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Review on Preformulation Studies of the Herbal Drugs

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ABSTRACT

Preformulation studies are actions taken before the creation of a formulation. It offers the empirical foundation for formulating policies. The two main classes of preformulation studies are (1) fundamental properties and (2) derived properties. Preformulation properties that are fundamental to a drug molecule are specific to it and rely on its chemical structure. On the other hand, research on derived preformulation properties is done to find out more about the problems associated with developing a specific dosage form, such as parenteral, liquid, or solid. The following are basic preformulation properties: oraganoleptic properties stability profile, solubility, solubility profile, purity, incomatibiltystudies, dissolution kinetics, etc. Preformulation properties that are derived are particular to the dosage form that is intended to be created.

Keywords- Preformulation, herbal drug candidate

INTRODUCTION

Preformulation is a subfield of pharmaceutical science that determines the physicochemical characteristics of medicinal substances by applying biopharmaceutical concepts. It is the initial phase of a pharmacological substance's logical dosage form development. It is the study of a drug substance's physical and chemical characteristics both on its own and in combination with excipients. A crucial step in the pre-formulation stage of product development is characterizing the therapeutic molecule. The creation of a novel drug's basic physical and chemical qualities is a prerequisite before any dosage form is created. Accelerated stability (stress) tests, the development of stability-indicating analytical methods, and other physicochemical characterizations aimed at identifying stability issues and facilitating formulation improvement are examples of preformulation research.

Need Of Dosage Form

The process of characterizing a pharmacological moleculeThroughout the medication development process, formulation development is necessary at several points. Drugs are rarely delivered alone, as we have previously mentioned. Adding the medication to a formulation offers a number of benefits, such as improved stability, improved bioavailability, and convenience of handling and administration. As previously mentioned, different formulations are needed for different phases of clinical trials. A thorough preformulation study aids in comprehending the medicinal molecule's physico-chemical characteristics. It offers the framework for creating a strong dosage form that can withstand the demands of processing and storage. Long-term cost savings are achieved by preformulation efforts, which lessen difficulties encountered during formulation development.

- To offer a method for the easy and safe administration of precise dosage.
- To shield against environmental factors, such as the damaging effects of humidity or oxygen.
- To shield against the damaging effects of gastric acid after oral ingestion.
- To mask the nauseating, salty, and bitter smell of the drug substance.
- To offer preparations for liquids that are erratic or insoluble in a vehicle.
- To give substance dosage forms that are unambiguous.
- To deliver drug action at a controlled rate.
- To give topical administration of drugs the best possible action.

The goals of Preformulation-

- To create elegant, stable, and safe dosage forms.
- Before developing a dosage form, it's critical to comprehend the physical characteristics of a drug substance.
- It is the initial phase in the methodical development of a drug substance's dosage form prior to dosage form development.

Need of preformulation studies of herbal medicine.

- Provide effective and safe medications.
- Adherence by patients to specific drug dosage forms
- To lower a medication's dosage.
- To improve the drugs' bioavailability.
- To investigate and produce novel combinations.
- To apply contemporary drug manufacturing technology while preserving the core tenets of herbal products.

Preformulation and herbal medicine

Over the last ten years, the focus has shifted to the extraction of pure bioactive compounds from herbal products and other substances, the medicinal benefits of which are extensively recorded in traditional texts.

Scientists in research and industry have chosen to use modern organic solvent extraction methods to isolate bioactive components from the original plants/substances because traditional traditional methods of preparing crude drugs and formulations are labor intensive, time consuming, and require validation and standardization.

The extraction and isolation of pure chemical compounds from medicinal plants is controversial, though, as single or multi-herbal formulations have traditionally been recommended for herbal medicine systems. Thousands of years of empirical research have, in fact, produced strict guidelines for the preparation of therapeutic herbal products with the fewest possible side effects.

Preformulation studies can begin after the individual extract has been characterized and its resemblance to previously approved safe use material has been established. However, the field of herbal medicine lacks the large guidance and techniques found in preformulation studies in pharmaceuticals based on synthetic drugs. To determine whether it is possible to produce high-quality solid dosage form formulations, it is necessary to investigate the properties of phytopharmaceuticals using a variety of measurement techniques and aspects.

Potential parameters for a herbal drug preformulation study.

Organoleptic characteristics	Stability
Purity	Being hygroscopic
Particle form and size	Binding attributes
The ability to dissolve and disperse	Concept of Drug-Drug Interaction
Relationship among excipients	Incompatibility

Organoleptic Properties-

This includes the physical attributes like color, taste, smell, and touch that can only be assessed by the senses.Every material's color is closely related to its composition; extracts are typically dark brown or black in color.

Stability-

The stability profile of a novel drug substance is crucial to moving forward with product development before it is used in clinical trials. Environmental factors may cause changes in the substance. It might break down, losing some of its effectiveness, or it might react and transform into a different molecule, making it dangerous to use. Consequently, the main method for evaluating the shelf lifeand storage circumstances of pharmaceutical products is stability testing. Stability studies are associated with the establishment and guarantee of the drug product's quality, safety, and efficacy from the beginning of its development to the end of its lifecycle.

Purity-

This is yet another crucial element for research on Preformulation. Every compound has a defined limit of impurity based on its toxicity and dose. Other studies, such as those on stability, degradation, and toxicity, cannot be carried out until the drug's purity is guaranteed. The drug substance's purity is determined by a number of factors, including TLC, HPLC, UV absorption, and IR spectra. herbal purification techniques may cause a reduction in purity percentage, but from a medicinal standpoint, they eliminate certain toxins.

Being Hygroscopic-
This could be taken into account in stability studies. The moisture in the air can cause significant structural alterations in herbal extracts. They could be effervescent or hygroscopic. Environmental controls on the manufacturing, packaging, and, most crucially, the stability and microbiological properties of the material and formulations could be seriously impacted during the manufacturing process.

Particle form and size-
The size, shape, and surface morphology of the drug particles directly affect bulk flow, formulation homogeneity, and surface-area controlled processes like dissolution and chemical reactivity. Generally speaking, in order to facilitate the preparation of homogenous samples and optimize the drug's surface area for interactions, every new drug candidate should be tested during preformulation with the smallest particle size that is practicable. The shapes and sizes of drug substances' particles have an impact on a range of their chemical and physical characteristics. In certain cases, the impact extends to the biopharmaceutical behavior of solid drugs in addition to their physical characteristics.

Binding Attributes-
An idea of potential excipients can be obtained from the data on binding properties. It might also imply the medication's dosage form, such as a tablet or capsule.

The ability to dissolve and disperse-
The impact of drug solubility on particle size, shape, and surface area makes it a crucial physicochemical property. The rate at which the drug releases into the dissolving medium, its solubility and bioavailability, and, ultimately, its therapeutic efficacy . The first step is to ascertain a molecule's solubility in different solvents. Having this knowledge is helpful when creating a formulation. If the molecule is lipophilic, its solubility is usually ascertained in a range of widely used solvents and certain oils. Water, polyethylene, propylene, glycerin, sorbitol, ethyl alcohol, methanol, benzyl alcohol, isopropyl alcohol, tweens, polysorbates, castor oil, peanut oil, sesame oil, buffers at different pH levels, etc. are common solvents used for solubility determination.

Concept of drug-drug interaction-
The interactions between the components could be favorable or unfavorable. The elements might work in concert to strengthen one another's effects. Their interactions could be antagonistic and work against each other's effect

Relationship among excipients-
to see if the chemical makeup of the herbal extract has changed after being combined with the excipients or polymers. Through the acquisition of the extract -excipient interaction checked FTIR spectra.

Concept of Incomatibility
Incompatibilities occur when two or more herbal APIs and/or excipients are combined and, if they are antagonistic and negatively impact safety, therapeutic efficacy, elegance, or appearance, they are considered incompatible. Utilizing FTIR spectroscopy to obtain various spectra within the appropriate range allows for the incomatibility to be checked.

CONCLUSION

This is where the development of logical, secure, and effective herbal medications greatly depends on the preformulation. For herbal drugs, the traditional preformulation R&D techniques might not work, and its structure might need to be changed to live up to our expectations. The industry can effectively use the wealth of knowledge regarding the properties of single drugs and multi-ingredient formulations that has been preserved in ancient texts during preformulation research and development. It is important to emphasize the interactions between the different parts of compound medications as well as their stability, therapeutic efficacy, and safety. Typical conditions for the handling, formulation, storage, dispensing, and administration of a herbal drug candidate may be included in these studies, along with solid state and solution experiments.

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