

Formulation and Evaluation of Oral Film for the Treatment of Oral Ulcer

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ABSTRACT

Mouth ulcers are another issue that significantly impacts oral health and patient comfort. These lesions are breaks or ruptures in the mucous membrane lining the interior of the mouth, and they can appear anywhere within the oral cavity. The ulcer's appearance is typically yellow or white, with a depressed center that may cause significant discomfort.

This study focused on developing and testing fast-dissolving oral films comprising extracts of Hibiscus rosa-sinensis and Moringa oleifera for the treatment of mouth ulcers. The extracts were mixed into films made using the solvent casting method with a polymers using HPMC. Glycirine served as a plasticiser and sweetener. The films were tested for thickness, weight variation, folding endurance, surface pH, % moisture uptake, percentage moisture loss, disintegration time, in vitro drug release, and stability. The dry powder of Hibiscus rosa-sinensis and Moringa oleifera were used in this research. The film focused on the treatment of oral ulcer with improved bioavailability and patient compliance. The developed formulation can be the modern dosage form for the improvement of the drug release.

Keywords : Solvent casting, endurance , rupture , Moisture loss .

INTRODUCTION :

Oral route of administration is widely regarded as the most common and convenient method for delivering systemic pharmacological effects, due to its ease of use, painlessness, and high patient compliance. The simplicity of administration and the comfort it provides to patients make oral delivery a preferred choice for both healthcare providers and patients. Furthermore, it is one of the most costeffective treatment methods, contributing to its popularity. Fast-Dissolving Films: A Modern Solution ,Fast-dissolving films represent an innovative advancement in the realm of oral drug delivery. These films, when placed on the tongue or mucosal surfaces of the mouth, dissolve rapidly, releasing the active pharmaceutical ingredient for systemic absorption. This method provides a number of significant advantages over traditional solid dosage forms such as tablets or capsules: Improved Patient Compliance: Fast-dissolving films are easy to use, especially for patients who have difficulty swallowing pills, such as children or elderly individuals. The ability to dissolve quickly in the mouth means no water is required, and the dosage can be administered discretely. Rapid Disintegration: The films are designed to disintegrate within seconds upon contact with the wet environment of the oral cavity. This facilitates rapid absorption through the mucosa or gastric lining, providing quicker onset of therapeutic effects. Enhanced Drug Delivery: The large surface area of the film exposed to the moist oral environment accelerates the disintegration process, ensuring that the drug is quickly available for absorption, either through the buccal mucosa (for direct entry into the bloodstream) or through the stomach for gastrointestinal absorption. Avoiding Swallowing Issues: For individuals with swallowing difficulties or aversions, fast-dissolving films eliminate the need to swallow pills, thus addressing one of the major barriers to patient adherence to prescribed therapies.

Mouth Ulcers: A Common Oral Health Issue :Mouth ulcers are another issue that significantly impacts oral health and patient comfort. These lesions are breaks or ruptures in the mucous membrane lining the interior of the mouth, and they can appear anywhere within the oral cavity. The ulcer's appearance is typically yellow or white, with a depressed center that may cause significant discomfort. Ulcers in the mouth are primarily caused by mechanical trauma, such as from ill-fitting dentures, broken teeth, or fillings, though they can also be linked to viral infections, stress, hormonal changes, or autoimmune disorders. The most common symptoms associated with mouth ulcers include: Pain- This is the most prominent symptom and is exacerbated when eating, drinking, or speaking, especially if the ulcer is located in a movable part of the oral cavity (such as the tongue or cheeks).



Hibiscus Rose Sinensis :

Hibiscus rosa-sinensis, commonly known as hibiscus, is a flowering plant that has been traditionally used in various herbal medicines for its potential health benefits. It contains a variety of bioactive compounds, including antioxidants, flavonoids, and polyphenols, which may contribute to its therapeutic properties. For the treatment of oral ulcers, hibiscus rosa-sinensis is believed to offer several potential benefits: Anti-inflammatory properties -The plant contains compounds with anti-inflammatory effects that may help reduce the swelling and discomfort associated with oral ulcers (canker sores). Antioxidant effects- The antioxidants in hibiscus can help protect the affected tissues from further damage and promote healing. Antibacterial and antimicrobial effects - Hibiscus has been shown to have mild antimicrobial properties, which might help prevent secondary infections in the ulcerated area. Healing promotion- Some traditional uses of hibiscus suggest that it can aid in tissue regeneration, which may speed up the healing process of oral ulcers. Although hibiscus rosa-sinensis shows potential benefits for oral ulcer treatment, especially if the ulcers are persistent or recurrent.

Phytoconstituents of Hibiscus rosa-sinensis for Ulcer Treatment

Hibiscus rosa-sinensis is a widely recognized medicinal plant with a rich phytochemical profile that contributes to its therapeutic potential, including its effectiveness in the treatment of ulcers. The plant contains a variety of bioactive compounds, including flavonoids, phenolic acids, alkaloids, tannins, saponins, and mucilage. These phytoconstituents play a crucial role in promoting ulcer healing through anti-inflammatory, antioxidant, and cytoprotective activities. Flavonoids, abundant in Hibiscus rosa-sinensis, are known for their potent antioxidant properties, which help in neutralizing free radicals and reducing oxidative stress a common factor in the pathogenesis of ulcers. These compounds also contribute to strengthening the gastric mucosa and promoting its repair by enhancing microcirculation and reducing inflammation. Phenolic acids in the plant exhibit significant anti-inflammatory activity by inhibiting pro-inflammatory mediators, such as cytokines and prostaglandins, which are often elevated in ulcerative conditions. Tannins, another key group of phytochemicals in Hibiscus rosa-sinensis, contribute to wound healing by forming a protective layer over the affected mucosa, preventing further damage and promoting tissue regeneration. Mucilage, a polysaccharide present in the plant, provides a soothing and protective effect on the mucous membranes. It forms a barrier that shields the ulcerated area from irritants, allowing the tissue to heal. Additionally, alkaloids and saponins contribute to the plant's antimicrobial properties, reducing the risk of secondary infections that could complicate ulcer healing. In summary, the diverse phytoconstituents of Hibiscus rosasinensis offer a multifaceted approach to ulcer treatment by addressing inflammation, oxidative stress, microbial infections, and mucosal protection. These properties make the plant a valuable natural resource for developing effective and safe therapeutic interventions for ulcer management.

Moringa Oleifera :

Moringa oleifera, commonly known as the drumstick tree or miracle tree, is a highly nutritious plant that has been traditionally used for its medicinal and health benefits. The leaves, in particular, are packed with essential nutrients, and various parts of the tree (leaves, seeds, pods) have been used in treating a range of conditions.

Nutritional Value of Moringa oleifera: Moringa leaves are rich in - Vitamins: High in vitamins A (beta-carotene), C, and several B vitamins, especially B6 and folate. Minerals: A good source of calcium, potassium, magnesium, iron, and zinc. Proteins: Moringa leaves contain all nine essential amino acids, making them a complete protein source. Antioxidants: Rich in flavonoids, polyphenols, and other compounds that help reduce oxidative stress. Essential Fatty Acids: Omega-3, omega-6, and omega-9 fatty acids. Fiber: High in dietary fiber that aids in digestion and overall gut health.

Potential Benefits of Moringa for Oral Ulcers:

Moringa's nutritional profile may be beneficial in managing and healing oral ulcers through several mechanisms: Antiinflammatory: Moringa contains compounds like quercetin and chlorogenic acid, which have potent anti-inflammatory properties. This can help reduce the swelling and pain associated with oral ulcers. Antioxidant properties: The high levels of antioxidants in moringa (e.g., vitamin C and beta-carotene) may help combat oxidative stress and promote the healing of ulcerated tissues by neutralizing free radicals. Antibacterial effects: Moringa has mild antibacterial properties, which could help prevent secondary infections in open or ulcerated areas in the mouth. It can inhibit the growth of bacteria commonly found in the oral cavity, helping to keep the ulcer site clean and prevent further irritation. Wound healing: Moringa's high vitamin C and zinc content plays a crucial role in collagen formation and tissue repair, which is essential for the healing of oral ulcers. Immune support: Moringa's rich content of vitamins and minerals helps support the immune system, which is critical for recovery from infections or inflammatory conditions like oral ulcers.



Material and Methods:

Material :

The dry powders of Hibiscus rosa-sinensis and Moringa oleifera, which are the primary components for this study, were procured from a trusted local market to ensure the availability of high-quality raw materials. These powders were selected for their well-documented medicinal properties, including anti-inflammatory and antimicrobial activities. Additionally, other essential materials required for the formulation, such as hydroxypropyl methylcellulose (HPMC), used as the polymer base, ethanol as the solvent, and glycerin as the plasticizer, were sourced from the laboratory facilities at RIPSR, Bhilai, Chhattisgarh. The laboratory provided access to pharmaceutical-grade chemicals to ensure the consistency and reliability of the formulation process. All materials were carefully selected and handled in compliance with standard laboratory protocols to maintain the integrity of the study.

Methods :

Solvent Casting method is incorporated for the preparation of the film.

Formulation of Buccal film:

The buccal films were formulated using the solvent casting method, a widely accepted and effective technique for preparing thin and uniform films. Hydroxypropyl methylcellulose (HPMC), known for its excellent mucoadhesive and wound-healing properties, was selected as the primary polymer to ensure robust film-forming capability and enhance the therapeutic potential of the formulation. Glycerin was incorporated as a plasticizer to impart flexibility and improve the mechanical strength of the films, ensuring ease of handling and application.

The detailed composition of the formulation is provided in Table 1, showcasing the precise proportions of each ingredient. The films were cast in a Petri dish with a surface area of 90 mm, specially fabricated for this purpose. The total volume of the film-forming solution was adjusted to 10 mL using ethanol as the solvent, ensuring a uniform distribution of the components and optimal film formation. This systematic approach facilitated the production of high-quality buccal films with desirable physical and chemical characteristics for the intended therapeutic application.

Table 1 Ingredients

S. No.	Ingredients	Percentage (%) of distribution	Quantity for 10 ml
			casting method
1.	Hibiscus rose sinensis	30	0.300
2.	Moringa oleifera	20	0.200
3.	Hpmc	30	0.300
4.	Glycerine	20	0.6 ml
5.	Ethanol	Volume makeup	q.s.10ml

Preparation of buccal film :

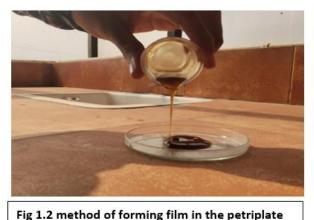








Fig 1.4 film can be obtained in the polybag

The formulation of the buccal film begins with the preparation of a solution containing Hibiscus rosa-sinensis and Moringa oleifera These extracts are dissolved in ethanol, serving as the solvent, to ensure thorough mixing and uniform distribution of the active components. The prepared solution is then gradually incorporated into hydroxypropyl methylcellulose (HPMC), a polymer known for its excellent film-forming and muccoadhesive properties. To achieve the desired gel mass, an exact amount of glycerin is added as a plasticizer, which improves the flexibility and mechanical strength of the film. The resulting gel is carefully poured into a Petri dish and evenly spread to ensure uniform thickness. The gel mass is left undisturbed at room temperature to allow the solvent to evaporate gradually, forming a thin and consistent film. The specific quantities of each ingredient used in the formulation are outlined in Table 1, ensuring reproducibility and standardization of the process. This method ensures the development of highquality films suitable for therapeutic applications.

Evaluation Tests :

1.Folding Endurance :

The flexibility and mechanical stability of the films were assessed using a folding endurance test. This involved repeatedly folding the film at a single point until it either broke or showed visible cracks. A higher folding endurance value indicates superior flexibility, which is crucial for the film's usability and durability during handling.

2. Morphological Properties :

The physical appearance of the films, including their uniformity, color, transparency, and surface texture, was examined visually. These characteristics are important for ensuring the film's aesthetic quality and user acceptability. The films were stored in airtight containers at room temperature (25-30 °C) to maintain their integrity during the study.

3. Weight Variation :

The weight of individual films was measured using an analytical balance to determine the average weight. This test ensures consistency in the formulation by verifying that each film contains the correct proportion of ingredients, including the active substance and excipients.

4.Film Thickness Uniformity :

The thickness of the films was assessed using a precise screw gauge. Measurements were taken at multiple locations, including the center and four corners of the films, to ensure uniformity in thickness, which is crucial for consistent dosing and mechanical properties.

5.Folding Endurance:

The folding endurance of the films was determined by folding a $2x2 \text{ cm}^2$ strip repeatedly at the same spot until it showed cracks or broke. The number of folds required to cause failure was recorded as the folding endurance value. This test evaluates the mechanical strength and flexibility of the films, ensuring their robustness during handling and application.



6. Percentage Moisture Loss:

The percentage moisture loss test assessed the films' ability to retain their integrity under dry conditions. Three film samples were accurately weighed and stored in a desiccator containing fused anhydrous calcium chloride for 72 hours to ensure a dry environment. After the specified duration, the films were reweighed, and the percentage moisture loss was calculated using the formula:

Percentage moisture loss=(Initial weight-Final weight/Initial weight)×100

This test ensures the films remain stable and maintain their physical properties in low-humidity conditions.

7.Surface pH:

To evaluate the surface pH of the films, each film was placed in a Petri dish and moistened with 5 mL of distilled water. After allowing the film to equilibrate for a few minutes, the pH was measured by bringing the electrode of a calibrated pH meter in contact with the surface of the film. The pH was recorded after 1 minute to ensure accurate equilibration. Maintaining a surface pH close to neutral is crucial to avoid irritation when the film is applied.

8. Disintegration Time :

The in vitro disintegration time of the films was assessed using a glass beaker containing 25 mL of distilled water maintained at 37°C to simulate body temperature. Each film was added to the beaker, and the time taken for it to completely disintegrate was recorded visually. A shorter disintegration time ensures rapid onset of action, which is critical for fast-dissolving films.

9. Content Uniformity:

The content uniformity of the films was evaluated to ensure consistent distribution of the active ingredient. A 2 cm² film sample was cut and placed in a 100 mL volumetric flask, where it was dissolved in methanol. The volume was adjusted to 100 mL using distilled water, and the solution was filtered through Whatman filter paper. The filtrate was analyzed to determine the active ingredient content. The films meet the content uniformity criteria if the amount of active ingredient in each film falls within the range of 90-110% of the labeled content, as per standard guidelines.

10. In vitro dissolution test :

The in vitro dissolution test for oral films of Hibiscus rosa-sinensis and Moringa oleifera can be conducted using standard pharmaceutical methods.

Test Parameters-Apparatus: USP Dissolution Apparatus I (Basket) or Apparatus II (Paddle) ,Dissolution Medium: Phosphate buffer pH 6.8 (to simulate the oral environment) ,Volume: 900 mL ,Temperature: 37 ± 0.5 °C ,Rotation Speed: 50–75 rpm (depending on the apparatus) ,Sampling Time Points: 2, 4, 6, 8, 10, 15 minutes ,- The withdrawn volume is replaced with an equal volume of fresh dissolution medium to maintain sink conditions. Time (2 minutes) % Drug Release (25 ± 2.5) Both the Hibiscus rosa-sinensis and Moringa oleifera films demonstrated rapid dissolution, with over 90% of the drug released within 10 minutes, ensuring quick bioavailability. These results suggest that the films are suitable for fast-dissolving applications.

Result and Discussion :

Fast-dissolving oral films represent a cutting-edge drug delivery system designed for rapid disintegration upon application to the tongue or oral mucosa. These films enable the swift release of active ingredients, which are absorbed through the mucosal lining and, in some cases, bypass the first-pass metabolism to achieve faster therapeutic effects. In this study, herbal fast-dissolving films were specifically developed for the treatment of mouth ulcers, leveraging the therapeutic potential of herbal extracts to reduce the side effects often associated with synthetic drugs. These natural formulations offer a safer alternative by facilitating direct absorption into the bloodstream through the oral mucosa. The films were formulated using extracts of Hibiscus rosa-sinensis and Moringa oleifera, plants that are well-documented for their anti-ulcer, antimicrobial, and anti-inflammatory properties. These herbal extracts not only promote wound healing but also provide a protective barrier against microbial infections, making them highly suitable for oral healthcare applications. The solvent casting method was employed for film preparation, utilizing hydroxypropyl methylcellulose (HPMC) as the primary polymer to ensure good film-forming properties. Glycerin was incorporated as a plasticizer to enhance flexibility and prevent brittleness, while ethanol served as the solvent to ensure uniform dispersion of the active ingredients. Comprehensive physical and chemical evaluations were conducted to assess the quality of the films. Tests for weight uniformity, thickness, folding endurance, and surface pH were performed to ensure consistency and stability. Additionally, the films



were evaluated for moisture loss, moisture uptake, and disintegration time to confirm their suitability as fast-dissolving dosage forms. The results indicated that the films were uniform in appearance, mechanically stable, and capable of disintegrating rapidly within seconds, making them convenient and effective for use. In summary, these fast-dissolving films offer an innovative, cost-effective, and user-friendly approach to treating mouth ulcers. They combine the therapeutic benefits of herbal extracts with advanced drug delivery technology, providing a safe and efficient alternative to conventional treatments. With minimal side effects and enhanced patient compliance, this formulation holds great promise for addressing oral health issues.

Conclusion :

The present study focused on the formulation and evaluation of fast-dissolving oral films containing extracts of Hibiscus rosasinensis and Moringa oleifera for the treatment of mouth ulcers. The dry powder can be used and phytochemical analysis confirmed the presence of bioactive compounds such as flavonoids, tannins, and saponins, which are known for their anti-ulcer, antiinflammatory, and antimicrobial properties with also possessing the nutritional value of vitamin b complex . The oral films were successfully formulated using the solvent casting method with polymers such as HPMC along with glycerin as a plasticizer and ethanol as the solvent. The prepared films were evaluated for various physicochemical properties, including thickness, folding endurance, moisture uptake, moisture loss, surface pH, disintegration time, and drug release. The results indicated that the formulated films were uniform in appearance, with smooth texture and consistent properties. Among the tested formulations, one exhibited optimal drug release, excellent stability, and favorable physicochemical characteristics. In conclusion, the study demonstrated that extracts of Hibiscus rosa-sinensis and Moringa oleifera can be effectively incorporated into fast-dissolving oral films. These herbal films provide a promising, patient-friendly alternative for mouth ulcer treatment, combining therapeutic efficacy with minimal side effects and improved patient compliance.

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