PREFACE

Now a days, the method development of drug molecule is a major concern as it affects the safety, quality and efficacy of the drug product. The regulatory guidelines like US-FDA (food and drug administration), EMEA (European medicines evaluation agencies), ICH (international conference on harmonization) etc., stresses the importance of method development of the drug. Stability testing of API (active pharmaceutical ingredient) is performed by subjecting the drug to forced degradation studies or stress studies. The concept of stress studies was discussed in ICH Q2 guidelines as it helps in finding out the intrinsic stability of the molecule, likely degradation products, which in turn is helpful in establishing the degradation pathways and to authenticate the validation of analytical procedures developed. The type and degree of the stress testing is dependent upon the nature of individual drug substance and drug product involved. But these guidelines are very broad and does not provide real world approach in conducting stress studies.

This research thesis comprises of investigation on development of suitable analytical method to estimate the drug and identify their validations of the forced degradation studies. This investigation is a current trend in pharmaceutical stress studies, which requires validation of developed method as per ICH.

All the above methods were accurate, precise, specific and selective for the API and to the degradants. The developed methods were validated as per ICH Q2 guidelines. The API’s selected were
1. Armodafinil
2. Sofosbuvir
3. Tofacitinib citrate
4. Levo milnacipran HCL
5. Leflunamide

The methods developed by RP-HPLC are validated in accordance with ICH Q2 guidelines. The entire thesis can be framed in to seven chapters which includes as follows:

Chapter-1 This chapter gives brief picture on introduction to different analytical techniques and their role in pharmaceuticals. Brief introduction of chromatography and HPLC along with regulatory perspectives were also discussed.
Chapter-2 This chapter reviews several literature work connected to the selected research topic i.e., a complete insight on drug profile, chemistry, mechanism of action, pharmacology and different analytical techniques available for the quantification of selected drugs.

Chapter-3 This chapter gives an idea about aim, objective of the work along with commercial formulations, standard drugs, chemicals, regents and instruments, buffers and methodology followed in the experimental investigations.

Chapter-4 Fourth chapter reflects about various experimental investigations carried for chosen drugs using RP-HPLC.

Chapter-5 This chapter deals with various experimental results obtained during RP-HPLC method development and validation for selected drugs.

Chapter-6 This chapter is meant for discussion of results on selected drugs which are obtained during method development and validation by RP-HPLC.

Chapter-7 This chapter connected with overall summary, conclusion and recommendations of the present research work.