

Background

The application of ^{68}Ga -labeled PSMA-11 for positron emission tomography (PET) has shown extraordinary results in clinical application over the past years. The preparation of ^{68}Ga -PSMA-11 has been performed using manual procedures as well as synthesizers. In order to allow labeling of PSMA-11 with a device which is also capable of handling cold/shake & bake kits, the reliable synthesis of ^{68}Ga -PSMA-11 using SCX purification has been transferred. Using the KitLab not only provides the user with suitable radiation protection but also a printed batch report. Automation allows generation of reproducible results. It is possible to upgrade the system for further applications.

Method

In the first step of the automated ^{68}Ga -PSMA-11 synthesis process the GalliaPharm® generator is eluted with a speed of 2 mL/min according to its Summary of Product Characteristics (SMPC). The eluted ^{68}Ga is trapped on an SCX cartridge which is then rinsed with saline. Subsequently, ^{68}Ga is eluted using the eluent and transferred into the reaction vial, which already contains the reaction buffer as well as the precursor. After four minutes reaction time at room temperature the product is transferred to the product vial via a WCX cartridge and a sterile filter (0.22 μm). Due to dilution with saline solution, the final volume of the product is (5.4 \pm 0.2) mL with a pH of 4.1 to 4.3.

Cassettes

Every sterile, disposable cassette comes with an RFID card. The RFID chip contains all information required for the synthesis. All synthesis cassettes are assembled under GMP-compliant clean room conditions and sterilized with gamma-radiation (validated process) according to AAMI TIR33/ISO 11137. The cassettes contain needle free connections to avoid metal impurities and V-vials to minimize liquid residues. Color coding between vials and spikes prevents incorrect use and facilitates the preparation process.

Accessories

The application of the reagent set EZ-102 (Eckert & Ziegler Eurotope GmbH, Berlin, Germany) is mandatory. The reagent set contains all chemicals required for a successful synthesis and further consumables such as syringes and spikes. The precursor is not part of the reagent set.



Results

The automated synthesis of ^{68}Ga -PSMA-11 including pre- and post-purification steps showed excellent radiochemical yields (d.c.) and chemical purity of the product. All parameters are well inside the standard Ph.Eu.'s limits.

Relevant process and QC data determined by a pre-validation of 12 runs performed by four different operators are shown in the following table.

Data on synthesis and product for ^{68}Ga -PSMA-11	
Synthesis time	~ 13 min
Radiochemical yield (d.c.)	> 87 %
Handling Loss	< 10 %
Radiochemical purity (TLC)	> 99 %
Radiochemical purity (HPLC)	> 98 %
Ethanol concentration	< 4 % (optional)
Final volume	(5.4 \pm 0.2) mL
pH	4.1 - 4.3

Key Features

- Increased radiation protection
- Fully automated synthesis process, no user intervention necessary
- Pre-validated process for standardized and reproducible synthesis
- Several PSMA-11 doses with one synthesis run
- Cost-efficient consumables
- Easy and intuitive handling
- Traceability of the complete process via an automatically printed batch report
- Upgradeable for further applications

Eckert & Ziegler Eurotope GmbH

Robert-Rössle-Strasse 10
13125 Berlin
Germany
Phone: +49 30 941084 197
Fax: +49 30 941084 470

eurotope@ezag.de
www.radiopharma.com

Your contact in USA & Canada: Eckert & Ziegler Radiopharma, Inc.

63 South Street, Suite #110
Hopkinton MA 01748
USA
Phone: +1 508 497 0060
Fax: +1 508 497 0061

eurotope@ezag.com
www.radiopharma.com