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Iothalamate Sodium I 125 Injection

» Iothalamate Sodium I 125 Injection is a sterile solution of Iothalamic Acid in Water for Injection prepared with the aid of Sodium Bicarbonate. A portion of the molecules contain radioactive iodine (^{125}I) in the molecular structure. It may contain small amounts of suitable buffers or a stabilizer.

Iothalamate Sodium I 125 Injection contains not less than 90.0 percent and not more than 110.0 percent of the concentration of Iothalamate Sodium and of the labeled amount of ^{125}I as Iothalamate Sodium expressed in kilobecquerels (or in microcuries) per mL at the time indicated in the labeling. Other chemical forms of radioactivity do not exceed 2.0 percent of the total radioactivity.

Packaging and storage—Preserve in single-dose or in multiple-dose containers that are adequately shielded.

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 ^{125}I as iothalamate sodium expressed as total megabecquerels (microcuries or millicuries equivalent) per mL at the time 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.

Bacterial Endotoxins Test ⟨85⟩—It contains 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.

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 photoelectric peak having an energy of 0.035 MeV.

Radiochemical purity—Place a measured volume of Injection, 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 methanol and ammonium hydroxide (100:1.5) adjusted with 2 N sulfuric acid to a pH of 3 to 6, and air-dry. Determine the radioactivity distribution with a suitable collimated radiation detector. The radioactivity under the free radioiodide peak is not more than 2% of the total area of all peaks: not less than 98% of the total activity is found at the point of application (as iothalamate sodium).

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*, except that it is not subject to the recommendation in *Container Content*.

Assay for radioactivity—Using a suitable counting assembly, determine the radioactivity, in kilobecquerels (or µCi) per mL, of the 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
IOTHALAMATE SODIUM I 125 INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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