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REVIEW ON NATURAL POLYMERS USED IN MOUTH-DISSOLVING TABLETS

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ABSTRACT

Because it is the most convenient, affordable, and safest mode of administration for various medications, the oral route is the most preferred approach. Mouth-dissolving tablets are popular these days since they dissolve in the mouth in a matter of seconds without the need for water. Mouth-dissolving tablet has solved a variety of difficulties in juvenile and geriatric patients. Natural polymers are preferred over synthetic polymers because they are chemically inert, nontoxic, less expensive, biodegradable, and readily available. Natural polymers are derived from nature and therefore have no side effects. Previous research has shown that natural polymers are more safe and effective than synthetic polymers. Natural polymers increase tablet characteristics and are employed as a binder, diluent, and super disintegrant. They also improve the solubility of poorly water-soluble drugs, reduce disintegration time, and give nutritional supplement. The purpose of this review is to investigate several natural polymers used in mouth dissolving tablets.

INTRODUCTION

Mouth-dissolving tablets are a solid dosage form that disintegrates or dissolves in the mouth in 1 minute without the need for water or chewing. Rapi Melt, Quick Disintegrating, Fast Dissolving, Orally Disintegrating, Oro-Dispersible, Quick Dissolve, Melt-in-Mouth, porous tablets, and other synonyms for "mouth dissolving tablets" exist. The United States Pharmacopoeia (USP), Centre for Drug Evaluation and Research, recently approved fast dissolving tablet technology (CDER). This formulation is useful for patients with Dysphagia (difficulty swallowing), choking risk, and hand tremors. MDTs are usually beneficial for geriatric, paediatric, and bedridden patients who are nauseous or disobedient. MDTs have higher bioavailability than conventional tablets, a faster onset of action because absorption occurs in a matter of seconds, a better taste and thus improved palatability, and improved patient compliance. Natural-source polymers are preferred over synthetic polymers because they are more effective and safe. The majority of formulations contain natural polymers. Natural polymers are inexpensive and readily available in sufficient quantities. They are non-toxic and have no negative side effects on the body. Natural polymers are environmentally friendly, biodegradable in nature, and do not pollute the environment. Natural polymers are more patient-friendly, offer nutritional supplements, and are renewable. Synthetic polymers have some disadvantages, such as high cost because they must be created through various processes or reactions employing pricey tools and equipment, and lengthy production times. Synthetic polymers are made from non-renewable resources, have a greater number of side effects because they are created through various chemical reactions that may

interact with body components and cause allergic reactions or toxicity in the body, cause environmental pollution during their synthesis, and are not biodegradable. Patients typically do not prefer synthetic polymers due to these side effects. The purpose of this review is to compare the features of tablets improved by employing natural polymers over synthetic polymers and to explore various natural polymers and their pharmacological activity which are utilized in mouth dissolving tablets. Natural polymers speed up the disintegration of tablets because they act as a superdisintegrant, causing the tablet to disintegrate quickly within a few seconds. Natural polymers used include Pullulan, Locust Bean Gum, Mango Peel Pectin, etc. The impact of natural polymers on hardness and friability are notable**.**[1]

IDEAL PROPERTIES OF FAST-DISSOLVING TABLETS:

1. When put in the mouth, they dissolve instantly.
2. They don't need water to dissolve.
3. Because they are unit dosage forms, they should to offer accurate dosing.
4. Rapid oral cavity absorption and dissolution.
5. Simple to understand.
6. Tablets are produced at low cost using standard equipment.
7. Less sensitive to environmental factors like temperature and humidity
8. They should be more durable and keep their hardness.[2]

ADVANTAGES OF MOUTH DISSOLVING TABLET:

1. Mouth dissolving tablets (MDTs) are solid unit dosage forms that allow for precise dosing, high drug loading, and ideal dosage for geriatric and paediatric patients. They also make an excellent substitute for traditional tablets.
2. It produces fast action as soon as it is ingested by the patient, starts melting when it comes into contact with saliva, is quickly absorbed in the oral cavity, and melts quickly.
3. Pregastric absorption affects the drugs' bioavailability and reduces their dosage requirements, which improves patient compliance and changes clinical reports.
4. Mouth dissolving tablets have few leaves and completely dissolve in the tongue without leaving any residue, giving the pill a pleasing mouth feel and enhancing its palatability.
5. Mouth dissolving tablets are particularly steady since they are less responsive to environmental mental conditions.
6. Mouth dissolving tablets are inexpensive since they are packaged in straightforward blister packing and don't require any specialised or expensive packaging.
7. Mouth dissolving tablets provide budding commercial opportunities such as product differentiation, product promotion, line extension, uniqueness, and life cycle management.
8. Fast-dissolving pills don't need expensive ingredients, making them cost-effective. Natural polymers may be packaged in straightforward blister packs and are readily and inexpensively accessible when used as excipients. They do not require specific packaging materials.
9. They are a multifaceted technology since they are used to create prescription, over-the-counter (OTC), and veterinary pharmaceuticals.[3, 4]

ADVANTAGES OF NATURAL POLYMERS:

Natural plant-based products have the following benefits among others.

1) Biodegradable: Since all living things make them and they are naturally occurring, they are biodegradable.
2) All of these plant compounds are essentially repeating sugar polysaccharides, which makes them biocompatible and non-toxic.
3) They are less expensive to use as natural sources. Compared to synthetic material, the cost of production is lower. Agriculture is the primary industry in India and many other developing nations, and agriculture receives significant financial investment.
4) Environmentally friendly processing: Due to the straightforward production procedures involved, a variety of natural chemicals produced from various plant sources are extensively used in the pharmaceutical sector and collected in enormously vast numbers.

5) The government in India and other similar developing nations is encouraging the production of plants as pharmaceutical excipients, and it also offers the facilities for bulk production of products like gum and mucilage because of their numerous industrial applications.
6) Patient toleration and public acceptance: Natural materials have a lower risk of side effects and negative impacts than synthetic ones.[5]

LIST OF NATURAL POLYMERS:

1. Gum acacia
2. Gum tragacanth
3. Xanthan gum
4. Cassia fistula gum
5. Locust Bean Gum
6. Aeglemarmelos Gum
7. Gellan Gum
8. Guar Gum
9. Gum Karaya
10. Chitin and Chitosan
11. Agar and Treated Agar
12. Soy Polysaccharide
13. Mango Peel Pectin
14. Dehydrated Banana Powder (DBP)
15. *Cucurbita maxima* pulp powder
16. Pullulan
17. Rosin
18. Ocimum basilicum seeds
19. Maltodextrin
20. Sodium alginate
21. *Cucurbita maxima* pulp powder
22. Lepidiumsativum Mucilage
23. Plantagoovata Seed Mucilage
24. Fenugreek Seed Mucilage

1. Gum acacia: Acacia gum, a member of the Leguminosae family and also known as Arabic gum, Acacia, Senegal gum, and Indian gum. It is made of acacia tree sap that has dried out. Acacia gum is mostly composed of arabinogalactan, a biopolymer made of arabinose and galactose monosaccharides. Gum Acacia is a versatile industrial ingredient that can be used as a stabiliser, thickener, emulsifier, suspending agent, and tablet binder. The gum acacia is water soluble and ranges in colour from light orange to pale white.[6]

2. Gum tragacanth: The substance known as tragacanth gum, which has a molecular weight of approximately 840 kDa, is formed from plants and is found in the stems and branches of Astragalus. It is a thick, flavourless, and water-soluble substance. It is a complex blend of polysaccharides that makes up an anionic, branching carbohydrate. Tragacanth gum is made up of two main fractions: tragacanthin, which is water soluble, and bassorin, which is not soluble but is water swellable. Tragacanth is employed as a thickening, stabiliser, emulsifier, and suspending agent. At a pH of 4 to 8, tragacanth is stable.[7, 8]

3. Xanthan gum: High molecular weight polysaccharide Xanthan Gum is produced by fermenting Xanthomonas campestris bacterium. High hydrophilicity and low gelling tendency are characteristics of xanthan gum. Its substantial swelling and low water solubility contribute to its quick disintegration. The viscosity of xanthan gum is very stable over a wide pH and temperature range. Xanthan gum is not metabolized by enzymes.[9]

4. Cassia fistula gum:

Other names for Cassia fistula include Indian laburnum, purging cassia, and golden shower. It's a member of the Fabaceae family. Gum produced from Cassia fistula tree seeds. The side chain of Cassia fistula gum has a mannose: galactose ratio of 3:0 and is made up of random distributions of (1→4) linked d-mannopyranose units and (1→6) linked d-galactopyranose units. Compared to native gum, carbamoylethylation and carboxymethylation of cassia gum are said to boost microbial resistance, improve viscosity, and make it more soluble in cold water. As a superdisintegrant, fistula gum is used in the development of the FDT formulation.[10]

5. Locust Bean Gum: It is referred to as carob bean gum. It is a galactomannan vegetable gum prepared from the seeds of the carob tree (Ceretoniasiliqual), which is a tree native to the Mediterranean region. This gum is known as locust bean gum. Locust bean gum is used as a bio glue, a gelling and thickening agent, and to improve solubility. The gum is an odourless powder that ranges in colour from white to yellow-white. Most organic solvents cannot dissolve it. It dissolves in either hot or cold water, generating a pH-ranged sol that can be

transformed into a gel. In water at room temperature and in hot water, it partially dissolves. Heat must be applied above 85 °C for 10 min for complete solubility.[11]

6. Aeglemarmelos Gum (AMG): Aeglemarmelos the fruits of the Rutaceae plant family member Aeglemarmelos are used to make gum. This broke down more quickly and reliably than croscarmellose sodium. The ripe fruit pulp is red in colour and has an astringent, mucilaginous flavour. Carbohydrates, proteins, vitamins C and A, angelenine, marmeline, dictamine, o-methyl fordinol, and isopentylhalfordinol are all present in the pulp. AMG is made through a heat-treating process. It improves poorly soluble drug solubility, raises blood glucose levels and glycosylated haemoglobin in diabetic patients, lowers plasma insulin and liver glycogen in diabetic patients, stimulates macrophage activity, and significantly alters GSH (glutathione) concentrations in the liver, kidney, stomach, and intestine. Pristine gum D-galactose, D-galacturonic acid, L-rhamnose, and L-arabinose are all components of polysaccharide.[12]

7. Gellan Gum: Pseudomonas elodea, a bacterium, provides the source of gellan gum. It is a biodegradable, high molecular weight linearanionic polysaccharide that is mostly made up of a repeating unit of tetrasaccharide, which consists of two residues of D-glucose and one residue of each of D-glucuronic acid and L-rhamnose. By using fermentation, it is produced. It comes in two varieties: High acyl (HA) and Low acyl (LA). Due to its high hydrophilic nature, Gellan Gum is utilised as a tablet superdisintegrant since tablets swell quickly when they come into touch with water. With a gellan gum concentration of 4% weight-for-weight in the current trial, the pill completely disintegrated in 4 minutes, and 90% of the medication was dissolved in 23 minutes.[13, 14]

8. Guar Gum: Guar gum, a naturally occurring high molecular weight polysaccharide with an approximate molecular weight of 50, 000–8, 000, 000, is frequently utilised in pharmaceutical formulations, food goods, and cosmetics. It comes from the endosperm of the seed of the Cyamopsistetragonoloba (L) Taub, a species of guar plant, and is composed of galactomannans units joined by glycosidic connections. Also known as Galactosol, guar flour, jaguar gum, meprogat, and meyprodor, among other names. It is utilised in numerous pharmacological preparations as a stabiliser, thinner, and emulsifier. Guar gum is produced by de-husking, milling, and screening guar seeds. Off-white powder that flows freely is how it is made. In the pH range of roughly 1.0-10.5, guar gum solutions are stable. In both hot and cold water, it dissolves quickly. Organic solvents cannot dispense with it. In medicines, guar gum is employed as a controlled-release carrier, a suspending, thickening, and stabilising ingredient, as well as a binder and disintegrant in oral and topical treatments.[15]

9. Gum Karaya: Gum karaya is a complex polysaccharide of high molecular weight, obtained from the exudation of trees of the '*genus Sterculia'*, Family-*Sterculiaceae*. Its synonyms are Karaya, gum karaya, Sterculia, gum sterculia, Kadaya, Katilo, Kullo, Kuterra. Chemically, gum karaya is an acid anionic polysaccharide and composed of the sugarslike, containing 43%. D-galacturonic acid, 13% D-galactose and 15% L-rhamnose. Gum karaya is compatible with proteins, carbohydrates and plant hydrocolloids. It is used as a adhesive, binding agent in pharmaceuticals. The colour of a gum karaya powder ranges from off white to pink to tan. It can be used as a alternative for gum tragacanth. The gum has ability to absorb water and its wells to 70–100 times greater than its original volume. The high viscosity nature of gum limits its uses as binder and disintegrant in the development of conventional dosage form.[16]

10. Chitin and Chitosan: N-acetyl-D-glucosamine is a long chain polymer found in chitin. It is a pure polysaccharide derived from the shells of crab and shrimp. As opposed to the liberated amino group in chitosan, it has an amino group covalently bonded to an acetyl group. Chitin, the structural component in the exoskeleton of crustaceans (such as crabs and shrimp), and the cell walls of fungi, is converted into chitosan, a cationic polymer. It is the most prevalent natural polymer that is also non-

toxic. Products made with chitosan are extremely viscous and resemble natural gums.[17, 18]

11. Agar and Treated Agar: Agar is a complex polysaccharide made of dried gelatin that is mostly obtained from the species Gelidium, Gracilaria, Acantkopeltis, Ceramium, and Pterocladia. Agarose and agaropectin are the two components that make up the majority of agar. Agarose gives gel its strength, and agaropectin gives agar solutions their viscosity. Due of its ability to gel and stabilise, agar is frequently employed. Agar has a mucilaginous flavour and no colour or smell. It comes in strips, sheet flakes, and coarse powder forms. At low concentrations, typically between 0.5% and 2%, agar can create a hard gel.[2, 19]

12. Soy Polysaccharide: It is a natural superdisintegrant that can be used in nutritional products because it doesn't include any starch or sugar. In tablets manufactured by direct compression using lactose and dicalcium phosphate dihydrate as fillers, soy polysaccharide (a category of high molecular weight polysaccharides obtained from soy beans) was assessed by Halakatti et al. in 2010. As a control, cross-linked sodium carboxymethyl cellulose and corn starch were used. In direct compression formulations, soy polysaccharide performs admirably as a disintegrating agent, with outcomes comparable to those of cross-linked CMC.[20, 21]

13. Mango Peel Pectin: The waste from mango processing that makes about 20–25% of mango peel is a useful source for pectin extraction. This pectin is suitable for making Film and Gelly because it is of high quality. Pectin is a hydrophilic colloid that has a structural heteropolysaccharide. Due to its high swelling index and good solubility, mango peel pectin can be employed as a superdisintegrant in the creation of quickly disintegrating tablets. Anhydrogalactouronic acid and methoxyl components make up this pectin.[2, 22]

14. Dehydrated Banana Powder (DBP): Plantain is another name for banana. DBP is a member of the Musaceae family. It is used to treat diarrhoea and stomach ulcers since it includes vitamin A. Additionally, it contains vitamin B6, which is helpful in lowering anxiety and tension. Due to its high carbohydrate content and potassium level, which is essential for better than average brain function, it is a very good source of energy.[23]

15. *Cucurbita maxima* pulp powder: Cucurbita is a genus of herbaceous vines in the Cucurbitaceae family. Cucurbita maxima fruit must first be washed with water to remove any dust before the skin was peeled off and the pulp powder was obtained. The pulp was added to a mixer along with the seeds to create a thick liquid. This liquid was further lyophilized to produce a solid, porous mass, which was then shrunk and collected as powder. The gathered powder was appropriately stored after being sifted via an 80# sieve. The pulp powder from the Cucurbita maxima plant, which is naturally derived, works well as a tablet disintegrant and a medicinal adjuvant.[24]

16. Pullulan:

Pullulanis is an organic, water-soluble polysaccharide that is made from starch through the fermentation of the fungus Aureobasidiumpullulans. It has the chemical formula C6H10O5 and is a maltotriosetrimer made of α-(1 → 6)-linked (1 → 4)-α-d-triglucosides. Pullulan is a white, flavourless, and odourless dry powder. The substance is edible, biodegradable, not toxic, not mutagenic, and not carcinogenic. It is nonhygroscopic and breaks down at temperatures between 250 and 280°C. Pullulan creates antistatic, transparent, water-soluble, and fat-resistant films. The mechanical properties of films are excellent, and they have low oxygen and moisture permeability.[25]

17. Rosin: Other names for rosin include colophony and Greek pitch. It is a solid type of resin that is obtained from conifers, including pines, and other plants. Its primary constituents are various resin acids, particularly abietic acid, and it is semi-transparent and varies in colour. Derivatives of rosin are effective at coating and forming films. Rosin is fragile and friable by nature, and it smells faintly like pine. Typically a glassy solid, it crystallises when placed in a solution. Alcohol, ether, benzene, and

chloroform can all dissolve it. Casting or solvent evaporation are two methods for creating rosin film.[26]

18. Ocimum basilicum seeds: Other names for Ocimum basilicum include great basil and saint-wort-joseph's. This herb is a member of the Lamiaceae family. The pericarp of the ocimum basilicum seed, often known as sweet basil seed, contains mucilage, which is used in fast-dissolving tablets as a natural superdisintegrant. O. It was discovered that basilicum mucilage was soluble in distilled water but insoluble in other solvents. The high molecular weight polysaccharides (2320 kDa), which included glucose, galactose, mannose, arabinose, xylose, and rhamnose, made up the majority of the mucilage.[27, 28]

19. Maltodextrin: An oligosaccharide called maltodextrin is made from starch through partial hydrolysis. It is often a white, hygroscopic spray-dried powder that is quickly absorbed, easily digested, and has a mild sweetness or nearly no flavour. The majority of maltodextrin is made up of a variety of chains with lengths ranging from three to seventeen glucose units. Maltodextrin is a non-toxic, palatable substance that can be purchased powdered.[2]

20. Sodium alginate: Brown seaweeds produce alginate, an inedible biomaterial. It provides dietary fibre. A mixture of polyuronic acids made up primarily of leftovers from D-mannuronic acid and L-guluronic acid, sodium alginate is the sodium salt of alginic acid. Alginate possesses colloidal qualities that include thickening, stabilising, suspending, film formation, gel production, and emulsion stabilisation. It also aids in the formation of biopolymer film or coating components. A solution containing alginate has the ability to gel when calcium is present. Alginate is used to make edible films that are robust and have poor water resistance due to their hydrophilic nature. The mechanical qualities of edible film are enhanced by a starch and alginate mixture.[29]

21. Cucurbita maxima pulp powder:

The herbaceous vine genus Cucurbita is a member of the Cucurbitaceae family. Cucurbita maxima fruit must first be washed with water to remove any dust before the skin was peeled off and the pulp powder was obtained. The pulp was added to a mixer along with the seeds to create a thick liquid. This liquid was further lyophilized to produce a solid, porous mass, which was then shrunk and collected as powder. The gathered powder was appropriately stored after being sifted via an 80# sieve. The pulp powder from the Cucurbita maxima plant, which is naturally derived, works well as a tablet disintegrant and a medicinal adjuvant.[30]

22. Lepidiumsativum Mucilage: The Cruciferae family includes Lepidium sativum, sometimes referred to as garden cress ora Saliyo. Lepidiumsativum Mucilage, the dimeric imidazole alkaloids lepidine B, C, D, E, and F, and the semilepidinoside A and B are all abundant in seeds. The features of Lepidiumsativum's mucilage include binding, dissolving, gelling, and more. Different methods can be used to remove the mucilage from seeds. Mouth-dissolving tablet formulations utilize the extracted mucilage. Mucilage is a brownish-white powder that decomposes at temperatures exceeding 200°C and has a strong stench. The values of swelling index, angle of repose, bulk density, and tapped density are calculated to be 18, 32°C, 0.58g/cc, and 0.69g/cc, respectively, based on its various physicochemical properties.[31, 32]

23. Plantagoovata Seed Mucilage: Ispaghula mucilage is made up of mucilage found in the epidermis of the dried seeds of Plantagoovata. The husk of the plantagoovata seed is ground off to produce the mucilage. Plantagoovata's mucilage possesses binding, dissolving, and supporting qualities. In order to increase patient compliance, prochlorperazine maleate fast-disintegrating tablets were created using PlantagoOvata (2-8% w/w) as a superdisintegrant.[33, 34]

24. Fenugreek Seed Mucilage: Trigonella Foenum-graceum, a herbaceous plant from the leguminous family that is also known as fenugreek. In every region, it has numerous uses as a meal, a culinary additive, and a traditional medicine. The mucilage made of polysaccharides and derived from fenugreek seeds. Mucilage is an amorphous powder with a cream colour. In warm water, this rapidly dissolves to create a viscous colloidal solution. Studying its physicochemical

properties revealed that its compressibility index, bulk density, and angle of repose had values of 22.25°C, 0.64g/cc, and 15.20%, respectively. Fenugreek mucilage creates a thick, gooey substance when it comes into contact with liquids; it does not dissolve in water. In place of synthetic superdisintegrants, fenugreek seed mucilage can be utilized in the formulation of a variety of mouth-dissolving tablets.[35, 36, 37]

TABLE NO. 1: NATURAL POLYMERS EMPLOYED IN MOUTH DISSOLVING TABLETS:[2]

Sr. No.	Name of Natural Polymer with marketed drug	Time required for Disintegration	Used Concentration
1	Locust Bean Gum / Nimesulide	13 seconds	10% w/w
2	Hibiscus rosa-sinensis mucilage / Aceclofenac	20 seconds	6% w/w
3	Agar and treated agar / Theophylline	20 seconds	1-2% w/w
4	Mango peel pectin / Aceclofenac	11.59 seconds	0.1–4% w/w
5	Guar gum / Glipizide	30 seconds	1% w/w
6	Dehydrated banana powder / Ondansetron HCl, propranolol, gabapentin	15–36 seconds	6% w/w
7	Gum karaya / Amlodipine, granisetron HCl	17.10 seconds	4% w/w
8	Fenugreek seed mucilage / Metformin hydrochloride	15.6 seconds	4% w/w
9	Mangifera indica gum / Metformin HCL, paracetamol	3–8 minutes	6% w/w
10	Soy polysaccharide / Lornoxicam	12 seconds	8% w/w
11	Lepidium sativum / Nimesulide	17 seconds	10% w/w
12	Gellan gum / Metronidazole	155 seconds	4% w/w
13	Lepidium sativum mucilage / Nimesulide	17 seconds	5–15% w/w
14	Aegle marmelos gum / Aceclofenac	8–18 minutes	6% w/w
15	Plantago ovata seed mucilage / Granisetron HCl	17.10 seconds	5% w/w

CONCLUSION:

Synthetic polymers do not have the same predominant effects on fast-dissolving tablets as natural polymers do. Natural polymers are used as binder superdisintegrants and diluents because they increased the drug release rate from the tablet and decreased the dissolution and disintegration times. Because they are nontoxic, easily accessible, cheap, and naturally extracted to provide dietary supplements, natural polymers are preferred over synthetic polymers. In comparison to synthetic super disintegrants, the disintegrating abilities of Plantago ovata, Lepidium sativum, gum karaya, Guar gum, mucilage from fenugreek seeds, mango peel pectin, and other natural substances have been studied. Because of their increased bioavailability and quicker drug dissolution, natural superdisintegrants enable more effective therapy and better patient compliance.

As a result, the natural superdisintegrant can be effectively used in tablet formulations as disintegrants.

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