exceeding 0.2 mL, into the caudal or external jugular vein of each of three 175- to 250-g rats. Approximately 1 hour after the injection, sacrifice the animals, and carefully remove the liver, both kidneys, and one femur of each by dissection, freeing the femur from soft tissue. Remove the tail 20 to 30 mm above the injection site, and discard. Place each organ, both kidneys, and the remaining carcass 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 radioactivity in the liver, kidneys, and femur 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 liver, kidneys, femur, and carcass. Not more than 5.0% of the total radioactivity is found in the liver or in the kidneys, and not less than 1.0% of the total radioactivity is found in the femur, in not fewer than 2 of the rats.

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 the Injection by use of a calibrated system.

Topic/Question	Contact	Expert Committee
TECHNETIUM TC 99M PYROPHOSPHATE 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-20C56809-CB33-4332-A180-DC29C7E4D48D_3_en-US
Previous DocID: GUID-20C56809-CB33-4332-A180-DC29C7E4D48D_1_en-US
DOI: https://doi.org/10.31003/USPNF_M80770_03_01
DOI ref: nd490