The labelling conditions apply to the generator.

LABELLING
The storage conditions apply to the generator.

STORAGE
The storage conditions apply to the generator.

THE RADIOACTIVITY DUE TO RADIONUCLIDES OTHER THAN KRYPTON-81M IS NOT GREATER THAN 0.1 PER CENT, EXPRESSED AS A PERCENTAGE OF THE TOTAL RADIOACTIVITY IN THE PREPARATION AND CALCULATED WITH REFERENCE TO THE DATE AND TIME OF ADMINISTRATION.

CHARACTERS
A clear, colourless gas.

KRYPTON-81M HAS A HALF-LIFE OF 13.1 S AND EMITS GAMMA RADIATION.

IDENTIFICATION
A. Record the gamma-ray and X-ray spectrum using a suitable instrument. The gamma photon of krypton-81m has an energy of 0.190 MeV.

B. The half-life is 11.8 s to 14.4 s.

TESTS
RADIONUCLIDIC PURITY
Elute the generator as prescribed. Pass a sufficient amount (2 litres to 10 litres) of eluate at a suitable flow rate through a suitable absorber such as water. Determine the amount of radioactivity eluted. Allow the krypton-81m to decay for 5 min and record the gamma and X-ray spectrum of the residual radioactivity on the absorber using a suitable instrument. Examine the gamma-ray and X-ray spectrum of the absorber for the presence of radioactive impurities, which must be identified and quantified. The absorbed radioactivity is not more than 0.1 per cent of the radioactivity passed through the absorber, calculated with reference to the date and time of administration.

RADIOACTIVITY
Determine the radioactive concentration of the preparation using suitable equipment such as an ionisation chamber or a gamma ray spectrometer. The measurement equipment may be calibrated by reference to a primary calibrated instrument at a laboratory recognised by the competent authority. The radioactivity is measured under defined operating conditions, such as gas flow rate and measurement geometry, that are identical to those used for the calibration of the instrument.

STORAGE
The storage conditions apply to the generator.

LABELLING
The labelling conditions apply to the generator.
L-Homocysteine thiolactone hydrochloride

Specific optical rotation (2.2.7): +20.5 to +21.5, determined on a 10 g/l solution at 25 °C.

Infrared absorption spectrophotometry (2.2.24): 220 m²/g, a pore size of 8 nm and a carbon loading of 2.6 m/g.

Flow rate: 1 ml/min.

Detection: spectrophotometer at 225 nm and radioactivity detector connected in series.

Injection: loop injector.

Run time: 10 min.

Relative retention with reference to methionine (retention time = about 2.6 min): impurity B = about 0.8, impurity A = about 2.7.

System suitability: reference solution (a):
- resolution: minimum of 2.5 between the peaks due to methionine and impurity B.

Limits: examine the chromatogram obtained with the spectrophotometer:
- impurity A: not more than the area of the corresponding peak in the chromatogram obtained with reference solution (a) (0.6 mg/V),
- impurity B: not more than the area of the corresponding peak in the chromatogram obtained with reference solution (a) (2 mg/V),
- methionine: not more than the area of the corresponding peak in the chromatogram obtained with reference solution (a) (2 mg/V).

Residual solvents (2.4.24): maximum 50 mg/V for the concentration of acetone, V being the maximum recommended dose in millilitres. The preparation may be released for use before completion of the test.

RADIONUCLIDIC PURITY

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

A. Gamma-ray spectroscopy.

Comparison: standardised fluorine-18 solution, or by using an instrument calibrated with the aid of such a solution. Standardised fluorine-18 solutions and/or standardisation services are available from 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.

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

RADIOCHEMICAL PURITY

L-[Methyl-11C]methionine and impurity E. Liquid chromatography (2.2.29) as described in the test for impurity A, impurity B and methionine.

Injection: test solution and reference solution (b).

Limits: examine the chromatogram obtained with the radioactivity detector:
- total of L-[methyl-11C]methionine and impurity E: minimum of 95 per cent of the total radioactivity,
- other peaks in the chromatogram may be due to impurity C, impurity D and impurity F.

ENANTIOMERIC PURITY

Impurity E. Thin-layer chromatography (2.2.27).

Test solution. The preparation to be examined.

Reference solution (a). Dissolve 2 mg of DL-methionine R in water R and dilute to 10 ml with the same solvent.

Mobile phase: TLC octadeclsilyl silica gel plate for chiral separations.

Plate: TLC octadeclsilyl silica gel plate for chiral separations.


Application: 2-10 µl.

Development: over a path of 8 cm.
Norcholesterol injection, iodinated (\(^{131}\text{I}\))

**DEFINITION**

Iodinated \(^{131}\text{I}\) norcholesterol injection is a sterile, bacterial endotoxin-free solution of 6\(\beta\)-\[^{131}\text{I}\]iodomethyl-19-norcholest-5(10)-en-3\(\beta\)-ol. It may contain a suitable emulsifier such as polysorbate 80 and a suitable antimicrobial preservative such as benzyl alcohol. Iodine-131 is a radioactive isotope of iodine and may be obtained by neutron irradiation of tellurium or by extraction from uranium fission products. The injection contains not less than 90.0 per cent and not more than 110.0 per cent of the declared iodine-131 radioactivity at the date and hour stated on the label. Not less than 85 per cent of the radioactivity corresponds to iodine-131 in the form of 6\(\beta\)-\[^{131}\text{I}\]iodomethyl-19-norcholest-5(10)-en-3\(\beta\)-ol. Not more than 5 per cent of the radioactivity corresponds to iodine-131 in the form of iodide. The specific radioactivity is 3.7 GBq to 37 GBq per gram of 6\(\beta\)-iodomethylnorcholesterol.

**CHARACTERS**

A clear or slightly turbid, colourless or pale yellow solution. Iodine-131 has a half-life of 8.04 days and emits beta and gamma radiation.

**IDENTIFICATION**

A. Record the gamma-ray spectrum using a suitable instrument. The spectrum does not differ significantly from that of a standardised iodine-131 solution by direct comparison with such a solution. The most prominent photon of iodine-131 has an energy of 0.365 MeV. Standardised iodine-131 solutions are available from laboratories recognised by the competent authority.

B. Examine the chromatogram obtained in test (a) for radiochemical purity. The distribution of radioactivity contributes to the identification of the preparation.

**TESTS**

**pH** (2.2.3). The pH of the solution is between 3.5 and 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.

**RADIONUCLIDIC PURITY**

Record the gamma-ray spectrum using a suitable instrument. The spectrum does not differ significantly from that of a standardised iodine-131 solution. Determine the relative amounts of iodine-131, iodine-133, iodine-135 and other