BIOEQUIVALENCE STUDY OF FENOFIBRIC ACID 135mg DELAYED RELEASE CAPSULE UNDER FASTING CONDITION

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ABSTRACT

Objective: The objective of present study was to assess the bioequivalence of two Test Products (A)/(B): Fenofíbric Acid 135 mg delayed release capsules with Reference Product (C): Trilipix® 135 mg delayed release capsules (containing choline fenofibrate equivalent to 135 mg of fenofibric acid) of Abbott Laboratories North Chicago, IL 60064, U.S.A. in healthy human volunteers after administration of single capsule of either test A or B or reference C formulation under fasting condition, in each period.

Methods: This single-dose, randomized, 2-period, 3- Treatment, 2- Sequence, 2- Group, crossover study compared the pharmacokinetic properties within healthy human volunteers under fasting condition. Volunteers were assigned to receive, in randomized order, a single oral dose of test formulation (A) or a reference formulation(C) to Group I and a single oral dose of test formulation (B) or a reference formulation(C) to Group II. Each study period was separated by a 10-days washout period. Blood samples were collected at pre-specified times over a period of 96 hours after administration. An LC-MS/MS method was used for the estimation of plasma Fenofibric acid concentrations. A non-compartmental method was employed to determine the pharmacokinetic properties (Cmax, Tmax, AUC0–t, AUC0–∞, and Thalf) to test for bioequivalence. The predetermined regulatory range of 90% CI for bioequivalence was 80% to 125%. Safety was assessed using physical examination, including vital sign measurement, and direct questioning.

Results and discussion: The study was conducted in 48 volunteers divided in two groups 24 in each from both male and female (18-45 yrs; BMI (According to LIC chart)). For test formulation versus the reference formulation, the least squares mean test A/reference C ratios of Ln(Cmax) and Ln(AUC(0–t)) were 103.89% and 96.32% for Group I and the least squares mean test B/reference C ratios of Ln(Cmax) and Ln(AUC(0–t)) were 87.64% and 88.38% for Group II. CI for Ln(Cmax) and Ln(AUC(0–t)) were 98.50-113.84 and 90.43-106.91 for Group I and CI for Ln(Cmax) and Ln(AUC(0–t)) were 83.67-99.73 and 84.45-95.26 for Group II. No Serious adverse events were found or reported by volunteers throughout the study. In this study, both the test formulations was found bioequivalent to the reference formulation as per predetermined regulatory criteria.

Conclusion: These observations confirm that the both the test formulations of Fenofibric acid 135mg Delayed release capsule are bioequivalent with the Trilipix® and it is found to be safe.