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STABILITY INDICATING RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF ANTI-DIABETIC AND ANTI-HYPERTENSIVE DRUGS

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ABSTRACT

A new simple, selective, accurate, rapid, stability indicating High Performance Liquid Chromatographic (HPLC) method was developed and validated for the analysis of such a combination of losartan potassium, glimepiride and metformin. Chromatographic separation was achieved isocratically on C18 column [PRINCETON SPHER – 100, (100 A^0- 5µm, 150 mm x 4.6 i.d.).] utilizing a mobile phase composition of 10 mM disodium hydrogen phosphate and 10 mM sodium dodecyl sulphate buffer and acetonitrile (68:32, v/v), with a pH of 7.5 (adjusted with orthophosphoric acid) at a flow rate of 1.0 mL/min, with UV detection at 230 nm. The calibration graphs were linear with r^2 >0.999 and % RSD> 3 for intra-day and inter-day precision. The retention time of losartan, glimepiride and metformin was 1.39, 4.27, 9.36 min., respectively. The limit of detection and limit of quantitation for losartan, glimepiride and metformin was 0.0382, 0.00473, 0.09331 and 0.1273, 0.0157, 0.31104 respectively. The drugs were subjected to various stress conditions, as per ICH guidelines. The stability indicating studies showed that neither the degradation products nor the excipients interfered in the estimation of drugs. Hence, this method was specific and can be successfully used for the estimation of these drugs in combined dosage forms.

Keywords: RP-HPLC, Stability studies, Sulfonyl urea, Angiotensin receptor blockers. Antihyperglycemic agent, Losartan, Glimepiride and Metformin.

INTRODUCTION

Diabetes mellitus is a global disease and the epidemic of type 2 diabetes in the United States and the rest of the world continue to grow rapidly; an estimated 285 million people had diabetes worldwide and more than 1 billion adults are currently affected from hypertension.[1,2] Patients with diabetes have a much higher rate of hypertension than would be expected in the general population. In a diabetic person, microvascular [renal disease, sexual dysfunction, orthostatic hypotension, eye disease] and macrovascular [cardiac disease, cerebrovascular disease, peripheral vascular disease] complications are contributed by elevated blood pressure and the presence of these binary complications, such as diabetes with hypertension, result in a high risk for the development of cardiovascular disease (CVD), renal impairment and diabetic retinopathy. A wide range of medications is currently used in the treatment of diabetic patients suffering from hypertension, included from the different class of drugs, such as angiotensin receptor blockers (ARBs), sulfonylurea and an oral antihyperglycemic agent.[3-5]

ARBs may be considered as the first line therapy for treatment of hypertension, associated with diabetes, in the absence of contraindications. ARBs have been shown to reduce microalbuminuria in diabetic patients independent of their effect on blood pressure. [6] Losartan Potassium (LP) (Fig.-1a), Monopotassium salt of 4-butyl-4-chloro-1- [[2'-(1H- tetrazol-5-yl)[1,1'-biphenyl]-4-yl]methyl]-1H-imidazol-5-methanol, an antihypertensive drug is a competitive antagonist of the angiotensin II type 1 (AT_1) receptor. It decreases daytime and nighttime blood pressure without affecting the autonomic nervous activity and also decreases urinary albumin excretion in type 2 diabetes with macroalbuminuria.[7] It is also approved for diabetic nephropathy and renoprotective in type 2 diabetes associated with hypertension.[8] Metformin (MT) (Fig.-1b)