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Extended Abstract

Improved Method for Determination of Chemical and Radiochemical Purity †

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Radiopharmaceuticals are radioactive compounds that have in their structure a radioisotope attached to drugs, which accumulate in certain organs or tissues. The radioisotope undergoes decay processes that result in specific amounts of radiation, which are used in nuclear medicine to diagnose and treat different types of diseases. The radiopharmaceutical product 2-[^{18}F]fluoro-2-deoxy-D-glucose ([^{18}F]FDG) is a fluorinated glucose analog, which is used for positron emission tomography (PET) for diagnostic purposes, which are based on the evaluation of cellular glucose metabolism and cell viability [1]. [^{18}F]FDG is obtained by a nucleophilic substitution (SN II type) [2]. The aim of this study was to identify the most suitable method for the determination of radiochemical and chemical purity of [^{18}F]FDG. A fast analytical approach for the determination of chemical and radio-analytical impurities in radiopharmaceutical [^{18}F]FDG was developed using radio-high performance liquid chromatography (radio-HPLC).

Following on the radiopharmaceutical synthesis of [^{18}F]FDG, the chemical impurities resulted are: 2-fluoro-2-deoxy-D-glucose (FDG), 2-chloro-2-deoxy-D-glucose (ClDG), and 2-fluoro-2-deoxy-D-mannose (FDM). The equipment used to accomplish the purpose has been proposed as a high-performance liquid chromatograph—Agilent 1260 Bio-inert, which is equipped with both the RayTest Gaby Star gamma radiation detector and the DECADE II electrochemical detector. The separation was obtained using a strong anion exchange column (CarboPac PA100, 4 × 250 mm).

The HPLC method was developed for chromatographic separation of standards 2-fluoro-2-deoxy-D-glucose, 2-chloro-2-deoxy-D-glucose, and 2-fluoro-2-deoxy-D-mannose, considering the shorter retention time and better operation. Separation on CarboPac 100 was performed at flow rates in the range of 0.5–1.1 mL/min to the CarboPac PA100 column; the best resolution was obtained using 0.5 mL/min from a rate at 40 °C. The chromatographic method for determining the chemical and radiochemical purity was validated according to ICH (The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) standards.

Excellent repeatability and internal precision were obtained. The linearity of the method was proved using six concentrated levels. The method was found to be precise, accurate, and specific for FDG determination.

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