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Indium In 111 Pentetreotide Injection

» Indium In 111 Pentetreotide Injection is a sterile solution, suitable for intravenous administration, containing radioactive indium (^{111}In) in the form of a chelate of pentetreotide. It contains not less than 90.0 percent and not more than 110 percent of the labeled amount of ^{111}In as the pentetreotide complex expressed in megabecquerels (or in millicuries) per mL at the time indicated in the labeling. It may contain sodium chloride, stabilizers, and buffers. Other forms of radioactivity do not exceed 10.0 percent of the total radioactivity.

Packaging and storage—Preserve in single-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 ^{111}In as labeled pentetreotide complex expressed as total megabecquerels (or millicuries) and the concentration expressed as megabecquerels (or millicuries) per mL on the date and 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 states that the radioactive half-life of ^{111}In is 67.3 hours.

Radionuclide identification ⟨see *Radioactivity* ⟨821⟩⟩—Its gamma-ray spectrum is identical to that of a specimen of ^{111}In that exhibits major photopeaks having energies of 0.171 and 0.245 MeV.

Bacterial Endotoxins Test ⟨85⟩—It contains not more than 175/*V* USP Endotoxin Unit per mL, in which *V* is the maximum recommended total dose, in mL, at the expiration date or time.

pH ⟨791⟩: between 3.8 and 4.3.

Radiochemical purity—

Solution A—Dissolve 6.8 g of sodium acetate in 500 mL of water. Adjust with glacial acetic acid to a pH of 5.5, dilute with water to 1000 mL, and mix. Filter through a filter having a porosity of 0.5 µm or less, and degas.

Solution B—Use methanol.

Mobile phase—Use variable mixtures of *Solution A* and *Solution B* as directed under *Chromatographic system.*

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 3.9-mm × 30-cm stainless steel column that contains 10-µm packing L1. It is also equipped with a flow-through gamma-ray detector having a cell volume of about 50 µL and calibrated to provide a linear response within the range of 0.5 to 15 MBq (14 to 400 µCi). The column temperature is maintained at 35°. The chromatograph is programmed to provide variable mixtures of *Solution A* and *Solution B*, and the initial flow rate is about 1 mL per minute. The column is equilibrated for at least 15 minutes with a mobile phase consisting of 60% *Solution A* and 40% *Solution B*. After injection, the composition of the mobile phase is changed linearly to 20% *Solution A* and 80% *Solution B* at 20 minutes, then changed to 100% *Solution B* over the next 0.1 minute, and is held at that percentage while the flow rate is increased linearly from 1 to 2 mL over the next 5 minutes, which is the end of the run. Counts are recorded and charted for 25 minutes at about 2-second intervals.

Procedure—Constitute the Injection, and allow to stand for 30 minutes. Inject a volume of Injection having an activity of 0.5 to 15 MBq (14 to 400 µCi) into the chromatograph, and record the chromatogram. The retention time of the ^{111}In pentetreotide peak (which should elute as a double peak) is between 4 and 5 relative to that of unbound ^{111}In. Record the counts for the ^{111}In pentetreotide, unbound ^{111}In, other impurity peaks, and a representative baseline segment, and calculate the percentage of radioactivity from ^{111}In pentetreotide by the formula:

$$100P/(P + O)$$

in which *P* is the count of the ^{111}In pentetreotide peak, and *O* is the count for all other peaks, each being corrected for its corresponding baseline count. The radioactivity of ^{111}In pentetreotide is not less than 90% of the total radioactivity.

Radionuclidic purity (see *Radioactivity*⟨821⟩)—Using a suitable counting assembly, determine the radioactivity of each radionuclidic impurity, in kBq per MBq (or µCi per mCi) of ^{111}In, in the Injection by use of a calibrated system.

Indium 114m—The presence of ^{114m}In in the Injection is demonstrated by a characteristic gamma-ray spectrum with prominent photopeaks having energies of 0.192, 0.558, and 0.724 MeV. ^{114m}In decays with a radioactive half-life of 49.5 days. The amount of ^{114m}In is not greater than 3 kBq per MBq (3 µCi per mCi) of ^{111}In.

ZINC 65—The presence of ^{65}Zn in the Injection is demonstrated by a characteristic gamma-ray spectrum with a prominent photopeak at 1.115 MeV. ^{65}Zn decays with a radioactive half-life of 243.9 days. The amount of ^{65}Zn is not greater than 3 kBq per MBq (3 µCi per mCi) of ^{111}In.

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 Tests* ⟨71⟩, the latter test being started on the day of final manufacture, and except that it is not subject to the recommendation on *Container Content*.

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

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

Topic/Question	Contact	Expert Committee
INDIUM IN 111 PENTETREOTIDE INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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