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Technetium Tc 99m Medronate Injection

» Technetium Tc 99m Medronate Injection is a sterile, aqueous solution, suitable for intravenous administration, of sodium medronate and stannous chloride or stannous fluoride that is labeled with radioactive Tc 99m. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of Tc 99m as stannous medronate complex expressed in megabecquerels (microcuries or millicuries) per mL at the date and time indicated in the labeling. It may contain antimicrobial agents, antioxidants, and buffers. 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 specified in the labeling.

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 7.8.

Radiochemical purity—Not more than 10.0% of unbound Tc 99m (free pertechnetate), hydrolyzed Tc 99m, and technetium-tin colloid is present, determined as follows.

System A—Under an atmosphere of nitrogen, place a measured volume of Injection, such that it provides a count rate of about 20,000 counts per minute, about 25 mm from one end of a paper chromatographic strip (see *Chromatography* ⟨621⟩). Immediately develop the chromatogram over a suitable period by ascending chromatography, using sodium chloride solution (0.9 in 100), 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 dilute methanol (85 in 100). Free pertechnetate is located at an R_F of 0.6 to 0.8. The sum of the percentage of radioactivity at the origin in *System A* plus the percentage of radioactivity at an R_F of 0.6 to 0.8 in *System B* is not greater than 10.0%.

Other requirements—It meets the requirements of the tests for *Radionuclide identification* and *Radionuclidic purity* under *Sodium Pertechnetate Tc 99m Injection*, and meets the requirements for *Labeling*, *Biological distribution*, and *Assay for radioactivity* under *Technetium Tc 99m Pyrophosphate 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 manufacture, and except that it is not subject to the recommendation on *Container Content*.

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

Topic/Question	Contact	Expert Committee
TECHNETIUM TC 99M MEDRONATE 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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