PREFACE

Medicinally important organic compounds are the chemical substances which are having the pharmacological activities on the human body. These are the chemical compounds originated from synthetic origin or semi synthetic origin some of which are molecules from natural products. These should be pure enough to have its therapeutic activity when it was got synthesized/extracted from natural source known as Active Pharmaceutical Ingredient (API) and the API converted into a pharmaceutical dosage form which is an acceptable form for Human consumption to cure a particular disease. The purity of API is dependent on various factors such as route of synthesis, purification process, manufacturing process, storage, transportation etc. where no one can produce 100% pure API as well as Pharmaceutical dosage form, and also during the process synthesis of API/manufacturing of a pharmaceutical dosage form drugs prone get contaminated with toxic impurities (such as process impurities and degradation impurities) which will tremendously impact on its therapeutic activity. In this scenario the analytical method plays vital role to determine the purity of drug which ultimately helps to protect Human beings from furious drugs.

The major challenge of pharmaceutical industry in today’s scenario is to develop new drugs with high safety, efficacy and potentiality through advanced therapeutic techniques for the safe human health. Drug eminence in quality, stability, metabolism, pharmacokinetics,
and toxicity studies oblige the amount of medicine in pharmaceutical formulations and biological samples. Likewise, competent and validated analytical methods are very indispensable for all these explorations. Most of the pharmaceutical manufacturing endeavours rely on both quality and quantitative chemical analysis to make certain that the substance used ought to meet required specifications and furthermore to ascertain the eminence quality of the finished dosage forms. Quantitative analysis is performed to establish the proportion of the essential components which is often referred as the “Related Substances” and “Assaying”. The Drug substances and finished dosage form is subjected to quality control to ascertain that its essential constituents are extant within the specification limits. For these determination it is therefore very much important to have a precise and accurate “VALIDATED ANALYTICAL METHODS”.

In initial stage of drug development, the finished product will be subjected to accelerated stability conditions to know the life time of the drug and to provide stability indicating methods. During this stage at different time points the drug will be subjected to quality control testing to know whether the drug product is meeting all the specifications. For this purpose we should have stability indicating methods is required.

Validation of an analytical procedure is the course of action by which the analytical method shall be demonstrated for its suitability,
specificity and its intended purpose. Various analytical parameters as prescribed in the ICH, USP guidelines like precision, accuracy, linearity, sensitivity, specificity/selectivity, ruggedness and robustness. These data shall also become a documentary evidence for the technology transfer from Analytical Research and Development laboratory to Quality Control laboratory.

In this perspective, “analytical chemistry of medicinally important compounds” has been taken up by using high performance liquid chromatography which is most popular chromatographic technique in confiding for Related Substances, Assay and Dissolution profile and results are incorporated in this thesis.

At the end referred to coverage of literature in the present investigations shown in the form of bibliography. The reference in this thesis is followed by appendix where in listed the published research articles in international journals of repute and list of seminars/conferences attended.