



HPLC method development for simultaneous estimation of hydrochlorothiazide, amlodipine besylate and telmisartan in tablet dosage form

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ABSTRACT

A reverse phase high performance liquid chromatographic assay method has been developed and validated for simultaneous estimation of hydrochlorothiazide, amlodipine besylate and telmisartan in tablet dosage form. Stationary phase was 150 mm x 4.6 mm, 5 µm C-18 column, from Novapak, mobile phase was degassed mixture of 50mM ammonium acetate buffer pH 4.5, and acetonitrile in the ratio of 65:35 and flow rate at 1.2 ml/min, at ambient condition with detector setting at 235nm. The retention times of hydrochlorothiazide, amlodipine and telmisartan are 3.0 min, 4.0 min and 5.1 min, respectively. Above method was validated as per ICH guidelines. Specificity was confirmed by comparing the placebo chromatogram with that of standard. Linearity of the method was achieved from 80 per cent to 120 per cent of test concentration. The precision of the method is carried out by six different test preparations and the % relative standard deviation was calculated. The accuracy of the method extracted in triplicate at three concentration levels, i.e. 50 per cent, 100 per cent and 150 per cent of test concentration and recovery calculated. Robustness was performed by changing flow rate, mobile phase ratio. Above validated method can be recommended for simultaneous analysis of these drugs in tablets.

Key words : Hydrochlorothiazide, Amlodipine besylate, Telmisartan, High performance liquid chromatography

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INTRODUCTION

Hydrochlorothiazide (Budavari, 2001) is 6-chloro-3,4-dihydro-2H-1,2,4-benzothiazine-7-sulfonamide 1,1-dioxide. It is white or almost white, odourless crystalline powder, freely soluble in dimethylformamide, very slightly soluble in water and alcohol; insoluble in chloroform, in ether, and in dilute mineral acids. Hydrochlorothiazide dissolves in dilute solutions of alkali hydroxides. Amlodipine besylate (Sweetmau, 2005) is 3-ethyl 5-methyl 2-[(2-amino-ethoxy)methyl]-4-(2-chlorophenyl)-6-

methyl-1,4-dihydropyridine-3,5-dicarboxylate benzenesulfonate. It occurs as white or almost white powder. Amlodipine besylate is slightly soluble in water and in isopropyl alcohol; sparingly soluble in dehydrated alcohol; freely soluble in methyl alcohol. Telmisartan (Budavari, 2001) is potassium 4'-[(1,7'-dimethyl-2'-propyl-1H,3'H-2,5'-bibenzimidazol-3'-yl)-methyl]biphenyl-2-carboxylate. It is white to off-white crystalline powder that is insoluble in water, sparingly soluble in strong acid, methylene dichloride, methanol, ethanol, ethyl acetate and acetone, it is soluble in chloroform, and in strong base.

Keeping cost and time with technical requirement as main aspect, method has been developed. Profound search from data and literature available, it reveal that several methods have been reported including colorimetric determination, LC-MS, ultraviolet spectrophotometry, high performance liquid chromatography for the analysis of hydrochlorothiazide, amlodipine besylate and telmisartan either alone or in

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