Transfer of an analytical method to the workshop

Benoît LARGERON

Introduction

In order to improve the production of drugs, and optimize workshops production, Sanofi-Aventis decided to develop an analytical technique that could be carried out by the workshop workers. They chose the method Thin Layer Chromatography without migration because it does not require special test conditions and gives fast and clear results. This new technique was validated by comparing analytical results with those obtained with identical analyses performed by Thin Layer Chromatography.

Experimental methods

This method relies on a visual comparison of three chromatographic deposits after revelation. Its accuracy stands between 20% and 30%for quantitative experiences.
Analysis by TLC without migration has four steps. The first one involves the preparation of the analysed samples (dilution and concentration) and the preparation of witnesses chosen with the help of a chemical table.
Then, three deposits of identical volumes, the background, the witness and the sample are laid down on the Silicium.
Deposits are then blown dry with nitrogen during fifteen minutes in an oven.
Finally the technician reveals the silicium plate with several chemical reagents (UV 244nm, UV 366nm)

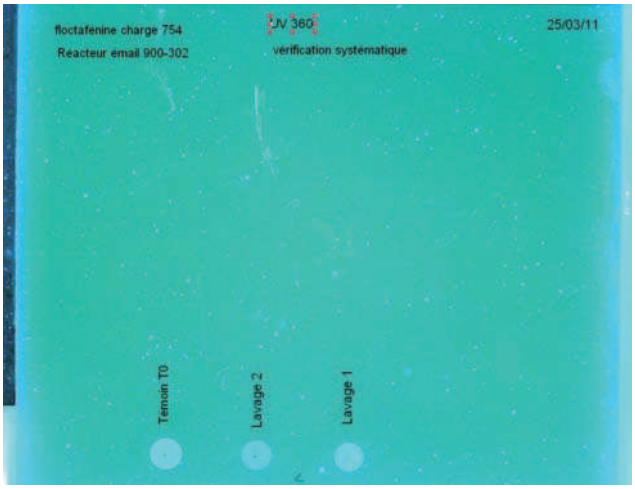

Figure 1 : *Photograph of analysis with the new method*

Results

The results of the validation of this method showed that the TLC technique achieved similar results to those obtained by Thin Layer Chromatography on both a quantitative and visual (colour of samples) point of view for the majority of the study compounds. However, the study revealed some isolated products, a shortfall of the method since results were different between two methods.

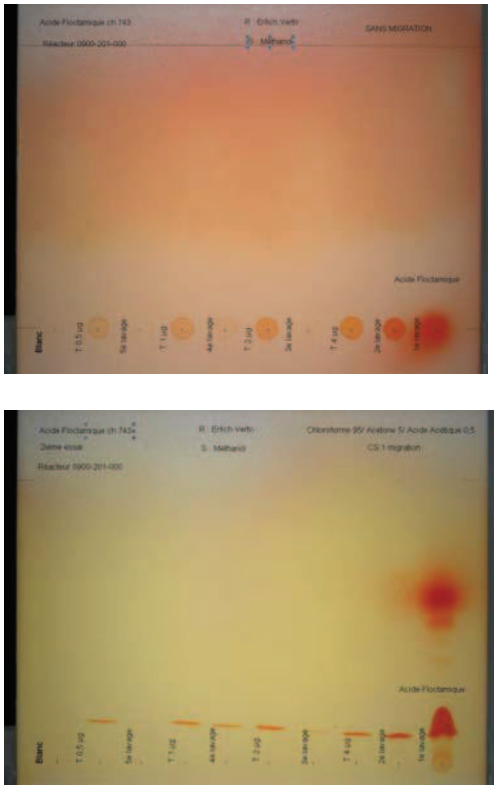

Figure 2 : *Photograph of analysis for comparison of methods*

Conclusion

The project to transfer and implement this new analytical technique is only at a starting point, the laboratory is still conducting tests to establish the list of analyzable products in order to improve and adjust the method to achieve a perfect reproducibility between the two studied methods.

Université Claude Bernard Lyon 1
43 Bd du 11 novembre
69622 Villeurbanne