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"Gheorghe Asachi" Technical University of Iasi, Romania

AN IMPROVED METHODOLOGY FOR DETERMINATION OF RADIOCHEMICAL AND CHEMICAL IMPURITIES IN THE SYNTHESIS PROCESS OF ^{18}F-FDG (2-[^{18}F] FLUORO-2-DEOXY-D-GLUCOSE)

Mirela Mihon[1,2], Catalin Tuta[2], Radu Leonte[2,3], Alina Catrinel Ion[1], Vasile Lavric[1], Dana Niculae[2*]

[1]University Politehnica of Bucharest, Faculty of Applied Chemistry and Materials Science, 1-7 Polizu Str., 011061 Bucharest, Romania
[2]National Institute for Physics and Nuclear Engineering "Horia Hulubei", 30 Reactorului Str., 077125 Magurele Ilfov, Romania
[3]University Politehnica of Bucharest, Faculty of Applied Sciences, 313 Splaiul Independenței, 060042 Bucharest, Romania

Abstract

^{18}F-FDG is a glucose analog in which the hydroxyl group on the second carbon is substituted with ^{18}F, being used as an indicator of glucose uptake and cell viability.
The aim of this work was to synthesize the ^{18}F-FDG and to validate the methodology for the assessment of its both radiochemical and chemical purities, according to the European Pharmacopoeia. The proposed methodology encompasses three chromatographic methods: radio-HPLC, radio-TLC and HS/GC.
Radiochemical impurities may originate from radionuclide production, incomplete purification and radiolysis after synthesis. Chromatographic methods should effectively separate these species, as radioactive impurities can affect the clinical outcome of positron emission tomography imaging studies because of nonspecific uptake. Chemical impurities, on the other hand, can affect nucleophilic substitution mechanism. Keeping these contaminants at as low concentrations as possible is the key of a successful synthesis. Therefore, the determination of both type of impurities in short time is an essential step in characterizing of each batch, due to the rapid decay of ^{18}F (109.8 min half-life).
By optimizing the operating conditions, both chemical and radiochemical impurities analysis can be done within 12 min. The optimized methodology shows good performance: linearity, specificity, precision, limit of quantification, limit of detection and reproducibility, thus it could be successfully applied in the quality control tests of radiopharmaceuticals according to the European Pharmacopoeia.

Key words: 18F-FDG, chemical impurities, gas chromatography, quality control, radio-HPLC, radio-TLC

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[*] Author to whom all correspondence should be addressed: e-mail: dana.niculae@nipne.ro; Phone: +40 21 404 5033; Fax +40 21 457 4945