

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



1. PRISMAP biomedical facility: POLATOM/NCBJ

The POLATOM radioisotope centre 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.

The radionuclides from the PRISMAP portfolio that are already approved in the POLATOM/NCBJ radiochemical and biomedical facility are listed in Table 1. Additional radionuclides can be made available upon request. A complete list can be requested at <a href="https://helphase.ncbi.nlm.ncbi.nl

Table 1: PRISMAP radionuclides already approved for use in the POLATOM/NCBJ facility.

Radionuclide	Remark
Sc-47	Available on request. Dose calibrator, gamma counter and small animal in vivo/ex vivo normalized and calibrated for this radionuclide.
Sc-44	Available on request
Tb-161	Available on request. Dose calibrator, gamma counter and small animal in vivo/ex vivo normalized and calibrated for this radionuclide.
Ac-225	Available on request. Dose calibrator, gamma counter and small animal in vivo/ex vivo normalized and calibrated for this radionuclide

POLATOM/NCBJ is fully equipped to conduct preclinical research with novel radiotracers. The team of the POLATOM Radioisotope Centre offers support in the formulation of radiotracers for the pre-clinical and first in human clinical trials (including IMPD). The following premises are available:

<u>Clean room facility</u> GMP certified clean room 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 clean-rooms are equipped with 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 scaner (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).

<u>Laboratory of Radioactivity Standards</u> (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 detectors (Canberra, ORTEC), 2π and 4π proportional counter with gas and set of scintillation counters with NaI(TI) 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.

<u>Small animal facility for in vivo</u> 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(TI) 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 ⁹⁰Y, ⁶⁸Ga, ²²⁵Ac and ¹³¹I. 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 10⁶ and a linear range within the same image over 10⁴.

Table 2 summarises the Photonimager specifications.

Table 2: PhotonImager specifications.

Scanner	Modality	Detector technology	Collimators	File type	Reconstruction algorithm	Animal	Gating
Photon IMAGER	OI	CCD camera for visible spectrum	NA	Dynamic capabilities in planar mode	NA	1-5 animals. Heating pad. Isoflurane	NA

For further technical details, please contact our helpdesk at: helpdesk@prismap.eu.



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