PREAMBLE

Quality control is an essential operation of the pharmaceutical industry. Drugs must be marketed as safe and therapeutically active formulations whose performance is consistent and predictable. Day by day new and better medicinal agents are being produced at an accelerated rate. At the same time there exists the need of more accurate and sophisticated analytical methods for their quantification.

Analytical method development, validation and transfer are key elements of any pharmaceutical development program. Method development should be done with the goal to rapidly test preclinical samples, formulation prototypes and commercial samples.

The novel analytical methods involve the analytical methods in combination with various statistical aids. The combination of the conventional analytical methods with statistical methods results into such techniques which can be applied for the analysis of complex and large number of data. In routine practice, it becomes a daunting challenge for an analyst to work with such a complex data which can be easily simplified and resolved with the novel techniques as presented in the research work. The pathway of statistics helps the journey of analytical methods to reach their destination with a clear cut aspect of understanding and recognizing the risks and failures well in advance. Hence the work presented involves the techniques like chemometrics and quality by design by which various analytical methods have been explored to reach their ultimate goal.

Chemometric techniques like regression analysis have been used to integrate and simplify the complicated data of spectrophotometry, FTIR spectrometry, Raman spectrometry and NIR spectrometry. The techniques like partial least square and principle component regression analysis have been fruitful in achieving desired quantification for UV spectrophotometric data. The very complex and huge data of FTIR, Raman and NIR have been qualitatively analyzed with the help of principle component analysis and cluster analysis.

The Quality by Design (QbD) approach extended to Analytical QbD (AQbD) has proven to give successful results in method development by working out various design of experiments (DoE) like Full factorial, Plackett-Burman and Box-Behnken designs.

At the time of initiating this study, the techniques like chemometrics and QbD had just been introduced and were at evolving stage and hence have been explored and studied through the research work.

The stability indicating analytical methods have been developed with the objective of understanding the degradation mechanism and degradation kinetics. The bioanalytical method has been developed for the estimation of the drugs by LC-MS analysis.

Thus the work presented, includes various novel analytical methods which have a wide scope and can be applied very successfully in routine analytical estimations.