OMICS Group Conferences
Accelerating Scientific Discovery

4th World Congress on
Bioavailability and Bioequivalence:
Pharmaceutical R & D Summit
May 20-22, 2013 DoubleTree by Hilton Beijing, China

A bioequivalence study of two finofibrate tablet formulations in indian healthy subjects

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Abstract

Aim: To compare the bioavailability of two Finofibrate 145 mg tablet as test formulation and 145 mg tablet as reference formulation.

Method: Randomized, single dose, open-label, three-treatment, three-period, three-sequence, crossover design under fasting period with 9 days wash out period was evaluated in 18 subjects. For the analysis of pharmacokinetic properties, the blood samples were taken up to 72 hours after dosing. Plasma concentration of Finofibrate was determined using High Performance Liquid Chromatography (HPLC) – Mass Spectrometry method. Pharmacokinetic parameters AUC_{0-t}, $AUC_{0-\infty}$ and C_{max} were tested for bioequivalence after log-transformation of data and ratios of t_{max} were evaluated.

Result: The point estimates and 90% confidence intervals (CI) Avs. C for C_{max}, AUC_{0-t} and $AUC_{0-\infty}$, for Finofibrate were 62.84%, 85.03%, 86.34% respectively. The point estimates and 90% confidence intervals (CI) Bvs. C for C_{max}, AUC_{0-t} and $AUC_{0-\infty}$, for Finofibrate were 82.89%, 95.87% and 96.63% respectively.

Conclusion: Based on clinical, pharmacokinetic and statistical data obtained from 18 healthy adult male human subjects under fasting conditions, it may be concluded that a single dose of test formulation of drug 'Finofibrate' 145 mg tablet manufactured by Wockhardt Limited, India does not meet bioequivalence criteria of 80% to 125% for C_{max}, AUC_{o-t} and $AUC_{0-\infty}$ when compared with reference formulation 145 mg Finofibrate®'Tablet.

Biography

N.J.Gaikwad has awarded Ph.D. in 1988 from Nagpur University and working as Professor in Department of Pharmaceutical Sciences, RTM Nagpur University. He has teaching and research experience of 34 years. He supervised 4 All India Council for Technical Education major project as a Principal Investigator, published 30 research papers in reputed journals and also published 4 books in Pharmacy. He guided 21 Doctoral and 44 Post-graduate students, chief Coordinator in International Conference on Brain Research organized by International Brain Research Organization, Switzerland. He act Board of Governer in National Education and research, Govt. of India, Director in Hindustan Organic Chemical Limited, Mumbai, Zim Lab.Ltd.,Kalmeshwar, Unijules Nagpur.He is associated with various professional and Social organization.