

Modular-Lab eazy

Routine production of theranostic tracers

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The small and cost-efficient solution for routine production of theranostic tracers with ^{68}Ga , ^{177}Lu and ^{90}Y



Introduction

Radiometal labeled compounds containing ^{68}Ga , ^{177}Lu and ^{90}Y become more widely used in diagnosis with positron emission tomography (PET) and therapy. Personalized medicine and the ongoing theranostic trend in combination with the cyclotron-independent availability of ^{68}Ga boost their application. To facilitate the daily work with these tracers, Eckert & Ziegler has developed Modular-Lab eazy - the innovative and ultra smart radiosynthesis system.

Functionality

Modular-Lab eazy works with a technology which uses pressure differences to transfer the liquids instead of solenoid valves or stopcocks. The innovative cassette design makes the handling of Modular-Lab eazy as easy as never before. By just clicking on the synthesis cassette the pressure supply system is connected automatically. After connecting the generator and adding the reagents the complete synthesis is executed without user interaction. The process steps can be monitored via the intuitive user interface. The software is based on the established and reliable Modular-Lab Software complying with the highest standards of GMP (annex 11 for computerized systems), GAMP5, 21 CFR 210/211 cGMP and 21 CFR part 11 regulations.

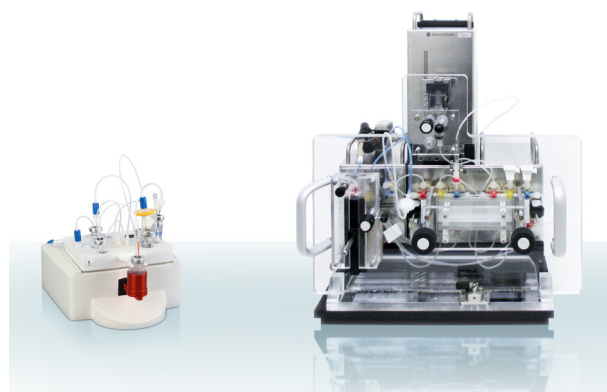
Cassettes

The sterile, disposable cassettes are equipped with a barcode which can be scanned by a barcode reader. This feature helps to support the GMP conform production of radiopharmaceuticals through electronic support of batch reporting and prevention of the incorrect use of cassettes. The synthesis cassettes are assembled under GMP-compliant clean room conditions and sterilized with gamma-radiation (validated process) according to AAMI TIR33/ISO 11137.

The cassettes are delivered with all necessary consumables (no reagents) for the specific synthesis and have been tested for their suitability.

Key features

- Smallest radiosynthesizer on the market - one module with complete functionality
- Short synthesis time and easy handling
- High yield and high radiochemical purity
- Highest product quality through sterile and disposable synthesis cassettes (validated sterilization method incl. 18 months shelf-life)
- Pre-defined software template with easy-to-operate user interface
- GMP and GAMP 5 compliance
- Automatic generating of batch protocols containing all relevant data and information of each synthesis run
- Annual maintenance to ensure long operational life



Modular-Lab eazy in comparison to Modular-Lab PharmTracer

Methods and applications

Method	Synthesis	Average yield d.c.	Purity	Synthesis time	Reagent set available
⁶⁸ Gallium*	DOTA-peptides	86 %	≥ 98 %	16 min	✓
	HBED-PSMA	86 %	≥ 98 %	12 min	✓
	DOTA-PSMA	86 %	≥ 98 %	16 min	✓
⁹⁰ Yttrium	DOTA-peptides	87 %	99 %	39 min	✓
	DOTA-PSMA	87 %	99 %	39 min	✓
¹⁷⁷ Lutetium	DOTA-peptides	94 %	99 %	34 min	✓
	DOTA-PSMA	94 %	99 %	34 min	✓

* Pre-purification of generator eluates with NaCl/HCl – All of these methods to label ⁶⁸Gallium DOTA-conjugated peptides fall under the patent: DE 102004057225 B4. Eckert & Ziegler is the exclusive licensee of the mentioned patent.

Technical features

Dimension of synthesizer:	201 x 227 x 101 mm (W x D x H)
incl. synthesis cassette with tubing:	201 x 227 x 220 mm (W x D x H); Weight: 1.8 kg
Power supply via EC eazy:	Dimensions: 160 x 160 x 170 mm (W x D x H) excl. cable outlet Control unit, outside of hot cell, 230/115 V PCAN USB adapter included
Peristaltic pump	Dimensions: 100 x 150 x 100 mm (W x D x H) For elution of generator
Software	Modular-Lab SoftPLC eazy

We recommend

To be able to start with the production of theranostic tracers without any further delay, Eckert & Ziegler offers the all-in-one solution for your synthesis, consisting of:

- GalliaPharm® ⁶⁸Ge/⁶⁸Ga Generator
- [⁹⁰Y]Yttrium Chloride (Yttriga)
- Disposable synthesis cassettes
- Ready-to-use reagent sets
- Filter test module
- Quality control devices
- A wide range of additional consumables

For all customers working with ⁶⁸Ga, the latest optional feature is the **Multi Generator Elution tool** which increases the flexibility to use low and high activities. The eluate from up to three ⁶⁸Ge/⁶⁸Ga generators can be combined for one production process with Modular-Lab eazy. Furthermore, the tool can extend the period of use for each generator by combining the eluates from all connected devices.