Limits: examine the chromatogram obtained with the radioactivity detector:

– [*Methoxy-^{11}C] raclopride*: minimum of 95 per cent of the total radioactivity.

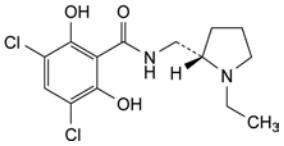
RADIOACTIVITY

Mesure the radioactivity using suitable equipment by comparison with a standardised fluorine-18 solution or by using a calibrated instrument.

LABELLING

The accompanying information specifies the maximum recommended dose in millilitres.

IMPURITIES



A. 3,5-dichloro-*N*-[[(2*S*)-1-ethylpyrrolidin-2-yl]methyl]-2,6-dihydroxybenzamide.

01/2008:1920

SODIUM ACETATE ([1-^{11}C]) INJECTION

Natrii acetatis ([1-^{11}C]) solutio iniectabilis

$CH_3{}^{11}COONa$

DEFINITION

Sterile solution of sodium [1-^{11}C]acetate, in equilibrium with [1-^{11}C]acetic acid.

Content: 90 per cent to 110 per cent of the declared carbon-11 radioactivity at the date and time stated on the label.

PRODUCTION

RADIONUCLIDE PRODUCTION

Carbon-11 is a radioactive isotope of carbon which is most commonly produced by proton irradiation of nitrogen. By the addition of trace amounts of oxygen, the radioactivity is obtained as [^{11}C]carbon dioxide.

RADIOCHEMICAL SYNTHESIS

[^{11}C]Carbon dioxide may be separated from the target gas mixture by cryogenic trapping or by trapping on a molecular sieve at room temperature. [^{11}C]Carbon dioxide is then released from the trap using an inert gas such as nitrogen at a temperature higher than the trapping temperature. [1-^{11}C]Acetate is usually prepared by reaction of [^{11}C]carbon dioxide with methylmagnesium bromide in organic solvents such as ether or tetrahydrofuran.

Hydrolysis of the product yields [1-^{11}C]acetic acid. It is purified by chromatographic procedures. The eluate is diluted with sodium chloride solution.

PRECURSOR FOR SYNTHESIS

Methylmagnesium bromide. The reactivity of methylmagnesium bromide is tested by decomposition of a defined amount with water. The amount of methane released during this reaction is not less than 90 per cent of the theoretical value.

CHARACTERS

Appearance: clear, colourless solution.

Half-life and nature of radiation of carbon-11: see general chapter *5.7. Table of physical characteristics of radionuclides.*

IDENTIFICATION

A. Gamma-ray spectrometry.

Results: the only gamma photons have an energy of 0.511 MeV and, depending on the measurement geometry, a sum peak of 1.022 MeV may be observed.

B. It complies with test B for radionuclidic purity (see Tests).

C. Examine the chromatograms obtained in the test for radiochemical purity.

Results: the principal peak in the radiochromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with the reference solution.

TESTS

pH (*2.2.3*): 4.5 to 8.5.

Sterility. It complies with the test for sterility prescribed in the monograph on *Radiopharmaceutical preparations (0125)*. The injection may be released for use before completion of the test.

Bacterial endotoxins (*2.6.14*): less than 175/*V* IU/mL, *V* being the maximum recommended dose in millilitres. The injection may be released for use before completion of the test.

CHEMICAL PURITY

Acetate. Liquid chromatography (*2.2.29*).

Test solution. The preparation to be examined.

Reference solution. Dissolve 28 mg of *sodium acetate R* in *water R* and dilute to *V*, *V* being the maximum recommended dose in millilitres.

Column:

– *size*: *l* = 0.25 m, Ø = 4.0 mm;

– *stationary phase*: *strongly basic anion exchange resin for chromatography R* (10 µm);

– *temperature*: 25 °C.

Mobile phase: *0.1 M sodium hydroxide* protected from atmospheric carbon dioxide.

Flow rate: 1 mL/min.

Detection: spectrophotometer at 220 nm and radioactivity detector connected in series.

Injection: loop injector.

Run time: 10 min.

System suitability: reference solution:

– *resolution*: minimum 4.0 between the peaks due to hold-up volume and acetate.

Limit: examine the chromatograms obtained with the spectrophotometer:

– *acetate*: not more than the area of the corresponding peak in the chromatogram obtained with the reference solution (20 mg per *V*).

Residual solvents are limited according to the principles defined in the general chapter (*5.4*), using the general method (*2.4.24*). The preparation may be released for use before completion of the test.

RADIONUCLIDIC PURITY

Carbon-11: minimum 99 per cent of the total radioactivity.

The preparation may be released for use before completion of the tests.

A. Gamma-ray spectrometry.

Comparison: standardised fluorine-18 solution, or by using a calibrated instrument. Standardised fluorine-18 solutions and/or standardisation services are available from laboratories recognised by the competent authority.

Results: the spectrum obtained with the solution to be examined does not differ significantly from that obtained with a standardised fluorine-18 solution.

B. Half-life: 19.9 min to 20.9 min.

RADIOCHEMICAL PURITY

[1-^{11}C]Acetate. Liquid chromatography (*2.2.29*) as described in the test for acetate.

Limit: examine the chromatograms obtained with the spectrophotometer and the radioactivity detector:

– *total of [1-^{11}C]acetate*: minimum 95 per cent of the total radioactivity.

RADIOACTIVITY

Measure the radioactivity using suitable equipment by comparison with a standardised fluorine-18 solution or by measurement with a calibrated instrument.

LABELLING

The accompanying information specifies the maximum recommended dose in millilitres.

01/2008:0279
corrected 7.0

SODIUM CHROMATE (^{51}Cr) STERILE SOLUTION

Natrii chromatis (^{51}Cr) solutio sterilis

DEFINITION

Sterile solution of sodium [^{51}Cr]chromate made isotonic by the addition of sodium chloride.

Chromium-51: 90 per cent to 110 per cent of the declared chromium-51 radioactivity at the date and time stated on the label.

Specific radioactivity: minimum 370 MBq of chromium-51 per milligram of chromate ion.

CHARACTERS

Appearance: clear, colourless or slightly yellow solution.

Half-life and nature of radiation of chromium-51: see general chapter *5.7. Table of physical characteristics of radionuclides*.

IDENTIFICATION

A. Gamma-ray spectrometry.

Result: the only gamma photon of chromium-51 has an energy of 0.320 MeV.

B. Examine the chromatogram obtained in the test for radiochemical purity (see Tests).

Result: the retardation factor of the principal peak in the radiochromatogram obtained with the test solution is about 0.9.

TESTS

pH (*2.2.3*): 6.0 to 8.5.

Total chromate: maximum 2.7 µg of chromate ion (CrO_4^{2-}) per MBq.

Test solution. The preparation to be examined.

Reference solution. 1.7 mg/L solution of *potassium chromate R*.

Measure the absorbance of the solutions (*2.2.25*) at the absorption maximum at 370 nm. If necessary, adjust the test solution and the reference solution to pH 8.0 by adding *sodium hydrogen carbonate solution R*. Calculate the content of chromate in the preparation to be examined using the measured absorbances.

Sterility. It complies with the test for sterility prescribed in the monograph *Radiopharmaceutical preparations (0125)*. The preparation may be released for use before completion of the test.

RADIONUCLIDIC PURITY

Chromium-51. Gamma-ray spectrometry.

Result: the spectrum obtained with the preparation to be examined does not differ significantly from that obtained with a standardised chromium-51 solution.

RADIOCHEMICAL PURITY

[^{51}Cr]Chromate ion. Ascending paper chromatography (*2.2.26*).

Test solution. The preparation to be examined.

Paper: *paper for chromatography R*.

Mobile phase: *ammonia R, ethanol (96 per cent) R, water R* (25:50:125 *V/V/V*).

Application: a volume of the solution sufficient for the detection method.

Development: immediately, for 2.5 h.

Detection: suitable detector to determine the distribution of the radioactivity.

Retardation factor: impurity A = 0.0 to 0.1; chromate ion = about 0.9.

Limit:

– *[^{51}Cr]chromate ion*: minimum 90 per cent of the total radioactivity due to chromium-51.

RADIOACTIVITY

Determine the radioactivity using a calibrated instrument.

IMPURITIES

A. [^{51}Cr]chromium(III) ion.

01/2008:2100

SODIUM FLUORIDE (^{18}F) INJECTION

Natrii fluoridi (^{18}F) solutio iniectabilis

DEFINITION

Sterile solution containing fluorine-18 in the form of sodium fluoride. It may contain carrier fluoride and a suitable buffer.

Content:

– *fluorine-18*: 90 per cent to 110 per cent of the declared fluorine-18 radioactivity at the date and hour stated on the label,

– *fluoride*: maximum 4.52 mg per maximum recommended dose in millilitres.

PRODUCTION

The radionuclide fluorine-18 is most commonly produced by proton irradiation of water enriched in oxygen-18. Fluorine-18 in the form of fluoride is recovered from the target water, generally by adsorption and desorption from anion-exchange resins or electrochemical deposition and redissolution.

CHARACTERS

Appearance: clear, colourless solution.

Half-life and nature of radiation of fluorine-18: see general chapter *5.7. Table of physical characteristics of radionuclides*.

IDENTIFICATION

A. Gamma-ray spectrometry.

Results: the only gamma photons have an energy of 0.511 MeV and, depending on the measurement geometry, a sum peak of 1.022 MeV may be observed.

B. It complies with test B for radionuclidic purity (see Tests).

C. Examine the chromatograms obtained in the test for radiochemical purity (see Tests).