IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

"Role and Significance of Excipients in Pharmaceutical Formulations: A Comprehensive Review"

Aniket patil*, Pallavi Pise*, Prachi Vedpathak*, Aditya Chavan*

Final Year Bachelor Of Pharmacy

Mandesh Institute Of Pharmaceutical Science And Research Centre Mhaswad 415509,tal-Man, District-Satara.

ASTRACT:

Herbal or natural excipients offer significant benefits over their synthetic alternatives as they are non-toxic, more affordable, and readily available. With growing awareness about these natural excipients, which are primarily plant-based polymers, pharmaceutical industries are increasingly adopting them in formulation development. Natural gums and mucilages derived from plants, such as carrageenan, thaumatin, lard, storax, agar, gum acacia, and tragacanth, fulfill various pharmaceutical excipient requirements. The traditional idea of excipients as just inactive and inexpensive substances has changed a lot. Now, they are considered an important part of a drug formulation. Excipients are any ingredients added to a dosage form, other than the active drug. This article provides an overview of herbal excipients used in both conventional dosage forms and modern drug delivery systems. These natural ingredients are preferred for formulation development due to their stability and fewer regulatory concerns compared to synthetic options. Additionally, they can be easily modified to meet specific formulation needs, making them a cost-effective and efficient medium for delivering active pharmaceutical ingredients. This study highlights the potential of natural excipients as diluents, binders, disintegrants, and lubricants in different formulations, as they are biocompatible and provide added nutritional value to the dosage form.

Keywords: Natural excipients, Plant-based pharmaceutical aids, Natural polymers, Herbal binders.

INTRODUCTION:

Excipients are mainly used as fillers, binders, disintegrants, adhesives, flow enhancers, and sweeteners in tablets and capsules. Since synthetic excipients face challenges like toxicity and strict approval from regulatory authorities, researchers are now more interested in herbal excipients. Although herbal excipients may sometimes contain heavy metals, they are preferred because they are non-toxic, easily available, and cost-effective compared to synthetic ones. Nowadays, consumers prefer natural ingredients in food, medicine, and cosmetics, believing they are safer and have fewer side effects. The traditional belief that excipients are inactive and do not affect the drug's therapeutic or biological action has changed. It is now recognized that excipients can influence the rate and extent of drug absorption. Herbal excipients, being non-toxic and compatible, play an important role in pharmaceutical formulations. This paper aims to review the use of herbal excipients in Novel Drug Delivery Systems. Many pharmaceutical excipients come from plants, such as starch, agar, alginates, carrageenan, guar gum, xanthan gum, gelatin, pectin, acacia, tragacanth, and cellulose. These are widely used in the pharmaceutical industry as binding agents, disintegrants, stabilizers, coating materials, thickening agents, gelling agents, and more. Since plant sources are renewable and can be cultivated

sustainably, they ensure a steady supply of raw materials. Additionally, waste from the food industry can be used to extract herbal excipients, further increasing their demand.However, plant-based excipients also have some challenges. They are often produced in small amounts and as complex mixtures, which can vary based on plant location, season, and other factors. This makes their extraction and purification a slow and costly process. Excipients are substances used as a medium to deliver a drug. Natural polysaccharide polymers play an important role in pharmaceutical formulations. They help in drug processing during manufacturing, improve stability and bioavailability, enhance patient acceptability, assist in product identification, and ensure the safe and effective delivery of the drug during storage or use.Many plant-based excipients, such as starch, agar, alginates, carrageenan, guar gum, xanthan gum, gelatin, pectin, acacia, tragacanth, and cellulose, are widely used in the pharmaceutical industry. They serve as binding agents, disintegrants, stabilizers, coating materials, thickening agents, gelling agents, and bases for suppositories.

Pharmaceutical Excipients

Pharmaceutical excipients are inactive ingredients mixed with active drugs to create medicines. Any ingredient in a medicine that is not the main active drug is called an excipient. Excipients play an important role in how a drug works and its overall effectiveness. Differences in active ingredients, excipients, and manufacturing processes can affect the final product.

Excipients are typically categorized based on their use and role in pharmaceutical formulations:

1. Binders, Diluents
2. Lubricants, Glidants, Disintegrants
3. Polishing Film formers and coatings agents
4. Plasticizers, Colorings
5. Suspending agents, Preservatives, antioxidants
6. Flavorings, Sweeteners, Taste improving agents
7. Printing inks, Dispersing agents Gums

Advantages of Herbal Excipients

- **Natural and Safe**: These excipients come from natural sources, making them safe to use and environmentally friendly.
- **Non-Toxic**: Since they are mainly made of carbohydrates, they do not harm the body.
- **Cost-Effective**: They are cheaper to produce compared to synthetic excipients.
- **No Side Effects**: Being naturally derived, they do not cause harmful effects on humans.
- **Easily Available**: They can be obtained from various natural sources with ease.

Disadvantages of Herbal Excipients

- During manufacturing, natural excipients are exposed to the external environment, increasing the risk of microbial contamination.
- Their production depends on environmental factors like location and climate, leading to variations in quantity and composition.
- The manufacturing process of natural excipients is slow because it depends on factors that cannot be easily controlled.
- There is a possibility of heavy metal contamination in herbal excipients.

BINDERS:

Binder excipients help hold the ingredients of a formulation together and give the API the proper volume. For example, in tablets, binders ensure mechanical strength by keeping granules, powders, and other dry ingredients together. Commonly used binders include microcrystalline.

Eg.

- **Starch (Corn starch, Potato starch)** – A natural binder commonly used in tablet formulations.
- **Gelatin** – A protein-based binder that helps in tablet formation.
- **Povidone (Polyvinylpyrrolidone or PVP)** – A synthetic binder that dissolves easily in water.
- **Hydroxypropyl Methylcellulose (HPMC)** – A cellulose-based binder used in controlled-release formulations.
- **Microcrystalline Cellulose (MCC)** – Acts as both a binder and filler in tablets.
- **Acacia Gum (Gum Arabic)** – A natural gum used as a binding agent.
- **Sucrose** – Used in chewable and lozenge tablets as a sweet binder.
- **Methylcellulose & Ethylcellulose** – Used in both immediate and controlled-release formulations.
- **Pregelatinized Starch** – A modified starch that provides good binding properties.

LUBRICANTS:

This helps to stop the material from sticking to the die and punches, keeping the powder mixture flowing smoothly during compression. Lubricants are excipients used to make the manufacturing process smooth by reducing friction. They help prevent ingredients from clumping together during formulation. Lubricants also reduce friction between particles and equipment while maintaining the proper texture of the formulation.

Eg.

- **Magnesium stearate** – Most commonly used lubricant in tablet and capsule manufacturing.
- **Talc** – Helps reduce friction and improves powder flow.
- **Stearic acid** – Used in tablets to prevent sticking.
- **Sodium stearyl fumarate** – An alternative to magnesium stearate with better stability.
- **Calcium stearate** – Used in tablets and capsules to reduce friction.
- **Hydrogenated vegetable oil** – A natural lubricant used in some formulation.
- **Polyethylene glycol (PEG)** – Helps improve lubrication and solubility.

GLIDANTS:

Glidants are excipients added to pharmaceutical formulations to **improve the flow properties of powder mixtures** by reducing friction between particles. They help ensure uniform filling of tablet dies and capsules, leading to consistent dosage forms.

Eg.

- **Colloidal Silicon Dioxide (Aerosil)**
- **Talc**
- **Magnesium Stearate** (also acts as a lubricant)
- **Calcium Stearate**
- **Stearic Acid**
- **Fumed Silica**
- **Corn Starch** (has mild glidant properties)
- **Sodium Stearyl Fumarate**

DISIENTEGRANT:

A **disintegrant** is a type of pharmaceutical excipient added to solid dosage forms like tablets and capsules to facilitate their breakdown (disintegration) into smaller fragments upon contact with a liquid, usually in the gastrointestinal tract. This enhances drug dissolution and absorption, ensuring the medication works effectively.

Eg.

- **Starch** (e.g., Corn starch, Potato starch)
- **Sodium Starch Glycolate** (Primogel®, Explotab®)
- **Croscarmellose Sodium** (Ac-Di-Sol®)
- **Crospovidone** (Polyplasdone®)
- **Microcrystalline Cellulose (MCC)**
- **Alginic Acid and Sodium Alginate**
- **Calcium Silicate**
- **Guar Gum & Locust Bean Gum.**

COATING AGENTS:

Coating agents are excipients used in pharmaceutical formulations to coat tablets, capsules, and granules. These agents provide various functional benefits such as protection, improved stability, controlled drug release, and enhanced patient compliance.

Functions of Coating Agents

1. **Protection** – Shields the drug from environmental factors like moisture, light, and oxygen.
2. **Taste Masking** – Covers bitter or unpleasant tastes of active pharmaceutical ingredients (APIs).
3. **Modified Release** – Controls drug release (e.g., immediate, sustained, or delayed release).
4. **Aesthetic Appeal** – Improves appearance and branding.
5. **Mechanical Strength** – Enhances tablet hardness and reduces friability.

Eg.

- **Hydroxypropyl Methylcellulose (HPMC)** – Used in film coating for moisture protection and controlled drug release.
- **Ethylcellulose** – Employed in sustained-release coatings.
- **Polyvinyl Alcohol (PVA)** – Used in film coatings for stability and aesthetics.
- **Shellac** – A natural resin used for enteric coatings and moisture protection.
- **Methacrylic Acid Copolymers (Eudragit®)** – Used for enteric and sustained-release coatings.
- **Sucrose** – Traditionally used in sugar coatings for taste masking.
- **Gelatin** – Used in capsule coatings for protection and controlled release.
- **Polyethylene Glycol (PEG)** – Functions as a plasticizer in film coatings.

PLASTISIZER:

Plasticizers are excipients used in pharmaceutical formulations to improve the flexibility, workability, and mechanical properties of materials, particularly in film coatings and polymer-based drug delivery systems.

Role of Plasticizers in Pharmaceuticals

- Reduce the brittleness of films and polymers.
- Enhance the flexibility and elasticity of coatings.
- Improve the mechanical strength of dosage forms like tablets and capsules.
- Modify drug release profiles in controlled-release formulations.

Eg.

- **Triacetin (Glycerol Triacetate)** – Used in film coatings and sustained-release formulations.
- **Polyethylene Glycol (PEG)** – Commonly used in tablet coatings and capsules.
- **Diethyl Phthalate (DEP)** – Used in enteric coatings and sustained-release formulations.
- **Dibutyl Sebacate (DBS)** – Used in film coatings to improve flexibility.
- **Castor Oil** – Acts as a natural plasticizer in soft gelatin capsules.
- **Glycerin** – Used in soft gelatin capsules and transdermal patches.
- **Propylene Glycol** – Used in semi-solid formulations and transdermal patches.

PRESERVATIVE:

Preservative excipients are inactive ingredients added to pharmaceutical formulations to prevent microbial contamination and extend the shelf life of the product. They help maintain the stability, safety, and efficacy of medicines during storage and use.

Eg.

- **Sodium benzoate** – Used in acidic foods and beverages.
- **Benzalkonium chloride** – Used in ophthalmic and nasal formulations.
- **Phenol** – Used in vaccines and antiseptic formulations.
- **Sorbic acid** – Used in foods like cheese and baked goods.

FLAVOURING AGENTS:

Flavouring agents are excipients used in pharmaceutical formulations to enhance the taste and odor of medications, making them more palatable for patients, especially children and elderly individuals.

Purpose of Flavouring Agents in Pharmaceuticals:

1. **Masking Bitter or Unpleasant Taste:** Many drugs have a naturally bitter or metallic taste, which can make them difficult to consume. Flavouring agents help mask these undesirable tastes.
2. **Improving Patient Compliance:** A well-flavoured formulation increases patient adherence, especially in pediatric and geriatric patients.
3. **Enhancing Organoleptic Properties:** They improve the sensory appeal of the drug by modifying its taste and smell.
4. **Differentiation of Products:** Different flavours can help distinguish between various formulations or dosages of the same drug.

DISPERSING AGENTS:

A **dispersing agent** (also called a **dispersant**) is an excipient used in pharmaceutical formulations to improve the distribution of solid particles in a liquid or semi-solid medium. These agents help prevent particle aggregation and ensure uniform dispersion, which enhances the stability, bioavailability, and effectiveness of the drug.

Functions of Dispersing Agents in Pharmaceuticals:

1. **Prevents Aggregation:** Keeps fine particles separate, avoiding clumping.
2. **Enhances Stability:** Improves the physical stability of suspensions and emulsions.
3. **Improves Bioavailability:** Ensures proper dispersion of the active pharmaceutical ingredient (API) for better absorption.
4. **Aids in Uniformity:** Helps in achieving uniform dose distribution in liquid formulations.
5. **Enhances Wettability:** Reduces surface tension to allow better mixing of solids with liquids.

Eg.

- **Polysorbates (e.g., Polysorbate 80)**
- **Sodium lauryl sulfate (SLS)**
- **Lecithin**
- **Polyvinylpyrrolidone (PVP)**
- **Carboxymethyl cellulose (CMC)**
- **Hydroxypropyl methylcellulose (HPMC)**
- **Bentonite**
- **Gelatin**
- **Tragacanth**

Conclusion :

Excipients play a vital role in pharmaceutical formulations by enhancing drug stability, bioavailability, and patient compliance. Their selection depends on various factors, including physicochemical properties, compatibility with active pharmaceutical ingredients, and regulatory considerations. Advancements in excipient technology, such as the development of multifunctional and novel excipients, continue to drive innovation in drug delivery systems. Future research should focus on improving excipient safety, exploring natural alternatives, and optimizing formulation strategies to meet the evolving demands of the pharmaceutical industry.

References:

1) Prashant Singh*, Tarique Mahmood, Arshiya Shameem, Paramdeep Bagga, Nesar Ahmad, March 2016, A review on Herbal Excipients and their pharmaceutical applications, Scholars Academic Journal of Pharmacy (SAJP), www.saspublisher.com
2) SHIRWAIKAR*, ANNIE SHIRWAIKAR1, S. LAKSHMANA PRABU AND G. ARAVIND KUMAR, July - August 2008, Herbal Excipients in Novel Drug Delivery Systems, Indian Journal of Pharmaceutical Sciences, file:///C:/Users/Admin/Desktop/EXCI%202.pdf
3) Gadhave Rohan. G* 1 Sonawane Sonali.S*2 , Rode Abhijit.R*3, A Review of herbal excipients, International Journal of Creative Research Thoughts (IJCRT) www.ijcrt.org.
4) Verma Poonam*, Gupta Sagar, Kushwah Abhishek, Saxena Yuvraj, : 18-08-2018. Remarkable Contribution of Natural Excipients in Finished Pharmaceutical Products (FPPs), International Journal of Pharmaceutical Sciences Review and Research, www.globalresearchonline.net
5) Rashmi Saxena Pal* , Yogendra Pal, Ankita Wal and Pranay Wal, : January 23, 2019, Current Review on Plant based Pharmaceutical Excipients, Open Medicine Journal, 10.2174/1874220301906010001, 2019.
6) Rahul Patel, James Barker and Amr ElShaer *,3 November 2020, Pharmaceutical Excipients and Drug Metabolism: A Mini-Review, International Journal of Molecular Sciences, https://www.mdpi.com/journal/ijms