



Review Article

A Review on Mouth Dissolving Film

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ABSTRACT

Mouth dissolving films (MDFs) have emerged as an innovative and patient-friendly oral dosage form designed to deliver therapeutic agents rapidly through dissolution in saliva. These thin, polymeric strips offer ease of administration without the need for water, making them particularly valuable for pediatric, geriatric, and dysphagic patients. This review summarizes the essential aspects of MDFs, including their historical background, formulation principles, polymers, plasticizers, preparation techniques, pharmaceutical evaluation parameters, and recent advances. The discussion highlights the growing industrial acceptance of MDFs due to their fast onset of action, improved bioavailability, and patient compliance. The review also explores challenges in film formulation and future prospects in expanding this novel technology into multidrug therapy, herbal segments, and nano based drug delivery.

INTRODUCTION

Oral drug delivery has long been considered the most convenient route for administering therapeutic compounds. However, conventional oral tablets may not always be suitable for patients who experience difficulty swallowing. Conditions such as dysphagia, nausea, vomiting, and psychological discomfort often limit the acceptability of tablets or capsules. To overcome such limitations, fast-dissolving dosage forms were developed, including orodispersible tablets and, more recently, mouth dissolving films (MDFs).

Mouth dissolving films are thin, flexible strips designed to disintegrate or dissolve in the oral cavity within seconds, releasing the active pharmaceutical ingredient (API) into saliva. They typically employ hydrophilic polymers that quickly hydrate and break down, ensuring immediate drug delivery without the need for water. This makes MDFs particularly valuable for motion sickness drugs, anti-histamines, analgesics, pediatric medicines, and emergency-use drugs such as anti-migraine or anti-emetic agents.

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Since their introduction, MDFs have gained significant attention from both academia and industry due to their ease of handling, portability, consumer acceptance, and favorable pharmacokinetic characteristics. Their potential to bypass first-pass metabolism through buccal absorption further enhances bioavailability in many cases.

2. HISTORICAL BACKGROUND OF MOUTH DISSOLVING FILMS

The concept of fast-dissolving technology originated in the late 1970s with the development of fast-disintegrating tablets. However, these tablets were brittle, difficult to manufacture, and required specialized packaging. Inspired by the success of breath-freshening thin strips (such as mint films), pharmaceutical companies explored the possibility of using similar polymeric films for drug delivery.

By early 2000s, several patented technologies emerged, and drug-loaded films were introduced commercially. Today, MDFs represent one of the fastest-growing oral drug delivery segments, particularly in the over-the-counter (OTC) and chronic-therapy markets.

3. ADVANTAGES OF MOUTH DISSOLVING FILMS

MDFs offer numerous pharmaceutical, therapeutic, and commercial advantages:

3.1 Patient-related Advantages

Convenient for patients who cannot swallow tablets No need for water, improving compliance during travel or emergencies.

Suitable for pediatric, geriatric, bedridden, and psychiatric patients.

Rapid onset of action reduces waiting time for symptom relief.

3.2 Pharmacokinetic Benefits

- Possible buccal, sublingual, or pre-gastric absorption enhances bioavailability.
- Reduced exposure to first-pass hepatic metabolism.
- Faster disintegration leads to quick therapeutic effect.

3.3 Manufacturing and Performance Advantages

- Simple, scalable manufacturing techniques such as solvent casting.
- Thin and lightweight products reduce shipping and storage cost.
- High drug content uniformity due to one-phase film casting.
- Excellent aesthetic appeal and patient acceptability.

4. LIMITATIONS OF MOUTH DISSOLVING FILMS

- Despite their advantages, MDFs have certain limitations that must be considered:
- Limited drug loading capacity (generally up to 30–40 mg).
- Possibility of API instability due to moisture sensitivity.
- Taste masking is challenging, especially for bitter drugs.
- Mechanical strength must be optimized to avoid tearing during handling.
- Certain polymers may interact with drugs affecting shelf-life.

5. IDEAL PROPERTIES OF MOUTH DISSOLVING FILMS



- An optimized MDF formulation should possess:
 - Rapid disintegration within 10–30 seconds.
 - Adequate tensile strength and flexibility.
 - Smooth surface texture without air bubbles.
 - Non-gritty mouthfeel.
 - Acceptable taste and aroma.
 - Stability under normal conditions.
 - Compatibility among all excipients.
3. Pullulan
 4. Polyvinyl alcohol (PVA)
 5. Sodium alginate
 6. Maltodextrin
 7. Polyvinylpyrrolidone (PVP K30)
 8. Gelatin

Each polymer affects mechanical strength, disintegration time, and film clarity.

6. COMPOSITION OF MOUTH DISSOLVING FILMS

MDFs are composed of several key components that influence film thickness, flexibility, drug release, and sensory characteristics.

6.1 Active Pharmaceutical Ingredient

The API may be hydrophilic or hydrophobic but must remain stable in the film matrix. Common drug categories used include:

1. Anti-emetics (ondansetron)
2. Anti-histamines (levocetirizine)
3. NSAIDs (ibuprofen, diclofenac)
4. Cardiovascular drugs (amlodipine)
5. Antipsychotics (risperidone)
6. Herbal extracts (ginger, tulsi, ashwagandha)

The drug loading is typically limited to prevent thick, brittle films.

6.2 Film-Forming Polymers

Polymers are the backbone of MDFs. Ideal polymers should be hydrophilic, flexible, and safe for oral use.

Commonly used polymers include:

1. Hydroxypropyl methylcellulose (HPMC E3, E5, E15)
2. Hydroxypropyl cellulose (HPC)

6.3 Plasticizers

Plasticizers improve film flexibility, reduce brittleness, and enhance folding endurance.

Typical plasticizers include:

1. Glycerol
2. Propylene glycol (PG)
3. Polyethylene glycol (PEG 400)
4. Triacetin

Their concentration usually ranges from 5–20% of the polymer weight.

6.4 Sweeteners and Taste-Masking Agents

Taste is crucial for patient acceptance. Sweeteners can be natural or artificial:

1. Sucrose, fructose
2. Aspartame, sucralose
3. Neotame, saccharin

Taste-masking agents such as cyclodextrins or flavors are added as needed.

6.5 Saliva-Stimulating Agents

Citric acid, malic acid, and tartaric acid increase saliva flow, promoting rapid disintegration.

6.6 Colorants and Flavors

Aesthetic appeal is improved using:

1. Fruit flavors (mint, orange, strawberry)
2. Natural or permitted synthetic colors

6.7 Surfactants

Surfactants improve wettability and drug uniformity.

Examples: sodium lauryl sulfate (SLS), polysorbate 80.

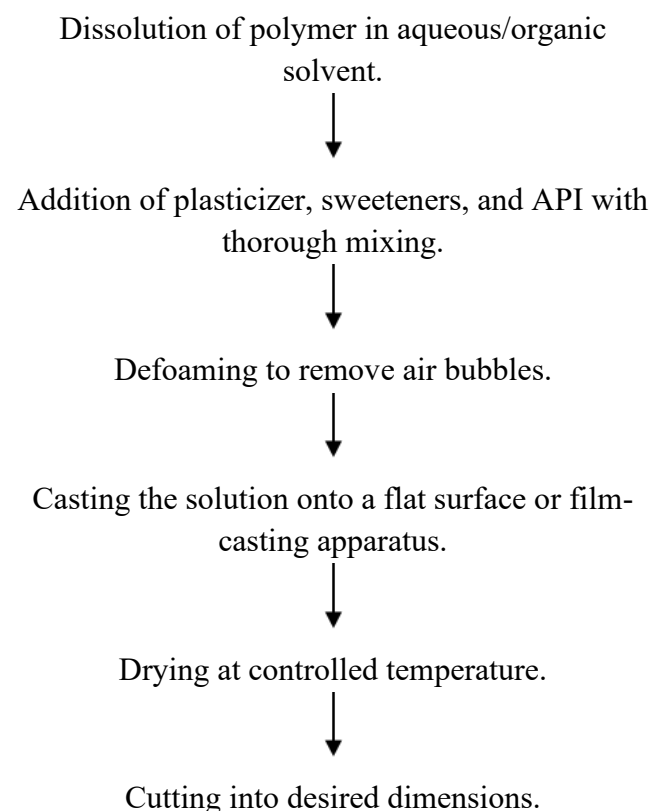
7. METHODS OF PREPARATION OF MOUTH DISSOLVING FILMS

Several techniques are used depending on drug solubility, polymer characteristics, and industrial scale.

7.1 Solvent Casting Method

The most widely used method due to its simplicity and uniformity.

Steps:



7.2 Hot-Melt Extrusion

A solvent-free method suitable for heat-stable drugs.

Process:

Drug and polymer are mixed and melted under

heat.



The molten mass is extruded through a film-forming die.



It is cooled and cut into strips.

Advantages: no solvents, shorter processing time.

7.3 Semisolid Casting Method

Involves preparing a semisolid gel mass using water-soluble polymers and casting onto a surface.

7.4 Rolling Method

A continuous manufacturing process where the mixture is rolled on a carrier and dried in ovens.

7.5 Electrospinning (Advanced Method)

Produces nanofibrous films with extremely fast disintegration.

Suitable for poorly soluble drugs.

8. EVALUATION OF MOUTH DISSOLVING FILMS

Quality control is essential to ensure consistent performance.

8.1 Thickness Measurement

Films are measured at multiple points using a digital micrometer to ensure uniformity.



8.2 Weight Variation

Randomly selected films are weighed and compared to determine uniformity.

8.3 Folding Endurance

Indicates flexibility; films are repeatedly folded until they break.

Ideal value: > 200 folds.

8.4 Tensile Strength

Measures the force required to break the film.

8.5 pH Evaluation

Surface pH should be near neutral to avoid oral irritation.

8.6 Disintegration Time

A key parameter; optimized films dissolve within 10–30 seconds.

8.7 In-Vitro Dissolution Studies

Drug release is measured using standard dissolution media.

8.8 Drug Content Uniformity

Ensures accurate dose per film.

8.9 Moisture Uptake and Loss

Assesses stability under humid conditions.

8.10 Morphology Studies (SEM)

Confirms surface smoothness and absence of defects.

9. APPLICATIONS OF MOUTH DISSOLVING FILMS

9.1 Emergency Medications

1. Anti-emetic (ondansetron)
2. Anti-migraine (sumatriptan)
3. Cardiovascular emergencies

9.2 Pediatric and Geriatric Therapies

- Vitamins
- Antipyretics
- Antihistamines

9.3 Chronic Therapies

Films improve adherence in patients requiring daily dosing.

9.4 Herbal and Nutraceutical Films

Increasing interest in:

- Ginger extract films
- Tulsi or clove extract for sore throat
- Ashwagandha films for relaxation

9.5 Veterinary use

Easy administration in animals.

10. CHALLENGES IN MDF DEVELOPMENT

- API solubility issues
- Maintaining mechanical strength
- Moisture sensitivity of polymers
- Unpleasant taste requiring extensive taste-masking
- Limited dose capacity

11. RECENT ADVANCES

11.1 Nano-embedded Mouth Films

Nanoparticles enhance solubility and permeation.

11.2 Bilayer and Multilayer Films



Allow sustained release and multidrug delivery.

11.3 3D-Printed Films

Offer precision dosing and personalization.

11.4 Smart Films

Incorporate sensors for diagnostic purposes (under research).

12. FUTURE PROSPECTS

With ongoing advancements, MDFs may soon dominate several therapeutic segments. Their potential in biologics, vaccines, herbal medicines, pediatric care, and personalized therapy is significant. As regulatory pathways evolve, MDFs will become more standardized and commercially viable worldwide.

13. CONCLUSION

Mouth dissolving films represent a highly promising dosage form that offers rapid action, improved patient compliance, and efficient drug delivery. Their versatility in formulation, ease of administration, and ability to bypass first-pass metabolism make them attractive for both conventional and advanced therapeutics. Continued research into polymers, nanotechnology, and scalable manufacturing will further expand their pharmaceutical applications. MDFs are poised to become a key technology in the future landscape of oral drug delivery.

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