ABSTRACT

In this thesis we provide new analytical methodologies UPLC/HPLC that can be improves the analysis throughput and cycle times. The proficient research work has been divided into five chapters, The thesis is composed of four articles, three active pharmaceutical ingredient (API) and their dosage forms, one key intermediate selected for the analytical investigate work, supervision objective to extend a modern analytical methods for the purpose of related components which are suitable for quality and safety at quality control to release drug substance by stability indicating analytical methods. After thorough prose investigation reveals that no stability indicating methods for estimating the related process bi-products in the above stated four selected API’s, its precursors and their dosage forms be offered as on date. Few methods appeared in the literature for the estimation of human plasma, Urine, LCMS/MS etc. suitable new, simple, cost effective and stability indicating analytical methods were developed, observance the laid down regulatory necessities in mind and the established methods were thoroughly validated. The consistence of the developed new analytical methods for its related compounds determination has been checked by applying the same to assess the quality of drug substance samples during its developmental stability studies. The above developed new analytical methods were performed in good healthy for the quality advancement of stability samples of API and its procuresses.
The first chapter contains of a concise preface on the need for development and establishment of new analytical methods for associated components assessment, source of bi-products in pharmaceutical substances, regio isomers, necessity for control of impurities, ICH quality guidelines, USP/EP/IP/JP pharmacopeial norms, control of organic bi-products, FDA recommendations, way forward for development of stability indicating methods associated LC contents of method validation parameters and dialogue on how to develop a new method approaches on the common methodology for LC analysis. The remaining chapter 2-5 consists (UPLC/HPLC) of introduction, investigational, validation, results and conversation. In the introduction part a concise description on the therapeutic activity, drug substance and product, and require to developing novel method advance were discussed. In the supplementary sections chemical used for the analysis, explanation of the desired instruments used, working or reference standard samples, test sample solution, a entire description on the steps taken for developing the latest analytical methods for the estimation of related components which are stability indicating and analytical validation methodology were discussed. Typical chromatograms, tables, figures, equations and related analytical information were also offered. The data of the method validation parameters, test sample study and the finishing outline of conclusion were also furnished. The detailed discussions were discussed in the individual chapters.