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Indium In 111 Pentetate Injection

» Indium In 111 Pentetate Injection is a sterile, isotonic solution suitable for intrathecal administration, containing radioactive indium (¹¹¹In) in the form of a chelate of pentetic acid. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of ¹¹¹In as the pentetic acid complex expressed in megabecquerels (microcuries or millicuries) per mL at the time indicated in the labeling. It may contain sodium chloride and buffers. Other chemical 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 ¹¹¹In as labeled pentetic acid complex expressed as total megabecquerels (millicuries or microcuries) and concentration as megabecquerels (microcuries 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 also indicates that the radioactive half-life of ¹¹¹In is 2.83 days.

BACTERIAL ENDOTOXINS TEST (85)—It contains not more than 14/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 8.0.

Radionuclide identification(see [Radioactivity \(821\)](#))—Its gamma-ray spectrum is identical to that of a specimen of ¹¹¹In that exhibits major photopeaks having energies of 0.173 and 0.247 MeV.

Radiochemical purity—Place 2 µL to 5 µL of Injection about 17 mm from one end of a 65- × 97-mm piece of silica gel-impregnated glass microfiber sheet (see under *Reagents* in the section [Reagents, Indicators, and Solutions](#)) (see also [Chromatography \(621\)](#)), and allow to dry. Repeat applications may be made to obtain a suitable count rate. Develop the chromatogram over a suitable period of time by ascending chromatography, using dilute methanol (8.5 in 10), and dry in an oven at 105 ± 5° for 5 minutes. Determine the radioactivity distribution by scanning the chromatogram with a suitable collimated radiation detector. The radioactivity of the indium pentetic acid complex band is not less than 90.0% of the total radioactivity, and the *R_f* value is between 0.8 and 1.0.

Radionuclidic purity—Using a suitable counting assembly, determine the radioactivity of each radionuclidic impurity, in kBq per MBq (µCi per mCi) of ¹¹¹In, in the Injection by use of a calibrated system as directed under [Radioactivity \(821\)](#).

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 ¹¹¹In.

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

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 final 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 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
INDIUM IN 111 PENTETATE INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

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