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An Overview of Natural Disintegrating Agent Used in Dispersible Tablets

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Abstract

The oral therapy is the most commonly used method for administering many medications since it is thought to be the safest, most practical, and least expensive method. Fast dissolving pills are highly popular right now because they dissolve or easily dissolve in the mouth after administration without the need for water. Fast dissolving tablets have been developed to address the drawbacks of conventional dose forms, particularly dysphagia (refers to problem in which it becomes difficult to swallow), in pediatric and geriatric patients. Natural materials offer an advantage in comparison to the synthetic ones since they are more easily accessible, cost effective, not harmful, and chemically inert. By acting as a binder, diluent, and superdisintegrant, natural polymers such as locust bean gum, banana powder, mango peel pectin, Mangifera indica gum, and Hibiscus rosa-sinensis mucilage improve tablet properties, increase the solubility of drugs which are insoluble or poorly soluble, helps in reducing the disintegration time, and aid as nutritional supplements. Natural polymer is derived from natural source, are economical, not harmful, decomposable, and environmentally helpful, free of negative effects, restorable, and serve as nutritional supplements. Studies have shown that natural polymers are more effective and safer than manufactured polymers. The aim of the current article is to study and examine natural polymers which have been approved by Food and Drug Administration for use in quick dissolving tablets.

Keywords: Oral route, Dispersible tablets, Patient compliance, Natural superdisintegrant

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Introduction

Oral drug delivery is a widely used route for administering medications due to its convenience, ease of administration, and high patient acceptance. It involves the delivery of drugs through the mouth, where they are absorbed into the bloodstream through the gastrointestinal (GI) tract. However, the effectiveness of oral drug delivery depends on various factors, which includes the physicochemical properties of the drug, formulation, and the patient's GI physiology.

One of the primary challenges in oral drug delivery is achieving adequate drug absorption. Many drugs have low solubility-y or stability in the acidic environment of the stomach, leading to poor absorption in the small intestine. To overcome this, various formulation strategies have been developed, such as using prodrugs, lipid-based formulations, and nanocarriers to enhance drug solubility and bioavailability.

Another challenge is achieving targeted drug delivery to particular regions of the GI tract. This is particularly important for drugs that are absorbed in such particular regions or have adverse effects on certain regions. To address this, various delivery systems, such as enteric coatings, pH-sensitive polymers, and micro/nanoparticles, have been developed to control drug release and improve site-specific targeting.

Tablets are a solid dosage form of medication that is designed to be taken orally. They are one of the most commonly used forms of medication and are widely used for their convenience, ease of use, and stability. Tablets are typically composed of active pharmaceutical ingredients (APIs) and other excipients, such as binders, fillers, and lubricants, which help to maintain the tablet's structural integrity and aid in the tablet's dissolution and absorption.

Tablets can be designed to release their active ingredients in different ways. Immediate-release tablets release their active ingredients quickly, whereas sustained-release or extended-release tablets release their active ingredients for a longer duration, often through a specialized coating or formulation.[1,2]

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Dispersible Tablet

According to European Pharmacopoeia Dispersible tablets are a type of tablet that dissolves in water or other liquids to form a homogeneous solution or suspension [Table 1]. These tablets are designed to disintegrate quickly when added to a liquid, allowing the active ingredient to be rapidly released and absorbed into the body.

Dispersible tablets are a convenient and effective dosage form that has gained popularity in recent years. They are made by compressing the active pharmaceutical ingredient (API), along with other excipients into a tablet form that rapidly dissolves in water or other liquids. This allows the medication to be easily administered, even to patients who have difficulty swallowing traditional tablets.

A dispersible pill is normally dissolved in 5–15 mL of water (for example, in a tablespoon or a glass of water). The resulting dispersion is then given to the patient. Dispersible pills must dissolve in water at temperatures ranging from 15 to 25°C in <3 min.

A dispersible tablet dispersion should be able to pass through a sieve screen with a nominal mesh aperture of 710 µm. The incorporation of an acid/base couple, in which the base releases carbon dioxide when the couple's components are dissolved in water, can improve the dispersion qualities of dispersible tablets.[3]

Ideal Features of Dispersible Tablets[4]

- They should be able to easily dissolve and disintegrate
- They should be able to guise unacceptable taste of drug
- They require water at the time of administration
- They must have high drug loading capacity
- Should be less sensitive against environmental surroundings like moisture etc.
- Ease of administration to patients who are mentally, disabled and uncooperative
- Should be transportable without the concerns related to breakability.

Special Features of Dispersible Tablets[5]

Dispersible tablets are not meant to be swallowed whole/chewed. Due to foaming or delayed dispersion, they should not be dissolved in milk or fizzy liquids. Dispersible tablets are created to provide a unit dosage form of medication that is easily given to children of all ages, the elderly, or other patients who may have trouble eating or swallowing whole medications.

Advantages of Dispersible Tablets[1,2]

There are several advantages of dispersible tablets, including:

Easy to swallow

Dispersible tablets are designed to dissolve quickly in water or other liquids, making them easier to swallow, especially for patients having problem in swallowing normal tablets.

Rapid absorption

Dispersible tablets dissolve quickly in liquids, allowing the active ingredients to be rapidly absorbed by the body.

Accurate dosing

Dispersible tablets are often formulated to be easy to break or divide, allowing for accurate dosing and flexibility in adjusting the dose.

Improved bioavailability

Dispersible tablets can improve the bioavailability of certain drugs by enhancing their solubility and dissolution rate.

Table 1: Dispersible tablets for common diseases

Disease condition	*Dispersible tablets available*
Tuberculosis	Rifampicin/isoniazid
Diarrhoea	Zinc sulphate
Malaria	Artemether/lumefantrine
Pneumonia	Amoxycillin, trimethoprim
Rheumatoid arthritis	Prednisolone
Pain and fever	Paracetamol

Convenient for travel

Dispersible tablets are convenient for travel, as they can be easily dissolved in water or other liquids without the need for additional equipment or tools.

Enhanced patient compliance

Dispersible tablets are often formulated with a pleasant taste and flavor, which can improve patient compliance and adherence to medication regimens, especially for children or elderly patients.

Limitations of Dispersible Tablets

Limited formulation options

Dispersible tablets may not be suitable for all types of medications. Certain drugs require sustained-release or enteric-coated formulations, which may not be achievable with dispersible tablets.

Shelf life

Dispersible tablets can be sensitive to moisture and may have a shorter shelf life than other tablet formulations. This can be a concern in areas with high humidity or where storage conditions are not optimal.

Taste and texture

Some dispersible tablets may have an unpleasant taste or texture, which can make them difficult to swallow or less appealing to patients.

Cost

Dispersible tablets can be more expensive to produce than traditional tablets, which can affect their availability and affordability for some patients and health-care systems.

Drug interactions

The quick absorption of drugs from dispersible tablets can increase the risk of drug interactions with other medications. This can be a concern, especially for patients who are taking multiple medications.

Disadvantages of Dispersible Tablets

- Drugs which are absorbed at particular site cannot be given.
- Drugs having high doses are difficulty to formulate.
- Due to their high friability and less hardness in comparison to conventional tablets, such tablets are difficult to handle and require special packaging.
- Due to their hygroscopic nature, such formulations require the need of special packaging for protection against moisture and retaining the stability of the products.
- In case of dosage forms which have been freeze dried, dose of the product should be <60 mg in case of soluble drugs and 400 mg in case of insoluble drugs.

Recommendations for Use of Dispersible Tablets

- They should be given in small quantity ranging about 5–10 ml in pure water or milk.

Table 2: Natural polymer used in dispersible tablets

Natural polymer	*Marketed drug*	*Disintegration time*	*Concentration used*
Chitin and chitosan	Cinnarizine	60 s	3% w/w
Mango peel pectin	Aceclofenac	12 s	0.1–4%w/w
Fenugreek seed mucilage	Metformin hydrochloride	15 s	4%w/w
Hibiscus rosa- sinensis	Aceclofenac	20 s	6%w/w
Lepidium sativum	Nimesulide	13s	10%w/w
Locust bean gum	Nimesulide	17 s	10%w/w
Dehydrated banana powder	Gabapentin	20 s	6%w/w
Mangifera indica gum	Paracetamol	3–8 min	6%w/w
Gum karaya	Amlodipine	18 s	4%w/w
Gellan gum	Metronidazole	2 min	4%w/w
Soy polysaccharide	Lornoxicam	12 s	8%w/w
Agar and treated agar	Theophylline	20 s	1–2%w/w
Plantago ovata seed mucilage	Granisetron HCL	17 s	5%w/w
Agele marmelose gum	Aceclofenac	8–18 min	6%w/w
Guar gum	Glipizide	30 s	1%w/w
Lepidium sativum mucilage	Nimesulide	17 s	5–15 w/w

- Before ingesting, the drink can be slightly swirled to help in dispersing.
- After ingesting, some of the medication may still be in the container. Therefore, it is advised to rinse with some water or milk before trying to swallow.
- These tablets need to be handled with extreme caution since they are substantially more brittle than conventional tablets.
- They should be taken right away after being unwrapped from the blister packaging because stability outside the blister cannot be guaranteed.[6,7]

Packaging of Dispersible Tablet

In standard packaging, some dispersible tablets can be maintained for up to three years without losing their stability. These tablets are generally kept in polyethylene bottles having high density, high blister packs, strip packs, and sachets packs.

Natural Polymer

Natural polymers come under the class of biomaterials. They are derived from renewable resources such as plants, animals, and micro-organisms, and are therefore considered to be environmentally friendly. Natural polymers are biodegradable, non-toxic, and biocompatible. These properties make them desirable for use in an extensive range of applications.

One of the most commonly known natural polymers is cellulose, which is derived from plant-based sources such as wood pulp and cotton. Cellulose is used in various areas including food additives, pharmaceuticals, and cosmetics. It is used as a packaging material due to its excellent barrier properties.[8] (Mechanism of action of superdisintegrant as shown in Figure 1).

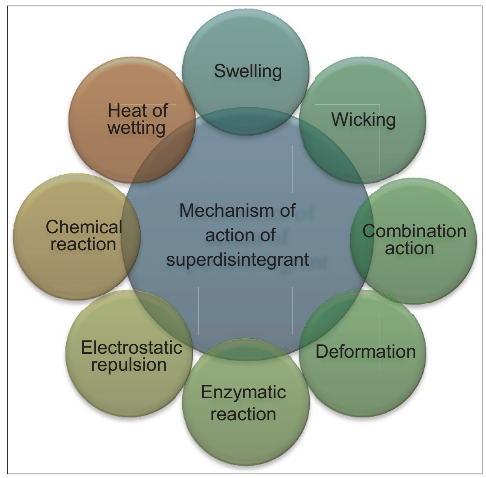

Figure 1: Mechanism of action of superdisintegrant

Advantages of Natural Polymers[2]

Biodegradability

Natural polymers are easily broken down by biological processes, making them environmentally friendly.

Renewable

Natural polymers can be sourced from renewable resources, such as plants and animals, unlike synthetic polymers that require petroleum-based feedstocks.

Non-toxic

Natural polymers are often non-toxic and safe for human use, whereas some synthetic polymers may contain harmful additives.

Biocompatibility

Natural polymers have a high degree of biocompatibility, meaning they are less likely to cause an immune response or rejection when used in medical applications.

Versatility

Natural polymers can be for various purposes, such as food packaging, textiles, and biomedical devices.[2]

Types of Polymers (Types of Polymers as Shown in Figure 2)

Classification of natural polymer

Classification by source

Polymers can be classified as natural polymers and synthetic polymers depending on their source. Natural polymers are made from natural resources such as plants, animals, and microorganisms, whereas synthetic polymers are made by chemical reactions.

Classification by structure

Polymers can be classified as linear, branched, or cross-linked depending on their molecular structure. Linear polymers have a simple straight chain structure, while branched polymers have branches that extend from the main chain, and cross-linked polymers have interconnected chains that form a three-dimensional network.

Classification by molecular weight

Polymers can be classified as low molecular weight or high molecular weight depending on their molecular weight. Small molecular mass polymers have molecular weights <10,000 g/mol, and high molecular weight polymers have molecular values greater than 10,000 g/mol.

Classification by application

Polymers can be classified according to their application, such as plastics, elastomers, fibers, coatings, adhesives, and composites.

Classification by chemical structure

Polymers can be classified according to their chemical structure, such as homopolymers, copolymers, and block copolymers. Homopolymers are made up of repeating units of a particular a substance category, while copolymers are composites of two or more different polymers. Block copolymers are copolymers in which the different types of monomers are grouped into blocks [Table 2].[9]

NATURAL POLYMER USED IN DISPERSIBLE TABLETS

Mango Peel Pectin

Mango peel pectin is a type of natural polymer that is extracted from mango peel, which is a waste product of the mango processing industry. Mango peel pectin is a complex polysaccharide that is composed of a chain[1-4] glycosidic linkage connect galacturonic acid residues. It is a form of pectin that is commonly used as an adhesive, thickener, and stabilizing agent in the food sector.

Mango peel, which accounts for 20–25% of mango processing waste, has been shown to be a good source of high-quality pectin extraction, making it ideal for the production of film and acceptable jelly. Pectin is an involute heteropolysaccharide that is a hydrophilic colloid. According to study, mango peel pectin is a great choice for a superdisintegrant. It is not as potent as synthetic superdisintegrants, but it can be utilized to manufacture fast-disintegrating tablets due to its good solubility and increased swelling index.[10] (Mango peel pectin powder as shown in Figure 3).

Dehydrated Banana Powder

Plantains are a substitute for banana. DBP is a member of the Musaceae family and is a kind of banana known as Ethan and nenthran (nenthra vazha). It works to treat diarrhoea and stomach ulcers due to the presence of the nutrient A. In addition, it contains Vitamin B6, which assists in lowering anxiety and tension due to the high carbohydrate content and potassium level, which is essential for the greatest than average activity in the mind, it is a very good source of energy.[11] (Dehydrate banana powder as shown in Figure 4).

Locust Bean Gum

Carob bean gum is what it's called. It is a galactomannan vegetable gum obtained from the seeds of the Mediterranean carob tree (Ceratonia siliqua). Locust bean gum is employed in the food industry as bio glue, a gelling and thickening agent, and to

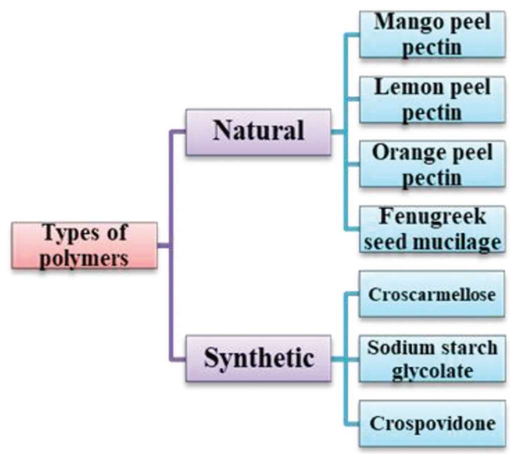

Figure 2: Types of polymers

Figure 3: Mango peel pectin

Figure 4: Dehydrated banana powder

improve solubility. The gum is powdered and odorless, ranging in color from white to yellow-white. It is insoluble in the vast majority of organic solvents, including ethanol. It takes 10 min of heating above 850° Fahrenheit to achieve entire solubility in water, which is only partially soluble at room temperature and soluble in heated water.[12] (Locust bean gum as shown in Figure 5).

Fenugreek Seed Mucilage

Fenugreek, commonly known as Trigonella foenum-graecum, is a legume family herb plant. Mucilage, a naturally occurring sticky component found in the covering of many seeds, accounts for a considerable amount of the weight of fenugreek seeds. Mucilage does not liquefy in water, but rather congeals into a thick, sticky mass when it comes into contact with liquids. Fenugreek seeds, like other materials containing mucilage, expand and become slippery when exposed to liquids. According to the study, this natural disintegrant (fenugreek mucilage) shown stronger preponderant disintegration property than the most popular synthetic superdisintegrants, such as Ac-Di-Sol, in FDT formulations.[12] (Fenugreek seed mucilage as shown in Figure 6).

Chitin and Chitosan

Chitosan is a derivative of chitin that is obtained by deacetylating chitin. This process removes the acetyl groups from the chitin molecule, resulting in a more soluble and flexible polymer. Chitosan has a number of unique properties, including its ability to form films and gels, and its antimicrobial and anti-inflammatory effects. Chitosan has a range of potential applications, including wound healing, drug delivery, and food preservation.[13] (Chitin and chitosan powder as shown in Figure 7).

Hibiscus Rosa Sinensis Mucilage

It is coming under the Malvaceae family and is also known as shoe rose mallow, garden hibiscus China rose, and Chinese hibiscus. Mucilages are employed in a variety of applications, including disintegrants, thickening agent, suspending agents, and water retention agents. The tree is freely accessible, and its leaves contain L-rhamnose, D-galactose, D-galacturonic acid, and D-glucuronic acid in its mucilage. By soaking agar in water for one day, it is transformed into yare.[14] (Hibiscus rosa sinensis mucilage as shown in Figure 8).

Lepidium Sativum Mucilage

Lepidium sativum mucilage is a type of natural polymer that is extracted from the seeds of the garden cress plant (Lepidium

Figure 5: Locust bean gum powder

Figure 6: Fenugreek seed mucilage

Figure 7: Chitosan powder

Figure 8: Hibiscus rsosa sinensis powder

sativum). It is a complex mixture of polysaccharides, including arabinogalactans, rhamnogalacturonans, and xylogalacturonans. It also has good adhesive properties, which makes it useful as a binder in tablets and capsules.

The extraction of Lepidium sativum mucilage involves soaking the seeds in water to release the mucilage, which is then collected and purified. This method is quite easy and may be carried out on tiny amounts, making it suitable for small-scale communities and producers.[15] (Lepidium sativum mucilage as shown in Figure 9).

Mangifera Indica Gum

Mangifera indica, commonly referred to as mango, anacardiaceae is a family of plants. It is non-toxic and is used as a disintegrant, binder, suspending agent, and emulsifying agent in a variety of applications a range of compositions. The gum powder is dissolved in water but nearly in dissolve in acetone, chloroform, ether, methanol, and ethanol. The gum is non-toxic, and every part of the tree has therapeutic benefits, including those for urethritis, diabetes, asthma, diarrhoea, and the skin diseases.[16] (Mangifera indica gum as shown in Figure 10).

Guar Gum

Guar gum, also known as Cyamopsis tetragonoloba (L) Taub. (Syn. Cyamopsis psoralioides), is a polysaccharide with a large molar mass (approximately 50,000–8,000,000) obtained from the endosperm of the guar plant's seed. It is allowed in the majority of nations (including the EU, the United States, Japan, and Australia) and is work as a thickening agent, stabilizer, and emulsifier. It is naturally occurring gum (sold under the brand name Jaguar). It is a neutral polymer composed of sugar units that is free-flowing, totally soluble, and permitted for use in food. It is unchanged by the pH, moisture content, or solubility of the medicine system. It is not continuously absolutely white in alkaline tablets and occasionally changes from the color off-white to brown. It is also going to discolor over time.[17] (Guar gum powder as shown in Figure 11).

Gum Karaya

Gum karaya is a form of vegetable gum that is derived from Sterculia tree exudates. According to its chemical composition, gum karaya is an acid polysaccharide composed of the sugars galactose, rhamnose, and galacturonic acid. Due to its high viscosity, gum cannot be employed as a disintegrant or binder in the production of conventional dosage forms. Gum karaya's potential as a tablet disintegrant has been investigated. Several studies have found that modified gum karaya causes tablets to disintegrate faster. Moreover, gum karaya is a low-cost, biocompatible, and readily available alternative superdisintegrant to commonly used synthetic and semisynthetic superdisintegrants.[18] (Gum karaya as shown in Figure 12).

Figure 9: Lepidium sativum mucilage

Figure 10: Mangifera indica gum

Figure 11: Guar gum powder

Figure 12: Gum karaya

Agar and Treated Agar

It is the dry sticky material. Material produced by Gelidium amansii (Gelidaceae), as well as a number of other species of Pterocladia (Gelidaceae) and Gracilaria (Gracilariaceae) are examples of red algae. Agar comes in the form of divests, it comes in the form of sheet flakes or coarse powder and ranges in color from yellowish-gray to white to almost colorless, odorless, and has a mucilaginous flavor. Agarose and agar pectin are the two polysaccharides that make up agar. Agarose gives gel its strength, and agar pectin gives agar solutions their viscosity. Agar is a prospective contender for use due to its high jelly material, as a disintegrant viscosity.[19] (Agar and treated agar as shown in Figure 13).

Soy Polysaccharide

Soy polysaccharide is a natural polymer that can be used in nutritional products because it does not include any starch or sugar. Soy polysaccharide, a kind of high molar mass polysaccharides derived from soy beans as a disintegrant in direct compression tablets using lactose and dicalcium phosphate dihydrate as fillers. Cross-linked sodium carboxymethyl cellulose and maize starch were utilized as controls. Soy polysaccharide functions wonderfully as a disintegrating agent in direct compression formulations, with results similar to connected CMC.[2]

Plantago Ovata Seed Mucilage

The terms "psyllium" and "ispaghula" are commonly used to refer to a variety of Plantago species whose seeds are utilized in the production of mucilage. Mucilage from Plantago ovata has an extensive amount of properties, involving connecting, liquefying, and supporting properties. As natural superdisintegrants, varying amounts of Plantago ovata mucilage were utilized in a study. A study used different amounts of Plantago ovata mucilage as natural superdisintegrants to compress fast dissolving tablets formulation, which showed faster *in vitro* dissolving within 16 min with a shorter *in vitro* disintegration time of 11.69 s of amlodipine besylate. A form of microbial polysaccharide known as gellan gum is frequently employed as a food ingredient and gelling agent. It is made through fermentation by the bacterium Sphingomonas elodea is a species of Sphingomonas. The gellan gum's cycles involve glucose, rhamnose, and glucuronic acid compositions.[20]

Aegle Marmelose Gum

It is made from Aegle marmelos fruits, which dissolve more quickly and uniformly as opposed to croscarmellose sodium. The scarlet pulp of the ripening fruit has a mucilaginous, astringent flavor. Carbohydrates, proteins, Vitamins C and A, angelenine, marmeline, dictamine, O-methyl fordinol, and isopentyl halfordinol are all found in this product are all present in the pulp. AMG is made through a heat-treating process. It makes medications that are not very soluble more soluble. It causes GSH (glutathione) concentrations in the liver, kidney, stomach, and intestine differ significantly. In diabetic people, it also raises glucose levels and glycosylated hemoglobin. It lowers plasma insulin and hepatic glycogen levels in diabetics. D-galactose accounts for 71% of the pure bael gum polysaccharide, with D-galacturonic acid, 7% L-rhamnose, and 6.5% L-arabinose.[21]

Ficus Indica Gum

The mucilaginous substance derived from the fruit of ficus-indica, is used as a superdisintegrant. The ficus-indica tree grows quite quickly, reaching heights of up to 3 m, and has spread-out branches and aerial roots. Cherry-sized fruits are produced by the ficus-indica. It has both therapeutic and nutritional value. 100 g, or 3.5 oz, of dried and uncooked ficus indica fruit contains 230 kcal (963 KJ), or energy. It is used to relieve fever, discomfort, inflammation, wound rejuvenation, blood clotting issues, and urinary issues.[22]

Gellan Gum

A form of microbial polysaccharide known as gellan gum is frequently employed as a food ingredient and gelling agent. It is made through fermentation by the bacterium Sphingomonas elodea is a species of Sphingomonas. The gellan gum's cycles involve glucose, rhamnose, and glucuronic acid compositions. It is widely utilized in food goods such sweets, jellies, and beverages as a highly effective gelling agent. Gellan gum is a desired food addition due to its numerous distinctive qualities. For instance, it is extremely stable in acidic and high-temperature environments, which makes it perfect for usage in a variety of culinary products. In addition, it has a very low viscosity at low concentrations, making it possible to include it into food products without causing any problems changing the taste or texture.[23] (Gellan gum powder as shown sin Figure 14).

Current Regulatory Status of These Polymer

In the United States, the use of natural polymers in food and drugs is regulated by the Food and Drug Administration (FDA). The FDA requires that all food additives, including natural polymers, be

Figure 13: Agar and treated agar

Figure 14: Gellan gum powder

evaluated for safety before they can be used in food products. The FDA also regulates the use of natural polymers in drugs and requires that they meet specific standards for purity and quality. Similarly, the European Union (EU) regulates utilization of plant-based in food, drugs, and cosmetics. The European Food Safety Authority (EFSA) evaluates the safety of food additives, including natural polymers, before they can be used in food products. The European Medicines Agency (EMA) regulates utilization of plant-based polymer in drugs and requires that they meet specific standards for purity and quality. The European Chemicals Agency (ECHA) regulates utilization of plant-based polymers in cosmetics and requires that they meet specific standards for safety and labeling.

Conclusion

In recent years, natural biodegradable polymers have gained popularity for their potential use in environmental protection and improving physical health. They can be used to create drug delivery systems in various forms and sizes, which release medications gradually. The choice of polymer is crucial for effective drug delivery as it impacts toxicity, drug compatibility, and degradation patterns. Natural polymers are considered a viable option to synthetic polymers since they can minimize the adverse effects associated with the latter. Therefore, it is important to consider natural polymers as an option when selecting a polymer for drug manufacturing.

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