Chemometrics Tools in Detection and Quantitation of the Main Impurities Present in Aspirin/Dipyridamole Extended-Release Capsules

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Abstract

Aspirin (ASP) and dipyridamole (DIP) in combination is widely used in the prevention of secondary events after stroke and transient ischemic attack. Salicylic acid is a well-known impurity of ASP, and the DIP extended-release formulation may contain ester impurities originating from the reaction with tartaric acid. UV spectral data analysis of the active ingredients in the presence of their main impurities is presented using multivariate approaches. Four chemometric-assisted spectrophotometric methods, namely, partial least-squares, concentration residuals augmented classical least-squares (CRACLS), multivariate curve resolution (MCR) alternating least-squares (ALS), and artificial neural networks, were developed and validated. The quantitative analyses of all the proposed calibrations were compared by percentage recoveries, root mean square error of prediction, and standard error of prediction. In addition, r(2) values between the pure and estimated spectral profiles were used to evaluate the qualitative analysis of CRACLS and MCR-ALS. The lowest error was obtained by the CRACLS model, whereas the best correlation was achieved using MCR-ALS. The four multivariate calibration methods could successfully be applied for the extended-release formulation analysis. The application results were also validated by analysis of the stored dosage-form solution, which showed a susceptibility of DIP esterification in the extended-release formulation. Statistical comparison between the proposed and official methods showed no significant difference.

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