PREFACE

As per current pharmaceutical market, drugs are formulated in combined dosage forms rather than a single drug dosage form due to increased attention of pharmaceutical industries on ANDA and also for their increased therapeutic action or decreased side effects. For such dosage forms safety and efficacy becomes the first priority in view of regulatory bodies such as FDA, ICH and WHO. The Quality of these dosage forms are tested by quality control department by making use of analytical techniques which are available and suitable for those dosage forms. The result of the analysis depends on the method of choice. So, it is essential to develop analytical methods for any dosage form and is continues effort to be made by analytical scientists.

Analytical method for simultaneous analysis is considerably fascinated the analyst to undertake the development of new method. The developed method has to be validated considering various parameters which prescribed by regulatory guidelines.

In view of the above discussions, three different combinations of drugs were selected, for which new methods were developed on different instruments. All these methods were found to be accurate, precise, simple and economic. All the work was done in accordance with the International Conference on Harmonization (ICH) guide lines for method development and validation.
The following three combination drugs were selected

1. Metformin hydrochloride and Sitagliptin
2. Sitagliptin and Simvastatin
3. Diclofenac potassium and Tizanidine hydrochloride

The entire research work was categorized as below

1. **Chromatographic methods**
   - Simultaneous estimation of metformin and sitagliptin by RP-HPLC method.
   - Simultaneous estimation of sitagliptin and simvastatin by RP-HPLC method.
   - Simultaneous estimation of diclofenac potassium and tizanidine hydrochloride by RP-HPLC method.

2. **Spectroscopic methods.**
   - Simultaneous estimation of metformin and sitagliptin by UV-spectroscopy.
   - Simultaneous estimation of sitagliptin and simvastatin by UV-spectroscopy.
   - Simultaneous estimation of diclofenac potassium and tizanidine hydrochloride by UV-spectroscopy.

The present study was designed to develop new, simple and economical RP-HPLC methods and UV-Spectroscopic methods for the above combination drugs.