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ROLE OF ANALYTICAL LABORATORY IN PHARMACEUTICAL INDUSTRY

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ABSTRACT

Pharmaceutical businesses may get their medicines to market faster with the help of accelerated stability testing and cutting-edge analytical procedures. To guarantee their effectiveness and safety for patients, pharmaceutical medicinal items must be stable. There may be negative outcomes for customers if the product quality is diminished due to deterioration, contaminants, or changes in formulation. This study intends to build reliable protocols that can properly assess product stability by exploring rapid and precise stability testing methodologies. The research aims to improve detection and quantification of degradation products, contaminants, and possible risks through the use of cutting-edge approaches such sophisticated analytical equipment and automated systems. Traditional methods of stability testing can need extensive investments of time, manpower, and money. The pharmaceutical industry may maximize efficiency and cut costs by switching to stability testing procedures that are both quick and accurate. The purpose of this research is to determine whether or not stability testing can be performed more cheaply using cutting-edge methods like automation and statistical modeling. A pharmaceutical company's productivity and market standing can benefit from better resource allocation, which can be achieved through discovering effective protocols and analytical tools. Pharmaceutical product development and commercialization relies heavily on adhering to regulatory criteria. In order to fulfill these mandates, stability testing is crucial. The purpose of this research is to determine if rapid and accurate stability testing procedures are enough to meet regulatory requirements. The study's goal is to ascertain the methodologies' compliance with existing regulatory frameworks by assessing their robustness and dependability, consequently easing medicinal product approval procedures. Scientific progress may be attributed, in part, to research into rapid and accurate stability testing methodologies for pharmaceutical medication product development. Researchers can learn more about product stability and find

new ways to tackle problems if they experiment with cutting-edge methods. This research hopes to contribute to our understanding of stability testing, opening the door to new discoveries in the pharmaceutical sciences.

KEYWORDS: Analytical Laboratory, Pharmaceutical Industry, Pharmaceutical product

INTRODUCTION

Medicine is "the art and science of disease prevention and treatment." Every year, new medications, either slightly altered versions of current pharmaceuticals or whole new chemical entities, enter the market. Since these medications are for the treatment of illness and human usage, there is a tremendous need to monitor quality of medicines, especially with the introduction of new types of dosage forms into the market, which is matrix of drug and diverse excipients and combination of multiple pharmaceuticals with excipients. The pharmaceutical sector bears the primary obligation to ensure that the medications available to the public are of the highest possible standard. The analytical laboratory's work is crucial to ensuring the safety and efficacy of pharmaceuticals. medicinal manufacturers must spend a sizable chunk of their budget on an analytical laboratory since regulatory agencies are extremely picky about the quality and safety of medicinal goods. The analytical laboratory is crucial to the entire drug development and testing process.

No effort is spared, and the highest standards are maintained, to ensure the highest quality pharmaceuticals and healthcare delivery.The quality of the finished product is ensured by one or more control processes to determine whether to reject or release the product, and the different procedures are designed to reduce mistakes during manufacturing. The pharmaceutical sector has expanded rapidly over the past several years, thanks in large part to developments in analytical technology and pharmaceutical analysis that allow for the study of complicated formulations using only relatively straightforward methods of analysis. The analytical techniques used must be able to isolate and quantify the numerous excipients and active components included in a complex pharmaceutical formulation.

Analytes are any organisms studied for their qualitative or quantitative characteristics [3]. Pharmaceutical analysis is used to ensure the active pharmaceutical ingredients, starting materials, and excipients are pure, effective, uniquely identified, and stable. The examination

of pharmaceutical active ingradients and medical goods are distinct processes. The latter includes the pharmaceutically active agent plus at least one pharmacological excipient, and can take many different forms (ointments, tinctures, tablets, lotions, suppositories, infusions, drops, etc.). Impurities are often tracked in accordance with ICH and pharmacopoeia regulations, having originated in the process of synthesizing the active component. There are two main types of analytical techniques: classical and instrumental [4].

CLASSICAL METHODS OF ANALYSIS

Wet chemistry is another name for the conventional approaches. No electrical or mechanical apparatus is utilized in this technique. In the traditional approach, precipitation, extraction, and distillation form the backbone of the separation process. Quantitative analysis involves measuring volume or weight, whereas qualitative analysis relies on observing changes in color, smell, or melting point. Both qualitative and quantitative approaches are used to categorize them. By definition, this type of analysis does not involve quantifying anything; instead, it just determines whether or not a compound exists. Quantitative analytical methods, on the other hand, allow for the precise determination of a compound's amount or concentration. The qualitative analysis is broken down into subcategories based on the kind of confirmatory tests (chemical, flame, etc.) that may be performed on a given component. Gravimetric tests include weighing a sample of the substance in question, whereas volumetric tests involve the analyst reacting with a known volume of the reactant until an equivalence point is achieved. Many contemporary methods of analysis have their roots in the principles of older methods. The current field of analytical chemistry places greater emphasis on high-tech instruments and the use of newly developed analytical techniques. In order to guarantee the purity and safety of the various substances, sophisticated analysis is required.

Advantages of Classical Methods:

Simple and accurate.

Specialized training is not required.

Equipment is cheap.

Limitations of Classical Methods:

Lack of specificity.

Experimentation is time consuming.

Chemical environment is critical.

Accuracy decreases with decreasing amount.

Types of Classical Methods:

1. Volumetric Method:

Titrimetric approaches are another name for these techniques. The amount of a material is calculated by measuring the volume of a solution of known concentration, making this a popular quantitative method.

2. Gravimetric Method:

In this quantitative method, the mass of a sample is used to calculate the amount of an analyte. The assay findings in this type of analysis are often acquired by determining the weight of a substance present in the sample, or the weight of any other material extracted from the sample, the equivalent weight of which is used as the foundation for calculating the result.

INSTRUMENTAL METHOD OF ANALYSIS

Conductivity, fluorescence, light emission or absorption, (m/e) mass to charge ratio, refractive index, and conductivity are all examples of physical qualities that form the basis of experimental technique. Distillation, precipitation, and extraction are no longer necessary for the separation of compounds of interest because they can be measured physically using efficient electrophoretic and chromatographic procedures. Instrumental methods of analysis are a set of contemporary techniques for identifying and disentangling many constituent interests. Light emission and absorption, electrode potential, conductivity, (m/e) i.e. mass to charge ratio, and fluorescence are all examples of physical properties that may be measured

using these techniques. These techniques are now routinely utilized for the quantitative measurement of many different types of organic and inorganic biochemical analytes.

Advantages of Instrumental Methods:

Complex mixtures can analysed.
High sensitivity.

Small amounts of sample reuired Measurements obtained are reliable.

Determination is very fast.

Limitations of Instrumental Methods:

Equipment's are costly.

The eluents are destructed and not available for further process.

Sensitivity and accuracy depends on type of instrument.

A Skilled person is required.

Sizable space is required.

Compound analysis may be done in a number of ways, each of which is predicated on the interaction of materials with varying energies. The recognized and processed interaction signal that reveals the nature of the encounter. Here are some of the methods you may use.

1. Electrochemical Analysis

Electrochemical investigation of how electric fields interact with matter. The following are examples of distinct forms of electrochemical analysis:

1. Potentiometry: The concentration of ionic species in a solution determines the difference in electrode potential.

2. Voltametric and Polarographic methods - Relationship between voltage, current, and time during electrolysis.

3. Stripping methods: Species of interest are electrochemically stripped off electrodes and returned to solution by placing ions in an electrode's surface area.

4. Amperometric methods: Difference in current as a function of titrating reagent volume at constant voltage.

5. Coulometry: The amount of an electrolyte's chemical reaction is directly correlated with the amount of electricity traveling through the electrode.

6. Electrogravimetry: A deposit of the electrolysis product is measured as weight using one of the electrodes.

7. Measurement of solution conductivity to identify ionic species using conductance methods.

2. Spectroscopic Analysis

Measurements will be made of electromagnetic radiation's effects on various materials. The following are some spectroscopic analysis methods:

1. UV and visible spectrophotometry - Valence electron excitation.

2. Infrared spectroscopy: Molecular vibrations are excited.

3. Raman spectroscopy: Excitation of light-scattering molecular vibrations.

4. Atomic absorption spectroscopy - Atomic resonance line absorption.

5. Atomic emission spectroscopy: Excited electronic states of atoms emit light.

6. X-ray diffraction, which is the X-rays' diffraction from crystal planes.

7. X-ray fluorescence: Excited atoms emit X-rays again.

8. Fluorimetry and phosphormetry - Electrons emitting light energy.

9. Ionization and fragmentation of molecules into ions in mass spectroscopy.

10. Magnetic nuclei can be reoriented in a magnetic field by use of NMR spectroscopy.

11. Nephelometry and turbidimetry, which measure the intensity of transmitted light as a function of dispersion phase concentration.

12. Reorientation of magnetic electrons in a magnetic field is the result of electron spin resonance spectroscopy,

3. Chromatographic techniques

Chromatographic technique provides a solution to the complexity of material mixes. Chromatography is the separation technique that is used the most frequently.

1. Gas chromatography (GC)
2. Liquid chromatography (LC)
3. Size- exclusion chromatography
4. High-performance thin layer chromatography (HPTLC)
5. Paper chromatography
6. Thin layer chromatography (TLC)
7. Affinity chromatography
8. Ion exchange chromatography

The signal must be detected and evaluated when the isolation of the material signal is formed. The current research was done using liquid chromatography, and it is thoroughly explained below.

4. Hyphenated Techniques

"Hybrid" or "hyphenated" procedures are combinations of several chromatographic techniques. Different instances of novel hybrid approaches are currently in widespread usage, and many more are under development.

1. Gas chromatography-mass spectrometry (GC-MS)
2. Inductively coupled plasma-mass spectrometry, or ICP-MS,
3. Infrared spectroscopy using gas chromatography
4. Mass spectrometry-mass spectrometry, or MS-MS

Instrumental procedures need a minimal quantity of material and are sensitive. Complex mixtures can be examined with or without their preceding separation, and the findings will still be sufficiently accurate and reliable.

CONCLUSION

An effective HPLC technique for the measurement of associated components of Olmesartan, Medoximil, and Hydrochlorothiazide in drug product was developed and confirmed after a stability study was conducted. The medicine underwent stress testing in accordance with ICH recommendations, and the findings showed that hydrolytic (acid and base) and oxidative conditions produced the breakdown products. For the separation and quantification of related compounds from the tablet formulation of emtricitabine and tenofovir disoproxil fumarate, a straightforward, speedy, and precise reverse phase LC approach was reported. The entire technique was validated, and the results for each of the examined method validation parameters were adequate. The created approach may be utilized to quantitatively determine related compounds from bulk and tablet formulations and is stability suggesting.

An effective HPLC technique for the measurement of associated components of emtricitabine and tenofovir disoproxil fumarate in drug product was developed and validated after a stability study was conducted. The medicine underwent stress testing in accordance with ICH recommendations, and the findings showed that hydrolytic (acid and base) and oxidative conditions produced the breakdown products. The goal of the current effort is to create a novel HPLC technique for the measurement of contaminants in medicinal product

combinations for pharmaceutical dosage forms. For simultaneous estimate and impurity profiling of degradation products and associated compounds from the combination drug product, the established techniques can be applied. The devised technique was verified in accordance with ICH guidelines and was proven to be exact, accurate, robust, and specific for quantifying related chemicals.

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