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DESIGN, DEVELOPMENT AND EVALUATION OF LOZENGES FOR MOUTH ULCER

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ABSTRACT

Lozenges are widely used solid dosage forms designed to dissolve slowly in the oral cavity, providing both local and systemic therapeutic effects. Historically utilized since the 20th century, lozenges remain an important and commercially viable drug delivery system due to their patient-friendly nature and ease of administration. This review highlights the formulation, evaluation, and applications of lozenges, emphasizing their versatility in incorporating a wide range of active pharmaceutical ingredients. Various types of lozenges, including hard candy lozenges, soft lozenges, and compressed tablet lozenges, are discussed along with their respective methods of preparation. The selection of excipients such as flavoring agents, sweeteners, and preservatives is critically reviewed to ensure palatability and stability. In addition, key evaluation parameters, quality control tests, packaging considerations, storage conditions, and dispensing practices are comprehensively covered. The advantages of lozenges, such as improved patient compliance, prolonged drug action, and targeted delivery, are examined alongside their limitations. Furthermore, examples of marketed formulations are presented to provide practical insights. Overall, lozenges demonstrate significant potential as an effective and innovative drug delivery system, with promising future prospects for both local and systemic therapies.

KEYWORDS: Bupivacaine HCl, Lozenges, Mouth Ulcers, Sustained Release, Local Anaesthetic, Oral Drug Delivery.

INTRODUCTION

Mouth Ulcer: Mouth ulcers are small, painful lesions that appear on the entrance's self-lubricating surface. They are still occasionally referred to as canker sores or aphthous sores. Consumption, eating, and talking are all uncomfortable due to these ulcers, which can significantly affect daily life. Among the things that could lead to their creation are stress, trauma, or underlying medical conditions. Effective therapies are required to manage symptoms and encourage healing.[1]

They can be made by moulding or by making hard candy lozenges with a base of cooked sugar. While hard candy lozenges are distinguished by their rigid, glassy structure created by boiling sugars to high degrees, moulded lozenges are sometimes referred to as pastilles.[9]

They are used for patients who have trouble swallowing solid oral dose forms, as well as for drugs that are meant to be given gradually in order to keep the drug level in the mouth steady or to soak the tissues in the throat with a medicated solution. In the past, lozenges have been used extensively to provide topical anaesthetics and to reduce minor sore throat pain and irritation.[3,9,18,19]

TYPES OF MOUTH ULCER[4]

Minor Aphthous Ulcers: usually less than 1 cm in diameter, are minor aphthous ulcers. oval or round in form. usually heal without leaving scars in one to two weeks.

Major Aphthous Ulcers: Usually larger than minor ulcers, with a diameter of more than 1 cm. It may be shaped erratically. Healing could take longer, and scarring might occur.

Herpetiform Ulcers: Each ulcer typically has a diameter of one to three millimeters. Small, oval or circular in form. They typically recover on their own in one to two weeks.[4]

BASIC TYPES OF LOZENGES[3,10,26]

Hard lozenges: Similar to how hard candy confections are formed, hard lozenges are typically made using sucrose or other sugars that result in a hardened, amorphous, glassy substance. Polymers like PEGs and HPMC can be added to delay the rate of dissolution. Compressed powders could be used to make another kind of hard lozenge. Clotrimazole troches (lozenges), which are huge, compressed tablets that dissolve gradually in the tongue, are one example of this. Dextrose, MCC, and povidone make up the tablet base material.

Soft lozenges: PEGs with a high enough molecular weight to dissolve slowly in saliva are frequently used to make soft lozenges. Hydrocolloids, like acacia, can also be used as an adhesive. This method of creating soft clotrimazole troches involves mixing the medication and acacia with melted PEG 1450 base, then pouring the mixture into troche-shaped cavities.

Chewable lozenges: Glycerinated gelatine, a mixture of glycerine, gelatine, and water, is the usual base for chewable lozenges. Drug, acacia, and suitable flavour and sweetening ingredients can be mixed with this base.[5]

ADVANTAGES[6]

Easy Administration: Patients who have trouble swallowing tablets or capsules can use lozenges since they are easy to use.

Local Action: They act directly and locally in the mouth and throat (e.g., for oral infections, coughs, and sore throats).

Palatability: They are frequently sweetened and flavoured, which makes them more enjoyable to consume, particularly for kids.

Extended Contact: By dissolving gradually, the medication can remain in contact with mucosal membranes for extended periods of time, increasing its therapeutic efficacy.

Convenience: Water-free, lightweight, and portable.

DISADVANTAGES[6]

Restricted Drug Types: Only medications that are stable in the mouth and throat are appropriate; medications that taste bad or irritate the oral mucosa are not.

Risk of Choking: Young children are particularly vulnerable to choking hazards.

Slow Onset: Compared to certain alternative dose forms (such as liquids or injections), medication release is slower.

Restricted Dose Size: The amount of active medication that can be added is limited.

Sugar Content: A lot of lozenges have sugar, which can cause tooth rot or cause issues for diabetics.

HARD CANDY LOZENGES

Hard candy lozenges are amorphous (no crystalline) or glassy combinations of sugar and other carbohydrates. These can be thought of as solid sugar syrups, and lozenges have long been used to administer topical anesthetics and antibiotics as well as to relieve minor sore throat pain and irritation. Lozenges are solid dosage forms with a variety of shapes that are meant to dissolve gradually in the oral cavity for either localized or systemic effects.

They often contain a medical drug and a flavouring element. Hard lozenges typically have a moisture level of 0.5 to 1.5%. They should dissolve or erode slowly and uniformly over a period of 5 to 10 minutes, not disintegrate, have a smooth surface texture, and have a pleasant flavour that masks the taste of the medicine.

The high temperature needed to prepare hard candy lozenges is one of their main drawbacks. The typical weight range for hard candy lozenges is 1.5 to 4.5 grams. Sorbitol and sugar are examples of excipients with demulcent actions that ease the discomfort of abraded tissue caused by irritation from coughing and sore throats. In fact, some of the active drug product may be absorbed through the buccal mucosa, avoiding the first-pass metabolism that happens when a medication is ingested and absorbed through the GI tract.[7-8]

FORMULATION PARAMETERS OF LOZENGES

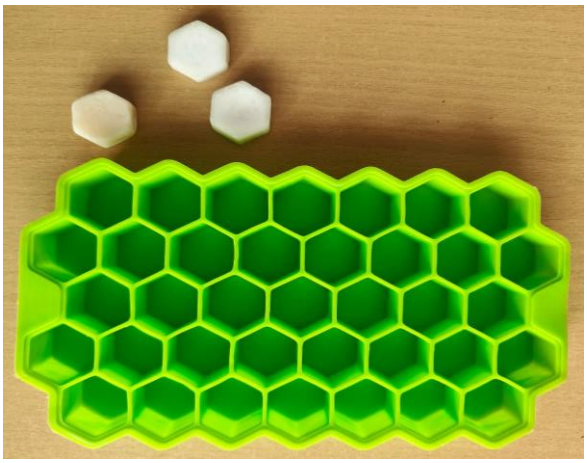
The formulation parameters of hard lozenges are important for ensuring their stability, effectiveness, texture, dissolution rate, and patient acceptability. In the present hard lozenge formulation, Bupivacaine was used as the active pharmaceutical ingredient (API) to provide the desired therapeutic action, particularly for pain relief and soothing effects in the oral cavity. The selection of excipients was carefully optimized to obtain lozenges with suitable hardness, taste, appearance, and dissolution characteristics. Mannitol was incorporated as a sweetening and bulking agent to improve palatability, provide a cooling sensation, and enhance the overall mouthfeel of the lozenges. Povidone (PVP) served as a binder to provide cohesiveness and maintain the structural integrity of the hard lozenges during manufacturing, handling, and storage. Stearic Acid was used as a lubricant to reduce friction, prevent sticking to molds or processing equipment, and facilitate smooth manufacturing operations. Glycerin acted as a plasticizer and humectant to maintain moisture balance, reduce brittleness, and improve the texture of the lozenges. Guar Gum was included as a thickening agent to control viscosity, improve consistency, and contribute to the desired texture of the formulation. Menthol was incorporated as a flavoring agent to mask the unpleasant taste of the API and

provide a cooling and soothing sensation in the mouth, thereby improving patient compliance. FD&C Colors were used to enhance the visual appearance and aesthetic appeal of the hard lozenges. Purified water served as the solvent for dissolving and uniformly dispersing the ingredients during formulation. Various formulation parameters such as hardness, moisture content, viscosity, dissolution rate, taste masking, flow properties, and stability were carefully controlled to ensure the production of uniform and effective hard lozenges. The dissolution rate was optimized to allow gradual release of the API in the oral cavity for prolonged therapeutic action. Proper balance of excipients also helped maintain suitable texture and prevented stickiness or brittleness during storage. Additionally, packaging materials were selected to protect the hard lozenges from moisture, light, and environmental conditions, thereby ensuring stability and shelf life of the final product.[10,11,39]

EXCIPIENTS USED FOR FORMULATION OF LOZENGES

Excipients play an essential role in the formulation of lozenges by improving their stability, appearance, taste, texture, and patient acceptability. In the present formulation, various excipients were selected carefully to achieve the desired physical and therapeutic properties of the lozenges. Bupivacaine was used as the active pharmaceutical ingredient (API) to provide the intended therapeutic action. Mannitol was incorporated as a sweetening and bulking agent, which enhances the palatability of the lozenges and provides a pleasant cooling sensation in the mouth. Povidone (PVP) served as a binder to hold the particles together and maintain the structural integrity of the lozenges during handling and storage. Stearic Acid was used as a lubricant to prevent sticking during manufacturing and ensure smooth processing of the formulation. Glycerin acted as a plasticizer by increasing the flexibility and softness of the lozenges, thereby improving mouthfeel and reducing brittleness. Guar Gum was included as a thickening agent to control the texture and consistency of the formulation. Menthol was added as a flavoring agent to mask the unpleasant taste of the active ingredient and provide a soothing cooling effect in the oral cavity. FD&C Colors were used to improve the appearance and aesthetic appeal of the lozenges, making them more attractive to patients. Purified water was used as a solvent to dissolve and uniformly disperse the ingredients during the preparation process. The combination of these excipients ensured the formulation of stable, effective, and patient-friendly lozenges with desirable sensory and mechanical properties.[10,12,17]

TYPES OF MOULD USED FOR LOZEGES



MANUFACTURING PROCESS OF LOZENGES

The manufacturing process of lozenges is carefully designed to produce a stable, effective, and patient-friendly dosage form with uniform quality and therapeutic efficacy. In the present formulation, Bupivacaine was used as the active pharmaceutical ingredient (API) to provide the desired pharmacological action. The formulation process began with the preparation of the base mixture by dissolving and dispersing the required excipients in purified water, which acted as the solvent for the formulation. Mannitol was incorporated as a sweetening and bulking agent to improve taste and provide sufficient body to the lozenges. Povidone (PVP) was added as a binder to ensure proper cohesion of the ingredients and to maintain the structural integrity of the lozenges during preparation, handling, and storage. Glycerin was used as a plasticizer to increase the flexibility and softness of the lozenges, thereby improving texture and mouthfeel. Guar Gum was included as a thickening agent to control the consistency and viscosity of the formulation. Menthol was incorporated as a flavoring agent to mask the unpleasant taste of the active ingredient and provide a cooling and soothing sensation in the oral cavity. FD&C Colors were added to improve the appearance and aesthetic appeal of the lozenges. During the manufacturing process, all ingredients were mixed uniformly to ensure homogeneity of the formulation. Stearic Acid was used as a lubricant to prevent sticking of the formulation to molds or processing equipment and to facilitate smooth manufacturing. The prepared mass was then poured into molds or compressed into suitable lozenge shapes and allowed to cool and solidify under controlled conditions. After preparation, the lozenges were evaluated for various quality control parameters such as appearance, weight variation, hardness, thickness, friability, drug content uniformity, and dissolution characteristics to ensure consistency, stability, and efficacy.

Finally, the prepared lozenges were packed in suitable packaging materials to protect them from moisture, physical damage, and contamination during storage and distribution.[13,16,23,24]

Table 1: Formulation Trials.

Sr.No	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8
1	Bupivacaine HCl (mg)	25	25	25	25	25	25	25	25
2	Mannitol (mg)	795	735	695	795	635	695	755	855
3	Dextrose (mg)	420	420	420	420	420	420	420	420
4	Povidone (mg)	90	90	30	30	90	90	30	30
5	Methylcellulose (mg)	30	90	90	90	90	30	30	30
6	PEG-1500 (mg)	50	50	150	50	150	150	150	50
7	Guar gum (mg)	60	60	60	60	60	60	60	60
8	Glycerine (ml)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
9	Menthol (mg)	15	15	15	15	15	15	15	15
10	Stearic Acid (mg)	15	15	15	15	15	15	15	15
	Total Weight (mg)	1500	1500	1500	1500	1500	1500	1500	1500

EVALUATION OF LOZENGES

Physical evaluation involves examining the appearance, size, shape, colour, and uniformity to ensure the lozenges meet the desired specifications. Weight variation tests are conducted to verify consistent dosing, while hardness testing ensures the lozenges have adequate structural integrity to withstand handling without breaking but are not too hard to dissolve properly in the mouth. Friability testing assesses the ability of lozenges to resist chipping or crumbling during transportation and storage. Dissolution and disintegration testing are performed to evaluate the rate at which the lozenge dissolves and releases the active pharmaceutical ingredient (API), ensuring the therapeutic effect is delivered as intended. For lozenges with systemic effects, content uniformity and assay testing confirm that the API is evenly distributed and present in the correct amount. Stability testing under various conditions, such as different temperatures and humidity levels, ensures that the lozenges maintain their physical and chemical properties over their shelf life. Additionally, sensory evaluation, including taste, mouthfeel, and flavour stability, is conducted to assess patient acceptability. Microbial testing is also essential to ensure the product is free from harmful contaminants. Comprehensive evaluation guarantees that the lozenges are safe, effective, and of high quality for consumer use. The evaluation of lozenges involves a series of comprehensive tests to ensure they meet quality, safety, and efficacy standards. This evaluation starts with physical and organoleptic assessments, where the lozenges are inspected for uniformity in size, shape, colour, and surface texture, as well as evaluated for taste, flavour, and overall mouthfeel to ensure patient acceptability. Weight variation tests are performed to confirm consistency in

dosing, ensuring that each lozenge contains the intended amount of active pharmaceutical ingredient (API). Mechanical strength tests, such as hardness testing and friability testing, are conducted to ensure the lozenges are durable enough to withstand handling and packaging but still dissolve at an appropriate rate in the oral cavity. Disintegration testing evaluates the time required for the lozenge to dissolve in the mouth, ensuring controlled release of the API. For systemic absorption or precise local effects, dissolution testing is crucial to measure the rate and extent of API release. Chemical evaluation involves assays to verify the content uniformity of the API, ensuring that it is evenly distributed across all lozenges, and to confirm the potency of the API aligns with the labelled claim. Stability studies are conducted under different environmental conditions, such as varying temperatures, humidity, and light exposure, to assess whether the lozenges maintain their physical, chemical, and sensory properties over time. Microbial testing, including total viable count and testing for specific pathogens, ensures that the lozenges are free from harmful microbial contamination, especially in formulations containing sugars or moisture-retentive components. Additionally, lozenges are evaluated for their packaging integrity, ensuring the packaging protects them from moisture, air, and contamination. Lastly, patient feedback and sensory analysis play a vital role in the evaluation process. Parameters like ease of dissolution, taste masking of the API, and overall user experience are considered to ensure the lozenges are both therapeutically effective and pleasant for the patient. This comprehensive evaluation process guarantees that the final product meets regulatory standards and delivers its intended therapeutic benefits effectively.[14,15,16]

Table 2: Evaluation Tests of Optimised formulation F5.

Sr. No.	Name of the Test	F5 (Optimized Formulation)	Specification/Limit
1	Weight Variation Test	0.29 g	± 5%
2	Friability Test	0%	± 1%
3	Disintegration Test	10 min	NMT 30 min
4	Drug Content	98.64 ± 0.21 %	90–110%
5	Thickness	3 ± mm	NMT 5 cm
6	Hardness Test	2 ± kg/cm²	NMT 8 kg/cm²
7	Loss on Drying	0.06%	NMT 5%
8	Dissolution	92%	—

Results and Discussion of Hard Lozenges for Mouth Ulcer

The prepared hard lozenges containing Bupivacaine were evaluated for various physicochemical and quality control parameters to ensure their suitability for the treatment of

mouth ulcers. The obtained results demonstrated that the formulated lozenges possessed satisfactory pharmaceutical characteristics, stability, and patient acceptability.

The prepared lozenges were evaluated for parameters like weight variation, hardness, drug cqontent, thickness, diameter, friability, moisture content, in-vitro dissolution test &stability.

I. Thickness & Diameter

The thickness of the lozenges was measured using Vernier callipers or screw gauge. The lozenges were inserted between the jaws after making sure that the pointer was set to zero. The readings of main scale and Vernier scale were measured. This is measured in mm. The mean thickness and diameter is calculated.

The thickness and diameter of the hard lozenges were found to be uniform, indicating proper moulding and consistency during manufacturing. Uniform dimensions are important for ensuring accurate dosing and maintaining aesthetic quality of the dosage form. The weight variation test showed that all lozenges were within acceptable pharmacopeial limits, with an average weight ranging from 1.5 g to 2 g. This confirmed uniform distribution of ingredients and proper control during formulation and moulding processes.

II. Weight Variation

The weight variation test was carried out on 20 randomly selected lozenges using a digital weighing balance. The average weight of the prepared lozenges was found to be approximately 0.30 g initially and slightly reduced to 0.29 g after storage studies. The results showed minimal variation in individual weights and complied with pharmacopeial limits, indicating uniform distribution of ingredients throughout the formulation.

III. Friability test

The friability test was performed using a Roche friabilator to determine the mechanical resistance of the lozenges during handling and transportation. The percentage friability of the prepared hard lozenges was found to be 0%, indicating excellent hardness and resistance to abrasion. The absence of weight loss after friability testing confirmed that the lozenges possessed adequate mechanical strength.

IV. Drug Content

The drug content analysis of Bupivacaine hard lozenges was carried out using UV-visible spectrophotometry at 215 nm. The drug content was found to be 98% on the initial day and

remained within acceptable limits after stability studies, showing 97% drug content after 3 months. These results confirmed uniform distribution of the drug in the formulation and indicated good stability of the active ingredient during storage.

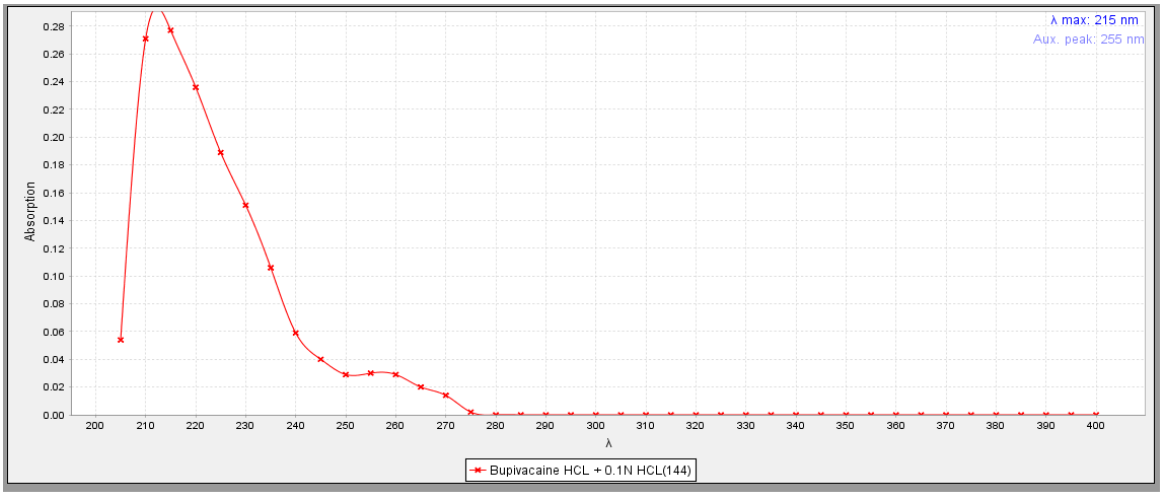


Fig. Bupivacaine UV-visible spectrophotometry graph.

V. Hardness

The hardness of the hard lozenges was evaluated using a Monsanto hardness tester. The prepared lozenges exhibited satisfactory hardness values, indicating sufficient strength to withstand handling without breaking. Proper hardness also ensured slow dissolution of the lozenges in the oral cavity, which is desirable for prolonged therapeutic action in mouth ulcer treatment.

VI. Moisture content analysis loss on drying Method

Moisture content analysis was carried out by the loss on drying method using a desiccator. The moisture content of the lozenges was found to be very low, ranging from 0.04% to 0.06% during stability studies. The low moisture content indicated good stability and reduced chances of microbial growth, stickiness, or deformation of the lozenges during storage.

VII. Mouth dissolving time test

The mouth dissolving time of the prepared hard lozenges was determined using a USP disintegration apparatus containing phosphate buffer of pH 6.4 at 37°C. The average oral retention and dissolving time of the lozenges was found to be approximately 30 minutes initially and 28 minutes after 3 months of storage. This prolonged retention time was considered beneficial for maintaining continuous drug release and prolonged contact of the drug with ulcerated tissues in the oral cavity.

VIII. Drug excipient interaction studies

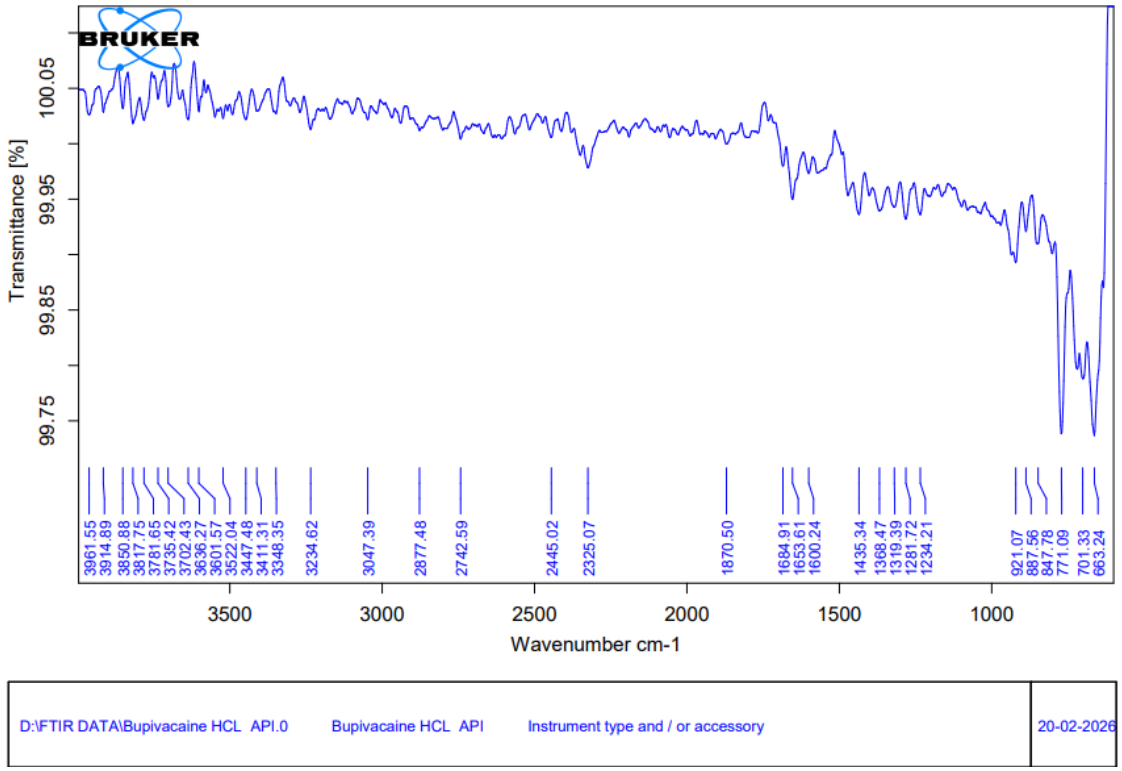


Fig. FTIR Bupivacaine HCL

The FTIR (Fourier Transform Infrared) spectrum you've provided is for Bupivacaine HCl, a common local anesthetic.

Looking at the graph, there is a very important technical observation to make first: The Transmittance (%) axis (the y-axis) is extremely zoomed in, ranging only from 99.75% to 100.05%. This means the signals are incredibly weak, likely due to a very low sample concentration or poor contact with the ATR crystal. Salt Identification: The peaks around 2445 cm^{-1} are quite diagnostic for the protonated nitrogen in Bupivacaine HCl. In the free base form, these peaks would look significantly different. Amide Signature: The sharpest features in the mid-range (1684 and 1653 cm^{-1}) confirm the presence of the amide linkage that connects the aromatic ring to the piperidine section.

Signal Quality: Because the transmittance is so high (nearly 100%), the "noise" (jagged lines) is quite prominent. For a formal lab report, you might want to re-run this sample with more material to get deeper peaks (lower transmittance) for better clarity.

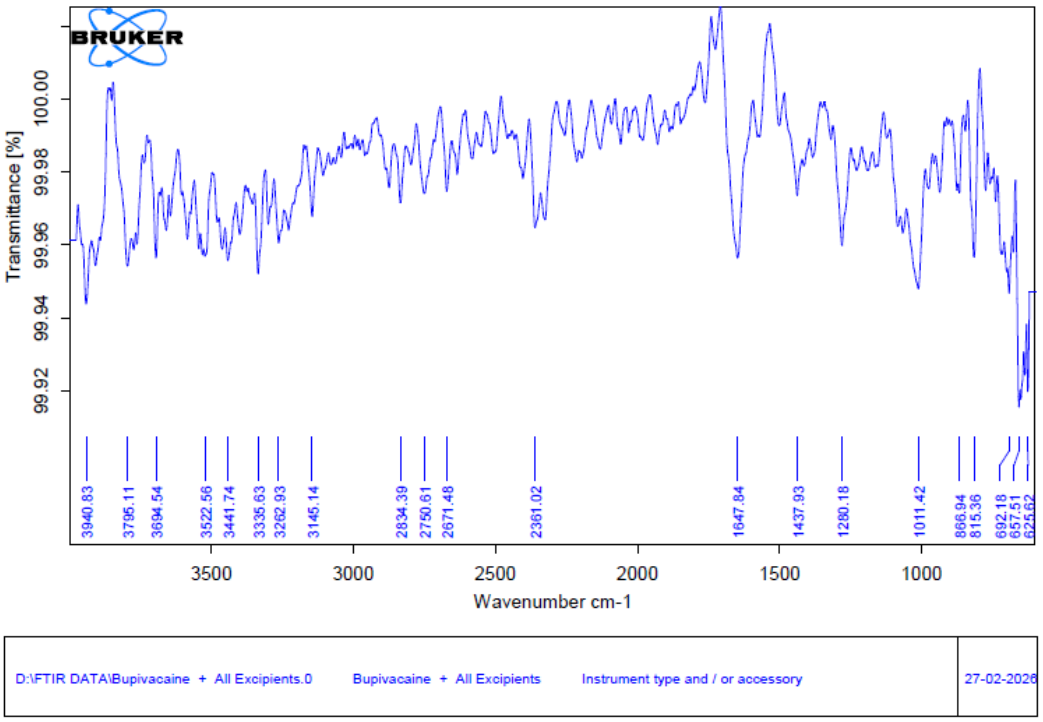


Fig. FTIR Bupivacaine HCL + All Excipients.

Drug–excipient compatibility studies were performed using FTIR spectroscopy. The FTIR spectra indicated no significant interaction between Bupivacaine and the excipients used in the formulation, confirming the compatibility and stability of the formulation components.

IX. In-vitro dissolution studies

The in-vitro dissolution study was performed using USP dissolution apparatus type II (paddle type) at 100 rpm in pH 6.8 phosphate buffer containing 2% SLS at 37 ± 0.5°C. The results showed gradual and controlled drug release from the hard lozenges over a period of 60 minutes. The formulation exhibited satisfactory drug release characteristics, ensuring prolonged therapeutic action for mouth ulcer management. The slow and sustained release pattern was suitable for maintaining local anaesthetic action in the oral cavity.

X. Stability testing

The stability studies were carried out for a period of 3 months under suitable storage conditions. The evaluated parameters included organoleptic properties, hardness, weight variation, friability, oral retention time, drug content, disintegration time, and moisture content. No significant changes were observed in colour, appearance, texture, or odour of the prepared lozenges during the stability period. Drug content remained within acceptable limits, and the formulations retained their hardness and mechanical properties.

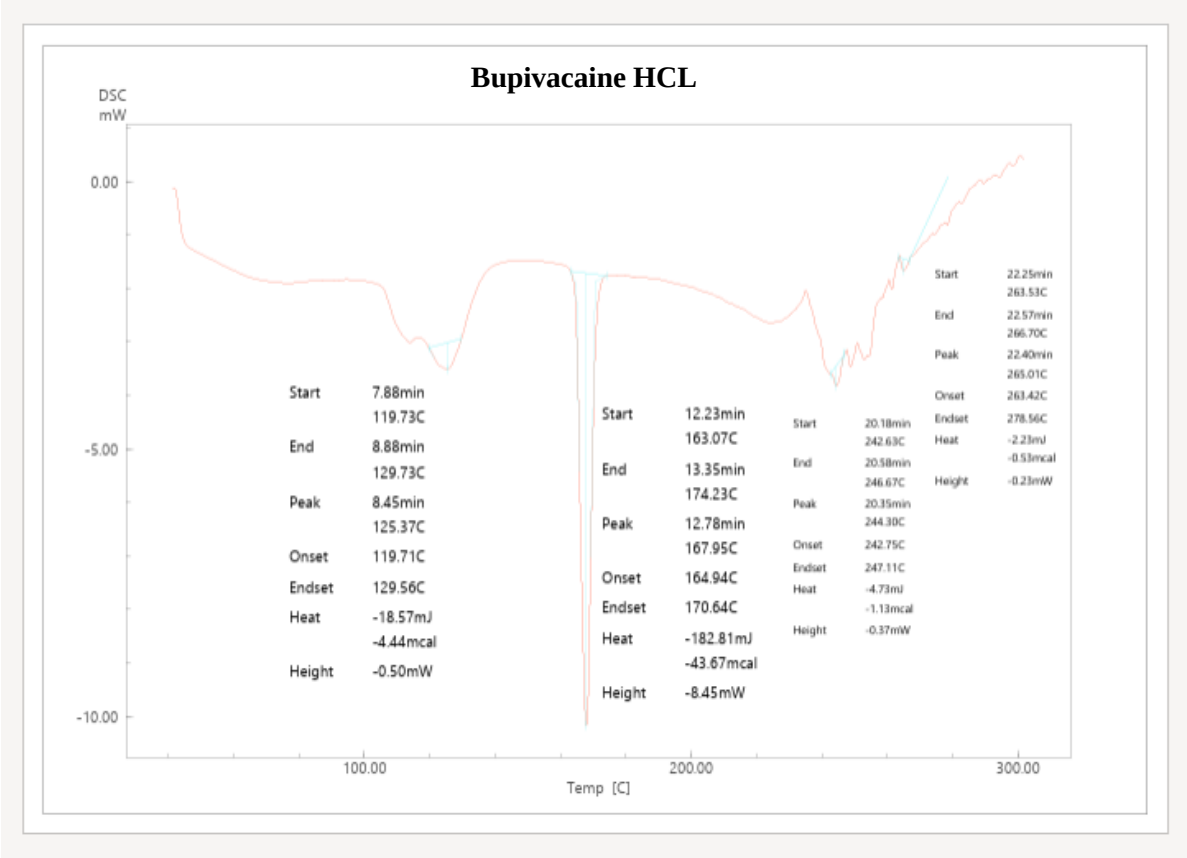
The moisture content and friability values also remained stable throughout the study period, indicating good stability of the prepared hard lozenges.

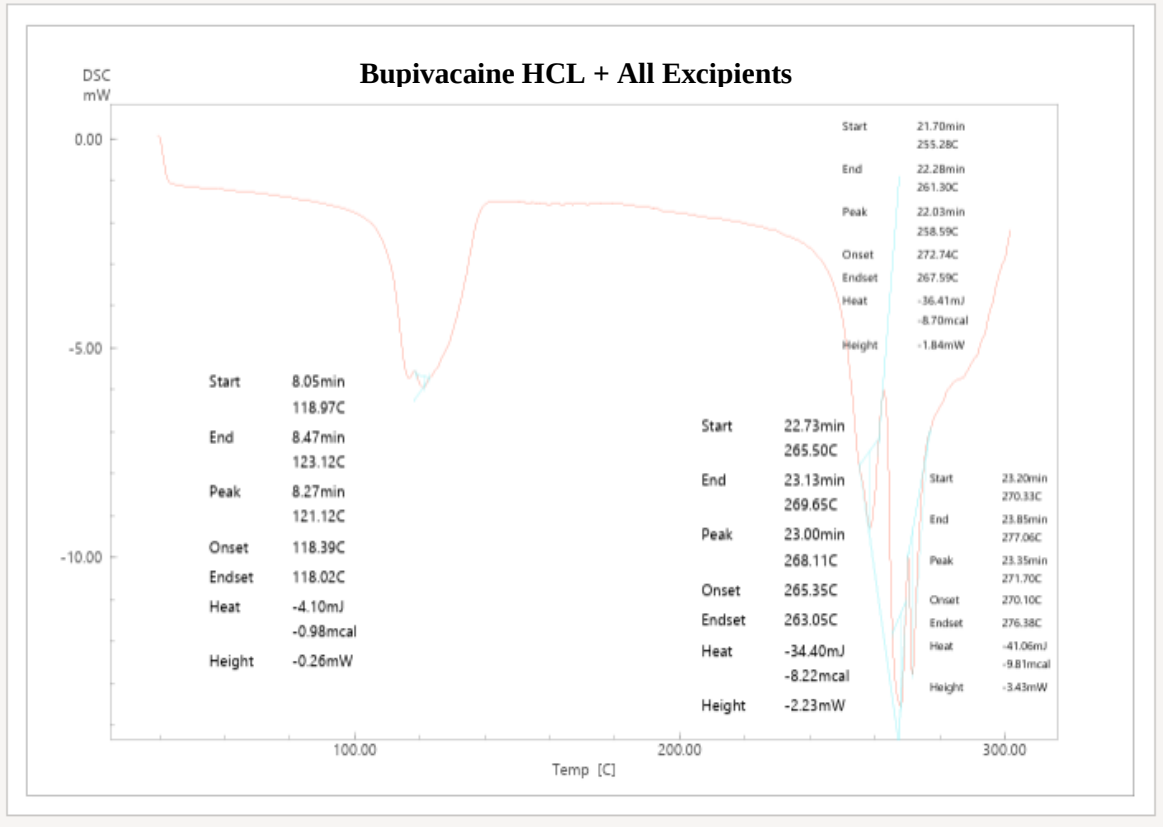
Table 3: Stability Data.

Evaluation Parameters	0 Day	After Stability of 1 Month	After Stability of 2 Months	After Stability of 3 Months
Organoleptic Evaluation	No Change	No Change	No Change	No Change
Hardness	2 ±	5 ±	2 ±	2 ±
Weight Variation (g)	0.30	0.30	0.29	0.29
% Friability	0	0	0	0
Oral Retention Time (min)	30	30	30	28
Drug Content (%)	98	98	97.5	97
Disintegration Time (min)	15	15	10	10
Moisture Content (%)	0.04	0.05	0.06	0.05

XII. Differential Scanning Calorimetry (DSC)

The thermal behaviors of the formulation was evaluated using Differential Scanning Calorimetry (DSC) to investigate critical properties such as melting point, crystallinity, degradation, and potential interactions between the drug and excipients. The DSC thermogram revealed a distinct endothermic peak at 121.12°C, occurring at approximately 8.27 minutes, which corresponds to the melting point of Bupivacaine HCL. This sharp peak indicates that the drug retains its crystalline structure within the formulation. Furthermore, the absence of additional peaks or significant shifts in the thermogram suggests that there are no significant interactions or incompatibilities between Bupivacaine HCL and the excipients used. The compatibility is thus confirmed by the DSC analysis, supporting the physical and chemical stability of the formulation.


Bupivacaine HCL
DSC
mW
0.00
-5.00
-10.00
100.00
200.00
300.00
Temp [C]
Start 7.88min
119.73C
End 8.88min
129.73C
Peak 8.45min
125.37C
Onset 119.71C
Endset 129.56C
Heat -18.57mJ
-4.44mcal
Height -0.50mW
Start 12.23min
163.07C
End 13.35min
174.23C
Peak 12.78min
167.95C
Onset 164.94C
Endset 170.64C
Heat -182.81mJ
-43.67mcal
Height -8.45mW
Start 20.18min
242.63C
End 20.58min
246.67C
Peak 20.35min
244.30C
Onset 242.75C
Endset 247.11C
Heat -4.73mJ
-1.13mcal
Height -0.37mW
Start 22.25min
263.53C
End 22.57min
266.70C
Peak 22.40min
265.01C
Onset 263.42C
Endset 278.56C
Heat -2.23mJ
-0.53mcal
Height -0.23mW


Bupivacaine HCL + All Excipients
DSC
mW
0.00
-5.00
-10.00
100.00
200.00
300.00
Temp [C]
Start 8.05min
118.97C
End 8.47min
123.12C
Peak 8.27min
121.12C
Onset 118.39C
Endset 118.02C
Heat -4.10mJ
-0.98mcal
Height -0.26mW
Start 22.73min
265.50C
End 23.13min
269.65C
Peak 23.00min
268.11C
Onset 265.35C
Endset 263.05C
Heat -34.40mJ
-8.22mcal
Height -2.23mW
Start 21.70min
255.28C
End 22.28min
261.30C
Peak 22.03min
258.59C
Onset 272.74C
Endset 267.59C
Heat -36.41mJ
-8.70mcal
Height -1.84mW
Start 23.20min
270.33C
End 23.85min
277.06C
Peak 23.35min
271.70C
Onset 270.10C
Endset 276.38C
Heat -41.06mJ
-9.81mcal
Height -3.43mW

CONCLUSION

The present research work successfully demonstrated the formulation and evaluation of hard lozenges as an effective and patient-friendly dosage form for the management of mouth ulcers. The developed formulation showed satisfactory pharmaceutical characteristics, good stability, and prolonged therapeutic action within the oral cavity. Hard lozenges were found to be highly suitable for localized drug delivery because they remain in contact with the oral mucosa for an extended period, thereby enhancing the therapeutic efficacy of the drug and providing prolonged relief from pain, irritation, and inflammation associated with mouth ulcers.

In this study, Bupivacaine was successfully incorporated as the active pharmaceutical ingredient to provide local anaesthetic action and effective symptomatic relief from oral ulcer pain. The selected excipients including Mannitol, Povidone, Stearic Acid, Glycerine, Guar Gum, Menthol, and FD&C Colours played significant roles in improving the hardness, texture, appearance, taste masking, stability, and overall patient acceptability of the hard lozenges. The optimized formulation exhibited satisfactory hardness, low friability, acceptable weight variation, appropriate moisture content, uniform drug distribution, and prolonged oral retention time, confirming the quality and consistency of the prepared lozenges.

The in-vitro dissolution studies indicated a gradual and sustained release of the drug, which is beneficial for maintaining prolonged therapeutic action in the oral cavity. Stability studies conducted over a period of three months showed no significant changes in organoleptic properties, drug content, friability, or other evaluation parameters, demonstrating the stability and reliability of the prepared formulation during storage. The FTIR studies further confirmed the compatibility between the drug and excipients used in the formulation.

Overall, the developed hard lozenges proved to be an effective, stable, convenient, and patient-compliant dosage form for the treatment and symptomatic relief of mouth ulcers. The formulation offers advantages such as ease of administration, portability, accurate dosing, prolonged drug release, improved patient compliance, and enhanced therapeutic outcomes. The study concludes that hard lozenges have strong potential as a promising oral drug delivery system for mouth ulcer management. Future research may focus on incorporating herbal or natural therapeutic agents, advanced taste-masking approaches, novel polymers, and

clinical studies to further enhance the efficacy, safety, and commercial applicability of hard lozenges for oral healthcare.

REFERENCESS

1. Rina Maskare G, Shital Thakre D, Om Patle D, Shirali Vishwakarma S, Dhyanesh Dahake, Rima Jagnit J, Rohit S. Rahangdale.
2. Pharmaceutical Dosage Forms: Tablets. 2nd ed. New York: Marcel Dekker, Inc, 2005; 419-577.
3. Allen LV. (200): Troches and Lozenges. Secundum Artem. Current & Practical Compounding Information for the Pharmacist, 4(2).
4. Gulabchand Nandkishor Prajapati 1, Omesh Pawar 2, Aditya Patil 3, Sweety Mishra 4, Rahul Madhvi 5, Pratima Bisen 6(Project Guide), Formulation and Evaluation of Herbal Lozenges for Mouth Ulcer, International Journal of Pharmaceutical Research and Applications, ISSN: 2456-4494.
5. American Laryngological Association. Laryngeal Papillomatosis. (https://alahns.org/wpcontent/uploads/PEM/CLD_6_Laryngeal- Papillomatosis.pdf) Accessed 1/17/2022.
6. https://askfilo.com/user-question-answers-smart-solutions/advantage-andamp-disadvantage-of-lozenges-3336393434313434
7. Kirti C. Godse, Dr. V. Y. Lokhande, Komal Shinde and Prachi Pawar, formulation and evaluation of polyherbal lozenges for the treatment of sore throat, World Journal of Pharmaceutical and Life Sciences WJPLS.
8. American Laryngological Association. Laryngeal Papillomatosis. (https://alahns.org/wp content/uploads/PEM/CLD_6_Laryngeal- Papillomatosis.pdf) Accessed 1/17/2022.
9. Pothu R, Yamsani MR. Lozenges formulation and evaluation: a review. In IJPR Adv Pharm Res, 2014; 5(5): 290-298.
10. Remington: The Science and Practice of Pharmacy. Pharmaceutical Press, 2012.
11. Banker GS, Rhodes CT. Modern Pharmaceutics. 4th ed. Marcel Dekker, 2002.
12. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy. 3rd ed. Varghese Publishing House, 2009.
13. Aulton ME, Taylor K. Aulton's Pharmaceutics: The Design and Manufacture of Medicines. 5th ed. Elsevier, 2018.
14. Indian Pharmacopoeia Commission. Indian Pharmacopoeia Commission Indian Pharmacopoeia. Ghaziabad, 2022.

15. British Pharmacopoeia Commission. British Pharmacopoeia. London, 2021.
16. United States Pharmacopeial Convention. United States Pharmacopeia and National Formulary (USP–NF). Rockville, MD, 2023.
17. Rowe RC, Sheskey PJ, Quinn ME. Handbook of Pharmaceutical Excipients. 8th ed. Pharmaceutical Press, 2017.
18. Chaturvedi M, Kumar M, Pathak K. A review on mucoadhesive buccal drug delivery systems. Int J Pharm Sci Res, 2011; 2(3): 418-432.
19. Patel VF, Liu F, Brown MB. Advances in oral transmucosal drug delivery. J Control Release, 2011; 153(2): 106-116.
20. Shojaei AH. Buccal mucosa as a route for systemic drug delivery. J Pharm Sci, 1998; 1(1): 15-30.
21. Smart JD. The basics and underlying mechanisms of mucoadhesion. Adv Drug Deliv Rev, 2005; 57(11): 1556-1568.
22. Nafee NA, Boraie NA, Ismail FA, Mortada LM. Design and characterization of mucoadhesive buccal patches. AAPS PharmSciTech, 2003; 4(1): 1-9.
23. Bhise KS, Shaikh S. Formulation and evaluation of medicated lozenges. Int J Pharm Sci Rev Res, 2012; 15(1): 45-50.
24. Parodi B, Russo E, Caviglioli G. Development and characterization of oral medicated lozenges. Drug Dev Ind Pharm, 1996; 22(5): 445-450.
25. Kulkarni GT, Gowthamarajan K, Suresh B. Stability testing of pharmaceutical products: an overview. Indian J Pharm Educ Res, 2004; 38(4): 194-202.
26. Allen LV Jr. Troches and Lozenges: Compounding and Formulation Considerations. Int J Pharm Compd, 2008; 12(3): 234-240.
27. Hirani JJ, Rathod DA, Vadalia KR. Orally disintegrating tablets and lozenges: a review. Trop J Pharm Res. 2009; 8(2): 161-172.
28. Bhavsar M, Varde N, Saini V. Formulation and evaluation of herbal lozenges containing natural extracts. Int J Pharm Innov, 2016; 6(2): 12-18.
29. Jain NK. Controlled and Novel Drug Delivery. CBS Publishers & Distributors, 2008.
30. Gupta A, Garg S, Khar RK. Measurement of bioadhesive strength of mucoadhesive buccal tablets. Indian Drugs, 1992; 30(4): 152-155.
31. Deore SL, Khadabadi SS, Baviskar BA. Mouth dissolving drug delivery systems: a review. Pharma Times, 2008; 40(1): 11-15.
32. Pawar VK, Kansal S, Garg G, Awasthi R, Singodia D, Kulkarni GT. Gastroretentive dosage forms: a review. AAPS PharmSciTech, 2011; 12(1): 1-17.

33. Singh MP, Nagori BP, Shaw NR, Tiwari M. Buccal drug delivery system: a review. Int J Pharm Sci Res, 2011; 2(6): 1303-1321.
34. Deshpande AA, Shah NH, Rhodes CT, Malick AW. Development of a novel controlled-release system for gastric retention. Pharm Res, 1997; 14(6): 815-819.
35. Khandelwal KR. Practical Pharmacognosy Techniques and Experiments. 23rd ed. Nirali Prakashan, 2013.
36. Kokate CK, Purohit AP, Gokhale SB. Pharmacognosy. 56th ed. Nirali Prakashan, 2020.
37. Tripathi KD. Essentials of Medical Pharmacology. 8th ed. Jaypee Brothers Medical Publishers, 2018.
38. Goodman LS, Gilman A. Goodman & Gilman's The Pharmacological Basis of Therapeutics. 13th ed. McGraw-Hill Education, 2018.
39. Sinko PJ. Martin's Physical Pharmacy and Pharmaceutical Sciences. 6th ed. Lippincott Williams & Wilkins, 2011.