Simultaneous determination of sitagliptin and metformin in ternary mixture with sitagliptin acid degradation product

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Abstract

In this work, the acidic degradation product of sitagliptin phosphate monohydrate (STG) was synthesized, separated and its structure was elucidated. Additionally, two reversed-phase liquid chromatographic (RP-LC) methods have been developed for the determination of STG. The first method comprised the determination of STG in binary mixture with sitagliptin acid degradation product (SDP) in laboratory prepared mixtures, in plasma and in dosage form. This method was based on isocratic elution using a mobile phase consisting of potassium dihydrogen phosphate buffer (pH =4.6) - acetonitrile (30:70, v:v) with fluorometric detection. The fluorometric detector was operated at 267 nm for excitation and 575 nm for emission. In the second method, the simultaneous determination of STG and metformin (MET) in the presence of SDP has been developed. In this method, the ternary mixture of STG, MET and SDP was separated using a mobile phase consisting of potassium dihydrogen phosphate buffer (pH = 4.6) - acetonitrile (15:85, v:v) with UV detection at 220 nm. Chromatographic separation in the two methods was achieved on a Symmetry® Waters C18 column (150 mm × 4.6 mm, 5 μm). The optimized methods were validated and proved to be specific, robust and accurate for the quality control of the cited drugs in pharmaceutical preparations.

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