

# Optimization of the production of Gallium-68 labeled peptides (PSMA et DOTATOC).

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## Background

Sharp increase in demand for <sup>68</sup>Ga-DOTATOC and <sup>68</sup>Ga-PSMA PET/CT, but limited availability (end-of-synthesis activity and required time between elutions).

Option to use two generators, but lower yields with the supplier's kits.

## Purpose

**Feasibility study of the fractionated elution method :**

- Increase in end-of-synthesis activity,
- BUT risk of radiolysis.

Validation of the quality of the preparations obtained.

## Conclusion

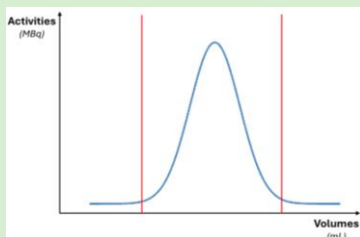
Increased available activity at the end of synthesis thanks to fractionated elution.

No degradation in production quality and no radiolysis detected.

More patients included per preparation (4 vs 2).

## Methods

**Fractionated elution into 3 parts** to retain the most concentrated fraction.



Selection of the most favorable profile

**5 validation batches for each peptide** (DOTATOC and PSMA) using the selected elution profile. The two eluates from the two generators are combined.

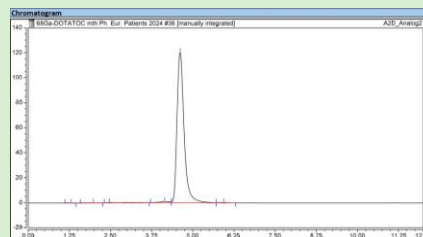
**Evaluation of the following parameters:** yields, radiochemical purity (RCP), and stability at 3 hours.  
RCP and stability assessed by HPLC and TLC.

## Results / Discussion

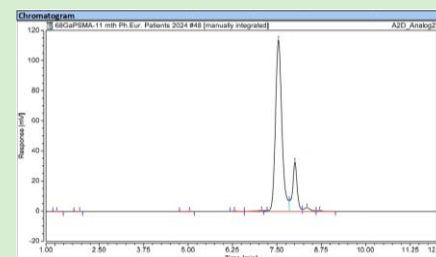
**Retained profile :** 1 mL – 2.5 mL – 1.5 mL.

83 ± 1.2 % of total activity.

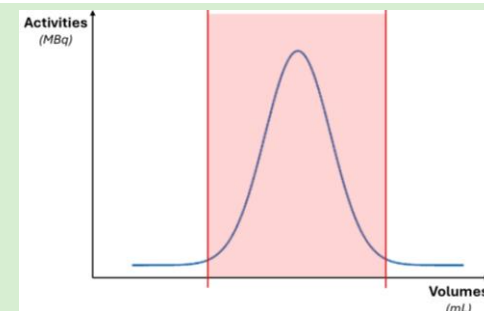
**Radiolabeling with 2 x 2.5 mL of fractionated eluates**



Chromatogram of <sup>68</sup>Ga-DOTATOC.



Chromatogram of <sup>68</sup>Ga-PSMA.



Parameter	PSMA	DOTATOC
Yield	78 ± 1.2 %	81 ± 3.0 %
RCP	96.6 ± 0.5 % (HPLC) 97.7 ± 1.4 % (CCM)	97.6 ± 0.4 % (HPLC) 99.6 ± 0.1 % (CCM)
Stability	96.6 ± 0.7 % (HPLC) 98.0 ± 1.2 % (CCM)	95.7 ± 0.7 % (HPLC) 99.7 ± 0.2 % (TLC)