

The information stated in this fact sheet is valid for the USA only.

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 matrix on which 68Ge is adsorbed. 68Ga is continuously produced by decay of its radioactive parent nuclide 68Ge and is eluted with sterile ultrapure 0.1 mol/L hydrochloric acid. GalliaPharm® is available with the following activities:

- 0.74 GBq (20 mCi)
- 1.11 GBq (30 mCi)
- 1.48 GBq (40 mCi)
- 1.85 GBq (50 mCi)
- 2.22 GBq (60 mCi)
- 2.59 GBq (70 mCi)
- 2.96 GBq (80 mCi)
- 3.33 GBq (90 mCi)
- 3.70 GBq (100 mCi)

Advantages

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.

With a guaranteed content of over 60 % of its nominal activity, GalliaPharm® boasts the highest yield of any GMP-grade 68Ge/68Ga generator.*

*according to the IFU's of currently available GMP-grade 68Ge/68Ga generators

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.

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 68Ga	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 eluate
Radiochemical purity	> 95 % free 68Ga3+
pH	0.5–2.0
Microbiological quality	Sterile
Bacterial endotoxins	< 20 EU / mL

Drug Master File

In the USA a $^{68}\text{Ge}/^{68}\text{Ga}$ generator is regarded as a drug substance. Eckert & Ziegler Radiopharma GmbH is holder of a Type II Drug Master File (DMF #28741) for GalliaPharm® and has successfully completed pre-approval and follow-up inspections by the FDA. The DMF can be referenced in New Drug (NDA) and Investigational New Drug (IND) applications. A letter of authorization can be provided upon request.

The sterile ultrapure 0.1 mol/L hydrochloric acid provided by Eckert & Ziegler Radiopharma GmbH is subjected to an own release procedure. Therefore it is an essential part of the DMF and must not be replaced by any substitute product.

GalliaPharm® Shelf-Life

Expected shelf-life of GalliaPharm® is dependent upon several factors such as frequency of use, number of elutions and others. The useful life of the generator has been investigated in a long-term study and may vary from country to country.

The generator shelf-life of 12 months or 700 elutions is justified for the US when used according to the Instructions for Use (IFU) provided by Eckert & Ziegler Radiopharma GmbH.

Technical Specifications

General data	
Dimensions (W x D x H)	132 x 133 x 230 mm ³
Weight	14 kg
Recommended time difference between two elutions	4 hours
Eluent*	Sterile ultrapure 0.1 mol/L hydrochloric acid
Elution speed	2.0 mL/min
Surface radiation	less than 0.14 µSv/h per MBq of ^{68}Ge
Available activities	in GBq: 0.74; 1.11; 1.48; 1.85; 2.22; 2.59; 2.96; 3.33 or 3.70 in mCi: 20; 30; 40; 50; 60; 70; 80; 90 or 100
Decay characteristics	
Half-life	^{68}Ge : 271 days ^{68}Ga : 68 minutes
Radiation type	Positrons: up to 1.90 MeV from ^{68}Ga ; 89 % abundance Photons: 0.511 MeV positron annihilation radiation; 178 % abundance 1.077 MeV gamma radiation; 3.2 % abundance
Additional information	
Countries of registration	USA: Type II DMF #28741 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) and Canada
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 IFU 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 Radiopharma GmbH for elution of GalliaPharm®.*

Eckert & Ziegler Radiopharma GmbH

Robert-Rössle-Strasse 10
13125 Berlin
Germany
Phone: +49 30 941084 280
Fax: +49 30 941084 470

radiopharma@ezag.de
www.radiopharma.com