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Indium In 111 Capromab Pendetide Injection

» Indium In 111 Capromab Pendetide Injection is a sterile, nonpyrogenic, murine monoclonal antibody, 7E11-C 5.3, (CYT-351), an immunoconjugate prepared by specific modification of the carbohydrate groups and covalent binding to the tripeptide linker chelator, glycyltyrosyl-(N, *E*-diethylenetriaminepentaacetic acid)-lysine hydrochloride that is complexed with ^{111}In. It contains not less than 90.0 percent and not more than 110.0 percent of the specified amount of ^{111}In capromab pendetide, expressed in megabexquerels (or millicuries) per mL at the time indicated in the labeling. Other chemical forms of radioactivity do not exceed 10.0 percent of the total radioactivity. Immediately prior to use, the radiolabeling is performed with Indium In 111 Chloride Solution in the presence of a sodium acetate buffer. It contains sodium chloride and buffering agents as stabilizers. The immuno-reactive fraction, determined by a validated method, is not less than 70 percent. The monomer content is not less than 95 percent determined by a validated electrophoretic mobility method.

Packaging and storage—Preserve in adequately shielded single-dose containers at controlled room temperature for not more than 8 hours.

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 capromab pendetide as total MBq (or mCi) and concentration of MBq (or mCi) per mL, at the time of calibration; the expiration date and time; and the storage temperature 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 ^{111}In is 67.2 hours.

Bacterial Endotoxins Test ⟨85⟩—The limit of endotoxin content is not more than 175/*V* USP Endotoxin Units 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 5.0 and 7.0.

Radiochemical purity—

Absorbent: 1-cm × 8-cm instant silica gel strip.

Test solution: a mixture of the Injection and 0.05 M pentetic acid (1:1).

Application volume: 10 µL.

Developing solvent system: 0.9% sodium chloride solution.

Procedure—Proceed as directed for *Thin-Layer Chromatography* under *Chromatography ⟨621⟩* by ascending chromatography. Determine the distribution of radioactivity on the chromatogram by scanning with a suitable collimated radiochromatogram strip scanner, and determine the percentage of radiochemical purity of the test specimen. Not less than 90% of the In 111 activity is present as a band between the R_F values of 0 and 0.1.

Other requirements—It meets the requirements for *Radionuclide identification* and *Radionuclidic purity* under *Indium In 111 Chloride Solution*. It meets also the requirements under *Injections and Implanted Drug Products ⟨1⟩*, except that the radioactive component may be distributed or dispensed prior to completion of the test for *Sterility*, the latter test being started on the date of manufacture.

Assay for radioactivity (see *Radioactivity⟨821⟩*)—Using a suitable counting assembly, determine the total radioactivity, in MBq (or µCi), of the unshielded 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 CAPROMAB PENDETIDE INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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