6. CHEMICAL PRECURSORS FOR RADIOPHARMACEUTICAL PREPARATION

Chemical precursors are non-radioactive substances obtained by chemical synthesis for combination with a radionuclide.

Where a chemical precursor not described in any individual monograph and is used in a radiopharmaceutical preparation prepared for the special needs of individual patients, the need for compliance is decided in the light of a risk assessment.

This risk assessment takes account of:

the quality of the chemical precursor and the information available for quality evaluation;

any further processing after radiolabelling (which may or may not include purification before administration to the patient);

the amount used to prepare a patient dose (e.g. diagnostic use versus therapeutic use) and the frequency of administration to the patient; and

chemical precursors manufactured using substances of human or animal origin.

Chemical precursors are prepared by procedures designed to ensure a consistent quality and provide compounds that comply with the requirements of the individual monograph or approved specifications. Chemical precursors must be produced within the framework of a suitable quality system.

Appropriate analytical methods, such as nuclear magnetic resonance spectrometry, infrared absorption spectrophotometry, mass spectrometry and chromatographic methods are used to provide confirmation of the identity of the chemical precursor. Unless otherwise justified and authorised, the content of chemical precursors for radiopharmaceutical preparations is determined using a suitable method.

Tests for residual solvents, metal catalysts or metal reagent residues, microbial contamination, bacterial endotoxins and related substances must be performed by validated procedures.

The storage of chemical precursors should not adversely affect its quality and ensure adequate stability.

The labelling of chemical precursors complies with the relevant national and international legislation where relevant information is available. The label indicates the intended use as a chemical precursor for radiopharmaceutical preparations.

The accompanying information may recommend testing the substance in one or more production runs before its use for the manufacture of radiopharmaceutical preparations to ensure that, under specified production conditions, the substance yields a radiopharmaceutical preparation in the desired quantity and of the quality specified.