Strontium (^{89}Sr) chloride injection (Strontii (^{89}Sr) chloridi injectio)

$Cl_2{}^{89}Sr$

Chemical name. [^{89}Sr]strontium dichloride.

Description. Strontium (^{89}Sr) chloride injection is a clear, colourless solution.

Strontium-89 has a half-life of 50.53 days.

Category. 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.

It is advised to use acrylic sheet for radiation protection and not lead.

Requirements

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

Definition. Strontium (^{89}Sr) chloride injection is a sterile solution of strontium-89 as strontium dichloride in presence of an excess of chloride ions, suitable for intravenous administration and that contains sufficient sodium chloride to make the solution isotonic with blood. The injection contains not less than 90% and not more than 110% of the content of strontium-89 stated on the label at the reference date and time stated on the label. Not less than 99% of the total radioactivity is due to strontium-89. The specific radioactivity is not less than 1.8 MBq (48.6 µCi) per mg of strontium at the reference date and time stated on the label. Not more than 0.6% of the total radioactivity is due to radionuclides other than strontium-89. The injection contains 6.0 mg per mL to 12.5 mg per mL of strontium.

Manufacture

Radionuclide production. Strontium-89 is produced by neutron irradiation of strontium enriched in strontium-88.

Production of radiopharmaceutical preparation. The injection may be sterilized by "Heating in an autoclave" or it may 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 beta-ray spectrum using a suitable instrument with a sample of strontium-89, suitably diluted if needed. The spectrum is concordant with the *reference spectrum* of a specimen of strontium-89 in that it exhibits a major peak of 1495 keV. The photon detected has an energy of 909 keV and is due to the short-lived daughter product, yttrium-89m (formed in 0.01% of the disintegrations), in equilibrium with strontium-89.

Standardized strontium-89 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 48 and 53 days.

C. A reddish-brown precipitate is formed when 0.1 mL of the injection to be examined is added with a freshly prepared 1g/l solution of sodium rhodizonate dibasic R.

pH value. Carry out the test as described in the monograph for "Radiopharmaceuticals". pH of the injection, 4.0 to 7.5.

Sterility. The injection complies with the test described under 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

Gamma-emitting impurities. Record the gamma- and X-ray spectra using a suitable instrument and measure the half-life using a suitable method. Determine the relative amount of gamma-emitting impurities. Not more than 0.4% of the total radioactivity is due to gamma-emitting radionuclides other than yttrium-89m.

Beta-emitting impurities. Using a suitable cationic exchange resin and a suitable chemical separation method, determine the relative amounts of sulphur-35 and phosphorus-32. Not more than 0.2% of the total radioactivity is due to beta-emitting impurities.

Chemical purity. Carry out the test as described under 1.8 Atomic spectrometry: emission and absorption. Record the atomic emission spectrum of a sample of about 50 µl of the injection to be examined and determine the contents of strontium-89 and any other metallic impurities.

Aluminium. Not more than 2 µg/mL.

Iron. Not more than 5 µg/mL.

Lead. Not more than 5 µg/mL.

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 strontium-89 solution or by measurement in an instrument calibrated with the aid of such a solution.

Standardized strontium-89 solutions are available from laboratories recognized by the relevant national or regional authority.