

Emerging Polymeric Systems in Oral Dispersible Films: A Classification-Based Review

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Date of Submission: 07-05-2026

Date of Acceptance: 18-05-2026

ABSTRACT: Oral dispersible films are innovative thin polymeric dosage forms designed to rapidly disintegrate in the oral cavity without water, improving patient compliance and ease of administration. They serve as an effective alternative to conventional tablets and capsules, especially for paediatric, geriatric, and dysphagic patients. This review highlights types of oral films and classification of polymers used in their formulation. Based on release behaviour and site of action, oral films are categorized into flash release, mucoadhesive sustained-release, and gastroretentive films. Polymers are classified into natural, semi-synthetic, and synthetic categories. Natural polymers such as chitosan, pullulan, sodium alginate, and pectin are biodegradable and biocompatible. Semi-synthetic polymers like hydroxypropyl methylcellulose and hydroxypropyl cellulose exhibit excellent film-forming and mechanical properties. Synthetic polymers such as polyvinyl alcohol, polyvinyl pyrrolidone, and polyethylene oxide provide flexibility, stability, and rapid drug release. The review also briefly discusses formulation components, manufacturing methods, evaluation parameters, packaging requirements, and recent technological advancements in oral film technology. Overall, these films represent a promising and patient-friendly approach for modern drug delivery systems in pharmaceutical applications globally today widely.

KEYWORDS: Oral dispersible films; Fast dissolving oral films; Buccal drug delivery; Film-forming polymers; Solvent casting.

I. INTRODUCTION

Introduced in the late 1970s, fast-dissolving medication delivery devices help with swallowing issues related to traditional oral dose forms¹. They are appropriate for children, the elderly, bedridden, and emetic patients, as well as for treatments requiring immediate or localized action, since they

offer quick drug release, improved absorption, and easy administration²⁻³. Numerous bio adhesive dosage forms have been created, and one of the most popular formulation techniques is polymeric oral thin films⁴⁻⁵.

Due to its variety and lack of discomfort, the oral route is the most popular and practical way to administer medications; more than 70% of marketed medications are available in oral dose forms⁶⁻⁷. A new oral medication administration method called mouth-dissolving films was created using transdermal patch technology. They are made up of thin strips that are applied to the tongue or oral mucosa, where saliva quickly hydrates the film and makes it stick to the application site⁸. Thin strips, wafers, melt-away films, and orally dissolving films are some of the terms used to describe them. But they are formally referred to as orodispersible films (ODFs) by the European Medicines Agency⁹. ODFs are not restricted to buccal delivery and are also applied in gastroretentive and sublingual drug delivery systems. This review presents an overview of film composition, including natural and synthetic polymers, fabrication techniques, packaging materials, and evaluation methods¹⁰.

Anatomy of the Oral Cavity:

The oral mucosa provides a specialized environment suitable for drug administration. This mucosal surface allows drugs to reach the systemic circulation directly, reducing the amount of first-pass processing in the liver. The oral cavity's epithelial lining is comparable to that of the skin, but it is different because of differences in keratinization and the existence of a mucous coating that provides protection and lubrication. The oral mucosa has higher permeability than the skin¹¹⁻¹⁴. The sublingual area, buccal mucosa, gingiva, palatal mucosa, and labial lining are among the physically different areas that make up the oral cavity's mucosal lining, which has a total surface area of around 100 cm². The mucus-covered, stratified

epithelial structure of the oral mucosa is maintained by the lamina propria via the basal lamina¹⁵⁻¹⁶.

Drug Absorption Mechanisms Via Oral Cavity: The main method of buccal drug absorption is passive diffusion of the drug's non-ionized form through the epithelial layer's intercellular gaps, which is mostly controlled by the concentration gradient. Non-ionic drug molecules passively traverse the buccal mucosa's lipid-rich membrane as part of the major transport route. The buccal mucosa, like other mucosal tissues, acts as a lipoidal barrier to drug penetration, wherein the drug's enhanced lipophilicity speeds up absorption. A first-order rate process provides an appropriate description of the absorption kinetics over the buccal mucosa¹⁷⁻¹⁹.

Major Route for Drug Absorption Through the Mucosa:

Drug delivery through the oral mucosal cavity can be classified into three main approaches:

- sublingual delivery, in which drugs are systemically absorbed through the mucosa of the floor of the mouth.
- buccal delivery, where drugs are administered via the mucosal lining of the cheeks.
- local delivery, which involves direct application of drugs within the oral cavity for localized action²⁰⁻²¹.




Key Advantages of ODFs:²²⁻²⁴

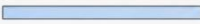
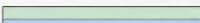
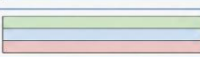
1. Offers easy and patient-friendly dosage.
2. Does not need the administration of water.
3. Removes the possibility of choking or trouble swallowing.
4. Provides efficient taste masking of bitter drugs.
5. Maintains stability and integrity of the formulation over time.
6. Promotes consistent dosing and formulation uniformity.
7. Reduces hepatic first-pass metabolism.




Limitations of ODFs:²⁵⁻²⁷

1. Requires advanced packaging technology for processing.
2. Incompatible with drugs unstable or irritating at oral pH.
3. Limited drug dose capacity.
4. Hygroscopic nature complicates long-term storage.
5. Best suited for drugs transported via passive diffusion.
6. Not yet included in pharmacopoeial standards.
7. Higher manufacturing cost than orally disintegrating tablets.

II. TYPES OF ORAL DISPERSIBLE FILM²⁸⁻³²

| TYPE 1 – BASED ON DISSOLUTION TIME | | | | |
|---|------------------|-------------|-------------------------------|--|
| SUB-TYPE | DISSOLUTION TIME | THICKNESS | USE / EXAMPLES | DESCRIPTION / FEATURES |
|  Fast-dissolving | < 30 seconds | 50 – 150 µm | Used in emergencies | Quick onset of action, rapid disintegration in saliva. |
|  Moderate-dissolving | 1 – 30 minutes | – | General use | Balance between disintegration time and drug release. |
|  Slow-dissolving | > 30 minutes | – | e.g., Nicotine-based products | Sustained release, longer duration of action. |

| TYPE 2 – BASED ON FILM LAYERS | | | |
|-------------------------------|---|--|--|
| SUB-TYPE | LAYER STRUCTURE (DIAGRAM) | COMPOSITION | DESCRIPTION / FEATURES |
| Monolayer |  | API + polymer + excipients | Single layer film containing drug and excipients. |
| Bilayer |  | Layer 1: API layer Layer 2: Taste-masking / permeation layer | Two layers: drug layer and taste-masking or permeation layer. |
| Multilayer |  | Layer 1: Protective layer Layer 2: API layer Layer 3: Protective layer | Multiple layers with API layer sandwiched between two protective layers. |

| TYPE 3 – BASED ON API SOURCE | | | |
|---|------------------------|----------------------------------|--|
| SUB-TYPE | EXAMPLES | SOURCE | DESCRIPTION / FEATURES |
|  Synthetic drugs | e.g., Sildenafil | Man-made / Chemical synthesis | Well-studied, stable, and easier to formulate. |
|  Natural products | e.g., Ginger, Turmeric | Plant / Herbal origin | Difficult to fabricate due to variability, potent taste & color. |
|  Nutrients / Minerals / Vaccines | e.g., Vitamin D ODFs | Essential nutrients / Biological | Used for supplement delivery, immunity support, and vaccines. |

Oral Dissolving Film Formulation

Consideration:

Oral dissolving films are thin dosage forms (1–20 cm²) designed based on drug load and dose requirements, with the ability to carry up to 30 mg of drug per film. The ingredients commonly used in fast dissolving strip formulations are listed below³³⁻³⁶.

1. Choice of Drug Candidates (API): Drugs used in oral dissolving films should be effective in small doses and remain stable in saliva and water. Various therapeutic agents such as analgesics, antiemetics,

antiallergics, antiasthmatics, antibacterial drugs, and medications for cardiovascular disorders, Parkinson's disease, Alzheimer's disease, and erectile dysfunction can be incorporated into these films. Drugs like omeprazole, salbutamol sulphate, paracetamol, meloxicam, and valdecoxib have shown suitability for this dosage form. Preferred drugs are generally potent, lipophilic, and slightly bitter³⁷⁻³⁹.

2. Film Forming Polymers: Polymers are the key ingredients in fast dissolving oral films (FDOFs)⁴⁰⁻⁴¹.

| Type of Polymer | Polymer Name | Source / Nature | Key Properties |
|-------------------------|---|--------------------------|---|
| Natural Polymers | Chitosan | Derived from chitin | Biodegradable, bio adhesive, good film-forming, antimicrobial |
| | Starch | Plant origin | Biodegradable, good film former, inexpensive, hydrophilic |
| | Pullulan | Microbial polysaccharide | Transparent films, tasteless, rapid dissolution |
| | Sodium alginate | Seaweed | Gel-forming, mucoadhesive, good mechanical strength |
| | Pectin | Plant cell walls | Film-forming, biodegradable, saliva soluble |
| | Gelatin | Animal collagen | Elastic films, good tensile strength, thermoreversible |
| | Guar gum | Plant seed | High viscosity, swelling property |
| | Xanthan gum | Microbial fermentation | High viscosity, stable over wide pH range |
| Semi-Synthetic Polymers | Hydroxypropyl methylcellulose (HPMC) | Cellulose derivative | Excellent film former, fast dissolving, non-toxic |
| | Sodium carboxymethyl cellulose (SCMC/CMC) | Modified cellulose | Water soluble, good swelling, viscosity enhancer |
| | Hydroxypropyl cellulose (HPC) | Cellulose derivative | Thermoplastic, flexible films |
| | Ethyl cellulose | Modified cellulose | Hydrophobic, controlled release film former |
| | Cellulose acetate | Cellulose derivative | Good mechanical strength, moisture resistance |
| Synthetic Polymers | Polyvinyl alcohol (PVA) | Synthetic | Strong, flexible, water soluble, excellent film former |
| | Polyvinyl pyrrolidone (PVP K-30 / K-90) | Synthetic | Good solubility, binder, enhances drug dissolution |
| | Polyethylene oxide (PEO) | Synthetic | High molecular weight, flexible, bio adhesive |
| | Polymethacrylates (Eudragit®) | Synthetic | pH-dependent solubility, controlled release |
| | Polyethylene glycol (PEG) | Synthetic | Hydrophilic, plasticizing property, improves flexibility |

Classification Of Polymers⁴²⁻⁴⁶

3. Plasticizer: These are added to improve the mechanical properties of the formulation, such as tensile strength and elongation. Commonly used plasticizers include glycerol, dibutyl phthalate, and polyethylene glycols⁴⁷⁻⁴⁹.

4. Saliva Stimulating Agent: Salivary-stimulating agents are added to increase saliva secretion. Commonly used agents include citric, malic, lactic,

ascorbic, and tartaric acids, while sweeteners may also help enhance salivary flow⁵⁰.

5.Surfactant:They are used for dispersing, emulsifying, and solubilizing. Non-ionic surfactants are preferred for better compatibility, with common examples being Tweens, sodium lauryl sulphate, Cremophor, and poloxamers⁴¹⁻⁵².

6.Sweetening Agent:

Natural sweeteners such as sucrose, dextrose, fructose, glucose, and maltose are commonly used but are limited in diabetic patients. Hence, artificial sweeteners like saccharin, cyclamate, aspartame, acesulfame-K, sucralose, alitame, and neotame are

widely preferred⁵³⁻⁵⁴.

7.Flavouring Agent:

Taste-modifying agents are selected based on patient preference and drug characteristics. Fruity flavours are preferred by younger patients, while mild flavours suit older patients. They are added to improve taste and mouthfeel, usually at levels above 10%w/w⁵⁵.

8.Coloring Agent:

Pigments like titanium dioxide or FD&C-approved colorants are added (below 1% w/w) when drug or formulation components are insoluble or in suspended form⁵⁶⁻⁵⁷.

III. FORMULATION METHODS OF ORAL DISPERSIBLE FILMS:

1)Solvent Casting Method:In this method, the water-soluble polymer and plasticizer are dissolved in distilled water and stirred continuously for 2 hours using a magnetic stirrer. The solution is then allowed to stand for removal of entrapped air. Separately, the drug and other excipients are dissolved and stirred for 30 minutes. Both solutions are mixed uniformly, cast onto a flat surface, dried, and peeled off to obtain the film⁵⁸⁻⁵⁹.

2)Hot Melt Extrusion:During the hot-melt extrusion method, the drug and suitable carriers are first blended in the solid state. The mixture is then melted with the help of an extruder equipped with heating elements, followed by shaping of the molten mass into films through dies⁶⁰⁻⁶¹.

3)Semisolid Solvent Casting:Initially, a film-forming polymer solution is prepared and mixed with an acid-insoluble polymer solution prepared using ammonium or sodium hydroxide. A suitable plasticizer is added to obtain a gel mass, which is then cast into films using heat-controlled drums. The homogeneous viscous solution is degassed under vacuum, coated onto a casting film, dried in an aeration oven, and finally cut into the desired shape and size⁶².

4)Rolling Method:In the rolling method, a premix of film-forming polymer, solvent, and excipients is first prepared, followed by addition of the drug to obtain a uniform matrix. The mixture is passed through metering pumps, where rollers regulate film thickness. The formed film is then dried under controlled conditions⁶³.

5)Solid Dispersion Extrusion:It involves dispersing one or more active pharmaceutical ingredients in an inert solid carrier, typically with amorphous hydrophilic polymers. Using hot-melt extrusion (HME), the drug and immiscible components are extruded together to form a solid dispersion, later converted into films using appropriate dies⁶⁴.

IV. EVALUATION OF ODFs: ⁶⁵⁻⁷⁴

1) Mechanical Properties:

a) Thickness:It is a crucial property of oral films and is assessed using a micrometre screw gauge. It is measured at different points during film formation to ensure consistent and uniform thickness.

b)Dryness Test:This test assesses the drying behaviour of films, which is categorized into eight stages: set-to-touch, dust-free, surface dry, dry-to-touch, dry-hard, dry-through, dry-to-recoat, and dry print-free.

c) Tensile strength: It is defined as the maximum stress that a film strip can withstand before rupture occurs. This property reflects the mechanical integrity of the film.

Tensile strength = Load at failure × 100/Strip thickness × Strip width

d) Percentage Elongation:When stress is applied, the film strip elongates, and this deformation is termed strain. It represents the change in dimension relative to the original length, with elongation percentage rising as plasticizer concentration increases.

% Elongation = Increase in length of strip × 100/Initial length of strip

e) Tear Resistance: It refers to the ability of a film to withstand tearing forces without rupturing. The test is performed by applying a low loading rate (about 51 mm/min) to initiate tearing, and the maximum force required is recorded in Newtons.

f) Young's Modulus: It determines the stiffness of the film and is defined by the stress-strain ratio within the elastic deformation range, representing the film's elasticity.

Young's modulus = Slope \times 100/Strip thickness \times Cross head speed

g) Folding Endurance: This method evaluates the film's ability to endure repeated folding at the same point. The number of folds it can withstand before breaking is recorded as folding endurance.

2) Organoleptic evaluation: It involves both in vivo taste evaluation using human volunteers and in vitro assessment using electronic taste sensing systems. Instruments like TS-5000Z and α -Astree use specific sensors to simulate human taste perception and are useful for evaluating taste masking and sweetness in oral films.

3) Swelling Property: Swelling behaviour of the film is evaluated using simulated saliva solution. A weighed film sample is placed on a pre-weighed stainless-steel mesh and immersed in 15 mL of medium. Weight gain is measured at regular intervals until it becomes constant.

4) Surface pH Test: For oral administration, the film's surface pH should be near salivary pH (~6.8) to prevent mucosal irritation. The formulations were evaluated in triplicate, showing surface pH values from 6.75 to 6.85 with an average of 6.80, confirming their acceptability.

4) Contact Angle: Using a goniometer at room temperature, surface wettability is assessed by placing a droplet of double-distilled water on the film surface. The image is captured within 10 seconds, and the contact angle is calculated as the mean of both droplet sides.

5) Disintegration Time: Different disintegration apparatuses are listed in pharmacopoeias to determine the disintegration time of oral films, which depends on their formulation. Typically, ODFs disintegrate in 5–30 seconds, but no standardized pharmacopoeial method is available.

6) Dissolution Test: Dissolution refers to the amount of drug that dissolves per unit time under defined conditions such as liquid-solid interface, temperature, and solvent concentration. It is carried out using standard pharmacopoeial Apparatus I (basket) or Apparatus II (paddle). The dissolution medium is selected to maintain sink conditions and accommodate the API dose. However, in paddle apparatus, film dosage forms may float on the medium surface, affecting accuracy and reproducibility.

7) Drug Content and Content Uniformity: This parameter is evaluated using standard assay procedures to determine the drug content of the film. The uniformity of content is assessed by calculating the API present in individual films, and the acceptable limit for content uniformity is 85–115%.

8) Transparency: Using UV spectrophotometry, film transparency is measured by inserting a rectangular film segment into the cell. Absorbance is taken at 600 nm, and transparency is calculated according to the given equation.

$$\text{Transparency} = (\log T_{600})/b = -\epsilon c$$

where, T_{600} = transmittance at 600nm; b = film thickness (mm); C = concentration.

9) Permeation Studies: The modified Franz diffusion cell technique is used for permeation studies with porcine buccal mucosa as the biological membrane. The mucosa is mounted between the donor and receptor compartments, with the receptor filled with buffer maintained at 37 ± 0.2 °C and stirred at 50 rpm using a magnetic bead. A weighed film is placed on the pre-wetted mucosal surface using simulated saliva, while the donor compartment contains 1 mL of simulated saliva (pH 6.8). Samples are withdrawn at set intervals and replaced with fresh medium, and drug permeation is determined by absorbance analysis.

8) Stability Testing: This study is carried out according to ICH guidelines, where oral wafers are stored at 25 °C/60% RH and 40 °C/75% RH for 12 months. The wafers are regularly evaluated for morphological changes, mass, thickness, tensile strength, moisture content, and dissolution performance.

V. PACKAGING OF ODFs:

ODF packaging is necessary to preserve stability and mechanical properties during storage. It acts as a protective barrier against light, heat, oxygen, and moisture. Various materials such as foil paper,

aluminium pouches, plastic pouches, and blister packs are used, with aluminium foil offering the highest protection⁷⁵.

VI. NOVEL TECHNOLOGIES USED FOR PREPARATION OF ODFs:⁷⁶⁻⁷⁷

a) Soluleaves: Soluleaves technology is used to manufacture oral delivery films that incorporate active ingredients along with sensory additives. These films dissolve rapidly in saliva, allowing quick release in the oral cavity. This system is especially beneficial for paediatric and geriatric patients who have difficulty swallowing conventional dosage forms, and it can also be designed for mucoadhesive or sustained-release applications.

III. CONCLUSION

Due to its quick disintegration and simplicity of administration without water, oral dispersible film (ODF) technology is a major breakthrough in drug delivery that provides a practical, patient-friendly substitute for traditional dosage forms, especially improving compliance in paediatric, elderly, and dysphagic patients. Film quality has been improved by recent advances in polymers, formulation methodologies, and production processes including solution casting and hot-melt extrusion. These improvements include increased mechanical strength, greater drug loading, effective flavour masking, and quicker disintegration. Research is still being done to overcome obstacles such as moisture sensitivity, limited dosage capacity, and stability problems. All things considered, ODFs are an effective and promising drug delivery method with great potential for use in both clinical and commercial settings in the future.

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b) X-gel: X-Gel technology represents a proprietary ingestible film delivery platform developed by Bio Progress and widely used in pharmaceutical applications. It has significantly improved manufacturing approaches and product stability. These films are produced using the solution casting method and are also applied in healthcare devices.

c) Wafertab: It is a patented wafer-based drug delivery system that produces thin, drug-loaded films for oral or topical use. After casting, the active ingredient is incorporated into the film, which dissolves rapidly upon contact with saliva. The system allows flexible design, including multiple films with different drugs.

d) Foamburst: Foamburst technology involves the incorporation of gas into film matrices to form a honeycomb structure. This lightweight structure allows the films to dissolve instantly in the mouth, creating a melting sensation. The voids within the film can also be used to carry active substances.

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