

**TO FORMULATE AND EVALUATE BENZOCAINE LOZENGES FOR OPTIMIZED
LOCAL TREATMENT OF MOUTH ULCERS WITH IMPROVED PATIENT
COMPLIANCE**

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ABSTRACT

Mouth ulcers (aphthous ulcers) are lesions in the oral mucosa, which cause pain and may affect eating, talking, and even affect the quality of life of an individual. Treatment options such as application of topical gels may help alleviate the condition temporarily; however, patient compliance is still affected by the bad taste and difficulty in applying the medication. This study intends to prepare medicated lozenges, which have Benzocaine as active ingredient to manage cases of mouth ulcers. The use of medicated lozenges ensures prolonged retention of the drug in the oral cavity, resulting in sustained release and enhanced effect. Lozenges were formulated using sucrose matrix and excipients appropriate for their purpose. These lozenges were subjected to various evaluations such as weight variation, hardness, and dissolution. Results obtained show that the medicated lozenges have acceptable physicochemical properties and have enhanced patient acceptance because of palatability. Therefore, medicated lozenges can be considered an ideal substitute for conventional gel formulations used for mouth ulcers

KEYWORDS: Mouth ulcers, Aphthous ulcers, Medicated lozenges, Benzocaine, Oral mucosa, Sustained drug release, Patient compliance, Topical drug delivery, Physicochemical evaluation, Palatability).

INTRODUCTION

Oral ulcers are among the most frequently encountered painful lesions of the oral cavity, affecting a significant proportion of the population at some point in their lifetime. These lesions are characterized by disruption of the oral mucosal epithelium, resulting in localized inflammation, pain, and difficulty in eating, speaking, and maintaining oral hygiene.^[1] Oral ulcers, also known as aphthous ulcers, are one of the most common lesions of the oral mucosa. These are painful, shallow lesions that typically appear on the inner lining of the lips, cheeks, tongue, or soft palate. Clinically, they present as round or oval ulcers with a yellow or white necrotic center surrounded by an erythematous halo. These lesions can cause significant discomfort, affecting eating, swallowing, and speech.^[3,4]

Oral ulcers are a common condition that can result from many underlying causes, although the exact cause is not completely known. However, some predisposing factors for the condition have been outlined. Some predisposing factors include injuries to the mouth such as biting oneself, nutrient deficiencies such as vitamin B12, iron, and folic acid, hormones, stress, food allergies, and immune disorders.^[2,1] Oral ulcers are a common condition that can result from many underlying causes, although the exact cause is not completely known. However, some predisposing factors for the condition have been outlined. Some predisposing factors include injuries to the mouth such as biting oneself, nutrient deficiencies such as vitamin B12, iron, and folic acid, hormones, stress, food allergies, and immune disorders.^[5,2]

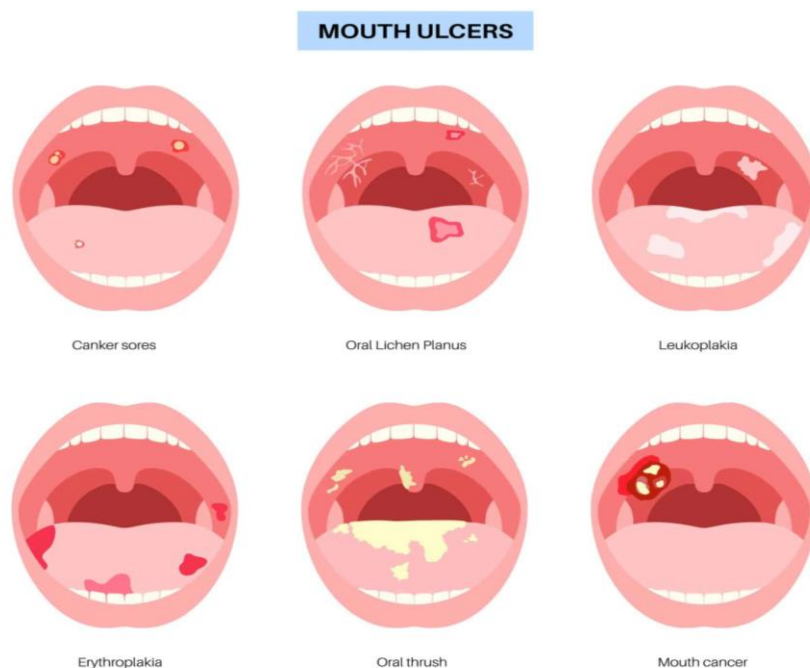
The history of treating mouth ulcers can be traced back to ancient forms of medicine like Ayurvedic and herbal treatments, which used natural remedies to soothe the ulcers. However, with the development of medicine at the end of the nineteenth century and the beginning of the twentieth century, pharmacological drugs became available and provided quick relief.^[6]

Benzocaine belongs to the ester group of local anesthetics and is commonly used as a topical analgesic in oral and skin disorders. It works through the inhibition of sodium ion channels in the nerves, preventing the passage of impulses and causing numbness. Benzocaine is most effective when applied orally because of its quick effects and low systemic absorption rate.^[7] Lozenges are solid formulations that are meant to disintegrate gradually in the mouth, allowing the gradual release of the medicinal component. They offer localized administration of the medicine, increase patient adherence, and increase the efficacy of the treatment

through prolonged interaction with the target site.^[8] Preparation of benzocaine lozenges has been identified as one of the strategies that can be effectively used to manage oral ulcers. With the use of the anaesthetic nature of benzocaine in the development of lozenges, it is possible to ensure that the drug will have a prolonged effect. Thus, the main objective of the current research is to develop and evaluate benzocaine lozenges for oral ulcers.^[9]

Oral Mouth ulcer (Apthous ulcers)

Definition of oral ulcers is the formation of painful sores on the surface of the oral mucosa that causes erosion of the epithelial lining, thus creating openings in the mucosa. They are mostly round or oval in shape and have a yellow or white necrosis center with a red halo surroundin them. Their occurrence is common within the mouth including the inner lips, cheeks, tongue, and soft palate.^[5]



Types of Oral Ulcers

1. Minor Aphthous Ulcer

Among all ulcers, minor aphthous ulcers are the most prevalent, comprising almost 70-80% of all oral ulcers. The ulcers are of small dimensions, usually not more than 1 cm in size, are shallow and have clearly demarcated erythematous edges along with a yellowish or whitish interior. Minor ulcers tend to appear in regions which do not have keratinized mucosa, i.e., inner lips, inner cheeks, and bottom of the mouth. Minor ulcers heal in 7-14 days, leaving no scar and causing minimal pain.

2. Major Aphthous Ulcer

Large aphthous ulcers, also referred to as Sutton's ulcers, occur rarely but tend to be serious in nature. Large ulcers

are characterized by their size that is greater than 1 centimeter and their depth. Moreover, they are very painful and usually last for several weeks. They often cause difficulty with speaking and eating. Large ulcers heal slower and frequently lead to scarring once they heal.

3. Herpetiform Ulcer

Herpetiform ulcers are the rarest form of ulcers, which are marked by many tiny ulcers numbering between 10 and 100. The ulcers are quite tiny (1–2 mm in size), but they join up to create large ulcers. Contrary to expectations, herpetiform ulcers are not a result of herpes virus 3.infection. The ulcers are excruciatingly painful and can heal without scars in a period of 7 to 14 days.^[10]

Etiology of Oral Mouth Ulcers

The exact cause of oral mouth ulcers (recurrent aphthous stomatitis) is not fully understood; however, several predisposing and triggering factors have been identified. These factors contribute either individually or in combination to the development of ulcers.

1. Local Trauma

- Trauma Occurring Locally
- Unintentional biting of the cheeks, fractured teeth, improperly fitted dentures, and vigorous tooth brushing may all harm the oral mucosa.
- The resultant physical trauma causes injury to the mucosal epithelium, thus causing ulcers.

2. Nutritional Deficiencies

- Deficiency of vital nutrients like vitamin B12, iron, and folic acid is often related to mouth ulcers.
- Vital nutrients help in epithelial cells regeneration and repair, and lack of them results in mucosal atrophy and ulcer formation.

3. Stress and Psychological Factors

- Emotional stress and anxiety are common triggering factors.
- Stress may alter immune function and increase inflammatory mediators, leading to ulcer formation.

4. Hormonal Changes

- Fluctuations in hormonal levels, particularly in women during their menstrual periods, pregnancy, or menopause, may contribute to the formation of oral ulcers.
- These hormonal changes may impact the mucosa's integrity and immune response

5. Immune System Dysfunction

- Oral ulcerations are also linked to alterations in the immune response, especially those affecting T cell-mediated immunity.
- Excessive production of cytokines results in inflammation and destruction of mucosa.

6. Food Hypersensitivity and Allergies

- Certain foods such as chocolate, nuts, acidic fruits, and spicy foods may trigger ulcers in sensitive individuals.
- This may be due to allergic or hypersensitivity reactions.

7. Microbial Factors

- Although not primarily infectious, bacteria and viruses may play a secondary role in aggravating the condition.
- However, aphthous ulcers are not directly caused by viral infections.

8. Genetic Predisposition

- Family history of recurrent aphthous ulcers suggests a genetic component.

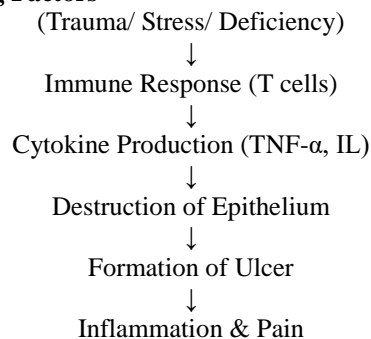
- Individuals with affected parents are more likely to develop ulcers.

Pathophysiology of Oral Mouth Ulcers

However, the complete mechanism involved in the pathogenesis of oral ulcers has yet to be elucidated completely. In fact, it has been stated to be an immune-mediated condition involving inflammatory factors, which is responsible for the destruction of epithelial cells of the oral cavity.

First, the initiating factor triggers the process of immune system activation. As a result of this, T-cells get activated and secrete various inflammatory substances including TNF- α and interleukins.^[12] This causes injury to the epithelial cells of the mucosal lining. Consequently, the disruption in the integrity of the mucosa takes place, resulting in the development of the ulcers. The area gets swollen, turning red with the presence of a necrotic core under a yellow fibrinous layer. Nerve ending exposure increases the sensation of pain. Therefore, it can be summarized that ulcers in the mouth are formed due to immune mediated damage of the oral epithelium tissue.^[11]

Triggering Factors



Common clinical Features

1. Pain: Most significant symptom, intensity varying according to type of ulcer.
2. Burning Soreness: Usually occurs prior to formation of an ulcer within 24-48 hours
3. Appearance of Ulcer: Lesion in round or oval shape, with yellowish or whitish color in central part and reddened halo around.
4. Location: Found in areas where non-keratinized mucosa occurs, such as inner side of lips, cheeks, tongue, and soft palate.
5. Size: Depends on type, minor being less than 1 cm, and major being more than 1 cm.
6. Number of Ulcers: May be single or multiple (herpetiform).
7. Difficulties in Chewing and Talking: Caused by pain and irritation.
8. Pattern of Healing: Minor heals with no scar, while major causes scarring.^[10]

Different Treatments Administered in Mouth Ulcers of Oral Cavity

The treatment options for mouth ulcers of oral cavity are designed to minimize pain, inflammation, prevent infection, and facilitate wound healing. The selection of appropriate treatment modality is based on the severity, frequency, and nature of ulcers. Many different treatments, including topical and systemic ones, are utilized to manage mouth ulcers efficiently.

1. Topical Anaesthetic Agents

Topical anaesthetic agents are frequently applied to numb the painful site temporarily. They act by blocking neural conduction and minimizing discomfort during chewing and talking. One of the most commonly used topical anaesthetics agents in the treatment of mouth ulcers is benzocaine.^[15] Topical anaesthetics create a sensation of numbness, thus relieving pain. Benzocaine, lidocaine, and dyclonine are often used topical anaesthetics. This treatment enhances patient comfort during chewing, swallowing, and talking.^[16]

2. Topical Corticosteroid Therapy

The topical application of corticosteroids is common practice for the treatment of oral ulcers since they decrease the inflammatory response, inhibit immunity, and facilitate healing. Examples of topical corticosteroids include triamcinolone acetonide, fluocinonide, and clobetasol, which are typically administered as gels, creams, or mouthwashes. They are especially useful for the treatment of recurrent aphthous stomatitis.^[11,12]

3. Antiseptic Mouthwash Therapy

Antiseptic mouthwashes play an important role in decreasing bacterial burden and preventing secondary infections. Chlorhexidine gluconate mouthwash is usually prescribed owing to its broad-spectrum antibacterial effects and ulcer-healing property.^[17]

4. Antibiotic Treatment

When there is recurrence and severity, patients are advised to use topical antibiotics like tetracycline and doxycycline mouth rinse. The role of these medications is to minimize colonization by bacteria and inflammation.^[18,19]

5. Anti-Inflammatory Treatment

Anti-inflammatory agents like benzydamine hydrochloride mouthwash are highly effective in treating pain and inflammation. These agents are often used for managing oral ulcers symptomatically.^[19]

6. Nutritional Supplement Therapy

Vitamin B12, folic acid, zinc, and iron supplementation therapy proves helpful for individuals who lack these nutrients. These therapies assist in enhancing mucosal healing and minimizing the occurrence rate.^[20,21]

7. Immunomodulatory Treatments

In case of persistent recurrent ulcers, systemic immunosuppressive medications like colchicine, thalidomide, and dapsone can be used. This helps in balancing immune responses and reducing the seriousness of ulcers.^[22,23]

8. Herbal Medicine

Natural products such as aloe vera gel, glycyrrhiza, turmeric, and honey exhibit anti-inflammatory and wound healing capabilities. These natural remedies are gaining popularity owing to lower side effects.^[24,25,26]

9. Laser Therapy

Low-level laser therapy (LLT) is a contemporary non-invasive treatment method, which reduces pain, inflammation, and healing time by promoting tissue regeneration and enhancing blood flow.^[27]

10. Drug Delivery System

There have been new developments in the field of pharmaceutical science that have led to the creation of innovative drug delivery systems for the effective treatment of oral mouth ulcers. The conventional drug delivery system of ointment, gel, and mouth rinse has its own set of limitations, such as short duration of action in the oral cavity, non-compliance on part of patients, and quick elimination through saliva.^[28] There are now advanced localized drug delivery systems available that include lozenges, buccal tablet, mucoadhesive patch, oral film, microsphere, hydrogel, and nanoparticle-based formulation. Among these advanced drug delivery systems, the lozenge is one of the most commonly used forms of medicine for the treatment of oral mouth ulcers because it dissolves slowly in the mouth. This leads to prolonged contact between the medicine and oral membrane. There are several lozenges that contain benzocaine as a local anesthetic, which provides rapid pain relief.^[29,30] As such, novel drug delivery systems possess several advantages that include a long drug retention period, increased effectiveness, better patient adherence, decreased dosing regimen, and localization, which make them viable candidates in the management of oral ulcers.^[31,32]

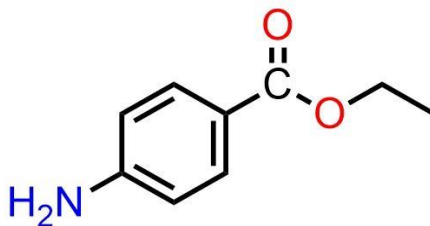
AIM

The aim of this study is to develop and test the efficacy of benzocaine medicated lozenges for treating oral mouth ulcers and ensuring sustained local pain relief with better compliance among patients.

OBJECTIVE

1. Preparation of benzocaine lozenges with appropriate pharmaceutical excipients.
2. Providing local anaesthesia to oral mouth ulcers.
3. Improving patient compliance with the medicated lozenges dosage form.
4. Investigation into the organoleptic characteristics of the formulated lozenges, including taste and appearance.

5. Optimization of the formulated lozenges for sustained drug delivery.



Benzocaine

Drug of Choice: Benzocaine

Parameter	Description
Generic Name	Benzocaine
Category	Local anaesthetics
Chemical Name	Ethyl p-aminobenzoate
Molecular formula	C ₉ H ₁₁ NO ₂
Molecular Weight	165.19 g/mol
Structure	The structure of benzocaine is the para-aminobenzoic acid ester structure with the presence of an ethyl group bound to the carboxyl group
solubility	Slightly soluble in water but readily soluble in alcohol and chloroform.
Melting Point	88-90°C
Storage Condition	Store in a cool, dry place away from light and moisture. ^[34,35]

Mechanism of action

The mode of action of benzocaine is to create a reversible blockade of sodium channels located in the cell membrane of nerve cells. It is responsible for preventing the conduction of nerve impulses. This results in the numbing effect, thus creating pain relief where the drug was applied. The poor solubility of benzocaine in water limits its systemic uptake.^[33]

Dose of Benzocaine in Lozenges for Oral Mouth Ulcer

The dosage for benzocaine for topical applications orally is between 2 to 10 mg per lozenge. Benzocaine works quickly because it acts as a local anesthetic and gives relief from pain and irritation caused by the oral ulcers in the mouth.^[34] The lower dose is preferable in oral preparations to avoid any complications but still retain its effect as an analgesic. Benzocaine works scientifically through the reversible inhibition of voltage-sensitive sodium channels in the membranes of peripheral nerves that prevent transmission impulses in the nerves to bring about temporary anesthesia. Due to its poor solubility in water, benzocaine is limited to the area where it is applied to the body, making it an ideal choice for oral application like in lozenges.^[35,38]

In the oral treatment of ulcers, a concentration of 5 mg per lozenge has been found to be effective in providing adequate analgesia without causing any side effects. Concentrations lower than 5 mg (2-3 mg) do not produce adequate pain relief, but a concentration higher than 10

mg may lead to irritation and toxicity of the body due to excessive use.^[37]

The distribution of benzocaine is uniform in the sugar or polymer matrix used in preparation of its lozenge formulation for controlled drug dissolution and continuous drug interaction with oral mucosa.^[38] The slow dissolution of the lozenge leads to effective drug delivery to the site of application,^[39] improved efficacy of drug action, and increased duration of analgesia. Therefore, the use of benzocaine lozenges in doses of about 5 mg per lozenge is regarded as an effective approach in localized treatment of oral ulcers with improved efficacy and patient compliance.^[40,41]

Uses of Benzocaine

1. Used as temporary analgesic remedy in cases of pain due to mouth ulcers.
2. Local anesthetic effect is seen in cases of sore throat.
3. Used as medicated lozenge, gel, spray, and ointment for oral analgesia.
4. Can help minimize pain and irritation during swallowing and talking.
5. Used for temporary relief of pain due to irritated gums.
6. Used in preparation to relieve pain during teething.
7. Used prior to minor dental and medical procedures as a pain reliever.
8. Also used in external preparations for minor skin irritations and itching.

9. Quickly numbs the area where it is applied.

10. Minimizes patient discomfort during oral ulcer therapy.

Excipient profile

Excipient	Category	Role in Lozenges
Sucrose	Sweetening agent and lozenge base	Improves taste, provides structural integrity, hardness, and slow dissolution of lozenges.
Dextrose	Sweetening agent and diluent	Enhances mouthfeel, improves taste, and helps in uniform drug distribution.
Acacia	Binder and mucoadhesive agent	Improves cohesiveness, stability, and prolongs retention time in oral cavity.
Gelatine	Binder and gelling agent	Provides elasticity, firmness, consistency, and improves texture of lozenges.
Saccharin Sodium	Artificial sweetening agent	Masks unpleasant taste of benzocaine and improves patient compliance.
Peppermint Oil	Flavoring agent	Provides refreshing sensation, improves taste, and enhances patient acceptability.
Magnesium Stearate	Lubricant	Reduces friction during formulation and prevents sticking to equipment surfaces. ^[38,40]

Formulation Table of Benzocaine Lozenges

Table: Composition of Benzocaine Lozenges.^[6,8,29,43]

Ingredients	Category	F1 (mg)	F2 (mg)	F3 (mg)
Benzocaine	Active drug	2mg	5mg	10mg
Sucrose	Sweetening agent / Base	850mg	847mg	842mg
Dextrose	Diluent / Sweetener	100mg	100mg	100mg
Acacia	Binder	20mg	20mg	20mg
Gelatine	Gelling agent	10mg	10mg	10mg
Peppermint Oil	Sweetening agent	5mg	5mg	5mg
Magnesium Stearate	Flavouring agent	5mg	5mg	5mg
Magnesium Stearate	Lubricant	5mg	5mg	5mg
Total weight	–	997mg	997mg	997mg

Lozenges formulation

Three benzocaine lozenge formulations, namely F1, F2, and F3, were developed using various amounts of benzocaine to enhance the effectiveness of pain relief. In formulating the lozenges, sucrose served as the principal constituent to act as a matrix material and sweetener because of its good taste and hardness formation capacity. The addition of dextrose enhanced the taste and consistency. To provide structure to the lozenges, acacia and gelatine were employed as binders. Artificial sweetener saccharin sodium was included to mask the taste of benzocaine. Peppermint oil was added to provide flavour. Magnesium stearate acted as a lubricant.^[6,43,29]

The formulated products were intended to deliver prolonged retention, prolonged effect of anaesthesia, enhanced compliance, and symptomatic relief of oral mouth ulcers.^[8]

Preparation Method of Benzocaine Lozenges

Heating and Congealing Technique: This technique was chosen due to its high frequency of application and efficiency in making medicated lozenges. In the process,

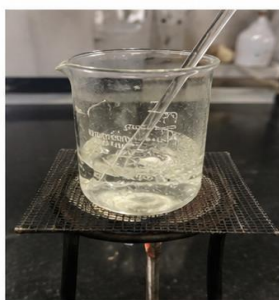
drug distribution will be uniform; hardness and dissolution properties will be adequate; and the final product will have improved stability and consumer acceptance.^[6,8,44]

Steps

1. All components used in the preparation were accurately weighed using a digital balance.
2. A solution of sucrose and dextrose in water and heating the mixture with constant stirring to make syrup.
3. Addition of hydrated acacia and gelatine to give more structural rigidity.
4. Slow addition of benzocaine into the mixture with constant stirring.
5. Addition of saccharin sodium and peppermint oil to improve taste and acceptance by patients.
6. Magnesium stearate was added to facilitate lubrication during moulding.
7. Moulding and cooling of the mass until the lozenge solidifies.
8. Storage of packaged products in an airtight place.



1. Weighing of ingredients



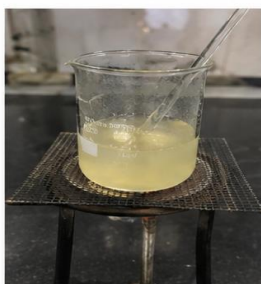
2. Preparation of syrup base (Sucrose + Dextrose)



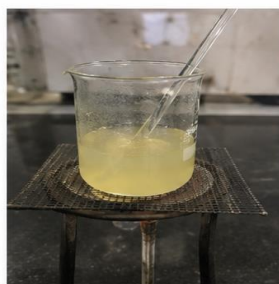
3. Addition of Acacia and Gelatin (Binders)



4. Drug (Benzocaine) incorporation



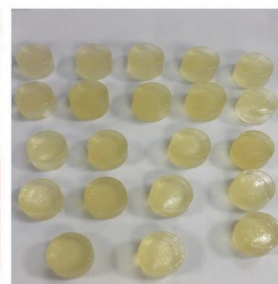
5. Addition of Saccharin Sodium and Peppermint oil



6. Addition of Magnesium stearate (Lubricant)



7. Pouring the mass into lozenge molds



8. Lozenges after cooling and removal from mold

PREPARATION OF BENZOCAINE LOZENGES IN COLLEGE LAB

Evaluation parameter	F1	F2	F3	Inference
Average Weight (mg)	996 ± 2.1	998 ± 1.8	997 ± 2.0	Within acceptable
Hardness (kg/cm ²)	4.2 ± 0.2	4.5 ± 0.3	4.8 ± 0.2	Adequate mechanical strength
Friability (%)	0.62%	0.58%	0.55%	Less than 1%
Drug Content (%)	98.4%	99.1%	99.5%	Uniform drug distribution
Taste Evaluation	Good	Very Good	Very Good	Acceptable palatability
Surface pH	6.7	6.8	6.8	Compatible with oral mucosa
Disintegration Time (min)	14min	16min	14 min	Sustained dissolution observed
In-vitro Drug Release (%)	92.3%	95.6%	97.1%	Effective drug release
Appearance	smooth	smooth	Smooth and glossy	Elegant formulation
stability	stable	stable	stable	No significant change

RESULT INTERPRETATION

The prepared benzocaine lozenges displayed satisfactory physicochemical parameters. Uniform weight variation and adequate hardness were observed among all preparations, showing that they had good physical strength. Friability values were observed below 1%, showing that there was sufficient resistance to abrasion while handling and transporting the preparations.^[6]

The drug content determination showed that benzocaine was uniformly distributed in all preparations. Near-neutral surface pH suggested compatibility with oral mucosa with little probability of irritation. Prolonged drug release was observed in the dissolution test results, which suggests that the lozenges have sustained effect on the mouth ulcer region.^[8] In all preparations tested, the one with optimum hardness, dissolution time, palatability, and drug release properties contained 5 mg of benzocaine, and that is preparation F2. Preparation F2 was therefore identified as the optimized formulation.^[45]

CONCLUSION

This research has been conducted to develop and evaluate the effectiveness of Benzocaine medicated lozenges for effective treatment of oral ulcers. Various formulations of Benzocaine lozenges have been developed using appropriate pharmaceutical excipients like sucrose, dextrose, acacia, gelatin, saccharin sodium, peppermint oil, and magnesium stearate by using the heating and congealing technique.

Various physicochemical evaluations of the formulated lozenges have been conducted that included weight variation, hardness, friability, uniformity of drug content, surface pH, disintegration time, dissolution studies, organoleptic evaluation, and stability testing. All formulations have passed various tests and provided satisfactory results.

Among all the formulations prepared, F2 which contained 5 mg of benzocaine proved to have the best

attributes like appropriate hardness, reduced friability, even drug content, satisfactory taste, sustained release of the drug, and stability. It also gave a sustained effect as a local anesthetic agent and improved patient compliance because it had slow dissolution in the mouth. Hence, benzocaine medicated lozenges can be said to be a viable option as a drug delivery system in the case of oral mouth ulcers owing to their rapid analgesic effect and better patient acceptability.

Future Prospects

Further studies, such as accelerated stability testing and clinical trials, could be performed to evaluate its efficacy. The developed Benzocaine medicated lozenges showed promising outcomes for the treatment of oral mouth ulcers. However, some more improvements and advancements in formulating and testing this formulation can be done.

For instance, future research can be directed towards the development of highly mucoadhesive lozenges, which would allow maintaining prolonged retention time in the oral cavity for enhanced delivery of active ingredients. Furthermore, inclusion of natural anti-inflammatory and wound-healing components like aloe vera, honey, curcumin, or herbal extracts alongside benzocaine can result in synergic effects during oral ulcer treatment.

Moreover, additional studies like accelerated stability studies, in-vivo tests, and even clinical trials can be carried out in order to study long-term safety, efficiency, and compliance of this preparation. Finally, taste-masking techniques and production of sugar-free lozenges might be used for treatment of diabetic and pediatric patients. Nanotechnology-based drug delivery systems can be another promising field for advancement. They include nanoparticles, nanofibers, and bioadhesive films that can significantly improve drug delivery and treatment of oral ulcers. In conclusion, Benzocaine medicated lozenges possess high future potential in treatment of oral mouth ulcers.

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