OBJECTIVE OF PRESENT WORK:

- To develop a simple, precise, accurate, rapid, and economical and stability indicating analytical method for estimation of API in formulation using HPLC method.
- To validate the developed method for estimation of API in formulation using HPLC method.
- Development of UV method for API in formulation using UV-VIS Spectrophotometer.
- To perform forced degradation study in solid dosage form.

Quantitative analysis of any drug is an important tool in an industry. It is important to determine that the raw material, intermediate product as well as final product meet its specification and are of required quality. The number of drugs and drug formulation introduced into the market has been increasing at an alarming rate. These drugs or formulations may be either new entities or partial structural modification of the existing ones or novel dosage forms.

Spectrophotometric method is to be developed first, as it is simple and quick. It was also aimed to validate the method, so that it can be employed for online analysis of the drug and its formulation.

Pharmacopeias are replacing the chemical methods and spectrophotometric methods by more sensitive and accurate HPLC methods for the analysis of drugs as well as their formulations. Hence it was thought proper to develop a validated HPLC method for analysis of API formulation.

Developed methods proposed to be validated using the various validation parameter such accuracy, precision, linearity, rang, limit of detection, limit of quantitation, selectivity, specificity, robustness, ruggedness, stability and system suitability.

Forced degradation study will be done to see the extent of degradation and interference from the various degradants. The developed method will be validated to observe its reliability.

Finally results of HPLC methods and dissolution study will be observed.