Dear Volunteer,

This document has been prepared to provide information required for your participation in a bioavailability/bioequivalence study. Please read this information and clarify if you have any queries before you decide to participate in the study.

- This is a research based study. You are being asked to participate in this research study.
- Take all the time you need to read and understand the information, before agreeing to participate in this study.
- If you are not able to understand any part of this document, please feel free to get your doubts clarified. An oral presentation of this document will also be held in the language you understand.
- Please sign the informed consent forms (A and B) and submit it for our records. You will be provided a copy of the same for your reference and record.
- During your participation in the clinical study, you will act as an independent individual, and not as an agent, partner or an employee of Ranbaxy Laboratories Limited.

PURPOSE OF THE STUDY

Bioavailability is the amount of a drug that becomes available in the body (eg: blood, urine) after consuming the drug. Two drugs are said be bioequivalent if the amount of drug in the body (eg: blood, urine) are similar after consuming the drugs.

Bioequivalence has to be proven between the marketed drug named reference and the generic drug (to be marketed) named test. Government agencies check the details of the results from the bioequivalence studies. When they are convinced that the two drugs are similar (bioequivalent), the test drug may be approved for marketing.
**ANNEXURE-II**

**GENERAL PROCEDURE OF A BIOAVAILABILITY/BIOEQUIVALENCE STUDY**

Given below is a general explanation of how a bioavailability/bioequivalence study is conducted.

You will be admitted to the study if you pass the screening tests and provide a written informed consent. On day of admission, breath test for alcohol, drug of abuse in urine and or other tests if required by the protocol will be done in each period. Baggage and pocket(s) will be checked prior to admission and you are not allowed to carry alcohol, xanthine, tobacco, cigarette, illicit drug, medicine in any form, any eatables (solid and liquid) and any electrical or battery operated appliances other than wrist watch and mobile phone without camera. You will be provided with Ranbaxy volunteer uniform(s) during your in-house stay. During your participation in this study, you will be provided lockers to keep your belongings and an identity card which will be required to be displayed during in-house stay. You may be monitored (e.g. through Close Circuit TV-camera) during your stay at CPU.

During the stay in the unit you will be provided standardised meal. (For detailed meal plan refer to study summary in INFORMED CONSENT FORM - B).

You will be required to consume one of the study drugs (either the test or reference) in each period.

As per protocol, blood samples will be collected at pre-determined time intervals in vacutainers (tubes) through a disposable needle and cannula which will be inserted into a blood vessel and kept fixed at the site. To prevent the needle from getting blocked, solution of heparin (which is a normal body constituent) will be added. Half milliliter of heparinised blood will be discarded before sample collection. Alternatively, blood samples may also be collected, directly with a sterile disposable needle and syringe. The collected samples will be processed and stored appropriately for further analysis. (Please refer to INFORMED CONSENT FORM - B for Sample collection time points.)

As per the study requirement other biological specimen (e.g.: Urine, Stool, Sputum samples etc) may be collected at predetermined time intervals.

Pain, swelling and/or numbness of the arm may occasionally result from the blood collections during the study. This procedure may also occasionally cause light headness or fainting. These reactions are usually of short duration and are reversible.

After the completion of in-house stay, you will be discharged, with information to return on a specific date at a specific time for the subsequent period(s) of the study or for walk-in samples (ambulatory samples or for end of study safety sample), vitals signs measurement and adverse event monitoring, if required.

Similar procedures will be followed in the subsequent period(s) except for the informed consent procedure.

Signature of Volunteer ____________________________
ANNEXURE-II

RESTRICTIONS TO BE FOLLOWED

If you participate in this study as a subject, you will be required to follow certain restrictions:

You will not be allowed to have tea, coffee, chocolates and cola during your stay in the unit. For 48 hours prior to admission and during the course of the study till last sample collection for pharmacokinetic analysis, you must not consume any alcohol or any products that contain alcohol (beverages, marinades, medicines, etc), grapefruit juice and/or grapefruit supplements. You must not have taken any medication including over the counter (OTC) medications 30 days before and throughout the study. Drinking water will be restricted before and after consuming the drug. Posture restriction will also be enforced after dosing. (For specific details of restrictions related to drinking water and posture, refer ICF - B).

BENEFITS

Since you do not require treatment with the study drug(s), you will receive no medical benefit from this study, other than the benefit of a free health check-up and the satisfaction of serving the interests of human beings in poor health.

NEW FINDINGS

Any new and important information which may be discovered during the study which may influence your willingness to continue in the study will be made available to you as soon as possible.

ALTERNATIVE TREATMENT

Since this study is for research only and the alternative would be not to participate.

INSURANCE POLICY

You are insured under the insurance policy no. OG-10-1113-3306-0000004 of Bajaj Allianz and you will be compensated in case of a trial related injury.

MAINTENANCE OF DISCIPLINE

You are expected to follow certain rules of the CPU and maintain discipline during your stay in the unit. In case you do not behave properly in the CPU you will be withdrawn from the study without any payment and/or excluded from participating in all future studies.

Signature of Volunteer_________________________
ANNEXURE-II

DETERMINATION OF FINANCIAL COMPENSATION DUE IN CASES NOT COMPLETING THE STUDY

1. Withdrawn from the study by the Investigator on objective medical grounds to safeguard your health, before administration of study drug  
   - On pro-rata basis

2. Withdrawn from the study by the Investigator on objective medical grounds to safeguard your health, after administration of study drug  
   - Full payment on completion of study/follow-up visits

3. Dropped-out of the study, on your own accord, after administration of study drug  
   - On pro-rata basis

4. Dropped from the study on compassionate grounds, with the permission of Investigator  
   - On pro-rata basis

5. Withdrawn from the study by the Investigator due to your failure to comply with the requirements of the study  
   - On pro-rata basis

6. Withdrawn from the study by the Investigator because of your wilful withholding of information regarding your past or present medical illness(es) relevant to the study and your misbehaviour during the study  
   - No payment

7. Non-compliance with the prescribed time-schedule for the follow-up visit (where applicable)  
   - 50% of the payment due for that visit

CONFIDENTIALITY

Records of your participation in this study will be confidential so far as permitted by law. However, the confidential data which identifies you by name will be available to the study personnel, Corporate Quality Assurance Auditor during audits and to the Institutional Review Board (IRB) & various regulatory agencies, as it becomes necessary. Any publication of the data will not identify you by name. Investigator’s representatives/designates shall act as data custodian for this study till it is sent for archiving.

MEDICAL TREATMENT FOR INJURY

In case of study related side effect(s), medical care will be offered at the Clinical Pharmacology Unit and treatment of side effect or event requiring hospitalization will be carried out at a nearby hospital and the expenses will be borne by Ranbaxy Laboratories Limited.

VOLUNTARY NATURE OF PARTICIPATION

Your participation in this study is entirely your choice. Whether you choose to participate or not will not involve any penalty or affect your selection for any future studies. You may also stop participating in the research at any time you wish. It is your choice and all your rights will be respected.

Signature of Volunteer ______________________________
ANNEXURE-II

Note: The Investigator can stop your participation in the study if the following are known- it appears to be harmful to your health; you fail to fulfill study requirements; you have withheld information related to your health record; the study is cancelled.

In case of emergency you can also call the study personnel by pressing the emergency bell which is available in the ward and toilet areas.

CONTACT DETAILS

At any time before, during or after the study, you can obtain further information about this study. In case of medical emergencies during the study, or if you have any urgent questions or queries concerning discomfort or injury associated with the study, please contact, Investigator at Ranbaxy Clinical Pharmacology Unit, Majeedia Hospital 2nd Floor, Hamdard Nagar, New Delhi 110 062, Telephone: 2995-6721.

If you have questions regarding your rights as a research subject, you may call Dr. Farhan Jalees Ahmad, Convener/Member Secretary, Jamia Hamdard Institutional Review Board (Telephone number 9810720387).

Note: You may also consult your family doctor at any time during the study

Signature of Volunteer ________________________________