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Indium In 111 Oxyquinoline Solution

» Indium In 111 Oxyquinoline Solution is a sterile, nonpyrogenic, isotonic aqueous solution suitable for the radiolabeling of blood cells, especially leukocytes and platelets, containing radioactive indium (^{111}In) in the form of a complex with 8-hydroxyquinoline, the latter being present in excess. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of ^{111}In as the 8-hydroxyquinoline complex expressed as megabecquerels (millicuries) per mL at the time indicated in the labeling. It may contain sodium chloride, surfactants, and buffers. Other chemical forms of radioactivity do not exceed 10.0 percent of the total radioactivity.

Specific activity: not less than 1.85 GBq (50 millicuries) per µg of indium.

Packaging and storage—Preserve in single-unit containers at a temperature between 15° and 25°.

Labeling—Label it to contain 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 the 8-hydroxyquinoline complex expressed as total megabecquerels (millicuries) and concentration as megabecquerels (millicuries) per mL on the date and time of calibration; the expiration date; the statement "Not for direct administration. Use only for radiolabeling of leukocytes in vitro. Administer radiolabeled cells subsequently by intravenous injection," 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 67.9 hours.

Pyrogen—It meets the requirements of the *Pyrogen Test ⟨151⟩*.

pH ⟨791⟩: between 6.5 and 7.5.

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.

Radiochemical purity—Place a suitable volume, about 100 µL, of Solution, dilute with 3 mL of 0.9 percent sodium chloride solution in a separator, and extract with 6 mL of *n*-octanol by vigorous shaking. Allow the phases to separate and then drain the lower, aqueous layer into a suitable stoppered counting tube. Drain the residual, organic layer into a similar counting tube. Rinse the separator with 1 mL of *n*-octanol, and drain this rinse into the counting tube containing the organic layer. Rinse the separator with 5 mL of 2 N hydrochloric acid, and drain this rinse into a third counting tube. Insert the stopper and measure the radioactivity in each of the three tubes in a suitable gamma counter or ionization chamber calibrated for ^{111}In. The radiochemical purity is calculated by the formula:

$$(A/B)$$

where A is the radioactivity measured in the organic layer and B is the sum of the radioactivity measured in the organic, aqueous, and acid solutions. The radioactivity of the 8-hydroxyquinoline complex is not less than 90.0% of the total radioactivity and is found in the organic layer.

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

Indium 114m—The limit of ^{114m}In is 3 kBq per MBq (3 µCi per mCi) of ^{111}In. ^{114m}In is quantified by counting the beta emissions of ground state ^{114}In using a beta-liquid scintillation counter with a high-energy channel set to discriminate against all counts arising from ^{111}In.

Zinc 65—The limit of ^{65}Zn is 3 kBq per MBq (3 µCi per mCi) of ^{111}In. The presence of ^{65}Zn in the Solution is demonstrated by a characteristic gamma-ray spectrum with a prominent photopeak at 1.116 MeV. ^{65}Zn decays with a radioactive half-life of 243.9 days.

Assay for radioactivity—Using a suitable counting assembly, determine the radioactivity, in MBq (mCi) per mL, of Solution by the 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 OXYQUINOLINE SOLUTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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