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REVIEW ON FORMULATION DEVELOPMENT

Pooja Maurya[1], Mohit Pratap Rao[1], Shreyansh Pathak[1], Kanchan Sahni[1], Nidhi Gupta[2]*, Rakesh Bharatia[2] and Preeti Upadhyay[2]

[1]Institute of Technology & Management Gida Gorakhpur-273209.
[2]ITM College of Pharmacy and Research Gida Gorakhpur-273209.

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***Corresponding Author**
Nidhi Gupta
ITM College of Pharmacy and Research Gida Gorakhpur-273209.

ABSTRACT
By ensuring product quality, safety, and efficacy, formulation development plays a crucial role in pharmaceutical research and is necessary for both therapeutic and commercial success. Up until and including market approval, the many components of formulation development interact with other phases in product development, such as discovery research. Because of the complexity of several routes that might impact product stability, the unique properties of the medicinal molecule, unique patient needs, and even marketing concerns, every drug product requires a custom formulation. There are several ways to approach formulation development: from a logical design based on scientific ideas to applying these insights to thousands of components This article reviews formulation development and explains pre-formulation and sop handling so that readers may understand the significance of these processes and recognize, respect, understand by all.

KEYWORD: Good manufacturing practices pre formulatios studies formulation evolution.

INTRODUCTION

A major trend in the biotechnology and pharmaceutical industries is drug development. Due to increasing obligations to investigate drug candidates from discovery to human Clinical Trials as quickly as feasible, the majority of biotech and pharmaceutical companies are contributing a share of their potential new drug development. Product development times are shortened and outsourcing is a more affordable option. Outsourcing offers a multiple cost structure, raising resources and spending when demand declines and decreasing when it does not. It also allows the organization to quickly address the changing needs of its workforce. A major trend in the biotechnology and pharmaceutical industries is drug development. Many pharmaceutical and biotech companies are outsourcing some of their drug development activities because to the increasing demand to move therapeutic proposals quickly from the discovery phase to human clinical trials. Product development timeframes are shortened by outsourcing, which is also a more affordable option. With this approach, businesses may react quickly to shifting customer demands, modify how they allocate resources, and effectively control expenses in response to changes in market demand.

Pharmaceutical products' long-term viability and patentability are largely dependent on the development of their formulas. To improve the caliber and efficacy of their medications, businesses integrate formulation development concepts, adherence to laws and regulations, and specialized staff into their product development procedures.

Definition

The successful creation of a commercial drug product is correlated with the discovery of a novel drug substance, according to pharmaceutical formulation development. Based on patient demand, formulation development experts must choose the best course of action for obtaining successful drug administration. They must then optimize the formulation's properties by taking into account the therapeutic product's bioavailability and processing needs.

History

The roots of pharmaceutical knowledge can be found in Ayurveda, an ancient Indian medical system credited to Hindu mythological figure Dhanvantari, who served as the gods' physician. The Atharvaveda is one of the Vedas' references to this age-old knowledge. In more recent times, German scientist Friedrich Sertürner is credited with introducing the first pharmaceutical drug in 1804, thus paving the way for the development of contemporary pharmaceutical therapy.

The majority of the natural sources used in traditional medicine were plants, herbs, roots, vines, and fungi. These organic substances were the main source of relief from human pain and suffering until the middle of the 1800s. An important turning point in the pharmaceutical.

The first synthetic medicine, chloral hydrate, was discovered in 1869 and was mostly used as a sedative-hypnotic. It's amazing that chloral hydrate is still accessible in some nations today.

The emerging pharmaceutical business was similar to the textile and synthetic dye industries in that it developed largely due to the plentiful supply of organic compounds that could be obtained from coal by distillation (coal-tar). Coal-tar byproducts were the source of analgesics and antipyretics, such as phenacetin and acetanilide. The application of white willow bark, a centuries-old treatment for a variety of fevers and inflammations, was another noteworthy finding. Salicin, also known as salicylic acid, which is bitter and irritating to the stomach, was present in white willow. Nevertheless, acetylsalicylic acid—famously known as Aspirin®—was the product of a simple chemical changewhich represents a critical turning point in the history of pharmaceuticals.

Steps in Formulations

1. **Identification and characterization of drug**-The The identification and characterization of drugs are crucial because they have an important effect on the finished product and can increase or decrease the drug's potency or toxicity.
2. **Excipient Compatibility Study:-**The greater the excipient's compatibility with the drug, the higher the likelihood of the drug's formulation success and its corresponding effect.
3. **Formulation development:-**The development of formulations to determine whether chemicals work with witch and witch excipients that are appropriate for medications is the focus of the following stage.
4. **Formulation Optimization:** This process takes a great deal of study and expertise, especially when dealing with complicated formulations like vaccines. Because of their intricacy and requirement for a significant amount of data, these formulations
5. **Evaluation of Formulations:** Evaluation studies are carried out to improve formulations that have already been developed by changing particular elements, including the kind of vehicle that is employed. The goal of these investigations is to enhance and optimize the formulation.
6. **Stability Studies:** To evaluate the formulation's endurance, stability Stability Studies: To evaluate the formulation's endurance, stability studies are crucial. To improve the stability of the formulation, so increasing its shelf life and guaranteeing product integrity, a number of tests are carried out.

Good Manufacturing Practices

When one abides by the laws and regulations provided by the G. M. P., good manufacturing practices assist in adhering to the guidelines given to maintain standards of the product, boost production, and maintain safety. In certain situations, the company is growing rapidly, and as a result of upholding the standards, its reputation has grown. This helps with product sales as well since, when good manufacturing processes are used, product quality is maintained and improved, which raises the customer satisfaction index. Because there are fewer issues during formulation development and the process moves more quickly as a result of the shorter process duration, the new product is introduced to the market as soon as possible.

Pre-Formulation Studies

Pre-formulation is based on the industrial pharmaceutical development paradigm, which establishes and characterizes the physicochemical features of medicinal compounds. Pre-formulation studies are laboratory investigations to identify the properties of the active ingredient and excipient that may have an impact on the design and performance of the formulation process. Pre-formulations are a set of research that focus on the physicochemical characteristics of novel drug candidates and how they interact with excipients to influence medicinal efficacy.

Goals and Objectives

1. To ascertain the product's stability and evaluate if it is compatible with common excipients.
2. To offer guidance on the proper processing and storage of pharmaceutical items in order to maintain their quality.
3. To produce relevant data for the purpose of designing a drug delivery system with high bioavailability.
4. To create a sophisticated, reliable, safe, and effective dosage form by determining the new API's physicochemical parameters and kinetic rate profile.
5. To produce relevant data that is required for creating safe dosage forms that are able to be produced commercially.

Properties and physical forms

Physical properties- The physical characteristics of the candidate drug molecule and excipient, such as color, odor, and taste, are displayed by simply analyzing them. For example, odor analysis reveals the constituents present, and color analysis reveals impurities.

1. Crystalline

It has repetitious spacing of constituents atom or molecules In dimensional array it is more stable than amorphous.

2. Amorphous

Does not have any fixed internal shape.

3. Partial Size And Shape

Its most crucial qualities are those that impact the substance's bulk qualities, such as test color performance, efficiency, solubility, stability, homogeneity, and texture. Surface area formulas are used to calculate particle size.

Equipment And Instrument Handling Tablet Compression Machine

Hydraulic pressure is the fundamental idea behind a tablet compression machine. Through the static fluid, this pressure is conveyed without decreasing. Through static fluid, pressure supplied externally is transmitted to all directions in an equal amount. Additionally, it enables the force to be multiplied as necessary.

Coating tablet

The technique of coating tablets involves applying a dry, outer layer of coating material to the dosage's surface; this provides certain advantages over the uncoated form. coatings used on a variety of oral dosage forms, including tablets, granules, powders, crystals, pellets, and particles.

CONCLUSION

The pharmaceutical industries depend on formulation development studies, pre-formulation studies, various tests, and SOP handling. Without these, the industries cannot function properly, and quality effectiveness and new solutions to problems that arise during development cannot be solved. It is also known that formulation development requires a great deal of work and knowledge because "small mistakes have big consequences.

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