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Bioequivalence study of Levofloxacin in healthy Kazakhs volunteers

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Levofloxacin is a synthetic chemotherapeutic antibiotic drug which is used for treatment of bacterial infections. There are many Levofloxacin generic drugs in Kazakhstan and relative bioavailability is important as it shows the drug quality. Therefore has been studied BA/BE of the test formulation Levolet (T) and reference formulation Tavanic (R) containing of Levofloxacin 500 mg tablets after single dose oral administration under fasting condition. Volunteers were healthy Kazakh adults randomly assigned to receive T- and R- formulation or vs. with a 1-week washout period between doses. A total of 18 participants were enrolled including 7 men and 11 women at the age of 28 years (range 19-40 years). Levofloxacin plasma concentrations were determined by HPLS assay using UV detection. For the analysis of pharmacokinetic parameters, including Cmax, $AUC_{0-24,}$ $AUC_{0-\infty}$ and Cmax/AUC_{0-24}, blood samples were collected at baseline and at 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, and 24 hours after oral administration of the drugs. The test formulations were considered to meet the criteria for bioequivalence if the geometric mean ratios (T/R) were in the range of 80% to 125%. Mean relative bioavailability was 100.3%. The 90% CIs of the mean of the difference between log-transformed values for Cmax, AUC_{0-24} and $AUC_{0-\infty}$ were 93.3% to 104%, 93% to 105% and 91% to 107%, respectively. This study shows that there is no significant difference in kinetic parameters between two products. Therefore, these two formulations are considered to be bioequivalent.

Biography

Shnaukshta Valentina graduated from Karaganda State University with a specialization in Chemistry. She has worked in the Pharmacology Research Institute (Moscow) and got PhD in biology at the age of 33. She has the research works in the sphere of psychotropic drugs pharmacology. She has been working as a professor of pharmacology at the Karaganda State Medical Academy for 7 years. During 6 years for present time she is the head of the pharmacological research laboratory in the state expert organization of the Republic of Kazakhstan. She has more than 10 publications in the field of pharmacokinetic studies and takes part in preclinical and clinical studies of medical drugs and pharmacokinetic bioequivalence studies.