

Modular-Lab PharmTracer

Cassette-based solution for routine production

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Extendable solution for efficient routine production of various tracers



Background

The increasing demand for radiotracers for a variety of applications in diagnosis, therapy and theranostics demands versatile radiosynthesis systems. Our fully automated Modular-Lab PharmTracer combines the high flexibility that is necessary for research applications with cassette-based production routines for GMP-compliant radiolabeling. The use of this radiosynthesis device significantly increases synthesis yields and reduces radiation exposure of the operator to a minimum when labeling different radiotracers.

Description

The laboratory equipment Modular-Lab PharmTracer has been specifically designed to allow versatile and efficient routine production of different tracers without cross contamination issues whilst complying with GMP requirements. The standard setup for radiometal applications consists of a 4-fold module (SLM-4) for the operation of 4 stopcock manifolds, a 1-fold module (SLM-1), a Heater Reaction Module (HRM) and a Syringe Module (SYM). The system can easily be upgraded for further applications by adding modules. Eckert & Ziegler offers assistance to find the ideal setup for your requirements. Sterile disposable cassettes ensure easy handling by click'n'start technology. An easy-to-program intuitive graphical interface is used to control the synthesis process.

Advantages

Modular-Lab PharmTracer is based on a unique, modular approach combining the speed and safety of a remote, fully-automated system with the possibility to configure syntheses for novel tracers on your own. With this multifunctionality, early-stage developments can easily be transferred into routine production later.

Several tested synthesis processes for routine production of a wide range of radiotracers with ^{18}F , ^{68}Ga , ^{90}Y , ^{177}Lu , ^{64}Cu , ^{11}C and other radionuclides are available, saving time spent on additional programming.

Modular-Lab PharmTracer can easily be combined with semipreparative HPLC. Analytical HPLC and TLC can be operated with the same PC as the synthesis system. The intuitive user interface of the Modular-Lab Software complies with GMP, cGMP, GLP and GAMP 5 requirements. Parameters such as temperature, activity detector readings, flow rates, or valve settings can be monitored easily in one window. After each run, reports containing all relevant data and information are created automatically.

Available Applications

Nuclide	
^{64}Cu / ^{67}Cu	ATSM
^{11}C *	Acetate Choline Methionine Methyl Iodide Choline Methyl Iodide Methionine Raclopride
^{18}F *	FDG FES FET FLT FMISO NaF PSMA-1007
^{68}Ga	DOTA compounds PSMA-11 PentixaFor FAPI
^{111}In	DOTA compounds
^{177}Lu	DOTA compounds PSMA
^{90}Y	DOTA compounds

* ^{11}C and ^{18}F applications require additional modules

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Sterile Disposable Cassettes

Cassettes are assembled under GMP-compliant clean room conditions, sterilized with gamma-radiation and double-vacuum-packed. 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. All cartridges are either included in the cassette or are part of the chemical kit. They are preconditioned automatically if necessary. Due to the cassette's single use, no cleaning, drying or sanitation routines are necessary. We also offer the development and/or manufacturing of customized cassettes for your individual synthesis projects.

Technical Data

Module Characteristics*	
Dimension of entire system	⁶⁸ Ga system incl. rack: 394 x 267.6 x 505.6 mm (L x W x H) ⁹⁰ Y, ¹⁷⁷ Lu systems with β -shielding: 469 x 450 x 535 mm (L x W x H) ¹⁸ F system: 280 x 268 x 515 mm (L x W x H)
1-fold Module (SLM-1)	Dimensions: 130 x 155 x 113 mm (L x W x H); only necessary for pressure test of cassette
2-fold Module (SLM-2)	Dimensions: 130 x 198 x 191 mm (L x W x H)
4-fold Module (SLM-4)	Dimensions: 262 x 198 x 191 mm (L x W x H)
Syringe Dispensing Module (SYM)	Dimensions: 130 x 184 x 268 mm (L x W x H); responsible for liquid transport
Heater Reaction Module (HRM)	Dimensions: 130 x 220 x 113 mm (L x W x H); heating via heating foil from room temperature to 180 °C, aircooled, internal activity detector
Pressure	Max. 2 bar
Cassettes	Can be supplied with 3 different filter options: without filter, with an integrated non-vented filter or a separately provided vented filter
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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