Liquid chromatographic determination of sitagliptin either alone or in ternary

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Abstract

Two reversed-phase liquid chromatographic (RP-LC) methods have been developed for the determination of sitagliptin phosphate monohydrate (STG). The first method comprised the determination of STG alone in bulk and plasma; and in its pharmaceutical preparation. This method was based on isocratic elution of STG using a mobile phase consisting of potassium dihydrogen phosphate buffer pH (7.8)-acetonitrile (70:30, v/v) at a flow rate of 1 mL min(-1) 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 sitagliptin alkaline degradation product (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-methanol (30:50:20, v/v/v) at a flow rate of 1 mL min(-1) with UV detection at 220 nm. Chromatographic separation in the two methods was achieved on a Symmetry® Waters C18 column (150 mm x 4.6 mm, 5 μm). Linearity, accuracy and precision were found to be acceptable over the concentration ranges of 0.25-200 μg mL(-1) for STG with the first method and 5-160 μg mL(-1), 25-800 μg mL(-1) for STG and MET, respectively with the second method. 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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