Evaluation of In Silico and In Lab Sample Enrichment Techniques for the Assessment of Challengeable Quaternary Combination in Critical Ratio

Dina Abbas Ahmed,Hayam Lotfy ,Dina Abbas Ahmed

Abstract

A comparative study of successive spectrophotometric resolution technique for the simultaneous determination of a challengeable quaternary mixture of Chlorpheniramine maleate (CPM), Pseudoephedrine hydrochloride (PSE), Ibuprofen (IBU) and Caffeine (CAF) is presented, without preliminary physical separation steps. Several successive steps were applied on built-in spectrophotometer software utilizing zero and/or derivative and/or ratio spectra of the studied components. These methods, namely, Dual amplitude difference (DAD) as a novel method, Constant multiplication coupled with spectrum subtraction method (CM-SS), Factorized first derivative coupled with derivative transformation method (FDĭ -DT) and Derivative ratio method (DDĭ).The calibration graphs are linear over the concentration range of 10.0ï80.0 εg/mL,150.0ï900.0 εg/mL, 200.0ï 1400.0 εg/mL and 3.0ï30.0 εg/mL for CPM, PSE, IBU and CAF, respectively. The specificity of suggested methods was studied via laboratory prepared (diverse ratios) mixtures and were successfully applied for AntifluÈ capsules' analysis. Moreover, sample enrichment via In Silico (via software of spectrophotometer) and In Lab (via spiking with pure sample) techniques was elected for a pharmaceutical dosage form analysis comprising CPM and PSE as minor components. Accuracy, precision and specificity were between the valid limits. Validation steps were done in accordance with the ICH guidelines. Moreover, statistical comparison was carried out between the obtained and reported results for pure powder form and no significant difference appeared.

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