

## Herbal Excipients- Significance of Substances of Natural Origin as Excipients

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**Abstract :** As in every field there is a transformation to improve the performance and satisfy the demand of consumer, in pharmaceutical word, need of “Excipient” have been changed from inert and cheap substance which forms bulk of formulation to a material which has potential to be placed in formulation as it accomplished the desirable objective of treatment. The Herbal or natural excipients have a great advantage over their synthetic analogues as these are non-toxic, less expensive and freely available. Due to advances in drug delivery technology, currently, excipients are included in novel dosage forms to fulfill specific functions and in some cases, they directly or indirectly influence the extent and/or rate of drug release and drug absorption. Recent trends towards use of plant based and natural products demand the replacement of synthetic additives with natural ones. Today, the whole world is increasingly interested in natural drugs and excipients, hence natural materials have many advantages over synthetic ones as they are chemically inert, nontoxic, less expensive , biodegradable, improve the shelf life of the product and widely available. This article gives an overview of natural excipients which are used in conventional dosage forms as well as novel drug delivery systems.

**Keywords :** Herbal Excipients, Natural Colorants, Natural Sweeteners, Natural Binders.

## Introduction

The term excipient was derived from the Latin word, excipients, which mean to receive, to gather, to take out. The quality of formulation depends on active pharmaceutical ingredient (API), production processes and the excipients used. These excipients contribute in a great way to the performance of the API and maintain the safety, efficacy of the product [1]. According to the International Pharmaceutical Excipients Council, The excipients are defined as “ Substance other than the active drug substances of finished dosage forms, which have been appropriately evaluated for safety and are included in drug delivery system to either aid the processing of the drug delivery system during its manufacture, protect, support or enhance stability, bioavailability or patient acceptability, assist in product identification or enhance any other attributes of the overall safety and effectiveness of the drug delivery system during storage or use”.

According to WHO excipient is defined as “The Substance other than active ingredients which have been appropriately evaluated for safety and or included in a drug delivery system to

- Aid in processing of drug delivery system during its manufacture.
- Protect, support and enhance stability, bioavailability or patient acceptability.
- Assist in product identification.
- Enhance any other attributes of the overall safety and effectiveness of the drug delivery system during storage or use.

In simple words, Pharmaceutical excipients may be defined as in-active substance added to medicinally active compounds to formulate dosage forms[2-4]. Several pharmaceutical excipients of plant origin, find applications in the pharmaceutical industry as binding agents, disintegrates, sustaining agents, protective's, colloids, thickening agents, gelling agents, bases in suppositories, stabilizers, and coating materials[5,6]. As plants sources are renewable and can be cultivated or harvested in sustainable manner, can supply constant availability of raw material. Waste from food industry can be achieved as a raw material to extract herbal excipients. These are other reasons for increase in demand of herbal material as excipients [7]. However, substances from plant origin also pose several potential challenges such as being synthesized in small quantities and in mixtures that are structurally complex, which may differ according to the location of the plants as well as other variables such as the season. This may result in a slow and expensive isolation and purification process. Another issue that has become increasingly important is that of intellectual property rights [8, 9]. The specific application of plant-derived polymers in pharmaceutical formulations include their use in the manufacture of solid monolithic matrix systems, implants, films, beads, microparticles, nanoparticles, inhalable and injectable systems as well as viscous liquid formulations [10-12]. Ability to produce a wide range of material based on their properties and molecular weight, natural polymers became a thrust area in majority of investigations in drug [13,14].

## Functions of Excipients: [15]

- Add bulk to the formulation.
- During manufacturing it helps to handle Active Pharmaceutical Ingredients.
- Assist in drug administration.
- Enhance patient compliance.
- Enhance drug solubility and bioavailability of Active Pharmaceutical Ingredients.
- Avoid drug degradation.
- Give robust and reproducible result of formulation.
- Modify the pH and osmolarity of the liquid dosage forms.
- Prevents drug aggregation and helps in drug particles dispersion.
- Helps to mask unpleasant taste, color and odour.\
- Helps to maintain stability.

**Advantages of Herbal Excipients:**

- Biodegradable - Naturally occurring polymers produced by all living organisms. They show no adverse effects on the environment or human being.
- Biocompatible and non-toxic - Chemically, nearly all of these plant materials are carbohydrates in nature and composed of repeating monosaccharide units. Hence they are non-toxic.
- Economic - They are cheaper, and their production cost is less than synthetic material.
- Safe and devoid of side effects - They are from a natural source and hence, safe and without side effects.
- Easy availability - In many countries, they are produced due to their application in many industries[16-19].

**Disadvantages of Herbal Excipients:**

- Microbial contamination - During production, they are exposed to the external environment and hence, there are chances of microbial contamination.
- Variation - Synthetic manufacturing is a controlled procedure with fixed quantities of ingredients while production of natural polymers is dependent on environment and various physical factors.
- The uncontrolled rate of hydration-Due to differences in the collection of natural materials at different times, as well as differences in region, species, and climate conditions the percentage of chemical constituents present in a given material may vary.
- Slow Process - As the production rate depends upon the environment and many other factors, it can't be changed. So, natural polymers have a slow rate of production.
- Heavy metal contamination - There are chances of Heavy metal contamination often associated with herbal excipients[16-19].

**Ideal Properties of Excipients:**

- They can be used practically.
- They should be non-toxic and non-irritant in nature
- They should be non-volatile in nature
- They should not be affected by temperature, light and hydrolysis.
- They should be easily available and cheap.
- They should not have specific colour, odour, and taste.
- They should possess good water and lipid solubility.
- They should be compatible with the active ingredient in the preparation and should not affect its function.
- They should be pharmacologically inert [20].

**Classification of Excipients:**

Excipients are commonly classified according to their application and function in the drug products:

- Binders, Diluents.
- Lubricants, Glidants, Disintegrants.
- Polishing Film formers and coatings agents
- Plasticizers, Colorings.
- Suspending agents Preservatives, antioxidants.
- Flavorings, Sweeteners, Taste improving agents.
- Printing inks, dispersing agents Gums[21]
-

The excipients are classified based on various parameters as follows.

**Based on regulatory aspects there are three main categories:**

- **Approved excipients:** This category includes excipients from food industry or pharmaceutical industry. They are safe and are in use for very long time.
- **Intermediate category essentially new excipients:** This category includes structurally modification compounds which are in use for very long time.
- **New compounds:** These are not used in the pharmaceutical industry and are new compounds.

**Classification based on sources of excipients:**

- **Products from animal sources:** e.g. Beeswax, Cochineal, Gelatine, Honey, Spermaceti, Lanolin etc..
- **Products from vegetable sources:** e.g. Kokum Butter, Pectin, Starch, Peppermint oil, Cardamon, Vanilla etc.
- **Products from mineral sources:** e.g. Bentonite, Kieselghur, Kaolin, Paraffins, Talc, fullers earth etc.
- **Synthetic products:** PEGs, Polysorbates, Povidone[22].

**Classification based on Chemical nature:**

**Table-1 Classification based on Chemical Nature [22]**

S.No	Chemical Nature	Role	Examples
1.	Alcohols	For Patient compliance	Volatile oils, Lanolin, Polyphenolic compounds.
2.	Esters, Ethers, Aldehydes, Carboxylic acids.	For dose precision and accuracy.	Fixed oil, citric acid, vanillin.
3.	Glycerides and waxes	To enhance stability	Bees wax,lanolin.
4.	Carbohydrates	Assist in manufacturing process	Gums and Mucilages.
5.	Hydrocarbons and Halogen derivatives.	Drug tolerance	Paraffins, Polyphenolic compounds.
6.	Polymers(natural and Synthetic)	To avoid drug disaggregation	Cellulose, Pectin.
7.	Minerals	Help in drug dissolution	Bentonite, talc, calamine
8.	Protein	To prepare controlled release formulations.	Gelatin, soyabean
9.	Preservatives, dyes,sweeteners, surfactants.	To enhance absorption, to preserve, to make bitter taste and colour.	Stevia, Honey, Henna, Cochineal, Antioxidants, Polysorbates, Emulsifying waxes.

## Classification according to application of excipients

**Table-2 Classification of Excipients According to their Application[22]**

S.No	Category	Examples
1.	Fillers	Plant cellulose, Gelatin, lactose, Sucrose, Glucose.
2.	Binders	Acacia, Alginic acid, Corn Starch.
3.	Disintegrating agents	Silicone, Guar gum, Agar.
4.	Coating agents	Gelatin, Shellac, Natural Polymers.
5.	Lubricants	Castor oil, Mineral oil, Paraffin oil.
6.	Antioxidants	Ascorbic acid, Potassium metabisulphite, Sodium metabisulphite, Gallic acid.
7.	Colouring agents	Annatto, Carotene, Chlorophyll, Cochineal, Curcumin.
8.	Flavouring agents	Strawberry, Raspberry, Lemon, Orange, Peppermint.
9.	Solvent	Purified water, Oils.
10.	Chelating agents	Onions, Garlic, Chlorella, Brazil nuts.
11.	Buffering agents	Lemon
12.	Surface active agents	Waxes, Saponins.
13.	Viscosity builder or emulsifiers.	Gelatin, Mucilage of Aloe, Gums.

## Different Types of Natural Excipients:

### Natural Colourants:

To understand the concepts of natural dyes and dye-yielding plants, there are three basic questions to be addressed: Why only certain plants are able to yield dyes? How does the

plant benefit by producing dyes? What is the evolutionary explanation for production of dyes? Answers to the first two questions can be substantiated with two further questions, i.e. 'Why do plants have so many different colours?' and 'What purpose might they serve for the plant?' Green in most leaves is surely the most ubiquitous plant colour. The green pigment chlorophyll in leaves helps capture the sun's energy and converts it to chemical energy, which is then

stored and used as food for the plant. Colours in flowers are adaptations that attract insects and other animals that in turn pollinate and help the plants reproduce. Some plants have colourful fruits that attract animals to eat them, thus inadvertently spreading the plant's seeds as they do so. Scientists believe that other pigments may help protect plants from diseases. Despite what we know about the role of a few of the thousands of plant pigments, the role of most colours in plants remains a mystery to us till date[23].

**Table-3 List of some natural excipients used as Natural colourants**

S.No	Plant Name	Botanical Name	Chemical Constituents	Applications
1.	Henna	<i>Lawsonia inermis</i> Lythraceae	Lawson, Coumarins, Xanthene	Hair dye and other cosmetics
2.	Turmeric	<i>Curcuma Longa</i> Linn Zingiberaceae	Curcuminoids, Curcumin.	Colourants, Cosmetics and Food Products.
3.	Annatto	<i>Bixa orellana</i> Bixaceae	Bixin	Colouring and Coating agents.
4.	Indigo	<i>Indigo tinctoria</i> Leguminosae	Indigo, rotenol	Colourant and food industry.

### Natural Sweeteners:

Preference for sweet taste at a range of intensities is characteristic of human species. In the fetus, taste buds are developed by the 16<sup>th</sup> week of gestation, and the new born infant is able to respond favorably to sweetened solutions. Sugar is a natural sweetener that provides 4 calories per gram. It is acknowledged that excess sugar ingestion amounts to increased energy intake which, in turn, can lead to weight gain and chronic diseases associated with obesity and dental caries. Therefore, there is need for sugar substitutes, which can help reduce caloric intake, particularly in overweight individuals[24]. The demand for new alternative “low calorie” sweeteners for dietetic and diabetic purposes has increased worldwide. As of mid-2002, over 100 plant-derived sweet compounds of 20 major structural types had been reported, and were isolated from more than 25 different families of green plants. Several of these highly sweet natural products are marketed as sweeteners or flavouring agents in some countries as pure compounds, compound mixtures, or refined extracts[25]. Many synthetic sweeteners, which are widely used are proved to be carcinogenic and are non-nutritive. Hence demand greatly increased for natural sweetening agents, especially for non-sacchariferous sweetening agents, because they are highly potent, useful, safe and low-calorie sugar alternatives. Recently it was found that Himalayan forests are good sources of plants containing non-saccharide sweetening agents.

**Table-4 List of some natural excipients used as Natural Sweeteners**

S.No	Name of Plant	Constituents	Sweetness Potency
1.	<i>Stevia rebaudiana</i> Compositae	Stevioside, Rebaudioside A	200-250
2.	<i>Glycyrrhiza glabra</i> Leguminosae	Glycyrrhizin	100
3.	<i>Dioscoreophyllum volkensii</i> Menispermaceae	Monellin	1500-2000
4.	<i>Thaumatococcus danielli</i> Marantaceae	Thaumatococcoside I and II	2000-1000
5.	<i>Abrus precatoris</i> Leguminosae	Abrusosides and Glycyrrhizin	30-100
6.	<i>Cinnamomum seqlawcum</i> Lauraceae	Trans-Cinnamaldehyde	50
7.	<i>Citrus aurantium</i> Rutaceae	Neo-Hesperidin	1000
8.	<i>Cyclocarya palurus</i> Juglandaceae	Cyclocaryoside	250
9.	<i>Eremophila glutinosa</i> Scrophulariaceae	Dihydroflavonals	400
10.	<i>Perilla frutescens</i> Labiatae	Perillartine	400-2000

### Natural Binders:

Excipients are additives used active pharmaceutical active ingredients convert in to pharmaceutical dosage form suitable for administration patients[26]. Binders are added to the tablet formulation to impart plasticity as well as increases interparticulate bonding strength in the tablet[27]. Granule and also increases the degree of consolidation or compactions while decreasing the brittle fracture tendency during tableting .the choice of a suitable binder for a tablet formulation requires extensive knowledge of the binder properties for enhancing the strength of the tablet and also interaction between various material constituting tablet[28]. Gums generally polysaccharides which are polymeric in nature of natural substance obtained from woody and non woody plant parts such as bark, seeds, sap, roots, rhizomes, fruit, leaves and plant gums are widely used in

formulation of pharmaceutical dosage forms. The major application of gum is a tablet, as binding agent[29,30]

**Table-5 List of some natural excipients used as Natural Binders**

S.No	Product	Examples of Use
1.	Acacia	Natural Binders for tablets, Thickener, Suspending and emulsifying agent
2.	Tragacanth	Binder and diluents in tablets
3.	Starch	Binder and diluents in tablets.
4.	Gelatin	Binder and thickener in tablets
5.	Accroides	Binder in fireworks and flares.
6.	Candelilla	Binder in chewing gum.
7.	Guar	Binder in baking, meat and tablets.
8.	Gum Arabic	Binder in baking, personal care products, incense, photography, watercolor paints, ceramic glazes and fireworks.
9.	Karaya	Binder in baking and paper manufacturing.
10.	Shellac	Binder in mascara, eyeliners, fireworks and pyrotechnics.
11.	Tragacanth	Binder in icing, tablets, incense and pastel paints.
12.	Xanthan	Binder in baking, laxatives and toothpaste.

### Natural Diluents:

Generally, in any pharmaceutical dosage form Active Pharmaceutical Ingredients (API) shows the therapeutic effect, but API does not administered directly, they combines with excipients to get a suitable form for patient compatibility. Fillers and Diluents are those excipients which are used to enhance the bulk of any solid formulation or to dilute any liquid formulation. The major function of fillers and diluents is that, they provide a structural form and fill the size of dosage form and make them suitable for administration by enhancing the bulk volume. Fillers are inert in nature and easily compatible with all ingredients of formulation. Fillers and diluents are used in solid, semi-solid and liquid dosage form[31-32] . Examples of dosage form in which fillers and diluents are used are as follow:- Tablets, Pills, Pallets, Paste, Solutions, Suspensions, Emulsions etc.

**Table-6 List of some natural excipients used as Natural Diluents.**

S.No	Product	Examples of Use
1.	Cellulose	Adsorbent; suspending agent; tablet and capsule diluent; tablet disintegrant.(cellulose microcrystalline) Adsorbent; glidant; suspending agent; tablet and capsule diluent; tablet disintegrant (cellulose powdered) Tablet and capsule diluent.(cellulose Silicified)
2.	Lactose hydrous or anhydrous or monohydrate or spray dried	Binding agent; diluent for dry-powder inhalers; lyophilization aid; tablet binder; tablet and capsule diluent.( lactose anhydrous) Binding agent; diluent for dry-powder inhalers; tablet binder; tablet and capsule diluent(lactose monhydrate) Binding agent; diluent for dry-powder inhalations; tablet and capsule diluent; tablet and capsule filler.(lactose spray dried)
3.	Mannitol	Sweetening agent; tablet and capsule diluent; tonicity agent; vehicle (bulking agent) for lyophilized preparations
4.	Calcium	Tablet and capsule diluent; therapeutic agent

	carbonate	
5.	Sodium alginate	Stabilizing agent; suspending agent; tablet and capsule disintegrant; tablet binder; viscosity-increasing agent.
6.	Sucrose	Base for medicated confectionery; granulating agent; sugar coating adjunct; suspending agent; sweetening agent; tablet and capsule diluent; viscosity-increasing agent.

### Natural Lubricants:

Lubricates are the excipients which is used for the purpose of lubrication means making the process smooth by applying some substances. Lubricants are used for preventing the clumping of ingredients which is used in formulation during process. Lubricants decrease the friction between the particles and processing equipment and maintain the stickiness of formulation. Lubricants are added in small quantities to formulation like solid dosage forms<sup>18</sup>. Lubricants also have properties like Antiadherents. Lubricants also enhance product flow by reducing inter particulate friction. There are generally two types of lubricants, first one is hydrophilic in nature. Generally hydrophilic lubricants have poor lubrication properties and do not show as Anti-adherents properties. Second is hydrophobic in nature. Hydrophobic lubricants are most widely used in pharmaceutical industries. These are used in low volume because they have high lubricating property. They also have Anti-adherent and Glidants like action<sup>[33]</sup>.

Examples of dosage form in which lubricants are used are as follow:- Tablets, Capsules, Pills, Pastes, Suppositories, Pallets etc.

**Table-7 List of some natural excipients used as Natural lubricants:**

S.no	Name of excipients	Sources
1.	Stearic acid	Animals
2.	Castor oils	Seeds of castor
3.	Sodium chloride	Minerals (sea)
4.	Paraffin oil	Paraffin plant

### Coating agents:

Coating agents have various benefits in pharmaceutical solid dosage forms and also equally beneficial for humans. Coating agents are used to coat or to make a film over the dosage form. These coating techniques enhance the drug protection and also modified the drug release. According to the specific site of drug release coating agents are used such as to avoid the stomach and to absorb the drug from intestines coating agents play important role. Coating agents also ensures the product safety from outer environments and they enhance the product effectiveness. Coating agents enhance the attractiveness of formulation<sup>[34-35]</sup>.

Examples of dosage form in which coating agents are used: Tablets, Pills, Capsules etc.

**Table-8 List of some natural excipients used as natural coating agents.**

S.no	Name of excipients	Sources
1.	Gelatin	Animals
2.	Xanthan gum	Secreted from bacterium <i>Xanthomona scampestris</i>
3.	Guar gum	Seeds of <i>Cyamopsistetra gonolobus</i> L. Taub.
4.	Pectin	Inner portion of citrus fruits and vegetables.



### Natural Perfumes and Flavoring Agents:

Flavors are the mixed sensation of taste, touch, smell & sight. Nowadays, many artificial flavors are manufactured with the help of technology in flavoring industries. Many pharmaceutical industries use flavors in many formulations like: cough syrups, sedatives, anti-malarial and anti-biotic. Flavors are also widely used in food industries. Flavoring agents comes under the category of organoleptic agents. Flavors are used as taste masking agents which hides the unpleasant taste or order of dosage form. A flavor enhances the likelihood of medicine and makes them more compatible for patient's administration. Due to the use of flavors in dosage form children take medicines without any problem<sup>26</sup>. Flavoring agents may be artificial or natural. Artificial flavoring agents are synthesized in laboratories while natural flavoring agents are extracted from plants. There are various types of flavoring agents such as sweetening agents, ordering agents (aromatic oils). Aromatic oils are also known as volatile oils which are extracted from various flowers and plants by using specific separation technique. Sweetening agents also separated from plants and also manufactured synthetically<sup>[36]</sup>. Example of dosage form in which flavoring agents are used are as follow:- Tablets, Pills, Pallets, Capsules, Pastes, Syrups, Emulsions, Suspensions, Mouth washes etc.

**Table-9 List of some natural excipients used as Natural Perfumes and Flavoring Agents.**

S.No	Name of excipients	Source (Plants)	Family
1.	Lemon	Peel of Citrus limon	Rutaceae
2.	Orange	Peel of Citrus sinensis	Rutaceae
3.	Raspberry	Fruit of Rubusrosi folius	Rosaceae
4.	Peppermint	Leaf of Menthas picata	Lamiaceae
5.	Ginger	Roots of Zingiber officinale	Zingiberaceae
6.	Sandal wood oil	Heartwood of Santalum album	Santalaceae
7.	Ajowan	Trachyspermum ammi	Apiaceae
8.	Anise oil	Pimpinella anisum	Apiaceae
9.	Balsam of Peru	Myroxylon balsamum	Fabaceae
10.	Bay oil	Cinnamomum tamala	Lauraceae
11.	Cardamom oil	Elettaria cardamomum	Zingiberaceae
12.	Citronella grass	Cymbopogon nardus	Poaceae
13.	Clove oil	Syzygium aromaticum	Myrtaceae
14.	Davana oil	Artemisia pallens	Asteraceae
15.	Lavender oil	Lavandula latifolia	Lamiaceae

### Natural Preservatives:

Preservatives are chemical substances that are used in all Pharmaceutical, Cosmetics and food industries. They are added in formulation to prevent the decomposition of products by microbial growth. They also stop the undesirable chemical changes. Generally preservatives are of two types first one is anti-microbial preservatives and second one is anti-oxidants<sup>[37]</sup>. An anti-microbial preservative prevents the product form degradation by inhibiting the growth of micro-organism. This is very ancient technique such as pickling and adding honey to prevent microbial growth by altering the pH level of formulation. Anti-microbial preservatives used to increase the shelf life of formulation. Anti-microbial preservatives work by denaturation of enzymes and protein constituents of microbes, by hydrolyzing the microbes, by modifying microbial membrane permeability and by oxidizing the cellular constituents of microorganisms<sup>[38-39]</sup>. Anti-oxidants preservatives are widely used in various industries. The oxidation process damages the most pharmaceutical as well as food materials especially those who contains large amount of fatty acids. Anti-oxidants inhibit the oxidation process. The functioning of antioxidants is done by blocking the oxidation chain reactions or by acting as reducing agent and anti-oxidants get itself oxidized and prevent oxidation process <sup>[40]</sup>. Example of dosage forms in which preservatives is used:- A preservative is used in all most whole formulations such as solid, liquid, semi-solid dosage forms.

**Table 10- List of some natural excipients used as natural preservatives.**

S.No	Name of excipients	Source (Plants)	Family
1.	Clove oil	Buds of Myrtaceae syzygium	Myrtaceae
2.	Neem oil	Fruits of Azadirachta indica	Meliaceae
3.	Cumin seeds	Seeds of Cuminum cyminum	Apiaceae
4.	Cayenne pepper	Fruits of Piper nigrum	Piperaceae
5.	Turmeric	Roots of Curcuma longa	Zingiberaceae
6.	Cinnamon	Bark of Cinnamomum verum	Lauraceae

## Conclusion

The aim of this review was to accumulate the knowledge or information about different pharmaceutical natural excipients which are obtained from natural sources such as plant, microbes, marines, animal, and mineral. As the natural excipients are biodegradable compounds, these can be chemically compatible with other excipients in drug delivery system. In addition natural excipients are non-toxic, easily available, and less expensive (economic) compared to the synthetic compounds. Natural excipients have an important role to play in pharmaceutical, cosmetic and food industries. Excipient, a partner of the API in a dosage form meanwhile have major share in a formulation sometimes and showing their unique pharmacokinetics and pharmacodynamics apart from Active Pharmaceutical Ingredients to complete the motive of medicine. Human, a creation of nature is well supplied with natural materials that were used as medicament too since thousands year even in many traditional medical sciences including Ayurveda in India. In this regards these natural excipients used in Ayurvedic pharmaceuticals may play a major role as advance nurture for Ayurvedic medicament as well as modern medicaments to fulfill the requirement of time demanding dosage form with quality, safety and efficacy along with cost effectiveness and serve the creation of nature by its natural nurture and medicament.

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