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Simultaneous Determination of Antidiabetic and Antihypertensive Drugs in Pharmaceutical Formulations by RP-LC

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Abstract : The objective of the study was the development and validation of an isocratic RP-LC method for the simultaneous estimation of rosiglitazone, glimepiride and amlodipine in a combined dosage form. The separation was achieved with a C_{18} 5micron {250 mm x 4.6 mm i.d.}column, using a mobile phase comprising of a mixture of methanol, water and ortho phosphoric acid (75: 25: 0.2, v/v), the pH of which was adjusted to 4.5 with the help of liquid ammonia. The flow rate was kept at 1 mL min^{-1}, with UV detection at 230 nm. The retention time for rosiglitazone, amlodipine and glimepiride was found to be 2.62, 3.9 and 7.387 minutes, respectively. The LOD was found to be 16.23, 19.88 and 15.81 ng mL^{-1}; while LOQ was found to be 54.16, 66.28 and 52.69 ng mL^{-1} for rosiglitazone, amlodipine and glimepiride, respectively. The developed method was rapid, isocratic, specific, sensitive, accurate and precise and has been successfully applied to the analysis of pharmaceutical dosage forms.
Keywords : Rosiglitazone Maleate**,** Amlodipine Besylate**,** Glimepiride, High Performance Liquid Chromatography.

Introduction

Diabetes rates are skyrocketing worldwide and have nearly doubled in the past three decades due to increase in obesity and sugary diets. An estimated 422 million adults were living with diabetes in 2014, up from 108 million in 1980[1]. Diabetes kills 1.5 million people every year worldwide: this number is expected to double by 2030[2].The burden of diabetic vasculopathy on the global population is enormous and ever growing. Besides the well-known microvascular complications in type 2 diabetes (T2DM), there is a growing epidemic of macrovascular complications. People with T2DM have a higher risk of death from cardiovascular (CV) diseases than persons without diabetes. This calls for an early detection and intervention in patients with T2DM as well as impaired glucose tolerance (IGT), not only to delay progression of IGT to T2DM but also to treat early macrovascular diseases in both groups [3]. The patients with both hypertension and diabetes have a particularly high risk of developing coronary artery disease. These patients take both antidiabetic and antihypertensive drugs. Literature survey revealed that attempts are going on to develop a single medicine which contains both antidiabetic and antihypertensive drugs, to reduce the number of pills taken by the patients having diabetes mellitus associated with hypertension [4-8]. The development of such a medicine requires the data providing drug-drug interaction, stability and pharmacokinetic parameters. For these studies, a quantitative