SIMULTANEOUS DETERMINATION BY HPLC METHOD AND IN VITRO DISSOLUTION STUDIES FOR ASSOCIATION OF VILDAGLIPTIN AND METFORMIN IN COATED TABLETS

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A HPLC method has been developed and validated to determine vildagliptin (VLG) and metformin hydrochloride (MET), drugs used for treatment of type 2 Diabetes Mellitus, in coated tablets. The determination was performed at two wavelengths (207 nm for VLG and 250 nm for MET) in order to obtain assay and in vitro drug release profile of drugs from coated tablet formulation. The analysis was performed on Zorbax Eclipse Plus C8 (150 mm x 4.6 mm, 5 µm) column with mobile phase composed by heptanosulfonic acid sodium salt solution pH 3.0, adjusted with phosphoric acid, acetonitrile and methanol (81:18:1), flow rate of 1.0 mL min⁻¹ and column oven set at 25 °C. For dissolution study, the sink condition has been established from quantitative solubility of VLG and MET in different dissolution media recommended by USP for immediate release formulation and optimized dissolution condition was satisfactorily obtained using potassium dihydrogen phosphate buffer pH 6.8, paddle rotation speed at 50 rpm and vessel volume of 900 mL. Profile releasing of VLG and MET achieved more than 98% of labeled amount over 15 min. The HPLC method and dissolution test condition were validated according to regulatory guidelines for specificity, linearity, precision, accuracy and robustness. The validated assay was successfully applied in dissolution studies to simultaneous determination for vildagliptin and metformin in coated tablets.