

Hydrogel-Based Mouth Dissolving Films for Drug Delivery: A Review

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Received: 01-08-2026 / Revised: 15-09-2026 / Accepted: 03-10-2026

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Conflict of interest: Nil

Abstract

Mouth dissolving films are thin oral dosage forms that dissolve quickly when placed in the mouth and can be useful for patients who have difficulty swallowing conventional tablets. Hydrogel-based mouth dissolving films combine the film-forming properties of polymers with the water-absorbing and swelling properties of hydrogels. This review discusses the basic concept of hydrogel-based mouth dissolving films, commonly used polymers and excipients, methods of preparation, drug release behaviour and different evaluation parameters. The review also covers the factors that affect film properties, including polymer concentration, plasticizer level, film thickness, moisture content and drug-polymer interaction. Their use in pediatric, geriatric and patients with swallowing difficulties is also discussed. Current research on natural polymers, biodegradable materials and improved drug delivery approaches is included. The review aims to provide a simple overview of the formulation, evaluation, advantages, limitations and future scope of hydrogel-based mouth dissolving films as an oral drug delivery system.

Keywords: Hydrogel, Mouth Dissolving Film, Oral Drug Delivery, Polymers, Drug Release, Film Formulation.

DOI: 10.25258/ijcpr.18.10.23

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Introduction

Oral drug delivery is the most commonly used route for the administration of medicines. Tablets, capsules, syrups, and suspensions are commonly given through the oral route because they are easy to use, convenient for patients, and generally economical. After oral administration, the dosage form reaches the gastrointestinal tract, where the drug is released, dissolved, and absorbed into the body. The absorption of a drug depends on several factors such as its solubility, dissolution rate, stability in the gastrointestinal tract, permeability, and metabolism. Among the different oral dosage forms, tablets and capsules are widely used because they are easy to manufacture, stable during storage, and provide an accurate dose. However, these dosage forms are not suitable for every patient. Children, elderly patients, bedridden patients, and patients having difficulty in swallowing may face problems while taking tablets or capsules. Such problems can affect the regular use of medicines and may reduce patient compliance. Therefore, alternative oral dosage forms that are easier to administer have been developed.

Limitations of Conventional Oral Dosage Forms: Conventional tablets and capsules have

some limitations despite their wide use. One of the main problems is difficulty in swallowing. This problem is more common in children, elderly people, and patients suffering from swallowing disorders. Some patients may need a large amount of water to swallow a tablet properly, which may not always be convenient. The drug in a conventional tablet usually needs to disintegrate and dissolve before it can be absorbed.

For drugs having poor aqueous solubility, this process may be slow and can affect drug absorption. Some drugs may also undergo degradation in the gastrointestinal tract or extensive first-pass metabolism in the liver, which can reduce the amount of drug reaching the systemic circulation.

Taste is another problem in some oral formulations. Drugs having a bitter or unpleasant taste may reduce patient acceptance, especially in pediatric preparations. These limitations have encouraged researchers to develop dosage forms that are easy to take, do not require water, and can provide rapid drug release.

Need for Mouth Dissolving Drug Delivery:

Mouth dissolving drug delivery systems have been developed to make oral drug administration easier and more convenient. These dosage forms are designed to dissolve or disintegrate quickly after coming in contact with saliva. They generally do not require water for administration, which makes them useful for patients who have difficulty swallowing conventional tablets or capsules.

Mouth dissolving dosage forms can be useful for children, elderly patients, patients who are bedridden, and patients with swallowing

difficulties. They can also be useful when water is not easily available. Due to their rapid disintegration in the mouth, these systems may provide faster availability of the drug in some cases. Different types of mouth dissolving dosage forms have been developed, including orally disintegrating tablets, oral wafers, and mouth dissolving films.

Among these systems, mouth dissolving films have received attention because of their thin structure, ease of administration, and convenient handling.

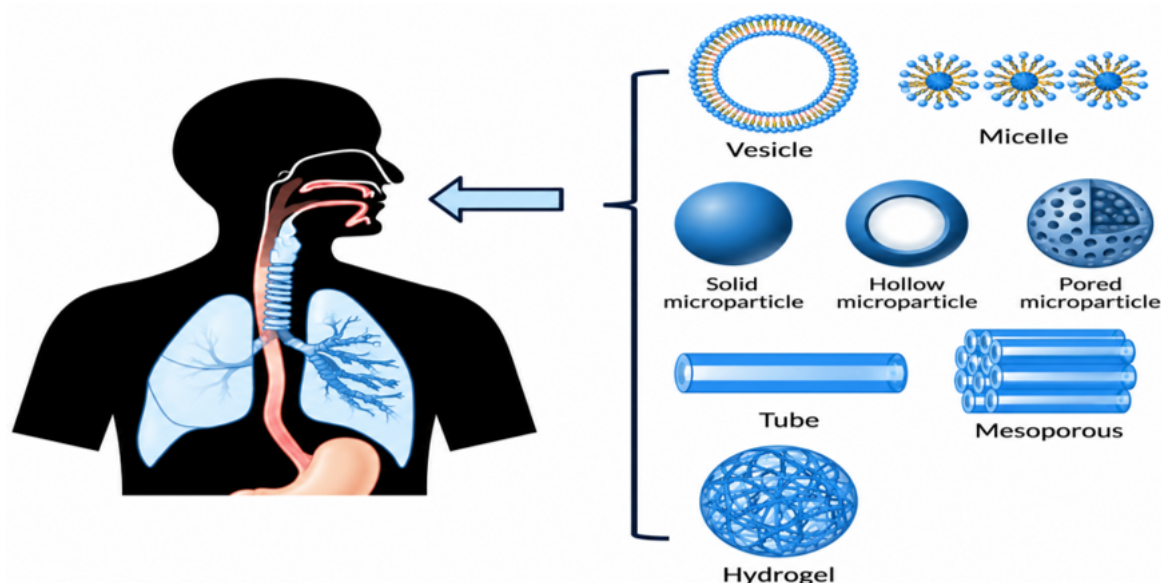


Figure 1: Oral Drug Delivery Systems

Mouth Dissolving Films: Mouth dissolving films are thin and flexible films containing a drug and suitable pharmaceutical excipients. The film is placed on the tongue or inside the oral cavity, where it comes in contact with saliva and rapidly hydrates and dissolves or disintegrates. The drug is then released from the film and becomes available for absorption. Mouth dissolving films are usually prepared using film-forming polymers. Other ingredients such as plasticizers, sweeteners, flavours, saliva-stimulating agents, and taste-masking materials may also be added according to the requirements of the formulation. The choice and concentration of the polymer have a direct effect on the thickness, flexibility, strength, disintegration time, and drug-release properties of the film.

Mouth dissolving films have some advantages over conventional tablets. They are thin, light in weight, easy to carry, and can be administered without water. However, problems such as low mechanical strength, brittleness, moisture sensitivity, unpleasant taste, and limited drug loading may occur during formulation development. Therefore,

the selection of suitable polymers and excipients is important for preparing a good-quality film.

Hydrogel-Based Mouth Dissolving Films:

Hydrogel-based mouth dissolving films are prepared using polymers that have a high affinity for water. These polymers can absorb saliva and become hydrated after the film is placed in the mouth. This property helps the film to soften, break down, and release the drug. Mouth dissolving films were developed as an alternative to conventional tablets and capsules, particularly for patients who have difficulty swallowing. They can be useful for children, elderly patients, bedridden patients, and people who cannot easily take medicines with water. Since the film is thin and light, it can also be carried and administered easily.

The main component of a mouth dissolving film is usually a water-soluble film-forming polymer. The polymer provides the basic structure of the film and affects its strength, flexibility, disintegration, and drug-release properties. Depending on the drug and purpose of the formulation, different polymers and excipients can be selected.

Principle of Dissolution in the Oral Cavity: The basic principle of mouth dissolving films is based on rapid interaction between the film and saliva. After the film is placed on the tongue, saliva comes in contact with the surface of the film. The water-soluble polymer absorbs saliva and starts to hydrate. As hydration increases, the polymeric structure becomes softer and the film begins to break down or dissolve. The drug present in the film is released during this process. The released drug may be swallowed and absorbed through the gastrointestinal tract or, depending on its properties and the site of administration, may be absorbed through the oral mucosa. The rate at which a film dissolves depends on several factors, including the type and concentration of polymer, film thickness, drug properties, amount of saliva, and other excipients used in the formulation. A properly designed film should have sufficient mechanical strength for handling but should still become wet and dissolve quickly after administration.

Advantages of Mouth Dissolving Films: Mouth dissolving films have several advantages compared with conventional tablets and capsules.

- They can be administered without water, which makes them useful during travelling or when water is not available.
- They are useful for patients who have difficulty swallowing tablets or capsules.
- They are suitable for children and elderly patients and may improve patient acceptance.
- The films are thin, light, and easy to carry.
- They can provide rapid disintegration and drug release in the oral cavity.
- A large surface area of the film comes in contact with saliva, which helps in rapid wetting and dissolution.
- Some drugs may undergo absorption through the oral mucosa, which can reduce exposure to gastrointestinal conditions and may reduce first-pass metabolism for the fraction absorbed through the oral mucosa.
- Accurate dosing can be achieved by preparing films of a fixed size and drug content.
- The film does not require chewing or swallowing a large solid dosage form.
- It can be useful for drugs where a rapid onset of action is required.
- Individual packaging can be used to protect the film from moisture and help maintain dose accuracy.

Hydrogels in Drug Delivery: Hydrogels are three-dimensional polymeric networks that can absorb and retain a large amount of water. They are formed by linking hydrophilic polymer chains through physical or chemical interactions. When a hydrogel comes in contact with water or biological fluids, it absorbs the fluid and swells while

maintaining its basic structure. Due to this property, hydrogels have been widely studied for drug delivery applications. Hydrogels can be classified according to their source and method of cross-linking. Based on their source, they may be natural, synthetic, or a combination of both. Natural hydrogels are prepared from polymers such as chitosan, alginate, gelatin, starch, pectin, and cellulose derivatives. Synthetic hydrogels include polymers such as polyvinyl alcohol, polyethylene oxide, polyvinylpyrrolidone, and polyacrylic acid. Depending on the method of network formation, hydrogels can also be physically or chemically cross-linked. The type of polymer and degree of cross-linking affect the swelling, strength, stability, and drug-release properties of the hydrogel.

Hydrogel-Based Mouth Dissolving Films:

Hydrogel-based mouth dissolving films are thin oral dosage forms prepared mainly using hydrophilic or hydrogel-forming polymers. The drug is incorporated into the polymeric film along with suitable excipients such as plasticizers, sweeteners, flavours, and other formulation ingredients. The polymer provides the basic structure of the film and helps maintain its physical integrity during handling.

When the film is placed on the tongue, it comes in contact with saliva. Water from saliva enters the hydrophilic polymer network and causes hydration and swelling. As hydration increases, the film becomes soft and starts to disintegrate or dissolve. This process helps release the drug from the polymeric matrix. The rate of hydration and disintegration depends on the type and concentration of polymer, film thickness, drug properties, and other excipients present in the formulation. Hydrogel polymers also have an important role in drug loading. The drug may be present in a dissolved or dispersed form within the polymeric matrix. The amount of drug that can be incorporated depends on its dose, solubility, compatibility with the polymer, and the physical properties required for the film. Excessive drug loading may affect the strength, flexibility, appearance, and dissolution of the film. Therefore, proper drug distribution throughout the film is required to obtain a uniform dose.

Drug release from hydrogel-based films mainly occurs after hydration of the polymer. Water enters the film and allows the drug to diffuse through the hydrated polymer network. At the same time, dissolution or breakdown of the polymer may further help in releasing the drug. The release mechanism can therefore involve diffusion, swelling, polymer dissolution, or a combination of these processes. The rate of release can be influenced by polymer concentration, drug solubility, film thickness, and the interaction between the drug and polymer. Hydrogel-based

mouth dissolving films provide several advantages over conventional solid oral dosage forms. They are thin, flexible, easy to carry, and can generally be administered without water. Their hydrophilic nature allows rapid interaction with saliva and can support quick hydration and drug release. They are particularly useful for patients who have difficulty swallowing tablets or capsules. The properties of the film can also be adjusted by changing the type and concentration of polymer and other excipients.

Applications in Drug Delivery: Hydrogel-based mouth dissolving films have applications in different patient groups and for both local and systemic drug delivery. Their thin structure and rapid interaction with saliva make them useful when conventional tablets or capsules are difficult to administer.

Pediatric and Geriatric Drug Delivery: Mouth dissolving films can be useful in pediatric drug delivery because children may have difficulty swallowing tablets and capsules. The thin film can be placed on the tongue and allowed to dissolve without the need to swallow a conventional solid dosage form. Sweeteners and flavours can also be added to improve taste and make the formulation more acceptable to children. Dose adjustment and uniform drug distribution are important during the development of pediatric films.

Similar advantages can be seen in geriatric patients. Elderly patients may have difficulty swallowing due to age-related changes or other conditions. A mouth dissolving film provides a simple method of administration and does not require a large amount of water. This can help make medicine administration more convenient and may support better patient compliance.

Recent Developments: Recent work in mouth dissolving film development has focused on improving film properties, drug loading, drug release, and patient acceptability. Natural and biodegradable polymers are receiving greater attention because of their availability and favourable safety characteristics. Materials such as chitosan, alginate, gelatin, starch, pectin, and cellulose-based polymers have been investigated for film preparation. Novel hydrogel materials are also being studied to obtain better control over hydration, mechanical properties, and drug release. The use of two or more polymers in the same film is another approach used to improve the properties of the formulation. One polymer may provide better strength, while another may improve hydration and dissolution. This approach can help in obtaining a suitable balance between film strength and rapid disintegration.

Nanocarrier-loaded films are another area of development. Nanoparticles, liposomes, and other

carrier systems can be incorporated into oral films to improve the delivery of drugs with poor solubility or stability. Such systems may also help modify drug release and improve the performance of the drug delivery system. Taste masking has also received attention because direct contact of the drug with the mouth can be a major problem for bitter drugs. Sweeteners, flavours, complexing agents, polymer coating, and other taste-masking approaches can be used to improve the taste of the formulation. At the same time, changes in polymer composition and film structure are being investigated to obtain the desired drug-release profile.

Challenges and Limitations: Despite their advantages, hydrogel-based mouth dissolving films have some formulation and manufacturing challenges. Moisture sensitivity is one of the major concerns because hydrophilic polymers can absorb moisture from the surrounding environment. Excess moisture may make the film sticky or soft and can affect its mechanical properties and stability. Proper moisture-protective packaging is therefore important. Mechanical strength is another important consideration. The film should be strong enough to withstand handling, cutting, packaging, and administration. At the same time, it should not be so strong that it takes a long time to hydrate and dissolve. The type and concentration of polymer and plasticizer have a major effect on this balance.

Taste masking can be difficult, particularly for drugs having a strong bitter taste. Since the film dissolves directly in the mouth, the drug can come into contact with taste receptors. Suitable taste-masking techniques are therefore required to improve patient acceptance. Another limitation is drug loading. A thin film can accommodate only a limited amount of drug while maintaining acceptable thickness, flexibility, and mechanical strength. High-dose drugs may therefore be difficult to formulate as mouth dissolving films. In addition, maintaining uniform drug distribution throughout the film is important to ensure dose accuracy.

Stability and packaging are also important during product development. Changes in moisture content, temperature, and storage conditions can affect the appearance, flexibility, disintegration, and drug content of the film. Individual protective packaging, moisture-resistant materials, and suitable storage conditions may be required to maintain the quality of the formulation during its shelf life.

Future Perspective: The future development of hydrogel-based mouth dissolving films is likely to focus on obtaining better combinations of polymers that can provide good mechanical strength along with rapid hydration and drug release. Combining

natural and synthetic polymers may provide useful film properties while allowing greater control over the formulation. Natural and biodegradable hydrogel systems may receive more attention because of the growing interest in materials obtained from renewable sources. Further research is also needed to improve drug loading, particularly for drugs that require higher doses or have poor aqueous solubility. Advanced drug delivery approaches such as nanocarrier-loaded films, polymeric nanoparticles, liposomal systems, and other drug-carrier technologies may provide new possibilities for improving drug solubility, stability, absorption, and release. Better taste-masking techniques and improved moisture-resistant packaging may also increase the practical use of these films.

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