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Determination of interchangeability of different brands of metformin extended/ sustained release tablets in healthy Indian male volunteers by regulatory defined bioequivalence criteria

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Reducing pharmaceutical care costs with generic drugs while maintaining quality of care is an important societal goal in both developed and developing countries, as these produces immense savings to national economy. However it is critical that these savings are not accepted at the expense of quality of health care. Interchangeability from innovator/leading product to a generic product is of great concern especially in the developing and least developed countries, where there is no provision of effective monitoring the quality of the marketed generic drug products. A randomized, three-treatment, single-dose, crossover, bioavailability study was undertaken to compare the interchangeability of three marketed product of metformin extended/sustained release formulation in 18 Indian male volunteers. A single oral dose of 500 mg metformin extended/sustained release products was administered during three period of the study having 7 days of washout period. A LCMS method for the determination of metformin in human plasma was developed and validated using metformin-D6 as an internal standard. A noncompartment pharmacokinetic method was employed to determine the pharmacokinetic parameters (C_{max}, $T_{max,}$ $AUC_{0-t,}$ $AUC_{0-\infty}$ and t½) of metformin using WinNonlin-Node 4.0 softwere. The 90% confidence intervals for log transformed data for C_{max}, AUC_{0-t} and $AUC_{0-\infty}$ for Glycomet SR versus Cetapin XR were 82.11-98.91, 86.29-102.17 and 86.34-102.59 respectively whereas for Bigomet SR versus Cetapin XR were 104.39-125.76, 94.78-112.22 and 92.85-110.33 respectively. Results concluded that the Glycomet SR was bioequivalent to Cetapin XR, whereas Bigomet SR was not bioequivalent to Cetapin XR as per predetermined regulatory defined criteria.

Biography

Dr. Muzaffar Iqbal has completed his Ph.D in Pharmaceutical Medicine at the age of 30 years from Jamia Hamdard, New Delhi. He is the Assistant Professor at College of Pharmacy, King Saud University, Riyadh KSA. He has published 7 papers in reputed journals and serving as reviewer of repute.