International Journal For Advanced Research In Science & Technology
A peer reviewed international journal
www.ijarst.in
ISSN: 2457-0362

A STUDY OF PHARMACEUTICAL DRUG PRODUCTS USING MODERN TECHNIQUE

KOUSHAL SINGH PATEL, DR. NARENDRA SINGH

DESIGNATION- RESEARCH SCHOLAR MONAD UNIVERSITY HAPUR U.P
DESIGNATION - (PROFESSOR) MONAD UNIVERSITY HAPUR U.P

ABSTRACT

Drug products with improved stability are in high demand as the pharmaceutical industry works to keep up with rising patient expectations for reliable and effective medicines. To ensure that pharmaceutical items maintain their quality, potency, and safety during their designated shelf life, stability testing is essential. Opportunities to efficiently meet this need are opening up thanks to the development of quick and accurate solutions that make use of cutting-edge processes. The purpose of this research was to examine pharmaceutical medication product stability utilizing rapid and accurate methodologies based on cutting-edge approaches. The study's goal is to shed light on the possible uses and effect of these methods in the pharmaceutical business by analyzing their benefits and limits. Long-term studies, used for traditional stability assessment, can last for years. The delayed release to market is a direct result of this increased timeframe. This research intends to find approaches that can speed up the assessment process without sacrificing accuracy or dependability by studying rapid and accurate stability testing methodologies. Pharmaceutical businesses may get their medicines to market faster with the help of accelerated stability testing and cutting-edge analytical procedures.

KEYWORDS: Pharmaceutical Drug Products, Modern Technique, pharmaceutical industry, Pharmaceutical businesses, pharmaceutical medication product

INTRODUCTION

It is hardly unexpected that man has sought cures for ailments throughout history. Food and herbs are two natural sources that have been extensively investigated by humans for their potential to reduce pain and suffering. The ancient civilization's thorough definition of plants and mixtures of them to alleviate and treat ailments characterized the "corpus therapeuticum. The quest for cures predates modern humankind. There is evidence that even ancient

societies like China, India, Mesopotamia, and Egypt used medications derived from plants, animals, and minerals to cure a wide range of illnesses.

Dioscorides and Galen of the Roman Empire, as well as Hippocrates and Theophrastus of Greek antiquity, have been methodically managing the treatments. Araebian intellectuals' (like Avicenna's) contributions to medical knowledge are built upon and eventually employed as the foundation of healthcare. Indian Ayurveda (which literally translates to "science and knowledge of life") has been around since at least 900 BC. Ayurveda is an ancient medical practice with a long history in India. Hypertension treatments based on cannabis, plants, serpaghanda (now called rauwolfia serpentine), and Datura (a metal) date back thousands of years.

It would be difficult to overstate the impact that organic chemistry's development and rise to prominence around the turn of the 19th century had on the advancement of science. There have been significant limits placed on the use of medications derived from natural and inorganic compounds. Now, people have begun to develop organic, synthetic medications on purpose, with chemicals extracted from plants known to have therapeutic effects serving as the foundation. Pharmaceutical synthesis has advanced to the point where a large number of active components may be synthesized in a relatively short amount of time. In this setting, scientists have been able to correlate the drugs' chemical composition with their functional properties.

Screening natural materials and isolating the active elements to cure ailments has been a primary focus of scientific research since the early 19th century. Because of the low yield and restricted availability of natural products obtained by extraction, scientists were compelled to develop synthetic routes to get the active components. These are often novel chemical entities (NCEs), which are synthetic copies of natural compounds. These NCEs have undergone a number of interactions with inert chemicals to produce safe and effective pharmaceuticals in the form of tablets, capsules, solutions, injections, etc.

PHARMACEUTICAL INDUSTRY

The pharmaceutical sector is responsible for the discovery, production, and distribution of medications, ushering in a new age for the treatment of a variety of illnesses. There is a growing worldwide pharmaceutical business worth an estimated $300 billion. We now have access to a plethora of drugs that may be used to treat a broad variety of illnesses.

Researchers face more difficulties in drug discovery and the need to defeat illnesses including cancer, AIDS, hypertension, and others. In the future decades, we will be even more medically advanced and inventive in our pursuit of healing more and more ailments, as researchers work to uncover new ideas and answers. In the early 1930s, scientists had to rely on limited natural resources to develop effective treatments for a wide range of illnesses. These drugs are now produced in a very efficient manner utilizing a synthetic method.

Each new medicine goes through a series of formulation procedures, including combining with inert chemicals and the creation of tablets, capsules, creams, gels, ointments, injections, and transdermal patches. Pre-clinical research and clinical practice are the two primary categories of new pharmaceutical development procedures. The initial phase of drug development is the pre-clinical work, which comes before clinical investigation. The primary goal of animal testing done before human trials begins is to establish an adequate dosage. In this research, the medicine is put through toxicological, pharmacokinetic, and pharmacodynamic testing on animals. Research into pharmacodynamics focuses on the medication's effects on the body, whereas research into pharmacokinetics examines the effects of the drug on the body. The data gathered from these research forms the foundation for the clinical trial necessary for product development.

The clinical work is broken up into three phases, with the first phase including a small group of healthy volunteers (often between 20 and 100 people). Information on safety and pharmacology has been gleaned from these trials by starting with a low dosage and progressively increasing it. Volunteers with the illness the new medicine is designed to treat participated in the study's second phase. With this study's sample size of 100–300 participants; we have data with adequate statistical power to draw conclusions on the study's effectiveness. The third and final stage of drug development entails testing the medication in human subjects at various locations. These trials, which enrolled between 1,000 and 3,500 participants, corroborated the prior findings and provided more evidence of the treatment's safety and efficacy. Phase III studies are necessary before the FDA will approve a medicine, after which formulation development can commence. In exchange for paying a patent fee, the applicant will be granted commercial permission for his patented process invention for a period of around 20 years. When the patent on a product runs out, other companies can legally begin selling generic versions of it. The generic medicine product is the same as the innovator product in every manner, including dosage, strength, safety, and effectiveness.

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ROLE OF PHARMACOPOEIAS TO ENSURE THE SAFETY OF DRUGS [1]

The term "pharmacopeia" comes from the extremely archaic Greek "o" (pharmakopoiia), which comes from the root "pharmako-," meaning "drug," followed by the verb stem "poi-," meaning "to make," and finally the noun suffix "- ia," meaning "a collection." Together, these three simple words might mean "to make a medication" or "drug-mak-ing." United States Pharmacopeia (USP), European Pharmacopeia (EP), British Pharmacopeia (BP), and Japanese Pharmacopeia (JP) are all official compendia that emerged from the harmonization of national regulations. The purpose of Pharmacopeias is to ensure that medicine quality and safety are consistently excellent across the globe's pharmaceutical business. They are legal safeguards for the general public that promote responsible drug usage. The test techniques or processes, requirements, and standards included in pharmacopeias can be used to conduct your own research. When it comes to public health, pharmacopeias' primary function is to prohibit and reject enterprises that produce fake medications.Controlling the quality of excipients and active medicinal components used by industrial manufacturers is another crucial function of pharmacopeias in the regulatory process.

Collects essential processes and specifications as a public resource and for maintaining the quality of components utilized, such as excipients and active pharmaceutical compounds and their dose forms. Often, a monograph will have both a general element (such as test techniques and procedures for reagents and solutions) and a more particular (active ingredient or dose form) section. To keep up with the latest scientific findings, pharmacologies often undergo minor updates in the form of corrections, supplements, and new editions. The quality of a medicine must be maintained despite variations in rules from country to country; therefore, it is important to adhere to universal principles and regularly update scientific advancements.

According to the World Health Organization (WHO), in order for a drug to be made accessible on the market, it must first meet certain requirements regarding its safety, quality, and efficacy. Safety, quality, and efficacy may be maintained throughout time if the production process and final product testings are subjected to constant scrutiny. The pharmacopoeia serves as a foundation upon which to construct these qualities. A number of national pharmacopoeias have evolved via the process of harmonization; these include the Japanese (JP), Indian (IP), American (USP), and European (EP). All of the many drugs created by various companies adhere to the same standards since the pharmacopeial

monographs offer general information, test techniques using similar reference materials, and their approval criteria. It is the hope of the pharmacopoeia and other stakeholders that one day all medications traded nationally and internationally would adhere to the highest possible standards for the public. Once this goal is reached, professionals and patients will know for certain that they are providing and receiving high-quality medicines for the purposes of health maintenance and disease treatment, while also protecting ideal manufacturers from criminals.

ANALYTICAL CHEMISTRY

Analytical chemistry is not a subfield of chemistry but rather the practical use of chemical principles. It is the job of analytical chemists to conduct analyses. Quantitative and qualitative methods are used in analytical chemistry to characterize material composition. New ideas, principles, and methods for determining the properties of chemical species are being developed and used in analytical chemistry. Not only did it perform standard analysis on such samples, but it also pioneered techniques for determining chemical composition in hitherto untested sample types.

Analytical chemists have a five-step procedure for addressing issues, which they apply to the study of the chemistry of a single chemical species.

i. Recognize and characterize the issue.

ii. Plan the mechanics of the experiment.

iii. Carry out an experiment and collect relevant data.

iv. Examine the results of the experiments.

v. to offer a workable answer to the issue at hand.

In conclusion, the process of development did not follow a predetermined, linear course as determined by the analytical strategy. Steps 1-4 of the analytical process are repeated until the problem is fully understood and a solution has been developed. When devising techniques for the precise and reliable measurement of components, several factors must be taken into account. The designed procedure has to share the following characteristics:

The method shoud be specific

- The method shoud be simple, economical and feasible
- The method shoud be precise and more accurate
- The method shoud be robust
- The methodshoud be rapid and having possible short run time.

CONCLUSION

The goal of this thesis is to create a few novel HPLC-based analytical techniques for pharmaceutical medicines. Due to its versatility in terms of application, selectivity, sensitivity, and speed, this approach was chosen above other contemporary techniques. It is also crucial to utilize a highly specialized, delicate, straightforward, and precise approach to evaluate the quality of these drugs in today's regulated pharmaceutical businesses. Using the HPLC technology, the study has been done on two combination medication products. The work's conclusion may be summed up as follows: For the quantitative determination of associated chemicals from Olmisartan Medoximil and Hydrochlorothiazide in tablet format, a straightforward, specific, linear, precise, and accurate RP-HPLC technique has been designed and validated. As both peaks are clearly separated from their contaminants and excipient peaks with a total duration of 70 minutes, the approach is relatively straightforward and precise, making it particularly ideal for routine quality control analytical work.

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