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Production and quality control of ¹⁷⁷Lu for labelling

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Lutetium-177 is a radionuclide used in nuclear medicine for therapeutic application. Both β and γ radiations emitted from ¹⁷⁷Lu allow imaging of the therapeutic radionuclide without need of adding any other radionuclide. It can be prepared in the nuclear reactor via direct (n, γ) activation from enriched lutetium target or via indirect neutron activation from ytterbium oxide. In this case, carrier free ¹⁷⁷Lu is prepared, however, separation from irradiated target is necessary. ¹⁷⁷Lu decays with a half life of 6.7 days. The research was focused on development of the semi-automatic module for processing the neutron irradiated targets and on optimizing the conditions of production and quality control of the ¹⁷⁷Lu radiopharmaceutical precursor.
Enriched lutetium oxide in 5 M nitric acid was put into the titanium vial and evaporated to dryness. The screwed and tightened vial was irradiated for 96 hours in LVR-15 nuclear reactor (reactor power 7-9 MW) at the approximate neutron flux of 5x10¹³ n.cm⁻²s⁻¹. The irradiated penal was allowed to cool for two days and then processed using semi-automatic module. Titanium ampoules were opened and filled subsequently by four aliquots 0.5 –1.5 mL of nitric acid 1mol/L in order to dissolve irradiated target. All aliquots were collected, evaporated to dryness and re-dissolved with hydrochloric acid 0.01 mol/L. Final solution was passed through 0.22 mm filter and after dispensing, final solution was autoclaved for 20 minutes at 125℃. All production steps were operated using touch screen set-up on the front wall of the hot cell.
The radioactivity was measured by ionization chamber Atomlab 100. The radionuclidic purity was determined by γ spectrometry. The radiochemical purity was determined by radio-TLC with ITLC-SG strips as a solid phase. The method consisted of two steps: Test for insoluble and colloid forms –liquid phase 0.15 M NaCl in 0.02 M HCl and the test for lutetium organic forms –liquid phase mixture of NH₂OH : CH₃OH : H₂O (0.2 : 2 : 4) . The gas-flow proportional counting tube (Minigita, Raytest) was used for detection. The pH was measured by microelectrode Hamilton Biotrode. Bacterial endotoxins test was carried out using kinetic turbidimetric methods. The chemical impurities of Ti and Fe were checked by ICP for couple of batches (external collaboration with Nuclear Research Institute Řež, plc.).
The specific activities of ¹⁷⁷Lu at the end of irradiation ranged from 100 to 264 GBq/mg (2.9 to 7.1 Ci/mg), Specific acrivity of ¹⁷⁷Lu at the time of production ranged from 61 to 86 GBq/mg (1.6-2.3 Ci/mg). The γ-spectrometric measurements showed the content of ^{177m}Lu at the level 0.005% at the time of production. Content of Ti ranged from 0.004 to 0.385 μg/GBq of ¹⁷⁷Lu and content of Fe ranged from 0.023 to 0.708 μg/GBq of ¹⁷⁷Lu at the time of production.
The semi-automatic elution device for production of ¹⁷⁷Lu was developed, tested and the operation qualification was carried out. Manufacture process was validated on three batches of ¹⁷⁷Lu product. Methods for quality control were verified and GMP compliance documentation is currently under preparation.

Primary author: Dr KROPACEK, Martin (Nuclear Physics Institute of the ASCR, 25068 Rez by Prague, Czech Republic)

Co-authors: MELICHAR, Frantisek (Nuclear Physics Institute of the ASCR, 25068 Rez by Prague, Czech Republic); PAVLIK, Jan (Nuclear Physics Institute of the ASCR, 25068 Rez by Prague, Czech Republic); SRANK, Jiri (Nuclear Physics Institute of the ASCR, 25068 Rez by Prague, Czech Republic); VENTRUBA, Jiri (Nuclear Physics Institute of the ASCR, 25068 Rez by Prague, Czech Republic); PROCHAZKA, Libor (Nuclear Physics Institute of the ASCR, 25068 Rez by Prague, Czech Republic); TOMES, Marek (Nuclear Physics Institute of the ASCR, 25068 Rez by Prague, Czech Republic)

Presenter: Dr KROPACEK, Martin (Nuclear Physics Institute of the ASCR, 25068 Rez by Prague, Czech Republic)

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