



## ITM $^{68}\text{Ge}/^{68}\text{Ga}$ GENERATOR

Easy and direct labeling of PET tracers

$^{68}\text{Ga}$  as radiopharmaceutical precursor, not intended for direct use in patients.

## Easy and direct labeling of PET tracers.

$^{68}\text{Ga}$  PET imaging is an excellent approach for healthcare professionals looking for precise localization in diagnostic imaging. With the GMP certification of our ITM  $^{68}\text{Ge}/^{68}\text{Ga}$  Generator we have set yet another milestone in order to establish  $^{68}\text{Ga}$  as next generation radioisotope for diagnostic purposes.

The generator columns unique metal free design and its low acidic eluent allow the fast and convenient onsite production of short-lived high-quality  $^{68}\text{Ga}$  for radiolabeling without prior prepurification.

Benefit from our innovative fully integrated  $^{68}\text{Ga}$  platform for the manufacturing of  $^{68}\text{Ga}$  radiolabeled PET tracers.



### ITM $^{68}\text{Ge}/^{68}\text{Ga}$ GENERATOR

**Metal-free generator  
in GMP quality.**

The metal free ITM  $^{68}\text{Ge}/^{68}\text{Ga}$  Generator allows fast and convenient onsite production of  $^{68}\text{Ga}$  for radiolabeling.



### iQS-TS

**Fully automated Theranostics  
Synthesizer.**

iQS-Theranostics Synthesizer is a multipurpose automated cassette-based module for the preparation of  $^{68}\text{Ga}$ ,  $^{177}\text{Lu}$  and  $^{90}\text{Y}$  radiolabeled biomolecules.



### RADIOLABELING SETS

**iQS GMP chemicals to  
obtain highest yield.**

For both iQS systems there are suitable Sets available.



## KEY ADVANTAGES

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Fast and convenient labeling of PET tracers

- Metal free matrix allows direct labeling
  - Low acidic eluent (0.05 M HCl)
  - Small elution volume (4 ml)
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### iQS® Ga-68 FLUIDIC LABELING MODULE

**Self-shielded synthesis module  
for convenient labeling**

The iQS® Ga-68 Fluidic Labeling Module is the most compact and self-shielded system for radiolabeling of DOTA-peptides.

**PRECISELY FOR ME.**



- ✓ Benefit from attractive financing options
- ✓ Monthly payment negotiable

## PHYSICAL DATA

<b>Mother nuclide</b>	<b><sup>68</sup>Ge</b>
Half-life	270.95 days
Decay mode	Electron capture
Decay energy	106 keV
<b>Daughter nuclide</b>	<b><sup>68</sup>Ga</b>
Half-life	67.71 min
Decay mode	Beta plus decay (89 %), Electron capture (11 %)
Decay energy	E (β <sup>+</sup> ) <sub>max</sub> = 1.9 MeV Gamma: 511 keV (178 %, annihilation)

## GENERATOR SPECIFICATION

Column material	Silica gel modified with dodecyl gallate (CAS: 166-52-5)
Primary package	Peek column
Secondary package	Lead container
Lead shielding	36–50 mm thickness
Eluent	Sterile 0.05 M aqueous hydrochloric acid solution
Elution volume	4 ml
Elution yield	Not less than 80 %
Elution speed	1-5 ml/min, max 6 bar
Shelf life	12 months or 250 elutions (whatever endpoint reached first)
Generator size (Nominal <sup>68</sup> Ge radioactivity)	0.3 GBq–2 GBq

## ELUATE SPECIFICATION

Chemical form	Gallium (III) chloride in 0.05 M HCl			
Appearance	Clear and colorless solution			
Volume	4 ml			
Chemical purity of the eluate	Fe ≤ 10 µg/GBq Nb ≤ 10 µg/GBq	Cu ≤ 10 µg/GBq Ni ≤ 10 µg/GBq	Ga-69 ≤ 10 µg/GBq	Pb ≤ 10 µg/GBq Zn ≤ 10 µg/GBq
Lauryl gallate in eluate	≤ 5 ppm			
Radiochemical purity	≥ 95 % gallium-68 in the form of Ga <sup>3+</sup> ion			
Radionuclidic purity of the eluate	Gallium-68 minimum 99.9 % of the total radioactivity			
Germanium-68 and gamma-ray-emitting impurities at calibration time	≤ 0.005 % of the total radioactivity			
Specific activity of Gallium-68	Product is carrier-free			
Microbiological status	Eluate sterile at release			
Bacterial endotoxins	≤ 20 EU/ml			
<b>Storage</b>	-10 to +40°C taking into account radiation protection guidelines			

<sup>68</sup>Ga is a radiopharmaceutical precursor and it is not intended for direct use in patients. It is to be used only for the radiolabeling of targeting molecules that have been specifically developed and authorized for radiolabeling with <sup>68</sup>Ga.

Distribution of this brochure only allowed in countries, in which the generator has Marketing Authorization or is not considered as a medical product.

### About the ITM Group

ITM Isotopen Technologien München AG is a privately owned biotechnology and radiopharmaceutical group of companies dedicated to the development, production and global supply of targeted diagnostic and therapeutic radiopharmaceuticals and radioisotopes for use in cancer treatment. ITM's main objectives are to significantly improve the treatment outcome and quality of life for cancer patients while at the same time reducing side effects and improving health economics through a new generation of Targeted Radionuclide Therapies in Precision Oncology.

### Your contact:

Phone: +49 89 329 8986-600  
Email: [info@itm.ag](mailto:info@itm.ag)  
[www.itm.ag](http://www.itm.ag)  
ITM Isotopen Technologien München AG  
Lichtenbergstrasse 1  
85748 Garching/Munich, Germany

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**ITM Medical Isotopes GmbH.**

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