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TITLE

Comparison of High-Pressure Liquid Chromatography and Microbiological Assay for Determination of Ciprofloxacin in Human Plasma Employed in Bioequivalence & Pharmacokinetics Study

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Ciprofloxacin was given orally to 28 healthy male volunteers for single oral dose of 500mg; Plasma samples were collected at different time's interval between 0 and 12h and analyzed both by high pressure liquid chromatography and by a microbiological assay. The detection limits (LOD) were 0.02ug/ml and 0.1ug/ml, for both methods respectively. For each method, coefficients of variation (R^2) were 0.9995 and 0.9918 in plasma and limit of quantitation (LOQ).02 and 0.5ug/ml. The Comparison of means maximum concentration 2.68 ug/ml at 1.5 hr for test and 2.43 ug/ml are attain in HPLC method of Reference at 2hrs respectively. The plasma concentrations measured by microbiological assay of reference tablet are 3.95µg/ml (mean ± SE) at 1 hour and 3.80µg/ml (mean ± SE) at 1 hour. The concentrations in plasma measured by microbiological method were markedly higher than the high-pressure liquid chromatography values which indicates the presence of antimicrobially active metabolites. The mean ± SE values of pharmacokinetic parameters calculated by HPLC method, for total area under the curve (AUC 0-∞) were 13.11, and 11.91 h.mg/l for both test and reference tablets respectively. The mean ± SE values of clearance measured in l/h were 44.91 and 48.42 respectively. The elimination rate constant Kel [l/h] showed 0.17 l/h for test and 0.15 l/h reference tablets and likewise, absorption half-life expressed in hours shown 0.67 h for test and 1.04 h for reference respectively. The Mean Residence Time for test is 5.48 h and 5.49 h for reference. The mean ± SE values of pharmacokinetic parameters (Microbiological assay) for total area under the curve (AUC 0-∞) were 22.11 and 19.33 h.mg/l for both test and reference tablets respectively. The mean ± SE values of clearance measured in l/h were 29.02 and 31.63 respectively. The elimination rate constant Kel [l/h] showed 0.21 l/h for test and 0.20 l/h reference tablets and likewise, absorption half-life expressed in hours shown 0.86h for test and 0.56 h for reference respectively. The Mean Residence Time for test is 5.27 h and 4.67 h for reference. Significant difference observed between two methods.

Biography

Muhammad Khalid Khan has completed his Ph.D at the age of 50 years from Faculty of Pharmacy Gomal University Dera Ismail Khan Pakistan. He is the director (Senior Government Analyst) of Provincial Drugs Testing Laboratory Govt. of Khyber Pukhtoonkwa Provincial Health Department Peshawar Pakistan. He has published more than 11 papers in reputed journals and serving as member of Central Licensing Board MOHPakistan.