PREFACE

Generally, the active pharmaceutical ingredients are manufactured either by a total synthesis approach or by changes of natural processes, during the course of this development process, wide range of reactive reagents and intermediate were used. So the presence of key starting materials, reagents, intermediates and by-products at very low-level in active pharmaceutical ingredient (API) or a drug product is common. Impurity profile of all active pharmaceutical ingredients and their products is very important in pharmaceutical industries as their acceptable limits (reporting, identification and qualification thresholds shall be calculated as per ICH) are very low.

Development of an appropriate validated stability indicating HPLC/UPLC method for the quantification of impurities in the active pharmaceutical ingredient and drug products at lower level is very vital. As per the current US FDA, ICH and other regulatory requirements, the stability samples should be analyzed through the methods with stability indicating nature. Development of quantification methods for the impurities in drug products is a challenge for the analytical scientist. The developed analytical methods must be validated to provide reliable data to regulatory agencies for the release of the drug products in the market.

Methods for the determination of impurities at a lower level, using ultraviolet-visible spectrophotometry, thin layer chromatography is difficult as these techniques are used for the identification purpose only. HPLC is the successor of the above mentioned techniques and has made significant contribution to the growth of analytical science due its diverse applications in pharmaceuticals, foods, polymers and plastics, environmental monitoring and clinical fields. In this view, our research work is aimed at developing simple, cost effective and shorn run time HPLC/UPLC methods for the determination of impurities in the following selected dosage forms.

- Erlotinib hydrochloride dosage forms
- Raloxifene hydrochloride dosage forms
- Fampridine dosage forms
- Combined dosage forms of lamivudine and tenofovir disoproxil fumarate

- Emtricitabine, tenofovir disoproxil fumarate and efavirenz pharmaceutical dosage forms.