ABSTRACT

The present research carried out to establish new analytical methods for active pharmaceutical ingredients (API) and the key intermediates of API in estimation of related substances and assay of new compounds and their dosage forms. The proficient research work has been divided into six chapters. The first chapter consists of a brief introduction on the need for development of new analytical methods for related components estimation, source of impurities in pharmaceutical substances, requirement for control of impurities, pharmacopeial norms, ICH quality guidelines, FDA recommendations, multi-detection system composed of ultraviolet, evaporative light scattering detection for the analysis of pharmaceuticals by liquid chromatography, new technology of stationary phases, various hyphenated techniques, approaches for development of stability indicating methods with LC contents of method validation parameters and discussion on how develop a new method approaches on the general methodology for LC analysis. The remaining chapters 2-6 consists of Introduction, experimental, Validation and results and discussion. In the introduction part a brief account on the drug molecule, therapeutic activity and method development approach were discussed. In the other sections chemical used for the analysis, description of the instruments used, reference standard solution, test sample solution, tablet details and their preparation, a detailed account on the steps taken for developing the new analytical methods for the determination of related components which are
stability indicating and validation methodology were discussed. Typical chromatograms, tables, figures and graphs and related analytical data were also presented. The results of the validation parameters, sample analysis data and the final summary of conclusion were also furnished.