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## Pharmacokinetic bioequivalence of the most economic brand of levofloxacin: An alternative to increasing cost of antibiotic therapy

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The pharmacokinetic bioequivalence of two cheaper brands of levofloxacin tablets 500 mg, following single dose oral administration in eighteen healthy, adult, male human subjects under fasting conditions were studied to evaluate whether the economical brands (Rs. 3-5 per tablet) of levofloxacin could replace safely & successfully the very expensive innovator/reference brand (Rs. 95/- per tablet). The protocol and informed consent form (ICF) were approved by Jamia Hamdard Institutional Review Board. The study employed an open label; balanced, randomized three-treatment, three-sequence, three periods, single-dose, cross-over design. Blood samples were collected before and at different time points up to 24 h after medication. The concentrations of the levofloxacin in plasma were measured by a newly developed & validated high-performance liquid chromatography method. The pharmacokinetic and statistical analyses were performed using WinNonlin and SAS system from USA respectively. The log-transformed pharmacokinetic parameters ( $C_{max}$ ,  $AUC_{0-t}$  and  $AUC_{0-\infty}$ ) were analyzed using a mixed effects ANOVA model using Type III sum of squares, with the main effects of sequence, period and formulations as fixed effects and subjects nested within sequence as random effect. The 90% confidence intervals for log transformed T/R ratios for  $C_{max}$ ,  $AUC_{0-24}$ , and  $AUC_{0-\infty}$  were 88.42-104.43, 95.22-110.73 & 95.07-109.63 for the test product A and 91.37-107.91, 95.08-110.56 & 95.42-110.03 for the test product B respectively, thus all values lying within the specified range of 80-125%. The two cheaper brands of levofloxacin tested could save huge amount by replacing very expensive reference product, without compromising the health status.

### Biography

Tajdar Husain Khan has completed his PhD in 2006 from Jamia Hamdard, New Delhi, India and currently working as Assistant Professor in Department of Pharmacology, College of Pharmacy, Salman bin Abdulaziz University, Al-Kharj, Saudi Arabia. He has published more than 30 papers in reputed journals and has been serving as an Editorial Board Member of repute. His area of expertise is cancer chemoprevention, microwave radiation, and chemical induced toxicity.

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