- Spectrofluorometric and Spectrophotometric Methods for the Determination of Sitagliptin in Binary Mixture with Metformin and Ternary Mixture with Metformin and Sitagliptin Alkaline Degradation Product

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Abstract

Simple, accurate and precise spectrofluorometric and spectrophotometric methods have been developed and validated for the determination of sitagliptin phosphate monohydrate (STG) and metformin HCL (MET). Zero order, first derivative, ratio derivative spectrophotometric methods and fluorometric methods have been developed. The zero order spectrophotometric method was used for the determination of STG in the range of 50-300 μg mL\(^{-1}\). The first derivative spectrophotometric method was used for the determination of MET in the range of ±μg mL\(^{-1}\) and STG in the range of 50-300 μg mL\(^{-1}\) by measuring the peak amplitude at 246.5 nm and 275 nm, respectively. The first derivative of ratio spectra spectrophotometric method used the peak amplitudes at 232 nm and 239 nm for the determination of MET in the range of 2–12 μg mL\(^{-1}\) and STG in the range of 50-300 μg mL\(^{-1}\) by measuring the peak amplitude at 246.5 nm and 275 nm, respectively. The first derivative of ratio spectra spectrophotometric method used the peak amplitudes at 232 nm and 239 nm for the determination of MET in the range of 2–12 μg mL\(^{-1}\). The fluorometric method was used for the determination of STG in the range of 0.25-110 μg mL\(^{-1}\). The proposed methods used to determine each drug in binary mixture with metformin and ternary mixture with metformin and sitagliptin alkaline degradation product that is obtained after alkaline hydrolysis of sitagliptin. The results were statistically compared using one-way analysis of variance (ANOVA). The methods developed were satisfactorily applied to the analysis of the pharmaceutical formulations and proved to be specific and accurate for the quality control of the cited drugs in pharmaceutical dosage forms.

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