PREFACE

Health is of prime importance to a human beings and wants to get cured in the least possible time whenever they falls ill. This desire and necessity has resulted in the use of a large number of synthetic organic compounds as medicines despite the fact that usually side effects are related with the utilize of these drugs. In recent times, practice of giving a number of drugs together has very much increased. Due to drug interaction, the levels of the active drugs together has very much increased. Due to drugs interaction, the levels of the active drug may be too high for a longer time to cause side effects. Further, the reduction/oxidation products of these medicines, which are produced during the metabolism may also be responsible for their side effects. It is therefore necessary to develop sensitive trace analytical methods for the analysis of the drugs by using most sophisticated and advanced chromatographic techniques like GC, HPLC, UPLC etc.

Main aim of present research work is to develop and validate new analytical methods by employing UPLC/HPLC techniques for qualitative and quantitative analysis of selected drugs which are very important medicinally for present research work. The objective of research work is to reduce analysis time, solvent consumption, sample quantity and simultaneous analysis of purity and assay. The developed analytical method must generate reproducible and reliable
data in order to permit valid interpretation of the studies they support.

Following category of drugs were selected for development and validation by employing Ultra performance liquid chromatography/High performance liquid chromatography Anti migraine and 5-alpha-reductase drugs. Zolmitriptan, Rizatriptan benzoate and Sumatriptan succinate were opted under anti migraine drugs, Finasteride and Dutasteride are selected under 5-alpha-reductase drugs in Pharmaceutical bulk drugs.

The systematic study of analytical method development and method of validation for purity and assay assessment has been carried out and presented in the thesis. The entire thesis consists of eight chapters.

**Chapter-1** was described general introduction, brief history of chromatography, method development, forced degradation studies and validation analytical methods for quality testing of Active pharmaceutical ingredients in pharmaceutical research and development.

**Chapter-2** refers to the survey of concerned literature on anti migraine and 5-alpha-reductase drugs.

**Chapter-3** to **Chapter-7** is devoted to the method development and validation of new analytical methods HPLC/UPLC for selected drugs for the present research work.
Chapter-8 described as Summary & conclusion of the present investigation and relevant recommendations.

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