

HEVESY LAB / DTU Roskilde, Denmark

Radiochemistry, radio analytical and radiation biology laboratories. Clean rooms/GMP suite with manufacturing and IMPD licenses. Shipping expertise.



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1. PRISMAP biomedical facility: HEVESY/DTU

Hevesy Lab is part of the Department of Health Technology at the Technical University in Denmark. The lab is a research lab but also both a radionuclide production site with cyclotrons and a routine manufacturer of radiopharmaceuticals.

As such Hevesy Lab is both a PRISMAP production site and a biomedical facility.

Hevesy Lab is situated in rural conditions 40 km from Copenhagen. We make daily supplies of PET radiopharmaceuticals to eastern Denmark and more special radiopharmaceuticals to all of Denmark and some sites in Sweden. We have strong tradition for research, development and supply of radionuclides and radiopharmaceuticals, both from our own accelerators and from foreign reactors. We routinely supply several small animal imaging facilities in Denmark, where we have strong imaging connections.

The radionuclides from the PRISMAP portfolio that are already approved at the facility are listed in Table 1.

Additional radionuclides can be made available upon request. There are already permissions in place for working with therapeutic quantities of I-131 and Lu-177.

| Radionuclide | Remark | | | | |
|--------------|---|--|--|--|--|
| Mn-52 | 200- 600 MBq/batch | | | | |
| Cu-64 | Available in research and GMP quality twice a week. Up to 15 GBq/batch | | | | |
| Cu-67 | 200 MBq/batch | | | | |
| Pd-103 | 1-3 GBq/batch- Produced in collaboration with ILL | | | | |
| Ag-111 | 1 GBq/ batch – Produced in collaboration with ILL | | | | |
| La-135 | 1 GBq/batch | | | | |
| Er-165 | 1 GBq/batch | | | | |
| Au-199 | 1-2 GBq/batch. Nanoparticle formulation available. Produced in collaboration with ILL | | | | |

All of the above radionuclides can be measured with traceable activity determination and will come with COA containing RNP, quantification of radionuclidic impurities and ICP-OES analysis.

Other PRISMAP radionuclides approved for use at Hevesy lab are listed in Table 2.

Table 2: Other PRISMAP radionuclides approved for use at Hevesy Lab.

| Radionuclide | | Remark | |
|--------------|-------------|--------|--|
| Sc-43, 44 | Up to 5 GBq | | |
| Sc-47 | Up to 2 GBq | | |

Hevesy/DTU has its own target development, target manufacture and target separation facilities. In addition to our normal radiochemical separation of products from target we have a preparative (hot-lab) HPLC.

Radioactivity can be quantified by:

Two HPGE gamma spectrometers (Canberra/Mirion/Genie2) with broad activity (0.1 kBq-50 GBq) and energy ranges (60-3000 keV), with traceable calibrations. In conjunction with this a germanium X-ray detector 4 – 80 keV, dose calibrators, triple-double coincidence TLC and alpha counting are available. We have two broad range dose calibrators with traceable Capintec and Veenstra settings.

Our analytical capability includes three general purpose HPLCs (under GMP) and two additional research HPLCs, three TLC scanners, pH, endotoxin and freezing point instruments, two ICP-OES instruments and a 400 MHz multinuclide NMR instrument approved for work with radioactive samples.



The GMP manufacturing facility contains two large class C clean rooms with hot cells (class C) and LAF work benches (A in C) and in addition airlocks, ante rooms and autoclavation room. The clean rooms are at present licensed to work with F-18, Cu-64 and Lu-177, but other radionuclides can be added to license.

Hevesy lab has the approval as a radiopharmaceutical manufacturing site with some additional analytical permissions – including sterility control on radioactive samples. The lab also has an IMPD manufacturing license for clinical trials.

The bio-lab has permissions to work with radioactivity up to 1% of the above limit. It has two CO2 incubators, LAF flow bench, cell counters (Millipore MUSE and Scepter), HIDEX LSC and gamma counting. Cells can be visualized, sampled and microinjected by a ZEISS Axiomat fluorescence microscope. Several standard cell lines are available.

Cells and tissues can for comparison be externally irradiated on site with electrons, MV, using Cs-137 and Co-60 beams in carefully calibrated facilities from few uGy/h up to several kGy/h.



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