World Academy of Science, Engineering and Technology
International Journal of Pharmacological and Pharmaceutical Sciences
Vol:12, No:03, 2018

Assessment of Aminopolyether on 18F-FDG Samples

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Abstract : The quality control procedures of a radiopharmaceutical include the assessment of its chemical purity. The method suggested by international pharmacopeias consists of a thin layer chromatographic run. In this paper, the method proposed by the United States Pharmacopeia (USP) is compared to a direct method to determine the final concentration of aminopolyether in Fludeoxyglucose (¹⁸F-FDG) preparations. The approach (no chromatographic run) was achieved by placing the thin-layer chromatography (TLC) plate directly on an iodine vapor chamber. Both methods were validated and they showed adequate results to determine the concentration of aminopolyether in ¹⁸F-FDG preparations. However, the direct method is more sensitive, faster and simpler when compared to the reference method (with chromatographic run), and it may be chosen for use in routine quality control of ¹⁸F-FDG.

Keywords : chemical purity, Kryptofix 222, thin layer chromatography, validation
Conference Title : ICRR 2018 : International Conference on Radiopharmacy and Radiopharmaceuticals
Conference Location : Madrid, Spain
Conference Dates : March 26-27, 2018