

## Bioanalytical Method Development and Validation of Pharmaceutical Dosage form by LC-MS Technology

Biswa Mohan Sahoo\*

Department of Medicinal Chemistry, Vikas College of Pharmacy, Andhra Pradesh, India

\*Corresponding author: Biswa Mohan Sahoo, Department of Medicinal Chemistry, Vikas College of Pharmacy, Vissannapeta, Krishna District-521 215, Andhra Pradesh, India, Tel: 9133055582; E-mail: [drbiswamohansahoo@gmail.com](mailto:drbiswamohansahoo@gmail.com)

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### Introduction

The process of getting a drug molecule to the market is both expensive and time consuming during drug development and discovery. To save time and improve the selection of candidates, physicochemical properties such as absorption, distribution, metabolism, elimination and toxicity are evaluated in drug discovery process. Currently, in modern technology, innovative technique is emerging up in the field of drug development. So, liquid chromatography-mass spectrometry (LC-MS) is used as bioanalytical technique which utilizes the liquid chromatography (or HPLC) with the mass spectrometry. It is generally used for both qualitative and quantitative analysis of various Pharmaceutical dosage form. LC-MS technology enables quick monitoring of pharmacokinetic parameters for large number of compounds. Development and validation of bioanalytical method is essential to determine the pharmacokinetic and toxicokinetic profile of drug substances. Bioanalysis is the method used to determine the concentration of drugs, their metabolites and endogenous substances in the biological matrices such as blood, plasma, serum, cerebrospinal fluid, urine and saliva. The method includes collection, processing, storage and analysis of a biological matrix for a drug. Bioanalytical method validation involves documenting established and verified specific laboratory investigations for quantitative measurement of a drug substance in a given biological matrix. The basic parameters of validation comprises all criteria determining data quality such as selectivity, sensitivity, calibration model, accuracy, precision, stability, limit quantification (LOQ), recovery, linearity, limit of detection, reproducibility, and ruggedness [1,2].

### Method Development and Validation Protocol

Analytical method development is the process of creating a procedure to enable a compound of interest to be identified and quantified in biological fluids. A compound can often be measured by several methods and the choice of analytical method involves many considerations, such as: chemical properties of the analyte, concentrations levels, sample matrix, cost of the analysis, speed of the analysis, quantitative or qualitative measurement, precision required and necessary equipment. Validation is a written plan stating how validation will be conducted, including test parameters, product characteristics, production equipment, and decision points on what constitutes acceptable results [3,4].

### Mechanisms of LC-MS Technology

HPLC instrumentation consists of a pump, injector, column, detector, integrator and a display system. The heart of the system is the column where separation occurs. Stationary phase is composed of micron sized porous particles; hence a high pressure pump is required to move the mobile phase through the column. The sample to be analyzed is introduced in small volume to the stream of mobile phase. Detector shows the retention times of the molecules.

### Methodology

1. Determination of physicochemical properties of the drug substances such as chemical structure, functional group, molecular weight, purity and stability
2. Determination of the solubility in suitable solvents
3. Development of sample preparation
4. Development and optimization of the HPLC
5. MS scanning and optimization

### Conclusion

Development of improved bioanalytical methods using HPLC and mass spectroscopy helps in performing quality control of pharmaceutical dosage forms as well as in achieving the pharmacokinetic, toxicokinetic and bioequivalence data of drugs in lesser time. This method gives information about identity, purity, potency and bioavailability of drugs. Therefore, LC-MS method development and validation is essential for the determination of a drug concentration in pharmaceutical dosage forms and to monitor and control impurities in drugs.

### References

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