

Elution Accessories

for GalliaPharm® Radionuclide Generator



The adequate usage of GalliaPharm® requires the elution with predefined Elution Accessories such as eluent and tubing.

Elution Setup for GalliaPharm®
Radionuclide Generator

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. It is produced under GMP conditions ensuring highest quality standards and is registered as a drug product in 17 European countries and Canada. Furthermore, Eckert & Ziegler Radiopharma GmbH is holder of a Type II Drug Master File in the USA.

To ensure highest quality and provision of ⁶⁸Ga suitable for pharmaceutical production, Eckert & Ziegler Radiopharma GmbH provides the appropriate elution supplies.

Accessories	Article No.
Sterile ultrapure 0,1 mol/l hydrochloric acid for elution of GalliaPharm®, container 250 ml	10027-00
Accessories for Elution of GalliaPharm®, sterile	10104-00

Accessories for Elution of GalliaPharm®

The Accessories for Elution consist of tubes and appropriate fittings to connect the inlet port of GalliaPharm® with the sterile ultrapure 0,1 mol/l hydrochloric acid container and the outlet port with a synthesis device or a vial. Please refer to the SmPC or IFU for further details. The Accessories for Elution are assembled under clean room conditions, vacuum packed and gamma-sterilized. All parts are chemical resistant and all materials are free of animal derived ingredients. A shelf-life of 12 months can be guaranteed.

Sterile ultrapure 0,1 mol/l Hydrochloric Acid - eluent for GalliaPharm®

To receive an eluate containing reactive ⁶⁸Gallium, GalliaPharm® is eluted with sterile, ultra pure 0,1 mol/l hydrochloric acid, which Eckert & Ziegler Radiopharma GmbH offers in a container of 250 ml with a shelf-life of 18 months. This amount is sufficient for at least 40 elutions.

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.

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 substance: germanium (⁶⁸Ge) chloride as mother nuclide, gallium (⁶⁸Ga) chloride as daughter nuclide, 0.74 - 1.85 GBq. Excipients: titanium dioxide (column matrix), 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). Contraindications: Hypersensitivity against the active substance or the excipients. Side effects: no side effects known. Warnings: Keep out of the reach and sight of children, 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. 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, 13125 Berlin, Germany

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

 Eckert & Ziegler