A comprehensive summary of the work incorporated in the thesis entitled “DEVELOPMENT AND VALIDATION OF NEW ANALYTICAL METHOD FOR BIOACTIVE COMPOUNDS” has been described as under.

Chapter-1 introduces the basic instrumentation of high performance liquid chromatography and ultra performance liquid chromatography, advancement of chromatography and the underlying physico-chemical principles which account for the retention of sample molecules in a chromatographic system.

Chapter-2 includes development of chromatographic methods for separation, identification, and quantification of pharmaceutical compounds, application of various functions in the drug development continuum. Explain the parameters that must be considered in the validation of analytical methods.

Chapter-3 deals with the simultaneous determination of ambroxol hydrochloride, cetirizine hydrochloride, methylparaben, and propylparaben in liquid pharmaceutical formulation using the developed and validated, stability indicating, RP-UPLC method. The developed method is able to separates AMB, CTZ, MP and PP with each other and from its all twelve (AMB impurities A, B, C, D, E and CTZ impurities A, B, C, D, E, F, CDH1) known impurities/ degradation products and one unknown degradation product within 3.5 min. The run time (3.5 min) enables rapid determination of drugs and preservatives. Developed method can be applied for individual and simultaneous determination of AMB, CTZ, LCTZ, MP and PP compound in pharmaceutical drug product and substance.

Chapter-4 emphasizes on the assay determination of quetiapine in solid oral dosage form using the developed and validated, stability indicating, RP-UPLC method. The developed method separates
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Quetiapine from its five impurities/degradation products within a run time of 5 min. The run time (5.0 min) enables rapid determination of drug. Moreover, it may be applied for determination of QUE in the study of blend uniformity, tablet content uniformity and in-vitro dissolution profiling of QUE dosage forms, where sample load is higher and high throughput is essential for faster delivery of results.

Chapter-5 covers with the low level (high sensitive) determination of Aniline/Genotoxic impurity in Mesalamine delayed release tablets using the developed and validated, stability indicating, RP-UPLC method. The total run time is 5min, within which drug and their degradation products are separated from aniline. Developed method provides high throughput solution for determination of aniline in the mesalamine delayed release formulation with excellent selectivity, precision and accuracy. This method can also be applied for quantifying the trace levels of aniline from drug substances, drug products and different type of samples.

Determination of mesalamine related impurities in mesalamine delayed release tablets using the developed and validated, stability indicating, RP-UPLC method is furnished in Chapter-6. The total run time is 15 minutes, within which drug and its six impurities/degradation products are well separated from each other. This method can be successfully applied for the routine analysis as well as stability study of mesalamine delayed-release drug product.

Chapter-7 deals with the determination of Metaxalone and its related substances in solid oral dosage form using the developed and validated, stability indicating, RP-UPLC method. The developed method separated META from its two known and two unknown impurities within 6.0 min. The run time (6 min) enabled rapid determination of META. This method exhibited an excellent performance in terms of sensitivity and speed. This stability-indicating method can be applied for the routine analysis of production samples and to check the stability of Metaxalone in bulk drug and formulation.