ABSTRACT

The fixed dose combination of azilsartan medoxomil, an angiotensin receptor II blocker and chlorthalidone, a thiazide-like diuretic from the class of the sulfamoylbenzamide has been introduced as an effective treatment for hypertension. Development of a specific and accurately precise Reverse-Phase HPLC method for simultaneous estimation of CLR and AZL was main objective of this study. All the validation parameters and degradation products of combination drug had studied after their exposure to stress degradation conditions. The developed method was also used for simultaneous quantification of AZL and CLR from human plasma. In this method mobile phase was composed of acetonitrile and water in the ratio 30:70 passing through C18 column (250 × 4.6 mm, 5 µm) with 1.2 ml/min flow rate. The detection was carried out at optimized wavelength of 230 nm. The recorded retention time was 1.61 and 4.12 for AZL and CLR respectively. All the validation parameters of proposed method were performed. According to this method linearity range was found between the concentration of 3.125-21.875µg/ml for CLR with 0.9991 correlation coefficient while the concentration range for AZL and CLR was 10-70 µg/ml with correlation coefficient 0.9997. For inter-day and intraday precision %RSD was found 0.37 and 0.20 for AZL and 0.83 and 0.34 for CLR. LOD of AZL and CLR was 0.010 µg/ml and 0.016 µg/ml while LOQ was 0.032 µg/ml and 0.048 µg/ml for AZL and CLR respectively. Stress degradation studies had been performed under different stress The method was found to be effective in pharmacokinetic study of AZL and CLR because the sensitivity of the developed method allowed the determination of protein binding capacity of AZL and CLR in human plasma.