AIM

The ever increasing number of drugs and their combinations in the market leads to the need for the development of analytical methods for their quality control. The methods have to be such that it takes less time in their development as well as the best accurate and robust results should be obtained. Based on this concept the aim of the research work was to develop novel analytical methods with the aid of statistical approach such as chemometrics and Quality by Design and to further extend this study to applicability of these methods.

OBJECTIVES

Keeping this aim in perspective, specific objectives of the study were planned as follows:

I. To develop analytical methods for multicomponent systems

- To develop and validate RP-HPLC method for the simultaneous determination of Phenylephrine hydrochloride, Paracetamol, Guaifenesin, Chlorpheniramine maleate and Bromhexine hydrochloride in tablet formulation, and to study the applicability of the method for dissolution studies.
- To develop and validate UV assisted chemometric methods i.e. partial least square regression method and principle component method, for the simultaneous determination Phenylephrine hydrochloride, Paracetamol, Guaifenesin, Chlorpheniramine maleate and Bromhexinehydrochloride in tablet formulation and to study the applicability of the method for dissolution studies.
- Statistical comparison of newly developed RPHPLC and chemometric methods by ANOVA.

II. To develop analytical methods by using the QbD approach

- To develop and validate RP-HPLC method by QbD approach i.e. by using full factorial design for the simultaneous estimation of Ofloxacin (OFX), Ornidazole (ORN), Terbinafine hydrochloride (TBH) and

Clobetasolpropionate (CBP) in cream formulation and to study the applicability of the method for permeability studies.

- To develop RP-HPLC method for the simultaneous estimation of Azelastine hydrochloride and Budesonide by using Plackett-Burman design for screening and Box-Behnken design for optimisation of various factors affecting the RP-HPLC separation.
- To extend the applicability of the method for bioanalytical application for the estimation of Azelastine hydrochloride and Budesonide in human plasma by LC-MS/MS method.

III. To develop stability indicating analytical methods (SIAM)

- To develop a stability indicating analytical method for simultaneous estimation of Azelastine hydrochloride and Budesonide, characterisation of the major degradation products with LC-MS/MS analysis and proposing their degradation pathways.
- To develop a stability indicating analytical method for simultaneous estimation of Silodosin, characterisation of the major degradation products with LC-MS/MS analysis and proposing their degradation pathways.

IV. To develop analytical methods for quality control of different brands

- To develop chemometric models which can be applied to study the quality and differentiate various brands of Amoxicillin trihydrate from the spurious or placebo samples.
- To develop chemometric models which can be applied to study the quality and differentiate various brands of the combination of Amoxicillin trihydrate and Potassium clavulanate from the spurious or placebo samples.