WORK PLAN AND METHODOLOGY

1. Literature survey
   - Perform literature survey of physicochemical properties, dosage forms, dose strengths and pharmacokinetic profile of interested drug molecules.
   - Search available method for selected molecules in the published journals, books, research article and industrial regulatory guidelines.

2. Characterization of working drug standards will be carried out by using full scan parent ion molecular weight (m/z) determination.

3. Solubility data: Determine the solubility, pH and pKa of the selected drug molecules, if data is not published.

4. Instrumental Method Development: During the development of analytical method different parameters will be optimized. Some of important parameters are mentioned below.
   - Information on Drug molecular weight, physicochemical properties etc.
   - Tuning of the molecule in MS in full scan for the determination of Q1 and Q3 molecular (m/z) values of drug reference standard working solution.
   - Selection of interface type, which separates the sample from the solvent, and allows the introduction of the sample in the form of dry particles into the high vacuum region
   - HPLC procedure includes the selection of Column, mobile phase and compositions of solvents for separation.
   - Optimise the best Separation conditions for selectivity and to avoid the matrix effect.

5. Optimization of Extraction procedures
   Drugs and metabolites sample cleanup from biological fluid from interfering compounds is possible using different types of extraction technique which are summarized below.
   - Liquid-Liquid Extraction
   - Solid phase extraction:
     - Precipitation method
     - Ultra filtration
     - Hybrid SPE-PP

6. Validation of the developed methods
   Bioanalytical method validation (BMV) is a tool of quality assurance which provides confirmation of the quality in equipment system, manufacturing processes, software and testing methods. Validation assures that products with pre-determined quality characteristics and attributes can be reproduced consistently within the establish limits. Bioanalytical
validation is the process of demonstrating that analytical procedures are suitable for intended use.

Method Validation Parameters
The fundamental validation parameters will be carried out are described below.

- Selectivity and Matrix effect.
- Accuracy and Precision
- Linearity
- Sensitivity Recovery
- Stability of Freeze thaw cycle, Short-Term stability etc.

The developed method may be employed as a base for further research. They should be greatly useful for routine quality control of any of the class of compounds studied and would be useful to any analytical chemist working on the class of compounds.