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Iodinated I 125 Albumin Injection

Albumin labeled with iodine-125.

» Iodinated I 125 Albumin Injection is a sterile, buffered, isotonic solution containing normal human albumin adjusted to provide not more than 37 megabecquerels (1 millicurie) of radioactivity per mL. It is derived by mild iodination of normal human albumin with the use of radioactive iodine (^{125}I) to introduce not more than one gram-atom of iodine for each gram-molecule (60,000 g) of albumin.

Iodinated I 125 Albumin Injection contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of ^{125}I as iodinated albumin, expressed in megabecquerels (microcuries or in millicuries) per mL at the time indicated in the labeling. Other forms of radioactivity do not exceed 3 percent of the total radioactivity. Its production and distribution are subject to federal regulations (see Biologics ⟨1041⟩ and Radioactivity ⟨821⟩).

Packaging and storage—Preserve in single-dose or in 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 date of calibration; the amount of ^{125}I as iodinated albumin, expressed as total megabecquerels (microcuries or millicuries), and concentration as megabecquerels (microcuries or millicuries) per mL on the date of calibration; the expiration date; 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 ^{125}I is 60 days.

Radionuclide identification (see *Radioactivity ⟨821⟩*)—Its gamma-ray spectrum is identical to that of a specimen of ^{125}I of known purity that exhibits a major photopeak having an energy of 0.0355 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 7.0 and 8.5.

Radiochemical purity—Place a measured volume, diluted with a suitable diluent so 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⟩*), and allow to dry. Develop the chromatogram over a period of about 4 hours by ascending chromatography, using dilute methanol (7 in 10), and air-dry. Determine the radioactivity distribution by scanning the chromatogram with a suitable collimated radiation detector: not less than 97.0% of the total activity is found as albumin (at the point of application).

Other requirements—It meets the requirements under *Biologics ⟨1041⟩* and under *Injections and Implanted Drug Products ⟨1⟩*, except that it is not subject to the recommendation on *Container Content*. It meets all other applicable requirements of the FDA.

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

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

Topic/Question	Contact	Expert Committee
IODINATED I 125 ALBUMIN INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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