doi:10.4172/0975-0851.1000016

TITLE

BIOEQUIVALENCE STUDY OF TWO FDC FORMULATIONS CONTAINING METFORMIN, GLIBENCLAMIDE AND PIOGLITAZONE IN HEALTHY INDIAN VOLUNTEERS

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This study presents the results of a two-way, two-period, two-treatment crossover investigation in 12 healthy Indian male subjects to assess the bioequivalence of two FDC tablet formulations containing metformin HCl 500mg, glibenclamide 5mg and pioglitazone 15mg. Both formulations were administered orally as a single dose separated by a one-week washout period. The content of the three drugs in plasma was determined by a validated liquid chromatographic and tandem mass spectrometric method. The formulations were compared using the parameters, area under the plasma concentration-time curve (AUC_{0-t}), area under the plasma concentration-time curve from zero to infinity ($AUC_{0-\infty}$), peak plas¬ma concentration (C_{max}), and time to reach peak plasma concentration (t_{max}). The results of this study indicated that there were no statistically significant differences between the logarithmically transformed $AUC_{0-\infty}$ and Cmax values of the two preparations. The 90 % confidence interval for the ratio of the logarithmically transformed AUC0-t, $AUC0_{0-\infty}$ and Cmax were within the bioequivalence limit of 0.8-1.25 and the relative bioavailability of the test formulation was 96.04 %, 97.47 % and 93.94 % for metformin, glibenclamide and pioglitazone respectively of that of the reference formulation. Thus, these findings clearly indicate that the two formulations are bioequivalent in terms of rate and extent of drug absorption.