A REVERSED PHASE HIGH - PERFORMANCE LIQUID CHROMATOGRAPHIC METHOD FOR THE DETERMINATION OF ZAFIRLUKAST IN PHARMACEUTICAL FORMULATIONS AND HUMAN PLASMA

Süslü, İ., Altınoz, S.

Department of Analytical Chemistry, Faculty of Pharmacy, University of Hacettepe, 06100, Sihhiye, Ankara, TURKEY.

Zafirlukast (ZAF) is a cysteinyl leukotriene which used in the prophylaxis and treatment mild to moderate persistent and chronic asthma [1]. ZAF has been shown effective in the inhibition of allergen, exercise, sulphur dioxide and aspirin induced asthma [2]. ZAF effectively improved symptoms and benefited lung function with asthmatic patients [1]. Only a few methods including HPLC [3-5] and derivative spectrophotometry [5] for the determination of ZAF in pharmaceutical formulation and biological samples have been reported in literature. In this study, a simple and sensitive reversed phase HPLC method for the determination of zafirlukast in pharmaceutical formulations and human plasma. Piribedil was used as an internal standard. Analysis was carried out on Nucleosil C_{18} 100A (150 mm x 4.6 mm, i.d., 5 µm) column with a mixture of acetonitrile : acetate buffer (pH 3.5) (70 : 30, v/v) as the mobile phase, at a flow rate of 0.8 mL/min. Detection wavelength was set at 240 nm. The retention times were about 3.9 min for piribedil and 5.7 min for zafirlukast. The developed method was applied to the determination of zafirlukast in its pharmaceutical formulation and human plasma. Plasma proteins were precipitated with ethanol before the chromatographic analysis. The calibration ranges were linear from 25.00 - 900.00 ng mL^{-1} and 49.69 - 437.50 ng mL^{-1} in pharmaceutical formulation and plasma, respectively. The limits of detection and quantitation were 10.00 and 25.00 ng mL^{-1} in tablet and 19.23 ng mL^{-1} and 49.69 ng mL^{-1} in plasma, respectively. The absolute recovery was 98.73 ± 0.42 % at level 254.78 ng mL^{-1} of plasma zafirlukast concentration.