Summary

Quality, Safety and Efficacy are of paramount importance for any medicinal product. For launching of any new drug product or abbreviated new drug product, it is necessary to submit quality, safety and efficacy of the drug product to different regulatory bodies. Many drugs are recalled or banned for either they are not complying with one of the criteria. To study all the three aspects of drug product, it is required that a strong analytical method should be developed to detect and quantify the components of the drug product either in dosage form or in serum or plasma.

Today's scenario, in pharma industry high performance liquid chromatography is the leading technology to separate and quantify the drug substances. No other chromatographic technique so far has matched with the HPLC technique. One of the most sophisticated technology available today is high performance liquid chromatographic technique. Due to the continuous development in the pharmaceutical products, the challenges are more for analytical science to develop the specific, accurate and precise method to monitor the quality of the products. The regulatory authorities requires the validation package of the methods. So, when method is used for monitoring the quality and stability studies of the products. It should be validated for different parameters like linearity, recovery, specificity, solution stability and ruggedness.

Considering this, in the present research work attempt has been made to develop the HPLC methods for the estimation of active ingredients in the pharmaceutical combination.

Chapter 1 covers the introduction, about the HPLC instrumentation, technique applied for present research work and ion pair chromatography. Ion pair chromatography is a powerful tool to separate ionic compound from non ionic compound. The number of drugs developed by this method were Furosemide, Zonisamide, Glipizide, Glibenlamide Glimeperide and Gliclazide.

Chapter 2 deals with the development of HPLC method for the determination of Telmisartan. There were few published method for the estimation of Telmisartan by
HPLC as stability indicating. In this method the diluent used was the mixture of methanol and acetonitrile where telmisartan is easily soluble. Due to the higher solubility of telmisartan, concentration of 1mg/ml of was used for assay. The method is clearly distinguished telmisartan from all its degradants. Due to the higher concentration of telmisartan, trace quantity of degradants is also detectable by this method. The method is successfully applied to the marketed products.

Chapter 3 covers the estimation of gabapentin by HPLC. There were many published methods for determining the gabapentin in tablet or other dosage form. Due to its poor absorbance in UV region, many reported methods are of pre column derivitisation method. Few UV methods are reported for estimating Gabapentin in dosage form. In the present method, strong cation exchange column and UV wave length of 200nm were used. The method was successfully validated using ICH guidelines. The method is specific, precise, accurate and robust. The method was successfully applied for the marketed products as stability indicating.

Chapter 4 covers the estimation of Efavirenz using phenyl column and mixed phosphate buffer. There is only one published stability indicating methods for determining the efavirenz in tablet or other dosage form. The method was successfully validated using ICH guidelines. The method is precise, accurate and stability indicating. Compared to the reported methods, it has a less run time and no gradient elution was applied. The method was successfully applied for the marketed products as stability indicating.

Chapter 5 describes the estimation of valsartan and hydrochlorothiazide using normal phase using Cyano column. There were many published methods for determining the valsartan and hydrochlorothiazide in tablet or other dosage form. The method was successfully validated using ICH guidelines. The method is precise, accurate and stability indicating. Compared to the reported method, this method is faster and economical. The method was successfully applied for the marketed products in tablet form.

Chapter 6 describes the estimation of Zonisamide and Furosemide using ion pair chromatographic technique. Since both drugs have same functional group of sulfonamide with different medicinal activity, the method applied is the same with change in mobile
phase composition. There were many published methods for determining the Zonisamide and Furosemide in tablet or other dosage form. This method was successfully validated using ICH guidelines. The method is precise, accurate and stability indicating. The method is simple isocratic method which separates all the degradants from the drug product. The method was successfully applied for the marketed products in tablet and capsule form.

Chapter 7 describes the estimation of Glipizide, Glibenclamide and Glimeperide using ion pair chromatographic technique in the presence of Metformin Hydrochloride. All the three components are available in market with metformin hydrochloride used for type II diabetis. They were glipizide with metformin HCl, glibenclamide with metformin HCl and glimeperide with metformin HCl, separately. There were no published methods available as stability indicating for determining the glipizide, glibenclamide and glimeperide in tablet or other dosage form in the presence of metformin hydrochloride. This method was successfully applied to the marketed product as a single component and with metformin hydrochloride. In both the cases no degradants are interfering with principal peak of glipizide, glibenclamide and glimeperide. The method is precise, accurate and stability indicating. The method is simple isocratic method which separates all the degradants from the drug product. The method was successfully applied for the marketed products in tablet form.

Chapter 8 covers the estimation of Gliclazide using ion pair chromatographic technique in presence of Metformin Hydrochloride. The method is same as mentioned in the chapter 7. The gliclazide and glipizide elutes at nearest RT, this was separately developed. This method was successfully applied to the marketed product as a single component and with metformin hydrochloride. In both the case no degradants are interfering with principal peak of gliclazide. The method is precise, accurate and stability indicating. The method is economical and simple isocratic method which separates all the degradants from the drug product in tablet form. The method has been successfully developed and validated as per ICH guidelines and applied for the analysis of marketed product.
Publications


5. Determination of Furosemide and Zonisamide as a drug substance and in dosage form by ion pair–reversed phase liquid chromatographic technique: Manuscript is

*METHOD DEVELOPMENT AND STABILITY INDICATING STUDIES OF SOME NEW THERAPEUTIC AGENTS BY HPLC TECHNIQUE*
communicated for publication to online journal “Journal of liquid chromatography and related technologies.”

6. Determination of Gliclazide in a tablet dosage form in the presence of Metformin hydrochloride by ion pair–reversed phase liquid chromatographic technique: Manuscript is communicated for publication to online journal “African Journal of Pharmacy and Pharmacology”

**Presentation**

Errata


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