RESEARCH METHODOLOGY AND PLAN OF WORK

- Literature survey:
  Literature survey will be carried out by referring the books, related journals. Also by using Internet Access various National as well as international journals will be followed for referencing.

- Development of Study Documents:
  The essential documents required for this Clinical study like study protocol, Study ICF (Informed Consent Form), CRF (Case Report Form) etc. will be generated.

- Ethics committee approval:
  The Ethics Committee will be invited for the evaluation of the study and for the approval of the study. The study documents generated will be submitted to the Ethics Committee two days prior to the meeting.

- Procurement of study drugs:
  For this study, marketed formulation of the Itopride will be taken.

- Method development and validation for analysis of drug
  For the evaluation of the study drug in the given blood sample, new HPLC method will be developed and validated.

- Study subject recruitment
  Sufficient number of healthy human volunteers will be enrolled in the study as per the inclusion and exclusion criteria. The study subjects will be screened for the eligibility criteria and will be randomized in two arms.

- Drug dosing to subjects and sample collection
  Dosing of the study drug and collection of the blood samples will be done as per the protocol approved by Ethics Committee.

- Sample processing and analysis
  Their blood samples will be analyzed by high performance liquid chromatography (HPLC). A validated HPLC method will be employed for the estimation of Itopride in human plasma.

- Data collection and Statistical analysis
Pharmacokinetic parameters will be calculated using Non compartmental pharmacokinetic data analysis software. The statistical analysis of the obtained results will be carried out using ANOVA.