Sodium iodide (^{131}I) solution (Natrii iodidi (^{131}I) solutio)

$Na^{131}I$

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

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

Category. Diagnostic and therapeutic.

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 "Liquid preparations for oral use" and with that for "Radiopharmaceuticals".

Definition. Sodium iodide (^{131}I) solution is a solution of iodine-131 as sodium iodide, suitable for oral administration. The solution 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 not less than 185 MBq (5 mCi) 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 or by extraction from uranium fission products.

Production of radiopharmaceutical preparation. Sodium iodide (^{131}I) solution may contain sodium thiosulfate, sodium hydrogen carbonate or other suitable reducing agents and may contain a suitable buffer. Sodium iodide (^{131}I) solution 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 solution, 7.0 to 8.0.

Sterility. The solution 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 solution 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-131, iodine-133, iodine-135 and other radionuclidic impurities that may be present. Iodine-133 has a half-life of 20.8 hours and exhibits major peaks of 530 keV and 875 keV. Iodine-135 has a half-life of 6.55 hours and exhibits major 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 solution (A) prepared as follows: mix an equal volume of the solution 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. Allow the paper to dry in air. Apply on the same paper 10 µl of a 2 g/l solution of potassium iodide R (solution B) and 10 µl of a 2 g/l solution of potassium iodate R (solution C) and allow the paper to dry in air. 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.

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