Development of an automatized production of ^{68}Ga-FAPI-46 in an University Hospital

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Introduction

^{68}Ga-FAPI-46 peptides are positron emitters molecules and also Fibroblast Activation Protein (FAP) inhibitors. This promising radiopharmaceutical is being developed with the aim of improving the early detection and the management of FAP overexpressing tumors.

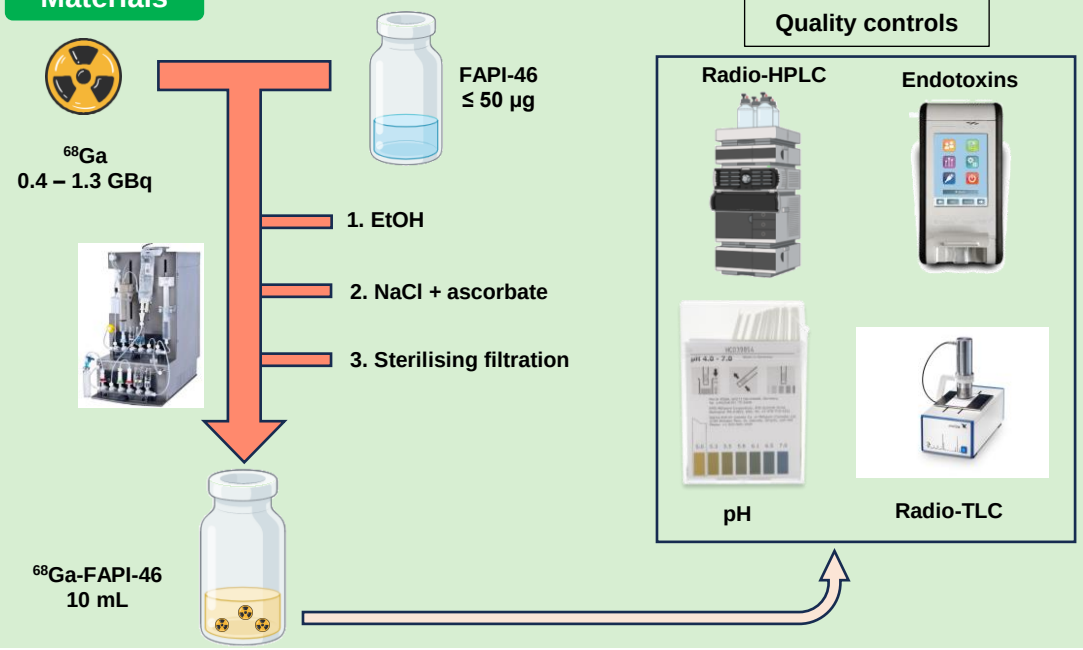
Objectives

To develop and validate an automatized labeling protocol of ^{68}Ga-FAPI-46 in order to set up clinical trials in our hospital.

Conclusion

^{68}Ga-FAPI-46 is fully produced aseptically with the MiniAiO® synthetizer. All quality controls are compliant with European Pharmacopea criteria. These data allow us to consider conducting clinical trials and a theranostic approach with labelling FAPI-46 with ^{177}Lu.

Materials



Results

Parameters	Specifications	Batch 1	Batch 2	Batch 3
Appearance	Transparent solution	Conform	Conform	Conform
pH	4-8	5.5	5.5	5.5
Identity	RRT between ^{nat}Ga-FAPI-46 and ^{68}Ga-FAPI-46 0.95-1.05	0.99	0.99	0.99
Radiochemical purity	Impurities ≤ 5.0%	0.6 %	0.3 %	0.5 %
	^{68}Ga ≤ 5.0%	0.9 %	0.7 %	0.7 %
Ethanol content	≤ 10.0%	7.2 %	7.2 %	7.2 %
Amount of peptide	≤ 80 µg	26 µg	24 µg	28 µg
Filter integrity	2.5 bars	> 2.4 bars	> 2.4 bars	> 2.4 bars
Sterility	Complies Ph. Eur.	Conform	Conform	Conform
Endotoxins	≤ 175 UI/vial	< 2.0 UI/mL	< 2.0 UI/mL	< 2.0 UI/mL
Stability (i.e PRC 3h after synthesis)	PRC > 95% (radio-HPLC)	99.1 %	99.3 %	98.8 %
	PRC > 95% (radio-TLC)	98.8 %	99.2 %	99.2 %

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