

REVIEW ON LOZENGES: A TREATMENT OF MOUTH ULCERS

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ABSTRACT

Mouth ulcers are a prevalent issue that might occasionally indicate a gastrointestinal illness. Although patients with oral ulcer signs and symptoms are occasionally referred to gastroenterology clinics, the ulcers typically do not indicate gastrointestinal disorders. Within The term "breach" refers to wounds in the underlying connective tissue, the epithelium, or both. Oral ulceration is the most common oral mucosal lesion. Patients with oral cavity ulcers may primarily see a general practitioner or a dentist. Ulcerations can be categorized according to three parameters: length of onset; number of ulcers; and etiological factors. An ulcerative lesion that persists for two weeks is classed as a chronic ulcer. Acute ulcers are usually painful and last no more than two weeks but chronic ulcers can last more than two weeks and recurrent ulcers have a

history of similar occurrences with uneven healing.^[1] An overactive immune response can cause prolonged healing, increased fibrosis, and scar formation, all of which hinder cutaneous wound healing. Chronic inflammation is a hallmark of delayed wound healing. Appropriate mucosal adhesion materials are essential for reducing discomfort and accelerating the healing process. In order to achieve this, the review thoroughly examines the anatomical and structural features of the oral cavity, clarifies the mechanisms by which oral ulcers heal, investigates the elements that lead to scar-free healing in the oral mucosa, and looks into the use of mucosal adhesive materials as drug delivery systems. This project aims to provide fresh ideas and insights for the management of mouth ulcers.^[2]

KEYWORDS: Mouth ulcers; Lozenges; Chlorhexidine gluconate; Drug delivery; Buccal therapy.

1. INTRODUCTION

Ulcers can be roughly categorized as either acute (short term) or chronic (long term) based on their duration. Traumatic ulcers, aphthous ulcers, herpetic ulcers, and chancres are examples of acute ulcers that go away on their own after three weeks. Major aphthous ulcers, ulcers from odontogenic infections, malignant ulcers, gummas, ulcers from crippling systemic diseases, and some traumatic ulcers (with a persisting traumatic feature) are examples of chronic ulcers that last for weeks or months. Additionally, depending on how they are presented, they can be typed as single or several. A single ulcerative lesion may be the result of a malignancy, trauma, or infection. Viral infections and autoimmune illnesses can cause multiple lesions, which can manifest as several ulcerations. A history of comparable episodes and sporadic healing may be seen in recurrent ulcers. The ulcers can range in size from a few millimetres to centimetres, and they can occasionally cause fever and localized lymphadenopathy. Oral ulcers can occasionally be difficult to diagnose, thus it's crucial to take the differential diagnosis into account. When taking a history, it's important to note the length of time, any accompanying symptoms, any recurring patterns, and any related systemic disorders.^[3] As the most prevalent oral ulcerative disorder, chronic recurrent oral aphthous ulcers require adequate treatment. Anaesthetics, corticosteroids, and topical antiseptics may be applied (source). However, avoiding hard and acidic meals that irritate the mouth is crucial for preventing oral ulcer flare-ups. Individualized management is necessary for optimal treatment, according to the ulcers' frequency and severity. This emphasizes that in order to guide effective therapeutic decision-making, a comprehensive awareness of the clinical picture and its concomitant elements is necessary. Furthermore, oral aphthous ulcers are among the most common symptoms in IBD patients; therefore, it is a systemic illness that can emerge as both intestinal and mouth symptoms.^[4]



Figure no. 1 mouth ulcer.

2. Soft Lozenges

Soft lozenges have gained the most popularity due to their versatility and ease of spontaneous preparation. They are designed to either be chewed or to release drugs gradually in the mouth. It is able to PEG 1000 and PEG 1450, or sugar-acacia base can be used to make several soft candies. They are easy to use convenient to carry easy to store and generally pleasant tasting.^[10] Soft lozenges are comparable to the "confection," a traditional drug that is making resurgence. Confections are described as soft, highly saccharinated masses that contain medicinal substances. The use of polymers (polyethylene glycols) as the matrix for the dosage form is primarily responsible for the improvement in their current use. They are often tasty, simple to use, portable, and easy to store at room temperature. Lozenges made of polyethylene glycol may be hygroscopic and soften in hot temperatures. As a result, it should be advised to store in a cool, dry location.^[13]



Figure no. 2 soft lozenges.

3. Drug Profile

1. Chlorhexidine Gluconate^[11]

Chlorhexidine gluconate (CHG), with the chemical formula $C_{22}H_{30}Cl_2N_{10}$, has antimicrobial qualities is used to cleanse skin and sanitize surgical instruments before to surgery because of its antibacterial properties.

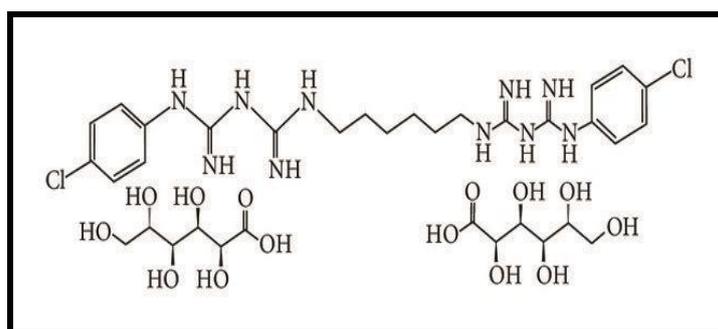


Figure no. 3: Chlorhexidine gluconate structure.

The biguanide chlorhexidine penetrates both the inner and outer cell membranes of gram-positive and gram-negative bacteria, rendering them inert. It tends to stick to skin and mucous membranes. Its antiviral effectiveness varies, mycobacteria are resistant to it, and spores are unaffected. Gluconic acid and chlorhexidine gluconate (CHG) are commonly used together. The bactericidal effect of CHG increases with its concentration. CHG may have an impact on a range of bacteria at dosages as high as 1%, according to a controlled in-vitro investigation. Salmonella and Escherichia coli were the most susceptible bacteria to CHG, exhibiting 100% bacterial suppression at levels below 0.01%. It is also used to treat wounds, prevent urinary catheter obstructions, lessen tooth plaque, and treat oral yeast infections. Chlorhexidine gluconate (CHG) solution is a broad-spectrum antibacterial medication that works on microbes and promotes wound healing. CHG interacts with bacterial lipids. It also inhibits essential enzymes in microbes, causing metabolic abnormalities and impeding reproduction; it binds to DNA, preventing transcription and microbial replication; and it causes structural and functional disruptions in cell membranes, ultimately leading to cell lysis and death.^[12]

4. Need For Lozenges In Mouth Ulcer Therapy

Mouth ulcers are uncomfortable oral mucosal lesions that make eating, speaking, and swallowing difficult. Conventional dose forms, such as mouthwashes, gels, or ointments, only offer short-term comfort because saliva quickly removes them and they are unable to stay in contact with the afflicted area for an extended period of time.

Therefore, a dosage form that may remain in the mouth for a longer period of time and transport the medication straight to the ulcer site is required.

Lozenges Are Made Specifically For This Use

1. Extended Local Action

Lozenges deliver medication continuously because they disintegrate slowly in the mouth. The medication is more effective since it stays in contact with the ulcer surface for a longer period of time.

2. Drug Delivery Directly

They administer medication directly to the oral mucosa, where the ulcer is located. This minimizes the need for systemic (whole-body) medication and guarantees quicker relief.

3. Healing and Pain Reduction

Anesthetic, antibacterial, anti-inflammatory, or herbal components may be found in lozenges. These promote quicker healing, infection prevention, and pain reduction.

4. Improved Patient Adherence

Lozenges are ideal for people of all ages because they are portable, tasty, and simple to use. They are better than liquid mouthwashes or bitter gels.

5. Diminished adverse reaction

Lozenges have fewer systemic side effects because they operate locally, allowing only a minimal amount of medication to enter the bloodstream.

5. Advantages^[7]

- Administering medication to elderly and pediatric patients is simple.
- The mouth cavity has both local and systemic effects.
- A longer duration of drug interaction.
- Steer clear of first-pass medication metabolism.
- Water is not necessary for ingestion.
- Suitable for those with dysphasia, or trouble swallowing.
- If the dosage is not required, lozenge is removed.
- Reduced production time.
- Production costs are lower.
- It gives the mouth a pleasing taste and flavor.
- Improved patient adherence.

6. MECHANISM OF ACTION OF LOZENGES

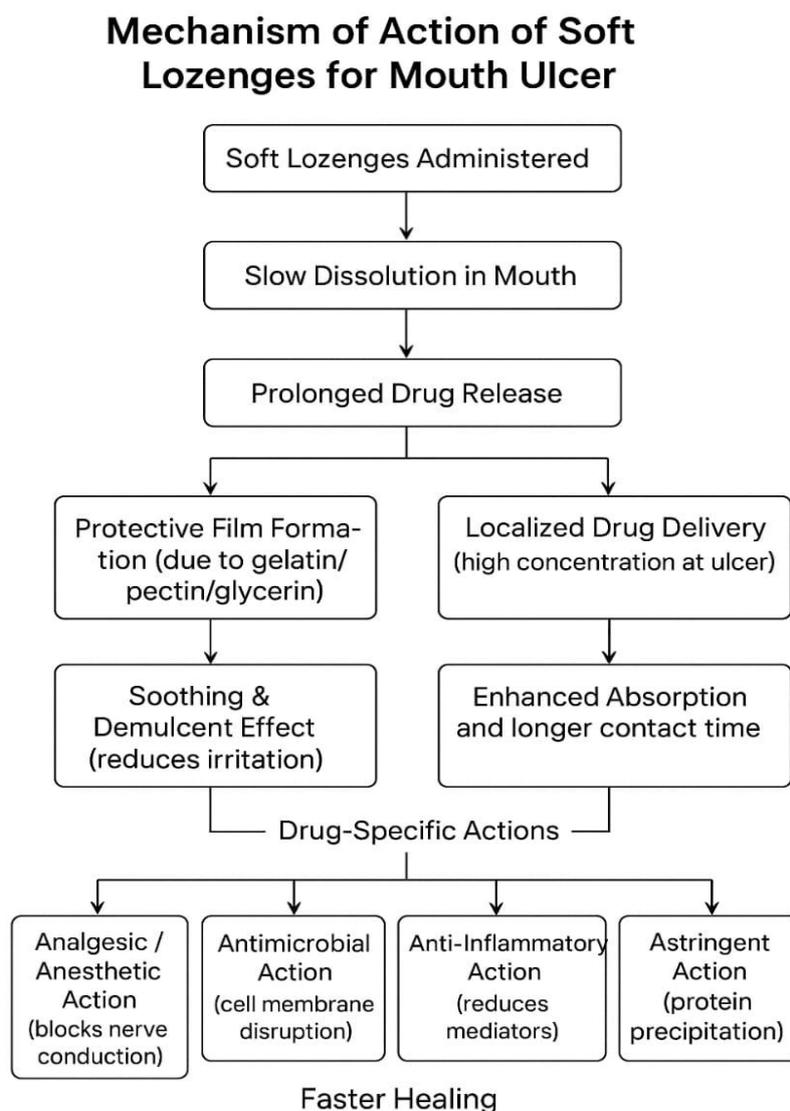


Figure no.4: Mechanism of Action of Chlorhexidine Gluconate.

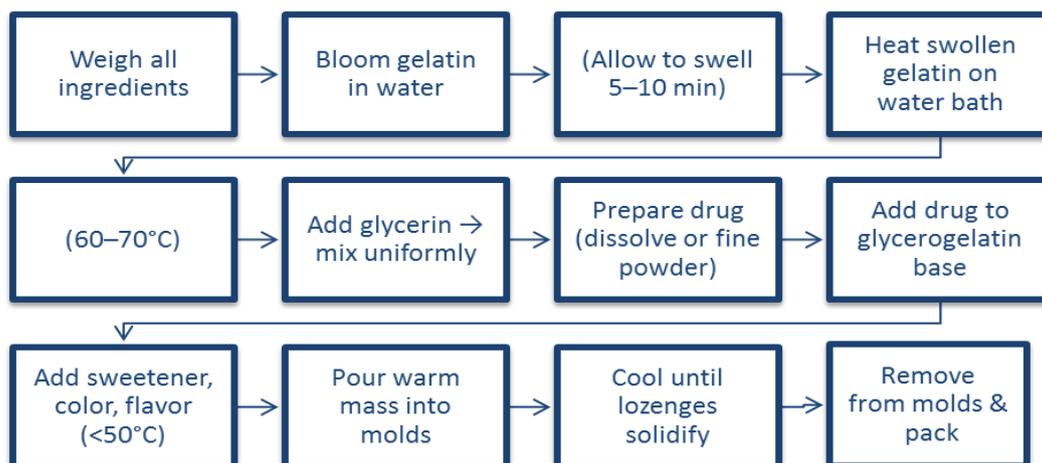
7. METHODOLOGY

7.1 Formulation of Lozenges^[6]

Table no. 1: Formulation of Lozenges.

SR.NO.	INGREDIENTS	ROLE
1	Phenol	Local anesthetics
2	Menthol	Flavoring and soothing agent
3	Citric acid	Taste enhancer, salivary stimulant
4	Sorbitol	Sweetener
5	Chlorhexidine gluconate	Antimicrobial agent
6	Glucose syrup	Binder
7	Gelatin	Base, give structure
8	Glycerin	Plasticizer, provide softness

7.2 Method of Preparation



7.3 Evaluation of lozenges

- **Organoleptic properties:** visual inspection to evaluate odour, test, colour, and overall appearance. This is crucial for patient acceptability.^[5]
- **Weight variation:** To perform the USP weight variation test, 20 lozenges are weighed separately. The average is then calculated and compared as follows.^[5]



Figure no.5 weighing balance.

- **Friability:** Friability testing is done for the same purpose as hardness testing. Soft lozenges typically have a low friability (tendency to crumble) with an acceptable value generally considered to be less than 1%. This low friability ensures the lozenges are resistant to breakage during handling, transport and storage, while still being able to dissolve or erode slowly in mouth as intended.^[5]



Figure no. 6 friability tester.

- **In-vitro drug release:** This test, commonly known as the dissolution test, is conducted using USP-II paddle-type dissolving. The primary in vitro test for soft lozenges is simulation of how the drug is release in oral cavity. Standard methods are often insufficient for predicting in vivo performance, leading to development of specialized method.^[5]



Figure no. 7: Dissolution Test Apparatus.

- **Disintegration test:** Lozenges' disintegration time is measured using USP Disintegration instrument. The rate at which the medicine dissolves in the lozenges determines the rate of drug absorption. The effectiveness of lozenges is directly correlated with their rate of dissolving and bioavailability.^[5]

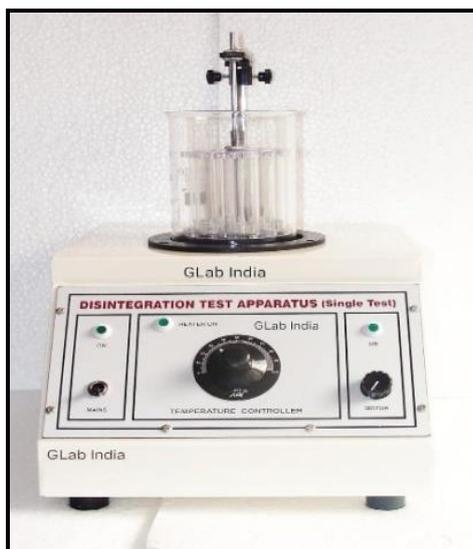


Figure no. 8: Disintegration Test Apparatus.

- **Diameter and Thickness:** Measured using of vernier calliper to ensure uniformity in size, which is important for packaging and handling.^[5]
- **Moisture Content Analysis:** determines the percentage of moisture in the final product using methods like gravimetric method or Karl Fischer titration, which is important for stability and preventing microbial growth.^[5]



Figure No. 9: Hot Air Oven.

8. Storage

"This preparation should be stored out of children's reach and out of direct sunlight. It needs to be kept free from dampness.^[9]

9. Packaging

Hygroscopic in nature on a local scale for complex packaging and more. Since the adoption. Each unit is individually wrapped in a polymeric moisture barrier and placed in a sturdy or moisture-resistant glass, polyvinyl chloride, or metal container coated in aluminium foil or cellophane membrane.^[9]

10. CONCLUSION

Lozenges are an effective and time-saving composition. For pediatric patients, they are especially popular and well-liked. Children are best served by medicated lozenges, which are frequently used to treat sore throats and throat infections. Enhanced patient compliance, comfort, and efficient treatment with a quick onset of action are among the benefits of lozenges. They are also economically feasible, require a lower dosage, and require fewer doses. Lozenges have made a name for themselves in the pharmaceutical industry and will probably continue to do so in the future.^[8]

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