

# PRODUCTION AND QUALITY CONTROL OF $^{68}\text{Ga}$ -PENTIXAFOR WITH THE MINI AIO® SYNTHESIZER.

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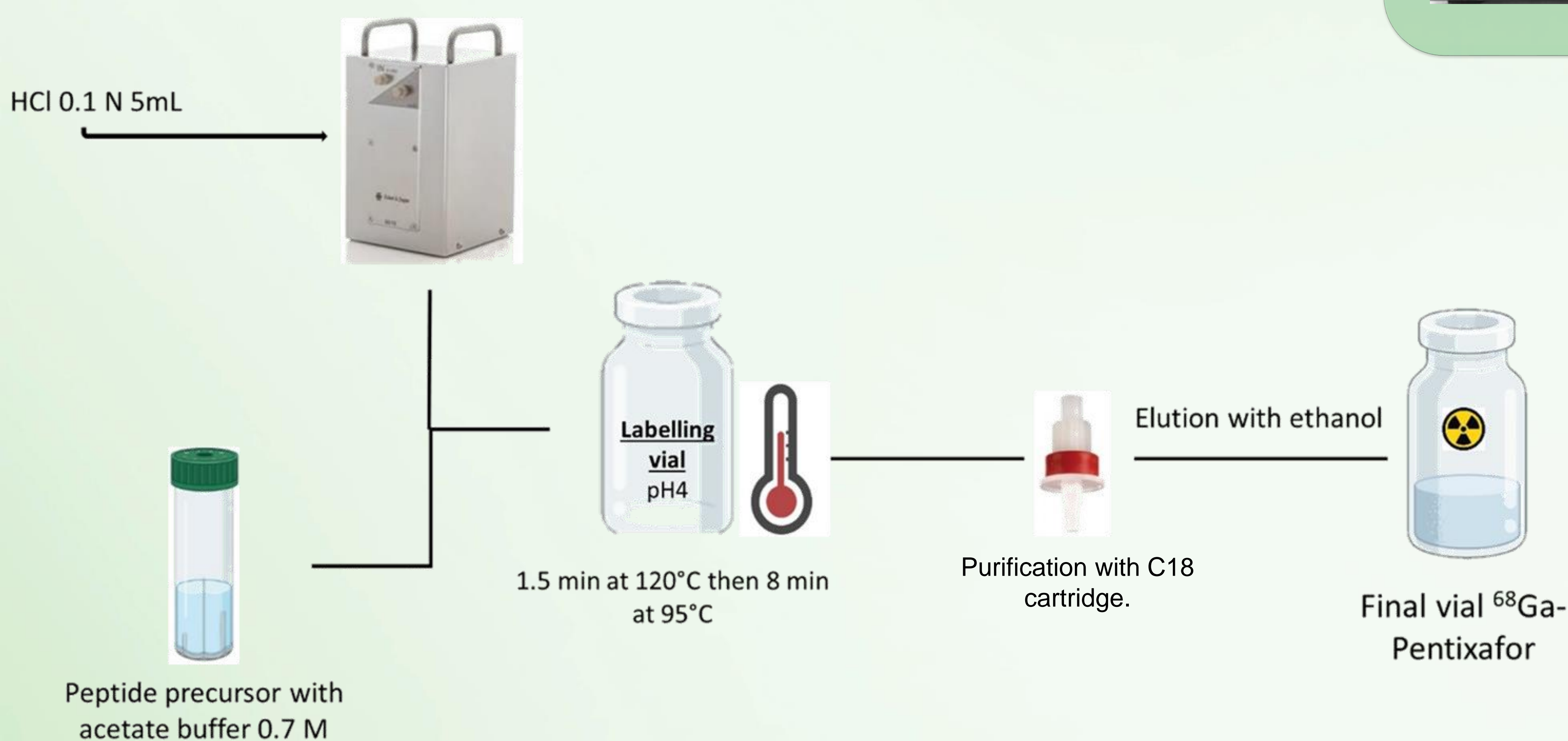
## Introduction :

The CXCR4/CCL12 axis is involved in many pathological processes and upregulation is found in tumors and auto-immune diseases.  $^{68}\text{Ga}$ -Pentixafor showed a strong affinity and selectivity to CXCR4 and is used for PET imaging in many clinical studies. The synthesis of  $^{68}\text{Ga}$ -Pentixafor has been described with few synthesizers but not with the Mini AiO® (Trasis, Belgium).

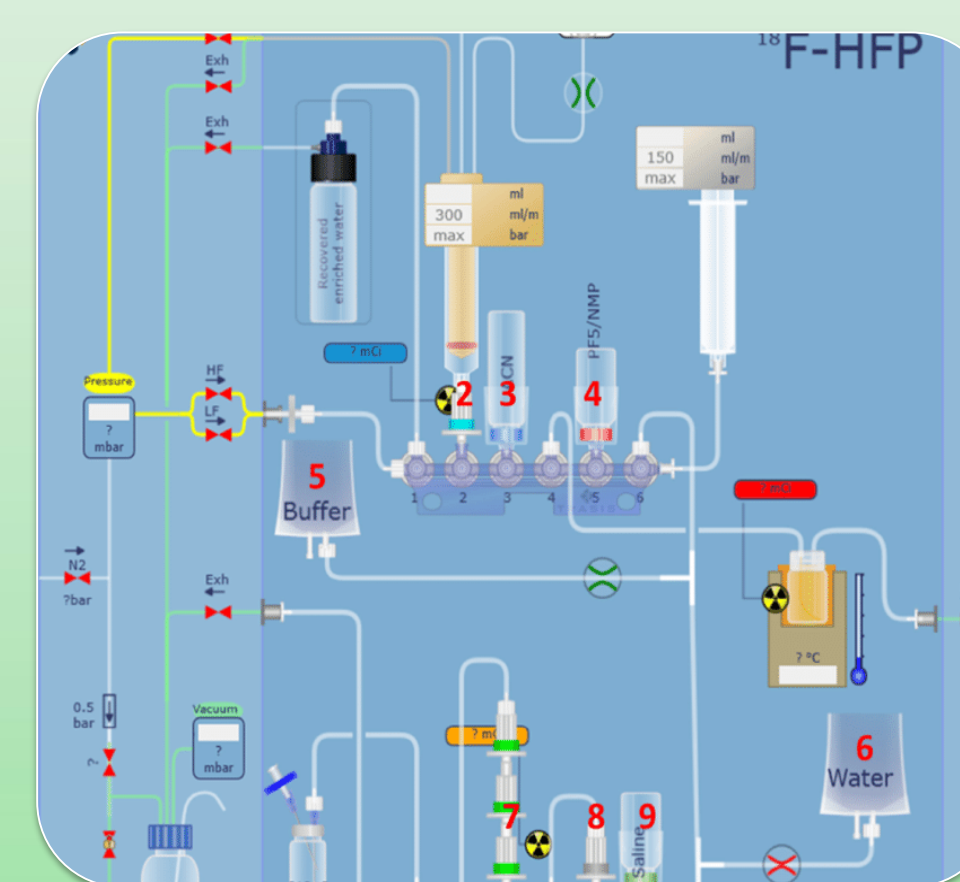
## Purpose :

The aim of this work was to develop  $^{68}\text{Ga}$ -Pentixafor production with the Mini AiO® for clinical studies in our hospital.

## Material and methods :



## Results and discussion :



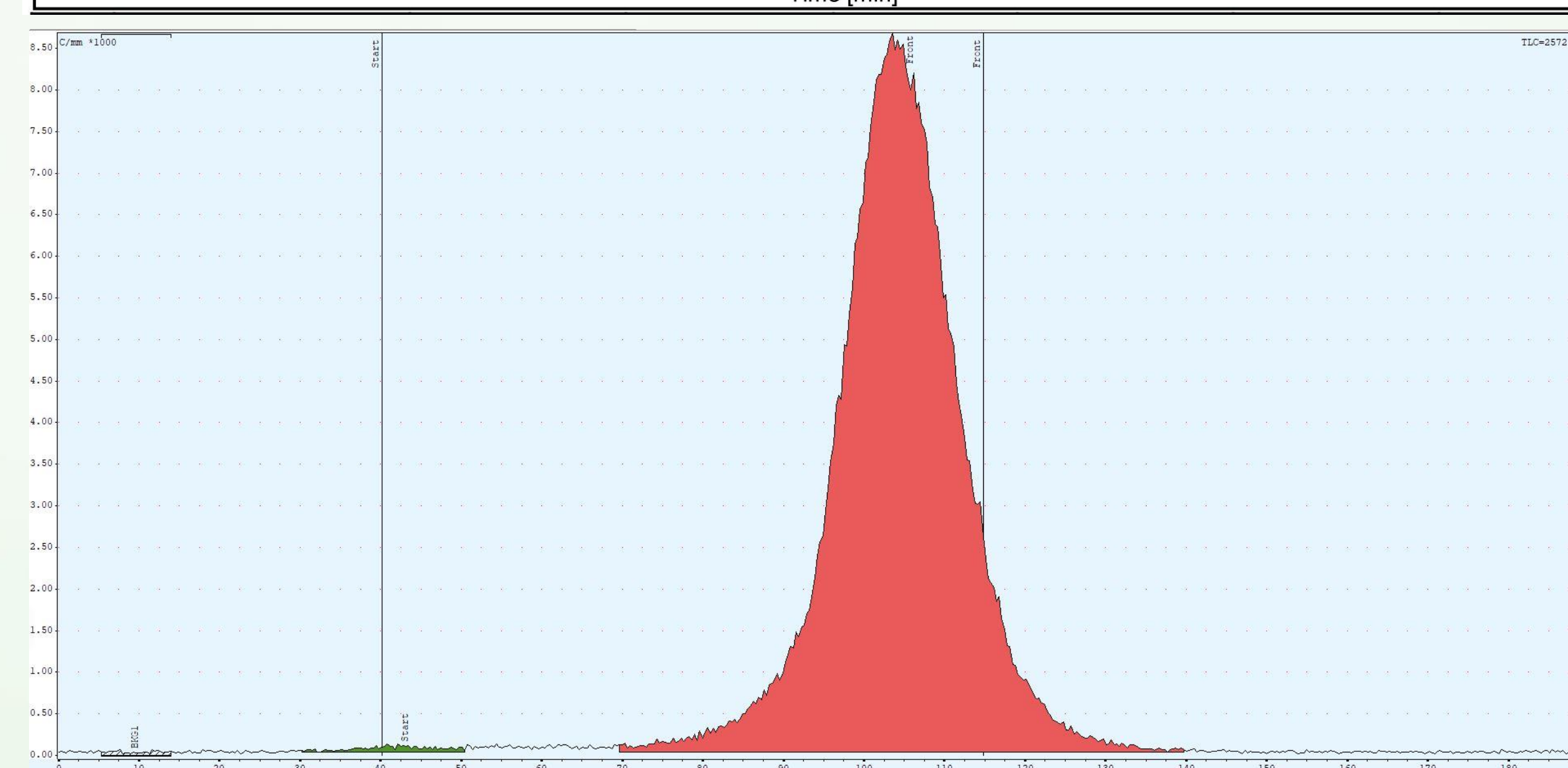
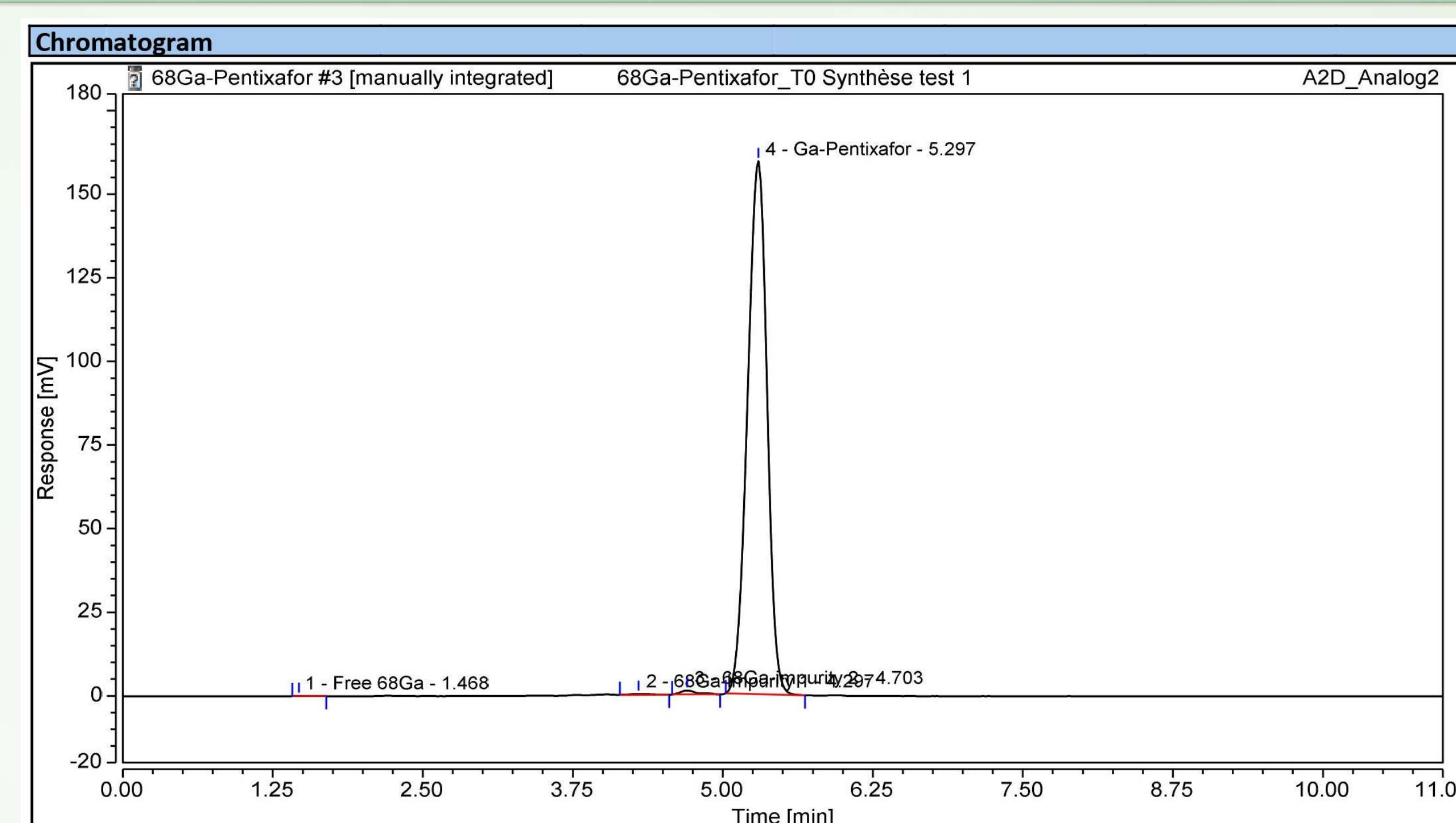
### $^{68}\text{Ga}$ -Pentixafor synthesis:

- Activity yield:  $94.8 \pm 2.6$  %
- Radioprotection benefits due to automatized process.



### QC parameters:

- Radiochemical purity :  $99.4 \pm 0.4$  % (HPLC) and  $99.5 \pm 0.2$  % (TLC).
- Radiochemical purity at 3h :  $99.5 \pm 0.4$  % (HPLC) and  $99.5 \pm 0.4$  % (TLC).
- Residual ethanol:  $8.5 \pm 0.2$  %
- Sterile conditions in the entire process (microbiological analyses).
- Endotoxin < 2.0 EU/mL.
- Filter integrity test successful.



Radiochromatograms of  $^{68}\text{Ga}$ -Pentixafor on HPLC and TLC

## Conclusion :

$^{68}\text{Ga}$ -Pentixafor was conveniently prepared in sterile conditions, with a fully automated and highly reproducible process. The final product was conform with EP specifications. This production insures availability of the tracer and allows to perform clinical studies in our hospital. Extension with  $^{177}\text{Lu}$ -Pentixather production will allow to provide the complete CXCR4-targeted theranostic approach.

### Quality dossier for Swissmedic.

#### Description of the synthesis process :

- 5 validation batches.
- Synthesizer : Mini AiO® (TRASIS, Belgium).
- Aseptic conditions (class A hotcell).

#### Description of quality control (QC) process :

- All required QC in European Pharmacopeia (EP) 8<sup>th</sup> edition.
- Filter integrity test (Mini AiO®).
- Microbiological analysis : sterility + endotoxin (NEXGEN PTS®).
- Stability assessed at 3h after end of synthesis (HPLC and TLC).