INTRODUCTION
Achieving adequate concentration of the drug in the systemic circulation, for a sufficiently long duration of time, is indeed the ideal goal for rational therapeutics. It is a well-established fact that there are a host of factors that influence this, more so if the drug in contention happens to be an anti-infective or one with a narrow therapeutic window.

Anti-infective drugs can be further classified to be acting either in a concentration dependent manner or in a time dependent manner. The objective behind the prescription of these drugs has been to administer the concentration dependent drugs using widely spaced dosing intervals and time-dependent ones with short dosing intervals. Thus, for optimizing the use of an anti-infective regimen, based on this principle, the target drug concentration becomes utmost important. This directly implies that all the factors that can influence drug absorption need to be considered thoroughly before such a regimen is chosen.

Factors affecting oral drug absorption can be classified as drug factors and host factors. The drug factors include physiochemical properties of drug substances and dosage form characteristics. The host factors include, age, blood flow through gastrointestinal tract (GIT), gastric emptying time, gastrointestinal pH, intestinal transit time, disease states, gastrointestinal contents such as other drugs, food, fluids and other normal GI contents, and presystemic metabolism by enzymes in the gut wall or in the liver.

Amongst the various factors that influence drug absorption food indeed plays an important role. Food induces changes in the physiology of the GIT. Physiological changes induced by food can result in delayed gastric emptying, stimulation of bile flow, changes in pH and increase in splanchnic blood flow. Food can also alter luminal metabolism and physically or chemically interact with a drug substance. In general, intake of food within thirty minutes to two hours before an oral dose may affect the absorption of the drug, but these effects are usually unpredictable. Indeed intake of food or non-intake of it, in certain circumstances can greatly influence the outcome of therapeutic regimens.
The type and size of a meal may have a marked effect on the nature of a drug-food interaction. Liquid meals, which are often used in an attempt to obtain mechanistic information, might have a totally different effect on drug absorption compared with solid meals, which are nonetheless more clinically relevant. The time interval between eating and medication will also affect the nature and extent of a drug-food interaction. Knowing that both the nature of the food and formulation of the drug play an important role it becomes essential to precisely define their interaction.

Drug-food interactions are a particular problem for oral controlled release products. These delivery devices present a greater quantity of drug to the patient per single dose unit than conventional dosage forms do and are designed to deliver the drug at a controlled rate over a prolonged period. With these formulations, a marked effect by administered food on systemic availability may have a serious and prolonged effect on circulating drug levels. The extent to which food may alter circulating levels of an orally dosed compound is frequently far greater than that which may occur due to changing drug brand or formulation, so that the enormous expense involved in producing a particular drug formulation may be wasted if due attention is not paid to this easily controllable and yet often ignored factor.

Cefaclor is a semi-synthetic cephalosporin anti-infective drug that exhibits time dependent activity. Rate of absorption of this drug, which is influenced by food intake, determines the time period during which its concentration remains above the minimum inhibitory concentration and thus its efficacy.

As the dosage form under consideration happens to be an extended release tablet formulation of Cefaclor (Ceclor CD®) it becomes more important to explain to the patient the way it should be consumed. The package insert of Ceclor CD® states that this formulation needs to be taken along with food, but does not provide any details regarding the type and source of food. Recently, some evidence has been obtained that the package insert claim could only be reproduced by administration of a non-vegetarian diet and not otherwise (Dr. V. Srivatsan, Personal Communication).
India being a country largely inhabited by vegetarians it does seem prudent to further define the interaction with the administration of this drug along with an equicaloric diet, which varies both in type and source.

Hence this study was designed with 5 different types of diets viz., high fat vegetarian, high fat non-vegetarian, low fat vegetarian (wheat based), low fat non-vegetarian, low fat vegetarian (rice based) diets in normal human male subjects to compare the bioavailability after administration of a single dose of an extended release tablet formulation of Cefaclor 500 mg (Ceclor CD®). The data obtained under fasting condition was used as the baseline for purpose of comparison.