## CHAPTER 42

# PHARMACY PHARMACEUTICAL SCIENCES

## **Doctoral Theses**

#### 01. RAVI KANT

Analytical Method Development and Validation using Quality by Design Approach of Few Selected Fixed Dosage Forms and their Pharmacokinetic Studies in Rats.

Supervisor: Dr. Ramesh Bodla

Th 25163

Abstract (Not Verified)

In a fixed dose form it is not possible to analyse a single drug by traditional method of UV scan in the presence of excipients and other drugs absorbing at the same wavelength range. In the present work spectroscopic analytical methods for simultaneous estimation of three different fixed dose combination drugs were developed and validated as per the ICH guidelines: Absorbance correction method was developed and validated for the estimation of Tazobactam and Cefepime. Difference spectrophotometry method was developed and validated for the quantification of Moxifloxacin and Cefixime in bulk and fixed dosage combinations and The Spectrophotometric Method for the estimation of Metformin and Pioglitazone was developed by two techniques: Area under curve method and the Dual wavelength method. Liquid chromatography method using HPLC was used for separating the analytes from complicated matrix. It is highly specific in nature with high sensitivity and acceptable precision. In the present work three different reverse phase HPLC analytical method have been developed and validated for the estimation of drugs in combined dosage forms and then applied for the assay of marketed formulations as well as for pharmacokinetic studies in rat plasma. Bioanalytical HPLC-DAD method for quantifying Tazobactam and Cefepime using Box Wilson Design in blood plasma of rats was developed. Optimization of HPLC-DAD method in quantifying Moxifloxacin and Cefixime in rat plasma using solidphase extraction (SPE) and Central Composite Design was carried out. Application to pharmacokinetic study, optimization of single HPLC-PDA method for the quantification and estimation of Metformin, Gliclazide, Pioglitazone, Dapagliflozin, Empagliflozin, Saxagliptin, Linagliptin and Tenegliptin using central composite design. HPLC method was also developed and validated for the determination of Alogliptin enantiomers in tablets and rat plasma. Enantioselective Box Behenken optimized HPLC-DAD method was developed for the determination of Alogliptin enantiomers in tablets and rat plasma for the purpose of application to pharmacokinetic study.

## Contents

1. Introduction 2. Literature review 3. Spectrophotometric absorbance correction method for the estimation of Tazobactam and Cefepime in fixed dosage forms 4. Analytical method for the quantification of moxifloxacin and cefixime in bulk and fixed dosage combination by difference spectrophotometry 5. Analytical methods for estimation of pioglitazone and metformin in fixed dosage forms using ultraviolet spectrophotometry 6. Bioanalytical HPLC-DAD method for quantifying

tazobactamand cefepime using box Wilson design in blood plasma of rats: Application to the pharmacokinetic study7. Optimization of HPLC-DAD method in quantifying moxifloxacin and cefixime in rat plasma using solid-phase extraction (SPE) and central composite design: Application to pharmacokinetic study 8. Optimization of a single HPLC-PDA method for the quantifying metformin, gliclazide, pioglitazone, depagliflozin, empagliflozin, saxagliptin, linagliptin and tenegliptin using central composite design 9. Enantioselective box behenken optimized HPLC-DAD method for the determination of alogliptin enantiomers in tablets and rat plasma: Application to pharmacokinetic study 10. Summary and conclusion. Appendix. Publications.