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Formulation and Evaluation of Mucoadhesive Oral Patches for the Management of Mouth Ulcer

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ABSTRACT:

Mucoadhesive buccal patches are widely recognized as an effective approach for delivering drugs directly to the oral mucosa for the treatment of mouth ulcers. The present investigation was undertaken to develop and evaluate mucoadhesive oral patches for improved management of oral ulcer conditions. The formulations were prepared by employing the solvent casting technique using suitable polymers, including Hydroxypropyl Methylcellulose (HPMC) and Carbopol, to obtain effective mucoadhesive and film-forming characteristics. OraTrust Gel was utilized as the therapeutic preparation to provide anti-inflammatory and pain-relieving activity. The prepared patches were evaluated for several physicochemical properties such as thickness, weight variation, folding endurance, surface pH, and visual appearance. The formulated films demonstrated satisfactory flexibility, uniform structure, and appropriate surface properties for buccal administration. The overall findings suggest that the developed mucoadhesive patches could enhance drug retention at the affected site, improve therapeutic response, and provide greater convenience and comfort to patients suffering from mouth ulcers.

Keywords: Buccal adhesive film, Oral ulcer management, Buccal therapeutic delivery, Choline Salicylate, Lignocaine Hydrochloride, Bio-adhesive system, Solvent casting technique.

INTRODUCTION:

The advancement of pharmaceutical science has encouraged the development of innovative drug delivery systems that can improve treatment efficiency, provide controlled release of medication, and enhance patient convenience. Among these approaches, mucoadhesive drug delivery systems have attracted considerable interest because they are capable of maintaining the formulation at the site of application for an extended period. The oral cavity is regarded as an effective site for drug administration due to its high vascularization, easy accessibility, and relatively low enzymatic activity. Administration of drugs through the oral mucosa may improve absorption and help overcome certain limitations associated with conventional oral dosage forms, including extensive first-pass metabolism and degradation within the gastrointestinal tract.

Oral ulcers are painful lesions commonly found within the oral cavity and are often associated with inflammation, irritation, and difficulty in routine activities such as eating and speaking. Traditional treatments including gels, ointments, and mouth rinses generally provide short-term relief because they are easily displaced by saliva and continuous oral movements, which reduces their contact time with the affected region. To address these limitations, mucoadhesive buccal patches have been introduced as a promising localized drug delivery system. These formulations are designed to adhere to the oral mucosa and provide prolonged drug release at the site of action, thereby improving therapeutic performance and patient acceptability. Hence, the present study focuses on the formulation and evaluation of mucoadhesive buccal patches for the effective management of mouth ulcers.

Buccal Drug Delivery System:

Buccal drug delivery has emerged as an important approach in modern pharmaceutical science for delivering medications through the mucosal lining of the oral cavity. This route of administration offers significant advantages over conventional oral dosage forms because drugs absorbed through the buccal mucosa can directly enter systemic circulation without undergoing extensive hepatic first-pass metabolism. As a result, improved bioavailability and enhanced therapeutic effectiveness can be achieved. The buccal mucosa is richly supplied with blood vessels and exhibits relatively low enzymatic activity, which supports efficient drug absorption and rapid therapeutic response.

Traditional oral dosage forms such as tablets and capsules may undergo degradation in the gastrointestinal tract or metabolism in the liver before reaching systemic circulation. Buccal drug delivery systems help overcome these limitations by providing direct absorption through the oral mucosal membrane. In addition to improved drug absorption, buccal formulations are non-invasive, easy to administer, and suitable for both localized and systemic drug delivery. Different buccal dosage forms including films, gels, tablets, lozenges, and patches have been developed to improve treatment outcomes and patient convenience.

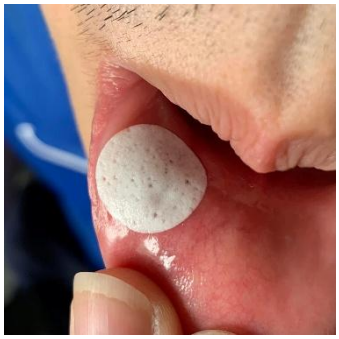


Fig1: Buccal D rug Delivery System

Mouth Ulcers:

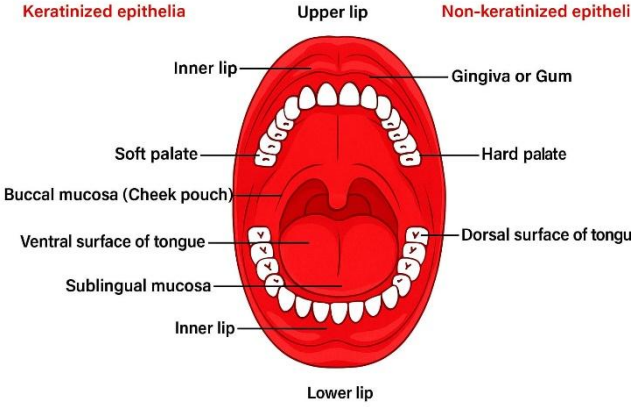
Mouth ulcers are painful lesions that occur on the soft tissues of the oral cavity, including the inner cheeks, lips, tongue, gums, and palate. These lesions are commonly associated with inflammation, redness, irritation, and discomfort, which may interfere with routine activities such as eating, drinking, and speaking. The development of mouth ulcers may be associated with several factors such as emotional stress, nutritional deficiencies, accidental trauma, infections, hormonal changes, allergic reactions, and immune-related disorders. Deficiency of nutrients such as iron, folic acid, and vitamin B complex may also contribute to ulcer formation.

Various conventional therapies including topical gels, ointments, creams, and mouth rinses are available for the treatment of mouth ulcers. However, these formulations generally provide temporary relief because they are rapidly diluted or removed by saliva and oral movements. Consequently, reduced contact time between the formulation and the affected area limits therapeutic efficiency and requires repeated application.

Anatomical and physiological features of the oral cavity:

The oral mucosa, which covers an area of 170 cm^2, has three distinct layers: epithelium, lamina propria, and submucosa. The buccal epithelium serves as a protective membrane and is classified as either flexible non-keratinized mucosa, found in areas like the soft palate, ventral surface of the tongue, and inner lips, or keratinized mucosa, which covers the hard palate and gingiva and dorsal surface of tongue in the oral cavity.

Fig2: A schematic diagram depicting the key regions of the



Mucoadhesive Buccal Patches:

Mucoadhesive buccal patches are specially designed pharmaceutical formulations intended to adhere to the oral mucosa and release drugs in a controlled manner over an extended period. These patches maintain close contact with the affected site, thereby increasing local drug concentration and improving therapeutic response. Buccal patches are generally thin, flexible, and comfortable for patient use, making them highly suitable for oral application.

One of the major advantages of mucoadhesive buccal patches is their ability to provide targeted drug delivery directly to the affected area while reducing systemic side effects. These systems also reduce dosing frequency by maintaining prolonged drug release and improving patient compliance. Furthermore, the prolonged retention of buccal patches minimizes drug loss caused by saliva washout and enhances overall treatment effectiveness.

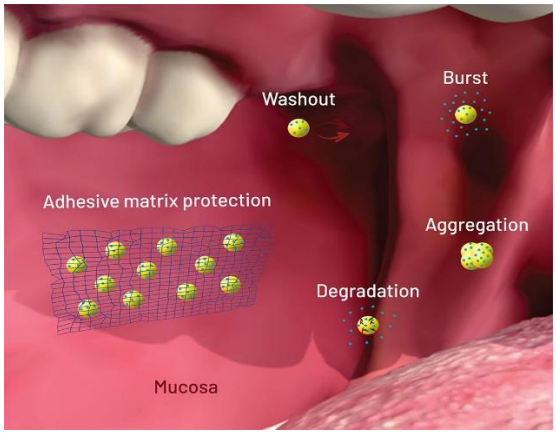


Fig3: Adhesive matrix protection

Mechanism of muco-adhesion

For a bio-adhesive system, it typically progresses through three distinct physical and chemical phases:

- **Wetting and Swelling:** The process begins when the bio-adhesive polymer absorbs water from the mucous membrane. This causes the polymer to swell, creating intimate contact and "wetting" the interface between the delivery system and the biological tissue.
- **Structural Penetration:** Once the polymer is hydrated, its chains gain mobility. These chains begin to physically penetrate the surface layers of the mucosal tissue.
- **Intermolecular Interpenetration:** The polymer chains and the mucin glycoproteins of the mucus layer entangle with one another. Following this physical intertwining, weak chemical interactions—such as hydrogen bonds, van der Waals forces, and electrostatic attractions.

Choline Salicylate

Choline salicylate is a water-soluble non-steroidal anti-inflammatory drug (NSAID) widely used in topical oral formulations for its analgesic and anti-inflammatory properties.Due to its high solubility and rapid absorption through the oral mucosa, it provides quick relief from pain and irritation.

Chemical Name (IUPAC)	2-hydroxyethyl, trimethylazanium2hydroxybenzoate.
Molecular Formula	$C_{12}H_{19}NO_4$.
Molecular Weight	241.28 g/mol.
Melting Point	49–51°C.
Category	Non-Steroidal Anti-Inflammatory Drug (NSAID)
Mechanism of Action	Inhibits prostaglandin synthesis to reduce pain and inflammation

Table1: Physiological properties of Choline Salicylate

Lignocaine Hydrochloride

Chemical Name (IUPAC)	2-(Diethylamino)-N-(2,6-dimethylphenyl) acetamide hydrochloride**.**
Molecular Formula	$C_{14}H_{22}N_2O$. HCl
Molecular Weight	270.80 g/mol
Melting Point	74–79°C
Category	Local Anaesthetic Agent
Mechanism of Action	Blocks nerve impulse conduction to provide pain relief

Table2: Physiological Properties of Lignocaine HCL

2. Material

OraTrust Gel containing Choline Salicylate and Lignocaine Hydrochloride was used as the therapeutic agent, combined with HPMC and Carbopol for their mucoadhesive properties. Glycerine was employed to provide structural flexibility.

S.NO	Ingredient	Purpose
1	Choline Salicylate	Anti-inflammatory, promotes healing of ulcer
2	Lignocaine	Local anaesthetic for immediate pain relief
3	HPMC	Film–forming and mucoadhesive polymer
4	Carbopol	Mucoadhesive polymer, improves adhesion
5	Glycerine	Plasticizer, gives flexibility
6	Ethanol + Distilled water	Solvent (dissolves drugs & polymers)

Table3: List of Material

3. Method of Preparation

Solvent Casting Method

The solvent casting method is a widely used technique for preparing thin films, particularly in the pharmaceutical and biomedical industries. It involves dissolving a polymer and active ingredient in a suitable solvent, casting the solution onto a substrate, and allowing the solvent to evaporate.

- **Formulation Composition:** The mucoadhesive patches were prepared by combining the active drug (Oratrust gel) with primary film-forming polymers (HPMC and Carbopol) for adhesion, glycerine as a plasticizing agent to ensure structural flexibility, and a hydro-alcoholic solvent system (water/ethanol) to facilitate a uniform blend of all components.

- **Polymer Base Preparation:** HPMC and Carbopol were hydrated in distilled water for 4-5 hours, followed by the addition of glycerin for flexibility. The mixture was stirred until uniform and left to stand to ensure a bubble-free solution through natural degassing.
- **Drug Integration:** The medicament was solubilized in a minimal quantity of solvent and blended into the polymeric mixture under constant agitation to ensure a homogeneous drug distribution.
- **Film Casting:** The mixture was poured into a glycerin-lubricated glass Petri dish and placed on a level surface to ensure uniform thickness. The films were then dried gradually at room temperature or in a hot-air oven at 40–45°C.
- **Patch Fabrication:** After drying, the film was carefully peeled and cut into cm dimensions. The resulting patches were then stored in a desiccator within airtight foil pouches to maintain stability.

Fig4: Mucoadhesive patch

4. Evaluation parameter

Physical appearance and surface texture of films: This parameter was checked simply by visual inspection of films and evaluation of texture by feel or touch.

Thickness: Using Vernier callipers with a least count of 0.01 mm, the thickness of the patch was calculated. The thickness uniformity was calculated at five different points and the average reading was taken.

Weight Variation: Three films of every formulation were selected randomly and individual weight of each 2cm × 1cm film was noted on digital balance. The average weight was calculated

Folding endurance: Three films of each formulation of 2 cm × 1 cm were cut by using sharp blade. Folding endurance was determined by repeatedly folding a small strip of film at the same place till it breaks. The number of times, the film could be folded at the same place without breaking gives the value of folding endurance.

Surface pH study: pH paper may be used for this purpose. Every patch was allowed to swell for 2 hours at room temperature by holding it in contact with 1 ml of distilled water and the pH was noted by bringing pH paper into contact with the surface of the patch and allowing it to balance for 1 minute (pH 6.5±0.5).

5. RESULT:

S.NO	Evaluation parameter	Results
1.	Appearance	Smooth solid
2.	Colour	Transparent
3.	Odour	Odourless
4.	Texture	Flexible / sticky
5.	Thickness	0.071mm
6.	Weight variation	125mg
7.	Folding Endurance	125
8.	Surface pH	6.5 ± 0.5

Table4: Evaluation of Mucoadhesive Oral Patches for the Management of Mouth Ulcers.

6. CONCLUSION:

The present investigation successfully focused on the formulation and evaluation of mucoadhesive buccal patches incorporating OraTrust Gel for effective oral ulcer management. The patches were prepared using the solvent casting technique with polymers such as HPMC and Carbopol, which provided suitable adhesive and film-forming characteristics. The prepared formulations exhibited satisfactory physicochemical properties including uniform thickness, acceptable weight consistency, good flexibility, and an appropriate surface pH suitable for buccal administration.

The developed buccal patches may enhance drug retention at the application site, improve therapeutic response, and provide prolonged drug release through the buccal mucosa while avoiding first-pass metabolism. In addition, the formulation may improve patient comfort and reduce the need for frequent drug application. Overall, the study suggests that mucoadhesive buccal patches can serve as a promising alternative for the effective treatment of mouth ulcers.

7. REFERRENCES:

1. Ziyi Pan, Xu Zhang, Wangni Xie, Jing Cui, Yue Wang “Revisited and innovative perspectives of oral ulcer: from biological specificity to local treatment” Frontiers in Bioengineering and Biotechnology 2024.
2. Mohit and Md. Sadique Hussain “A brief review on buccal drug delivery system: advantages, limitations, and impact on healthcare system” World Journal of Pharmaceutical Research 2021.
3. Anu A. L, Prasobh G. R, Subash Chandran M. P, Juno S, Subodh S. Satheesh “A review on mucoadhesive bilayer buccal patches” World Journal of Pharmaceutical Research 2020.
4. Karande Trupti, Pawar Sanika, Kasabe Manisha, Korde Shweta “Pathophysiology of Mouth Ulcers” International Journal of Research Publication and Reviews 2025.
5. Shery Jacob, Anroop B. Nair, Jigar Shah, Sai H. S. Boddu, Bapi Gorain “An Updated Overview of the Emerging Role of Patch and Film-Based Buccal Delivery System” Multidisciplinary Digital Publishing Institute 2021
6. Sonal Jadhav, Isha Kanoj, Yashpal M. more “A review mucoadhesive buccal patches” World Journal of Pharmaceutical 2025.
7. Gitanjali a. chavan, Aarti s. tawani, Yogesh n. gavhane “Buccal Patches: A Promising Buccal Bio-adhesive Drug Delivery System - A Review” International Journal of Pharmacy and Pharmaceutical Research 2020.
8. Christina Viju John, Nisarga Arun Vavre, Shilpa Sampat Sawant, Abhishek Lalan Sharma, Kajal Shankar Shah and Shrutika Dipesh Patil “Oral mucoadhesive drug delivery system: Formulation strategies and evaluation techniques” World Journal of Advanced Research and Reviews 2024.

9. Lewis Shipp, Fang Liu, Laxmi Kerai-Varsani, Tochukwu C. Okwuosa "Buccal films: A review of therapeutic opportunities, formulations & relevant evaluation approaches" Journal of Controlled Release 2022.
10. Chinna Reddy P, Chaitanya K.S.C., Madhusudan Rao Y "A review on bio-adhesive buccal drug delivery systems: current status of formulation and evaluation methods" DARU Journal of Pharmaceutical Sciences Vol. 19, No.6 2011.
11. J Thimmasetty, Gs Pandey and Pr Sathesh Babu "Design and In Vivo Evaluation of Carvedilol Buccal Mucoadhesive Patches" Pak. J. Pharm. Sci., Vol.21, No.3, July 2008.
12. Natallia V. Dubashynskaya and Yury A. Skorik "Patches as Polymeric Systems for Improved Delivery of Topical Corticosteroids: Advances and Future Perspectives" International Journal of Molecular Sciences 2022.
13. Eleti Bunny Priya, R. Shireesh Kiran, Dr. T. Rama Rao "A Review on Mucoadhesive Tablets by Anti-Ulcer Drug Esomeprazole" International Journal of Novel Research and Development 2024.