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A Review on Formulation and Evaluation of Polyherbal Mouth Dissolving Film for Mouth Ulcer

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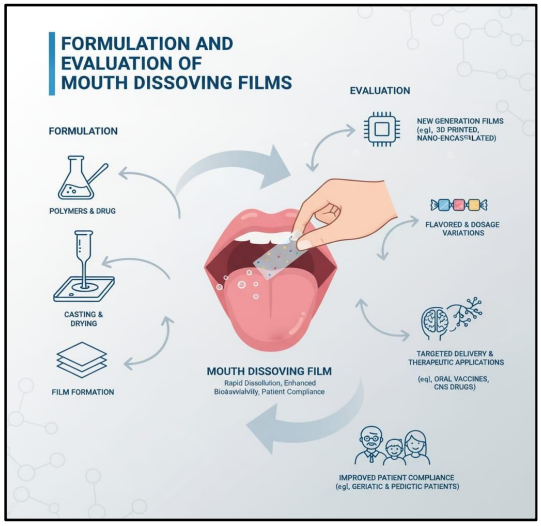
Abstract: *Mouth ulcers are one of the most prevalent oral mucosal disorders, often associated with pain, discomfort, and difficulty in eating or speaking. Conventional dosage forms for treating oral ulcers have limitations such as poor patient compliance, low bioavailability, and short residence time at the site of action. In recent years, herbal mouth dissolving films (MDFs) have emerged as an innovative and patient-friendly drug delivery system. These thin, flexible, and fast-disintegrating films dissolve rapidly in the oral cavity without the need for water, thereby ensuring faster onset of action and improved therapeutic efficacy[1,2]. Herbal extracts such as Ocimum sanctum, Glycyrrhiza glabra, and Punica granatum have demonstrated significant anti-inflammatory, antimicrobial, and wound-healing properties, making them promising candidates for ulcer management [4,3,5]. This review highlights the formulation strategies, polymers, plasticizers, and superdisintegrants commonly employed in the preparation of herbal MDFs using techniques such as solvent casting. Additionally, it discusses the evaluation parameters including thickness, folding endurance, disintegration time, surface pH, drug release, and stability. Advantages such as avoidance of first-pass metabolism, enhanced bioavailability, and improved patient compliance are critically analyzed along with challenges and future prospects[6,8]. Overall, herbal mouth dissolving films offer a novel and effective therapeutic approach for the treatment of mouth ulcers and hold potential for wider clinical application in oral drug delivery.*

Graphical Abstract:



Keywords: Orodispersible film, Mouth ulcer, Aphthous stomatitis, Buccal film, Solvent casting, Mucoadhesion

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I. INTRODUCTION

Mouth ulcers, also referred to as aphthous ulcers or stomatitis, are one of the most common disorders of the oral mucosa. They are characterized by painful, shallow lesions that interfere with speaking, eating, and oral hygiene, thereby impairing patients' quality of life. Their etiology is multifactorial, including local trauma, stress, nutritional deficiencies, infections, hormonal imbalance, and immune-mediated mechanisms. Conventional treatment strategies mainly rely on topical formulations such as gels, pastes, and rinses, or on systemic drugs in severe cases. However, these approaches have limitations such as poor retention time at the site of action, frequent reapplication, dilution by saliva, and possible systemic side effects[9,10].

Mouth Dissolving Films (MDFs), also called orodispersible films (ODFs) or fast dissolving oral strips, represent a novel and patient-friendly dosage form designed to disintegrate or dissolve rapidly in the oral cavity without the need for water or chewing. They are thin, flexible polymeric films loaded with an active pharmaceutical ingredient (API) that release the drug within seconds upon contact with saliva. MDFs offer several advantages, including rapid onset of action, avoidance of first-pass metabolism, improved patient compliance (especially in pediatric, geriatric, and dysphagic populations), and ease of administration[11,12].

For mouth ulcer therapy, MDFs provide distinct benefits compared to conventional formulations. They enable localized drug delivery, ensuring high drug concentration at the lesion site with reduced systemic exposure. Their mucoadhesive properties can prolong residence time and maintain drug contact with the affected mucosa, thereby enhancing therapeutic efficacy. Moreover, they are discreet, painless to apply, and minimize discomfort compared to sticky or bulky gels and pastes. By delivering anti-inflammatory, antimicrobial, or analgesic drugs directly to the ulcer site, MDFs can accelerate healing, reduce pain, and improve patient comfort [13,14].

The development of MDFs requires careful formulation design, including the choice of film-forming polymers (e.g., hydroxypropyl methylcellulose, hydroxypropyl cellulose, polyvinyl alcohol, chitosan), plasticizers (e.g., glycerol, polyethylene glycol), sweeteners, flavoring agents, and, when necessary, mucoadhesive polymers. The method of preparation—commonly solvent casting, hot-melt extrusion, or newer 3D printing techniques—affects film uniformity, mechanical strength, drug release behavior, and patient acceptability [15,16].

Evaluation of MDFs includes assessment of physical and mechanical parameters (thickness, tensile strength, folding endurance), physicochemical properties (drug content uniformity, surface pH, moisture absorption), disintegration and dissolution profiles, mucoadhesion, and in vivo efficacy in ulcer models. Recent studies have demonstrated that corticosteroid- and antimicrobial-loaded MDFs show promising results in reducing pain and enhancing ulcer healing [9,14].

Thus, MDFs hold significant potential as an innovative and effective platform for localized treatment of mouth ulcers. This review aims to critically summarize advances in formulation strategies, manufacturing methods, evaluation techniques, and therapeutic applications of MDFs for mouth ulcer management, while highlighting current challenges and future research directions.

History of Mouth Dissolving Films for Mouth Ulcer :

The concept of mouth dissolving films (MDFs), also known as oral thin films (OTFs) or orally disintegrating films (ODFs), evolved from the need to develop patient-friendly dosage forms that dissolve rapidly in the oral cavity without the requirement of water. The idea originated in the late 1970s with the introduction of fast-dissolving oral dosage forms, such as orally disintegrating tablets (ODTs) designed for patients with swallowing difficulties[17].

In the 1980s and 1990s, technologies like the Zydis® system revolutionized fast-dissolving tablets, inspiring further innovation toward thinner, more flexible, and rapidly dissolving polymeric films[18]. The transition from tablets to thin films occurred in the early 2000s, when researchers began adapting transdermal film technologies to create oral films capable of delivering drugs through the buccal and sublingual mucosa[19]. Early commercial examples included breath-freshening strips, which demonstrated the feasibility and consumer acceptance of thin film dosage forms.

Subsequently, the pharmaceutical industry developed drug-loaded oral thin films for both systemic and local delivery. A notable advancement was the patenting of pullulan-based fast dissolving films in the early 2000s (US Patent 7,407,669 B2), which standardized formulation approaches and spurred further research[20].

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In recent years, attention has shifted toward using MDFs for local treatment of oral conditions, including aphthous ulcers and oral mucositis, due to their ability to adhere to the mucosa, form a protective layer, and provide sustained release of therapeutic agents at the lesion site[21,22]. Herbal extracts such as *Glycyrrhiza glabra*, *Ocimum sanctum*, and *Punica granatum* have been successfully incorporated into polyherbal films for their anti-inflammatory, analgesic, and wound-healing properties[23].

Thus, the evolution of mouth dissolving film technology—from conventional fast-dissolving tablets to sophisticated polymer-based local delivery systems—represents a significant advancement in the management of mouth ulcers, offering improved efficacy, patient compliance, and safety.

Aim of this review :

This review aims to critically summarize the state-of-the-art in formulation and evaluation of mouth-dissolving films for mouth-ulcer therapy: to catalogue active agents and excipient strategies used for local ulcer treatment; to compare manufacturing methods (advantages, limitations, scale-up issues); to evaluate in-vitro and in-vivo performance metrics and translational evidence; and to identify current knowledge gaps and offer recommendations for future research, including standardized evaluation protocols and clinically-oriented study designs.

Pathophysiology and therapeutic targets in mouth ulcers :

Etiology of RAS is multifactorial: immune dysregulation, genetic predisposition, local trauma, nutritional deficiencies (e.g., iron, vitamin B12, folate), hormonal changes, stress, and microbial factors have been implicated (D'Amario et al., 2025). Key therapeutic targets include: pain control, reduction of local inflammation, prevention of secondary infection, and acceleration of mucosal re-epithelialization. Herbal actives that exert anti-inflammatory, antimicrobial, analgesic and wound-healing effects are theoretically well-suited for local treatment via MDFs.

Herbal actives: pharmacognocy of Herbs :

Aloe vera

Biological source: Dried latex or gel obtained from leaves of *Aloe barbadensis Miller* (syn. *Aloe vera*).

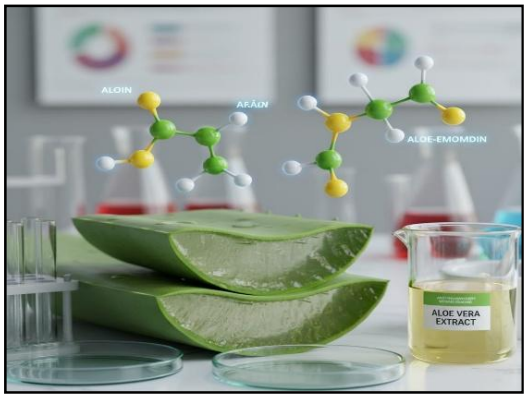
Family: Liliaceae (now Asphodelaceae).

Macroscopical characters: Succulent leaves, lanceolate, green with white flecks; cut surface shows transparent mucilaginous gel.

Microscopy: Parenchymatous cells with mucilage; pericyclic cells contain calcium oxalate crystals.

Phytoconstituents: Anthraquinone glycosides (aloin, barbaloin), polysaccharides (acemannan), enzymes, vitamins.

Medicinal uses: Anti-inflammatory, wound healing, antioxidant, antiulcer, antimicrobial, used in treatment of burns and oral ulcers.



Curcumin (from Turmeric)

Biological source: Rhizomes of *Curcuma longa* Linn.

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Family: Zingiberaceae.
Macroscopical characters: Cylindrical, branched rhizomes, yellow to orange in color, characteristic aromatic odor, slightly bitter taste.
Microscopy: Cork with polygonal cells, starch grains in parenchyma, oleoresin cells present.
Phytoconstituents: Curcuminoids (curcumin, demethoxycurcumin, bisdemethoxycurcumin), essential oils (zingiberene, turmerone).
Medicinal uses: Anti-inflammatory, antioxidant, antimicrobial, wound healing, anticancer, widely used in oral ulcer management.

Glycyrrhiza glabra (Liquorice)
Biological source: Dried roots and stolons of *Glycyrrhiza glabra* Linn.
Family: Fabaceae (Leguminosae).
Macroscopical characters: Roots cylindrical, straight or branched, brownish, sweet taste due to glycyrrhizin.
Microscopy: Cork cells lignified; secondary phloem with numerous phloem fibers; starch abundant.
Phytoconstituents: Glycyrrhizin (triterpenoid saponin), flavonoids (liquiritin, isoliquiritin), glycyrrhetinic acid.
Medicinal uses: Antiulcer, expectorant, demulcent, anti-inflammatory, antioxidant, used in aphthous ulcers.

Clove Oil
Biological source: Volatile oil obtained by distillation from dried flower buds of *Syzygium aromaticum* (Linn.) Merr. & Perry.
Family: Myrtaceae.
Macroscopical characters: Clove buds are nail-shaped, dark brown, strongly aromatic, pungent taste.

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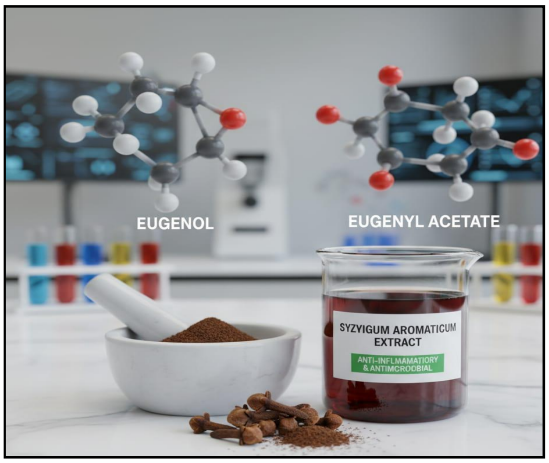
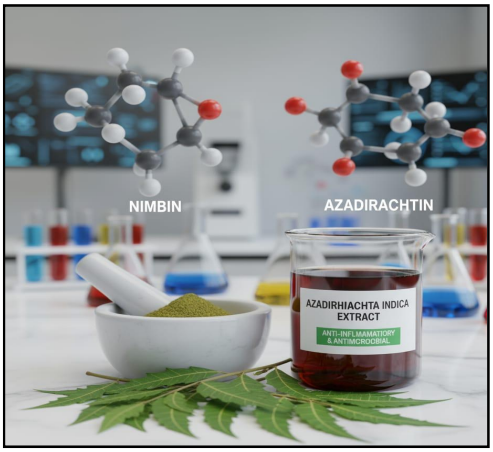
Microscopy: Oil cells, abundant calcium oxalate crystals.
Phytoconstituents: Volatile oil (mainly eugenol 70–90%), acetyl eugenol, caryophyllene, tannins.
Medicinal uses: Analgesic (especially dental pain), antiseptic, antimicrobial, antioxidant, local anesthetic in oral ulcer pain relief.



Neem (Azadirachta indica)
Biological source: Leaves, bark, and seeds of *Azadirachta indica* A. Juss.
Family: Meliaceae.
Macroscopical characters: Leaves are compound, serrated margin, bitter taste; bark grayish-brown, rough.
Microscopy: Parenchymatous cells with tannins, calcium oxalate crystals; oil globules in seed.
Phytoconstituents: Limonoids (azadirachtin, nimbin, salannin), flavonoids, tannins, essential oil.
Medicinal uses: Antimicrobial, anti-inflammatory, wound healing, antiulcer, antioxidant; widely used in oral hygiene.



Pomegranate Leaves (Punica granatum)
Biological source: Leaves of *Punica granatum* Linn.
Family: Lythraceae.
Macroscopical characters: Simple, opposite, glossy green leaves, oblong to lanceolate, slightly bitter taste.
Microscopy: Epidermis with cuticle, mesophyll differentiated into palisade and spongy parenchyma, calcium oxalate crystals present.
Phytoconstituents: Tannins (punicalagin, ellagic acid, gallic acid), flavonoids, alkaloids, triterpenes.

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Medicinal uses: Astringent, antioxidant, antimicrobial, anti-inflammatory, promotes wound healing, beneficial in oral ulcers and gingivitis.

Overview of Mouth Dissolving Film Formulation:

Mouth dissolving films (MDFs) represent an advanced oral drug delivery system designed to dissolve rapidly upon contact with saliva, releasing the drug directly in the oral cavity. This system provides localized therapeutic action for oral lesions, including mouth ulcers, while avoiding the limitations of conventional formulations such as poor retention, first-pass metabolism, and delayed onset of action[24,25].

Polyherbal MDFs combine multiple herbal extracts possessing anti-inflammatory, antimicrobial, and wound-healing properties, providing synergistic effects with minimal adverse reactions. The formulation of MDFs involves careful optimization of **film-forming polymers, plasticizers, superdisintegrants, and bioactive agents**, ensuring mechanical stability and fast disintegration.

Component	Examples	Function
Active agents (Herbal extracts)	*Ocimum sanctum*, *Glycyrrhiza glabra*, *Punica granatum*	Anti-inflammatory, antioxidant, antimicrobial, wound-healing
Film-forming polymers	HPMC, HPC, PVA, Sodium alginate, Pullulan	Provides film integrity, flexibility, and rapid dissolution
Plasticizers	PEG 400, Glycerol, Propylene glycol	Reduces brittleness, improves flexibility
Superdisintegrants	Crospovidone, SSG, Croscarmellose sodium	Promotes rapid film disintegration
Sweeteners and flavoring agents	Mannitol, Stevia, Menthol, Peppermint oil	Improves taste and acceptability
Solvents	Distilled water, Ethanol	Medium for polymer and drug dispersion

Methodology of Mouth Dissolving Film Preparation:

The **solvent casting technique** is the most preferred method for preparing mouth dissolving films due to its simplicity, reproducibility, and excellent uniformity[29]. Other methods like **hot-melt extrusion**, **semisolid casting**, and **rolling** are used at industrial levels but require more stringent process controls[30].

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Solvent Casting Method (Preferred Laboratory Technique)

Step-wise Process:

Polymer dispersion:

The selected film-forming polymer (e.g., HPMC or HPC) is dissolved in an aqueous or hydroalcoholic solvent with continuous stirring until a clear solution is obtained.

Addition of plasticizer and excipients:

Plasticizers such as PEG 400 or glycerol are added to enhance flexibility. Sweeteners, flavors, and superdisintegrants are mixed to achieve uniformity.

Drug/herbal extract incorporation:

The active herbal extracts (*Ocimum sanctum*, *Glycyrrhiza glabra*, *Punica granatum*) are dissolved or uniformly dispersed into the polymeric matrix.

Casting and drying:

The mixture is poured into a flat Petri dish or glass mold and dried in a hot air oven at 40–45°C until a dry, flexible film is formed.

Film cutting and storage:

The dried film is cut into 2×2 cm strips (typically containing an equivalent dose of the extract) and stored in air-tight aluminum pouches to protect from moisture.

Evaluation Parameters for Mouth Dissolving Films:

A series of **physicochemical and mechanical evaluations** are conducted to ensure the quality, efficacy, and stability of MDFs :

Parameter	Method/Instrument	Purpose
Thickness	Vernier caliper	Uniformity check
Folding endurance	Manual folding test	Mechanical strength
Surface pH	pH paper/moistened film	Compatibility with oral mucosa
Disintegration time	Stopwatch (in simulated saliva)	Speed of film breakdown
Drug content uniformity	UV spectrophotometer	Dose consistency
In-vitro drug release	Dissolution apparatus, pH 6.8 buffer	Drug release kinetics
Tensile strength & % elongation	Texture analyzer	Film flexibility
Stability testing	ICH guidelines (40°C/75% RH)	Storage durability

II. CONCLUSION

Mouth dissolving films (MDFs) have emerged as a novel and patient-friendly dosage form offering rapid drug release, localized action, and enhanced bioavailability for the management of oral mucosal disorders such as mouth ulcers. Conventional therapies often provide only temporary symptomatic relief, whereas polyherbal MDFs combine multiple phytoconstituents with synergistic anti-inflammatory, antimicrobial, and wound-healing effects, ensuring both therapeutic efficacy and safety.

The integration of natural extracts such as *Ocimum sanctum*, *Glycyrrhiza glabra*, and *Punica granatum* with advanced film-forming polymers like HPMC and HPC enables the development of flexible, fast-disintegrating films with excellent patient acceptability. The solvent casting technique remains the most efficient and reproducible method for formulating MDFs, while evaluation parameters—such as disintegration time, surface pH, tensile strength, and in-vitro release—ensure consistency and stability of the formulation.

Despite promising experimental outcomes, the field still faces challenges, including lack of standardized formulation protocols, limited clinical validation, and variable quality control methods across studies. Future research should focus

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on standardizing formulation parameters, performing comprehensive in-vivo and clinical evaluations, and exploring nanotechnology or bioadhesive polymer integration to further enhance residence time and therapeutic efficacy.

Overall, polyherbal mouth dissolving films represent a safe, effective, and innovative approach for the treatment of mouth ulcers, bridging traditional herbal wisdom with modern pharmaceutical technology. With further optimization and regulatory validation, these films hold substantial potential for translation into commercial and clinical use.

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