4. PLAN OF WORK AND METHODOLOGY

1. Literature review - It will performed as per National, international journals and E-journals.
2. Procurement of drugs and Chemicals.
3. Identification of procured drugs.
4. Physico-chemical characterization of procured chemical entities.
5. Development of validated analytical method.
6. Optimization of various variables during analytical method development.
7. Application of analytical method for the marketed formulation of drugs or synthetic mixture.
8. Studies on different validation parameters for the analytical methods

4.1 UV-Visible spectroscopy:

1. Selection of solvent for solubility of the formulation and reference standard: The appropriate solvent for solubilizing drug is selected by using different solvent having different polarity.
2. Determination of maximum wavelength: A single concentration of the drug will be prepared in the solvent selected to determine the \( \lambda_{\text{max}} \).
3. Preparation of calibration curve: Different concentrations of the standard drug are prepared and their absorbances curved are obtained. Then the calibration curve is plotted for getting standard deviation, relative standard deviation and r-co-efficient.
4. Selection of UV-Visible spectrometry method and application to formulations: The different UV-Visible spectroscopy methods are conducted such as derivative spectroscopy, QA absorption ratio, simultaneous estimation, etc. The method which shows good resolution will be selected for analysis of formulations or synthetic mixtures.
5. Validation of developed method: The same method also is validated as per ICH guidelines with respect to linearity, precision, sensitivity, accuracy, selectivity etc. to prove the suitability of the method.
4.2 High performance liquid chromatography:

1. **Selection of the mobile phase:** Depending on the solubility of the drugs the mobile phase will be selected. The different solvent in different combination will be tried as the mobile phase and the mobile phase which give the better resolution and peak will be selected for the further optimization of the procedure.

2. **Selection of the column:** Different columns are available in the market. From the literature review the proper column for the separation and identification of drugs will be selected.

3. **Determination of maximum wavelength:** With the help of UV-Visible spectrometer the maximum wavelength of the drug will be found out using the mobile phase as the solvent.

4. **Preparation of calibration curve:** Different concentrations of the standard drug are prepared and their spectrums are obtained. Then the calibration curve is plotted for getting standard deviation, relative standard deviation and r-co-efficient.

5. **Analysis of commercial formulations by the proposed method:** commercially available formulations of drugs from the Indian market will be taken for estimation of total drug content by the proposed method.

6. **Validation of the same method:** The same method will also be validated as per ICH guidelines with respect to linearity, precision, sensitivity, accuracy, selectivity etc. to prove the suitability of the method.