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FORMULATION AND EVALUATION OF EDIBLE MUCOADHESIVE ORAL STRIPS FOR THE TREATMENT OF MOUTH ULCER

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ABSTRACT

Edible mucoadhesive oral strips are innovative drug delivery systems designed to adhere to the oral mucosa and release therapeutic agents directly at the site of action. These thin, flexible films dissolve or swell in saliva, ensuring prolonged drug contact and improved bioavailability. This review focuses on the formulation strategies, evaluation parameters, and therapeutic applications of oral strips for the management of mouth ulcers. Various polymers such as HPMC, PVA, and sodium alginate are discussed for their role in mucoadhesion and controlled drug release. Methods of preparation including solvent casting and hot melt extrusion are elaborated. The importance of excipients like plasticizers, sweeteners, and flavoring agents in improving patient acceptability is highlighted. Furthermore, key quality control tests such as thickness, folding endurance, drug content uniformity, disintegration time, and surface pH are described. The advantages of oral strips, including rapid onset, ease of administration, and bypassing first-pass metabolism, are discussed along with certain limitations. Marketed formulations and future prospects of this dosage form are also reviewed. Overall, edible mucoadhesive oral strips offer a promising and patient-friendly alternative for effective treatment of oral ulcers.

KEYWORDS: *Mucoadhesive Oral Strips, Mouth Ulcer, HPMC, Buccal Drug Delivery, Fast Dissolving Films, Local Therapy*

INTRODUCTION

Mouth ulcers, also known as aphthous ulcers, are small painful lesions occurring on the oral mucosa. These ulcers can interfere with eating, speaking, and overall oral comfort. Common causes include stress, nutritional deficiencies, trauma, and systemic conditions. Effective local treatment is essential to reduce pain and accelerate healing.

Mucoadhesive oral strips represent an advanced drug delivery system that adheres to the buccal mucosa and releases medication in a controlled manner. These strips are particularly beneficial for patients who have difficulty swallowing conventional dosage forms. The system ensures prolonged drug retention at the site, enhancing therapeutic efficiency and minimizing systemic side effects.

Mouth ulcers, also known as aphthous ulcers, are among the most common lesions affecting the oral cavity and are characterized by pain, inflammation, and discomfort that can interfere with speaking, eating, and overall quality of life. These lesions may arise due to factors such as local trauma, stress, nutritional deficiencies, infections, and systemic conditions. Conventional dosage forms used for the management of mouth ulcers, including gels, ointments, and mouthwashes, often suffer from limitations such as poor retention at the site of application, frequent dosing requirements, and reduced patient compliance due to unpleasant taste or swallowing difficulties. Fast-dissolving oral strips have emerged as a promising drug delivery system for localized treatment of oral conditions. These thin, flexible films rapidly disintegrate upon contact with saliva, enabling quick drug release directly at the site of action without the need for water or swallowing. Their ease of administration, rapid onset of action, accurate dosing, and improved patient compliance make them particularly suitable for pediatric, geriatric, and dysphagic patients.

Lidocaine is a widely used local anesthetic that provides effective and rapid pain relief by reversibly blocking sodium channels and inhibiting nerve impulse conduction at the site of application. Due to its proven analgesic efficacy, lidocaine is commonly employed in the management of painful oral conditions, including mouth ulcers. However, conventional lidocaine formulations such as gels and sprays may exhibit limited residence time in the oral cavity, resulting in reduced therapeutic effectiveness and the need for repeated application.

In this context, the formulation of lidocaine into fast-dissolving oral strips represents an innovative approach to enhance local drug delivery for mouth ulcer treatment. By providing rapid disintegration and direct mucosal contact, oral strips can improve drug bioavailability at the ulcer site while minimizing systemic exposure. The present study focuses on the formulation and evaluation of lidocaine-loaded fast-dissolving oral strips using suitable film-forming polymers, with the aim of achieving rapid pain relief, improved patient convenience, and enhanced therapeutic efficacy

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Lidocaine plays a crucial role in mouth ulcer strips as a **local anesthetic agent** that provides rapid and effective pain relief at the site of ulceration. It acts by **reversibly blocking voltage-gated sodium channels** in neuronal cell membranes, thereby inhibiting nerve impulse conduction and preventing the transmission of pain signals from the affected oral mucosa. This mechanism helps in reducing pain, burning sensation, and discomfort associated with mouth ulcers.

When incorporated into fast-dissolving oral strips, lidocaine is released quickly upon contact with saliva, allowing **direct mucosal absorption** and immediate onset of action. This localized delivery ensures high drug concentration at the ulcer site while minimizing systemic exposure and associated side effects. The rapid disintegration of the strip enhances patient comfort and eliminates the need for frequent reapplication commonly required with conventional dosage forms such as gels or sprays.

Additionally, lidocaine improves **patient compliance** by providing prompt symptomatic relief, enabling easier speaking, chewing, and swallowing during ulcer healing. Its incorporation into mouth ulcer strips also ensures **uniform dosing, precise drug delivery, and prolonged contact with the affected area,** which enhances therapeutic effectiveness. Overall, lidocaine serves as a key active pharmaceutical ingredient in mouth ulcer strips by offering fast, localized analgesia and improved treatment outcomes for painful oral ulcer conditions.

TYPES OF MOUTH ULCERS

Minor Aphthous Ulcers
Small, round lesions less than 1 cm in diameter that heal within 7–14 days without scarring.

Major Aphthous Ulcers
Larger and deeper ulcers exceeding 1 cm, often painful and may take weeks to heal, sometimes leaving scars.

Herpetiform Ulcers
Multiple small ulcers (1–3 mm) occurring in clusters, which may merge to form larger lesions and usually heal within 1–2 weeks.

BASIC TYPES OF ORAL STRIPS

Fast Dissolving Oral Strips:
These dissolve quickly upon contact with saliva, releasing drug rapidly for immediate relief.
Mucoadhesive Buccal Strips:
Designed to adhere to the mucosa and provide sustained drug release over a longer duration.
Sustained Release Oral Films:
Formulated using polymers that control drug release for extended therapeutic action.

ADVANTAGES

- **Ease of Administration:** Suitable for pediatric and geriatric patients.
- **Rapid Onset of Action:** Direct drug absorption through oral mucosa.
- **Avoidance of First-Pass Metabolism:** Enhances bioavailability.
- **Improved Patient Compliance:** Thin, flexible, and easy to carry.
- **Localized Drug Delivery:** Effective for treating mouth ulcers directly at the site.
- **No Need for Water:** Convenient for use anytime.

DISADVANTAGES

- **Limited Drug Loading Capacity:** Only small doses can be incorporated.
- **Moisture Sensitivity:** Requires careful packaging and storage.
- **Taste Masking Challenges:** Bitter drugs need proper masking.
- **Mechanical Fragility:** Films may tear if not handled properly.
- **Stability Issues:** Some drugs may degrade in the polymer matrix.

FORMULATION COMPONENTS/ MATERIAL

- **Polymers:** HPMC, Sodium alginate (for film forming and mucoadhesion)
- **Plasticizers:** Glycerin, PEG (to improve flexibility)
- **Sweeteners:** saccharin sodium
- **Flavoring Agents:** Mint, orange, or fruit flavors

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- **Active Pharmaceutical Ingredient (API):** Local anesthetics, antiseptics, anti-inflammatory agents
- **Saliva Stimulating Agents:** Citric acid

FORMULATION TABEL

Sr. No.	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8
1.	Lidocaine	20	40	20	40	20	40	20	40
2.	HPMC E15(mg)	10	20	30	40	10	20	30	10
3.	Sodium Alginate(mg)	10	15	20	25	25	30	35	40
4.	Polyvinyl Alcohol(ml)	4	2	4	2	4	2	4	2
5.	Propylene Glycol(ml)	2	2	2	2	2	2	2	2
6.	Sodium Starch Glycolate (mg)	3	3	3	3	3	3	3	3
7.	Saccharin sodium (mg)	2	2	2	2	2	2	2	2
8.	Water(ml)	10	10	10	10	10	10	10	10

METHOD OF PREPARATION (SOLVENT CASTING METHOD)

Preparation of Polymer Solution

Dissolve selected polymer in distilled water with continuous stirring.

Addition of Plasticizer

Add plasticizer to improve flexibility and prevent brittleness.

Drug Incorporation

Dissolve or disperse the drug uniformly in the polymer solution.

Addition of Excipients

Incorporate sweeteners, flavors, and other additives.

Casting

Pour the solution onto a flat surface or mold and spread uniformly.

Drying

Allow solvent evaporation at controlled temperature.

Cutting and Packaging

Cut dried film into desired size and pack in moisture-resistant packaging.

CASTING METHOD

We used the solvent casting approach to create edible mucoadhesive oral strips.As film-forming polymers, we precisely weighed sodium alginate, polyvinyl alcohol (PVA), HPMC E5, and HPMC E15. After dispersing HPMC E5 and HPMC E15 separately in distilled water while stirring constantly, we let them hydrate for 30 to 60 minutes. PVA was dissolved in distilled water by heating it to between 60 and 70 °C. while stirring continuously until a clear solution was produced. We made a different sodium alginate aqueous solution while stirring constantly. To create a uniform polymeric mixture, we progressively mixed all of the polymer solutions while using magnetic stirring. Propylene glycol was used as a plasticizer to increase the mechanical strength and flexibility of the film. As a superdisintegrant, we added sodium starch glycolate and evenly distributed it throughout the polymeric solution. To get rid of trapped air bubbles, we let the finished solution stand. We evenly poured the mixture onto a glass plate that had been leveled. To guarantee full solvent evaporation, we dried the cast films for 24 hours at 40–45 °C. The dried films were carefully peeled off and cut into strips of consistent size. Until further analysis, we kept the created oral strips in sealed containers.

PHYSICOCHEMICAL EVALUATION

- **Thickness Measurement:** Ensures uniformity of film
- **Weight Variation:** Maintains dose accuracy
- **Folding Endurance:** Measures flexibility and strength
- **Surface pH:** Should be neutral to avoid irritation
- **Drug Content Uniformity:** Ensures consistent drug distribution

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- **Disintegration Time:** Determines how quickly the strip dissolves
- **In-vitro Drug Release:** Evaluates release profile
- **Moisture Content:** Affects stability and shelf life

Evaluations tests

Morphological properties

The morphological features, including the films' homogeneity, color, transparency, and surface roughness, were visually observed. All of the formulations were kept in airtight containers at room temperature (25±30 °C).

Weight variation

The average weight of each film can be ascertained by weighing them on an analytical scale. It helps guarantee that a film contains the right quantity of drug and excipients.

Film thickness uniformity

A screw gauge was used to accurately measure the film's thickness. The film's center and four corners were among the strategic areas from which the measurements were obtained. (15)

Endurance in Folding

A little strip of film (2x2cm2) was folded repeatedly until it broke in order to assess the film's folding durability. The value of folding endurance is determined by how many times the film can be folded in the same spot without breaking. (16)

Percentage Moisture loss

The integrity of the films in dry conditions was examined using a percentage moisture loss test. Three films were precisely weighed and stored in a desiccator filled with fused anhydrous calcium chloride. After 72 hours, the films were taken out and weighed. The formula below was used to determine the percentage moisture loss. (17)

Percentage moisture loss = ((intial weight – final weight) / intial weight) x 100

Surface pH

Five ml of distilled water were used to moisten the film in a Petri dish, which was then left for a short while.

After contacting the formulation's surface with the pH meter's electrode and letting it equilibrate for one minute, the pH was recorded. (18)

Disintegration time

In a glass beaker, the in vitro disintegration time was measured visually. The OFDF strip was introduced to a beaker containing 25 ml of distilled water that was kept at 37°C. The duration of the film's disintegration is recorded.

Content Uniformity

The consistency of the films' content was examined. A 2 cm2 film was sliced, put in a 100 ml volumetric flask, and dissolved in methanol before the volume was increased to 100 ml with water. Wattman filter paper was used to filter the solution. If each film has between 90 and 110% active component, the content uniformity requirements are satisfied. (19)

In Vitro Dissolution studies

The USP Dissolution Test Apparatus-II was used to calculate the fast-dissolving films' release rate. The release test was conducted at 37±5 °C and 50 rpm in 900 cc of pH 6.8 phosphate buffer. To maintain the sink conditions, an aliquot of the solution was taken and replaced with new medium every two minutes. Wattman filter paper was used to filter the solution. Using a double beam UV spectrophotometer, the absorbance of the filtrate was determined at 280 nm (ocimum sanctum) and 282 nm (glycyrrhiza glabra), respectively. (20)

Stability studies

The film was kept at room temperature for up to 30 days in order to test the accelerated stability.

Samples were assessed for drug release and assay.

PACKAGING AND STORAGE

Oral strips should be packed in moisture-resistant materials such as aluminum foil pouches or blister packs. Storage conditions should be cool and dry to prevent degradation and maintain film integrity.

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APPLICATIONS

- Treatment of mouth ulcers
- Delivery of analgesics and antiseptics
- Systemic drug delivery through buccal absorption

CONCLUSION

Edible mucoadhesive oral strips represent a novel and effective drug delivery system for the treatment of mouth ulcers. Their ability to provide localized action, improved patient compliance, and enhanced bioavailability makes them a superior alternative to conventional dosage forms. Proper formulation and evaluation ensure optimal therapeutic outcomes. With ongoing advancements, oral strips hold significant promise for future pharmaceutical applications.

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