Developed and validated script for ^{18}F – PSMA – 1007 Synthesis in IBA – Synthera version-01.

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Introduction

Prostate cancer is the most frequent cancer among males around the world. According to the American Cancer Society's website, one out of every nine males is likely to be diagnosed with prostate cancer [1]. It is the world's second greatest cause of death among males. PSA, or prostate-specific antigen, is a popular biomarker for prostate cancer. For early disease detection, standard imaging technologies such as CT and MRI have not proved sufficient information. PET imaging in conjunction with CT/MRI is a useful tool for detecting prostate cancer [2]. PSMA (prostate-specific membrane antigen) tagged with radioisotopes is a promising agent for both early detection and therapy of prostate cancer. In prostate cancer cells, PSMA is overexpressed. As a service provider, we decided to create and supply the ^{18}F-PSMA-1007 in response to the clinical need for PSMA in nuclear medicine departments. We've been commercially generating ^{18}F-FDG and ^{18}F-NaF since 2009, and we thought ^{18}F-PSMA was a tracer with clinical potential as well as economic potential and added value to the company. Despite the fact that we had already purchased a synthesiser (Trasis AllInOne) capable of producing ^{18}F-PSMA-1007, installation and commissioning were nowhere to be found. As a result, we used Synthera v1 to make ^{18}F-PSMA-1007 (Synthera v1; already retired by IBA, the manufacturer). Regent kits to make ^{18}F-PSMA-1007 with more recent versions of Synthera (Synthera v2 and Synthera Plus) were available, and the product may be used in our experiments, but there was no approved synthesis script / sequence for Synthera v1. As a result, the first task was to write the /sequence script.

Objectives

Our aim was to develop and validate a script for Synthera v1 to produce ^{18}F-PSMA-1007 with high quality and reproducible yield.

Materials and Methods

Used IBA-Synthera Version-01 with MPB software. Integrated Fluid Processor (IFP), Reagents and PSMA-1007 precursor obtained from M/s ABX, Germany. Used self-developed ^{18}F-PSMA -1007 synthesis script and synthesize the same. [3]. Finally fine tune few parameters like reaction time, reaction temperature and cleaning step [4].

Results and Discussion

User interface and script was developed.^{18}F-PSMA -1007 was tested for quality of the product. Radiochemical purity was always > 90%. pH, residual solvents and endotoxins were within limits. The radiochemical yield varies between 35 – 58 %, with the average yield around 46 %. The radiochemical yield becomes inconsistent at higher ^{18}F activities. Most importantly, the radiochemical impurities start becoming prominent beyond 5 - 6Ci of ^{18}F.

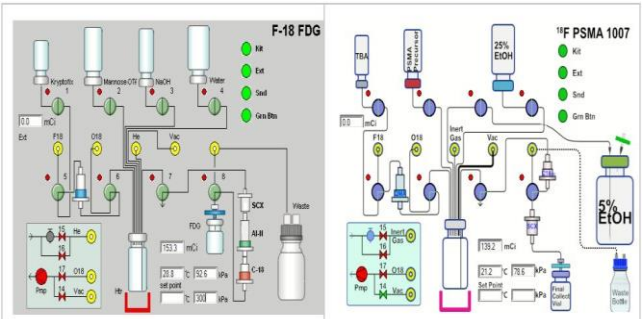

Fig: *Interface for 18F FDG Production from IBA*

Fig: *Interface for 18F PSMA 1007 designed by us*

Figure 1: User Interface – IBA Synthera

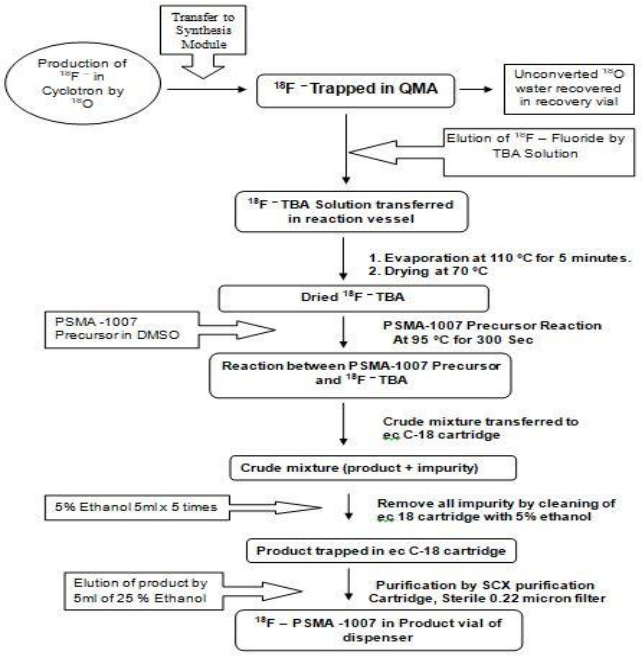

Figure 2: Flow chart for ^{18}F-PSMA -1007 Production

Production Data for 18F- PSMA-1007			
Run No.	Activity from Cyclotron (mCi)	Final product activity in dispenser (mCi)	% yield Decay non corrected (DNC)
1	3850	1752	45.5
2	3552	1579	44.45
3	5460	2462	45.09
4	4700	2670	56.08
5	8829	4054	45.91

Table 1: ^{18}F-PSMA-1007 Production Data

QC Data for 18F-PSMA-1007						
Run No.	pH	Half life in (Minutes)	Gamma Ray Energy (Kev)	% Radio chemical purity by HPLC	DMSO mg/ml (by GC)	Endotoxin (EU/ml)
1	6.5	109	504	95.95	0.041	<2.5
2	6.5	109	504	91.73	0.12	<2.5
3	6.5	110.32	504	94.32	0.112	<2.5
4	6.5	109	508	96.61	0.018	<2.5
5	6.5	110	508	89.69	0.006	<2.5

Table - 2: ^{18}F-PSMA-1007 Quality Control Data

Conclusion

We found that the ^{18}F-PSMA -1007 produced with our developed script meets all of the quality requirements set forth in the current standard. Product yield and quality have also been shown to be repeatable. Since we ship to long distance centres, our requirement from a single production could be quite high. To take care of such quantities of ^{18}F PSMA, we intend to experiment with ways to improve radiochemical purity even at higher activity.

References

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