CHAPTER IX

SUMMARY AND CONCLUSIONS
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The drug analysis aims at obtaining data that can contribute to the maximal efficacy, safety and economy for the production of drugs since they are extremely important issues from the point of view of public health, financial and political. The analysis includes the investigation of bulk drug materials, the intermediates formed in their route of synthesis, products of drug research, drug formulations, impurities and degradation products, biological samples containing the drug and their metabolites. Thus, pharmaceutical and biomedical analysis forms the most important branches of applied analytical chemistry.

Quality assurance and quality control of pharmaceutical dosage forms are essential for ensuring the availability of safe and effective dosage forms to consumers. Hence, pharmaceutical analysis occupies a pivotal role to statutory certification of drugs and their dosage forms either by the industry or by the regulatory authorities. The complexity of problems encountered in pharmaceutical analysis, coupled with the importance of achieving the selectivity, speed, cost, simplicity, sensitivity, precision and accuracy, results in new methods of analysis being quickly adopted by the pharmaceutical industry and chemical industries, depending upon the facilities available.

Pharmaceutical dosage forms often contain combination of drugs for potentiating or complementing one another in therapy. In some cases, no precise analytical methods are reported and quite often the reported methods need
improvement or changes because of lack of specificity and sensitivity with existing methods.

The author developed totally seven HPLC methods for the estimation of different categories of drugs in bulk samples and pharmaceutical formulations either in single or combined forms. The author selected three drugs (Lamotrigine, Quetiapine fumarate and Levetiracetam) acting on Central nervous system for estimation in single dosage forms and three drugs (Atorvastatin calcium, Simvastatin and Ezetimibe) acting on Cardiovascular system and two Antiviral drugs (Lopinavir and Ritonavir) for estimation in combined dosage forms.

The author developed isocratic new HPLC method for the estimation of Lamotrigine in bulk sample and pharmaceutical formulation which is simple, faster and economic than earlier reported methods. The developed method was validated as per ICH guidelines. The total chromatographic run time is only 10 min allows the analysis of large number of samples with shorter time. This developed chromatographic method fulfilled all the requirements to be identified as reliable and feasible method including linearity, precision and accuracy data. Hence this simple HPLC method with UV detection can be adapted for routine analysis.

The author attempted and succeeded in the development of simple and specific HPLC method for the estimation of Quetiapine fumarate in bulk sample and pharmaceutical formulation. This developed method was validated as per ICH guidelines and developed method was simple, rapid and precise than the earlier reported methods. This chromatographic method fulfilled all the requirements to be
identified as reliable and feasible method including linearity, precision and accuracy data. It is highly precise and specific analytical procedure and its chromatographic run time of 10 min allows the analysis of large number of samples in a short period of time. Hence this simple HPLC method with UV detection can be adopted for routine analysis.

The author also developed a new HPLC method for the estimation of Levetiracetam in bulk sample and pharmaceutical formulation. The method was validated and validated parameters were reported. It is highly precise and specific analytical procedure and its chromatographic run time of 10 min allows the analysis of large number of samples in a short period of time. Hence, the method can be adopted for the routine determination of Levetiracetam in the pharmaceutical dosage forms.

The author developed an isocratic HPLC method for simultaneous estimation of Atorvastatin calcium and Ezetimibe in bulk sample and combined pharmaceutical dosage forms. In this method, a full scale validation to assess the viability of the method has been performed. The validation includes selectivity, specificity, linearity, precision, accuracy, limit of detection and quantification etc. Statistical evaluation of the data is also included and has been performed by the method of least square using regression factor, slope and intercept. Hence, this method can be adopted for the simultaneous analysis of Atorvastatin calcium and Ezetimibe in bulk samples and combined pharmaceutical formulations.
The author developed an isocratic HPLC method for simultaneous estimation of Simvastatin and Ezetimibe in bulk sample and combined pharmaceutical dosage forms. In this method, a full scale validation to assess the viability of the method has been performed. The validation includes selectivity, specificity, linearity, precision, accuracy, limit of detection and quantification etc. Statistical evaluation of the data is also included and has been performed by the method of least square using regression factor, slope and intercept. Hence, this method can be adapted for the simultaneous analysis of Simvastatin and Ezetimibe in bulk samples and combined pharmaceutical formulations.

The author also developed an isocratic HPLC method for simultaneous estimation of Lisinopril and Hydrochlorothiazide in bulk sample and combined pharmaceutical dosage forms using cyano silane column. In this method, a full scale validation to assess the viability of the method has been performed. The validation includes selectivity, specificity, linearity, precision, accuracy, limit of detection and quantification etc. Statistical evaluation of the data is also included and has been performed by the method of least square using regression factor, slope and intercept. Hence, this method can be adapted for the simultaneous analysis of Lisinopril and Hydrochlorothiazide in bulk samples and combined pharmaceutical formulations.

The author developed an isocratic HPLC method for simultaneous estimation of Lopinavir and Ritonavir in bulk sample and combined pharmaceutical dosage forms. In this method, a full scale validation to assess the viability of the method has been performed. The validation includes selectivity, specificity, linearity, precision,
accuracy, limit of detection and quantification etc. Statistical evaluation of the data is also included and has been performed by the method of least square using regression factor, slope and intercept. Hence, this method can be adapted for the simultaneous analysis of Lopinavir and Ritonavir in bulk samples and combined pharmaceutical formulations.

All the methods reported were simple and specific and can easily be adapted for the estimation of the selected drugs in the bulk samples and pharmaceutical formulations for the regular quality control applications.