**"Emerging Trends in Herbal Excipients: A Sustainable Alternative to Synthetic Excipients"**

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**Abstract:**

Excipient use in pharmaceutical formulations is essential for maintaining the stability, bioavailability, and patient acceptance of drugs. However, there is increased interest in investigating herbal alternatives due to worries about the safety and environmental impact of synthetic excipients. An overview of the latest developments in herbal excipients, a safe substitute for synthetic excipients, is provided in this book chapter.

Over synthetic excipients, herbal excipients have a number of benefits. They come from organic materials like plants and are frequently renewable, biodegradable, and environmentally favorable. Additionally, they have innated therapeutic qualities that might boost medicine effectiveness and offer extra health advantages. The usage of herbal excipients is in line with rising customer demand for eco-friendly and natural goods.

This study addresses numerous herbal excipients, highlighting their uses in pharmaceutical formulations, including polysaccharides, gums, essential oils, and plant extracts. It investigates their special physicochemical characteristics, suitability as pharmaceutical active components, and potential pathways for boosting medication transport and stability.

The newest developments in herbal excipients offer encouraging outcomes, such as increased medication solubility, controlled release, and decreased toxicity. To enable the broad use of herbal excipients in the pharmaceutical business, issues including standardization, quality control, and regulatory considerations must be resolved.

The development of herbal excipients offers a sustainable and natural substitute for synthetic excipients, in conclusion. To fully realize the potential of herbal excipients and reap their benefits in pharmaceutical formulations, more study and collaboration between regulatory agencies, businesses, and academia are required.

# INTRODUCTION:

According to the definition, excipients are "the substance used as a vehicle for administering a medication" [1]. Natural polysaccharide polymers, specifically, are used in pharmaceutical products to process the drug delivery system during manufacturing, protect, support, or enhance stability, bioavailability, or patient acceptability, help identify the product, or improve any other aspect of general safety, effectiveness, or delivery of the medication during storage or use [2]. It is now generally acknowledged that excipients have the potential to impact both the rate and extent of a medication's absorption, contrary to the long-held assumption that excipients are inert, do not perform any therapeutic or biological activity, and do not modify the biological action of the drug component. Herbal excipients have a significant place in the formulation of pharmaceuticals since they are non-toxic and compatible with other substances [3].

Herbal excipients are quickly becoming more popular in the pharmaceutical sector as a substitute for their synthetic counterparts due to their lower toxicity levels, greater ease of accessibility, and more affordable prices. And consumers are also interested in elements that are natural or herbal. Consumers have a preconceived notion that natural drugs are inherently safer than their synthetic counterparts. Excipients, from the perspective of today, also help formulations become more permeable and boost the rate of absorption. In today's world, the use of herbal excipients in pharmaceutical products is becoming more widespread. [4].

# PHARMACEUTICAL EXCIPIENTS:

In the pharmaceutical industry, non-active substances called "excipients" are combined with therapeutically active compounds to create medications. This process is known as "excipient mixing." Excipients are any components of medicine that aren't "active" compounds. Excipients have a major and increasingly functional impact on the behavior and effectiveness of medicinal products. It should come as no surprise that factors contributing to product variability include the active substances, excipients, and processes involved [5].

# NATURAL EXCIPIENTS:

The natural world has endowed us with a wide range of goods that, either directly or indirectly, contribute to the enhancement and maintenance of the well-being of all human beings. The development and manufacturing processes for pharmaceutical dosage forms both utilise natural polysaccharide polymers. The stability, bioavailability, and patient acceptance are all protected, maintained, or improved. aid in the identification of the product and improve every other facet of the medication's general safety, effectiveness, or delivery when it is being used or kept [6].

# Advantages of Herbal Excipients

1. Biodegradable polymers are substances found in nature that are produced by all living things. Individuals or the environment, they don't seem to have any detrimental effects.
2. Since they are mainly mostly made of repeating monosaccharides made from carbohydrates, they are practically fully biocompatible and non-toxic. They are not poisonous as a result.
3. Compared to synthetic materials, they are more inexpensive and less expensive to produce.
4. Since they're based on their nature that they are derived from a natural source, they are risk-free and without side effects.
5. Due to their widespread use across a variety of industries, they are readily available and produced in many nations [7-10].

# Disadvantages of Herbal Excipients

1. Since they are exposed to the outside environment when generating, the potential of microbial contamination is increased.
2. Unlike natural polymer manufacture, which is influenced by the environment and a number of physical parameters, synthetic polymer manufacturing is a regulated process with fixed constituent quantities.
3. The proportion of chemical components present in a specific substance may change depending on when the material was collected, the region, the species, and the climate conditions.
4. Since the environment and a host of other factors affect the production rate, it is unchangeable. Natural polymers, therefore, produce at a sluggish rate.
5. There is a possibility of heavy metal contamination. With herbal excipients, heavy metal pollution is frequently related [7-10].

# CLASSIFICATION OF EXCIPIENTS:

As the amount of API used in formulation is going to depend on its potency, for designing and developing a proper and patient actable formulation is challenge. It needs use of number of components as excipients with specific role or function to be carried out for successful formulation. The excipients are classified into a number of groups based on their various roles as pharmacological aids [11].

1. Binders
2. Fillers and Diluents
3. Lubricating Agents
4. Coating agents
5. Flavoring Agents
6. Coloring Agents
7. Preservatives

In each of above class or category in majority of formulations use of synthetic excipients is done. But as a challenge as well as increasing the patients acceptability use of synthetic or semisynthetic excipients have to be replaced by natural excipients. It is need of hour.

# Binders

The binders used to give the granules cohesiveness or glue are plant-derived. This specifies granules of a certain hardness and size, which ensures that the pill remains in recoverable shape when packed, regardless of the stream characteristics. The purpose of folio excipients is to act as a sort of cement, “combining powders, powdered forms, and other dry substances to strengthen the finished item mechanically” Covers can be used to increase the volume of low dynamic measurement tablets, which are widely employed in wet granulation, and to provide more effective and predictable granule designs. For instance, after dissolving in a soluble substance like gelatin or cellulose subsidiary, arrangement coverings are separated by the application [12]. The following are some examples of dose forms when binders are employed:

* + Pallets, grains, pastes, pills, tablets, and so forth.

# Advantages of Natural Binders

Due to the following factors, natural binders are frequently employed as excipients in the pharmaceutical and food industries.

* have a low hazardous level
* Biodegradable
* Easily accessible
* Low price
* Boosts stability
* Make the texture better
* Prevent dosage form collapses, etc. [13]

# Disadvantages of Synthetic Binders

Processing problems such rapid over-granulation, formulation hardness, and diminished formulation dissolving properties can be brought on by synthetic binders. When synthetic binders are utilised in formulations, the process calls for the mixing of potent disintegrants. However, using synthetic binders is typically highly expensive. Due to the usage of synthetic binders, formulation stability is negatively impacted and film coating look is frequently seen on finished products. [14,15]

# Table. No. 1: List of some natural and synthetic binders

|  |  |  |
| --- | --- | --- |
| **Sr. No** | **Natural Binder** | **Synthetic Binder** |
| **1** | Tragacanth | Polyvinyl Pyrrolidone (PVP) |
| **2** | Xanthan | Methylcellulose |
| **3** | Guar | Hydroxy Propyl Methyl Cellulose (HPMC) |

1. **Fillers and Diluents**

Most of the time, Dynamic Drug Fixings (Programming interface) exhibit a beneficial effect in any drug measures structure. While working with excipients to acquire the right structure for patient similarities, the programming interface is not managed directly. Excipients like fillers and diluents are used to make strong plans heavier or to weaken fluid definitions. The crucial characteristic of diluents, which are fillers, is that they increase the mass volume while giving an underpinning structure, filling the size of measuring structures, and making them suitable for organization. Since fillers are passive substances by nature, they complement every facet of detailing. Measurement structures for strong, moderately strong, and fluid, fillers and diluents are used. Many chemical compounds can be glucose-ed by lactose milk sucrose. Gelatin creatures. Benefits of Typical Fillers and Diluents. Today, a variety of pharmaceutical and culinary activities use common fillers and diluents. Due to their biodegradable nature, they have no adverse effects and no side effects of any kind. They are also non-toxic, easily accessible, inexpensive, and have no impact on the environment [16]. Examples of dosage forms that contain diluents and fillers include the following:

* + Tablets, pills, pallets, paste, solutions, suspensions, and emulsions are a few examples.

# Advantages of natural fillers and diluents

The food and pharmaceutical industries now frequently use natural fillers and diluents. Due to their biodegradable nature, they have no toxicity or side effects, are readily available, affordable, or environmental repercussions [17].

# Disadvantages of natural fillers and diluents

In factories and laboratories, synthetic fillers and diluents are created. They are therefore costly economically. Additionally, their production harms the ecosystem. Additionally, synthetic filler has a number of significant negative effects. They occasionally clash with particular substances. Synthetic fillers also exhibit toxicity as a result of any production errors [18].

# Table. No. 2: List of some natural and synthetic fillers and diluents

|  |  |  |
| --- | --- | --- |
| **Sr. No** | **Natural fillers and diluents** | **Synthetic fillers and diluents** |
| **1** | Cellulose | Calcium carbonate |
| **2** | Lactose | Talc |
| **3** | Sucrose | Alumina trihydrate |

1. **Lubricating Agents**

Grease-ups are the excipients that are used to smooth out the cycle by adding a few chemicals. Grease is used to prevent the bunching of ingredients that are used for detailing throughout the procedure. Oils maintain the tenacity of definition while reducing the grating between particles and handling equipment. Small quantities of oils are used to define measuring structures with strength. Additionally, ointments have characteristics similar to anti-adherents. By invoking entomb particle grinding, oils also improve the item stream. One of two categories best describes most ointments; the first is hydrophilic in nature. In general, hydrophilic oils lack enemies of followers features and have undesirable oil qualities. The second kind of nature is hydrophobic.

The majority of hydrophobic oils are used in the production of drugs. Due to their considerable ability to grease up, these are used in minimal volumes. They also engage in hostile to follower and glider-like behaviour. Castor oil, paraffin oil, and stearic corrosive are common excipients used in ointments [19]. Here are some examples of dose forms used to provide lubricants:

* + tablets, capsules, pastes, suppositories, pallets, etc.

# Advantages of Natural Lubricants

* Pharmaceutical formulation frequently includes natural lubricants.
* Natural lubricants are easily accessible from a variety of sources.
* Natural lubricants don't harm either people or the environment.
* They work well with every component of formulations.
* The usage of natural lubricants is incredibly economical.

# Disadvantage of Synthetic Lubricants

The main problem with synthetic lubricants is that because of the extensive processes required to create them, they are more expensive than natural lubricants. A synthetic lubricant has a little impact and is hazardous [20].

# Table. No. 3: List of some natural and synthetic lubricants agents

|  |  |  |
| --- | --- | --- |
| **Sr. No** | **Natural Lubricants Agents** | **Synthetic Lubricants Agents** |
| **1** | Coconut oil | Polyalphaolefin oil |
| **2** | Aloe vera | Poly alkylene |
| **3** | Avocado oil | Silicon oils |

1. **Coating agents**

For both patients and pharmaceutical solid dosage forms, coating agents have a number of benefits. Coating agents are used to coat or make a film over the dosage form. The medication release is altered while drug security is improved by these coating approaches. Coating agents may be utilized, for example, Depending on the precise site of drug release, one may want to bypass the stomach and absorb the medication from the intestines. Coating agents also increase a product's effectiveness and provide environmental protection. The formulation looks more appealing thanks to coating agents [21-22]. Typical dose forms for coating agents include

* + tablets, capsules, pills, etc.

# Advantages of Natural Coating Agents

* The effectiveness of dosage forms is increased by natural coating agents.
* They do not negatively impact either humans or the environment.
* They are quickly eaten and eliminated from the body, as well as easily biodegradable.
* Materials for natural coatings are widely accessible.
* additionally economical [23]

# Disadvantages of Synthetic Coating Agents

* Pharmaceuticals employ synthetic coating agents despite the fact that the body finds it difficult to absorb or degrade them.
* They exhibit a bitter taste, thus various sweetening and flavoring compounds are utilised to mask it.
* Coloring chemicals are often employed because many coating agents have unattractive looks.
* The cost of using synthetic coating agents is high.
* The environment is also harmed by these disposal methods. [24-25]

# Table. No. 4: List of some natural and synthetic coating agents

|  |  |  |
| --- | --- | --- |
| **Sr. No** | **Natural Coating agents** | **Synthetic coating agents** |
| **1** | Alginate | Hydroxypropyl Methylcellulose (HPMC) |
| **2** | Cellulose | Polyvinyl Pyrrolidone |
| **3** | Pectin | Methylcellulose |

1. **Flavoring Agents**

Seasoning ingredients can be obtained in a variety of ways, although they are typically derived from plants, such as blossoms, leaves, stems, or bark. They are also referred to as "severe blockers" or "veiling specialists". Prior to being replaced by a variety of revitalizing oils like anise, clove, caraway, pimento, eucalyptus, and citrus-based goods, as well as menthol, nutmeg, thyme, or cinnamon, the principal scents used in dental products were peppermint, spearmint, and wintergreen. These flavoring experts play a significant role in prescription decisions, particularly when it comes to masking medications with their natural flavors. Many drug companies utilize flavors in a wide range of products, including tranquilizers, anti-malarial, anti-toxin, and hack syrups. Additionally, flavors are frequently used in the food industry. Specialists in organoleptic include those who are knowledgeable about seasoning. Flavors are used as taste-veiling agents to mask unpleasant tastes or measurement structure requirements. A taste makes the drug more likely to be consumed and makes it easier to organize patients. Kids absorb medications readily due to the use of flavors in the measurement framework [26]. Here is an example of a dosage form that includes flavoring agents.

* + These consist of mouthwashes, tablets, pills, pallets, capsules, pastes, syrups, emulsions, and suspensions among other things.

# Advantages of Natural Flavoring Agent

* Because they generate a true flavor, natural flavoring ingredients are now commonly used in the food and pharmaceutical industries.
* Natural flavors are also in good order and do not harm either people or the environment.
* Natural flavors are often derived from a variety of fruits and vegetables using a procedure that prevents contamination or degradation of the natural extract.

# Disadvantages of Synthetic Flavoring Agent

Synthetic flavoring agents have the fundamental drawback of having to be employed in extremely small doses since they are so concentrated.

* They have a harmful character when used frequently. And because they are difficult to biodegrade, they also have an impact on the ecosystem [27].
* But since natural flavors must be extracted from plants, synthetic flavors are more affordable than natural ones [28].

# Table. No. 2: List of some natural and synthetic flavoring agents

|  |  |  |
| --- | --- | --- |
| **Sr. No** | **Natural Flavoring Agents** | **Synthetic Flavoring Agents** |
| **1** | Almond | Ethyl Acetate |
| **2** | Cinnamon | Methyl Salicylate |
| **3** | Orange | Peppermint Oil |

1. **Coloring Agents**

Regular colors are obtained from plants, animals, and minerals as colorants. The typical colors come from plant sources including roots, bark, leaves, and wood, as well as from other natural sources like creatures and lichens. Because they are non-carcinogenic, non-toxic, and biodegradable, colorants derived from natural sources end up being protected. Examples of common shading experts include henna, beetroot, saffron, and turmeric. There are more than 450 plants in India that produce color. Some of these plants not only have the ability to produce color, but they also have therapeutic value. The utilization of natural materials and their therapeutic properties dates back almost as far as human history, and for a very long time, the primary sources of medicines were minerals, plants, and living things. Henna and turmeric are excellent sources of diversity. Shading experts are also used to differentiate measurement structures or to simply discern dose structures in evidence. Mental patients are drawn to the dose structures as a result of the use of shade specialists in measuring frames.

In the beauty care goods industry, shading experts are frequently used as colors as well. All colour consultants used in drug projects have FDA endorsement or verification 31 [29]. An illustration of a dosage form that contains coloring agents

* + Tablets, pills, pallets, capsules, pastes, creams, syrups, emulsions, and suspensions are a few examples of these.

# Advantages of natural coloring agents

* Due to the fact that they are made from natural sources, natural coloring compounds do not hurt or infect humans.
* Natural colors are more frequently used in manufacturing than synthetic ones since they are more readily degradable, stable, and environmentally beneficial.
* Additionally, natural coloring ants exhibit some therapeutic qualities.[30]

# Disadvantages of Synthetic coloring agents

* When used, artificial coloring agents exhibit symptoms similar to allergies.
* They are naturally cancer-causing.
* They exhibit negative health impacts on people.
* They also have teratogenic effects because their chemical structures contain azo groups or aromatic rings.
* According to a WHO research report, synthetic dyes and coloring agents are to blame for a range of problems, including immune system problems, ADHD, low temperature to frustration, and impulsivity [31].

# Table. No. 3: List of some natural and synthetic coloring agents

|  |  |  |
| --- | --- | --- |
| **Sr. No** | **Natural Coloring Agents** | **Synthetic Coloring Agents** |
| **1** | Beta Carotene | Patent Blue |
| **2** | Beet Juice | Tartrazine |
| **3** | Blue Spirulina Extract | Indigo Carmine |

1. **Preservatives**

In the food, cosmetics, and pharmaceutical industries, preservatives are chemicals that are used. They are provided to prevent microbial growth from degrading items. They also stop the unfavorable compound changes. In general, there are two types of additives: those that fight bacteria and those that fight oxidants. To extend the realistic use timeframe of the strategy, antimicrobial additives are applied. The antimicrobial additives function by hydrolyzing the microbes, denaturing their chemicals and proteins, changing the porosity of the microbial film, and oxidizing their cell components.

Additives that fight oxidants are typically used in a variety of businesses. The oxidation interaction damages food and medicinal ingredients most, especially those that include large amounts of unsaturated fats. harmful oxidants Limit the contact between oxidation. By preventing oxidation chain reactions or by acting as an inhibitor of oxidants' capacity to get oxidized and stop the oxidation process, cell reinforcements complete their role. An illustration of a dosage form that contains preservatives

* In the majority of entire formulations, including dosage forms that are solid, liquid, or semi- solid, a preservative is utilized.

# Advantages of natural preservatives

* Since ancient times, natural preservatives have been utilised extensively for a wide range of reasons.
* To preserve particular foods, they are widely used in homes.
* Several ayurvedic medications also use them.
* Natural preservatives are being used into many formulas to prevent product deterioration.
* They are not toxic to people.
* Because they are environmentally friendly and biodegradable, there are no side effects or negative consequences on people or the environment [32].

# Disadvantages of Synthetic Preservatives

* Because they are created by chemical synthesis, synthetic preservatives are more hazardous than natural preservatives.
* Synthetic preservative disposal is extremely hazardous to the environment.
* In many instances, artificial preservatives also have side effects. Meat is preserved with substances like E249 and E250 to avoid botulism toxins. Additionally, they harm living things when they come into contact with them [33].

# Table. No. 5: List of some natural and synthetic Preservatives

|  |  |  |
| --- | --- | --- |
| **Sr. No** | **Natural Preservatives** | **Synthetic Preservatives** |
| **1** | Curcuma Longa | Sodium benzoate |
| **2** | Alpinia Speciosa | Propyl gallate |
| **3** | Bixa Orellana | Potassium sorbate |

**APPLICATIONS OF HERBAL EXCIEPIENTS:**

The widespread usage of excipients shows how manufactured materials have limited the abilities of the natural dynamic expert. The benefits of normal excipients are their benign nature, higher cost-effectiveness, and accessibility. The types of the chosen item are strongly tied to the excipients' components. Excipients are substances with restorative characteristics that are internal in nature, different from dynamic compounds, and enhance the functionality of dynamic combinations. Any ingredient, except dynamic compounds, that is sourced from common resources and is purposely incorporated into the specification of a measuring structure is regarded as reasonably routine excipients. The traditional Indian medicinal system known as Ayurveda uses plant extracts and actual plant parts to treat a variety of illnesses. Prior to the delivery of the prepared mixtures, patients are treated with herbal drugs such as agitation, baati, bhasma, and others. Manufactured intensifiers are only allowed to be used in specific situations due to their severe side effects or injury. Researchers today also advocate the use of natural excipients or the use of semi-manufactured combinations to boost the concentration of mixtures, as much as is practically practicable. All dynamic mixtures that are therapeutically beneficial can be found in nature or are furthermore made in laboratories using naturally existing dynamic mixtures. Additionally, people utilize more organic or natural goods because they are less damaging or hazardous [34].

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