

GalliaPharm® ⁶⁸Ge/⁶⁸Ga Generator

Cyclotron-independent production of the positron emitter ⁶⁸Gallium



Description

The GalliaPharm® ⁶⁸Ge/⁶⁸Ga Generator from Eckert & Ziegler Radiopharma GmbH is a pharmaceutical product for obtaining the positron emitter ⁶⁸Gallium, independent of a cyclotron.

The generator is a closed system consisting of pharmacopoeia grade borosilicate glass column containing a titanium dioxide bed on which ⁶⁸Ge is adsorbed. ⁶⁸Ga is continuously produced by decay of its radioactive parent ⁶⁸Ge and is eluted with sterile, ultra pure 0.1 M HCl. The generator is available with the following activities: 20 mCi, 30 mCi, 40 mCi and 50 mCi.

Output

In practice, the generator requires at least 4 hours to achieve full yield after being eluted. The output will decrease with decay of the ⁶⁸Ge parent.

Advantages

The GalliaPharm® is produced under GMP conditions ensuring highest quality standards and is designed to minimize both ⁶⁸Ge breakthrough and metal impurities. No metals are used within the closed system. All components are compliant with the monographs of the European Pharmacopoeia (if available) or their suitability for the respective application has been otherwise tested.

Generator Shelf-Life

Expected life of the generator is dependent upon several factors such as frequency of use, volume of elution and others. The useful life of the generator has been investigated in a long-term study. From the data obtained compliance with specification is given over 12 months. Therefore, a shelf-life of 12 months is justified when used according to the Summary of Product Characteristics (SmPC) provided by the manufacturer.

Marketing Authorization

The sterile and GMP compliant GalliaPharm® ⁶⁸Ge/⁶⁸Ga Generator is registered as a medicinal product in several European countries. Furthermore Eckert & Ziegler Radiopharma GmbH is a holder of a Type II Drug Master File (#28741) in the USA.

Quality Control Process

Every GalliaPharm® has to pass several tests according to the GMP conditions and tests mentioned in the 'Gallium (⁶⁸Ga) chloride solution for Radiolabelling' monograph of the European Pharmacopoeia before delivery. Additionally, Eckert & Ziegler also tests sterility of the eluate. Finally, the GalliaPharm® will be released by a qualified person.

The GalliaPharm® eluate complies with the following specifications (excerpt):

Test parameter	Specification
Appearance	Clear, colorless solution
Identity ⁶⁸ Ga	Half-life 62–74 min
Content	> 60 % of nominal activity
Chemical impurity	Fe < 10 µg / GBq Zn < 10 µg / GBq
Radionuclidic purity (γ-emitting impurities)	< 0.001 % of nominal activity
Radiochemical purity	> 95 % free ⁶⁸ Ga ³⁺
pH	0.5–2.0
Microbiological quality	Sterile
Bacterial endotoxines	< 30 EU / ml

Technical Specifications

General Data	
Dimensions (W x D x H)	132 x 133 x 230 mm
Weight	14 kg
Time of max. ⁶⁸ Ga accumulation	7 hours
⁶⁸ Ge breakthrough	Not more than 0.001 %
Eluent*	Sterile, ultra pure hydrochloric acid 0.1 mol/l
Elution Speed	2.5 ml/min
Available activities	20 mCi , 30 mCi , 40 mCi and 50 mCi
Decay Characteristics	
Half-life	⁶⁸ Ge: 271 days ⁶⁸ Ga: 68 minutes
Radiation type	Positrons: 1.90 MeV from ⁶⁸ Ga daughter; 89 % abundance Photons: 0.511 MeV positron annihilation radiation; 178 % abundance 1.077 MeV gamma radiation; 3.2 % abundance
Order Information	
Delivery Time	Upon request
Additional Information	
Countries of registration	The GalliaPharm® has been registered as a medicinal product in the following European countries: AT, BE, DE, DK, ES, FI, FR, IT, NL, NO, PL, SE
Return	Additional fees will apply if you want Eckert & Ziegler to take care of the final return of the used product.
Accessories	According to the marketing authorization the cassette tube for elution delivered with the generator has a length of 60 cm.

**To keep the warranty and pharmaceutical status it is mandatory to only use the sterile HCl solution provided by Eckert & Ziegler.*

Marketing authorization holder:

Eckert & Ziegler Radiopharma GmbH, Robert-Rössle-Str. 10, D-13125 Berlin. Name of medicinal product: GalliaPharm 0,74–1,85 GBq radionuclide generator, radionuclide generator. Active ingredient: germanium (⁶⁸Ge) chloride as mother nuclide, gallium (⁶⁸Ga) chloride as daughter nuclide, 0.74– 1.85 GBq. Excipients: column (matrix) titanium dioxide (E 171), hydrochloric acid 0.1 mol/l. Indications: Not for direct use in patients. For in vitro radiolabelling of carrier molecules for diagnostic imaging via positron emission tomography (PET). Contra-indications: Hypersensitivity against the active ingredient or the excipients. Side effects: no side effects known. Warnings: radioactive, handle in accordance with radiation protection requirements. Prescription only.

Drug Master File in the USA:

In the USA the FDA regards the ⁶⁸Ge/⁶⁸Ga Generator as a drug substance and accordingly Eckert & Ziegler Radiopharma GmbH has submitted a Type II DMF. DMF #28741 Drug Master File holder: Eckert & Ziegler Radiopharma GmbH, Robert-Rössle-Str. 10, D-13125 Berlin

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