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Development, Optimization, and Validation of a Synchronous Fluorescence Spectroscopic Method with Multivariate Calibration for the Determination of Amlodipine and Olmesartan Implementing: Experimental Design

Authors : Noha Ibrahim, Eman S. Elzanfaly, Said A. Hassan, Ahmed E. El Gendy

Abstract : Objectives: The purpose of the study is to develop a sensitive synchronous spectrofluorimetric method with multivariate calibration after studying and optimizing the different variables affecting the native fluorescence intensity of amlodipine and olmesartan implementing an experimental design approach. Method: In the first step, the fractional factorial design used to screen independent factors affecting the intensity of both drugs. The objective of the second step was to optimize the method performance using a Central Composite Face-centred (CCF) design. The optimal experimental conditions obtained from this study were; a temperature of (15°C ± 0.5), the solvent of 0.05N HCl and methanol with a ratio of (90:10, v/v respectively), Δλ of 42 and the addition of 1.48 % surfactant providing a sensitive measurement of amlodipine and olmesartan. The resolution of the binary mixture with a multivariate calibration method has been accomplished mainly by using partial least squares (PLS) model. Results: The recovery percentage for amlodipine besylate and atorvastatin calcium in tablets dosage form were found to be (102 ± 0.24, 99.56 ± 0.10, for amlodipine and Olmesartan, respectively). Conclusion: Method is valid according to some International Conference on Harmonization (ICH) guidelines, providing to be linear over a range of 200-300, 500-1500 ng mL^{-1} for amlodipine and Olmesartan. The methods were successful to estimate amlodipine besylate and olmesartan in bulk powder and pharmaceutical preparation.

Keywords : amlodipine, central composite face-centred design, experimental design, fractional factorial design, multivariate calibration, olmesartan
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