Reg. No: D7635654-AFIN ISSN No: 2348-7704

HEB

Journal of Hospital Pharmacy
An Official Publication of Bureau for Health & Education Status Upliftment
(Constitutionally Entitled As Health-Education, Bureau)

JOHP

ORAL BIOAVAILABILITY & BIOEQUIVALENCE STUDY OF FENOFIBRIC ACID

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Abstract

Background:

Fenofibric acid is generally used to treat Hyperlipidemia. Mixed Dyslipidemia, Hypertriglyceridemia and Hypercholesterolemia in adults who don't respond to non-pharmacological treatment.

Objective:

The study is conducted to evaluate the bioequivalence of Fenofibric Acid 135 mg Delayed Release Capsules in 6 normal, healthy, adult, male subjects under fasting conditions.

Method:

During study in each period volunteers will receive either Fenofibric acid 135 mg capsule (Test Product) or Trilipix™ 135 mg capsules (depending on randomization scheme) after an overnight fasting. A 10-days washout period is followed after first period. Then in second period volunteers will receive other treatment. Serial blood samples will be collected in both periods upto 24 hours. The pharmacokinetics parameters will be accessed for bioequivalence.

Result:

The 90% Confidence Intervals of ratio of Test product geometric mean to the Reference product geometric mean were within the 80% and 125% of pharmacokinetic parameters C_{max}, AUC_{0-t} and $AUC_{0-\infty}$ of log transformed data. No AE and SAE were reported during the study.

Keywords: *Hyperlipidemia, Pharmacokinetics, bioequivalence, Adverse Drug Reaction.*

Access this Article Online	Quick Response Code:
Website:http://www.journalofhospitalpharmacy.in	
Received on 12/02/2021	
Accepted on 17/02/2021 © HEB All rights reserved	