ABSTRACT

This research work emphasizes the development of High Performance/Ultra Performance Liquid Chromatography (HPLC/UPLC) methods for the determination and quantification of impurities in selected pharmaceutical finished dosage forms. The proposed work also covers the validation of the developed methods as per International Conference on Harmonization (ICH) requirements. This work demonstrates the fitness of the developed methods in checking the quality of the drugs and also in assessing the stability of finished dosage forms.

Five drug products, erlotinib tablets, raloxifene tablets, fampridine tablets, lamivudine and tenofovir double combination tablets and emitricitabne, tenofovir and efavirenz triple combination tablets, are selected for the present research work. The objective of the present research work is the development and validation of HPLC/UPLC methods for the determination and quantification of the impurities in above selected drug products.

The thesis entitled ***"Separation and quantification of impurities in important pharmaceutical drug products by liquid chromatography"*** has been divided into seven chapters as given below

1. Introduction
2. Literature survey
3. Development and validation of stability indicating RP-HPLC methods for determination of related substances in anti-cancer drugs
4. Development and validation of a stability indicating HPLC method for the quantification of impurities in fampridine dosage forms
5. Development and validation of a stability indicating HPLC method for the quantification of eleven impurities in lamivudine and tenofovir disoproxil fumarate
6. RP-UPLC method for the simultaneous quantification of related substances in emtricitabine, tenofovir disoproxil fumarate and efavirenz pharmaceutical dosage forms.
7. Summary, conclusion and recommendation