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# "Formulation Strategies and Evaluation Parameters of Oral Dissolving Films: A Comprehensive Review"

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**ABSTRACT:**
Oral fast dissolving films (OFDFs) are a modern drug delivery system developed to overcome the limitations of conventional dosage forms such as tablets and capsules. Many patients, especially children, elderly individuals, and people with swallowing difficulties, face challenges in taking solid oral medications. OFDFs provide a convenient alternative as they are thin, flexible films that rapidly dissolve in the mouth without requiring water, improving patient comfort and medication adherence.

This review highlights the formulation strategies, composition, evaluation methods, applications, and future scope of oral fast dissolving films. OFDFs are prepared using key ingredients such as active pharmaceutical ingredients, film-forming polymers, plasticizers, sweeteners, flavoring agents, surfactants, and saliva-stimulating agents. Each component plays an important role in ensuring proper mechanical strength, fast disintegration, and better patient acceptability. Various manufacturing techniques including solvent casting, hot-melt extrusion, spray coating, electrospinning, freeze drying, and rolling methods are commonly used to formulate these films.

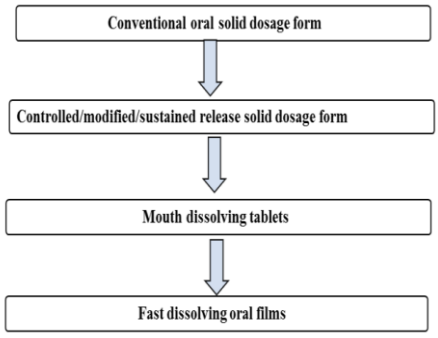
The quality and performance of OFDFs are evaluated using several parameters such as film thickness, tensile strength, folding endurance, drug content uniformity, disintegration time, dissolution rate, swelling behavior, and stability studies. These films offer several advantages including rapid drug release, improved bioavailability, reduced first-pass metabolism, and faster therapeutic action. Due to these benefits, OFDFs have gained significant attention in pharmaceutical research and industry. With ongoing technological advancements, oral fast dissolving films are expected to play an important role in future drug delivery systems.

**KEYWORDS:** Oral Fast Dissolving Films, Drug Delivery System, Solvent Casting, Film Evaluation, Bioavailability, Patient Compliance, Pharmaceutical Technology

## I. INTRODUCTION

Oral fast dissolving films (OFDFs) have revolutionized drug delivery systems in recent years by offering a convenient, effective, and patient-friendly alternative to conventional dosage forms. Traditionally, oral medications such as tablets and capsules presented multiple challenges—particularly for pediatric and geriatric populations—due to issues like swallowing difficulties, delayed onset of action, and first-pass metabolism that reduced drug bioavailability. The requirement for water during administration and the bitter taste of certain drugs further complicated medication adherence. Although orally disintegrating tablets (ODTs) emerged as a partial solution, their friable nature and need for specialized packaging limited widespread utility. These limitations paved the way for the innovation of oral fast dissolving films, a versatile formulation that dissolves quickly in the oral cavity, eliminating the need for water and enabling rapid absorption. [1]

**Evolution of fast dissolving films** [2]



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**Features of Oral Film**

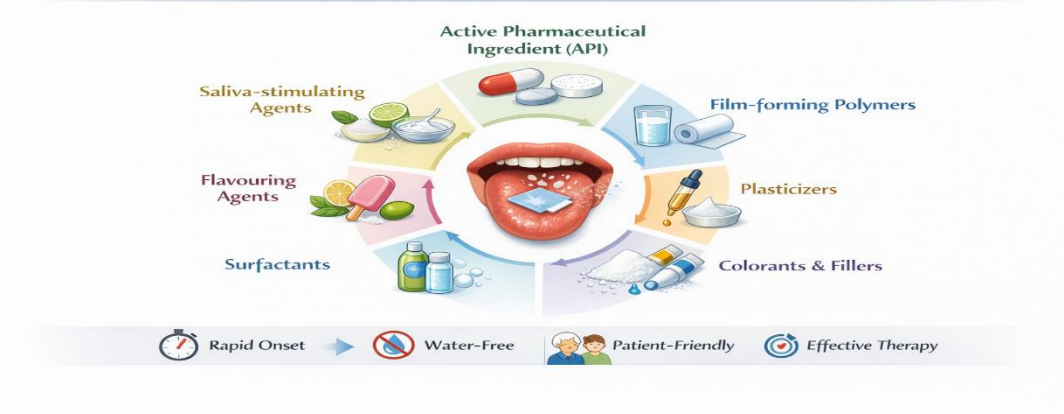
- Thin elegant film
- Available in various size and shape
- Unobtrusive
- Excellent mucoadhesion
- Fast disintegration and dissolution
- Rapid drug release
- Bypasses first pass effect [3-4]

**Advantages**

- ✓ There's no requirement for water to administer.
- ✓ Ideal for individuals with dysphasia, the elderly, and children who struggle with swallowing.
- ✓ Because of the films' greater surface area, they dissolve and disintegrate quickly in the oral cavity.
- ✓ Since it avoids the hepatic first pass effect, it has a rapid beginning of action and enhanced bioavailability.
- ✓ Lowering the dosage improves the medication's safety and efficacy while minimizing adverse effects.
- ✓ Because of their flexibility and portability, they are simple to handle, transport, and store.
- ✓ Simplicity of delivery to patients with limited liquid intake plans, nausea, mental illness, disability, and uncooperative behavior.
- ✓ Helpful in situations when an extremely quick start of action is needed, such as motion sickness, severe discomfort, an unexpected allergic reaction, an asthmatic attack, and coughing.
- ✓ Stability for an extended period of time due to the medication's solid dose form until it is ingested.
- ✓ Accurate dosage compared to liquid formulations.
- ✓ Provides a pleasant mouthfeel and leaves minimal or no residue after ingestion.

**Disadvantages:**

- ✓ It is not possible to incorporate high doses.
- ✓ Using bitter medications is not viable.
- ✓ Dose homogeneity is a technical difficulty.
- ✓ Special packaging is required to ensure product stability and safety.
- ✓ Drugs that irritate the oral mucosa cannot be administered by this route. [5-8]




**Standard composition of oral dissolving films**

✓ **Drugs:** Oral films can adapt variety of drug classes, such as antihistamines, antidiarrheals, antidepressants, vasodilators, antiasthmatics, and anti-emetics. Dimenhydrinate is also suitable for providing taste masking action. Salbutamol sulphate, rizatriptan benzoate, verapamil ondansetron, dexamethasone, rofecoxib, cetirizine, pilocarpine, tianeptine sodium, indomethacin, etc. are common examples of medications.

✓ **Film Formers:** Salient features like rapid disintegration, pleasant tongue feel, and mechanical strength of water-soluble polymers, therefore been applied as film formers.

✓ **Colorants:** When certain of the formulation ingredients or medications are present in insoluble or suspension form, pigments like titanium dioxide or FD&C approved colouring additives are incorporated (not exceeding concentration levels of 1%w/w) in oral strips.

✓ **Sweeteners:** Sweeteners are now a crucial component of both food and medicinal items that are meant to dissolve or disintegrate in the mouth.

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Artificial and natural sweeteners are both utilised to increase the mouth-feel of mouth-dissolving formulations.

- Hydrophilic Natural Sweetener: glucose, sucrose, maltose, xylose, ribose, glucose, and sativoside.
- Hydrophilic Artificial Sweetener: Acesulfame-K, sodium or calcium saccharin salts.
- Miscellaneous: aspartame, neotame. Stimulant: Salivary stimulants, which are often acidic in nature and stimulate saliva production in the buccal cavity, aid in the breakdown of ODFs.

✓ **Saliva-stimulating agents:** Citric acid, malic acid, tartaric acid, ascorbic acid, and lactic acid are a few of the regularly utilised saliva-stimulating substances.

✓ **Surface active agents:** Surfactants are employed as solubilizing, wetting, or dispersion agents to breakdown the film quickly and release the active ingredient. Additionally, surfactants enhance the solubility of poorly soluble medications in rapidly dissolving buccal films. Benzalkonium chloride, benzathonium chloride, tweens and spans, sodium lauryl sulphate, and poloxamer 407 are a few examples.

✓ **Flavouring agent:** To cover up the unpleasant or bitter taste of an included medicine, flavours are required. The flavor's intensity and nature are influenced by its strength. Any US-FDA authorised flavour, such as sweet, sour, or mint flavour, may be utilised. Research has shown that sucralose, liquorice, and a blend of the flavours mint and sucralose effectively disguise the bitter taste of diclofenac sodium. To differentiate between the effects of various taste-masking agents, electronic tongues are used (TMAs). [9-10]

**Ideal characteristics of a suitable drug candidate** [11]

- The drug should have pleasant taste.
- The drug to be incorporated should have low dose upto 40 mg.
- The drugs with smaller and moderate molecular weight are preferable.
- The drug should have good stability and solubility in water as well as saliva.
- It should be partially ionized at the PH of oral cavity.
- It should have the ability to permeate oral mucosal tissue.

**Standard concentration of components** [12]

| Sl. No | Ingredients | Amounts |
|---|---|---|
| 1 | Drug | 1-30% |
| 2 | Film-forming polymer | 40-50% |
| 3 | Plasticizer | 0-20% |
| 4 | Saliva stimulating agent | 2-6% |
| 5 | Sweetening agent | 3-6% |
| 6 | Flavouring agent | q. s |
| 7 | Surfactant | q. s |
| 8 | Colours | q. s |
| 9 | Fillers | q. s |

**Polymer selection criteria**

- Polymers with low glass transition temperature form films more easily at room temperature.

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- Minimum film formation temperature of films should be maintained in order to ensure coalescence.
- Solubility in water is essential for rapid disintegration in oral cavity.
- Balance between tensile strength and flexibility is key.
- Few polymers with taste masking ability (e.g., Pullulan, HPMC) help mask bitter taste of APIs.
- Moisture Sensitivity: HPC and PVA are less hygroscopic than gelatin or CMC.

Film-forming polymers are both water soluble and insoluble in nature. Water-soluble polymers give films their rapid disintegration, pleasing mouthfeel, and mechanical strength, which makes them useful as film formers. The kind and quantity of polymer used in the formulations determines how sturdy the strip is. Many different polymers can be used to prepare films; the most widely used ones are pullulan, gelatine, and Hypromellose. Water soluble polymers comprise a variety of substances, such as modified starches, PVPK30, guar gum, xanthan gum, pullulan, gelatine, and so on. HPMC E3/E5/E6/E15 Eudragit is water insoluble. [13]

## II. MATERIALS AND METHODS

**Approaches used for formulation of fast dissolving film**

The method used for the formulation of oral fast-dissolving films (OFDFs) depends on the specific formulation requirements and the equipment available. Some of the commonly used methods for the formulation of OFDFs include Solvent casting method, Hot-melt extrusion method, Spray-coating method, Electrospinning method, Freeze-drying method, Solid dispersion extrusion and Rolling method. [14]

i. **Solvent casting method:** In this method, film forming formers and plasticizer were dissolved in a suitable solvent resulting formation of a uniform solution. Thereafter the active ingredient and other excipients are added to the solution, which is then casted on a flat surface, dried, and been cut into film strips of the desired size.

ii. **Hot-melt extrusion method:** In this method, the film-forming polymer and plasticizer are melted together at high temperatures to form a homogenous melt. Followed by active ingredient and other excipients are added to melted portion, which is then extruded through a die and cooled to form a solid film.

iii. **Spray-coating method:** This method involves coating a substrate with a thin layer of film forming polymer solution or suspension containing the active ingredient and other excipients. The coated substrate is then dried to form a thin film.

iv. **Electrospinning method:** In this method, a high voltage is applied to a polymer solution or suspension containing the active ingredient and other excipients. The resulting electric field causes the solution to form fibers that are collected on a substrate, dried, and cut into film strips of the desired size.

v. **Freeze-drying method:** This method involves freezing a solution or suspension containing the film-forming polymer, plasticizer, active ingredient, and other excipients. The frozen mixture is then dried under vacuum to remove the solvent and form a solid film.

vi. **Solid dispersion extrusion**: The purpose is to diffuse the active ingredient into a melted polymer solution so that it may be loaded more easily. There can be one or more active ingredients that are dissolved in a suitable liquid solvent that functions as an inert carrier. This occurs in the presence of an amorphous hydrophilic polymer at 70°C without the requirement to remove the liquid solvent in order to get the solid dispersion required. Finally, the dyes are used to form the solid dispersions into films.

vii. **Rolling method:** The rolling method is a technique used for preparing oral fast-dissolving films (OFDFs). The steps involved include preparing a solution or suspension of the active ingredient and excipients, pouring the solution or suspension onto a flat surface, spreading it evenly with a spreading tool, and then rolling the film using a roller or a similar device. This method is commonly used in the manufacture of OFDFs due to its simplicity and scalability. [15-19]

**Evaluation parameters for fast dissolving oral film**

1. **Thickness test:** The dosage accuracy of the drug in the film is determined by its thickness. It is measured with the help of micrometer screw gauge or a calibrated digital Vernier caliper at five distinct crucial places, with the mean value indicating the film's final thickness. The film thickness should be between 5 and 200 micrometers.
2. **Tensile strength:** The greatest tension that can be applied to a film point before the strip specimen breaks is termed as tensile strength. Tensile strength is important in a film.
3. **Load failure:** It refers to the weight at which the film breaks. The applied load at rupture is

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divided by the strip's cross-sectional area to determine tensile strength.

4. **Percent elongation:** When a film is stressed, it begins to stretch, which is referred to as a strain. Strain is calculated by dividing the film's distortion by its initial dimension. It is entirely dependent on the amount of plasticizer used. The percentage elongation of the film increases as the number of plasticizers increases.

% elongation = Increase in length / original length × 100

5. **Young's modulus**: It is a measurement of the strip's rigidity. It's the proportion of applied stress overstrain in the elastic deformation zone. Hard and brittle films have high tensile strength and Young's modulus.

6. **Tear resistance:** It's the amount of force needed to tear the film. The load is applied at a relatively modest rate of 51 mm/min. The force is measured in Newtons or pounds.

7. **Folding endurance:** It indicates the film's brittleness. It can be done manually, depending on how many times the film has been folded without breaking or showing apparent cracks

8. **Morphology study:** Scanning electron microscopy (SEM) is used to examine the morphology of the films at high magnification.

9. **Contact angle:** It gives information on wetting behavior, disintegration time, and oral film dissolving. This can be done at room temperature with the use of a goniometer. Double distilled water should be utilized for this purpose. A dry film is taken, and a drop of double distilled water is placed on the dry film's surface. Within 10 seconds after deposition, a digital camera captures images of water droplets.

10. **Assay/drug content uniformity**: This can be done using any of the standard assay methods defined in the standard pharmacopeia for the medicine in question. It is calculated by evaluating the drug content of each batch. The content uniformity limit is 85-115 percent.

11. **In vitro disintegration test:** When a film is exposed to water or saliva, it breaks or disintegrates at a certain point. Placing the film in the phosphate buffer is how this test is done. The disintegration time can also be measured using a disintegration device from the United States Pharmacopeia (USP). Disintegration time should be between 5 and 30 seconds.

12. **In-vitro dissolution test**: Dissolution is defined as the amount of drug substance that enters the solution per unit time under standard parameters of temperature, solvent content, and liquid/solid interface. For dissolution testing, any of the pharmacopeia's standard basket or paddle apparatus can be utilized. It's difficult to undertake a dissolving study of oral film using a paddle-type dissolution device since they can float above the dissolution liquid. The dissolving media chosen is determined by the sink circumstances and the drug's maximal dose. The temperature of the medium should be kept at 37 ± 0.5 ˚C and 50 rpm during the dissolving investigation.

13. **Swelling property**: Film swelling tests are carried out in a saliva-like solution. Each film sample was weighed and kept in a stainless-steel wire mesh which was previously pre-weighed. In a plastic container, the mesh containing the film sample is submerged in a 15ml medium. At a predetermined time interval, the weight of the film was increased until a steady weight was recorded. The degree of swelling was determined using the parameters wt-w0/w0, where wt is the film's weight at time t and w0 is the film's weight at time zero.

14. **Stability studies:** The formulated films were kept at 45°C and 75% relative humidity for 3 months. Triplicate samples are collected at three sampling intervals during the stability investigations, namely 0, 1, and 3 months, and films should be examined for physical changes and its drug content. [20-25]

**Marketed Oral Film Product** [26]

| Product | API | Manufacturer | Applications |
|---|---|---|---|
| Listerine | Cool mint | Pfizer, Inc | Ulcer treatment |
| Triaminic | Diphenhydramine | Novartis | Anti allergic |
| Gas-x | Simethicone | Novartis | Anti-flatuating |

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| | | | |
|---|---|---|---|
| Suppress | Menthol | Innozen, Inc | Cough suppressant |
| Theraflu | Dextromethorphan | Novartis | Anti-allergic |
| Sudafed PE | Phenyl epinephrine | Wolters, lkuwer Health | Congestion |

**Applications of fast dissolving film**

- **Accessible for vulnerable groups** Ideal for elderly patients, young children, or individuals with neuromuscular swallowing issues who struggle with conventional tablets.
- **Critical in acute interventions** Rapid disintegration allows for swift therapeutic action in medical emergencies—think angina attacks or sudden nausea during chemotherapy.
- **Tailored for pain and psychiatric care** Offers ease of administration and quick onset for analgesics and psychotropics, minimizing delay in symptom control and improving adherence.
- **Nausea management made easier** Medications like ondansetron are frequently embedded in OFDFs to combat emesis, especially for oncology patients.
- **Discreet allergy and flu relief** Antihistamines and decongestants in film format allow easy, fast-acting symptom relief without water or pill swallowing.
- **A novel aid in quitting smoking** Nicotine-loaded films serve as compact, user-friendly delivery platforms for behavioral therapy support.
- **Smart supplementation strategy** Delivers essential micronutrients (e.g., Vitamin D, iron) in a convenient format, improving uptake in deficiency-prone populations.
- **Boosting oral hygiene and breath freshness** Mint oils or chlorhexidine in OFDFs help maintain oral health without traditional rinses or chewing gums.
- **Innovative routes for immunization** Researchers are exploring mucosal delivery of peptides and vaccines via thin films, leveraging the immunological activity of the oral cavity. [27]

**Market view**

Due to low patient compliance with current administration regimens, a small market for pharmaceutical companies and medication users, as well as significant disease treatment expenses, the demand for noninvasive delivery systems is still present. One factor contributing to the rise in fastdissolving/disintegrating products on the market is pharmaceutical marketing. Pharmaceutical companies frequently create a specific therapeutic entity in a new and enhanced dosage form as a drug entity approaches the end of its patent life. A dosage form enables the producer to increase the market exclusivity while providing a more practical dosage form or dosing schedule to its patient population. Fast dissolving/disintegrating formulations are comparable to several prolonged release formulations that are now widely accessible in this regard. A fast-dissolving or disintegrating dosage form can extend market exclusivity, which boosts sales while simultaneously focusing on the underserved and undertreated patient group.[28]

## III. FUTURE PROSPECTS

In the pharmaceutical industry, great advancements have been made in oral drug delivery technologies. The market has come a long way from the conventional tablets/ capsules to modern-day fast disintegrating and rapidly acting tablets/films. Various limitations such as lower bioavailability of oral solid drugs, the inconvenience of administering injections, inaccurate dosing by liquid formulations is keystone which has turned the focus of pharmaceutical companies to develop novel oral dosage forms that eliminate these limitations. Fast dissolving oral thin films are designed to meet most of these challenges. The concept isn't new and several over the counter oral thin films are readily available. Good acceptance from the users and an increasing demand of over-the-counter oral film products has led to the development of prescription drugs into oral thin films. This emerging area is gaining attention from both established and start-up pharmaceutical firms. Companies are utilizing their oral thin film technologies to develop different types of oral thin films (e.g. oral dispersible, sublingual, buccal). In addition to the drugs, several hormones and vaccines are also being formulated into oral thin films with the aim of providing improved patient Compliance. Some of the key players in this area include MonoSol Rx, Applied Pharma Research/Labtec GmbH, BioDelivery Sciences and NAL Pharma. Many companies are collaborating

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with these technology providers and utilizing oral thin films as a lifecycle management tool for their branded drugs that have lost patent in other dosage forms. There are not many prescriptions for oral thin films currently available in the market; however, the pipeline holds a wider promise. Despite the uncertainties related to the development, approval and penetration rate, the market is likely to witness stable growth in the coming decade. According to the clinical and regulatory aspects in the US Food and Drug Administration (US FDA), if the product is bioequivalent to that of the existing oral product the drug, an Abbreviated New Drug Application (ANDA) route is followed. There are no clinical studies associated with this generic approval processes (section 505 (j) of the Food, Drug, and Cosmetic Act). The example of such case would be a comparative bioequivalence between an orally disintegrating tablet (ODT) formulation and orally dissolving film (ODF) product. However, developed oral film product may exhibit different pharmacokinetic profile compared to the existing marketed product. The ODF is categorized as "new dosage form" and the section 505 (b) (2) approval processes needs to be followed. In this case, a new clinical study would be required. The advantage of new clinical study is that it would award 3 years of marketing exclusivity to the product. Preclinical toxicity studies are not required if the molecule is the same as that of the approved product. Safety, tolerability, and efficacy features are to be demonstrated in such trials. Oral mucosa-irritation testing is carried out in both animal models and humans. The future looks very promising for the film technology in the time to come as new technologies are rapidly introduced to prepare thin films. [29].

## IV. CONCLUSION

Oral fast dissolving films (OFDFs) have emerged as an innovative and promising drug delivery system that helps overcome many limitations of conventional oral dosage forms such as tablets and capsules. Their ability to rapidly dissolve in the oral cavity without the need for water makes them highly convenient, especially for pediatric, geriatric, and dysphagic patients who experience difficulty in swallowing. The development of effective OFDFs depends on the careful selection of suitable drug candidates, film-forming polymers, plasticizers, and other excipients to achieve proper mechanical strength, rapid disintegration, and efficient drug release. Different formulation methods and evaluation parameters play an important role in ensuring the quality, stability, safety, and therapeutic performance of these films. OFDFs offer several important advantages, including faster onset of action, improved bioavailability, reduced first-pass metabolism, and better patient compliance. Their increasing application in various therapeutic areas highlights their growing importance in modern pharmaceutical research. With continuous advancements in formulation technologies and increasing demand for patient-friendly dosage forms, oral fast dissolving films are expected to play a major role in future drug delivery systems. Overall, OFDFs provide a valuable platform for developing safer, more effective, and convenient pharmaceutical products that can improve patient care and treatment outcomes.

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