Sodium phosphate (^{32}P) injection (Natrii phosphatis (^{32}P) injectio)

$H_2NaO_4{}^{32}P$. $HNa_2O_4{}^{32}P$

Chemical name. Mixture of sodium dihydrogen [^{32}P]phosphate and disodium hydrogen [^{32}P]phosphate.

Description. Sodium phosphate (^{32}P) injection is a clear, colourless solution.

Phosphorus-32 has a half-life of 14.3 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. Sodium phosphate (^{32}P) injection is a sterile solution of phosphorus-32 as sodium hydrogen orthophosphate and disodium dihydrogen orthophosphate, 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 phosphorus-32 stated on the label at the reference date and hour stated on the label.

Not less than 95% of the total radioactivity is due to phosphorus-32. The specific activity is not less than 11.1 MBq (0.3 mCi) per mg of phosphate ion at the reference date and time stated on the label.

Manufacture

Radionuclide production. Phosphorus-32 may be produced by neutron irradiation of sulphur.

Production of radiopharmaceutical preparation. The 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 beta-ray spectrum using a suitable instrument with a sample of phosphorus-32, suitably diluted if needed. The spectrum is concordant with the *reference spectrum* of a specimen of phosphorus-32 in that it exhibits a major peak of 1.71 MeV.

Standardized phosphorus-32 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 13.5 and 15 days.

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, 6.0 to 8.0.

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. Record the beta-ray spectrum using a suitable instrument and measure the half-life using a suitable method. The curve should not differ significantly from that of a standardised phosphorus-32 solution obtained under the same conditions. Not more than 95% of the total radioactivity is due to phosphorus-32.

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 10 µl of a mixture of equal volumes of the injection to be examined, suitably

diluted to give an activity of about 20000 counts per minute, and phosphoric acid (~105 g/l) TS. Develop for a distance of 20 cm with a mixture of 40 volumes of 1-butanol R, 20 volumes of water R, and 5 volumes of formic acid (~1080 g/l) TS.

Allow the paper to dry in air and determine the position of the inactive phosphoric acid by spraying the paper with the following solution: dissolve 5 g of ammonium molybdate R in 100 mL of water R and pour, with constant stirring, into a mixture of 12 mL of nitric acid (~1000 g/l) TS and 24 mL of water R. Determine the radioactivity distribution by a suitable method. The radioactivity appears in only one band corresponding to phosphoric acid. Not less than 95% of the total radioactivity is in the spot corresponding to phosphoric acid.

Chemical purity

Total phosphate. Dilute the injection to be examined to produce a solution containing 370 kBq (10 µCi) of phosphorous-32 per mL. To 1 mL add 0.5 mL of a 0.25% solution of ammonium vanadate R , 0.5 mL of ammonium molybdate R, 1 mL of perchloric acid (~1170 g/l) TS and 2 mL of water R, mixing after each addition, and allow to stand for 30 minutes. The colour produced is not deeper than that produced by treating in the same manner 1 mL of a solution containing 47.3 mg of anhydrous sodium phosphate R per litre.

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 phosphorus-32 solution or by measurement in an instrument calibrated with the aid of such a solution.

Standardized phosphorus-32 solutions are available from laboratories recognized by the relevant national or regional authority.