



Medical-Radionuclides.eu

POLATOM/NCBJ Otwock, Poland

Research facilities for radiochemistry and biomedical studies, including small animal imaging and GMP certified labs for preparation of radiopharmaceuticals (IMP) for clinical trials



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PRISMAP+ Biomedical Facility POLATOM/NCBJ

Radioisotope Centre POLATOM at the National Centre for Nuclear Research (NCBJ) conducts research and development programmes for novel radiopharmaceuticals. The centre is located near Otwock, Poland, about 30 km from the centre of Warsaw. On site is the MARIA Research Reactor, where several PRISMAP+ radionuclides are produced, and the newly launched facility with multi-particle Cyclone 30 XP, a 30 MeV cyclotron that accelerates protons, deuterons and alpha particles.

POLATOM/NCBJ holds a broad license regarding radionuclide handling, therefore, all the radionuclides available in the PRISMAP+ radionuclide portfolio can potentially be used on site.

POLATOM/NCBJ also has permissions to work with Y-90, I-131 and Lu-177 at therapeutic dose levels.

Infrastructure and experiments available

The POLATOM/NCBJ facility is fully equipped to conduct radiolabelling studies, cell studies, as well as animal imaging and therapy studies with novel radiotracers. The team of Radioisotope Centre POLATOM offers support in the formulation of radiotracers for preclinical and first-in-human clinical trials (including IMPD).

The following premises are available:

- **Clean room facility:** GMP-certified cleanroom facility: grade C for preparation of freeze-dried powders (kits) with laminar flow chamber, grade A, and another cleanroom in grade D with radiopharmaceutical isolator grade A (Telstar). These cleanrooms are equipped with a Christ Epsilon 2-6D LSCplus freeze-dryer with max. capacity for 264 vials (10 mL vials), magnetic stirrer (IKA RCT), Eppendorf pipettes and in-house developed dispensers (accuracy $\pm 1\%$ for 1mL volumes). Vial crimping machine with interchangeable heads for 20mm and 13 mm flip-off caps. Bubble point control unit (Millex Integrity Tester).
- **Radiochemical laboratory** equipped with: dry heater for vial incubation in temp. range: 25-100°C (Alchem), iTLC scanner (Cyclone Plus Storage Phosphor System); HPLC (Shimadzu LC-20); Dose Calibrator (Capintec™ CRC-55tR); CAPRAC® -t Wipe Test / Well Counter; XRF spectrometer (S2 PICOFOX, Bruker); Electrochemical Unit & Impedance Analyzer (ATLAS 0531, Atlas-Sollich); High temperature tube furnace, suitable for use in hydrogen and nitrogen atmosphere (Carbolite model CTF 300/1800); Turbomolecular pump (PFEIFER VACUUM DCU); Metallographic microscope equipped with camera (Nikon MA100). Lab space is equipped with fume hoods (Koettermann).
- **Laboratory of Radioactivity Standards** (PN-EN ISO/IEC 17025:2018-02 accreditation) measures the activity of α -, β - and γ -radioactive radionuclides with absolute methods and calibrates radioactive solutions and sources. Laboratory is also equipped with liquid scintillation spectrometers α/β (PerkinElmer TriCarb 2910 TR; WALLAC 1411), γ spectrometric systems with a HPGe detector (Canberra, ORTEC), 2π and 4π proportional counter with gas and set of scintillation counters with NaI(Tl) detectors.
- **In vitro laboratory** with: Laminar flow-hood for cell maintenance; Incubator CO₂ (Binder) and incubator for 37°C; Inverted microscope Leica DMIL with Infinity microscope camera; NucleoCounter® NC-3000™ image cytometer utilizing fluorescence imaging to characterize cell properties (Chemometec); Eppendorf centrifuge 5702. Automated cell counter.
- **Small animal facility for in vivo** studies with conventional cages for mice and rats (Techniplast, Allentown); IVC cages for mice and rats (Techniplast, Allentown); Metabolic cages (Techniplast); Laminar flow-hood; Autoclave (Tuttenauer); Gamma counter equipped with a NaI(Tl) crystal for organ activity measurement; Cryostat (RWD); PhotonIMAGER (BioSpace Lab) for optical imaging, this system enables the in vivo acquisition of bioluminescence and fluorescence signals in small animals within the visible spectrum, ranging from violet to near infrared. It is suitable also for Cerenkov luminescence imaging for radioisotopes such as Y-90, Ga-68, Ac-225 and I-131. Detection technology: CCD camera, File type: raw data. The photo-counting technology combined with the high-dynamic of the optical chain allows to reach a global linear range over 10^6 and a linear range within the same image over 10^4 .

Details regarding the equipment available for imaging at the POLATOM/NCBJ biomedical facility can be found in Table 1.

Table 1. Imaging equipment details.

Equipment	Modality	Remarks
SPECT/PET/CT VECTor7, MiLabs	SPECT/PET/CT	
β- cube, X- cube, Molecubes		

Animal models available

- healthy mice, including commonly used immunocompetent strains such as BALB/c and C57BL/6;
- immunodeficient mice, including BALB/c nude mice;
- healthy rats, including Wistar rats;
- tumour-bearing mouse models, including subcutaneous xenograft models;
- selected models for biodistribution, pharmacokinetics, imaging and therapy studies;

Other disease or tumour models may be considered depending on feasibility, cell line availability, biosafety requirements and ethical approval.

Support available

The support available to the users before, during and after their visit to the POLATOM/NCBJ biomedical facility can be found in Table 2.

Table 2. Support available at the POLATOM/NCBJ biomedical facility.

Support	Remarks
Assistance to apply for experiment permission	
Assistance with project writing	
Help/supervision with radiolabelling	
Help/supervision with radiolabelling quality control	
Help/supervision with labelled compound stability studies	
Help/supervision during cell studies setup	
Help/supervision during cell studies follow-up and results reading	
Help/supervision with animal handling	
Help/supervision with animal scanning	
Help/supervision with image generation and analysis	
Help with results processing and interpretation	
Help with publication writing	

POLATOM may also provide support in experimental design, selection of appropriate radionuclide and radiolabelling strategy, selection of animal model, preparation of protocols for biodistribution, pharmacokinetic, imaging and therapy studies, radiation safety planning, preparation of study reports, graphical presentation of results and scientific interpretation

Services available

The services available at the POLATOM/NCBJ biomedical facility (without the presence of the user) can be found in Table 3.

Table 3. Services available at the POLATOM/NCBJ biomedical facility.

Service	Remarks
Activity measurement, dose calibrator	
Activity measurement, gamma spectrometry	
Radiolabelling according to protocol provided by the user	
Formulation of radiolabelled compound for cell incubation or animal injection	
Radiolabelling quality control TLC	
Radiolabelling quality control HPLC	
Growing cell lines available in-house	
Growing cell lines provided by user	
Radiopharmaceutical stability in non-biological media	
Radiopharmaceutical stability in biological media	
Cell studies setup	
Cell studies follow up (after setting up with user)	
Animal preparation (healthy animals)	
Animal preparation (tumour-bearing animals, in house model)	
Animal preparation (tumour-bearing animals, external model)	
Animal handling (injection, scanning process, sacrifice)	
Animal handling follow-up	

Additional services may include biodistribution studies, pharmacokinetic studies, ex vivo gamma counting of organs and biological samples, preparation of samples for further analysis, small-animal imaging, image reconstruction and analysis, tumour growth monitoring, toxicity monitoring, dosimetry-related data preparation and preparation of study reports.

Manufacturing infrastructure & clinical supply capabilities: The facility is equipped with specialised technological capabilities dedicated to the formulation and manufacturing of freeze-dried products, in particular kits for radiopharmaceutical preparation. Processing operations are executed within qualified cleanroom environments operated in strict conformity with cGMP standards, featuring a direct interface with an Epsilon 2-6D LSC Plus pilot-scale freeze dryer (Christ). The system provides an adaptable batch capacity, accommodating either 264 vials of 10 mL or 495 vials of 2 mL per lyophilisation cycle. This infrastructure is utilised for R&D activities and the manufacturing, compounding, and filling of Investigational Medicinal Products (IMPs) for clinical trials.