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Technetium Tc 99m Oxidronate Injection

» Technetium Tc 99m Oxidronate Injection is a sterile, clear, colorless solution, suitable for intravenous administration, of radioactive technetium (^{99m}Tc) in the form of a chelate of oxidronate sodium. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of ^{99m}Tc as chelate expressed in megabecquerels (microcuries or millicuries) per mL at the time indicated in the labeling. It may contain buffers, preservatives, 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.

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 oxidronate 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.

pH (791): between 2.5 and 7.0.

Other requirements—It meets the requirements for [Bacterial endotoxins](#), [Radiochemical purity](#), [Biological distribution](#), [Other requirements](#), and [Assay for radioactivity](#) under [Technetium Tc 99m Pyrophosphate Injection](#).

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
TECHNETIUM TC 99M OXIDRONATE 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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