



A Comprehensive Review: Natural Polymers Used for Fast Dissolving Mouth Film

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ABSTRACT

Current innovations have introduced suitable measurement choices from the oral course for pediatrics, geriatric, abnormal, nauseous or turbulent patients. Fast dissolving mouth Film is formulated utilizing hydrophilic polymers that quickly disintegrate on the tongue or buccal pit, conveying the medication to the systemic circulation through disintegration when contact with the fluid is made. Hydrophilic polymers are utilized as film formers for quick dissolving films. The water-soluble polymers accomplish quick dissolution, great mouth feel, and mechanical properties to the films. Quick dissolving oral thin film offers quick, exact dosing in a safe, effectual format that is advantageous and convenient, without the requirement for water or estimating gadgets. These days, because of numerous issues related to drug release and side effects producers are slanted towards utilizing natural polymers. In this review article, various polymers are utilized for the formulation of fast dissolving mouth film like Pullulan, Gelatin, Sodium Alginate, Pectin, Rosin, Starch, Chitosan are discussed together about their physicochemical properties and film shaping properties.

Keywords: Natural polymers, Plasticizers, Fast dissolving mouth film, fast dissolving thin film, oral mouth film.

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INTRODUCTION

The oral course is the most secure and attractive course for the administration of therapeutic agents for the utilization of human just as the veterinary.^{1,2} Thin films are certainly not an on-going detailing rather, they had been at first acquainted in late 1970 with beat gulping challenges as found in tablets and capsules. A few different names of these oral films have been shown up; for instance, oro-dispersible films (ODFs), oral soluble films, mucoadhesive films, oral strips, oral thin films, buccal films, wafers, ophthalmic films, and transmucosal films. It is an ultrathin strip (50-150 microns thick) of postage stamp size with a functioning specialist and different excipients created based on transdermal patch technology.^{3,4} Oral Dissolving Films are quick breaking down thin films having a zone going from 5 to 20 cm² in which active pharmaceutical ingredient (API) is solidified as a matrix using hydrophilic polymer. The active pharmaceutical ingredients are frequently merged up to 15 mg related to different excipients i.e., plasticizers, sugars, taste modifiers, colorants, and so forth. Prescriptions stacked in buccal adhesive films are assimilated legitimately through a buccal tissue layer that passes on it to the foundational flow to show its impact.⁵

As the fast-dissolving strip uses a sublingual course, fast ingestion of medication is conceivable; this at long last prompts the quick beginning of medication activity. New and novel oral drug delivery framework disintegrates or scatters rapidly in a couple of seconds after placing in the mouth without drinking and biting.⁶ It at that point quickly breaks down surprisingly fast and disintegrates to discharge medication for oro-mucosal assimilation.⁷ Dissolvable oral thin film or oral strip has developed in recent years from confection and oral care advertises as breath strips and become a novel and broadly acknowledged structure by shoppers for conveying nutrients and individual care items.⁸ Buccal film favours the delivery of medications having a threat of wastage through first pass impact, having low permeability, enzymatic debasement, and can be influenced by the variable condition of the gastrointestinal tracts.⁹

Medications with poor bioavailability just as with shorter half-life can be managed without any problem. Buccal films can discharge the topical medications with continued and controlled impacts and profitable over the customary drug delivery systems that are utilized in the current of different diseases. The oral film fuses various components for its itemizing which joins polymers, dynamic pharmaceutical fixing, film offsetting administrators, sugars, flavours, colours, salivation strengthening experts, added substances, surfactants, etc. yet the first and far most an amazingly fundamental fixing which helps in film advancement is a Polymer. Assortments of polymers are accessible for the readiness of fast dissolving mouth films. The utilization of film framing polymers in oral films has pulled in impressive consideration in clinical and nutraceutical applications. The determination of polymer



is one of the most significant and basic parameters for the effective improvement of the film formation. The polymers can be utilized alone or in the blend to acquire the ideal film properties. Oral fast-dissolving film is generally another dose structure in which thin film is readied utilizing hydrophilic polymers, which quickly disintegrates on the tongue or buccal cavity.¹⁰ As the strip framing polymer (which shapes the stage for the FDF) is the most basic and significant part of the FDF at any rate 45%w/w of polymer ought to, for the most part, be available dependent on a complete load of the dry film however regularly 60 to 65%w/w of polymer is wanted to get wanted properties.¹¹

The polymers employed in the oral film preparation should be-- Non-Toxic and Non-Irritant, devoid of leachable impurities, not retard disintegration time of the film, tasteless, should have good wetting and spreadability property, should exhibit sufficient peel, shear and tensile strength, readily available, inexpensive, should have sufficient shelf life, should not aid in causing secondary infections in the oral mucosa or dental regions.¹²

Hydrophilic polymers can be biocompatible and have hence pulled in broad consideration in biomedical and drug delivery applications. They can be tailor-structured at both the molecular level and the gadget level. Significant applications in the biomedical field have been found by Hydrophilic polymers.¹³

Now a day, both natural and synthetic polymers are utilized for the preparation of fast mouth dissolving film.

Classification of polymers used for Mouth dissolving film is as shown in Table 1.

Table 1: Polymer Available for Preparation of MDF^{1, 7, 8, 11}

S.No.	Polymer	Examples
1.	Natural Polymers	Pullulan, Starch, Gelatin, Pectin, Sodium alginate, Maltodextrins, Polymerized Rosin
2.	Synthetic Polymers	Hydroxypropyl methylcellulose, Sodium Carboxy methyl cellulose, Polyethylene oxide, Hydroxypropyl cellulose, Polyvinyl pyrrolidone, Polyvinyl alcohol

Both synthetic and natural polymers are accessible yet the utilization of normal polymers for pharmaceutical applications is appealing because they are efficient, promptly accessible, and non-dangerous. They are fit for medical modifications, conceivably biodegradable, and with hardly any special cases, likewise biocompatible.^{14, 15} Biopolymers are also used in the controlled release delivery systems. Substances of plant starting point represent a few potential difficulties, for example, being combined in little amounts and in blends that are perplexing, which may vary as per the area of the plants just as different factors, for example, the season. This may bring about a moderate and costly detachment and

sanitization process. Error! Reference source not found., 17 Another issue that has become progressively significant is that of intellectual property rights.

Importance of Herbal Polymers over Synthetic Polymers is-¹⁸

They are biodegradable, biocompatible and non-toxic, economic, safe and devoid of side effects and also easily available.

Therefore, due to these above superiorities of natural polymers over synthetic polymers, the natural polymers are now preferred instead of the synthetic ones.

Classification of Natural Polymers:¹⁸

Classification of natural polymers is as shown in Figure 1.

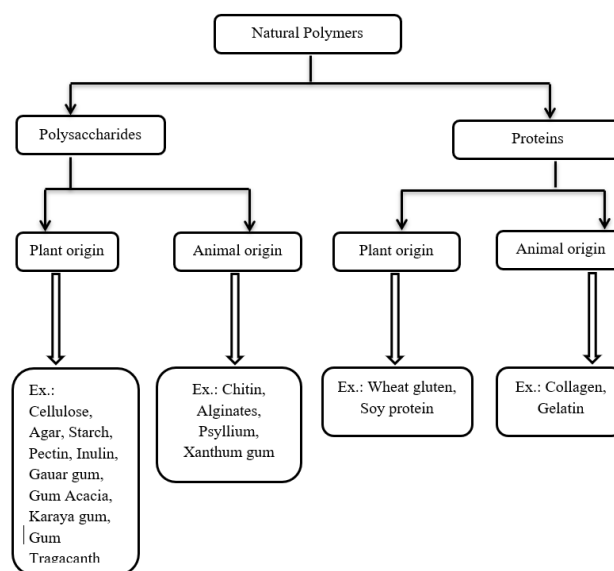


Figure 1: Classification of Natural polymers¹⁸

This review aims to study the natural polymers used for fast mouth dissolving films, and this is performed by studying the research and review work done of the last 10 years.

Different polymers are utilized for the preparation of fast dissolving oral film. Some of them are discussed beneath together with their physicochemical properties and film forming capacities.

1. Pullulan:

The fundamental structure is a straight α -glucan one, produced using three glucose units connected α -(1, 4) in maltotriose units which are connected in α -(1, 6) way. The three glucose units in maltotriose are associated with α -(1, 4) glycosidic bond, though back to back maltotriose units are associated with one another by α -(1, 6) glycosidic bond. The standard rotation of (1 \rightarrow 4) and (1 \rightarrow 6) bonds brings about two unmistakable properties of auxiliary adaptability and upgraded dissolvability. The one of a kind linkage design likewise enriches pullulan with distinctive physical attributes alongside adhesive properties and its ability to form fibers, compression moldings, and strong,

oxygen impermeable films. The α -(1, 6) linkages that interconnect the rehashed maltotriose units along the chain are liable for the flexible adaptation.¹⁹ Chemical structure and some quality parameters are as shown in Figure 2 and Table 2.

2. Gelatin:

Gelatin is set up by the thermal denaturation of collagen, detached from animal skin, bones, and fish skins.¹⁸ Gelatin is a conventional term for a blend of filtered protein divisions acquired either by partial acid hydrolysis (type A gelatin) or by partial alkaline hydrolysis (type B gelatin) of animal collagen and additionally may likewise be a blend of both. The protein parts consist for the most of amino acids consolidated by amide linkages to form linear polymers.¹²

Mammalian gelatins ordinarily have better physical properties and thermo stability than most fish and this has been connected for the most part to their higher amino acid substance. There is the utilization of mammalian gelatin in the elaboration of palatable film or coating.²⁰ Chemical structure and some quality parameters are as shown in Figure 2 and Table 2.

3. Sodium Alginate:

Alginate is an indigestible biomaterial. Primarily sodium alginate comprises sodium salt of alginic corrosive, which is a blend of polychronic acids made out of deposits of D-mannuronic acid and L-guluronic acid.²¹

Palatable films made from alginate structure solid films and show poor water resistance because of their hydrophilic nature. A blend of starch and alginate to form edible film improves the mechanical properties of the film. Chemical structure and some quality parameters are as shown in Figure 2 and Table 2.

4. Pectin:

Pectin is a heterogeneous gathering of acidic polysaccharides. This complex anionic polysaccharide is made out of β -1,4linked d-galacturonic acid residues, wherein the uronic acid carboxyl are either completely (HMP, high methoxy gelatin) or in part (LMP, low methoxy gelatin) methyl esterified.^{12, 14}

With Chitosan, HMP or LMP forms magnificent films. To be sure, the cationic nature of chitosan offers the likelihood to exploit the electrostatic interactions with anionic polyelectrolytes, for example, pectin.⁷ Chemical structure and some quality parameters are as shown in Figure 2 and Table 2.

5. Rosin:

Rosin is a thermoplastic acidic item. It is a hydrophobic and biodegradable biomaterial. It is principally a resin acid. Rosin is otherwise called colophony or colophonia resina from its native in Colophon, an old Ionic city.^{1, 14}

Films prepared from the plasticizer-free solutions were smooth and transparent yet brittle. The addition of

plasticizers plays an important role in the presentation of film coating, which brings about diminished tensile strength, decreased Tg, and expanded elongation and flexibility of the films.^{7, 12} Chemical structure and some quality parameters are as shown in Figure 2 and Table 2.

6. Starch:

Biopolymer starch is made out of glucose units and having two fundamental constituents are amylose and amylopectin.²² The starch got from various sources has a varying quantity of amylose and amylopectin normally 16-28% of amylose content in starch granules, though waxy starch exclusively contained amylopectin. Starch observed in nature in three principle crystalline allomorphs assigned as A, B, and V-type. B-type crystalline is quickly formed by amylose rich starch films and gradually by the aging of amylopectin rich starch films. Amylose is liable for the film-forming ability of starch.⁷

Starch mostly or completely replace plastic polymer. The films are see-through or translucent, flavorless, tasteless, and colorless.

Films of high-amylose corn starch or potato starch were progressively stable during aging, lost little of their elongation, and had not or a slight expansion in tensile strength.

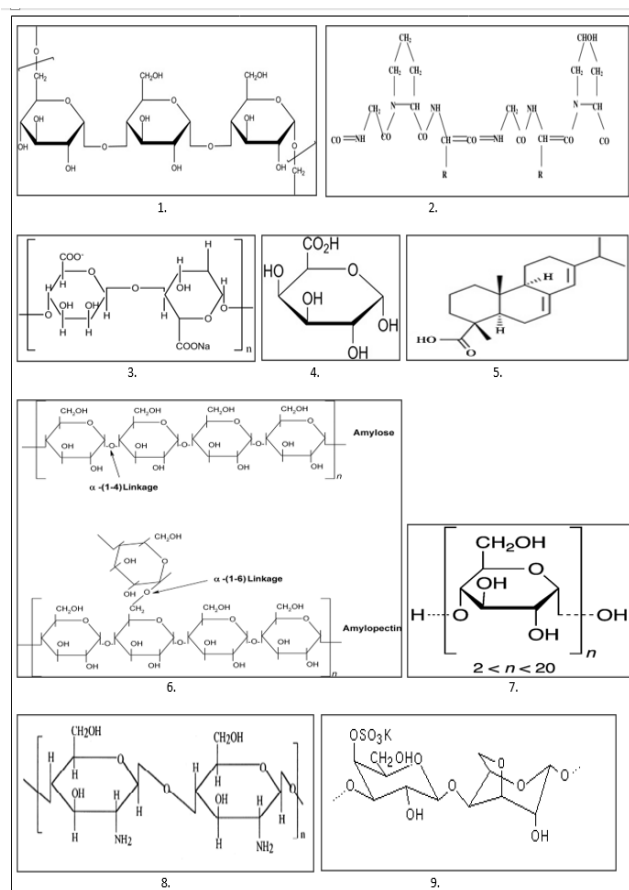


Figure 2: Chemical structures of some different natural polymers.

1.Pullulan. 2.Gelatin. 3.Sodium alginate. 4.Pectin. 5.Rosin. 6.Starch. 7.Maltodextrin. 8.Chitosan. 9.Gum carrageenan

Table 2: Some quality parameters of some different natural polymers ^{7, 8}

S. No	Polymer	Quality parameters					Solubility	Properties	Reference
		Appearance	Water solubility (25°C)	pH	Moisture (% loss on drying)	Molecular weight (kDa)			
1.	Pullulan	White or yellowish-white powder.	It's easily soluble.	5-7	Maximum 6	100–250	Water soluble	Neutral, non-toxic, non-immunogenic, biodegradable, non-mutagenic, non-carcinogenic, impermeable to oxygen, high adhesion and film forming abilities, non-ionic polysaccharide and is blood compatible. It is flexible and spinnable, being a good adhesive and binder. Pullulan can be made into films of high elasticity and which are oil and grease resistant.	7, 8, 9, 12, 24, 25
2.	Sodium Alginate	White to pale yellowish-brown colored powder.	It's slowly soluble in water, forming a viscous colloidal solution.	7.2	Maximum 15	1828	Practically insoluble in ethanol and ether, also insoluble in other organic solvents and acid.	Typical properties: - Melting point: 20°C. Specific gravity: 1.26. Viscosity: 20-400 mPa. Functional category: It's stabilizing agent; suspending agent; tablet and capsule disintegrant; tablet binder; viscosity-increasing agent.	7, 8
3.	Pectin	Yellowish white, odorless powder.	It is soluble in water.	6-7.2	Maximum 10	30,000-1000,000	Pectin is partially soluble in cold water. It is insoluble in organic solvents and alcohol.	Pectin is free-flowing, fine powder, and is a stable material. Aqueous solutions are over a wide pH range (pH 3-12) and temperatures between 60°C. Typical properties: Acidity/alkalinity pH: 3.2-4.5 Melting point: 270 °C The heat of combustion: 14.6 J g Specific gravity: 1.600 at 25°C Viscosity: 1200-1600 mPa. Functional category: Stabilizing agent; gelling agent; thickening agent.	7, 8, 26, 27
4.	Gelatin	Amber to faintly yellow-colored, vitreous, brittle solid.	It swells in water and softens. It's soluble in hot water.	3.8-6.0 (type-A) 5.0-7.4 (type-B)	Maximum 10	15,000-250,000	Practically insoluble in acetone, chloroform, ethanol (95%), ether, and methanol. Soluble in glycerine, acids, and alkalis, although strong acids or alkalis cause precipitation.	The higher the average molecular weight, the better the nature of the film. <small>Error! Reference source not found., Error! Reference source not found., 18.</small> Functional category: It's a coating agent, film former, gelling agent, suspending agent, tablet binder, viscosity increasing agent.	7, 8, 28
5.	Maltodextrin	White powder or granules.	It swells in water and softens. It's	4-7	Maximum 6	Variable	It is slightly soluble to insoluble in anhydrous alcohol. <small>Error! Reference</small>	Maltodextrins are characterized by DE (dextrose equivalent) and have a DE between 3 to 20. ¹ The higher the DE esteem, the shorter	7, 8, 29

			soluble in hot water.				source not found., Error! Reference source not found.	the glucose chains, the higher the solubility, the lower the heat resistance, and the higher the sweetness. Typical properties: - Well free-flowing, no specific smell; Well solubility with legitimate mucosity; Low hygroscopicity, less agglomeration, Good transporter for sugars, aromatizer, and stuffing.	
6.	Rosin	Yellow to Black semi-transparent crystalline solid. Faint piney smell.	It's not soluble in water.	4.5-7.9	Maximum 11	3,02,000.5	It is dissolvable in alcohol, ether, benzene, and chloroform. Error! Reference source not found.	Rosin is fragile and friable. Functional property: - a film-forming polymer, a coating material in pharmaceuticals. Typical properties: - The practical melting point of semi-liquid at the temperature of boiling water, others get liquefy at 100°C to 120°C.	30, 31, 32
7.	Chitosan	It is an odorless pale white fine powder. It can also be produced from chitin in the form of pastes, films, and fibers.	Insoluble in water.	6-7.5	Maximum 7	38,00,000 - 200,00,000	A significant downside of chitosan is its poor solubility in neutral solutions. Soluble in 1% acetic acid solution.	Typical properties: - Chitosan items are highly thick, looking like natural gums. Unadulterated chitosan films are commonly cohesive, smaller and the film surface has a smooth contour without pores or cracks.	33, 34
8.	Gum Carrageenan	Usually in the form of a white or tiny yellow powder, free of <i>smell</i> or taste.	Soluble in water.	(sol 1.5% at 20°C) 7-10	Maximum 18	above 100	All carrageenan types are dissolvable in heated water at temperatures over its gel softening temperature. In chilled water, just lambda-carrageenan and the sodium salts of kappa and particle carrageenan are dissolvable. It is water-dissolvable and insoluble in most natural solvents.	Types of carrageenan:- Kappa – It is rigid and brittle gel, thermo-reversible, high gel strength, showing syneresis. Iota – It is elastic gel, thermo-reversible, no syneresis, thixotropic. Lambda – It is cold soluble, non-gelling, high viscosity. Functional properties: - They are broadly utilized in the food business, gelling, thickening, and stabilizing properties. Their primary application is in dairy and meat items, because of their strong binding to food proteins. Additionally as film-forming material.	35, 36, 37

Some Literature review on natural polymers that are utilised for the preparation of mouth dissolving film, they are as shown in Table 3.

Table 3: Literature Review on Natural Polymers Used for some Preparation of MDF ⁷

S. No.	Polymer	Drug	Description
1.	Pullulan	Cetirizine HCl ³⁸	The film shows acceptable thickness, great mechanical properties, great disintegration time, even dispersion and consistency in the film.
		Pilocarpine HCL	A film was easily swell and quickly disintegrate.
		Propranolol hydrochloride ³⁹	The developed formulations demonstrated acceptable outcomes for peel ability, tackiness, weight variation, surface pH, folding endurance, percentage moisture loss, film softening upon storage, percent elongation, disintegration time, transparency, and drug content. Disintegration time of 47 sec and demonstrated promising drug release of 93% after 20 min.
		Enalapril Maleate ⁴⁰	The pullulan-enalapril maleate blends exhibit good physicochemical properties, as well as a high dissolution rate, which makes these formulations usable as a mucoadhesive buccal film.
		Ropinirole hydrochloride ⁴¹	There is the fulfillment of all the desirability.
2.	Starch	Benzocaine	Lycoat RS720 (25%w/w) was utilized to prepare the oral film. This structure offered dose homogeneity with quick dissolution. It permitted hydrophilic, hydrophobic, and also temperature sensitive API's incorporation.
		Tianeptine Sodium	Lycoat NG73 was utilized as a new film-forming agent. Lycoat NG73 indicated most prominent dissolution, acceptable disintegration, and wanted physicommechanical properties.
3.	Sodium Alginate	Medicinal carbon	The addition of sorbitol or mannitol in it caused improvement in the adsorption capacity of therapeutic carbon film when contrasted with its powder structure alongside adequate quality and disintegration time.
		Levocetirizine HCl	Film-forming polymer used was Sodium alginate.
		Salbutamol Sulfate ⁴²	The film was formulated by using Sodium alginate.
		Perindopril ⁴³	Perindopril films were prepared by solvent casting method using sodium alginate at 100,150,200,250,300 mg respectively.
4.	Gelatin	Montelukast sodium ⁴⁴	Montelukast sodium fast dissolving film was made by the solvent casting technique with various concentrations of super disintegrants like microcrystalline cellulose and crospovidone utilizing PEG 400 as a plasticizer. It was shown that 4% crospovidone and 10% MCC with 4% gelatin as a film base was reasonable for preparing fast dissolving films of Montelukast sodium.
5.	Maltodextrin	Piroxicam	Maltodextrin with low dextrose comparable as film-forming material was utilized to form an oral film by both casting and an extrusion technique. The homogenous film was acquired by loading a lot of water-insoluble powders more than 15%w/w.
		Nicotine	Two distinctive dextrose reciprocals, in particular, DE 6 and DE12 were chosen to assess the impact of polymer molecular weight on film ductile properties. It shows that diminishing the DE estimation of Maltodextrin the tenacity of the film improved.
6.	Pectin	Propranolol HCl ⁴⁵	Fabrication and Evaluation of Fast Disintegrating Oral Hybrid Films of Propranolol Hydrochloride were formulated by using different combination of pectin:HPMC; pectin:PVA; pectin:carbopol; pectin:HPMC E15 LV; with different ratios. But the combination of Pectin:HPMC E15 LV and Pectin:Carbopol results were comparable with that of marketed conventional films of verapamil.
		Perindopril ⁴³	Film formed pectin was found to be optimised amongst other polymers film. The in-vitro drug study was found to give the highest % diffusion than other formulation. From the in-vitro diffusion studies of fast dissolving films, it was observed that the film showed more % diffusion at 16 minutes.

Films from cassava starch had great flexibility and low water permeability, showing potential applications as palatable films. Amylose rich starch is less delicate to aging phenomena than amylopectin rich starch. The changes in elongation are identified with the changes in starch structure and B-type crystallinity.¹⁸

Lycoat NG 73 is a magnificent film-forming polymer from pea starch. Lycoat is a novel granular hydroxypropyl starch polymer. Lycoat scatters easily in cold water without the development of lumps.⁷ Chemical structure and some quality parameters are as shown in Figure 2 and Table 2.

7. Maltodextrin:

Maltodextrin is effectively digestible, being retained as quickly as glucose. Maltodextrin is ordinarily made out of a mixture of chains that differ from three to seventeen glucose units long.¹² Chemical structure and some quality parameters are as shown in Figure 2 and Table 2.

8. Chitosan:

Chitosan (β -(1, 4) - 2-amino-2-deoxy-D-glucopyranose), which is chiefly produced using crustacean shells, is the second most abundant natural and non-poisonous polymer in nature after cellulose.²³ Chemical structure and some quality parameters are as shown in Figure 2 and Table 2.

9. Gum Carrageenan:

Carrageenan is a straight chain of partially sulphated galactans.

These sulphated polysaccharides are removed from the cell walls of different red seaweeds (Rhodophyceae). Various seaweeds produce various carrageenans. Recently, carrageenan films were likewise seen as less misty than those made of starch.^{12, 14} Chemical structure and some quality parameters are as shown in Figure 2 and Table 2.

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