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A Review on Formulation and Evaluation of Polyherbal Mouth Dissolving Film

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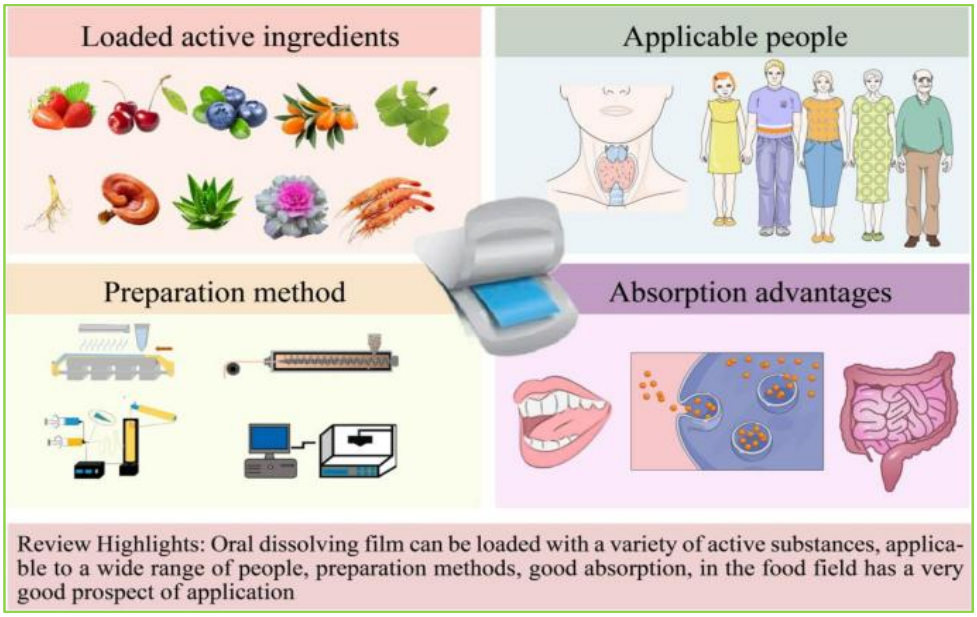
Abstract: *Mouth ulcers, also known as aphthous ulcers, are painful sores in the oral cavity that affect daily activities like eating and speaking. Conventional treatments often provide only temporary relief and may cause side effects with long-term use. Polyherbal mouth dissolving films are an innovative drug delivery system that can deliver herbal medicines directly in the mouth, providing fast relief and improving patient comfort. These films are made using natural plant extracts that have anti-inflammatory, antimicrobial, antioxidant, and wound-healing properties. This review focuses on the formulation, evaluation, and therapeutic benefits of polyherbal mouth dissolving films for treating mouth ulcers. It also discusses the role of polymers, plasticizers, and herbal actives in creating films with good mechanical strength, fast disintegration, and effective drug release. Recent research shows that these films are safe, effective, and patient-friendly. Overall, polyherbal mouth dissolving films represent a promising alternative to conventional treatments, combining the advantages of herbal medicine with modern pharmaceutical technology.*

Graphical Abstract:



Keywords: Mouth ulcer, Antioxidants, Plasticizers, Patient Friendly, Conventional Treatment

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I. INTRODUCTION

Oral health plays a crucial role in overall well-being, and conditions such as mouth ulcers (aphthous stomatitis) are among the most common oral disorders affecting people of all ages. Mouth ulcers are painful lesions of the oral mucosa that can cause difficulty in eating, speaking, and maintaining oral hygiene, significantly reducing the quality of life. The exact cause of these ulcers is multifactorial, including stress, nutritional deficiencies, microbial infections, trauma, or autoimmune conditions. Conventional treatments, such as topical corticosteroids, analgesics, and antiseptic mouthwashes, mainly provide symptomatic relief and may have side effects, especially when used long-term.

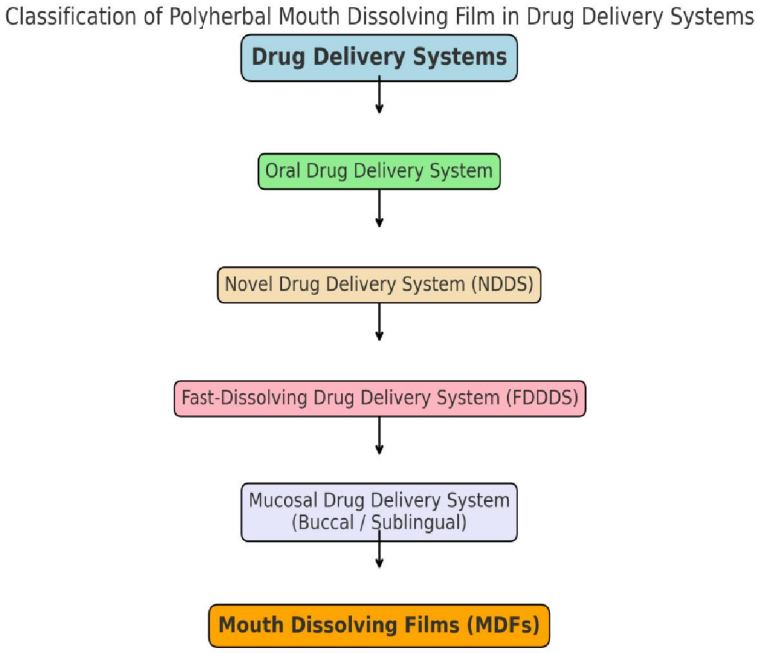
In recent years, there has been growing interest in herbal medicines due to their safety, affordability, and therapeutic potential. Various plant extracts, including *Ocimum sanctum*, *Glycyrrhiza glabra*, *Punica granatum*, and *Aloe vera*, have been reported to possess anti-inflammatory, antimicrobial, antioxidant, and wound-healing properties, making them suitable candidates for the management of oral ulcers.

Mouth dissolving films (MDFs) are an innovative oral drug delivery system designed to disintegrate and release the active pharmaceutical ingredient rapidly in the oral cavity without the need for water. These films offer several advantages over conventional dosage forms, such as tablets and gels, including faster onset of action, ease of administration, improved patient compliance (particularly in pediatric, geriatric, and dysphagic patients), and avoidance of first-pass metabolism.

Polyherbal mouth dissolving films combine the benefits of multiple herbal extracts into a single dosage form, providing synergistic therapeutic effects. The formulation of these films involves careful selection of polymers, plasticizers, and herbal actives to achieve desirable mechanical properties, rapid disintegration, uniform drug release, and acceptable organoleptic properties. Evaluation of these films includes assessing parameters such as thickness, tensile strength, folding endurance, surface pH, disintegration time, in-vitro drug release, and antimicrobial activity.

Recent research highlights the successful development of polyherbal mouth dissolving films with optimized physicochemical and pharmacological properties, demonstrating their potential as a safe and effective alternative to conventional oral ulcer treatments. These advancements reflect a growing trend toward integrating traditional herbal medicine with modern pharmaceutical technologies to improve therapeutic outcomes and patient compliance.

Diagrammatic classification chart :



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II. MATERIALS AND COMMON EXCIPIENTS

2.1 Polymers

Common film-forming polymers:
- Hydroxypropyl methylcellulose (HPMC)
- Polyvinyl alcohol (PVA)
- Pullulan
- Sodium alginate
- Chitosan
- Polyvinylpyrrolidone (PVP)

Polymers are chosen based on mechanical strength, mucoadhesion, disintegration profile and compatibility with herbal extracts.

2.2 Plasticizers and Sweeteners

- Plasticizers: Glycerol, Propylene glycol, Polyethylene glycol (PEG 400)
- Sweeteners and taste-masking agents: Sucralose, Aspartame, Xylitol
- Permeation enhancers and saliva stimulants: Citric acid, menthol (use cautiously)

Formulation techniques :

Main manufacturing methods:
- Solvent casting: polymer and excipients dissolved in suitable solvent, cast onto a backing and dried. Widely used for herbal ODFs.
- Hot-melt extrusion (HME): solvent-free, suitable for thermally stable components; produces uniform films.
- Semisolid casting / Rolling: viscous gels spread and dried on carriers.

Key considerations: solvent choice (water/ethanol), extract solubility, temperature sensitivity of phytoconstituents, and drying conditions to preserve bioactivity.

Phytoconstituents and Their Structures :

The following major phytoconstituents are widely investigated for their role in polyherbal MDFs:

Punicalagin

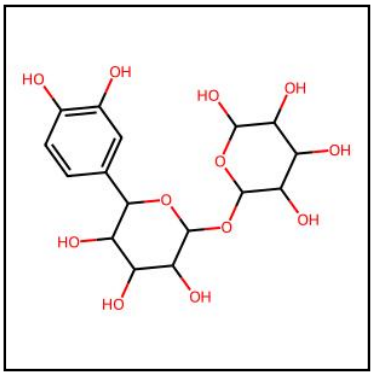

Figure: Chemical structure of Punicalagin.

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Curcumin

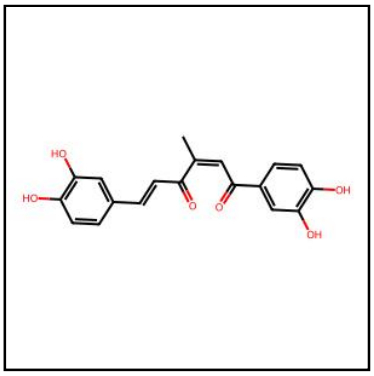

Figure: Chemical structure of Curcumin.

Aloin

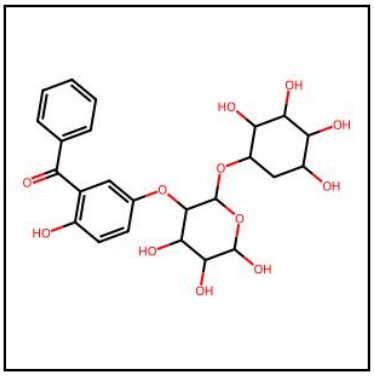

Figure: Chemical structure of Aloin.

Eugenol

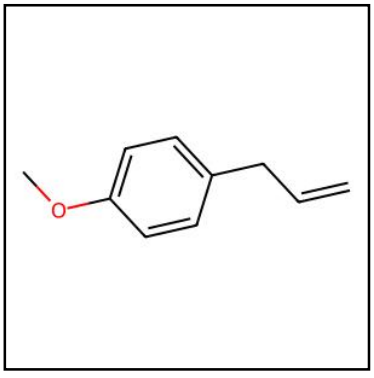

Figure: Chemical structure of Eugenol.

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Evaluation and Characterization :

Essential quality tests for mouth dissolving films include:

Thickness and weight uniformity

Mechanical properties: tensile strength, percent elongation, folding endurance - Surface pH and smoothness - Disintegration time (in vitro) and wetting time - Dissolution / in vitro release profile - Mucoadhesive strength (for buccal films) - Microbial limit test and preservative efficacy (important for herbal matrices) - Stability testing (ICH conditions) and accelerated aging

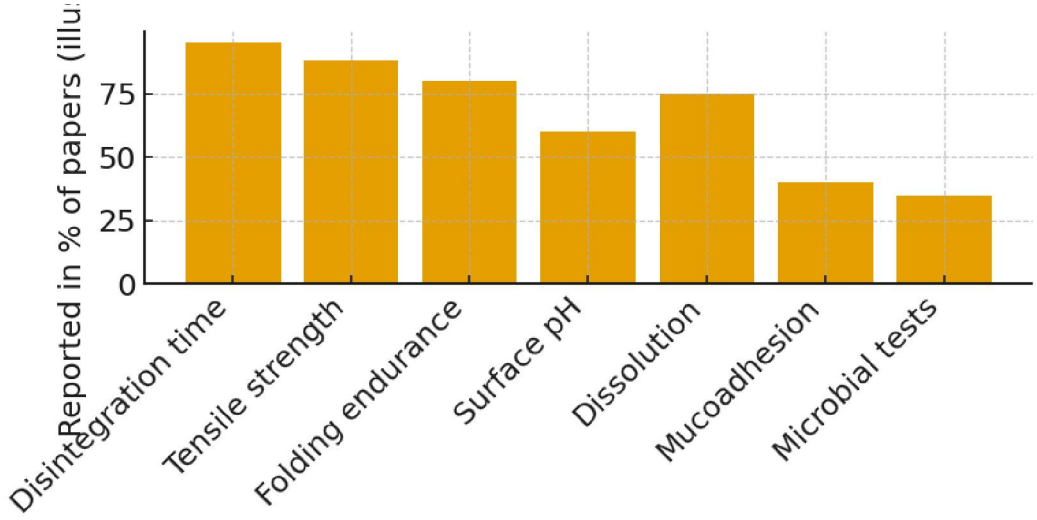

Figure 1: Frequency (illustrative) of evaluation parameters reported in mouth-dissolving film literature.

Example polyherbal film formulation (literature-derived template) :

A sample solvent-casting formulation (per 10 cm² film):

- HPMC (film former): 200 mg
- PVA (co-polymer): 50 mg
- Herbal extract A (Punica granatum standardized extract): 50 mg
- Herbal extract B (Aloe vera extract): 50 mg
- Plasticizer (glycerol): 20 mg
- Sweetener (sucralose): 5 mg
- Solvent: purified water/ethanol (q.s.)

Method: Dissolve polymers in solvent with heating (if needed), add plasticizer, incorporate extracts under stirring, degas, cast on a petri dish or liner, dry at 40°C till constant weight, cut films and condition in desiccator.

Safety, Stability & Regulatory Considerations :

Polyherbal films should be evaluated for residual solvents, microbial contamination, heavy metals (if relevant), and batch-to-batch consistency of phytochemical markers. Follow ICH stability guidelines for accelerated and long-term testing. For locally acting oral products, local tolerability (mucosal irritation) and taste acceptability are crucial.

Discussion and Future Perspectives :

Polyherbal ODFs present opportunities for targeted local therapy in the oral cavity for ulcers and infections. Challenges include standardizing plant extracts, ensuring stability of active phytoconstituents during processing, and achieving acceptable mechanical and organoleptic properties. Emerging manufacturing technologies (HME, 3D printing) and analytical methods (HPLC markers, spectroscopic fingerprinting) will help advance quality and reproducibility.

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III. CONCLUSION

Polyherbal mouth dissolving films represent a promising and innovative approach in the management of oral conditions such as mouth ulcers. This drug delivery system offers significant advantages over conventional dosage forms, including rapid onset of action, improved patient compliance, ease of administration, and avoidance of first-pass metabolism. The incorporation of herbal extracts, known for their anti-inflammatory, antimicrobial, antioxidant, and wound-healing properties, further enhances the therapeutic potential of these films while minimizing adverse effects commonly associated with synthetic drugs.

Formulation strategies, including the choice of polymers, plasticizers, and herbal actives, critically influence the mechanical strength, disintegration time, drug release profile, and overall efficacy of the films. Recent studies have demonstrated successful development of polyherbal mouth dissolving films with optimized physicochemical and pharmacological properties, indicating their feasibility as an effective alternative for oral ulcer therapy.

Despite the promising outcomes, there is a need for further research, including clinical trials, stability studies, and standardization of herbal extracts, to ensure consistent efficacy, safety, and large-scale applicability. Overall, polyherbal mouth dissolving films hold substantial potential as a patient-friendly, safe, and effective drug delivery system for the management of oral ulcers, aligning with the growing trend of integrating traditional herbal remedies with modern pharmaceutical technology.

REFERENCES

[1]. Jacob S., et al. Orodispersible Films: Current Innovations and Emerging Applications. 2023. PubMed Central. *https://pmc.ncbi.nlm.nih.gov/articles/PMC10747242/*

[2]. Bala R. et al. Design, Formulation and Evaluation of Oral Films. 2014. PMC article. *https://pmc.ncbi.nlm.nih.gov/articles/PMC4195261/*

[3]. Shipp L., et al. Buccal films: A review of therapeutic opportunities. 2022. *https://www.sciencedirect.com/science/article/pii/S0168365922007362*

[4]. Harini K., et al. Formulation and evaluation of oral disintegrating films (2022). PMC article. *https://pmc.ncbi.nlm.nih.gov/articles/PMC9205350/*

[5]. Takeuchi Y., Mechanical characteristics of orally disintegrating films. 2020. *https://www.sciencedirect.com*

[6]. Ghalayani P., et al. Efficacy of Punica granatum extract in management of RAS. 2013. PMC article. *https://pmc.ncbi.nlm.nih.gov/articles/PMC4076909/*

[7]. Aslani A., Design, Formulation and Evaluation of an Oral Gel from Punica granatum flower extract. 2016. PMC article. *https://pmc.ncbi.nlm.nih.gov/articles/PMC5071802/*

[8]. Li Y., Advances in oral dissolving film research in the food field. 2025. *https://fppn.biomedcentral.com/articles/10.1186/s43014-024-00285-x*

[9]. Hussain A., Ahmad Z. A review of orodispersible films for enhanced drug delivery. 2024/2025. *https://cellulosechemtechnol.ro/pdf/CCT1-2%282025%29/p.1-10.pdf*

[10]. FormulationBio. Oral Thin Film Folding Endurance Testing. (industry reference). *https://www.formulationbio.com/oral-thin-film/oral-thin-film-folding-endurance-testing.html*

[11]. Kote S., Effect of pomegranate juice on dental plaque. 2011. *https://journals.lww.com/asol/fulltext/2011/31020/effect_of_pomegranate_juice_on_dental_plaque.4.aspx*

[12]. Global Research Online. Oral Thin Films: A Multi-Faceted Drug Delivery System. 2021. *https://globalresearchonline.net/journalcontents/v72-1/13.pdf*

[13]. IJRR Journal. Oral Dissolving Films: A Review. 2023. *https://www.ijrrjournal.com/IJRR_Vol.10_Issue.9_Sep2023/IJRR46.pdf*

[14]. IRJMETS. Review on Mouth Dissolving Film. 2024. *https://www.irjmets.com/uploadedfiles/paper//issue_1_january_2024/48451/final/fin_irjmets1705643077.pdf*

[15]. ResearchGate. A REVIEW ON FAST-DISSOLVING ORAL FILM. (2023) *https://www.researchgate.net/publication/374828960_A_REVIEW_ON_FAST-DISSOLVING_ORAL_FILM*

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[16]. Semanticscholar. Pomegranate peel extract mucoadhesive patch (2021). *https://pdfs.semanticscholar.org/52a2/1cc426da339ad3c89c86366f723603c35869.pdf*

[17]. Design Optimization and In Vitro–In Vivo Evaluation (Bala et al., 2014). *https://pmc.ncbi.nlm.nih.gov/articles/PMC4195261/*

[18]. WHO/ICH Stability guideline (Q1A(R2)) - Stability Testing of New Drug Substances and Products. *https://www.ich.org/page/quality-guidelines*

[19]. FDA Guidance for Industry: Orally Disintegrating Tablets (ODT) considerations (for regulatory context). *https://www.fda.gov*

[20]. R&D study example: Formulation and evaluation of active ODF with plant extracts (Harini 2022). *https://pmc.ncbi.nlm.nih.gov/articles/PMC9205350/*

[21]. Takeuchi Y., Mechanical characteristics of orally disintegrating films (2020). *https://www.sciencedirect.com/science/article/abs/pii/S0378517320308619*

[22]. Journal article on hot-melt extrusion for films (review). *https://www.tandfonline.com/doi/full/10.1080/03639045.2025.2510581?af=R*

[23]. Advances in oral film research (food film review). *https://fppn.biomedcentral.com/articles/10.1186/s43014-024-00285-x*

[24]. Studies on mucoadhesive testing methods (Alaei 2021). *https://www.sciencedirect.com/science/article/abs/pii/S0928098721002682*

[25]. Study: Formulation of active ODF using Vaccinium oxycoccos extract (Harini 2022). *https://pmc.ncbi.nlm.nih.gov/articles/PMC9205350/*

[26]. Review: Oral Thin Films in drug delivery (Cellulose Chem Technol 2025). *https://cellulosechemtechnol.ro/pdf/CCT1-2%282025%29/p.1-10.pdf*

[27]. Paper: Uses of Pomegranate in Dentistry. Malaysian Journal (2024). *https://medic.upm.edu.my/upload/dokumen/2024113013215442_MJMHS_0631.pdf*

[28]. General review: Oral dissolving films literature (IJBPAS 2024). *https://ijbpas.com/pdf/2024/October/MS_IJBPAS_2024_8406.pdf*

[29]. Research on mucoadhesive patches and pomegranate (2021–2022 studies). *https://pdfs.semanticscholar.org/52a2/1cc426da339ad3c89c86366f723603c35869.pdf*