Sodium iodide (^{131}I) injection (Natrii iodidi (^{131}I) injectio)

$Na^{131}I$

Description. Sodium iodide (^{131}I) injection is a clear, colourless solution.

Iodine-131 has a half-life of 8.06 days.

Category. Diagnostic and therapeutic.

Storage. 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 iodide (^{131}I) injection is a sterile solution of iodine-131 as sodium iodide. The injection contains not less than 90% and not more than 110% of the content of iodine-131 stated on the label at the reference date and time stated on the label. Not less than 99.9% of the total radioactivity is due to iodine-131. Not less than 95% of the total iodine-131 radioactivity is present as iodide.

The specific radioactivity is:
- for therapeutic use, not less than 185 MBq (or 5 mCi) per microgram of iodine at the reference date and time stated on the label;
- for diagnostic use, not less than 185 kBq (or 5 µCi) per microgram of iodine at the reference date and time stated on the label.

Manufacture

Radionuclide production. Iodine-131 may be obtained by neutron irradiation of tellurium as carrier free sodium iodide or by extraction from uranium fission products.

Production of radiopharmaceutical preparation. Sodium iodide (^{131}I) injection may be sterilized by "Heating in an autoclave" (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-131, suitably diluted if needed. The spectrum is concordant with the *reference spectrum* of a specimen of iodine-131 in that it exhibits a major peak of 364 keV.

Standardized iodine-131 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 184 and 203 hours.

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 8.0

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. Determine the relative amounts of iodine-131, iodine-133, iodine-135 and other radionuclidic impurities that may be present. Iodine-133 has a half-life of 20.8 hours and main peaks of 530 keV and 875 keV. Iodine-135 has a half-life of 6.55 hours and main peaks of 527 keV, 1132 keV and 1260 keV. Not less than 99.9% of the total radioactivity is due to iodine-131.

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 each of the 3 following solutions and allow the paper to dry in air between each application. For solution (A) mix an equal volume of the injection to be examined, suitably diluted to give an optimum count rate and a solution containing 0.1 g of potassium iodide R, 0.2 g of potassium iodate R and 1 g of potassium bicarbonate R in 100 mL of water R. For solution (B) use a 2 g/l solution of potassium iodide R. For solution (C) use a 2 g/l solution of potassium iodate R. Develop for 2 hours with a mixture of 3 volumes of methanol R and 1 volume of water R. Allow the paper to dry in air and determine the position of the inactive potassium iodide and potassium iodate by the application of filter papers impregnated with a mixture of acetic acid R and potassium iodide R and a mixture of acetic acid R and potassium iodate R respectively. Determine the radioactivity distribution by a suitable method.

Not less than 95% of the total radioactivity is in the spot corresponding to iodide.

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-131 solution or by measurement in an instrument calibrated with the aid of such a solution.

Standardized iodine-131 solutions are available from laboratories recognized by the relevant national or regional authority.