REVIEW ARTICLE

Emerging Developments Of Oral Mouth Dissolving Films: A Critical Review

Sanika Pawar, B.V. Nagarjuna Yadav*, Sachin Padole, Vaibhav Thakare, Pratiksha Agam and Kirtiraj Jadhao
Department of Pharmaceutics, School of Pharmacy, G H Raisoni University Amravati, 444701, Maharashtra
Corresponding Author Email ID: gunnu.pharma@gmail.com

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Abstract

Oral mouth-dissolving films (MDFs) are innovative pharmaceutical dosage forms designed to rapidly dissolve or disintegrate in the oral cavity, providing an alternative to conventional oral solid dosage forms. They are thin, flexible polymeric films that facilitate rapid drug release and offer convenient administration, particularly for patients who experience difficulty in swallowing conventional tablets or capsules. The growing interest in MDFs is associated with their patient-centric characteristics, portability, ease of administration, and potential to improve patient compliance. The performance of MDFs is influenced by various formulation components, particularly film-forming polymers and other pharmaceutical excipients, which contribute to their physical, mechanical, and drug-release characteristics. A variety of formulation and manufacturing approaches have been investigated to develop MDFs with desirable properties and therapeutic performance. Recent developments in this field have focused on advanced polymeric systems, innovative manufacturing technologies, personalised drug delivery, and improved strategies for enhancing patient acceptability. This review provides an overview of oral mouth-dissolving films, with emphasis on their formulation, development, advantages, limitations, and recent advancements as a patient-oriented drug delivery system.

Keywords: Oral Mouth-Dissolving Films, Drug Delivery, Film-Forming Polymers, Patient Compliance, Rapid Drug Release, Patient-Centric Dosage Form.

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Introduction

The oral route is one of the most widely used routes of pharmaceutical administration due to its versatility in accommodating different dosage-form sizes and shapes, ease of formulation, patient acceptability, and cost-effectiveness. Conventional dosage forms primarily include tablets, capsules, powders, and liquids. However, traditional solid dosage forms may present limitations in administration and acceptability among certain patient populations, including children, geriatric patients, and dysphasic patients (Himani, 2018; Reddy TUK, 2018). These limitations have prompted the development of several novel oral drug delivery systems designed to improve patient convenience and therapeutic administration. Among these, thin oral dosage forms requiring minimal administration effort, such as oral mouth-dissolving films (MDFs), have emerged as patient-centric dosage forms intended to undergo rapid dissolution or disintegration within the oral cavity (Himani, 2018; Khatoon *et al*., 2013). Mouth-dissolving films comprise a polymeric matrix, an active pharmaceutical ingredient (API), and suitable pharmaceutical excipients. Upon administration, the film rapidly hydrates upon contact with saliva, causing the hydrophilic polymer to swell, undergo disintegration and dissolution, and facilitate the release of the incorporated drug(Himani, 2018; Reddy TUK, 2018).(Somasundaram *et al*., 2016) .

The thin structure of the film provides a high surface-area-to-mass ratio, thereby facilitating rapid interaction with saliva. This characteristic promotes rapid disintegration and drug release, providing an alternative to conventional tablets and capsules, which may not always be convenient for certain patients (Himani, 2018; Jain *et al*., 2023). Oral thin films (OTFs) are innovative solid oral dosage forms that have gained considerable attention owing to their potential to combine the advantages of conventional solid dosage forms with improved ease of administration. Various fabrication techniques, including solvent casting, hot-melt extrusion, semisolid casting, rolling, electrospinning, and printing, have been investigated for the preparation of OTFs (B *et al*., 2025; Bodake SY, 2025; Reddy TUK, 2018).

Oral Mouth-Dissolving Films

Mouth-dissolving films (MDFs) are thin, flexible polymeric matrices designed to undergo rapid hydration, dissolution, or disintegration within the oral cavity (Himani, 2018). Upon administration into the oral cavity, the film comes into contact with saliva. Salivary fluid is rapidly absorbed into the polymeric matrix, resulting in hydration and disruption of the film structure, thereby facilitating the release of the incorporated active pharmaceutical ingredient(s) (Himani, 2018; Reddy TUK, 2018) release of the incorporated active pharmaceutical ingredient(s) (Fig. 1). An ideal MDF should

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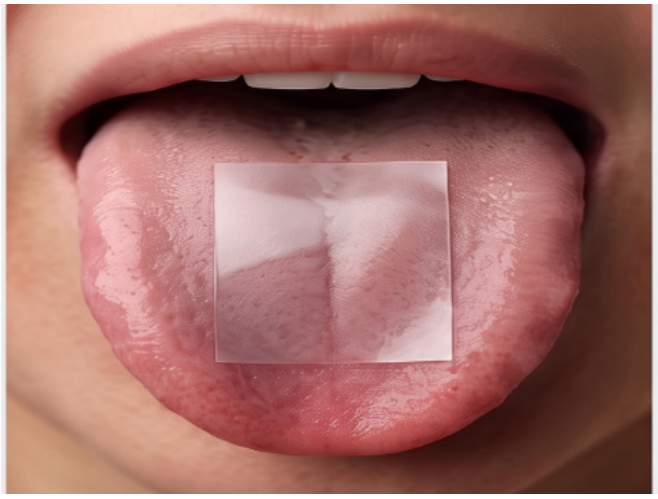

Fig. 1: Mouth Dissolving Films

exhibit adequate flexibility, mechanical strength, uniformity, physical stability, acceptable mouthfeel, and rapid dissolution or disintegration characteristics (Himani, 2018; Jain *et al*., 2023). Oral films can be formulated for administration on the tongue, buccal mucosa, or sublingual region, depending on the intended site of drug delivery (Mahajan *et al*., 2011). The type and concentration of formulation components, including polymers, plasticisers, active pharmaceutical ingredients, and other excipients, significantly influence the physicochemical, mechanical, and performance characteristics of the resulting oral film (Himani, 2018; Jain *et al*., 2023).

Need for Oral Mouth Dissolving Films

Several limitations associated with conventional oral dosage forms have contributed to the development of mouth-dissolving films (MDFs) as an alternative drug delivery system (Jain *et al*., 2023; Mohamed & Rahi, 2025). Pediatric, geriatric, and dysphasic patients may experience difficulties in administering conventional tablets and capsules due to dosage-form size and impaired swallowing ability. MDFs provide an alternative oral dosage form that undergoes rapid dissolution and/or disintegration within the oral cavity, thereby facilitating ease of administration (Himani, 2018; Reddy TUK, 2018). Upon administration, MDFs rapidly interact with salivary fluid and undergo prompt hydration, followed by disintegration and/or dissolution, enabling rapid drug release and convenient administration (Himani, 2018; Khatoon *et al*., 2013).

Application Of Oral Mouth Dissloving Films

Water-independent administration

MDFs undergo rapid hydration, disintegration, and dissolution in the oral cavity without requiring additional water, thereby facilitating convenient drug administration (Himani, 2018).

Ease of administration

The thin, flexible, and lightweight nature of MDFs facilitates easy handling and administration compared with conventional solid oral dosage forms (Khatoon *et al*., 2013).

Improved patient compliance

Rapid disintegration in the oral cavity and elimination of the requirement for swallowing intact tablets may enhance patient acceptability and compliance, particularly in patients with dysphagia (Jain *et al*., 2023).

Enhanced portability

The small dimensions and low weight of MDFs provide advantages in terms of portability, allowing convenient transportation and use during travel or in situations where conventional dosage forms may be less convenient (Himani, 2018).

Convenient storage

The compact dosage form requires minimal storage space and can be packaged individually, facilitating ease of handling, transportation, and storage (Jain *et al*., 2023).

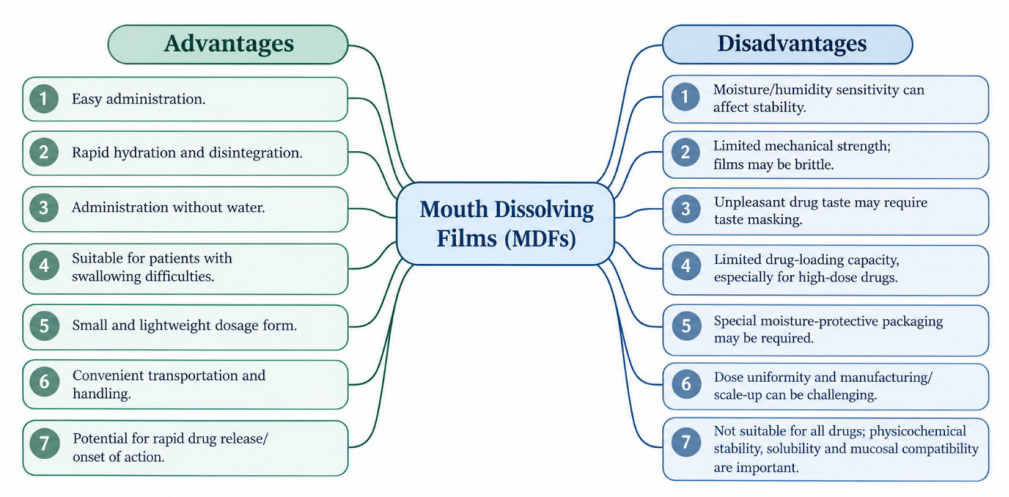

Fig. 2: Advantages and Disadvantages of Mouth-Dissolving Films

Special Features

In addition to their conventional advantages, oral mouth-dissolving films (MDFs) offer distinctive features such as water-free administration, improved patient acceptability, accurate dosing, portability, dose flexibility, and rapid drug availability.

Water-independent and swallow-friendly administration:

MDFs can be administered directly into the oral cavity and rapidly hydrate, disintegrate, or dissolve in the presence of saliva without requiring additional water. This feature is particularly advantageous for patients with dysphagia, pediatric and geriatric populations, bedridden patients, and individuals who may not have immediate access to drinking water. The absence of an intact tablet or capsule to swallow may also reduce the difficulty associated with conventional solid dosage forms (Khan *et al*., 2022; Klingmann *et al*., 2020).

Demonstrated patient acceptability

Patient acceptability is an important factor influencing successful drug administration and treatment adherence. Unlike conventional tablets and capsules, MDFs are thin, flexible, and designed to disintegrate rapidly in the oral cavity. A clinical acceptability study involving infants and preschool children demonstrated a high degree of acceptance of orodispersible films among both children and caregivers. Among children aged 3 years and above, 78% provided a positive rating for the film, while 72% indicated willingness to take the dosage form again. These findings support the potential of oral films as age-appropriate dosage forms for populations in which conventional oral dosage forms may be difficult to administer (B.V. Nagarjuna Yadav & Sathesh Kumar S, 2015; Orlu *et al*., 2017).

Evidence of improved swallowability

The swallowability of MDFs represents an important advantage in paediatric drug delivery. In a randomized controlled trial involving 150 neonates and infants, an orodispersible film demonstrated non-inferior and statistically superior acceptability compared with glucose syrup, with significantly better swallowability and favourable palatability outcomes ($p < 0.0001$). This evidence indicates that oral films may provide a practical alternative to liquid formulations in selected paediatric populations (Klingmann *et al*., 2020).

Accurate unit-dose administration and dose flexibility

MDFs can be manufactured into predetermined dimensions containing a defined quantity of active pharmaceutical ingredient, thereby providing a convenient unit-dose system. Compared with liquid formulations, which may require measuring devices during administration, individual film strips can provide a pre-measured dose and reduce dose-measurement errors. Furthermore, film dimensions, drug loading, polymer composition, and manufacturing approaches can be modified to obtain different dose strengths, supporting the development of flexible and patient-oriented dosage regimens (Khan *et al*., 2022; Ruchika *et al*., 2024).

Rapid drug availability and potential for rapid onset of action

The high surface-area-to-mass ratio and rapid hydration of thin oral films facilitate rapid disintegration and drug release in the oral cavity. Depending on the physicochemical properties of the drug and the site of administration, oral and transmucosal films may provide rapid drug availability. Buccal and sublingual films can additionally facilitate drug absorption through the oral mucosa, and suitable formulations may reduce exposure to gastrointestinal degradation and hepatic first-pass metabolism. However, these pharmacokinetic benefits are formulation- and drug-dependent and should not be generalized to all MDFs (Ahmad *et al*., 2025; *Pharmacokinetic Studies of Gemcitabine Loaded PLGA Nanoparticles in Animal Model | Request PDF*, n.d.).

Portability, discreet administration and improved convenience

The thin and lightweight structure of MDFs requires comparatively little storage space and permits individual packaging. Their small size facilitates transportation and discreet administration during travel, at work, or in other situations where administration of conventional tablets, capsules, or liquid formulations may be inconvenient. This combination of portability and water-independent administration contributes to the patient-centric nature of oral film dosage forms (Ruchika *et al*., 2024).

Overall, these features establish MDFs as patient-oriented drug delivery systems that offer ease of administration, improved patient acceptability, accurate dosing, portability, and flexibility in formulation and drug delivery.

Limitations of Oral Mouth Dissolving Films

Although MDFs offer several advantages, they also present certain formulation and manufacturing challenges that must be carefully considered during product development (Jain *et al*., 2023; Mohamed & Rahi, 2025). The limited thickness and dimensions of oral films may restrict the maximum drug loading capacity of an individual film, particularly for APIs requiring higher doses (Bodake SY, 2025). The primary advantages and formulation limitations of mouth-dissolving films are summarized in Fig. 2. The unpleasant taste of an API may adversely affect patient acceptability, as the film remains in the oral cavity until complete or substantial disintegration occurs (Jain *et al*., 2023). Certain hydrophilic polymers exhibit hygroscopic characteristics and may absorb moisture from the surrounding environment, potentially resulting in alterations in the physical and mechanical properties of the film during storage (Bodake SY, 2025).

The film should possess adequate mechanical strength and flexibility to withstand the stresses associated with

manufacturing, handling, packaging, and administration, thereby minimizing the risk of tearing or breakage (Jain *et al*., 2023). MDFs may require protective packaging systems to minimize exposure to environmental moisture and mechanical stress during storage, handling, and transportation (Bodake SY, 2025; Jain *et al*., 2023). During scale-up and large-scale manufacturing, achieving uniform film thickness, drug distribution, content uniformity, and consistent drying throughout the film matrix may present significant challenges (B *et al*., 2025).

Components of Oral Mouth Dissolving Films

The oral dissolving film consists of components as outlined below

The selection of formulation components is a critical aspect of MDF development, as it directly influences the physical, mechanical, and dissolution characteristics of the resulting films. The principal formulation components include film-forming polymers, plasticisers**,** active pharmaceutical ingredients (APIs)**,** sweeteners/flavouring Agents, surfactants/ solubilising agents, saliva-stimulating agents, fillers, and other suitable pharmaceutical excipients (Jacob *et al*., 2023; Ruchika *et al*., 2024).

API Selection

The selection of an appropriate active pharmaceutical ingredient (API) is an essential consideration in the formulation and development of oral mouth-dissolving films. The selected API should possess favourable physicochemical properties, including adequate aqueous solubility and appropriate permeability, to facilitate its effective incorporation and subsequent release from the film matrix (Daharwal *et al*., 2022; Morath *et al*., 2022).

Salt Form Selection

APIs may be incorporated in different salt forms, such as sodium or potassium salts, depending on their physicochemical and biopharmaceutical properties (Khan *et al*., 2022; Patil *et al*., 2025). The selection of an appropriate salt form may enhance dissolution and absorption characteristics and may be particularly beneficial when a rapid onset of therapeutic action is desired (Sanap *et al*., 2022; SEVİNÇ ÖZAKAR & ÖZAKAR, 2021).

Micronization

The use of a micronized or amorphous API and incorporation into solid-dispersion systems may enhance the dissolution rate, reduce surface roughness, and improve the homogeneity of the resulting film (Ferlak *et al*., 2023; Sharma *et al*., 2025). Due to the dimensional constraints associated with oral thin films, typically ranging from 2 to 8 cm^2 in area and 20 to 100 µm in thickness (Gangurde *et al*., 2024) incorporation of high-dose APIs into rapidly dissolving films can be challenging. Therefore, APIs requiring relatively low therapeutic doses are generally more suitable for incorporation into MDFs, with typical drug loads ranging from approximately 10 to 25 mg per strip (D. Borude *et al*., 2024; Palezi *et al*., 2023).

Film-forming polymers

Film-forming polymers constitute the continuous polymeric matrix of oral mouth-dissolving films (MDFs) and play a major role in determining their structural and functional properties, including mechanical strength, flexibility, hydration, and disintegration. An ideal film-forming polymer should possess good film-forming ability, adequate mechanical strength and flexibility, compatibility with other formulation components, suitable hydration and dissolution characteristics, and good safety and acceptability (Mohamed & Rahi, 2025). Various polymers have been investigated for MDF preparation, including cellulose derivatives such as hydroxypropyl cellulose (HPC) and hydroxypropyl methylcellulose (HPMC), pullulan, polyvinyl alcohol (PVA), sodium carboxymethyl cellulose (NaCMC), starch and modified starches, and natural gums. These polymers provide desirable film-forming, mechanical, flexibility, swelling, dissolution, and mucoadhesive properties depending on their type and concentration. Polymer blending and combination of different polymers may further be employed to modify and optimize the mechanical and functional characteristics of the resulting films(Hoffmann *et al*., 2011).

Plasticizers

Oral films may contain plasticisers to enhance film flexibility and reduce brittleness. Plasticisers interact with polymer chains within the film-forming matrix and modify its mechanical properties. Commonly used plasticisers include propylene glycol, polyethylene glycol 400 (PEG 400), and glycerol. The concentration of the plasticiser must be carefully optimized, as insufficient or excessive amounts may result in brittle, soft, or tacky films, respectively, and may also influence the drying behaviour and disintegration characteristics of the formulation(*Orally Fast Dissolving Films: Innovations in Formulation and Technology | Request PDF*, n.d.) (Olechno *et al*., 2021).

Sweeteners

Sweetning agents are important formulation components in oral mouth-dissolving films (MDFs) because the film remains in the oral cavity during administration and therefore requires acceptable palatability. Commonly used sweeteners include saccharin, mannitol, sorbitol, sucralose, and aspartame. Sugar alcohols such as mannitol and sorbitol may additionally contribute to improved mouthfeel and provide a cooling sensation in the oral cavity. Sweeteners may be used alone or in combination with suitable flavouring and other taste-masking approaches to reduce the unpleasant taste of incorporated active pharmaceutical ingredients and improve patient acceptability. The selection

and concentration of sweetening agents should be optimized to achieve adequate palatability without adversely affecting the physical and functional properties of the film, including flexibility, disintegration, dissolution, and stability (Preis *et al*., 2013).

Surfactants and Solubilisers

Surfactants may be incorporated into oral film formulations to enhance wettability, dispersion, and interaction between the formulation and salivary fluid**.** Commonly used surfactants include polysorbates and poloxamers**.** By modifying the surface tension of the formulation, surfactants may facilitate rapid wetting and hydration of the film. However, excessive concentrations of surfactants may adversely affect the physical and mechanical characteristics of the film; therefore, their concentration should be carefully optimized (Galgatte *et al*., n.d.; Jacob *et al*., 2023).

Saliva Stimulating Agents

Saliva-stimulating agents may be incorporated to promote salivary secretion, thereby facilitating hydration and subsequent disintegration of oral films**.** For this purpose, suitable organic acids may be incorporated into the formulation. In addition to their saliva-stimulating effect, these agents may contribute to improved flavour perception and mouthfeel**,** thereby enhancing the overall palatability of the formulation(Jain *et al*., 2023). The key formulation parameters and factors influencing the physicochemical and mechanical performance of mouth-dissolving films are summarized in Table 1.

Types Of Oral Films

Oral films may be described in terms of their site of application and their intended use.

Orodispersible Films (ODFs)

Orodispersible films are thin oral dosage forms that rapidly disperse or disintegrate in the presence of saliva, allowing administration without the need to swallow an intact solid dosage form. Their rapid dispersion and ease of administration may improve patient convenience and acceptability, particularly in individuals experiencing difficulty with conventional solid dosage forms (Himani, 2018; Khatoon *et al*., 2013).

Mouth-Dissolving Films

Mouth-dissolving films are thin, flexible polymeric dosage forms designed to undergo rapid hydration, disintegration, and/or dissolution within the oral cavity. They are typically administered without the need for water, thereby providing a convenient alternative to conventional solid oral dosage forms. Their ability to rapidly disintegrate or dissolve upon contact with salivary fluid makes them particularly suitable for patients with swallowing difficulties who may experience difficulty in administering conventional tablets and capsules (Himani, 2018; Jain *et al*., 2023).

Sublingual Films

Sublingual films are designed to be placed beneath the tongue, where the drug can undergo absorption through the highly vascularized sublingual mucosa. This route may facilitate rapid onset of systemic drug action, making sublingual films potentially useful when a prompt therapeutic response is required (Mahajan *et al*., 2011).

Buccal Films

Buccal films are applied to the inner surface of the cheek and maintained in contact with the buccal mucosa for a predetermined period. Depending on their formulation and polymeric composition, they can be designed to provide either rapid drug release or prolonged and controlled drug release. Their flexibility allows them to conform to the contours of the buccal mucosal surface, thereby facilitating prolonged mucosal contact (Mahajan *et al*., 2011).

Mucoadhesive Films

Mucoadhesive films contain mucoadhesive polymers capable of interacting with the mucosal surface and maintaining adhesion at the site of application for a predetermined period. Mucoadhesive properties help retain the film at the application site and prolong its residence time, which may facilitate sustained drug release and absorption. The extent of mucoadhesion may vary depending on the type, concentration, and physicochemical characteristics of the polymer used (Naga Sowjanya Juluru, 2013).

Methods Of Preparation

- *Solvent Casting Method*

The solvent casting method is one of the most commonly employed techniques for the laboratory-scale preparation of oral films. In this method, the film-forming polymer is dissolved or dispersed in a suitable solvent along with the plasticiser, API, and other formulation components. The resulting mixture is continuously stirred to obtain a homogeneous film-forming solution or dispersion. It is then uniformly cast onto a suitable flat surface or casting plate and subjected to controlled drying to form a thin polymeric film. The dried film is subsequently carefully removed from the casting surface and cut into the required dimensions and shape. (Klingmann *et al*., 2020; Reuther *et al*., 2025).

Hot-Melt Extrusion

Hot-melt extrusion is a solvent-free manufacturing technique in which polymers and other formulation components are processed under controlled temperature and mechanical shear to produce a continuous film. The formulation components are first blended and subsequently fed into the extruder, where the mixture undergoes melting, mixing, and homogenization before being forced through an appropriate die to produce a continuous film. The extruded film is then cooled and cut into the desired dimensions. (Ahmad *et al*., 2025).

Semisolid Casting

Semisolid casting involves the preparation of a polymeric formulation in the form of a suitable semisolid mass, followed by casting and drying to obtain a film. The polymers and other formulation components are uniformly blended to produce a homogeneous semisolid formulation. This mass is subsequently spread uniformly onto a suitable substrate or casting surface and dried under appropriate conditions to form the film. After drying, the film is removed from the supporting substrate and cut into the required size. (Preis *et al*., 2013).

Extrusion Technique

The extrusion technique involves forcing a prepared film-forming formulation through an appropriate die to produce a continuous film of controlled dimensions. The formulation is prepared and introduced into the extrusion system, where it is transported and forced through the die to obtain a continuous film. The resulting film is subsequently cooled or dried, depending on the formulation and processing conditions, and then cut into the desired dimensions (SEVİNÇ ÖZAKAR & ÖZAKAR, 2021).

Roller Technique

The roller technique is a continuous film-manufacturing process in which the film-forming formulation is uniformly applied onto the surface of a rotating roller or drum. The formulation is distributed evenly over the rotating surface and subjected to controlled drying to facilitate film formation. Following adequate drying, the film is carefully removed from the roller and cut into the required dimensions.(Preis *et al*., 2013)

Electrospinning

Electrospinning is an advanced technique used for the fabrication of thin polymeric fibres with a high surface-area-to-volume ratio. In this process, a polymeric solution or dispersion is loaded into a syringe and subjected to a high-voltage electric field. The applied electric field causes the formation and elongation of fine polymeric fibres, which are collected on a suitable receiving substrate to form a non-woven fibrous film or membrane (Hoffmann *et al*., 2011; Nishi Thakur, 2013).

Two-Dimensional Printing

Two-dimensional printing is an advanced manufacturing approach in which formulation components are deposited in a controlled and predetermined pattern to fabricate customized oral films. In this technique, the formulation is converted into a suitable printable composition and introduced into a printing system. The formulation is then deposited onto an appropriate substrate according to a predefined pattern, followed by drying or solidification to obtain the final oral film (Qin *et al*., 2019).

Evaluation Parameters

Appearance

Films are visually assessed for colour, transparency, smoothness, uniformity, cracks, air bubbles and surface defects. The initial idea of the quality of the prepared film can be given from the appearance (Eleftheriadis *et al*., 2018; Himani, 2018).

Thickness

The thickness of the film is measured at various points with a digital micrometre, a vernier calliper or other appropriate instruments. The uniformity is important to realize even film properties and dose distribution (Khalid *et al*., 2021; Mohamed & Rahi, 2025).

Weight Variation

The weight of individual film strips are measured separately and the variation between samples is calculated. The low weight variation is a sign of high manufacturing uniformity (SEVİNÇ ÖZAKAR & ÖZAKAR, 2021).

Folding Endurance

Folding endurance-This refers to how many folds can be made in a film without it breaking. The film is repeatedly folded at the same spot until the point, when the film can be seen to be broken.The film is repeatedly folded at the same spot until the point is reached where it can be seen that the film has been broken (Centkowska *et al*., 2020; Mohamed & Rahi, 2025).

Tensile Strength

The maximum stress that a film can sustain without failure. It can give information on the mechanical strength of the film (Preis *et al*., 2014).

Percentage Elongation

Percentage elongation is related to flexibility and elasticity of the film and gives information on its stretching capacity before breaking point (Preis *et al*., 2014).

Surface pH

Surface pH is measured after adding an adequate amount of water or buffer to the film. It is desirable to have a surface pH that is near the physiological oral conditions in order to reduce irritation of the oral mucosa (Cupone *et al*., 2020; Eleftheriadis *et al*., 2018).

Disintegration time

Disintegration time is an important performance parameter for MDFs. It is a measure for the duration of time it takes a film to decompose or dissolve under certain conditions (Al-Oran & Yenilmez, 2023). One of the main features of mouth dissolving films is that they disintegrate quickly (Mohamed & Rahi, 2025).

Table 1: Formulation and Factors Influencing the Physicochemical and Mechanical Performance of Mouth Dissolving Films (MDFs)(Ferlak *et al*., 2023; Khan *et al*., 2022; Patil *et al*., 2025; Sanap *et al*., 2022;)

Factor	*Effect on MDF Performance*
Polymer Concentration	Polymer concentration affects film thickness, weight, mechanical strength, flexibility, folding endurance, swelling, and drug release. Increasing polymer concentration can increase film thickness and affect disintegration.
Plasticiser Concentration/Type	Plasticisers improve flexibility, elongation, and folding endurance and reduce film brittleness. The type and amount of plasticiser can also influence film properties and drug release.
Film Thickness	Film thickness affects the physical characteristics, hydration, disintegration, and drug release of the film. Increasing polymer concentration can increase film thickness.
Drug Loading/ Drug Polymer Ratio	The amount of drug and drug-to-polymer ratio can affect drug content, film properties, swelling, and drug-release behaviour. High drug loading can also create difficulties in preparing thin films.
Disintegrant	Disintegrating agents help the film break down rapidly when exposed to saliva/moisture, reducing disintegration time and promoting rapid drug release.
Moisture/ Drying Conditions	Moisture content and drying conditions influence film stability, flexibility, mechanical properties, handling, and disintegration. Excessive drying or moisture loss can negatively affect film quality.

Dissolution study

In vitro dissolution is a study of the dissolution of active pharmaceutical ingredient from the film. The dissolution profile can give information regarding: Percentage drug release, release rate, time for maximum release and overall release behaviour (Preis *et al*., 2013).

Content Uniformity

Content uniformity is the uniformity of individual film units with respect to quantity of intended active pharmaceutical ingredient. The use of appropriate validated analytical techniques may be considered as per active ingredient (Ferlak *et al*., 2023).

Moisture content

Moisture content is an important parameter as it can affect the flexibility, mechanical strength, stability, appearance and packaging requirements of the product (Wang Y, n.d.).

Moisture Uptake

Moisture uptake studies are used to assess the moisture uptake of films under controlled environmental conditions. This is a special parameter for films with hydrophilic polymers (Ferlak *et al*., 2023).

Surface morphology

Microscopic techniques like the scanning electron microscope could be used to study surface morphology, porosity, cracks and other structural features (SEVİNÇ ÖZAKAR & ÖZAKAR, 2021).

Fourier Transform Infrared Spectroscopy

Functional group identification and the possible interactions between the formulation components can be studied using Fourier Transform Infrared Spectroscopy (Wasilewska & Winnicka, 2019).

Differential Scanning Calorimetry

DSC can be used for the study of thermal behaviour and physical state changes of formulation components (Ferlak *et al*., 2023).

X-Ray Diffraction

XRD can be used to investigate the crystalline or amorphous characteristics of formulation components (Wasilewska & Winnicka, 2019).

Stability Studies

Stability studies are used to determine if the physical, chemical and performance properties of the film are acceptable over storage. Stability testing can be used to monitor parameters like appearance, thickness, mechanical properties, disintegration, dissolution and content uniformity (Ferlak *et al*., 2023).

Recent Advances In Oral Mouth Dissolving Films

Recent research has focused on the investigation of synthetic, semi-synthetic, and natural polymers, either individually or in combination, to optimize the mechanical strength, flexibility, disintegration behaviour, and patient acceptability of oral films (Jain *et al*., 2023) summary of Oral Mouth Dissolving Film (MDF) Formulations (listing APIs, film-forming polymers, preparation methods, evaluation parameters, and outcomes) in Table 2. Electrospinning has emerged as an advanced technique for fabricating ultrathin fibrous structures with a high surface-area-to-volume ratio, which may facilitate rapid wetting and dissolution (Tatwashil Kshirsagar, 2024). Two-dimensional printing technologies enable precise and controlled deposition of formulation components and may facilitate the fabrication of customized oral films (Galgatte *et al*., n.d.). These printing-based approaches also provide the potential to tailor dosage-form characteristics according to individual patient requirements, thereby supporting the development of personalized drug delivery systems (Mahajan *et al*., 2011)(*Preparation and Characterization of Gemcitabine Loaded MPEG-PCL Polymeric Nanoparticles for Improved Transportation across Blood Brain Barrier | Request PDF*, n.d.).

Table 2: Recent Advances In Oral Mouth Dissolving Films

Sr. No	*Diseases / Application*	*Drug*	*Excipients*	*Mechanism*	*Procedure*	*Evaluation Parameters*	*Result*
1	Type 2 Diabetes Mellitus	Exenatide	Sodium docusate (DOC), Cremophor EL, Labrafil® M 1944 CS, Capmul PG-8, propylene glycol	Hydrophobic ion pairing increases lipophilicity; SEDDS improves mucus permeation and oral absorption	Exenatide was lipidised by hydrophobic ion pairing with DOC and incorporated into SEDDS	Log P, droplet size, drug release, mucus permeation, oral bioavailability, ch glucose reduction	Improved mucus diffusion, oral bioavailability and reduction in blood glucose levels
2	Liver disorders	Silymarin	Ethyl linoleate, Tween 80, ethyl alcohol	SMEDDS enhances solubilization, dissolution and oral bioavailability of poorly soluble silymarin	SMEDDS prepared by spontaneous mixing and optimized using a pseudo-ternary phase diagram	Particle size, dissolution, HPLC, pharmacokinetics, bioavailability	Enhanced dissolution and oral bioavailability
3	Cancer / Inflammatory disorders	Curcumin	Isopropyl myristate, Cremophor RH40®, ethanol	SMEDDS improves solubilization, dissolution and systemic absorption of curcumin	Components were spontaneously mixed and optimized using a pseudo-ternary phase diagram	Solubility, droplet size, dissolution, stability, bioavailability	Improved dissolution and bioavailability of curcumin
4	Immune deficiency	Pidotimod	Tween 80, Span 80, Span 85, PGPR, MCT oils	Double-emulsion system improves drug solubilization, permeability and oral bioavailability	SDEDDS prepared as a w/o/w double-emulsion system	Droplet size, CLSM, pharmacokinetics, stability	Improved permeability and oral bioavailability
5	Breast cancer	Exemestane	Optimized oil, surfactant and cosurfactant combinations	SMEDDS improves solubility, dissolution and oral absorption of exemestane	SMEDDS optimized using a pseudo-ternary phase diagram	Globule size, zeta potential, TEM, stability, dissolution	Enhanced dissolution and oral bioavailability
6	Solid tumors	Paclitaxel	Sodium deoxycholate, Cremophor-free lipid matrix	SEDDS improves drug dispersion and delivery while avoiding Cremophor-related effects	Cremophor-free SEDDS was prepared and optimized	Droplet size, MTT cytotoxicity assay, stability	Formulation showed cytotoxic activity with acceptable formulation stability
7	Peptide delivery limitations	Peptide / Protein drugs	Thiolated polymer, emulsifying lipid matrices	Thiolated SEDDS improves mucus penetration and cellular uptake, enhancing systemic absorption	Thiolated SEDDS prepared using thiolated polymer and lipid-based emulsifying matrices	Mucus permeation, cellular uptake, oral bioavailability	Enhanced mucus penetration and potential systemic absorption
8	Cancer / Lymphatic drug delivery	Paclitaxel	Tween 80, Carbitol, PEG 400, Aerosil 200	Solid SEDDS enhances lymphatic transport through lipid digestion and chylomicron pathways	Liquid SEDDS converted into solid SEDDS by spray drying	DSC, XRD, pharmacokinetics, lymphatic targeting	Improved lymphatic delivery and oral drug transport
9	Poor aqueous solubility disorders	Lipophilic drugs (General)	Oils, surfactants, cosurfactants, cosolvents	SEDDS/SMEDDS/ SNEDDS improve drug solubilization and gastrointestinal absorption	Review of different emulsion-forming drug delivery technologies	Droplet size, stability, bioavailability trends	Improved solubilization and gastrointestinal absorption of lipophilic drugs

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10	Inflammatory disorders	Baicalein	Cremophor RH40, Transcutol P, ODO (medium-chain triglycerides)	SMEDDS improves solubility and oral bioavailability of baicalein	Optimized SMEDDS formulation prepared using selected oil, surfactant and cosurfactant	Solubility, pharmacokinetic profile, HPLC analysis	Improved solubility and pharmacokinetic performance
11	Alzheimer's disease	Huperzine A	Castor oil, Cremophor RH40, propylene glycol	SMEDDS enhances solubilization and lymphatic uptake, improving systemic exposure	Components mixed to form a fine microemulsion	Droplet size, PDI, zeta potential, TEM, AUC, Cmax, SPIP, lymphatic uptake	Enhanced bioavailability and lymphatic uptake
12	Rheumatoid arthritis, osteoarthritis, acute pain	Celecoxib	PEG-8 CCG, Tween 20, MPG, Tween 80, DPG, water	SMEDDS improves solubility, dissolution and oral absorption of celecoxib	SMEDDS optimized using simplex lattice mixture design	Solubility, phase diagram, dissolution, PK, clarity, DE, t85%	Improved dissolution and oral bioavailability
13	Inflammatory / Antimicrobial applications	Cinna-maldehyde	Oil phase, surfactants, cosurfactants	SEDDS alters mucus properties, enhancing mucus penetration and tissue distribution	SEDDS preconcentrate prepared to form spontaneous nanoemulsion after dilution	Particle size, SEM, DSC, ATR-FTIR, drug release, mucus structure, rheology, tissue distribution	Enhanced mucus penetration and tissue distribution
14	Acute Coronary Syndrome (ACS)	Ticagrelor	Capmul MCM, Cremophor EL, Transcutol P	SMEDDS improves solubility and bioavailability, thereby enhancing antiplatelet activity	SMEDDS optimized using Scheffé's mixture design and response surface methodology	Solubility, emulsification, phase diagram, droplet size, TEM, dissolution, Caco-2, PK, antiplatelet efficacy	Enhanced bioavailability and antiplatelet activity
15	Chronic Hepatitis B virus infection	Adefovir dipivoxil	Optimized oil/ surfactant/ cosurfactant mixture, D-mannitol	SNEDDS improves solubilization, permeability and absorption	SNEDDS optimized and lyophilized to produce solid SNEDDS	Phase diagram, transmittance, globule size, PDI, zeta potential, TEM, SEM, DSC, XRD, drug release	Improved drug release and delivery characteristics
16	Multiple systemic disorders	Multiple drugs (General)	Various oils, surfactants, cosurfactants	SMEDDS improves solubility, dissolution and biopharmaceutical properties of poorly soluble drugs	Comprehensive review of SMEDDS formulation and optimization approaches	Solubility, phase diagrams, self-emulsification efficiency, PDI, zeta potential, dissolution, PK	SMEDDS improves solubility and oral bioavailability of lipid-soluble drugs
17	Pain and inflammation	Diclofenac	Goat fat, Tween 65	Solid self-emulsifying system improves dissolution and gastrointestinal drug delivery	Solid SES tablets prepared by pour-moulding method	Weight uniformity, drug content, liquefaction, dissolution, drug release	Improved tablet dissolution profile and drug release
18	Cancer chemo-prevention, cardiovascular diseases, inflammatory disorders	Resveratrol	Cod liver oil, soy phosph-atidylcholine, Eumulgin® HRE-40, Tween® 80, sodium oleate, colloidal silicon dioxide, sodium croscarmellose	Solid SEDDS improves solubilization and dissolution of resveratrol	Liquid lipid formulation spray-dried onto solid carriers	Drug incorporation, spray-drying yield, dissolution, microscopy, solubility, self-emulsification	Improved solubility and dissolution performance

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19	Pain and acute inflammation	Dex-ibuprofen	Tween 80, Kolliphor EL, hydrophilic carrier matrix	Solid SNEDDS enhances dissolution and intestinal membrane permeation	Liquid SNEDDS converted into solid SNEDDS / self-nanoemulsifying granules	SEM, FTIR, PXRD, DSC, dissolution profile, oral bioavailability	Improved dissolution rate and oral bioavailability
20	Cancer prevention / Antioxidant therapy	Apigenin	Corn oil, HP-β-CD, calcium silicate, MCC	SMEDDS improves gastrointestinal solubilization and stability of apigenin	SMEDDS optimized using simplex lattice design	Phase diagram, TEM, dissolution kinetics	Improved solubilization and dissolution characteristics
21	Organ transplant rejection / Autoimmune disorders	Cycl-osporin A	Cremophor EL, Transcutol HP, Capryol 90	SEDDS improves oral absorption and facilitates lymphatic transport	SEDDS prepared and encapsulated in soft gelatin capsules	Self-emulsification time, droplet size, bioavailability	Improved oral absorption and systemic bioavailability
22	Viral infections / Poor oral bioavailability	WIN 54954	MCT oil, synthetic surfactant, PEG 600	SEDDS forms fine oil-in-water dispersion, enhancing drug uptake	SEDDS optimized and filled into soft capsules	Pharmacokinetics, droplet size metrics	Improved dispersion and oral uptake of the lipophilic compound
23	Oxidative stress / Cardiovascular protection	Coenzyme Q10	Labrafil, Labrasol, Capryol 90	SEDDS enhances solubilization and systemic bioavailability of CoQ10	Liquid SEDDS prepared and optimized at approximately 6% CoQ10 loading	Pharmacokinetics, in-vitro dispersion parameters	Enhanced oral bioavailability and dispersion
24	Systemic fungal infections	Itraco-nazole	Transcutol, selected oils and surfactants	SEDDS enhances dissolution and gastrointestinal absorption of itraconazole	SEDDS prepared using selected oil and surfactant components	Solubility enhancement index, pharmacokinetic parameters	Improved dissolution and oral absorption
25	Breast cancer	Exem-estane	Natural and synthetic oils, surfactants, cosurfactants	SMEDDS improves solubilization, dissolution and oral bioavailability	SMEDDS prepared by selecting components through solubility screening and spontaneous microemulsion formation	Solubility studies, pseudo-ternary phase diagram, droplet size, zeta potential, dissolution, PK	Increased absolute oral bioavailability

Advanced taste-masking strategies are being investigated to enhance the palatability and patient acceptability of oral films, particularly when formulations contain unpleasant-tasting active pharmaceutical ingredients (APIs) (Jain *et al*., 2023). Modern analytical techniques, including scanning electron microscopy, X-ray diffraction, differential scanning calorimetry, Raman spectroscopy, near-infrared spectroscopy, and moisture-analysis techniques, enable detailed characterization of film morphology, solid-state properties, thermal behaviour, and moisture-related characteristics, thereby providing valuable information regarding film quality and stability (*Orally Fast Dissolving Films: Innovations in Formulation and Technology | Request PDF*, n.d.). In addition, hot-melt extrusion and roller-based manufacturing approaches offer potential advantages for continuous processing, scale-up, and large-scale production of oral films (Naga Sowjanya Juluru, 2013).

Challenges in The Development Of MDFS

Although considerable advances have been made, several challenges remain in the development, scale-up, and commercialisation of oral mouth-dissolving films (OMDFs). The major challenges include limited drug-loading capacity, unpleasant taste associated with certain active pharmaceutical ingredients (APIs), moisture sensitivity, inadequate mechanical stability, specialized packaging requirements, variability in film thickness and content uniformity, difficulties associated with scale-up and process reproducibility, lack of standardized evaluation methods, long-term stability concerns, and patient acceptability. The establishment and implementation of appropriate Good

Manufacturing Practices (GMP) and suitable protective packaging systems are essential for maintaining the quality, stability, and integrity of the finished product during transportation and storage.(Naga Sowjanya Juluru, 2013)

Future Perspectives

Advances in formulation materials, personalized drug delivery, manufacturing technologies, and product performance are expected to remain key areas of research for the future development of oral mouth-dissolving films (B *et al*., 2025; Ruchika *et al*., 2024). Future research challenges include the identification and optimization of novel film-forming polymers and polymer combinations, development of advanced taste-masking strategies, personalized dosing approaches, two-dimensional and three-dimensional printing technologies, continuous manufacturing processes, electrospinning-based fabrication, advanced analytical characterization, moisture-resistant packaging systems, standardized evaluation methodologies, improved packaging technologies, long-term stability assessment, and patient-specific formulations.(*Preparation and Characterization of Gemcitabine Loaded MPEG-PCL Polymeric Nanoparticles for Improved Transportation across Blood Brain Barrier | Request PDF*, n.d.) The integration of pharmaceutical formulation science with digital manufacturing technologies may provide new opportunities for the development of customized, patient-centric oral dosage forms with tailored drug-loading and performance characteristics (B *et al*., 2025; Mahajan *et al*., 2011).

Conclusion

Oral mouth-dissolving films (MDFs) represent a promising and patient-centric dosage form for oral drug delivery. They offer several advantages over conventional solid oral dosage forms, including thinness, flexibility, ease of administration, rapid hydration, and rapid disintegration and dissolution, making them particularly useful for paediatric, geriatric, and dysphagic patients. The appropriate selection and optimization of film-forming polymers, plasticisers, taste-masking agents, surfactants, and other formulation excipients are critical determinants of successful MDF development. The solvent casting method remains widely employed for laboratory-scale preparation, while advanced manufacturing approaches such as hot-melt extrusion, roller processing, electrospinning, and printing technologies offer potential for continuous, scalable, and customized film manufacturing. Comprehensive evaluation of the physical, mechanical, physicochemical, and performance characteristics of MDFs is essential to ensure product quality, batch-to-batch consistency, reproducibility, and long-term stability. Despite their potential, several challenges remain, including limited drug-loading capacity, taste masking, moisture sensitivity, mechanical integrity, specialized packaging requirements, manufacturing scale-up, process reproducibility, and standardization of evaluation methods. Continued advances in polymer science, formulation technology, digital manufacturing, and analytical characterization are expected to further expand the potential applications of oral mouth-dissolving films. Overall, MDFs provide a versatile platform for the development of convenient, patient-oriented, rapidly disintegrating oral dosage forms.

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