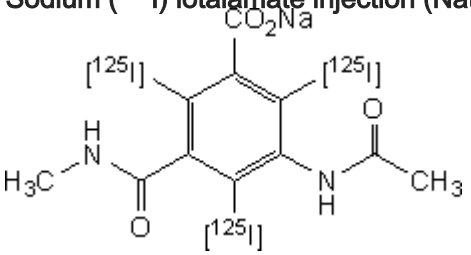
Sodium (^{125}I) iotalamate injection (Natrii (^{125}I) iotalamatis injectio)



$C_{11}H_8I_3N_2NaO_4$

Relative molecular mass. 635.9

Chemical names. Sodium 3-(acetylamino)-2,4,6-tri[^{125}I]iodo-5-(methylcarbamoyl)benzoate; sodium 5-(acetylamino)-2,4,6-tri[^{125}I]iodo-*N*-methylisophthalamate.

Description. Sodium (^{125}I) iotalamate injection is a clear, colourless aqueous solution.

Iodine-125 has a half-life of 59.4 days.

Category. Diagnostic

Storage. Sodium iotalamate (^{125}I) injection should be kept at a temperature between 2°C to 8°C, protected from light.

After aseptic withdrawal of the first dose from a multidose container, the container should be stored at a temperature between 2°C to 8°C and the contents used within 7 days.

Labelling. State the date of withdrawal of the first dose for multidose containers.

Additional information. Wherever V is used within the tests of this monograph, V is the maximum recommended dose in millilitres.

Requirements

Complies with the monograph for "Parenteral Preparations" and with that for "Radiopharmaceuticals".

Definition. Sodium iotalamate (^{125}I) injection is a sterile aqueous solution of iodine-125 in the form of iothalamic acid, suitable for intravenous administration and that contains sufficient sodium chloride to make the solution isotonic with blood. A small percentage of the molecules of iotalamate will contain iodine-125 in place of non-radioactive iodine. Sodium (^{125}I) iotalamate injection contains not less than 90% and not more than 110% of the content of iodine-125 stated on the label at the reference date and time stated on the label. Not less than 95% of the total radioactivity is due to iodine-125. Not less than 98% of the total iodine-125 radioactivity is present as iotalamate.

Manufacture

Radionuclide production. Iodine-125 may be obtained by neutron irradiation of xenon.

Production of radiopharmaceutical preparation. Sodium iotalamate (^{125}I) is generally prepared by exchange labelling and contains iotalamate in the unlabelled form. The injection may have the pH adjusted with sodium bicarbonate and may contain stabilizing and filling agents as well as antimicrobial preservatives and buffers. The injection may also be prepared under aseptic processing combined with sterilization by Filtration (see 5.8 Methods of sterilization).

Identity tests

• Either tests A and C or tests B and C may be applied.

A. Record the gamma-ray and X-ray spectrum using a suitable instrument with a sample of iodine-125, suitably diluted if needed. The spectrum is concordant with the *reference spectrum* of a specimen of iodine-125 in that it exhibits a major peak of 27 keV, corresponding to the X-ray of tellurium. Iodine-126 has half-life of 13.0 days and main peaks of 388 keV and 666 keV.

Standardized iodine-125 and caesium-137 solutions are available from laboratories recognized by the relevant national or regional authority.

B. The half-life determined using a suitable detector system is between 55 and 65 days.

C. Examine the radiochromatogram obtained in the test for radiochemical purity. The distribution of the radioactivity contributes to the identification of the preparation.

pH value. Carry out the test as described in the monograph for "Radiopharmaceuticals". pH of the injection, 7.0 to 8.5.

Sterility. The injection complies with 3.2 Test for sterility, modified as described in the monograph for “Radiopharmaceuticals”. Test for sterility will be initiated on the day of manufacture. The injection may be released for use before completion of the test.

Bacterial endotoxins. Carry out the test as described under 3.4 Test for bacterial endotoxins, modified as described in the monograph for “Radiopharmaceuticals”. The injection contains not more than 175/V I.U. of endotoxins per millilitre. The injection may be released for use before completion of the test.

Radionuclidic purity. Record the gamma-ray and X-ray spectrum using a suitable instrument and measure the half-life using a suitable method. Determine the relative amounts of iodine-125, iodine-126 and other radionuclidic impurities that may be present, on the assumption that the 666 keV gamma photon of iodine-126 is emitted in 33% of disintegrations, and that the 661 keV gamma photon of caesium-137 is emitted in 85.4% of disintegrations. Not less than 95% of the total radioactivity is due to iodine-125. Not more than 1% of the total radioactivity is due to iodine-126.

Radiochemical purity. Carry out the test as described under 1.14.2 Paper chromatography and ascending conditions, using paper for chromatography R.

Apply to the paper 10 µl of the injection to be examined, suitably diluted to give an optimum count rate and develop for a distance of 20 cm with a mixture of 100 volumes of methanol R and 1.5 volumes of ammonium hydroxide, adjusted with sulfuric acid (~100 g/l) TS to pH 3 to 6. Allow the paper to dry in air and determine the radioactivity distribution by a suitable method. In this system, iotalamate has an Rf value of about 0 and free iodine-125 has an Rf value of about 1. Not more than 2% of the total iodine-125 radioactivity is in the spot corresponding to free iodine-125. Not less than 98% of the total iodine-125 radioactivity is in the spot corresponding to iotalamate.

Radioactivity. Measure the radioactivity as described under R.1.1 Detection and measurement of radioactivity in a suitable calibrated counting equipment by comparison with a standardized iodine-125 solution or by measurement in an instrument calibrated with the aid of such a solution.

Standardized iodine-125 solutions are available from laboratories recognized by the relevant national or regional authority.