COMPARISON OF THREE DIFFERENT APPROACHES FOR UNCERTAINTY ESTIMATION CONSIDERING LC AND CE METHODS

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Multiple comparisons were done for the uncertainty estimates obtained from three different approaches (validation, robustness and inter-laboratory) while using two analytical methods (liquid chromatography (LC) and nonaqueous capillary electrophoresis (NACE)) developed for the determination of *R*-timolol impurity in *S*-timolol maleate sample. In the validation approach, a novel validation strategy based on the accuracy profile (total error measurement) was used, allowing to calculate the uncertainty estimates. The robustness approach uses the results obtained from different experimental conditions (minimum eight) elaborated by mean of a Plackett-Burman design that are assimilated to laboratories. By adopting the ISO 5725-2 guide, the uncertainty was determined in the robustness as well in the inter-laboratory approach that includes a minimum of eight laboratories. Since the variance was modelled as function of the concentration and the study, the comparison of the different studies was made. It was found that the uncertainty obtained in robustness predicted well that of the inter-laboratory, while the uncertainty obtained in validation is lower than those obtained with the two other approaches but is still acceptable as long as the analytical method will be used in a single laboratory. The uncertainty obtained in LC was found to be lower than that obtained in NACE.