

# Modular-Lab PharmTracer

Cassette based solution for routine production

## Modular-Lab PharmTracer

Solution for efficient routine production of  $^{68}\text{Ga}$ -,  $^{111}\text{In}$ -,  $^{177}\text{Lu}$ - and  $^{90}\text{Y}$ -DOTA conjugated peptides by using the same setup



### Background

Positron emission tomography (PET) is widely used for a variety of applications involving radioisotope techniques. The use of our fully automated radiosynthesis device Modular-Lab PharmTracer significantly increases synthesis yields and reduces radiation exposure of the operator to a minimum when labeling  $^{68}\text{Ga}$ -,  $^{111}\text{In}$ -,  $^{177}\text{Lu}$ - and  $^{90}\text{Y}$ -DOTA conjugated peptides.

### 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 and complying with GMP requirements. Modular-Lab PharmTracer setup for the labeling of  $^{68}\text{Ga}$ -,  $^{111}\text{In}$ -,  $^{177}\text{Lu}$ - and  $^{90}\text{Y}$ -DOTA peptides will be combined with a Heater Reaction Module (HRM), a Syringe Module (SYM) and, if necessary, with a Single Stopcock Module (SMM) when performing the pre-purification method for  $^{68}\text{Ga}$  labeling. 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.

### 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 12 months can be guaranteed. All cartridges are included and preconditioned automatically if necessary. Due to the cassettes one-time use no cleaning, drying or sanitation routines are necessary.

### Advantages

Modular-Lab PharmTracer is based on a unique, modular approach combining the speed and safety of a remote, fully-automated system with the option to configure syntheses for

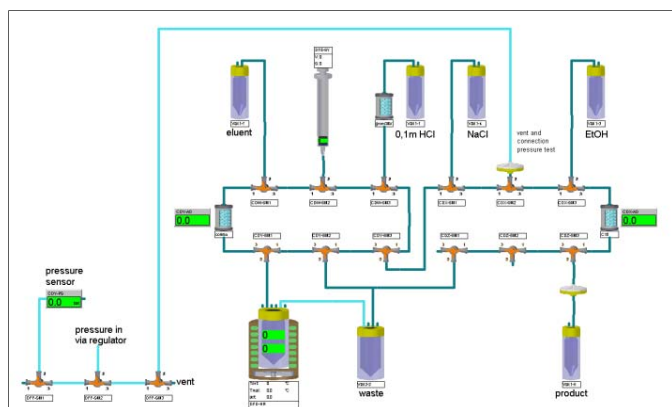
novel tracers. The GMP-manufactured sterile disposable cassettes avoid intense cleaning and sanitation routines. Synthesis process is programmed by Eckert & Ziegler Eurotope making additional programming dispensable. Modular-Lab PharmTracer's multifunctionality supports routine production of  $^{68}\text{Ga}$ -,  $^{111}\text{In}$ -,  $^{177}\text{Lu}$ - and  $^{90}\text{Y}$ -DOTA peptides. The setup can also be combined with an analytical HPLC and TLC. The intuitive user interface 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. Reports containing all relevant data and information are created automatically after each run. **NEW!** A cost and space efficient alternative to the conventional electrical cabinet (EC) is now available for specific systems with low power consumption. It consists of a Power Interface Module (PIM) in combination with the software Modular-Lab SoftPLC.

### Application Results\*

$^{68}\text{Ga}$ -DOTA peptides (fractionated method)	Yield: $85.1 \pm 6.7$ % d.c. Purity: HPLC > 95 %; TLC > 99 % Synthesis time: 20 min
$^{68}\text{Ga}$ -DOTA peptides (pre-cleaning method)	Yield: $81.8 \pm 1.6$ % d.c. Purity: HPLC > 95 %; TLC > 99 % Synthesis time: 25 min
$^{111}\text{In}$ -DOTA peptides	Yield: $88.5 \pm 5.0$ % d.c. Purity: HPLC > 97 %; TLC > 99 % Synthesis time: 25 min
$^{177}\text{Lu}$ -DOTA peptides	Yield: $88.6 \pm 6.9$ % d.c. Purity: HPLC > 97 %; TLC > 99 % Synthesis time: 30 min
$^{90}\text{Y}$ -DOTA peptides	Yield: $92.5 \pm 7.7$ % d.c. Purity: HPLC > 97 %; TLC > 99 % Synthesis time: 30 min

\*Source: Petrik, M. / Knetsch, P. / Knopp, R. et al. (2011): "Radiolabelling of peptides for PET, SPECT and therapeutic applications using a fully automated disposable cassette system"

# Modular-Lab PharmTracer



## Technical Data

### Module Characteristics

Footprint of entire system	<sup>68</sup> Ga system incl. rack: 394 x 267.6 x 505.6 mm (W x D x H) <sup>90</sup> Y, <sup>177</sup> Lu systems need additional space for β-shielding devices and handling: 469 x 450 x 535 mm (W x D x H)
----------------------------	---

1-fold Modular-Lab PharmTracer Module (SLM-1)	Dimensions: 130 x 155 x 113 mm (W x D x H); Weight: 1.7 kg Only necessary for pressure test of cassette
---	--

4-fold Modular-Lab PharmTracer (SLM-4)	Dimensions: 262 x 198 x 191 mm (W x D x H); Weight: 5.0 kg
--	--

Syringe Dispensing Module (SYM)	Dimensions: 130 x 184 x 268 mm (W x D x H); Weight: 3.8 kg Responsible for liquid transport
---------------------------------	--

Aircooled Heater Reaction Module (HRM) or	Dimensions: 130 x 220 x 113 mm (W x D x H); Weight: 2.0 kg Heating via heating foil from room temperature to 220 °C
---	--

Watercooled Heater Reaction Module (HRM)	Dimensions: Controlling Module 130 x 147 x 113 mm (W x D x H); Heater Module 130 x 88 mm, Ø 84 mm (W x D x H); Laboratory Bottle 94 x 94 x 370 mm (W x D x H); Weight: 2.0 kg Heating with heating-foil from room temperature to 150 °C. Cooling to room temperature with water from laboratory bottle.
--	---

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) / Power Interface Module (PIM): 115 V ~ 60 Hz or 230 V ~ 50 Hz
--------------	---

Power consumption	EC: Standard 480 W, 2 x bus 1,050 W, extension to 2,100 W possible PIM: Standard 180 W; Type of external power supply depends on the setup
-------------------	---

Environment temperature	+10 °C to +40 °C
-------------------------	------------------

Environment humidity	Max. 70 % rel.
----------------------	----------------

### Unit Control

Software	Modular-Lab Software / Modular-Lab SoftPLC
----------	--

Interfaces	Ethernet / USB
------------	----------------

Before delivery all components are being tested in-house. If requested, a performance qualification of the complete system will be provided on-site. Extensive documentation will be provided upon request. Module dimensions include handles.

### Eckert & Ziegler Eurotope GmbH

Robert-Rössle-Straße 10  
13125 Berlin  
Germany  
Phone: +49 30 941084-197  
Fax: +49 30 941084-470

eurotope@ezag.de  
www.ezag.com/radiopharma

### Your contact in USA & Canada: Eckert & Ziegler Radiopharma, Inc.

63 South Street, Suite #110  
Hopkinton MA 01748  
USA  
Phone: + 1 508 497 0060  
Fax: + 1 508 497 0061

eurotope@ezag.com  
www.ezag.com/radiopharma