

Modular-Lab PharmTracer Tower

Cassette-based solution for routine production

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The Modular-Lab Tower is an advancement of Modular-Lab PharmTracer allowing cost-efficient routine production of Theranostic agents on a minimal footprint.



Background

The increasing importance of Theranostic applications in positron emission tomography requires reliable and efficient solutions for laboratories. To meet these trends Eckert & Ziegler further developed its Modular-Lab PharmTracer, providing a synthesis device for routine production with maximum reliability, minimum footprint, low investment and running costs thanks to the cost-efficient accessories and a new synthesis process which uses less amount of peptide.

Functionality

The Modular-Lab PharmTracer Tower is based on the established Modular-Lab PharmTracer technology, decreasing size and complexity of cassettes for Theranostic agents. The laboratory equipment has been specifically designed to allow the fully automated GMP compliant synthesis of ^{68}Ga -DOTA peptides and HBED-PSMA. This includes all process steps as fractionated elution of the ^{68}Ga from a $^{68}\text{Ge}/^{68}\text{Ga}$ generator, the synthesis process and the post-purification of the product with a light CM cartridge. A filter and cassette test can be performed optionally without any additional equipment.

The system is delivered pre-validated and ready for synthesis.

Setup

The synthesizer consists of a 2-fold manifold module (SLM-2), a Heater Reaction Module (HRM) and a Syringe Module (SYM) in combination with disposable cassettes using the click'n'start technology. The Modular-Lab software offers an easy-to-program and intuitive graphical interface.

Disposable Cassettes

Cassettes are assembled under GMP-compliant clean room conditions, sterilized with gamma-radiation and vacuum-packed (ISO 14644-1). All consumables are chemical resistant and have been tested for their suitability with the specific syntheses.

Features and Benefits

- Small footprint
- Cost-efficient cassettes and smaller amount of peptide reduce costs per synthesis
- Short synthesis time, fast and easy preparation
- High and reliable radiochemical purity
- Optional cassette and filter test
- Tried and tested Modular-Lab PharmTracer technology
- Open Modular-Lab software for R&D work
- Expandable with further modules to enable the production of other and new tracers
- High precision liquid transportation
- No pre-purification needed when using ^{68}Ga from a registered $^{68}\text{Ge}/^{68}\text{Ga}$ generator

Application Results

	^{68}Ga DOTA-peptides	^{68}Ga HBED-PSMA
Radiochemical yield (n.d.c.)	> 65 %	> 70 %
Radiochemical yield (d.c.)	> 75 %	> 80 %
Radiochemical purity (HPLC)	> 99 %	
Radiochemical purity (TLC)	> 98 %	
Synthesis time (without optional tests)	< 14 min	< 12 min
Amount of peptide / per synthesis	20 μg	15 μg

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Technical Specifications

Module Characteristics	
Footprint of entire system	130 x 267.5 x 514.4 mm (W x D x H) (height incl. handles; additional space for bus cable, activity and pressure sensor required)
Weight	12.5 kg
2-fold manifold module (SLM-2)	Dimensions: 130 x 198 x 191 mm (W x D x H)
Syringe Dispensing Module (SYM)	Dimensions: 130 x 184 x 268 mm (W x D x H); responsible for liquid transport
Heater Reaction Module (HRM)	Dimensions: 130 x 220 x 113 mm (W x D x H); heating via heating foil from room temperature to 220 °C
Accessories	ADII, Pressure Sensor

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. Please contact us if a DMF letter of intent is needed.

We recommend

To ensure high quality and best results, Eckert & Ziegler offers all equipment which is necessary for the synthesis from a single source, consisting of:

- Modular-Lab PharmTracer Tower - the small and reliable synthesizer
- Registered GalliaPharm® ⁶⁸Ge/⁶⁸Ga generator - to obtain the radionuclide
- Disposable synthesis cassettes
- Quality control devices
- Ready-to-use reagent sets and more

We recommend to only use Modular-Lab PharmTracer Tower with the Eckert & Ziegler GalliaPharm® or IGG100 ⁶⁸Ge/⁶⁸Ga generator.

Please note: The IGG100 ⁶⁸Ge/⁶⁸Ga generator is a chemical grade product and is not intended for use in humans. It has not been validated as a pharmaceutical product.