Appendix – IV
INFORMED CONSENT FORM

I, ______________________________ exercising my free power of choice, hereby give my consent to be included as a patient in the clinical study “Impact of CYP2C19 Genetic Polymorphism on Population Pharmacokinetics of Omeprazole in South Indian Patients”

I agree to the following:

1. I am over 18 years of age. [ ]

2. I understand that I will not be given any new study medication for participation in the study. [ ]

3. I understand that, since I am already taking the drug omeprazole as prescribed by doctor, I become eligible to be included in the study. [ ]

4. I also understand that I may need to give three to four blood samples on different days that will be used to estimate the drug level in my body. [ ]

5. I also understand that the information thus gathered will be helpful in optimizing drug therapy. [ ]

6. I have been informed to my satisfaction by the investigator about the purpose of the clinical study and study procedures including the investigations to monitor and safeguard my body functions. [ ]

7. I have been given a full explanation by the investigator, of the nature, purpose, likely duration of the study and about what I will be expected to do. I have fully understood the information sheet given to me. [ ]

8. I have been given the opportunity to question the investigator on all the aspects of the study, and I have understood the advice and information as a result. [ ]

9. I have informed about all medications that I have taken in the recent past and those I am currently taking. [ ]

10. I have not taken part in any investigational study for the past one month. [ ]
11. I am also aware of my right to opt out of the study at any time without giving any reason for doing so.                       

12. I am also aware that my DNA will be isolated from my blood sample and analysis will be done. I give permission to use such genetic information only to this study. 

13. I hereby give permission for the investigators of this study to release the information regarding or obtained as a result of the participation in the study to Mr. Arun K P. I understand that medical records that reveal my identity will remain confidential except that they will be provided as noted above or as may be required by law.                       

Signature of the patient* with date

Signature of the impartial witness* with date

I confirm that I have explained the nature, purpose and possible hazards of the above study to _______________________________

Signature of the Investigator with date

* Signature of the impartial witness is required only if the patient is illiterate; Impartial witness will ensure that the patient information sheet and patient consent form were explained to the patient in a language understood by the patient.

Name and address of the impartial witness____________________________