A Randomized, Open Lable, Balanced, Two-Treatment, Two-Period, Two-Sequence, Single Dose, Crossover, Bioequivalence Study of Atorvastatin Calcium Tablet 80 mg in Normal, Healthy, Adult, Human Subjects Under Fasting Condition.

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ABSTRACT

Objective: The objective of present study was to carry out bioequivalence of **Test Product:** Atorvastatin Calcium 80 mg Tablet and **Reference Product:** Citalor (Atorvastatin Calcium 80 mg Tablet) of Pfizer Ireland Pharmaceuticals, under Fasting condition in normal, healthy, adult, human subjects, in a randomized, open label, crossover study.

Experimental Work Done: Total 18 normal, healthy, adult, human subjects were enrolled. The subjects willingly signed the informed consent form before participating in the study. Single oral dose of test product or reference product was administered in each study period considering 07 days washout period. A total of 22 blood samples (5 ml each) were collected from the subjects during each study period. Analysis of

plasma concentrations of Atorvastatin was done by a validated LCMS/MS analytical method. A non-compartmental method was used to calculate the pharmacokinetic parameters using drug concentration time profile. Statistical comparison of the pharmacokinetic parameters of both the formulations was performed to assess bioequivalence.

Results And Discussion: In the study total 18 subjects were enrolled from which data of 17 subjects were analyzed and one subject was withdrawn due to vomiting. For test formulation versus the reference formulation, the least squares mean test/reference ratios of Ln(C_{max}) and Ln(AUC_{0-t}) were 96.59%,97.82%.The 90% confidence interval for log-transformed data of Test Product compared to that of the Reference Product was 83.59-115.67% for C_{max} and 82.63-115.79% for AUC_{0-t}. In this study test formulation was found bioequivalent to the reference formulation as per predetermined regulatory criteria.

Conclusion: Based on the statistical analysis of the results, it can be concluded that the Test Product Atorvastatin Calcium Tablet 80 mg is bioequivalent to the Reference Product in terms of rate and extent of absorption under fasting condition. As well as it is well tolerated and safe.