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Review Article

**POLYMERS USED IN MOUTH DISSOLVING  
FORMULATIONS: A REVIEW**

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Punjab, 140111**Article Received:** April 2022**Accepted:** June 2022**Published:** July 2022**Abstract:**

Rapid advancement in the technology have developed a feasible dosage alternative for pediatrics from the oral route, geriatrics, non-compliant or queasy persons. Mouth dissolving formulations consist of ingredients such as API, polymers, saliva stimulating agents, preservative, flavors, sweetness, film stabilizing agents, surfactants, plasticizers etc. however, polymer is a pivotal ingredient which aid in film formation. Specifically hydrophilic polymers are used for film formation as they disintegrate quickly and have high bioavailability. These mouth dissolving formulations provide rapid, accurate dosing in a safe and efficacious manner, have better patient compliance. In this review article, the different polymers such as pullulan, sodium alginate, maltodextrin, starch, gelatin, pectin, polymerized rosin, Xanthan, HPMC, NaCMC, PVA, PVP, Kollicoat, polyethylene glycol, HPC, HEC, along with their properties and applications are highlighted.

**Keywords:** - Mouth dissolving films, Polymers, HPMC, Formulation, Applications

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**INTRODUCTION:**

The oral route is the most compliant for the patient of the several options. For pediatrics, geriatrics, non-compliant, or nauseated patients, the majority of pharmaceutical companies have focused their research efforts on finding viable oral dose alternatives. [1] Fast dissolving dosage forms have grown in relevance in the pharmaceutical industry due to their distinct characteristics and advantages.

Mouth dissolving formulations consist of numerous ingredients which includes active pharmaceutical ingredient, polymers, flavouring, stabilizing, colouring agents, sweetness, preservatives, surfactant etc. among which polymer is a crucial ingredient.[2] It is derived from Greek word polymeros which refer to many parts or units of high molecular mass, these high molecular mass, these high molecular weight molecules are known as macromolecules which are further formed by joining large no. of small molecules named as monomers.[3]

Polymers can be classified in a variety of ways, including:

- i. Source/origin (Natural, Synthetic, semi-synthetic)
- ii. Structure (Linear, branched, crosslinked)
- iii. Type of polymerization (addition, condensation)
- iv. Molecular forces (fibers, thermoplastics, elastomers, thermosetting)
- v. Degradability (biodegradable, non-biodegradable)
- vi. Chain growth polymerization (free radical governed)[4]

Mouth dissolving formulations utilize hydrophilic polymers as they disintegrate quickly on the tongue or in the buccal cavity [2]. Film formers are typically made of water-soluble polymers. They have good mechanical qualities and can be used in a variety of industries, including food, pharmaceuticals, paper, construction, water treatment, coatings, textiles, and paint[5].

They work by dissolving in the oral cavity's salivary secretions within a minute, releasing the active pharmaceutical components. Without the use of water or measurement apparatus, mouth dissolving formulations provide rapid, precise dosing in a safe, effective manner that is convenient and portable. In such circumstances, the drug's bioavailability is much higher than in traditional tablet dose forms. Some of the water-soluble polymer used as film former are HPMC E-3 and K-3, Methylcellulose A-3, A-6, and A-15, Pullulan, carboxymethylcellulose 30, Pectin, Gelatin, Polyvinyl pyrrolidone PVPK-90, Sodium

alginate, hydroxy propyl cellulose, Polyvinyl alcohol, Maltodextrins, Eudragit RD 10[6-9]. Polymerized rosin, for example, is an unconventional film-forming polymer [10].

**Ideal characteristics of film forming polymers [11, 12]**

1. The polymer must be non-toxic, non-irritating, and free of leachable contaminants.
2. It should be easily available and inexpensive.
3. It should provide good mechanical properties.
4. The shelf life of the employed polymer should be sufficient.
5. It should have low molecular weight.
6. Polymer must be tasteless and colourless.
7. Polymer must be tasteless and colourless.

The water-soluble polymers have been classified into two groups, as shown below [13]:

**Natural polymer**

- Pectin
- Pullulan
- Maltodextrin
- Xanthan
- Sodium alginate
- Starch gelatin
- Starch gelatin
- Polymerized rosin

**Synthetic polymer**

- Hydroxyethyl cellulose
- Kollicoat
- Hydroxypropyl cellulose
- Polyethylene glycol
- Polyvinyl pyrrolidone
- HPMC (hydroxy propyl methyl cellulose)
- Polyvinyl alcohol (PVA)
- Carboxymethylcellulose (CMC)

**Special features mouth dissolving formulations [14]**

- Rapid release they offer quick onset of action.
- They can be easily administered.
- They provide rapid accurate dosing in a safe efficacious format.
- They can improve patient compliance.

Plasticizers also play a critical role in the formulations of oral strips they tend to enhance flexibility and reduce brittleness of the strip. The plasticizer is chosen on the basis of its compatibility

with the selected polymer [15]. The use of plasticizers increases the strength and flow of polymers. Glycerol, low molecular weight polyethylene glycol, phthalate derivatives, propylene glycol, Castor oil, citrate derivatives are commonly used plasticizers. Normally, the concentration of 0-20% w/w of dry powder weight of plasticizers is used [16].

### Natural polymers

Biopolymers commonly known as natural polymer are obtained from natural sources, they are non-toxic, safe and efficacious. They are easily available and cost-effective owing to its properties it has various applications in pharmaceutical, food, cosmetic industries and have better consumer acceptance [125]. Some commonly used natural polymers are Pullulan, starch gelatin, pectin, sod. Alginate, maltodextrin, polymerized rosin, xanthan, organic polymers act as thickening, stabilizing, solubilizing, film forming, binding, suspending agents [126]. Natural polymers have both pros and cons which are discovered below: -

#### Pros: -

- Low toxicity
- Cost effective
- Abundance in nature
- High efficacy
- High water solubility
- Biodegradable

#### Cons: -

- More contamination
- Complex structure
- Rate of production is low
- Chances of variation in different batches

### Pullulan

It is a naturally occurring, water soluble polysaccharide made up of maltotriose units linked by a glycosidic bond of -1,6. Pullulan is produced by fungus *Aureobasidium pullans*. They can be easily altered chemically to produce pH sensitivity or to decrease water solubility. Films made of Pullulan exhibit good mechanical properties and due to its high-water solubility, it has countless industrial applications [17]. Pullulan has following properties [18].

- It is non-toxic in nature.
- It has low oxygen permeability.
- It has high tensile strength and film forming properties.
- It is stable over wide range of temperature.
- The prime advantage of pullulan is that it is a blood compatible, non-ionic polysaccharide.

Pullulan was named by Bender et al. who studied the novel glucan. The basic structure of pullulan was discovered in the 1960s. [19]. films made from pullulan are tasteless, odourless, colourless, heat sealable. Pullulan is used as binder for fertilizers and in food, gelling agent, coating, and packaging material as a low-calorie ingredient. Pullulan is commonly used in conjunction with gelatin, amylose, and polyvinyl alcohol. It can be used as substitute for HPMC or other film forming polymers [20-24].

### Maltodextrin

Maltodextrin is a nutritive saccharide polymer prepared as white powder by partial hydrolysis of starch with safe and suitable enzymes and acids [55]. It consists of mixture of chains that lie between three to nineteen 3 to 19, glucose units. These glucose units are further attached to a (1→4) glycosidic bond [56]. Maltodextrins are classified on the basis of DE (dextrose equivalent) and have a DE between 3 to 20. The higher DE value leads to shorter glucose chains, better sweetness, higher solubility, and reduced heart resistance [57].

Maltodextrin is a simple carbohydrate that is quickly digested and absorbed at the same rate as glucose. It is odourless water soluble, nontoxic, edible polymer which has food shelf life. Maltodextrin is widely used as film former [58]. The unique features of maltodextrin films are that they are extremely thin, elegant and are available in different sizes and shapes [55].

### Starch

Starch is a polysaccharide consisting of a glucose monomer joined in a  $\alpha$ -1,4 linkages. In plant tubers and seed endosperm starch is the major carbohydrates reserve in the form of granules each consisting of a large number of amylopectin molecules, as well as a greater amount of amylose molecules of lower size. Amylose is the simplest form of starch which contributes for its film forming properties [25]. Corn is the most common source of starch although wheat, rice, potato, and Tapioca are also used [26]. The starch with enhanced and targeted functionality has been developed through genetic modification of starch crops. To replace plastic polymers, starch is widely used to produce biodegradable films [27]. The films are transparent/translucent, flavourless, and tasteless. Yet due to its poor mechanical strength, its applications are limited during ageing films of high mileage cornstarch or potato starch show more stability [27]. Films made of cassava starch show good flexibility and low water permeability signifying

its dormant applications as edible films and require plasticizers to overcome the problem of brittleness in fast dissolving films. Most commonly, glycerol and sorbitol are used as plasticizers for starch films [28].

Oral films consist of following starches:

1. Pre gelatinized starch including lycoat.
2. Modified starch.
3. Amylase rich starch.

Starch is a natural polymer which has countless applications [28]. It is mainly used as binder, diluents, disintegrants, thickening, and gelling agents in food industry [29-32]. The starch-based polymers exhibit good biocompatibility and are non-toxic in nature. The hydroxyl functional groups in the structure of starch contributes to its hydrophilic nature [33]. Starch's hydrophilicity is utilized to enhance the degradation rate of some degradable hydrophobic polymers. [34-37].

### Pectin

Pectin is a high molecular weight carbohydrate polymer which is composed of  $\beta$ -1,4- linked  $\alpha$ -galacturonic acid residues [41]. It is derived from proto pectin found in the middle lamellae of plant cells [42]. It is extracted from apples and citrus fruits. Pectin is water soluble in nature. Pectin has wide range of applications in the pharmaceutical industries [43]. In tablets standardized and pure pectin serve as binding agent. The high methoxy pectin has been used to prepare beads for sustained release drug delivery. Through emulsification technique pectin-based microspheres are also prepared [44-48]. Due to its gelling properties, it is used in food industry. It has special characteristics which enabled it to be used as matrix for the entrapment and/or delivery of a wide range of medicines, proteins, and cells [49]. Pectin hydrogels can be used as binder in tablet formulation. Some other researchers suggest that pectin has been used to develop drug delivery systems [50].

### Polymerized Rosin

Rosin also known as colophony is a thermoplastic acidic product which is isolated from pines and some other plants. It is basically a resin acid which is used as film forming polymer and coating material in pharmaceutical industry. The method of casting/solvent evaporation is used to make free film of rosin, and its derivatives are expected to be biodegradable [59]. Rosin and its esters have good film-forming characteristics, therefore they can be used for enteric coating and prolonged drug release. Polymerized rosin is produced from gum rosin by polymerization with the help of catalyst. It exhibits excellent properties such as anti-oxidation, non-

crystallizing, high softening point and good compatibility with film forming agents [60].

### Gelatin

Gelatin is a universal biopolymer which has countless applications in food, confectionary, pharmaceutical, and cosmetics. It can be obtained via thermal denaturation or partial hydrolysis of collagen. It is also a protein and consists 19 amino acids. On the basis of acids or alkaline pre-treatment gelatin can be divided into two types type A or type B. Type A is obtained by partial acid hydrolysis and type B by partial alkaline hydrolysis of animal collagen or may be used as mixture of both [38].

The presence of the functional groups mainly -OH, -COOH, -NH<sub>2</sub>, contributes to water solubility of gelatin. Molecular weight of Gelatin is directly proportional to the properties and film forming abilities of gelatin i.e., higher the average molecular weight of gelatin will result in better quality of film gelatin films dissolve quickly and provide smooth mouth feel [39]. They can also be used as emulsifiers, forming agents, colloid stabilizers, biodegradable film forming material and micro encapsulating agents. These various uses make gelatin a multipurpose ingredient [40].

### Sodium alginate

Sodium alginate is a naturally occurring anionic polymer consisting of sodium salts of alginic acids. Furthermore, it is a mixture of polymeric acids composed of residues of D-mannuronic acid & L-guluronic acid [51, 52]. The conversion of alginic acid to sodium alginate contributes to its water solubility. Due to the hydrophilic nature of alginate its edible films are strong and poor water resistant [53].

The colloidal properties of alginate such as gel producing, film forming, emulsion stabilizing, thickening, suspending properties aid to produce biopolymer film [52]. As compared to synthetic films the mechanical properties and water permeability can be considered as moderate with the addition of starch, the mechanical properties of alginates can be enhanced [54].

### Xanthan

Xanthan gum is an exopolysaccharide which is obtained from a plant pathogenic micro-organisms of the genus *Xanthomonas*, the strain *X. campestris* NRRL-1459 being the mostly used [61].

Structure of Xanthan gum consist of backbone of repeating sub units which consist of 3 to 8 monosaccharides basically Xanthan gum is composed of D-glucose, D-mannose and D-glucuronic acid[62,64].

Xanthan is a natural water-soluble polymer and its ability to control the rheology of water-based systems has industrial significance [65]. As compared to other polysaccharide solutions even at low concentrations it gives highly viscous solutions due to which it is widely used as thickener and stabilizer. Pseudoplastic behavior is shown by Xanthan gum solutions which enhances mouthful effect and flavour release [66-67].

They are highly stable and are least affected by pH change. Xanthan is compatible with other film forming polymers. Xanthan gum has broad range of applications in cosmetics a toothpaste [68]. In personal care products such as creams, eye gels it is used as thickener and stabilizer. It is used in combination with other gumsto reduce the production cost [61]. The major uses of Xanthan gum are in food industry. It provides, flavor release properties as required by food products [69].

### Synthetic polymers

Synthetic polymers are produced artificially in laboratory by humans. Through various chemical processes as they are not present in nature. Synthetic polymers are further classified in two major categories i.e.,

- i. Biodegradable synthetic polymers.
- ii. Non-biodegradable synthetic polymer [132].

Synthetic polymers have numerous unique characteristics which is a significant which is a significant advantage [134]. They are flexible, resistive, chemically inert, and have good mechanical strength and other qualities like microbial contamination, complex structure, limited manufacturing rate, and fluctuations in different batches are some of the drawbacks of natural polymers which are conquered by synthetic polymers [135]. As a result, their inclusion in the in-mouth dissolving formulation is intended however along with the advantages these also have some disadvantages.

### Disadvantages [133]

- They are more expensive.
- They are non-degradable in nature.
- They are producing toxicity.
- The process of production is complicated.
- They have relatively low water solubility.

Some commonly used synthetic polymers are

HPMC, polyvinyl alcohol (PVA), Kollicoat, polyvinyl pyrrolidone, polyethylene oxide, cellulose derivatives i.e., hydroxypropyl cellulose derivatives (HPC), sodium carboxymethylcellulose (NaCMC), Hydroxyethyl cellulose, and PEG.

### HPMC

Hydroxypropyl methylcellulose is a hydrophilic, biocompatible, biodegradable polymer. It belongs to the class of cellulose ethers. HPMC is classified on the basis of viscosity, degree of methoxy substitution it can be divided into several grades [70]. For film formation lower grades of HPMC like Methocel E3, E5, and E15 are selectively used as they have low viscosity. It is also used as raw material for coating. It is intensively used on as binder thickening agent, film forming material, hydrophilic matrix material in pharmaceutical manufacturing units [71]. HPMC is utilized in a variety of drug delivery systems as a polymer used for coating and a matrix forming agent. It is used in controlled release dosage form because of its gelling properties. HPMC's medication release profile is improved when ionic polymers are added. In conclusion it may be said that it offers broad range of applications in Biomedical field [124].

### Functions [122]

HPMC has a wide range of applications such as

- Thickening agent
- Binding agent
- Film forming material
- Viscosity enhancer
- Suspending agent

### Advantages [123]

1. Consumer acceptance: Good products can be obtained with the right amount of plasticizer. They produce transparent, bright coatings, and are fully compliant with dyes, pigments. As a result, consumers are more accepting HPMC coated pills. Film formed by HPMC easily swells in the required region and show efficacy.
2. Flexibility: As it come in a variety of viscosities, grades and types, HPMC is a versatile material. The viscosity grades of HPMC can be repaved for each other depending on the sort of product desired.
3. Drug release: Medicine is released at a constant rate when HPMC is utilized as polymer for coating. Due to this steady rate and extent of drug delivery patient compliance is enhanced.

Moreover, HPMC can be used enhance the solubility an dissolution of poorly water-soluble drugs [2]. By using high concentration of high molecular weight grades of HPMC viscous gels can be prepared.

Coating produced by HPMC are tough, elastic, highly consistent, economical, non-toxic. Drug release profile of HPMC increase on the addition of ionic polymers. HPMC has versatile used in drug delivery [72].

#### **Polyvinyl alcohol (PVA)**

Polyvinyl alcohol is a water-soluble polymer. Its water-soluble characteristics are due to the presence of hydroxyl group (-OH) in its structure [73]. It is synthesized by the process of polymerization of vinyl acetate to polyvinyl acetate which is then hydrolyzed to obtain PVA. The crystallizable and solubility of polyvinyl alcohol depend on the content of acetate groups and extent of hydrolysis [74]. Any change in these factors affect the nature of hydrogen bonding in the aqueous solution and ultimately the solubility of PVA [75-77]. The viscosity, solubility, surface tension of PVA depend on concentration, temperature, molecular weight of the material and degree of hydrolysis [4]. PVA has capability of self-crosslinking due to the high density of hydroxyl groups which are located on its side chain [78].

It's mostly utilized in topical pharmaceutical and ophthalmic formulations to make water soluble films [2]. It is used as stabilizer in emulsions, lubricant for contact lens solution, viscosity enhancing agent for viscous formulations such as ophthalmic products, in sustained release oral formulation and transdermal patches [79]. PVA hydrogels are used for abundant biomedical and pharmaceutical application. These hydrogels are non- carcinogenic, non-toxic and efficacious.

#### **Kollocoat**

This is a polyvinyl alcohol poly ethylene glycol graft co polymer. It is a new pharmaceutical ingredient intended to use as a coating polymer for rapid release formulations [81]. The polyethylene glycol part behaves as an internal plasticizer whereas the polyvinyl alcohol part provides the good film forming characteristics. Kollocoat is a water-soluble polymer. The film formed by using Kollocoat is transparent in nature. It is an ideal film forming agent, cost effective, water soluble, safe, and efficacious [13].

#### **Polyvinyl pyrrolidone (PVP)**

Polyvinyl pyrrolidone is also known as polyvidone or Povidone is made from the monomer N-vinylpyrrolidone [82]. PVP is synthesized by polymerization of isopropanol or vinylpyrrolidone in water [83]. On the basis of molecular weight, it is available in different grades [84,85].

To improve the bioavailability of various drugs, soluble grades of PVP and polyvinyl pyrrolidone-vinyl acetate have been used. Povidone increases dissolution of active pharmaceutical ingredient. It provides excellent stability to the tablet formulation [86-90]. In solutions it has excellent wetting properties. All grades of povidone can be used to stabilize suspensions as hydrophilic polymers [91-94].

#### **Polyethylene glycol**

Polyethylene glycol also named as polyethylene oxide (PEO) is a synthetic hydrophilic, non-ionic polymer. They can only be differentiated on the basis of their molecular masses [13]. The molecular mass of PEG is below 20,000 g/mol whereas PEO have above 20,000 g/mol. Due to low toxicity and hydrophilic nature PEG can be used to sharpen the dissolution of various hydrophobic drugs [95]. It is also soluble in organic solvents. It has countless properties such as lubricant, binding agent, film former, additive, surfactant, plasticizer, solvent. Its water retention properties contribute to its laxative nature. Nowadays it is used to store blood and organs [127].

#### **Cellulose derivatives**

The most abundant polysaccharide on the planet is cellulose. It can be found in a variety of places, including wood and plant cell walls. Some bacteria and algae species, as well as Tunicates are the only known cellulose producing animals [96]. This natural abundance allows for the discovery of novel applications for such class of materials [128].

Polysaccharide are bio based long chain bio polymeric carbohydrate molecules made up mostly of monosaccharide units. Polysaccharides come in a variety of form [97]. The most significant natural fiber is cellulose and chitin. Chitin is derived from lower animals, whereas plants are the source of chitin.

Cellulose is the most abundant polymer formed of repetitive units of glucose. The majority of biodegradable polymers are derived from nature [98]. Because of their suitable physical and mechanical qualities, cellulose and its derivatives have gained a lot of interest as biocompatible polymers for biomedical purposes [130]. By utilizing its structure cellulose produces functionality, flexibility, and high specific strength naturally. It is economic and easily available [129].

The materials made up of cellulose allow for the fine control of porosity and interconnection which is ideal for biological applications. However, it has no. of disadvantages for biomedical applications including

hydrophobic nature, susceptibility to moisture and microbial resistance [131]. In order to produce cellulose with diverse characteristics it is modified by replacing its -OH group with functional group such as acid oxides, and chlorides[99].

Cellulosic materials/ materials made from cellulose have conventionally been utilized in paper and textile industries, but in present time they offer wide range of applications [100].

#### Properties [96]

1. Cellulose solubility: the hydrophobic nature of cellulose is a severe drawback in biomedical utility. This is as a result of hydrogen bonding including electrostatic and hydrophobic interactions. Some ionic liquids can be utilized to solubilize cellulose materials however they have drawbacks including being expensive, more power consuming etc. to solubilize cellulose N-methylmorpholine-N-oxide (NMO or NMO) is utilized. As a result, there is need to generate unique cellulose solvents with desirable characteristics so that they can be used in medical field.
2. Mechanical properties: For the design of high-performance mechanical and functional materials, cellulose materials, polymers are gaining popularity because of their high intrinsic stiffness and strength, crystals of cellulose provide potential substance with outstanding mechanical properties when properly constructed, offering a good choice for biological applications.
3. Hygroscopic properties: The low wet strength of cellulose, despite its outstanding mechanical qualities in a dry state is a barrier for its uses. The cause of this issue is owing to hygroscopic qualities of cellulose, due to its higher affinity hydrogen bonding with water. Water only penetrates the disordered regions of cellulose. Because of the cellulose water swelling, cellulose and materials based on it can be processed in water. The hygroscopic characteristics of cellulose may decide if it may be employed in a particular medical field.
4. Toxicity: In medical field, toxicity of a substance is an issue. Although particles of cellulose are collected from nontoxic or less toxic sources, their cytotoxicity and biocompatibility may be influenced by their size, alteration in surface, hydrophobicity, hydrophilicity and aggregation. The nanoscale diameter of particle has long been known as a feature that can cause toxicity in products made up of tiny particles.

#### Hydroxypropyl cellulose (HPC)

HPC is a cellulose derivative, water soluble thermoplastic polymer. It has excellent film forming properties on the basis of viscosity it can be divided into different grades which are commercially available [101]. Films produced by HPC are flexible and has good surface properties. At high temp. and pressure alkali cellulose is reacted with propylene oxide to yield hydroxypropyl cellulose. It is compatible with most of the natural and synthetic water-soluble polymers [102]. In oral and topical pharmaceutical preparations HPC is widely used. Above all it serves major functions as film former, binder in tablets, film coating, extended-release matrix former. It is also used in transdermal patches and ophthalmic preparations [103-106].

#### Sodium carboxymethyl cellulose (NaCMC)

NaCMC is one of the major products of cellulose ether. Due to the poor water solubility of carboxymethyl cellulose, it is stored as NaCMC [107]. It is non-toxic in nature and have more drug loading capacity [108,109]. It possesses excellent film forming properties that can be used in combination with ether polymers to produce oral films [110,111]. It has broad applications in the field of pharmaceutical [112]. It is used as water retaining, chelating, flocculating agents, emulsifier, and film forming agent [113].

#### Hydroxyethyl cellulose

Hydroxyethyl cellulose also known as Natrosol or cellosize is a cellulose derived synthetic water-soluble polymer which is used as thickening, film forming, emulsifying, and stabilizing agent [114]. It is often used with hydrophobic drugs to enhance its dissolution. It is also used in ophthalmic preparations, cosmetics, household cleaning products [115,116].

#### CONCLUSION:

The ongoing success and acceptance of mouth dissolving formulations in global market demonstrate the need of for "water less" pharmaceutical formulations. These formulations have well known advantages over conventional dosage form. As polymer play crucial role in the mouth dissolving formulations hence polymer must be selected wisely.

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