

Novel stability-indicating chemometric-assisted spectrophotometric methods for the determination of chlordiazepoxide and clidinium bromide in the presence of clidinium bromide's alkali-induced degradation product

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Abstract

In the presented work several spectrophotometric methods were performed for the quantification of canagliflozin (CGZ) and metformin hydrochloride (MTF) simultaneously in their binary mixture. Two of these methods; response correlation (RC) and advanced balance point-spectrum subtraction (ABP-SS) were developed and introduced for the first time in this work, where the latter method (ABP-SS) was performed on both the zero order and the first derivative spectra of the drugs. Besides, two recently established methods; advanced amplitude modulation (AAM) and advanced absorbance subtraction (AAS) were also accomplished. All the proposed methods were validated in accordance to the ICH guidelines, where all methods were proved to be accurate and precise. Additionally, the linearity range, limit of detection and limit of quantification were determined and the selectivity was examined through the analysis of laboratory prepared mixtures and the combined dosage form of the drugs. The proposed methods were capable of determining the two drugs in the ratio present in the pharmaceutical formulation CGZ:MTF (1:17) without the requirement of any preliminary separation, further dilution or standard spiking. The results obtained by the proposed methods were in compliance with the reported chromatographic method when compared statistically, proving the absence of any significant difference in accuracy and precision between the proposed and reported methods.

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