Novel Pure Component Contribution Algorithm (PCCA) and UHPLC methods for separation and quantification of amlodipine, valsartan, and hydrochloro-thiazide in ternary mixture.

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Abstract

Two accurate and sensitive methods were developed and validated for the simultaneous determination of amlodipine (AML), valsartan (VAL), and hydrochlorothiazide (HCT) in their ternary mixture. The first method is a novel simple algorithm capable of extracting the contribution of each component from a mixture signal in which the components are partially or completely overlapped. It is based on the use of a coded function that eliminates the signal of interfering components using mean centering as a processing tool. Determination was performed at 237.6, 250.0, and 270.6 nm for AML, VAL, and HCT, respectively. Two fit values were developed and calculated for optimization of the method for each drug, one to test that the absorptivity values of the extracted spectra are within the confidence limits of the slope, and the other for correlation between the pure and extracted spectra. The fit values for AML, VAL, and HCT were Ŭ = 0.0449, 0.03981, and 0.07251, respectively, and r = 1 for each drug. The second method is an ultra-HPLC (UHPLCÈ) method in which separation of AML, VAL, and HCT was carried out on a UHPLC C18 column (100 Ĭ 2.1 mm, 2.2 εm) using a mobile phase of acetonitrileïmethanolïphosphate buffer (pH 2.8; 25 + 50 + 25, v/v/v). The flow rate was 0.5 mL/min, and the detection was set at 255.0 nm. The proposed methods were successfully applied to the analysis of AML, VAL, and HCT in pharmaceutical formulations, without interference from the dosage-form additives. The results were statistically compared to a previously reported method, and no significant difference was found regarding accuracy or precision.

Journal of AOAC International 2017, June