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Stability Indicating HPLC Method Development: A Review

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ABSTRACT

High performance liquid chromatography is one of the most accurate method widely used for quantitative as well as qualitative analysis of drug product and it is used for determining drug product stability. Stability indicating HPLC methods are used to separate various drug related impurities that are formed during the synthesis or manufacturing of drug product. This article discusses the strategies and issues regarding the development of stability indicating HPLC system for drug substance.

Keywords: stability indicating method, high performance liquid chromatography, drug substance.

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INTRODUCTION - (1,2)

Forced degradation or stress testing is demonstrating specificity when developing stability-indicating methods, particularly when the little information is available about potential degradation products. These studies also provide information about the degradation pathways and degradation products that could form during storage. Stability testing of drug substance requires the accurate analytical method that quantitates the active pharmaceutical ingredients (API) without interfering from degradation products, process impurities and other potential impurities [1]. International Conference on Harmonization (ICH) guidelines, the requirement of establishment of stability-indicating assay method (SIAM) has become more clearly mandated. The guidelines explain forced degradation studies under a variety of conditions, like pH, light, oxidation, dry heat, etc. and the separation of drug from degradation products. High performance liquid chromatography (HPLC) is the most accurate analytical methods widely used for the quantitative as well as qualitative analysis of drug product and used for determining drug product stability.

STABILITY INDICATING METHOD DEVLOPMENT STRATERGIES:

There is not exact formula for developing stability indicating analytical method.

STEP 1: physiochemical properties of drug(4,5)

I. Physiochemical properties of drugs are important for method development.

II. Fluorescent properties chromatographic behaviour spectrophotometric properties, oxidation, reduction are useful in setting up preliminary experiments and helpful in stress study conditions and degradation mechanism.

III. Dissociation constant and partition coefficient are achieve good separation by developing efficient sample extraction scheme and determines the optimum pH in the mobile phase.

IV. Functional group or structure of analyte indicates potential active sites of degradation.

STEP 2: setup preliminary HPLC conditions (5,6)

I. Preliminary experimental conditions can be adapted from official or unofficial methods or literature review.

II. Official methods are published in (USP) United States of pharmacopoeia.

III. These methods are consider validated and can be used for stability testing.

IV. Experimental conditions should be based on API and properties of drug substance.

V. Selection of column and mobile phase is important.

STEP 3: Preparation of sample required for method development :(5)

I. Stability indicating methods are carried out by stressing the API under conditions which are normally used for accelerated stability testing.

II. In stability indicating method stress testing is also referred as force degradation and it can be used to provide information about degradation.

III. Force degradation study performing the thrombolysis, hydrolysis and oxidation of drug.

STEP 4: developing separation of stability indicating chromatographic conditions(7,8,9,10)

I. The most common separation variables are temperature, solvent type mobile phase, pH etc.

II. Initial chromatographic conditions for stability indicating method are new entity most important to degradants use in solution separated and detected.

IMPORTANT PARAMETERS IN METHOD DEVLOPMENT

I. Solvent type

II. Mobile phase

III. Isocratic or gradient mode

IV. Coloumn temperature

V. Peakpurity

DEGRADATION STUDY IN STABILITY INDICATING METHOD DEVLOPMENT.(9,11)

Forced degradation involves exposure of sample of drug substance or drug product.

This experiment play important role in drug development process.

Force degradation provides the following information, determination of degradation pathway of drug product or drug substance.

Structure elucidation of degradation product produced thermolytic, oxidative, photolytic, hydrolytic degradation mechanism.

CONCLUSION:

Stability indicating method is analytical method which is used to check purity of drug substance or product which occurs due to stress degradation during manufacturing of product.

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