Sodium iodide (^{131}I) capsules (Natrii iodidi (^{131}I) capsulae)

$Na^{131}I$

Description. White or coloured gelatine capsules.

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

Category. Diagnostic and therapeutic.

Storage. Sodium iodide (^{131}I) capsules should be stored in a fume hood or well ventilated room.

Requirements

Complies with the monograph for "Capsules"and with that for "Radiopharmaceuticals".

Definition. Sodium iodide (^{131}I) capsules contain radioactive iodine-131 as sodium iodide adsorbed onto a solid matrix, such as anhydrous sodium sulfate or anhydrous disodium hydrogen phosphate, which is contained in hard gelatine capsules. Sodium iodide (^{131}I) capsules are suitable for oral administration. The capsules contain 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 MBq (or 5 mCi) per milligram 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.

Identity tests

• Either test A or test B 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. 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.

Standardized iodine-131, iodine-133 and iodine-135 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.

Radionuclidic purity. Determine the relative amounts of iodine-131, iodine-133, iodine-135 and other radionuclidic impurities that may be present. 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) homogenize the contents of a capsule in 5 mL of water R, add 5 mL of methanol R and centrifuge. Mix an equal volume of the supernatant liquid 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 a distance of 20 cm 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.

Dissolution. In a water-bath at 37°C, warm 10 mL of a potassium iodide (2 g/l) TS solution. Add a capsule to be examined and stir with a magnetic stirrer at a rotation speed of 20 revolutions per minute. The shell and its contents dissolve completely within 15 minutes.

Uniformity of content. Determine the radioactivity of 10 capsules individually and determine the average radioactivity per capsule. The radioactivity of none of the capsules differs by more than 10% from the average radioactivity per capsule. The relative standard deviation is not greater than 3.5%.

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.