

^{177}Lu -ITG-PSMA-1 : Development of a fully automatized in-hospital production

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Introduction

^{177}Lu -ITG-PSMA-1 is a beta particle-emitting radioactive therapeutic agent indicated for the treatment of progressive, metastatic, castration-resistant prostate cancer (CPRCa). The substance is characterized by high selectivity and specificity to prostate-specific membrane antigen (PSMA), which is overexpressed in CRPCa patients.

This overexpression is the basis for targeted radiotherapy with radiometallic PSMA inhibitors.

Objectives

The aim of our work was to develop and automate the synthesis of ^{177}Lu -PSMA-1 in order to produce this new radiotracer in our hospital.

Conclusion

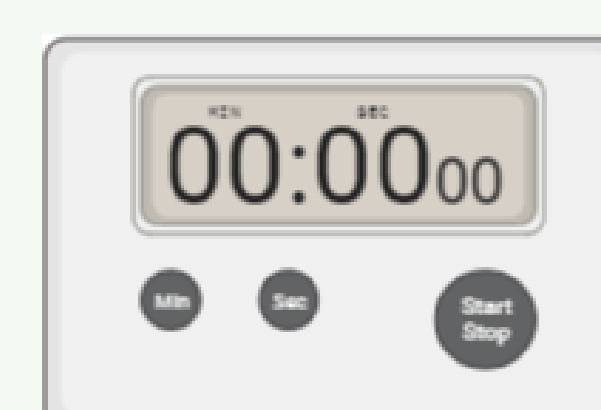
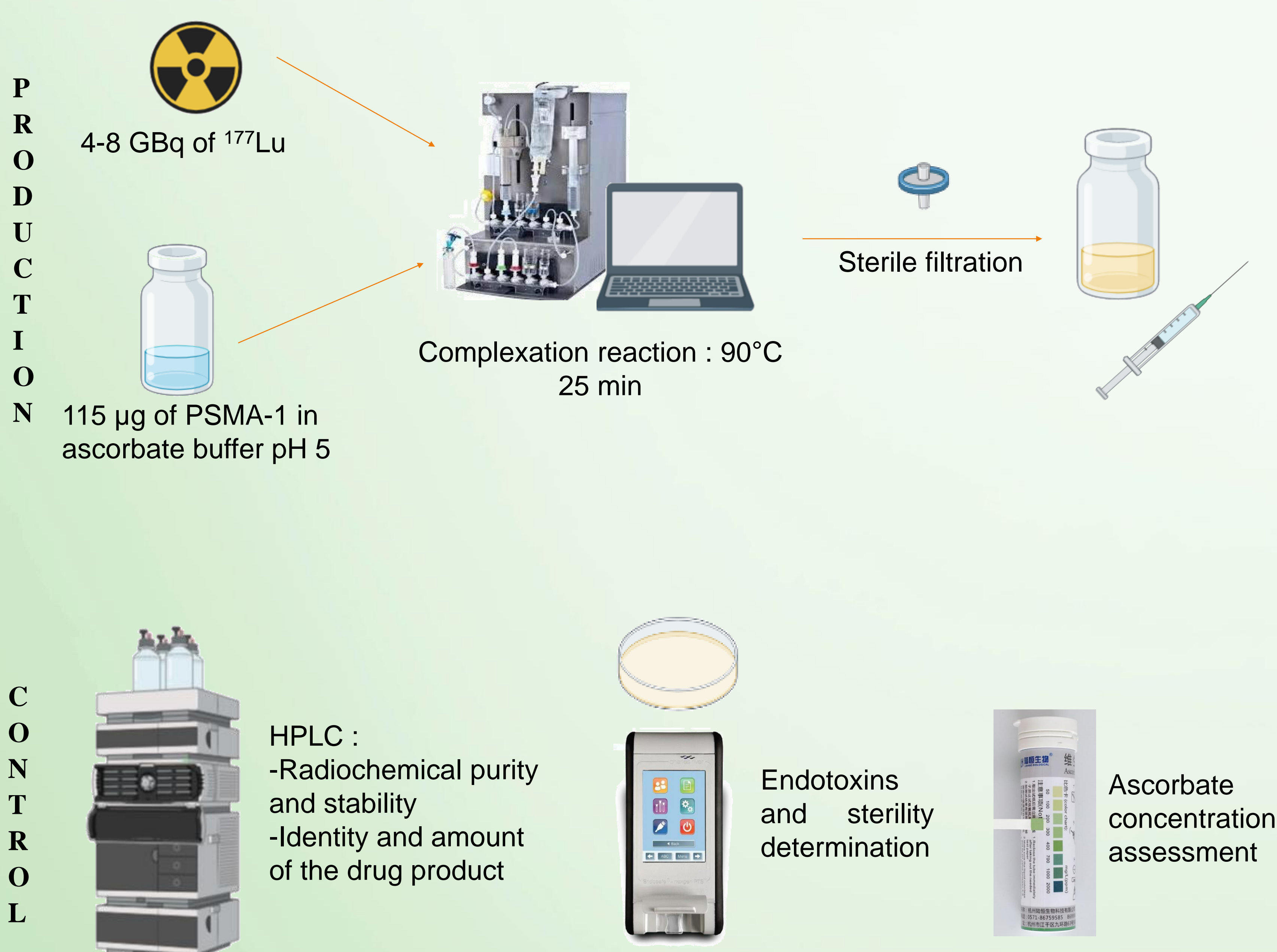
The automatized production of ^{177}Lu -ITG-PSMA-1 was successfully implemented in our hospital. The reproductibility, the cost and the availability of this in house production allows to increase the access of the patient with CRPa to this innovative therapeutic radiopharmaceutical in our hospital.

Results

Synthesis time	40 ± 2 min
Labeling time	30 ± 0.5 min
Integrity test	1.5 ± 0.5 min
Typical production yield	99%
Residual activity on the cassette	≤ 1% of the starting activity

Table 1 : Performance of the ^{177}Lu -PSMA-1 labelling process

Material and methods



Shelf-life of 6 hours validated

Parameter	Results of the validation batches (n=3)	Specification
Application volume	19 mL	18-20 mL
Final activity	7.75 ± 0.31 GBq	7.4 GBq ± 10%
Radiochemical purity	96.9 ± 0.25 %	≥ 95 %
$^{177}\text{LuCl}_3$ impurity	0.3 ± 0.1	≤ 3 %
Chemical purity	conform	< 6.0 µg/mL for 20 mL
Ascorbate concentration	conform	≥ 7 mg/mL
Endotoxin	conform	< 8 EU/mL
Sterility	conform	sterile

Table 2 : Validation batches data



All the results met the specifications