INFORMED CONSENT FORM

PROTOCOL NO: 323_PREGA_09

SUPERSEDES: Version 1; 10 March 2009

TITLE: An open label, balanced, randomized, three-treatment, three-period, three-sequence, crossover bioavailability study comparing single dose of two batches of Pregabalin 600 mg extended release tablet of Ranbaxy Laboratories Limited, with two oral doses of Lyrica 300 mg capsules (each dose containing Pregabalin 300 mg administered 12 hourly; total dose 600 mg of Pfizer GmbH) in healthy adult, human, male subjects under fed condition.

YOU ARE BEING ASKED TO TAKE PART IN THE ABOVE MENTIONED RESEARCH STUDY.

BEFORE AGREEING TO PARTICIPATE IN THE PRESENT STUDY IT IS IMPORTANT THAT YOU READ AND UNDERSTAND THE FOLLOWING INFORMATION. TAKE ALL THE TIME YOU NEED TO DO SO.

AN ORAL PRESENTATION OF THIS DOCUMENT WILL BE HELD. IF YOU HAVE ANY QUESTIONS/CLARIFICATIONS PLEASE DISCUSS DURING THE PRESENTATION.

YOU WILL BE PROVIDED TWO COPIES OF THIS FORM. PLEASE SIGN THE ORIGINAL COPY AND SUBMIT TO US FOR OUR RECORDS. PLEASE RETAIN THE DUPLICATE COPY FOR YOUR REFERENCE AND RECORDS.

DURING YOUR PARTICIPATION IN THE CLINICAL STUDY, YOU WILL ACT AS AN INDEPENDENT CONTRACTOR, AND NOT AS AN AGENT, PARTNER OR EMPLOYEE OF RANBAXY LABORATORIES LIMITED.

INTRODUCTION

This statement describes the purpose, procedures, benefits, risks/discomforts of the study, alternative procedures that are available to you and your right to withdraw from the study at any time.

PURPOSE

This study involves research to evaluate the amount of drug in the blood after administration of a new extended release tablet formulation of Pregabalin. Pregabalin belongs to a group of medicines used for:

- Management of neuropathic pain associated with diabetic peripheral neuropathy.

Signature ___________________
- Management of postherpetic neuralgia.
- Adjunctive therapy for adult patients with partial onset seizures.
- Management of fibromyalgia.

The usual adult starting daily dose of pregabalin is 150 mg daily upto a maximum dose of 600 mg per day.

In this study a single oral dose of two batches of Pregabalin 600 mg extended release tablets (containing Pregabalin 600 mg) of Ranbaxy Laboratories Ltd., India will compared with two doses administered 12 hourly of Lyrica capsules (each containing pregabalin 300 mg) of Pfizer Gmbh, Germany, in 18 healthy human male subjects under fed condition.

If the test drug meets certain prescribed criteria, it may be approved by the drug administration authorities for marketing.

ELIGIBILITY

You can participate in this study if you:

- are in the age range of 18-45 years.
- are neither overweight nor underweight for his height as per the Life Insurance Corporation of India height/weight chart for non-medical cases.
- have voluntarily given written informed consent to participate in this study.
- are of normal health as determined by medical history and physical examination of the subjects performed within 21 days prior to the commencement of the study.
- Non vegetarian

You cannot participate in this study if:

- You have history of hypersensitivity to pregabalin or any other drug.
- You have history of dizziness, ataxia, or in-coordination.
- You have history of recurrent headache.
- You have history of excessive somnolence / narcolepsy.
- You have history of drug-induced rashes/itching.
- You have history of confusion or abnormal thinking.
- You have history of peripheral edema or dry mouth.
- You have history of blurred vision.
- You are having abnormal fundoscopic findings at the time of admission of any period of the study.
- You have history of Myopathy, Myalgia.
- You have PR interval > 200 msec at the time of screening.
- You have any evidence of organ dysfunction or any clinically significant deviation from the normal, in your physical or clinical determinations.
- You have presence of disease markers of HIV 1 or 2, Hepatitis B or C viruses or syphilis infection.

Signature

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- You have presence of values, which are significantly different from normal reference ranges and/or judged clinically significant for hemoglobin, total white blood cells count, differential WBC count or platelet count.
- You are positive for urinary screen testing of drugs of abuse (opiates or cannabinoids).
- You are positive for breath alcohol test.
- You have presence of values, which are significantly different from normal reference ranges and/or judged clinically significant for serum creatinine, blood urea nitrogen, serum aspartate aminotransferase (AST), serum alanine aminotransferase (ALT), serum alkaline phosphatase, serum bilirubin, plasma glucose or serum cholesterol.
- You have clinically abnormal chemical and microscopic examination of urine defined as presence of RBC, WBC (>4/HPF), epithelial cells (>4/HPF), glucose (positive) or protein (positive).
- You have clinically abnormal ECG or Chest X-ray.
- You have history of serious gastrointestinal, hepatic, renal, cardiovascular, pulmonary, neurological or hematological disease, diabetes or glaucoma.
- You have history of any psychiatric illness, which may impair the ability to provide written informed consent.
- You are a regular smoker who smokes more than 10 cigarettes daily or have difficulty abstaining from smoking for the duration of each study period.
- You have a history of drug dependence or excessive alcohol intake on a habitual basis of more than 2 units of alcoholic beverages per day (1 unit equivalent to half pint of beer or 1 glass of wine or 1 measure of spirit) or have difficulty in abstaining for the duration of each study period.
- You have taken any enzyme modifying drugs within 30 days prior to Day 1 of this study.
- Participation in any clinical trial within 12 weeks preceding Day 1 of this study (except for the subjects who dropout/withdrawn from the previous study prior to period I dosing).
- You have a hemoglobin concentration of less than 13 gm%.
- You have problem(s) in complying with the study protocol.

**STUDY PROCEDURES**

In this study (cross-over design), you will receive one of the following formulations orally in the first period. Subsequently, you will receive the other formulations in the subsequent periods. The order in which you will receive each treatment will be randomly determined.

**Reference (R):** Two oral doses of Lyrica capsules (each containing Pregabalin 300 mg) manufactured by Pfizer GmbH, Germany will be administered each at an interval of 12-hours with 240 mL of drinking water at ambient temperature 45 minutes after starting of a standard meal.

The first dose will be administered after an overnight fast of at least 10 hours 45 minutes after starting of a standard meal. The second dose will be administered 12.00 hours after the first dose 45 minutes after starting of a standard meal

**Signature**

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Test (A): A single oral dose of Pregabalin 600 mg extended release tablet manufactured by Ranbaxy Laboratories Limited, will be administered with 240 mL of drinking water at an ambient temperature 45 minutes after starting of a standard meal.

Test (B): A single oral dose of Pregabalin 600 mg extended release tablet manufactured by Ranbaxy Laboratories Limited, will be administered with 240 mL of drinking water at an ambient temperature 45 minutes after starting of a standard meal.

You must not have taken any medications including: aspirin, non steroidal anti-inflammatories (Brufen®, Voveran®), acetaminophen (Crocin®) or any other pain medication, antihistamines, anti-acidity medicines (Zantac®, Pepfiz®), cough syrup for 14 days before and throughout the study. Also you should not have consumed certain drugs prescribed by doctors, like antiulcer medicines (Tagamet®, Lomac®), antitubercular medications (INH, rifampicin) and antiinfective medications like erythromycin, ketoconazole for 30 days before and throughout the study. For 48 hours before and during the stay at CPU, you must not consume any alcohol or any products that contain alcohol (beverages, marinades, medicines, etc). During in house stay you must not consume Xanthine or any products that contain Xanthine (chocolate, coffee, cola, medications, tea).

The study consists of 3 in-house stays of approximately 60 hours each at the Ranbaxy Clinical Pharmacology Unit (CPU), Majeedia Hospital (2nd floor), Hamdard Nagar, New Delhi 110 062.

Each phase of the study will be separated by a period of at least 05 days to ensure that the study drug(s) taken during the initial phase is (are) no longer in your body when the next phase begins.

Test for drugs of abuse (opioids and cannabinoids) and breath test for alcohol will be carried out prior to admission in each period. After discharge at 36 hours post-dose, you will have to make one visit to the Clinical Pharmacology Unit for further blood sample and vitals at 48 hours post-dose, in each period.

On the evening before receiving the study drug(s), after your admission, you will receive a standard evening meal. This will be approximately 12 hours before you receive the study drug (dosing). The study drug(s) will be taken in the next morning with approximately 240 mL of water. You will be required to fast overnight for at least 10 hours before dosing.

For Reference: After an overnight fast of at least 10 hours, subjects will start the standard meal 45 minutes prior to administration of the each dose of study drug at 0 and 12 hr. Study subjects will eat this meal in 30 minutes or less. The dose will be administered 45 minutes after start of the meal with 240 mL of water. No food will be allowed for at least 4 hours post-dose.

For Test: After an overnight fast of at least 10 hours, subjects will start the standard meal 45 minutes prior to administration of the study drug. Study subjects will eat this meal in 30 minutes or less. The dose will be administered 45 minutes after start of the
meal with 240 mL of water. The standard meals will also be served at 11.25 hour. No food will be allowed for at least 4 hours post-dose. (For detailed meal plan see study schedule).

In case of reference formulation, you will also be required to remaining fasting 2-hour pre and post evening dose. Standard meals – Lunch, breakfast, lunch and snacks at 4, 24, 28 and 32 hours, respectively, after drug administration. During your stays at the centre, you must consume all food and drink provided and no other food or drink will be permitted.

After receiving the study drug, you will be required to sit upright or remain ambulatory for 2 hours, thereafter you can resume only normal activities while avoiding vigorous exercise. However, should medical events occur at any time during housing you will be placed in an appropriate position or will be permitted to lie down on your right side. Drinking water will not be allowed from 1 hour before dosing until 2 hours post-dose.

Blood will be collected through a disposable needle and tube, which will be inserted into a blood vessel and kept, fixed at that site. The needle will not be allowed to get blocked by introduction of a very dilute solution of heparin (which is a normal body constituent). Half millilitre of heparinised blood will be discarded before the sample is collected. Alternatively, blood samples can be collected directly with a sterile disposable needle and syringe every time a sample is to be collected.

A total of Ninety (90), 4-mL blood samples {including duplicate (2 X 4 mL) predose samples} will be collected from each subject in CPDA vacutainers during the course of the study through indwelling cannulae placed in forearm veins.

Blood sample will be collected at the following time points:

**Test:** Predose (in duplicate) and at 1.000, 2.000, 2.500, 3.000, 3.500, 4.000, 4.500, 5.000, 5.500, 6.000, 6.500, 7.000, 7.500, 8.000, 8.500, 9.000, 10.000, 12.000, 14.000, 18.000, 24.000, 30.000, 36.000 and 48.000 hours in each period.

**Reference:** Prior to morning dose (in duplicate) and at 0.500, 1.000, 1.333, 1.667, 2.000, 2.333, 2.667, 3.000, 3.333, 3.667, 4.000, 4.500, 5.000, 6.000, 8.000, 10.000, 12.000, 12.500, 13.000, 13.333, 13.667, 14.000, 14.333, 14.667, 15.000, 15.333, 15.667, 16.000, 16.500, 17.000, 18.000, 20.000, 24.000, 30.000, 36.000 and 48.000 hour post morning dose.

- 4-mL per sample
- 87 draws in 3 periods including duplicate predose blood samples
- In case of reference formulation, the volume of blood collected until 24 hours postdose will be 156.5 mL and in case of test formulation, the volume of blood collected until 24 hours postdose will be 102.5 mL
- Total of 419.5 mL in 3 periods including 16 mL for screening, 37.5 mL as discarded blood prior to venous cannula collection and 06 mL for safety
analysis at the end of the study.

Pain, swelling and/or numbness of the arm may occasionally result from the multiple blood collections during this study. This procedure may also occasionally trigger vagal reactions (light headedness, fainting). These reactions are usually benign, of short duration and limited to a feeling of weakness, accompanied by sweating and decrease in heartbeats. Vital signs of oral temperature, sitting blood pressure and pulse rate will be measured and recorded after subject admission, before dosing, 2, 6, 10, 14, 24, 36 and 48 hours after drug administration. Brief clinical examination of the subject will be conducted by a qualified medical designate on duty after subject admission, prior to dosing of study drug, thereafter at every 12 hours interval until discharge. Adverse event monitoring will be done on admission, predose, every 4 hours post dose until discharge. Fundoscopy of each subject will be done at the time of admission of each period of the study.

You can leave the study site approximately 36 hours after receiving the study drug(s) in each period. After discharge at 36 hours post-dose, you will have to make one visit to the Clinical Pharmacology Unit for further blood sample, AE monitoring and vitals at 48 hours post-dose, in each period.

The laboratory parameters like Hemoglobin, Total WBC count, Platelets, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Total Bilirubin, serum creatinine, blood urea nitrogen, serum aspartate aminotransferase (AST), serum alanine aminotransferase (ALT), serum alkaline phosphatase will be repeated at the end of the study. In case of clinically significant laboratory values, you will have to come for follow up until the results are normal.

SIDE EFFECTS OF STUDY DRUG (S)

The most commonly observed adverse events in Pregabalin-treated patients in various studies are dizziness, somnolence, peripheral edema and dry mouth. Adverse events are usually mild to moderate in intensity. Other adverse reactions reported with Pregabalin, leading to discontinuation from controlled trials more frequently in the Pregabalin group compared to the placebo group are ataxia, confusion, asthenia, thinking abnormal, blurred vision, in-coordination, and peripheral edema.

In a review of seven controlled clinical trials in patients of painful diabetic peripheral neuropathy receiving Pregabalin ranging from 150 mg to 600 mg, most common treatment-emergent adverse events were dizziness, somnolence, and peripheral edema.

In a Phase I study conducted in 53 healthy subjects, pregabalin was given in rising, multiple doses (25 to 300 mg). Pregabalin was generally well tolerated. There were no serious AEs. The most frequent AEs were dizziness, headache, stupor, somnolence, rhinitis and amblyopia. Mild transient elevations in hepatic enzymes were observed.

Caution:
(a) Avoid operating Machines, driving vehicles or engage in other potentially hazardous activities during the period of the study.
(b) You must first sit down and then stand up slowly when getting out of the bed.
(c) Avoid consumption of alcohol till the completion of the study.

Signature __________________
(d) If you experience swollen face or tongue, rashes or if your skin turns red, please bring to the notice of the Medical Officer/Nurse/staff on duty immediately.

(e) If you feel unwell, or experience any uneasiness, please bring to the notice of the Medical Officer/Nurse/staff on duty immediately.

(f) If you have unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever, please bring to the notice of the Medical Officer/Nurse/staff on duty immediately.

**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 medical check-up and the satisfaction of serving the interests of ailing human beings.

**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, the alternative would be not to participate.

**FINANCIAL COMPENSATION**

A compensation package of Rs.8700/- (Rupees eight thousand seven hundred only) will be paid to you at the completion of the study. This is to compensate you for discomfort and inconvenience.

If you refuse to have your baggage searched at admission or you are uncooperative during conduct of the study procedures you will be discharged without any payment.

**INSURANCE POLICY**

You are insured under the insurance policy no. HCT0000012000100 of HDFC ERGO General Insurance Company Limited and you will be compensated in case of a trial related injury.

**MAINTENANCE OF DISCIPLINE**

You are expected to observe various rules of the CPU and maintain discipline during your stay in the unit. In case of any misconduct in the CPU or in the Jamia Hamdard campus, you will be (a) dropped from the study without any payment and (b) debarred from participating in all future studies.
DETERMINATION OF FINANCIAL COMPENSATION DUE IN CASES NOT COMPLETING THE STUDY

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Compensation Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Withdrawn from the study, before receiving any study medication, by the Clinical Investigator on objective medical grounds to safeguard your health</td>
<td>Payment on prorata basis</td>
</tr>
<tr>
<td>2</td>
<td>Withdrawn from the study by the Clinical Investigator on objective medical grounds to safeguard your health</td>
<td>Full payment on completion of study/ follow-up visits</td>
</tr>
<tr>
<td>3</td>
<td>Dropped-out of the study, on your own accord, after initiation of medication</td>
<td>Payment on prorata basis</td>
</tr>
<tr>
<td>4</td>
<td>Dropped-out from the study on compassionate grounds, with the permission of Clinical Investigator</td>
<td>Proportionate payment due in full</td>
</tr>
<tr>
<td>5</td>
<td>Withdrawn from the study by the Clinical Investigator after signing the consent form due to your failure to comply with the requirements of the study</td>
<td>No payment</td>
</tr>
<tr>
<td>6</td>
<td>Withdrawn from the study by the Clinical Investigator because of your wilful withholding of information regarding your past or present medical illness(es) relevant to the study</td>
<td>No payment</td>
</tr>
<tr>
<td>7</td>
<td>Non-compliance with the prescribed time-schedule for the follow-up visit in follow-up visits (where applicable)</td>
<td>50% of the payment due for that visit</td>
</tr>
</tbody>
</table>

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, Quality Assurance Auditor during audits and to the Jamia Hamdard Institutional Review Board (IRB) & various regulatory agencies, as it becomes necessary. Any publication of the data will not identify you by name. By signing this consent form, you authorise the Study Director to release your study related medical records, to the regulatory authorities and the IRB. Clinical 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 research related injury, first aid will be available at the Ranbaxy Clinical Pharmacology Unit and treatment of adverse reactions requiring hospitalization will

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be undertaken at a nearby hospital and the expenses will be borne by Ranbaxy Research Laboratories.

**CONTACTS FOR ADDITIONAL OR EMERGENCY INFORMATION**

At any time before, during or after the study, you can obtain further information about this drug research. You may also consult your personal doctor at any time during the study. If you wish to contact someone concerning possible risks related to the study or have additional questions about the study, please contact the Clinical Investigator directly at the following location:

Ranbaxy Clinical Pharmacology Unit  
Majeedia Hospital 2nd Floor  
Hamdard Nagar, New Delhi 110 062  
Telephone: 2995-6721

In case of medical emergencies during the study, or if you have any urgent questions concerning discomfort or injury associated with the study, please telephone the Clinical Investigator at (91-11) 2995-8529 (office).

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) or Prof. P.L. Sharma (Telephone number 2605-9688, Extn 440).

**VOLUNTARY NATURE OF PARTICIPATION**

You are free to participate or refuse to volunteer for this study. Your refusal to participate or withdrawal from the study will involve no penalty or loss of medical benefits to which you would otherwise be entitled and will not affect your selection for any future studies. You are advised to contact the Clinical Investigator or the Study Director if you decide to withdraw from the study. They will explain the best way for you to withdraw from the research study. The Clinical Investigator can stop your participation in the study at any time without your consent if it appears to be medically harmful to you. You may also be withdrawn from the study at any time without your consent if you fail to follow directions for participating in the study, or if it is discovered that you have withheld some vital information pertaining to your past medical history or you do not meet the study requirements or if the study is cancelled for administrative reasons.
STUDY SCHEDULE
The following is the schedule for the study: **Periods I, II and III**

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>12.00 p.m.</td>
<td>Admission of volunteers to Ranbaxy Clinical Pharmacology Unit, Vitals signs, and Clinical examination.</td>
</tr>
<tr>
<td>Admission</td>
<td>9.00 p.m.</td>
<td>Dinner</td>
</tr>
<tr>
<td></td>
<td>10.30 p.m.</td>
<td>Bed-time</td>
</tr>
<tr>
<td>Day 2</td>
<td>7.30 a.m.</td>
<td>Pre-dose blood sampling with cannulation, vitals signs, Clinical examination.</td>
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<tr>
<td>Dosing and Blood Sampling</td>
<td>8.30 a.m.</td>
<td>Breakfast</td>
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<tr>
<td></td>
<td>9.00 a.m.</td>
<td>First dosing of reference drug followed by post-dose blood sampling at 0.500, 1.000, 1.333, 1.667, 2.000, 2.333, 2.667, 3.000, 3.333, 3.667, 4.000, 4.500, 5.000, 6.000, 8.000, 10.000, 12.000, 12.500, 13.000, 13.333, 13.667, 14.000, 14.333, 14.667, 15.000, 15.333, 15.667, 16.000, 16.500, 17.000, 18.000, 20.000, 24.000, 30.000, 36.000 hours.</td>
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<tr>
<td></td>
<td>11.00 a.m.</td>
<td>Vital signs</td>
</tr>
<tr>
<td></td>
<td>1.00 p.m.</td>
<td>Lunch</td>
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<tr>
<td></td>
<td>3.00 p.m.</td>
<td>Vitals signs</td>
</tr>
<tr>
<td></td>
<td>7.00 p.m.</td>
<td>Vitals signs</td>
</tr>
<tr>
<td></td>
<td>8.15 p.m.</td>
<td>Dinner</td>
</tr>
<tr>
<td></td>
<td>9.00 p.m.</td>
<td>Clinical examination and II dosing of reference drug.</td>
</tr>
<tr>
<td></td>
<td>11.00 p.m.</td>
<td>Vitals signs</td>
</tr>
<tr>
<td>Day 3</td>
<td>9.00 a.m.</td>
<td>Breakfast, vitals signs, clinical examination and 24 hour sample</td>
</tr>
<tr>
<td>Discharge</td>
<td>1.00 p.m.</td>
<td>Lunch</td>
</tr>
<tr>
<td></td>
<td>5.00 p.m.</td>
<td>Snacks</td>
</tr>
<tr>
<td></td>
<td>9.00 p.m.</td>
<td>36-hour sample, vitals signs, clinical examination and discharge</td>
</tr>
<tr>
<td>Day 4 Visit</td>
<td>8.30 a.m.</td>
<td>Visit to CPU for 48-hour sample and vitals signs</td>
</tr>
</tbody>
</table>

Adverse event monitoring will be done on admission, predose, every 4 hours post dose until discharge and at every ambulatory visit during each period.

**Note:** Dosing and subsequent sample time will be suitably staggered.

*Thank you for the time spent by you in reading/understanding the information provided in this leaflet.*

Signature  ___________________
DECLARATION

Title of the study: An open label, balanced, randomized, three-treatment, three-period, three-sequence, crossover bioavailability study comparing single dose of two batches of Pregabalin 600 mg extended release tablet of Ranbaxy Laboratories Limited, with two oral doses of Lyrica 300 mg capsules (each dose containing Pregabalin 300 mg administered 12 hourly; total dose 600 mg of Pfizer GmbH) in healthy adult, human, male subjects under fed condition.

Protocol Number: 323_PREGA_09

Status of Study Drug: Available for clinical use

I hereby declare that:
- My participation in this study is voluntary.
- This study is a research project and provides me no medical benefits.
- I have the right to be provided with answers to questions arising during the course of the study.
- I will be provided any significant new findings coming to light during the research investigation.
- I have been provided with a copy of the Informed consent form.
- I can withdraw from the study at any time without prejudice to future medical care or selection for future studies.
- I can be dropped out from the study at any time if I violate the study protocols or to protect my health.
- My date of birth is ____________ and I am more than 18 years but less than 45 years of age.
- My reference number with respect to volunteer enrolment of Ranbaxy Research Laboratories is ____________.
- I currently require no medical treatment or care.
- I have withheld no information regarding my past medical history and current drug intake.
- I have read the consent form and any questions I had about the study, possible side effects or the consent form, have been answered to my satisfaction.
- I voluntarily give my consent for my personal data related to any information relating to me, as I have provided in the enrollment form, or as it is generated during screening and study procedures, including identification number, or factors specific to my physical, physiological, mental, economic, cultural or social identity, to be processed as required for the study requirements. I also voluntarily give my consent for the processing of data.
- I am aware that my biological samples shall be anonymized or destroyed as per the requirements of the procedures of the study.
- It is my right to obtain information at reasonable intervals and without excessive delay regarding whether or not data relating to me are being processed.
- It is my right that, unless required by law, or while fulfilling a contract, with suitable measures to safeguard my legitimate interests:

Signature ___________________
“No automated processing of my personal data shall be done which makes me subject to an automated decision, produces legal effects concerning me or significantly affects me.”

- “No automated processing of my personal data shall be done to evaluate certain personal aspects relating to me, such as my performance at work, creditworthiness, reliability, conduct, etc.”

- During the past 12 weeks I have not participated in any experimental studies conducted here or elsewhere.

- I will maintain discipline during my stay at the Jamia Hamdard campus.

- If I have any further questions regarding this research study or in the event of research related injury, I may contact, Clinical Investigator Phone No. 2995-8529 (Office) or Dr. Tausif Monif, Study Director mobile no. (9810191920). I may contact Dr. Farhan Jalees Ahmad, Convener/Member Secretary, Jamia Hamdard Institutional Review Board (Telephone number 9810720387) or Prof. P.L. Sharma (Telephone number 2605-9688, Extn 440), if I have any questions regarding my rights as a volunteer.

- My signature confirms that consent is based on information provided and that I had freely chosen to participate without prejudice.