



## 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)
- 



### 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.**



**OPTIMIZE YOUR AMOUNT OF <sup>68</sup>Ga ACTIVITY NOW**

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

**PHYSICAL DATA**

|                         |  |
|-------------------------|--|
| <b>Mother nuclide</b>   | <sup>68</sup> Ge   |
| Half-life               | 270.95 days  |
| Decay mode              | Electron capture   |
| Decay energy            | 106 keV  |
| <b>Daughter nuclide</b> | <sup>68</sup> Ga   |
| 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<br>Nb ≤ 10 µg/GBq                                 | Cu ≤ 10 µg/GBq<br>Ni ≤ 10 µg/GBq | Ga-69 ≤ 10 µg/GBq | Pb ≤ 10 µg/GBq<br>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.

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**About the ITM Group**

ITM, a radiopharmaceutical biotech company, is dedicated to providing the most precise cancer radiotherapeutics and diagnostics to meet the needs of patients, clinicians and our partners through excellence in development, production and global supply. With patient benefit as the driving principle for all we do, ITM is advancing a broad pipeline combining its superior radioisotopes with targeting molecules to create precision oncology treatments. ITM is leveraging its leadership and nearly two decades of radiopharma expertise combined with its worldwide network to enable nuclear medicine to reach its full potential for helping patients live longer and better.

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