METHODOLOGY AND WORK PLAN:

Methodology:
- Collection of standard & sample from reliable source in pure form.
- Solubility Determination for API in appropriate solvent or their mixture of solvents
- Determination of the λ max for API formulation by U.V. Spectroscopy
- Preparation of same concentration solution for both standard & sample by help of their label claim mentioned.
- Method development for the assay by UV spectroscopy.
- According to ICH guideline, validate the above new method.
- On the basis of solubility studies, the diluents & mobile phase composition can be decided for further research work.
- Preparation of same concentration solution for both standard & sample by help of their label claim mentioned.
- Selection of column on the basis of previous work done on individual drugs, mainly C8 or C18 column.
- Determination of isocratic or gradient mode for analysis on the basis of previous done as well as primary run on HPLC system.
- Determination of Solution stability by run on HPLC.
- Optimization will be done by changing the proportion of mobile phase, as well as doing trail on different grade column.
- According to ICH guideline, validate the above new method.
Various parameters studied for Method Validation

For validation the developed method is subjected to following studies:

- **Accuracy**: It is the concordance between it and the true or most probable value.
- **Precision**: It is the concordance of a series of measurements of the same quantity.
- **Linearity**: The linearity of an analytical procedure is its ability within a given range to obtain test results that are directly proportional to the concentration of analyte in the sample.
- **Specificity / Selectivity**: It is the ability to assess unequivocally the analyte in the presence of components that may be expected to be present.
- **Limit of detection**: It is the lowest amount of analyte in a sample that can be detected but not necessarily quantitated as an exact value.
- **Limit of quantitation**: The quantitation limit of an analytical procedure is the lowest amount of analyte in a sample that can be determined quantitatively with suitable precision and accuracy.

**Robustness / Ruggedness**: The robustness of an analytical procedure is a measure of its capacity to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal use.

**Plan of work:**

- Literature survey of API regarding their physical, chemical properties.
- To develop simple, precise, economical method in combination dosage form for a routine quality control analysis.
- Estimation of both drugs from capsule dosage form.
- Forced degradation studies.
- Validation of developed method according to ICH guidelines.