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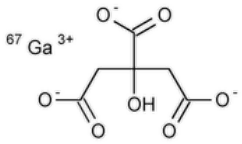
Gallium Citrate Ga 67 Injection



$C_6H_5{}^{67}GaO_7$

1,2,3-Propanetricarboxylic acid, 2-hydroxy-, gallium-^{67}Ga (1:1) salt.

Gallium-^{67}Ga citrate (1:1)

CAS RN®: 41183-64-6; 52260-70-5; UNII: 4LJK511Z86.

» Gallium Citrate Ga 67 Injection is a sterile aqueous solution of radioactive, essentially carrier-free gallium citrate Ga 67 suitable for intravenous administration. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of ^{67}Ga as citrate expressed in megabecquerels (microcuries or millicuries) per mL at the time indicated in the labeling. Other chemical forms of radioactivity do not exceed 3.0 percent of the total radioactivity. It may contain a preservative or stabilizer.

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 ^{67}Ga as labeled gallium citrate expressed as total megabecquerels (MBq) (microcuries [μCi] or millicuries [mCi]) and concentration as megabecquerels (μCi or mCi) 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 calibrations, correction is to be made for radioactive decay, and also indicates that the radioactive half-life of ^{67}Ga is 78.26 hours.

Bacterial Endotoxins Test ⟨85⟩—It meets the requirements of the *Bacterial Endotoxins Test*, the limit of endotoxin content being 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 8.0.

Radiochemical purity—Place 10 to 20 μL of Injection about 3 cm from one end of a 3- × 55-cm strip of chromatographic paper (see *Chromatography ⟨621⟩*). While spots are wet, immediately develop the chromatogram at room temperature to the 14-cm mark by ascending chromatography, using a solvent system consisting of a mixture of 1.36 g of sodium acetate and 0.58 mL of glacial acetic acid in each 100 mL of water. Allow the strip to partially dry, cover with clear tape, and determine the radioactivity distribution by scanning the chromatogram with a suitable collimated radiation detector: not less than 97.0% of the total radioactivity is found as gallium citrate when measured at the solvent front (R_F value equal to or greater than 0.9).

Radionuclide identification (see *Radioactivity ⟨821⟩*)—Its gamma-ray spectrum is identical to that of a specimen of ^{67}Ga of known purity that exhibits major photopeaks having energies of 93.3, 184.6, and 300.2 KeV.

Radionuclidic purity (see *Radioactivity⟨821⟩*)—Using a suitable counting assembly, determine the radionuclidic purity of the Injection: not less than 99% of the total radioactivity is present as ^{67}Ga at the time of calibration.

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—Using a suitable counting assembly , determine the radioactivity in MBq (μCi or mCi) per mL of Gallium Ga 67 Injection by use of a calibrated system as directed under *Radioactivity ⟨821⟩*.

Topic/Question	Contact	Expert Committee
GALLIUM CITRATE GA 67 INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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