AIM AND OBJECTIVES OF PRESENT STUDY

Every year the number of new drugs are being designed and introduced for therapy at constantly increasing pace. Subsequently, huge numbers of new dosage forms containing these drugs are introduced into the market. So, there is always a necessity for developing newer and efficient methods for determining these drugs in bulk samples and formulations. As a consequence of introduction of large number of newer drugs and their formulations, distribution of low quality or even counterfeit drugs and their formulations in the market is a main concern. Quality control and quality assurance of pharmaceutical chemicals and their formulations are essential for ensuring the availability of safe and effective drug formulations to the consumers and safeguarding the general public against the hazards of substandard drugs. With the outbreak of newer lifestyle diseases and increasing incidences of microbial resistance, use of the drugs and combinational therapies is increasing at an alarming rate due to advantage of their combined mode of action. Analytical methods are required to characterize drug substance and drug product composition during all phases of pharmaceutical development. Once an analytical method is developed for its intended use, it must be validated as per the guidelines given by International Conference on Harmonization. The ICH guideline Q1A on Stability Testing of New Drug Substances and Products emphasizes that the testing of those features which are susceptible to change during storage and are likely to influence quality, safety and/or efficacy must be done by validated stability-indicating testing methods. High-performance liquid chromatography is the fastest growing analytical technique for analysis of drugs. Its simplicity, high sensitivity and specificity make it ideal for the analysis of many drugs in pharmaceutical dosage forms and biological fluids. Present study aims to accept the challenge of complexity of multiple drug entities for the development of assay procedure.

Therefore the objective of present study is to develop stability indicating analytical methods for the estimation of drugs in their formulations. The specific objective of this study is to subject the drug formulation to forced degradation and subsequent separation, identification and quantitation of the drug substance in presence of degradation product if any. Second part of the deals with the optimization of chromatographic conditions and validation of the SIAM for the parameters such as specificity, precision, accuracy, linearity and range, LOD, LOQ, ruggedness,
Aim & Objectives

Stability Indicating HPLC Method Development and Validation for Simultaneous Estimation of Some Drugs in Bulk and Pharmaceutical Dosage Forms

Chapter 2

robustness and stability in analytical solutions. Following drugs in their combination dosage forms were selected for SIAM as there is a paucity of reported methods for their simultaneous estimation.

1) Lafutidine & Domperidone Maleate [Antihistamines, Antiemetic]
2) Darunavir Ethanolate & Ritonavir [Antiretroviral (Anti HIV)]
3) Azithromycin & Ofloxacin [Antibiotics]
4) Cefpodoxime Proxetil & Ofloxacin [Antibiotics]
5) Cefpodoxime Proxetil & Levofloxacin [Antibiotics]