Qualification of a thin layer chromatography system using a radioactivity detector

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Introduction

Fluorodesoxyglucose (FDG) is a molecule marked by a radioactive isotope (fluorine 18) intended for the visualization of an organ or pathology in medical imaging. One of the tests to determine the radiochemical purity of FDG is analysis by Thin Layer Chromatography (TLC), using a radioactivity detector. Therefore, qualifying the measurement system is essential for the good analytical process and result conformity. Qualification consists in checking the two parts of the system: the radioactivity detector and the moving support of the TLC plate.

Experimental Conditions

Several tests have been realized using the Miniscan system from Bioscan. To ensure the radioactivity detector performance, the first test consisted in measuring the background of TLC plate analysis system without radioactivity. The second test consisted in checking the linearity of the counts analysing one solution of FDG and by following the evolution of the FDG peak area according to time thus radioactive decay. The third test consisted in measuring the detector reproducibility by analysing a series of samples including the intralaboratory variability.

Another essential verification is the moving speed of the TLC plate support which allows us to ensure the reliability of the retention time obtained. Therefore, we verified the good position of peaks for a given speed.

Results and discussion

The value obtained for measurement of the background is 9V, so lower than the specification which is 70V. This means that the background is negligible compared to the FDG peak. The correlation coefficient of the FDG peak area evolution with result to the activity is 0.9994. We thus obtained a linear response for the radioactivity detector.

For the reproducibility the values had a 3.9 % standard deviation which less than 5 %, the limit of conformity. To check the moving support speed, we found a good correlation between the position of the experimental peaks compared to the theoretical position, with a maximum distance of up to 1.41 mm. This test was in compliance with the accepted limit (2mm).

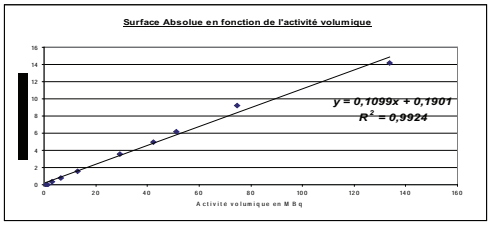

Figure 1 : Linearity of radioactivity detector

Conclusion

To conclude, all the results proved the suitability of the system used in order to authorize a drug. Tests permit to ensure the conformity of results obtained daily, which is in agreement with Good Laboratory Practices (management of material). The fact that samples analysed with such a system are radioactive requires a particular approach because all the tests must be realized in agreement with the reglementation of radioprotection.