Development and validation of a reversed phase liquid chromatographic method for the determination of three Gliptins and Metformin in the presence of Metformin impurity (1-cyanoguanidine)

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Abstract

A simple and precise liquid chromatographic method has been developed and validated for the determination of either sitagliptin (STG), vildagliptin (VLG) or saxagliptin HCl (SXG) and metformin HCl (MET) in the presence of metformin degradation product, 1-cyanoguanidine (CGN). Chromatographic separation was achieved on a Symmetry® cyanide column (150 mm × 4.6 mm, 5 μm). Isocratic elution using a mobile phase of potassium dihydrogen phosphate buffer (pH = 4.6) - acetonitrile (30:70, v:v) at a flow rate of 1 mL/min with UV detection at 210 nm was performed. The LC method was used for the simultaneous determination of STG, VLG, SXG and MET in the ranges of 5-200, 5-200, 0.5-80.0 and 20-800 μg/mL, respectively. The results were statistically compared with the reference method for each drug using one-way analysis of variance (ANOVA). The method developed was 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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