Contribution ID: **189** Type: **not specified**

[18F]-FPSMA1007 SYNTHESIS HPLC FREE ON FASTLAB PLATFORM QC EVOLUTION

Tuesday, 29 October 2019 23:44 (15 minutes)

Background:
Over the past years, many different PET agents have been developed to investigating on Prostate Cancer (PC) to make the non invasive approach a reality, in order to replace the biopsy and the related complications. The PC is the more common cancer that affect the male population. Due to the high incidence of this pathology are mandatory to investigate on a fluorine-18 tracer that give the possibility to overcame the Gallium-68 tracers limitations.
During the last year we have optimize a [18F]FPSMA1007 synthesis HPLC free on Ge FASTLab® module and related HPLC control. The aim of this study is to show the results of the routine productions in terms of yield and quality control by evaluation of two elution solutions (TBAHCO3/ACN or K222/ACN/K2CO3) and two HPLC methods, the reference one, based on Eclipseplus C18 and a new one based on Ascentis express Peptide Es C-18 column.
Methodology:
The synthesis method is based on one step synthesis using a new precursor commercialized by ABX and is tuned on Ge FASTLab® synthesizer. All the reagents are included on a single use cassette. The [18F]Fluorine was trapped on QMA and eluted with a mixture of TBAHCO3/ACN or K222/ACN/K2CO3 and after drying at 125℃ on synthesis reactor, the ABX precursor dissolved in DMSO was added to proceed with the nucleophilic [18F]-Fluorination. The reaction mixture was heated up at 95℃ for 10 min after the reaction step the mixture was cooled at 35℃ to starting the purification step followed by formulation. The total process takes place on 37 minutes.
HPLC analysis was performed on an Agilent 1260 Infinity HPLC equipped with an Agilent 1260 UV detector and a Raytest gamma-ray detector, controlled with OpenLAB. The analysis was performed on a 4,6x100 Eclipse Plus C18 3,5µm (Agilent) in isocratic conditions using CH3CN and 0.1 % TFA (70/30, run time 15 min) flow 0.8 ml/min and on 4,6x150 Ascentis express Peptide Es C-18 2,7um flow 1.3 ml/min in gradient methods using CH3CN and a solution of dihydrogen phosphate and phosphoric acid.
Results:
Two different elution solution was used to compare the final process yields, at the same time, high activity runs were performed, in different inlet activity range, to evaluating the yield and product stability in final formulation. For stability study a range of 1-2.5 GBq/ml radioactive concentration was evaluated at room and at 40℃ for up to 12h. According to final product formula specification the synthesis yield was stable on range 35-55 % at the inlet activity range (55-185 GBq) with a very high Am (800-3500 GBq/µmol) at EOS.
The radiochemical purity for all the runs were always higher than 95%. The chemical HPLC profile shows differences in separation for the FPSMA1007, OHPSMA1007 HPSMA1007 and reaction precursor that make difference in chemical purity evaluation.
All the synthesis performed by using the K222 elution solution shows slightly lower yield compared to TBA, at the same time only the HPLC methods based on Ascentics column allow to have a right chemical purity evaluation due to the more efficient peak resolution.

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