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Review Article

DEVELOPMENT AND VALIDATION BY HPLC METHOD

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Abstract

Validation of an analytical procedure is the process of demonstrate with suitable for its intended purpose. Chromatographic such HPLC methods play significant role in the pharmaceutical industry from the drug discovery, development of drugs, formulations and quality control of chemicals. Many validated analytical methods ensure that it provides consistent, reliable and accurate data for results. So these methods help pharmaceutical analyst to ensure quality products are released for market. This review explains general approach for validation process and validation parameters to be considered during validation of a HPLC method. It also used to refer for various regulatory requirements. The parameters described follow to ICH guidelines and include accuracy, precision, specificity and limit of detection, limit of quantitation, linearity, range and robustness.

Keywords: HPLC, Analytical, ICH, robustness

INTRODUCTION

Pharmaceutical Analysis may be defined as the application of analytical procedures used to determine the purity, safety and quality of drugs and chemicals. The pharmaceutical analysis comprises the procedures necessary to determine the "identity, strength, quality and purity" of such compounds. It also includes the analysis of raw material and intermediates during manufacturing process of drugs.

Quantitative analysis seeks to establish the amount of a given element or compound in a sample. Importance of analytical chemistry is to gain information about the qualitative and quantitative composition of substance and chemical species, that is, to find out what a substance is composed of and exactly how much it is present. For the past two decades, the pharmaceutical analyst has been a spur in development of analytical techniques for various medicinal principles both in pure and combined state and also in finished products. Some of the methods shine in modern technological and electronics and microprocessor-based developments have really shown faster and best results with more accuracy than the conventional methods.

There are various methods used for quantitative analysis of mixtures. One of them is spectrophotometry, which utilizes the measurement of intensity of electromagnetic radiation emitted or absorbed by the analytes. Another technique which has gained large popularity during last decade is high performance liquid chromatography. Chromatography is a fundamental technique in the detection, identification and quantization of chemical species. It comes in two basic formats, planar and column chromatography.

Different types of chromatographic techniques are available to analyze the samples, but one of the technique very familiar, is High Performance Liquid Chromatography. HPLC technique is not only useful for separation, but also useful for qualifying (identifying) and quantifying the small and neutral molecules also. A few microgram of sample (at the extreme, even less than a nanogram) is enough to ensure the required accuracy. Secondly, HPLC separations are usually relatively fast, precise, accurate and an analysis can be completed in short span possibly in a few seconds.

Analytical Methods Development

The number of drugs introduced into the market is increasing every year. These drugs may be either new entities or partial structural modification of the existing one. Very often there is a time lag from the date of introduction of a drug into the market to the date of its inclusion in pharmacopoeias. This happens because of the possible uncertainties in the continuous and wider usage of these drugs, reports of new toxicities (resulting in their withdrawal from the market), procedures for these drugs may not be available in the pharmacopoeias. It becomes necessary, therefore to develop newer analytical methods for such drugs.

Basic criteria for new method development of drug analysis:

•The drug or drug combination may not be official in any pharmacopoeias,

•A proper analytical procedure for the drug may not be available in the literature due to patent regulations,

•Analytical methods may not be available for the drug in the form of a formulation due to the interference caused by the formulation excipients,

•Analytical methods for the quantitation of the drug in biological fluids may not be available,

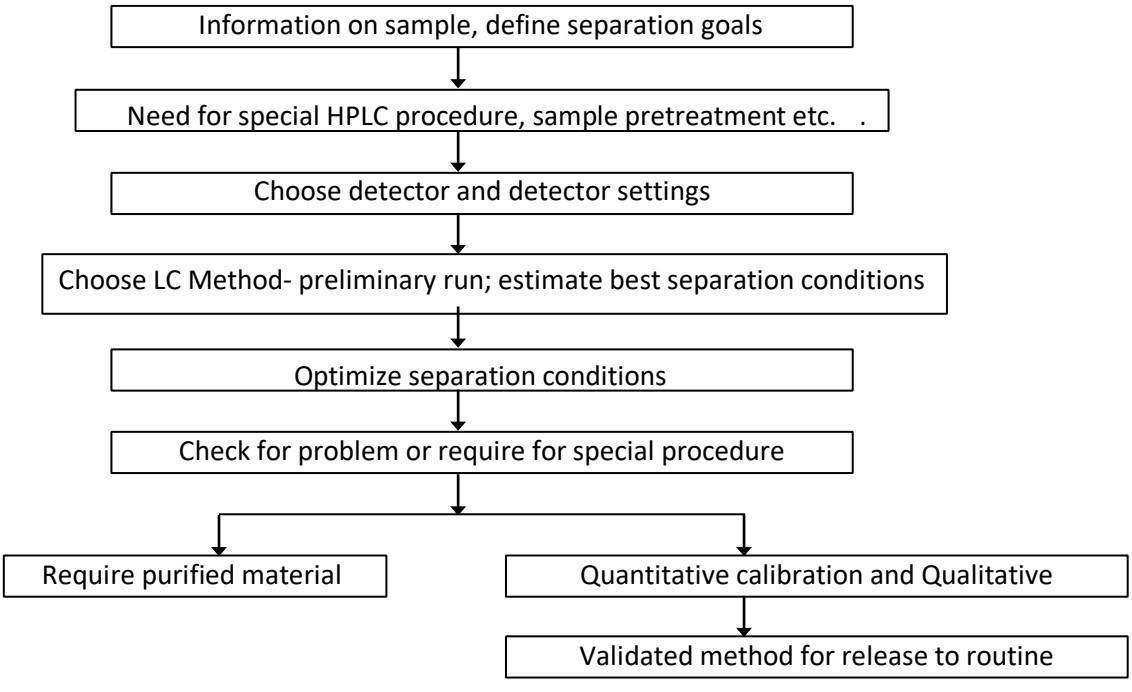
HPLC Methods of Analysis for Drugs in Combination

Most of the drugs in multi-component dosage forms can be analyzed by HPLC method because of the several advantages like rapidity, specificity, accuracy, precision and ease of automation in this method. HPLC method eliminates tedious extraction and isolation procedures. Some of the advantages are:

•Speed (analysis can be accomplished in 20 minutes or less),

•Greater sensitivity (various detectors can be employed)

HPLC Method Development



High-performance liquid chromatography (or high-pressure liquid chromatography, HPLC) is a chromatographic technique that can separate a mixture of compounds, and is used in biochemistry and analytical chemistry to identify, quantify and purify the individual components of the mixture. HPLC utilizes different types of stationary phase (typically, hydrophobic saturated carbon chains), a pump that moves the mobile phase(s) and analyte through the column, and a detector that provides a characteristic retention time for the analyte. The detector may also provide other characteristic information (i.e. UV/Vis spectroscopic data for analyte if so equipped).

High performance liquid chromatography is basically a highly improved form of column chromatography. Instead of a solvent being allowed to drip through a column under gravity, it is forced through under high pressures of up to 400 atmospheres. That makes it much faster. It also allows you to use a very much smaller particle size for the column packing material which gives a much greater surface area for interactions between the stationary phase and the molecules flowing past it. This allows a much better separation of the components of the mixture. The other major improvement over column chromatography concerns the detection methods which can be used. These methods are highly automated and extremely sensitive.

Classification of Analytical Methods:

Analytical methods can be broadly classified into following types:

•Class A: Identification tests for either bulk drug compounds or specific ingredients in completed dosage forms.

•Class B: Techniques intended to identify and quantify contaminants in a completed dosage form or a bulk pharmacological material.

•Methods used to quantify the concentration of a principal constituent or a bulk drug substance in a completed dosage form are classified as Class C methods.

•Methods used to evaluate the properties of completed dosage forms, such as dissolution profiles and content homogeneity, fall within the classification of Class D.

Analytical methods as per USP are:

•Category I: Analytical techniques for measuring the main elements of bulk medicinal compounds or active chemicals, such as preservatives, in pharmaceutical finished goods.

•Category II: Analytical techniques for identifying contaminants in bulk pharmaceuticals or for identifying degradation chemicals in pharmaceutical finished goods.

•Analytical techniques for identifying performance characteristics fall under category III (e.g. dissolution, drug release).

CONCLUSION

The intent of this review article is to provide a succinct elaboration of the HPLC approach for the determination of process validation. Literature data indicated that certain analytical techniques have been reported for this purpose.

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