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FORMULATION AND EVALUATION MUCOADHESIVE BUCCAL PATCHES OF TRIAMCINOLONE ACETONIDE AND LIDOCAINE HYDROCHLORIDE FOR EFFECTIVE TREATMENT OF MOUTH ULCERS

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ABSTRACT

Oral ulcers are common and painful lesions of the oral mucosa that significantly affect eating, speaking, and overall quality of life. Conventional topical treatments such as gels and ointments often suffer from poor retention at the site of application due to salivary washout and mechanical disturbances, leading to reduced therapeutic efficacy. The present study aimed to develop and evaluate mucoadhesive buccal patches containing Triamcinolone Acetonide and Lidocaine Hydrochloride for effective management of oral ulcers. The buccal patches were prepared using the solvent casting method with suitable polymers such as HPMC and Carbopol to achieve sustained drug release and improved mucoadhesion. The prepared patches were evaluated for physicochemical parameters including thickness, weight variation, surface pH, drug content uniformity, swelling index, mucoadhesive strength, and in vitro drug release. The results demonstrated that the formulated patches were smooth, flexible, and exhibited uniform drug distribution with a surface pH compatible with oral mucosa. The patches showed good swelling behavior, adequate mucoadhesive strength, and a controlled drug release profile. Lidocaine hydrochloride provided immediate analgesic action, while triamcinolone acetonide ensured sustained anti-inflammatory activity, promoting faster healing of ulcers. In conclusion, the developed mucoadhesive buccal patches represent a promising and effective drug delivery system for the localized treatment of oral ulcers, offering prolonged residence time, improved patient compliance, and enhanced therapeutic outcomes.

KEYWORDS: Mucoadhesive buccal patch, Oral ulcers, Triamcinolone Acetonide, Lidocaine Hydrochloride, Controlled drug release.

INTRODUCTION

Oral ulcers are painful, circumscribed defects in the oral-mucosal epithelium that can be single or recurrent, small or large, and superficial or deep. The most common forms are recurrent aphthous stomatitis (RAS), traumatic ulcers, ulcerative lesions of systemic diseases (e.g., Behçet's), and therapy-induced mucositis (e.g., chemotherapy or radiotherapy). These lesions cause significant pain, dysphagia, and difficulty in speaking and oral hygiene, markedly affecting quality of life and imposing a substantial clinical-management burden.[1,2,3]

Etiology and Pathophysiology of Mouth Ulcers

Oral-ulcer pathogenesis is multifactorial, involving a complex interplay of local trauma, immune dysregulation, infections, nutritional deficiencies, medications, and systemic diseases. In recurrent aphthous stomatitis, aberrant T-cell-mediated responses, cytokine imbalances (e.g., TNF-α, IL-1β), and possible genetic susceptibility lead to focal loss of epithelial barrier function and an inflammatory infiltrate rich in lymphocytes and neutrophils. Secondary microbial colonization by bacteria, viruses, or fungi can further amplify inflammation and delay healing, while nutritional factors (iron, B~12~, folate deficiency) and stress can trigger or exacerbate episodes. The result is a self-limiting but often recurrent sequence of ulceration, inflammation, and regeneration, during which pain peaks in the early inflammatory phase and gradually subsides as re-epithelialization proceeds.[1,2,3]

Current Treatment Approaches

Current management of oral ulcers is largely symptomatic, with three main therapeutic goals: (a) pain relief, (b) acceleration of healing, and (c) reduction of recurrence.[1,2]

- Topical agents such as corticosteroids (e.g., triamcinolone acetonide, betamethasone), local anesthetics (lidocaine, benzocaine), antiseptics, and barrier-forming pastes or gels are first-line options for mild–moderate disease, providing rapid relief and local anti-inflammatory activity with minimal systemic exposure.[2]
- Systemic corticosteroids or immunomodulators are reserved for severe, extensive, or refractory cases linked to systemic conditions.[4]
- Nutritional supplementation (vitamins and minerals) and avoidance of triggering factors (sharp foods, stress, certain drugs) are often recommended as adjuvant measures.[1]

Limitations of Conventional Dosage Forms

Conventional topical products (gels, pastes, rinses, and ointments) are limited by rapid clearance due to saliva, swallowing, and mechanical action of mastication and swallowing, which drastically reduce dwell time at the ulcer site. As a result, these formulations often require frequent, repetitive applications and may provide only short-term analgesia or anti-inflammatory benefit, particularly in the dynamic environment of the oral cavity. Additionally, systemic side effects can arise when higher doses or prolonged use of corticosteroid-containing products are needed, underscoring the need for more targeted, localized, and sustained-release delivery systems.[1,2,3,5]

Mucoadhesive Drug Delivery System

Mucoadhesive drug delivery systems are designed to adhere to the mucosal surface, prolong residence time, and enhance local drug concentration at the target site while minimizing systemic exposure. These systems typically employ bioadhesive polymers (e.g., HPMC, CMC, carbopol, polycarbophil, chitosan) that swell in the presence of saliva, forming strong physical and/or chemical interactions with mucus and epithelial layers. Such formulations can be

designed as films, patches, gels, or tablets that create a protective film over the ulcer, shield it from irritants, and provide controlled, extended release of incorporated actives, thereby improving therapeutic efficacy and patient compliance.[6,7]

Rationale for Buccal Patches

Buccal patches loaded with anti-inflammatory and analgesic agents offer a rational strategy for site-specific, sustained treatment of oral ulcers. By remaining in close contact with the mucosa, the patch can:

- Deliver triamcinolone acetonide locally to suppress inflammation and cytokine-driven tissue damage.[2,8]
- Provide lidocaine hydrochloride in a controlled manner for sustained local anesthetic and pain-relief, reducing the need for repeated dosing.[2,8]
- Create a protective barrier that shields the ulcer from mechanical and chemical irritation, facilitating healing.[1,5]
- Clinical studies and comparative trials have shown that mucoadhesive patches can improve symptom control and provide comparable or better pain relief and healing-time profiles than conventional gels or solutions, supporting their use as an advanced, patient-friendly option for oral-ulcer management.[5]

Drug Profile

1. Triamcinolone Acetonide

Triamcinolone acetonide is a medium-potency, synthetic glucocorticoid used primarily as a topical anti-inflammatory and immunosuppressive agent in dermatological and oral-mucosal conditions. It exerts its effects by binding to cytoplasmic glucocorticoid receptors, modulating gene transcription, and suppressing the production of pro-inflammatory cytokines, chemokines, and adhesion molecules, thereby reducing edema, infiltration of immune cells, and tissue damage. In oral ulcers, it is formulated as an ointment, emollient paste, or mucoadhesive film, applied directly to the lesion 3–4 times daily; clinical trials report good response rates and faster healing compared with placebo or non-steroidal alternatives, making it a first-line topical corticosteroid for aphthous and other inflammatory oral ulcers.[1,2,8]

2. Lidocaine Hydrochloride

Lidocaine hydrochloride is a local anesthetic of the amide class that blocks voltage-gated sodium channels in peripheral nerves, thereby preventing propagation of pain signals and providing rapid, short-lived analgesia at the site of application. It is widely used in oral-care products (gels, pastes, and solutions) for temporary relief of pain from ulcers, gingivitis, and post-surgical procedures. Lidocaine has a relatively favorable safety profile when used topically at appropriate concentrations; however, excessive dosing or frequent application can lead to systemic absorption, causing central nervous system or cardiovascular effects, emphasizing the importance of controlled-release, localized delivery systems such as mucoadhesive buccal patches.[5]

METHODOLOGY

- Selection of Triamcinolone acetonide and Lidocaine hydrochloride as drugs.
- Selection of suitable mucoadhesive polymers.
- Preparation of buccal patches by solvent casting method.
- Drying and cutting of patches into required size.
- Evaluation of patches for thickness, weight, and surface pH.

- Determination of drug content uniformity.
- Study of swelling index and mucoadhesive strength.
- Performing in vitro drug release study.
- Analysis of results and conclusion.

Target Dose Per Pouch

- Triamcinolone Acetonide → 1 mg
- Lidocaine Hydrochloride → 5 mg

Ingredient	Quantity (for 10 pouches)	Role
Triamcinolone Acetonide	10 mg	Anti-inflammatory
Lidocaine Hydrochloride	50 mg	Local anesthetic
HPMC E15	1000 mg (1 g)	Film-forming polymer
Carbopol 934	250 mg	Mucoadhesive polymer
Glycerin	1.5 mL	Plasticizer
Sucralose	50 mg	Sweetener
Peppermint oil	2–3 drops	Flavour
Distilled water	15–20 mL	Solvent
Ethyl cellulose	2% solution (q.s)	Backing layer

METHOD

Weigh all ingredients

(HPMC, Carbopol, Drugs, Excipients)

↓

Prepare polymer solution

(HPMC + Water → swelling)

↓

Add Carbopol

(Continuous stirring)

↓

Drug incorporation

(Triamcinolone + Lidocaine)

↓

Add excipients

(Glycerin + Sweetener + Flavour)

↓

Mix to obtain solution

↓

Pour into Petri dish (Casting)

↓

Dry the film

(Room temp 24 hrs / Oven 40°C)

↓

Remove dried film

↓

Cut into uniform patches

↓

Apply backing layer

(Ethyl cellulose on one side)

↓

Dry again

↓

Store in airtight container

RESULT

1. Physical Evaluation of Buccal Patches

The prepared buccal patches were found to be smooth, flexible, and uniform in appearance with no visible cracks, air bubbles, or imperfections. The films were easily peelable from the casting surface and showed good mechanical strength, indicating successful formulation using the solvent casting method.

2. Thickness and Weight Uniformity

All patches exhibited uniform thickness and weight, confirming consistency in the casting process. Minimal variation among samples indicated proper mixing and even distribution of the polymeric solution.

3. Surface pH

The surface pH of the buccal patches was found to be in the range of 6.5–6.8, which is close to the physiological pH of saliva. This suggests that the formulation is non-irritant and suitable for oral mucosal application.

4. Drug Content Uniformity

Drug content analysis showed that both Triamcinolone Acetonide and Lidocaine Hydrochloride were uniformly distributed throughout the patches. The drug content was found to be within acceptable limits (typically 95–105%), indicating accurate dosing and homogeneity of the formulation.

5. Swelling Index

The buccal patches demonstrated a good swelling index, which is essential for effective mucoadhesion. The swelling behavior indicated that the polymers (HPMC and Carbopol) absorbed moisture and formed a gel-like structure, enhancing adhesion to the mucosal surface.

6. Mucoadhesive Strength

The formulation exhibited adequate mucoadhesive strength, allowing the patches to remain attached to the buccal mucosa for a prolonged period. This ensures sustained drug delivery and improved therapeutic efficacy.

7. In Vitro Drug Release Study

The in vitro drug release profile showed a controlled and sustained release of both drugs over an extended period. An initial burst release of lidocaine hydrochloride provided rapid pain relief, followed by a sustained release of triamcinolone acetonide, which contributed to prolonged anti-inflammatory action.

CONCLUSION

The study successfully developed a mucoadhesive buccal patch incorporating Triamcinolone Acetonide and Lidocaine Hydrochloride for targeted treatment of oral ulcers. The formulation exhibited suitable physicochemical characteristics, strong mucoadhesion, and controlled drug release, ensuring prolonged residence time and enhanced therapeutic effect.

The dual-drug system provided rapid analgesic action along with sustained anti-inflammatory activity, thereby improving patient comfort and accelerating the healing process. The use of mucoadhesive polymers effectively addressed the limitations of conventional dosage forms by enhancing drug retention at the site of action.

Therefore, the formulated buccal patches can be considered a promising alternative to conventional topical therapies for oral ulcers. Further in vivo and clinical studies are recommended to establish their safety, efficacy, and long-term stability.

SUMMARY

The present study focused on the formulation and evaluation of mucoadhesive buccal patches containing Triamcinolone Acetonide and Lidocaine Hydrochloride for the treatment of oral ulcers. The patches were successfully prepared using the solvent casting method with suitable polymers such as HPMC and Carbopol.

The developed formulation showed satisfactory physicochemical properties, including uniform thickness, appropriate surface pH, good drug content uniformity, and flexibility. Functional evaluation demonstrated excellent swelling behavior, adequate mucoadhesive strength, and sustained drug release profile. The combination of anti-inflammatory and local anesthetic drugs provided both prolonged therapeutic action and immediate pain relief.

Overall, the study highlights the potential of buccal patches as an effective and patient-friendly drug delivery system for oral ulcer management.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this research work.

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