Technetium (^{99m}Tc) colloidal sulfur injection (Sulfuris colloidalis et technetii (^{99m}Tc) injectio)

Description. Technetium (^{99m}Tc) colloidal sulfur injection is a clear to opalescent, colourless to yellowish or brownish colloidal dispersion.

Technetium-99m has a half-life of 6.02 hours.

Category. Diagnostic.

Storage. Technetium (^{99m}Tc) colloidal sulfur injection should be kept at a temperature between 2°C to 8°C.

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. Technetium (^{99m}Tc) colloidal sulfur injection is a sterile, colloidal dispersion of sulfur labelled with technetium-99m. The injection is suitable for intravenous administration and contains sufficient sodium chloride to make the solution isotonic with blood. The content of technetium-99m is not less than 90% and not more than 110% of the content of technetium-99m stated on the label at the reference date and time stated on the label. Not less than 95% of the total technetium-99m radioactivity is present in colloidal form.

Manufacture

Radionuclide production. Technetium-99m is a radioactive nuclide formed by the radioactive decay of molybdenum-99. Molybdenum-99 is a radioactive isotope of molybdenum and may be produced by neutron irradiation of natural molybdenum or of molybdenum enriched in molybdenum-98 or it may be produced by uranium fission.

Production of radiopharmaceutical preparation. Technetium (^{99m}Tc) colloidal sulfur injection is prepared aseptically from sterile starting materials such as a sterile kit containing a colloidal dispersion of sulfur, the micelles of which are labelled with technetium-99m. Labelling of sulfur may be formed *in situ* by decomposition of thiosulfate in presence of sodium pertechnetate (^{99m}Tc) injection (fission or non-fission) and a suitable stabilizing, colloid-protecting substance such as gelatin, in acid medium. The injection may have the pH adjusted and may contain reducing, chelating and antioxidizing agents as well as antimicrobial preservatives and buffers.

Identity tests

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

A. Record the gamma-ray spectrum using a suitable instrument with a sample of technetium-99m, suitably diluted if needed. The spectrum is concordant with the *reference spectrum* of a specimen of technetium-99m in that it exhibits major peaks of 140 keV.

Standardized technetium-99m 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 5.72 and 6.32 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, 4.0 to 7.0.

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. Record the gamma-ray spectrum using a suitable instrument and measure the half-life using a suitable method. Determine the relative amounts of technetium-99m and radionuclidic impurities that may be present.

Radiochemical purity. Carry out the test as described under 1.14.2 Paper chromatography and ascending conditions, using cellulose paper strips. Apply to the paper about 5 µl of the injection to be examined, suitably diluted to give an optimum count rate and develop for a distance of 15 cm with 85% v/v methanol. Allow the paper to dry in air and determine the radioactivity distribution by a suitable method. In this system, technetium-99m colloidal sulfur has an Rf value of about 0 and the technetium-99m pertechnetate ion has an Rf value of about 0.6. Not less than 95% of the total radioactivity is in the spot corresponding to technetium-99m colloidal sulfur.

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 technetium-99m solution or by measurement in an instrument calibrated with the aid of such a solution (a good approximation may be obtained using an ionization chamber and employing a standardized solution of cobalt-57 provided that correction for the differences in the radiations emitted are made).

Standardized technetium-99m and cobalt-57 solutions are available from laboratories recognized by the relevant national or regional authority.

Biodistribution. Carry out the test as described under R3.1 Biological distribution using a set of three mice as described. At 30 minutes post injection, the sum of the percentages of radioactivity found in the liver and the spleen should not be less than 80 % of the injected radioactivity. Less than 5% of the injected activity should be found in lungs.