Novel univariate spectrophotometric determination of the recently released solid dosage form comprising dapagliflozin and saxagliptin via factorized response spectra: Assessment of the average content and dosage form uniformity of tablets

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Abstract

Dapagliflozin (DPF) and saxagliptin (SXG) are currently co-formulated in a tablet dosage form which is prescribed to improve glycemic control. The absorption spectra of DPF and SXG were highly overlapped which completely hindered their simultaneous estimation at their ∂max 224ϳnm and 209ϳnm, respectively. Thus, in this work three smart and simple univariate spectrophotometric methods were originally established and validated for the first time in order to quantitatively estimate DPF and SXG in bulk forms and in combined pharmaceutical formulation without the requirement for any initial separation or treatment. These methods are; factorized zero order method (FZM), factorized derivative method (FDM) and factorized ratio difference method (FRM). These methods were capable of determining DPF and SXG over the range of 2.5ï50.0ϳεg/mL and 2.5ï60.0ϳεg/mL, respectively. All the developed methods are based on a novel and unique approach for the spectral recovery of unresolved spectra named; factorized response spectrum (FRS). The exclusivity of the FRS originates from its ability to completely resolve the cited drugs in the mixture and retrieve their original spectra. Selectivity of all proposed methods was assessed by comparing the obtained results of the mixture analysis with those of the pure powdered drugs. Validation of the newly developed methods was applied as recommended by the ICH demonstrating acceptable accuracy and precision. In general, these methods could be effectively employed for the routine quality control investigation of bulk materials and available market formulations.

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