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DETERMINATION OF RADIOCHEMICAL YIELD IN 18F-FDG PREPARATION BY THIN-LAYER CHROMATOGRAPHY PLATES.

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Aim: Thin-layer chromatography plates (TLC) combined with radioactivity detection is one of the most important tools in the radiochemical purity control of radiopharmaceutical compounds. Several different methods are used for the determination of the spatial distribution of radioactivity on TLC plates. The aim of this study was to compare two methods for radioactivity measurement in the determination of radiochemical purity in 18F-FDG preparation using gamma counter with NaI detector and linear radiochromatography scanner. **Materials and methods:** 6 different batches of the 18F-FDG were analyzed. The analysis was carried out using thin-layer silica gel plate, 1.5 x 12.5 cm (Merck, Germany) and a mixture of acetonitrile and I of 18F-FDG injection in threemwater (95:5) as mobile phase. About 10 strips were used for each batch to obtain the data. In this system, the Rf value for 18F-FDG and 18F- were about 0.4 and 0.0, respectively. The radioactivity distribution was firstly determined by radiochromatography scanner (BioScan AR-2000) with high-resolution collimator and P10 gas. Each strip was measured for 1 minute. After radiochromatography scanner, the TLC strips were cut into 10 pieces and each piece was separately measured in a gamma-detector (Canberra) during 0.20 minutes in the energy range of 400-600 keV. **Results and discussion:** USP 28 and FDA specify that not less than 90% of the total radioactivity is in the spot corresponding to 18F-FDG. The calculation in linear scanner was made by integrating the areas related to the product and impurities. The areas of integration for 18F- and 18F-FDG were between Rf 0.02-0.16 (6.5–28.5 mm) and 0.30-0.60 (52.0–99.0 mm) respectively, representing the 1st to 3rd segment for 18F and 4th to 10th segment for 18F-FDG. All the results were in the allowable limit described in USP and FDA, above 99.90% and the standard deviation was below 0.5%. **Conclusion:** The radiochromatography scanner is suitable for compounds with good resolution for determination of radiochemical purity in the final preparation of 18F-FDG before releasing the drug product. The two systems to quantify the radioactivity on TLC exhibited good reproducibility and sensitivity.