

## Simplified Automation of the GMP production of $^{68}\text{Ga}$ -labelled peptides

David Goblet, Cristiana Gameiro, Neva Lazarova  
IBA, Louvain-la-Neuve, Belgium

### Introduction

Optimized automated process for the GMP production of  $^{68}\text{Ga}$ -DOTA-NOC and  $^{68}\text{Ga}$ -PSMA-11 using a cassette-based synthesizer (Synthera<sup>®</sup>, IBA, Louvain-la-Neuve, Belgium) in combination with a recently commercialized  $^{68}\text{Ge}/^{68}\text{Ga}$  generator (Galli Eo<sup>™</sup>, IRE-Elit, Fleurus, Belgium) have been developed in this work.

### Materials & Methods

The generator outlet is connected to an unmodified FDG-type disposable cassette with the appropriate reagent set and loaded onto the synthesizer. Once the automated process is started, vacuum elution takes place using only 1.1 mL of a 0.1 M HCl solution from the generator integrated reservoir. No purification being required, Ga-68 activity is directly sent to the reaction vessel.

DOTA-NOC labeling is conducted as follows: a solution of 50  $\mu\text{g}$  peptide in 1 mL 250 mM acetate buffer at pH 5 is added and the mixture is heated at 120°C for 5 min. The reaction bulk is then loaded on an HLB cartridge and washed with 10 mL of water.  $^{68}\text{Ga}$ -DOTA-NOC is then eluted with 1 mL of EtOH/water 65:35 v/v mix followed by 1 mL of saline 0.9% and collected through a 0.22  $\mu\text{M}$  Millex<sup>®</sup>-GV filter into a sterile vial containing 8 mL of saline 0.9%.

PSMA-11 labeling is conducted as follows: a solution of 10  $\mu\text{g}$  peptide in 1 mL 1.5 M acetate buffer at pH 4.5 is added and the mixture is heated at 95°C for 5 min. The reaction bulk is then loaded on a Sep-pak<sup>®</sup> Light C18 cartridge and washed with 10 mL of water.  $^{68}\text{Ga}$ -PSMA-11 is then eluted with 2 mL of EtOH/water 1:1 v/v mixture followed by 2 mL of phosphate buffered saline (PBS) and collected through a 0.22  $\mu\text{M}$  Millex<sup>®</sup>-GV filter into a sterile vial containing 6 mL of PBS.

### Results

$^{68}\text{Ga}$ -DOTA-NOC is produced in <20 min with  $81.5\pm 5.2$  % radiochemical yield (RCY) (decay-corrected-d.c.) and  $^{68}\text{Ga}$ -PSMA-11 is produced in 13 min with  $97.4\pm 2.5$  % RCY (d.c.). Reported process times include generator elution and formulation. In both cases, final products show high radiochemical purity (TLC > 97 % and 99 % respectively).

### Discussion/Conclusion

Automated processes for the production of both  $^{68}\text{Ga}$ -DOTA-NOC and  $^{68}\text{Ga}$ -PSMA-11 have been successfully achieved using a commercial synthesizer and a  $^{68}\text{Ge}/^{68}\text{Ga}$  generator. The labeling procedures are straightforward and efficient, thanks to the low elution volume and high purity of the generator eluate (no need for fractionation or post-elution purification).