

Modular-Lab eazy

The key to the world of ^{68}Ga



We don't say life is easy, but the production of ^{68}Ga based PET-tracers is now!

Introduction

^{68}Ga labeled components become more widely used for positron emission tomography (PET). The easy and cyclotron independent availability of ^{68}Ga advances this trend. To facilitate the daily work with ^{68}Ga , Eckert & Ziegler has developed an innovative and ultra smart radiosynthesis system.

Functionality

The synthesizer works with a new technology* which uses pressure differences to transfer the liquids instead of solenoid valves or stopcocks. Modular-Lab eazy comes with a completely new and innovative cassette design, which makes the handling of Modular-Lab eazy as easy as never before. By just clicking in the synthesis cassette all pressure connections are done automatically. After connecting the generator and filling the chemicals the complete synthesis works 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 read 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 according to AAMI TIR33/ISO 11137. It comes with all consumables (no chemicals) which are necessary for the specific synthesis and have been tested for their suitability.



Modular-Lab eazy in comparison to Modular-Lab PharmTracer

Packages

Two different packages are available:

	Basic	Full
Modular-Lab eazy incl. peristaltic pump	✓	✓
Notebook	✓	✓
1 unit cassettes	✓	✓
1 unit chemical kits	✗	✓
Barcode reader	✗	✓
IQ/OQ documentation	✗	✓
Synthesis template	1 template	2 templates

To be able to start with the production without any further delay, we offer the all-in-one solution for the synthesis of ^{68}Ga labeled compounds, consisting of $^{68}\text{Ge}/^{68}\text{Ga}$ Generator, synthesis device, disposable synthesis cassettes, chemical kits and a wide range of additional consumables.

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
- Pre-defined software template with easy-to-operate user interface
- System is GMP and GAMP 5 compliant
- Automatic generating of batch protocols and reports containing all relevant data and information after each run
- Annual maintenance ensures long operational life

*applied for a patent

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The key to the world of ⁶⁸Gallium

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 Soft PLC eazy

Typical Results

Yield: > 70 % n.d.c.
Purity: > 95 % without SPE purification
Synthesis time: < 15 min

Methods and Applications

⁶⁸Gallium

Methods	Synthesis	Synthesis established	Cassette available	Chemical kit available
Pre-purification with NaCl/HCl*	DOTA-conjugated peptides	✓	✓	✓
	PSMA ^{HBED}	✓	✓	u.d.
Fractionated	DOTA-conjugated peptides	✓	o.d.	o.d.
Pre-purification with Acetone/HCl*	DOTA-conjugated peptides	✓	o.d.	✓

* 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.

⁹⁰Y/¹⁷⁷Lu

Synthesis	Synthesis established	Cassette available	Chemical kit available
⁹⁰ Y/ ¹⁷⁷ Lu DOTA-conjugated peptides	✓	u.d.	u.d.

u.d. = under development

o.d. = on demand

Further methods and applications will follow soon.

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