

GalliaPharm® ⁶⁸Ge/⁶⁸Ga Generator

Cyclotron-independent production of the positron emitter ⁶⁸Gallium



Description

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

GalliaPharm® 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 ultrapure 0,1 mol/l hydrochloric acid. GalliaPharm® is available with the following activities: 740 MBq, 1110 MBq, 1480 MBq and 1850 MBq (20 mCi, 30 mCi, 40 mCi, 50 mCi).

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 tested otherwise.

Marketing Authorization

A ⁶⁸Ge/⁶⁸Ga generator is regarded as a drug product in Europe and requires full registration to receive marketing authorization. The sterile and GMP compliant GalliaPharm® has been registered in 17 European countries.

The sterile ultrapure 0,1 mol/l hydrochloric acid provided by Eckert & Ziegler Radiopharma GmbH is essential part of the registration and must not be replaced by any substitute product.

In the USA a ⁶⁸Ge/⁶⁸Ga generator is regarded as a drug substance.

Output

In practice, the generator requires seven hours to achieve full yield after being eluted. 90% yield will be achieved after four hours. The output will decrease with decay of the ⁶⁸Ge parent.

Quality Control Process

Every GalliaPharm® has to pass several tests, mentioned in the 'Gallium (⁶⁸Ga) chloride solution for Radiolabelling' monograph of the European Pharmacopoeia, before delivery. Additionally, Eckert & Ziegler Radiopharma GmbH also tests sterility of the eluate. Finally, GalliaPharm® is 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 impurity (γ-emitting impurities)	< 0,001 % of nominal activity
Radiochemical purity	> 95 % free ⁶⁸ Ga ³⁺
pH	0.5–2.0
Microbiological quality	Sterile
Bacterial endotoxins	< 30 EU / ml

GalliaPharm® Shelf-Life

Expected shelf-life of GalliaPharm® 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 and may vary from country to country. A shelf-life of 12 months is justified when used according to the Summary of Product Characteristics (SmPC). No additional testing for ⁶⁸Ge breakthrough will be necessary.

Technical Specifications

General Data	
Dimensions (W x D x H)	132 x 133 x 230 mm
Weight	14 kg
Recommended time between two elutions	4 hours
⁶⁸ Ge breakthrough	Not more than 0,001 %
Eluent*	Sterile ultrapure 0,1 mol/l hydrochloric acid
Elution Speed	2,0 ml/min
Available activities	740 MBq, 1110 MBq, 1480 MBq, 1850 MBq (20 mCi, 30 mCi, 40 mCi, 50 mCi)
Decay Characteristics	
Half-life	⁶⁸ Ge: 271 days ⁶⁸ Ga: 68 minutes
Radiation type	Positrons: up to 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 17 European countries: AT, BE, CZ, DE, DK, ES, FI, FR, IE, IT, LV, NL, NO, PL, SE, SK, UK Type II DMF in the USA: #28741
Return	Additional fees will apply if you want Eckert & Ziegler to take care of the final return of the used product.
Accessories	GalliaPharm® is delivered with Accessories for Elution to setup the GalliaPharm® for usage. The set contains i.a. tubes with three defined lengths to suit the local situation (refer to the SmPC for further details).

**To keep the pharmaceutical status it is mandatory to only use the sterile ultrapure 0,1 mol/l hydrochloric acid provided by Eckert & Ziegler for elution of GalliaPharm®.*

Marketing authorization holder:

Eckert & Ziegler Radiopharma GmbH, Robert-Rössle-Str. 10, 13125 Berlin, Germany. Name of medicinal product: GalliaPharm 0,74–1,85 GBq radionuclide generator. Active ingredient: germanium (⁶⁸Ge) chloride as mother nuclide, gallium (⁶⁸Ga) chloride as daughter nuclide. Excipients: column (matrix) titanium dioxide, sterile ultrapure 0,1 mol/l hydrochloric acid. 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.

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