Modular-Lab PharmTracer

Cassette-based routine production of ¹⁸F tracers



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A reliable and versatile solution for routine production of [18F]FDG, [18F]FES, [18F]FET, [18F]FMISO, [18F]NaF as well as [18F]PSMA-1007

Background

The cyclotron-based positron-emitter Fluorine-18 is one of the most widely used radioisotopes in positron emission tomography (PET). It provides a large number of possible applications, particularly in the diagnosis of different types of cancer.

Selection of [18F] tracers on Modular-Lab PharmTracer

Tracer	Suitable for
[¹⁸ F]FDG	Detection of various cancer types (versatile)
[¹⁸ F]FES	Investigation of primary and metastatic breast cancer
[¹⁸ F]FET	Detection of brain tumors/disease post surgery/radiation treatment
[¹⁸ F]FLT	Monitoring of therapy response, visualization of bone marrow tumors
[¹⁸ F]FMISO	Detection of hypoxic tissue caused by tumors (lung, brain head and neck) or in heart with myocardial ischemia
[¹⁸ F]NaF	Visualization of bone metabolism
[¹⁸ F]PSMA-1007	Prostate Cancer Imaging

Description

Eckert & Ziegler Eurotope GmbH offers one setup for the routine production of a wide range of Fluorine-18 based tracers using the reliable Modular-Lab PharmTracer technology. The laboratory equipment has been specifically designed to allow efficient, GMP compliant production of different tracers without cross contamination issues. All tracers are produced using sterile disposable synthesis cassettes. The system additionally supports research and development activities by using the freely programmable and intuitive Modular-Lab software and adaptable cassettes.

Using the cartridge-based SPE purification approach, the basic Fluorine-18 PharmTracer setup, consisting of the Heater Module (HRM), the Syringe Module (SYM), the 4-fold Module (SLM-4), the 2-fold Module (SLM-2) and a vacuum pump, will enable the production of [18F]FDG, [18F]FES, [18F]FET, [18F]FLT, [18F]FMISO and [18F]PSMA-1007. A heater and SLM-4 will not be required when producing [18F]NaF. By adding modules, Modular-Lab PharmTracer can also be used for the production of further tracers based on other nuclides such as Gallium-68, Lutetium-177, Yttrium-90, Carbon-11, Copper-64 and more. The appropriate system configuration can be provided upon request. Eckert & Ziegler offers assistance to find the ideal setup for your needs.

Accessories

The use of reagent kits from ABX GmbH (Radeberg, Germany) is mandatory. The kits contain all necessary chemicals, material and the precursor for the synthesis of the desired tracer. In connection with the cassette, no further material is required.

Key Features

- Fully automated synthesis
- Multiple tracer production using a single configuration
- Open Software for in-house tracer development
- Short synthesis time
- High and stable yields
- Easy cassette handling through click'n'start technology
- Compact size and small footprint
- GMP and GAMP5 compliance
- Expandable setup for production of other tracers



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Sterile Disposable Cassettes

Cassettes are assembled under GMP-compliant clean room conditions, sterilized with gamma-radiation and double-vacuumpacked. All consumables used are chemical resistant and have been tested for their suitability with the specific syntheses. A shelf life of 18 months can be guaranteed. For further information please refer to the respective user manual. Due to the cassettes onetime use no cleaning, drying or sanitation routines are necessary.

Technical Data

Module Characteristics*	
Dimension of entire system	280 x 268 x 515 mm (L x W x H) incl. cables and accessories
2-fold Modular-Lab PharmTracer (SLM-2)	130 x 198 x 191 mm (L x W x H)
4-fold Modular-Lab PharmTracer (SLM-4)	262 x 198 x 191 mm (L x W x H)
Syringe Dispensing Module (SYM)	130 x 184 x 268 mm (L x W x H); responsible for liquid transport
Heater Reaction Module (HRM)	Dimensions: $130 \times 220 \times 113$ mm (L x W x H); heating via heating foil from room temperature to $180 ^{\circ}$ C, internal activity detector
Vacuum Pump	164 x 90 x 141 mm (L x W x H); weight: 1.9 kg 230V/115V, single-head, dry-running device, 5 °C to 40 °C, 100 mbar
Pressure	Additional nitrogen supply required, 5-10 bar
Accessories	Two additional activity detectors and one pressure sensor included
Main Unit	
Power supply	Electrical Cabinet (EC mini): 100-240 V 50/60 Hz
Power consumption	up to 480 W
Environment temperature	+10 °C to +40 °C
Environment humidity	Max. 70% rel.
Unit Control	
Software	Modular-Lab Software
Interfaces	USB

* Module dimensions include handles

All available components are tested in-house before delivery. A performance qualification of the complete system on-site as well as extensive documentation will be provided upon request.

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