METHODOLOGY AND WORK PLAN:

- Literature survey of both API’s for their physicochemical properties
- Development of rapid, simple and robust method for combination drugs in tablet dosage form for a routine quality control analysis
- Optimization of developed method to meet the required goals
- Estimation of both drugs in tablet dosage form.
- Forced degradation studies as per recommendations of ICH guidelines
- Validation of developed method as per ICH guidelines

The proposed methods to be used in the study are:

- Collection of standard & sample from reliable source in pure form
- Solubility Determination for API in suitable solvent
- Selection of wavelength either by U.V. Spectroscopy or by using PDA detection
- Sample pretreatment if any (eg- extraction, filtration, derivitization, etc.)
- Selection of initial chromatographic conditions On the basis of structure, functional groups, pH and pka values of sample. This includes -
  - Selection of buffer
  - Selection of diluent
  - Selection of mobile phase
  - Selection of stationary phase
  - Selection of sample temperature
  - Selection of column temperature
  - Selection of sample volume
  - Selection of buffer concentration
- Selection of mobile phase pH

- Determination of Solution stability on the bench top

- Optimization of the method, based on the conclusions of the initial chromatographic Conditions

- Validation of the developed method as per ICH guidelines

For validation, the developed method is subjected to following parameters:

**Precision**: repeatability, reproducibility and ruggedness will be carried out by injecting the standard and samples in the system, and then the assay results will evaluate the precision parameter as per the ICH norms.

**Linearity**: Linearity of the proposed method will be carried out over the required range of samples assay concentration

**Specificity**: it will be carried out by checking any interference at the retention time of both of the drugs. Even interference from the degradation products will also be of consideration during the study.

**Limit of detection**: and **Limit of quantitation**: will be determined by studying the linearity and range values of the method and will be calculated according to the results obtained thereof.

**Robustness**: small but deliberate variations in method parameters such as buffer pH, column temperature, flow rate, injection volume, and wavelength will be applied to know the reliability of the method for its routine use.