

FORMULATION AND EVALUATION OF LOZENGES FOR MOUTH ULCERATION

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ABSTRACT

Medicated hard lozenges are a localized drug delivery system containing catechin as the active ingredient, which is released gradually upon dissolution in the oral cavity. Catechin is incorporated for its anti-inflammatory, antioxidant, and wound-healing properties, targeting mouth ulcers either for local action or potential buccal absorption. The oral mucosa serves as a protective barrier, and these lozenges are designed to enhance drug retention at the ulcer site for prolonged therapeutic effect. The medicated hard lozenges were formulated using a fusion method with catechin as the active constituent and excipients such as sucrose, corn syrup, and PEG to provide structural integrity and palatability. Different batches were prepared with varying concentrations of catechin (1–5% w/w). The formulations were evaluated for post-compression parameters (weight variation, hardness, % friability, drug content and disintegration time). Additionally, anti-ulcer activity was assessed by using the Acid neutralizing activity. The formulated catechin-based hard lozenges exhibited desirable phyto-chemical properties, and potent antiulcer activity, making them a promising natural remedy for mouth ulcers.

Keywords: Medicated lozenges, Catechin, anti-inflammatory, mouth ulcers, buccal absorption.

INTRODUCTION

Aphthous stomatitis, also referred to as aphthous ulcers, mouth ulcers or canker sores, is a common oral condition characterized by painful ulcerative lesions on the buccal and labial mucosa or the tongue. Aphthous stomatitis occurs in approximately 5–60% of the population in the UK and 2–50% worldwide. The term “aphtha” originating from the Greek “aphthi”, which means a burning sensation or inflammation. This term is dedicated to Hippocrates, who used the words for the first time to describe these mouth disorders. They can make activities like eating, drinking, and speaking uncomfortable, impacting daily life. Their occurrence may be linked to factors such as stress, oral injuries, or underlying health conditions.¹ Although the exact cause of Aphthous stomatitis remains unclear, the disease follows a progressive pathophysiological process. It begins with a burning sensation during the pre-aesthetic (pre-ulcerative) stage, followed by lymphocytic infiltration of the

epithelium. In the ulcerative stage, edema develops, leading to keratinocyte damage and localized vasculitis, which contribute to inflammation, ulcer formation, and immune cell infiltration (plasma cells, lymphocytes, and neutrophils). The immune response in Aphthous stomatitis is T-cell mediated, with macrophages and mast cells playing a significant role in inflammation. These immune cells release tumor necrosis factor-alpha (TNF- α), a pro-inflammatory cytokine that contributes to tissue damage and ulcer persistence. Finally, the healing process begins as epithelial regeneration occurs, restoring the affected mucosa.² The various types of Aphthous Stomatitis are Minor Aphthous Ulcers, Major Aphthous Ulcers and Herpetiform Ulcers.³ Acacia catechu, also known as Kathal White Catechu, is a member of the genus Acacia within the subfamily Mimosaceae of the Fabaceae family. The plant is also referred to as Cutch tree, Terra Japonica, and Black Catechu. In Hindi and Sanskrit, it is known as Khair and Khadira. Historically, it was also called Kat or Cacho.⁴ The plant is known for its diverse medicinal properties and is utilized in various pharmaceutical applications, including its use in treatments for skin conditions, ulcers, and other ailments.⁵ Acacia catechu, commonly known as the Cutch tree, has been extensively utilized in traditional medicine and has demonstrated various health-promoting functionalities. The heartwood extract, known as Katha, is particularly valued for its therapeutic applications.⁶ The heartwood of Acacia catechu majorly contains varying amounts of **catechin**, with reported concentrations of 3.30%, 66.9%, and 3.580%.⁷ Catechu suppresses the production of pro-inflammatory cytokines, which helps in managing inflammatory conditions. Mouth ulcers involve inflammation mediated by cytokines like TNF- α , IL-1 β , IL-6 and immune cell infiltration, leading to tissue breakdown. Catechin from Catechu inhibits NF- κ B activation, reducing the release of these cytokines and suppressing excessive inflammation.⁸ This helps reduce pain, redness, and swelling associated with ulcers. Studies suggest that topical applications of catechu-based gels or mouthwashes can reduce ulcer size, pain, and healing time.⁹ **Catechin**, a flavonoid derived from Acacia catechu (Catechu), has shown considerable promise in the treatment of mouth ulcers due to its anti-inflammatory, antioxidant, antimicrobial, and wound-healing properties. Catechu extract, known as Katha, is widely utilized in traditional medicine for promoting oral health.¹⁰ Lozenges are solid dosage form that contains flavoring and sweetening agents, designed to dissolve or disintegrate slowly in the mouth or oral cavity. They are primarily used for localized effects within the oral cavity but can also produce systemic effects if the drug is efficiently absorbed through the buccal lining and pharynx.¹¹ Lozenges gradually release the drug into the buccal cavity to deliver the required dosage. They can contain multiple drugs or ingredients and are available as both OTC and prescription medications, depending on their composition. Lozenges enhance the drug's local action and absorption, making them widely used for treating various conditions affecting the mouth, tongue, and throat.¹² Lozenges are

considered superior to other dosage forms for treating mouth ulcers due to several advantages such as Prolonged Contact Time, Localized Drug Delivery, Mucosal Adhesion, Reduced Systemic Side Effects, Ease of Administration and soothing effect and reducing irritation¹³. Medicated lozenges and Non-medicated lozenges are the various types of Lozenges. On the basis of site of action Lozenges are classified into Local Effect and Systemic effect. On the basis of its texture and composition Lozenges are classified into Chewable Lozenges, Hard Lozenges, Soft Lozenges and compressed Lozenges¹⁴.

MATERIALS AND METHODS:

Materials:

Acacia Catechu was obtained from. PEG 400, PEG 600, Maltose, Sucrose, Vanillin were purchased from Sulabh Pharmaceuticals. Corn powder was purchased from Prakash Pharmaceuticals. Peppermint oil was purchased from Qualikems Pharma.

Methods:

Isolation of Catechin from Acacia Catechu

Isolated catechu was taken in 5 ml beaker containing 1 litre distill water. It was boiled with constant stirring until complete dissolution and filtered through a filter paper. It was evaporated to 500 ml and allowed to stand for 24 hours. The precipitate was filtered. The aqueous filtrate was rejected and the residue was dissolved in methanol. The methanol solution was evaporated to dry and the residue was dissolved in 500 ml hot water. It was allowed to stand for 24 hours and after the precipitation was filtered and dried in air, the process of recrystallization was done with water for three times¹⁵⁻¹⁶.

Phytochemical tests for catechin extract¹⁷⁻²⁰

1. Ferric chloride test:

- 3 ml of an aq. Catechin extract was taken in a test tube.
- Few drops of the freshly prepared neutral ferric chloride solution were added to the sample solution drop wise.
- The color change was observed.

2. Alkaline test:

- 2ml of an aqueous catechin extract were taken in a test tube.
- Five drops of a diluted sodium hydroxide solution were added to the extract.
- The color change was observed.

3. Lead Acetate test:

- A small amount of aqueous extract was taken in a test tube.

- Few drops of 10% lead acetate solution were added to the extract. Precipitates were observed.

4. Alkaloid test:

- Few drops of Dragendorff's reagent were added to the filtered catechu extract.

An orange precipitate formed, indicating the presence of alkaloids.



Fig. 1a: Acacia catechu



Fig. 1b: Acacia catechu was filtered



Fig. 1c: Catechin was obtained

Procedure for TLC

The slurry of silica gel was prepared and poured on the slide. The slide was kept in hot air oven. Then the mobile phase was prepared using the ratio of toluene, ethyl acetate and formic acid (10:8:1). The slide was kept in the mobile phase to run up to 70%. The slide was taken out and dried. The iodine chamber was taken as stationary phase and the slide was dried. A spot was visible on the slide after the R_f value was calculated²¹⁻²³.



Fig. 2a: TLC plate was kept for run in mobile phase



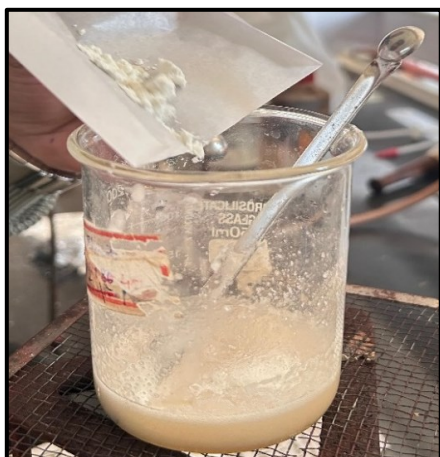
Fig. 2b: TLC plate

Table 1: Formulation of 10 Catechin Lozenges

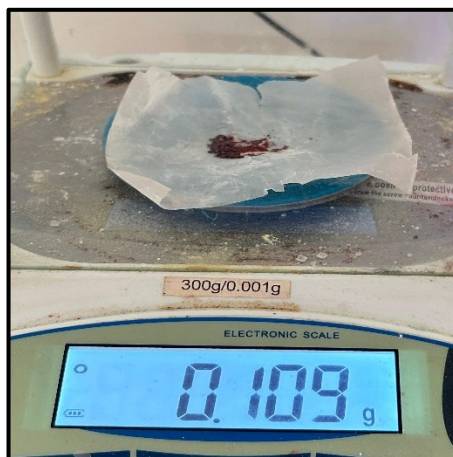
S. No.	INGREDIENTS	MHL1	MHL2	MHL3	MHL4	MHL5	MHL6
1.	Catechin Extract	0.1gm	0.1gm	0.1gm	0.1gm	0.1gm	0.1gm
2.	Maltose	18gm	15gm	20gm	20gm	30gm	40gm
3.	Sucrose	10gm	10gm	10gm	5gm	6gm	8gm
4.	Corn Powder	5gm	4.5gm	3gm	1.5gm	3gm	3.5gm
5.	PEG 400	5ml	4.5ml	2.5ml	2.5ml	---	---
6.	PEG 600	3.5ml	3.5ml	2.5ml	2.5ml	5ml	5.5ml
7.	Pepermint oil	q.s	q.s	q.s	q.s	q.s	q.s
8.	Vanillin	q.s	q.s	q.s	q.s	q.s	q.s
9.	Water	q.s	q.s	q.s	q.s	q.s	q.s

Method:

Maltose and sucrose were dissolved in water by heating it in a beaker until it became thick syrupy. Then, corn powder was added and the temp. was maintained at 105°C and 110°C. The base was allowed to cool and catechin extract were added with vanillin. Then, all the ingredients were mixed thoroughly to form a uniform mixture. The mixture was poured into lubricated mould. The lozenges were allowed to cool at room temp. and solidified. After solidification of lozenge, it was ejected. Later on, it was filled in aluminum foil ²⁴⁻²⁶.



Step 1: Addition of corn in sucrose & maltose solution



Step 2: Weighed of catechin extract



Step 3: Addition of catechin extract



Step 4: Addition of PEG



Step 5: Solution was poured into mould



Step 6: Lozenges

Preformulation Study:

FTIR Study

FTIR spectroscopy is a common method for analyzing, involving sample preparation, spectral acquisition, and peak analysis to identify functional groups.

Sample Preparation

- Dried catechin extract was ground into a fine powder.
- KBr Pellet Formation: The powdered sample was mixed with potassium bromide (KBr) at a ratio of ~1:100 (sample: KBr). This mixture was compressed under high pressure to form a transparent pellet for analysis ²⁷⁻²⁸.

Evaluation medicated hard lozenges

1. Hardness:

The hardness of ten hard lozenges was measured using a Monsanto hardness tester. The results were expressed in kg/cm², and the mean along with the standard deviation was calculated and reported. The average hardness value, together with individual observations and the standard deviation, was observation ²⁹.

2. Thickness & Diameter:

The diameter and thickness of the lozenges were measured using a Vernier calliper. These dimensional parameters are critical in the manufacturing process of hard candy lozenges. A total of ten lozenges were randomly selected from the batch, and their thickness and diameter were recorded ³⁰.

3. Friability test:

Friability was evaluated using a Roche friabilator. Ten lozenges were accurately weighed and placed in the apparatus, with all operating conditions properly set. The instrument was run at 25 rpm for 4 minutes, corresponding to 100 revolutions. After completion, the lozenges were removed, dedusted, and reweighed ³¹. The acceptable limit for mean weight loss was not more than 1.0%. The percentage friability was measured using the formula:

$$\text{Friability (\%)} = \frac{\text{Initial Weight (W1)} - \text{Final Weight (W2)}}{\text{Initial Weight (W1)}} \times 100$$

Where,

% F = Friability in percentage,

W1 = Initial weight of lozenges

W2= Final weight of lozenges after revolution

4. Weight variation:

Twenty Lozenges from the formulation were randomly selected and weighed together the Lozenges were then weighed individually. The batch passes the test for weight variation test, if not more than two of the individual lozenge weight deviates from the average weight by more than the percentage according to IP limits ³².

5. Drug content:

Lozenges were powdered and dissolved in small volume of methanol in 100ml volumetric flask and volume make up to 100ml of Phosphate buffer at pH 6.8. From this solution 1ml taken and diluted with Phosphate buffer at pH 6.8 in 50ml volumetric flasks then sonicated for 30 min then filtered using filter paper. The absorbance of this solution was measured at 269nm using appropriate blank. The drug content of medicated lozenges was calculated using calibration curve and observation reading³³.

6. pH of Lozenges:

Procedure to Determine pH of Lozenges for Mouth Ulcers:

Materials Required:

- Lozenges (crushed into powder)
- Distilled water
- pH meter (calibrated)
- Beaker/glass vial

Steps:

Sample Preparation: Crushed a lozenge into a fine powder. Dissolved a known amount (e.g, 10 g) in a fixed volume of distilled water (e.g, 1 mL). Stirred well (using a magnetic stirrer if available) to ensure complete dissolution. Calibration of pH Meter: Calibrated the pH meter using standard buffer solutions (e.g., pH 6.9). pH Measurement: Immersed the pH electrode into the lozenge solution. Allowed the reading to stabilize (usually 30–60 seconds). Recorded the pH value ^{33,34}.

7. Acid neutralizing capacity:

Back Titration: The lozenge was dissolved in a known volume of acid (e.g., hydrochloric acid) and then the mixture was titrated with a strong base (e.g., sodium hydroxide) until a neutral pH was reached. The amount of base required to neutralize the acid indicated the lozenge's acid-neutralizing capacity.

pH Monitoring: The pH change was measured over time after the lozenge were added to an acidic solution to assess how effectively it neutralized acids ³⁴.

Procedure:

Medicated Lozenges were accurately weighed. Then it was grinded in motor pastel. The powder was transferred into conical flask. 25ml 0.1N HCL was pipetted out. It was vigorously shaken and was allowed to dissolve. Excess HCL was titrated by 0.2 M NAOH. 3-4 drops of Phenolphthalein indicator were added. Burette was filled with 0.2M NAOH. Titration of HCL with NaOH was carried out. Blank titration was carried out without lozenges. 25ml of 0.1N HCL was added in conical flask. 10ml water and indicator was added, and was allow to titrate.

8. Mouth dissolving time test:

The time taken by the lozenges to dissolve completely was determined by USP disintegration apparatus, where lozenges were placed in each tube of the apparatus and time taken for the lozenges to dissolve completely was noted by using 900ml phosphate buffer of pH 6.8 at 37°C. This test was done in triplicate. The average dissolving time for lozenges was calculated and presented with standard deviation ³⁵.

Storage:

These preparations should be kept away from heat and stored out of children's reach. They must be safeguarded against extreme humidity. Based on the storage needs of both the drug and its base, they are typically maintained either at room temperature or under refrigeration ³⁶.

9. Packaging:

Hard candies are hygroscopic in nature and tend to absorb moisture from the surrounding environment. Therefore, factors such as the hygroscopicity of the candy base, storage conditions, duration of storage, and the possibility of drug interactions must be carefully considered ³⁶.

RESULTS AND DISCUSSION

Phytochemical Test

Phytochemical testing of lozenges involves analyzing bioactive compounds to ensure therapeutic efficacy and quality. The test like Tannic acid, Alkaloid, Alkaline, Ferric chloride, Lead acetate were successfully performed.

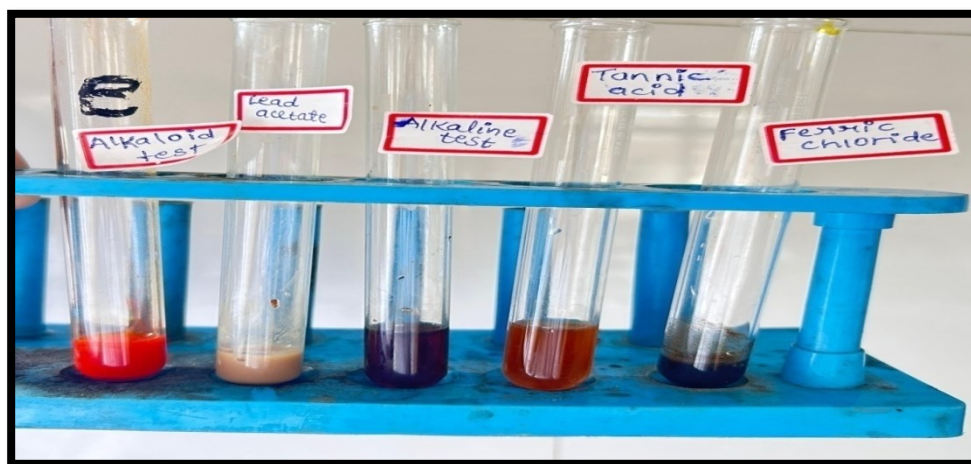


Fig. 4: Phytochemical tests

Table 2: Results of phytochemical Tests

Sr.No	Phytochemical Tests	Observation	Result
1.	Alkaloid test	Orange-red ppt.	+ve
2.	Lead Acetate	Bulky white ppt.	+ve
3.	Alkaline test	Violet colour	+ve
4.	Tannic acid test	Pink-red compound	+ve
5.	Ferric chloride	Blue-violet colour	+ve

FT-IR results

FTIR (Fourier Transform Infrared Spectroscopy) of catechin in lozenges is performed for several reasons, particularly when catechin is used as an active ingredient for its anti-ulcer properties:

- Confirmation of Catechin Presence
- Structural integrity
- Interaction with formulation components
- Quality control

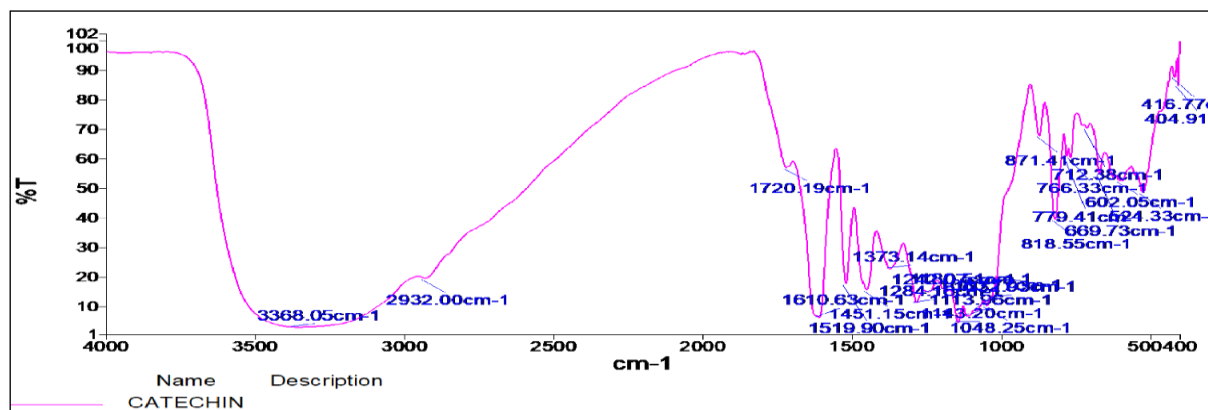


Fig. 5a: FTIR of Catechin

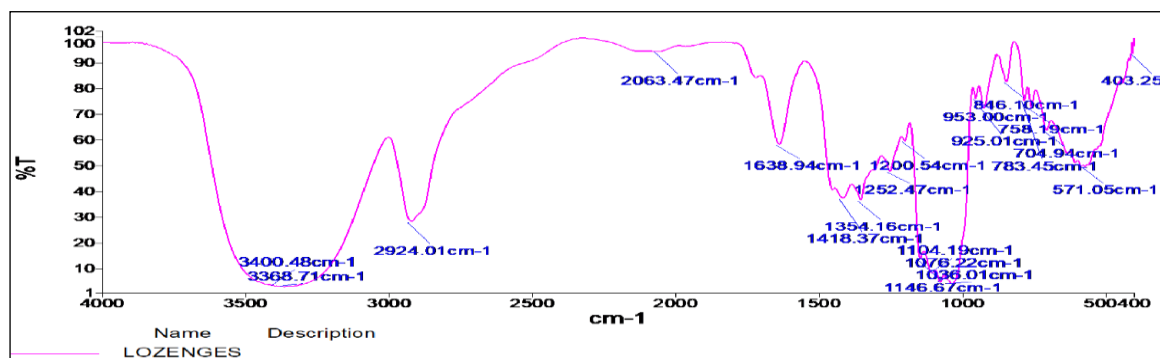


Fig. 5b: FTIR of Catechin and mixture

Interpretation Of IR Spectra:

Table 3: Interaction study of IR spectra

Functional group	Reported value	Catechin observed value	Lozenges observed value
C=C	1400-1600	1610	1639.52
C-O	1260-1000	1080	1146.67
O-H	3400-3200	3368.71	3400
C-H Stretch	2800-3300	2932	2924.01
C-H Bend	1470-1400	-----	1418

Physical parameter of medicated hard Lozenges

The Physical parameters of herbal lozenges were carried out successfully, and the outcome of the evaluation parameters was as follows:

Table 4: Physical Parameters

S.No	Physical Parameter	MHL1	MHL2	MHL3	MHL4	MHL5	MHL6
1	Colour	Very Dark brown	Dark brown	Dark brown	Yellowish brown	Yellowish brown	Yellowish brown
2	Odour	Odourless	Odourless	Odourless	Pleasant	Pleasant	Pleasant
3	Taste	Bitter	bitter	bitter	Less sweet	sweet	sweet
4	Texture	Smooth and sticky	Smooth and sticky	Smooth and sticky	Smooth	Smooth	Smooth
5	Shape	Irregular	irregular	irregular	Round	Round	Round

Post Compression study:

To obtain good chewability, flavoring, sweetness, softening of the lozenges, different batches of lozenges were formulated.

Table 5: Post-Compression studies

S.No.	Physical Parameter	MHL1	MHL2	MHL3	MHL4	MHL5	MHL6
1	Chewability	Not chewable	Good	Good	Good	Very Good	Very Good
2	Hardness	Soft	Slightly hard	Slightly hard	Hard	Hard	Hard
3	Stickiness	Yes	Yes	Yes	No	No	No

Evaluation parameter of Medicated Hard Lozenges:

Their formulation requires careful consideration of various physical properties and stability factors to ensure they meet therapeutic needs while providing a pleasant user experience. The evaluation processes are crucial in maintaining the quality standards necessary for effective pharmaceutical products.

Table 6: Evaluation Test

Sr. No	Tests	MHL1	MHL2	MHL3	MHL4	MHL5	MHL6
1.	Hardness (kg/cm ²)	4.07±0.19	4.16±0.23	4.38±0.24	3.82±0.2227	4.12±0.279	4.12±0.249
2.	Thickness (nm)	3.22±0.20	3.21±0.495	3.21±0.495	2.83±0.309	3.24±0.30	3.24±0.39
3.	Weight variation (gm)	3.36	3.33	3.33	2.78	3.32	3.32
3.	Friability	0.16	0.34	0.34	0.23	0.61	0.48
4.	Disintegration (sec/min)	1min 48sec	1min 59sec	1min 59sec	50sec	56sec	45sec
5.	pH	7.82	7.56	7.61	6.92	6.72	6.83
6.	In-vitro drug release (min)	7.06	6.52	6.49	6.12	10.1	9.10

Calibration curve of catechin

UV spectroscopy is a widely used method for analyzing catechin due to its simplicity, cost-effectiveness, and rapid results. Here's a detailed breakdown of its application and key findings:

Table 7: Value for Calibration curve of Catechin

Concentration (µg/ml)	Absorbance 269Mean ±S. D (n=3)
0	0
2	0.1297±0.0021
4	0.2417±0.0035
6	0.3610±0.0020
8	0.4723±0.0025
10	0.5907±0.0025

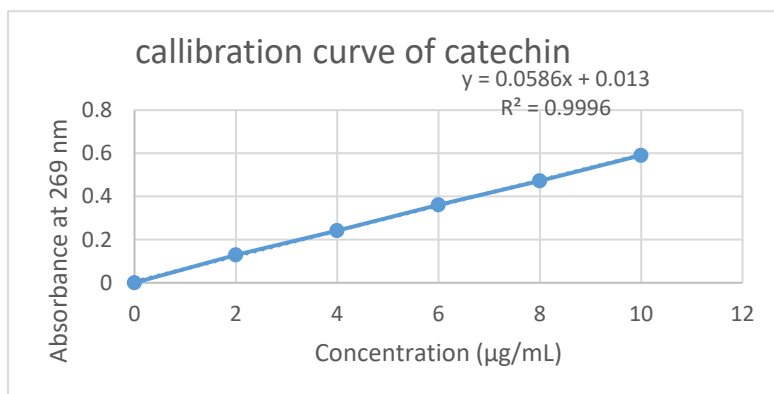


Fig.6: calibration curve of catechin in phosphate buffer in pH 6.8

Drug content:

The formulation complies with the test if the content is between 85% and 115% of the average content.

Based on the Dilution pattern, the absorbance was found to be 0.7100, 0.7117, 0.7134.

Average of Absorbance=0.7117

Put the average value of absorbance in the equation below, $Y = mx + c$

$Y = 0.0586x + 0.013$ (Taken from the standard curve of catechin)

$0.7117 = 0.0586x + 0.013$

$X = (0.7117 - 0.013) / 0.0586$

$X = 11.82 \text{ mg/ml}$

Here, 12.5mg/ml of catechin gives 100 percent 11.82 mg/ml of catechin gives 94.5% percent. Catechin content was 94.5% between 85% to 115 %.

pH of Medicated Hard lozenges:

Ideally, lozenges for mouth ulcers should have been slightly alkaline (pH 6.5-6.9) to neutralize excess oral acidity and promote healing. Acidic lozenges (pH 7.0-7.5) may have irritated ulcers further.

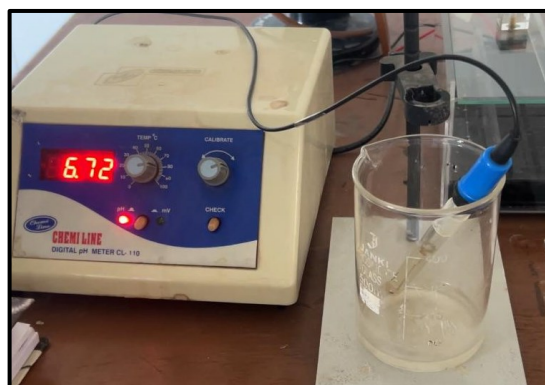


Fig. 7: pH of Medicated Hard Lozenges

Acid Neutralizing Capacity

Acid neutralizing activity is a crucial aspect in the management of mouth ulcers, particularly in alleviating pain and promoting healing. lozenges are alkaline substances that neutralize gastric acidity and can also be effective in the oral cavity. They work by increasing the pH level in the mouth, which helps to alleviate discomfort associated with ulcers.

Table 8: Acid Neutralizing Capacity of Test and Standard samples

Test sample (Lozenges)	Volume of HCl added (ml)	Volume of NaOH consumed (Blank titration)	Volume of NaOH consumed (Sample titration)	Mass of Lozenges (gm)	ANC
1.	25	15.3	14.4	3.5	0.30mEq H ⁺ /g
2.	25	14.9	14.1	3.4	0.32mEq H ⁺ /g
3.	25	15.7	14.5	3.6	0.29mEq H ⁺ /g
Standard (Alluminium hydroxide Gel)	Volume of HCl added (ml)	Volume of NaOH consumed (Blank titration)	Volume of NaOH consumed (Sample titration)	Standard solution (ml)	ANC
1.	25	10.3	13.2	2.5	0.47 mEqH ⁺ /g
2.	25	10.5	13.9	2.6	0.42mEq H ⁺ /g
3.	25	10.1	13.5	2.7	0.42mEq H ⁺ /g

Calculation

Mass of sample: 3.5 gm

Volume of HCl added: 25 mL

Normality of HCl added: 0.1 N

Volume of NaOH used for back titration: 14.4 mL

Normality of NaOH added: 0.1 N

Step 1: calculate total mEq of HCl added

mEq of HCl = volume × Normality

$$= 25 \times 0.1$$

$$= 2.5 \text{ mEq}$$

Step 2: Calculate mEq of NaOH used

mEq of NaOH= 14.4 × 0.1

$$= 1.44 \text{ mEq}$$

Step 3: mEq of H⁺ Neutralized by Lozenges

Neutralized= mEq HCl added – mEq NaOH used

$$= 2.5 - 1.44$$

$$= 1.06 \text{ mEq}$$

Step 4: Calculate ANC per gram

$$\text{ANC} = 1.06 / 3. = 0.30 \text{ mEq H}^+/\text{g}$$

Similarly, the same calculation applies to other samples.

Where, mEq H⁺/g stands for milliequivalents of hydrogen ions neutralized per gram of a substance typically used to describe the acid neutralizing capacity (ANC) of antacids or similar compounds.

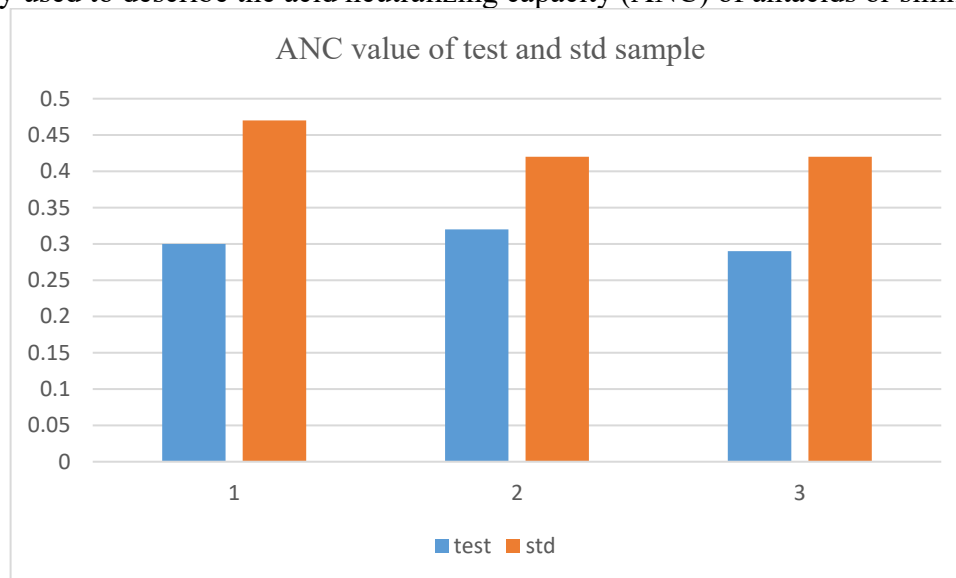


Fig. 8: Graphical presentation of ANC value of Test & Standard Sample

Discussion

The formulated medicated lozenges (MHL1–MHL6) underwent comprehensive organoleptic and post-compression evaluations in accordance with standard guidelines. Among the four batches, MHL6 demonstrated the most favorable characteristics, exhibiting optimal chewability (rated as "very good"), no stickiness, and desirable hardness. These properties are critical for patient acceptability and functional performance, making MHL6 the most suitable formulation among the tested batches.

Weight Variation and Friability: Weight uniformity is essential to ensure consistent dosing. In this study, 20 randomly selected lozenges from MHL1-MHL6 were evaluated, with 20 units meeting the acceptance criteria (maximum deviation of $\pm 5\%$ from the average weight). Although five units exceeded the limit, the majority complied, indicating acceptable weight uniformity. Additionally, the friability test confirmed the mechanical strength of the lozenges, with a percentage friability of 0.48%, well within the acceptable range (typically $\leq 1\%$). This suggests that the lozenges are sufficiently robust to withstand handling and packaging stresses without significant erosion.

Disintegration and Mouth Dissolving Time: A key requirement for medicated lozenges is rapid disintegration to ensure quick drug release. The disintegration time for MHL6 was 45 seconds, while

the mouth dissolving time was 9.10 seconds, both falling within the expected range for fast-dissolving formulations. These results indicate that the lozenge dissolves efficiently in the oral cavity, facilitating prompt drug delivery.

Drug Content Uniformity: Drug content analysis confirmed that MHL6 complies with pharmacopeial standards, as the active ingredient content was within 85–115% of the labeled claim. This ensures that each lozenge delivers a therapeutically consistent dose, minimizing batch-to-batch variability.

Acid Neutralizing Activity: The acid neutralizing capacity (ANC) of MHL6 was 4.427, which is within the acceptable range for antacid formulations. This property is particularly important for lozenges intended to alleviate gastric acidity, as it determines their efficacy in neutralizing excess stomach acid.

Overall, MHL6 exhibited superior performance in terms of organoleptic properties, mechanical strength, disintegration behavior, drug content uniformity, and acid-neutralizing ability. These findings suggest that the formulation is a promising candidate for further development and clinical evaluation. Future studies could explore long-term stability and *in vivo* performance to confirm its therapeutic effectiveness.

CONCLUSION

In the current research, Medicated lozenges were prepared for the treatment of Mouth Ulcers. The possible interaction between the drug and excipient was determined by FTIR spectroscopy which indicated that there was no interaction between the chosen drug and excipients. Lozenges were successfully prepared by heat congealing technique utilizing sugar, liquid glucose, Corn, Vanillin, PEG and Sucrose. Incorporation of synthetic polymers yielded great outcomes in terms of Drug Content. These results suggested that Medicated hard lozenges can be considered as a potential delivery system for the treatment of Mouth Ulcers. Lozenges represent one of the simplest forms of drug delivery. They are easy to prepare, convenient to store, and provide both local and systemic effects during use. Lozenges can incorporate a wide range of active ingredients, making them highly versatile. Modern, improved lozenge formulations have gained a prominent position in the pharmaceutical market and are expected to attract increasing attention as innovative dosage forms for potent drugs. Most medicated hard lozenges are available as over-the-counter (OTC) products and are relatively inexpensive compared to other dosage forms. Overall, medicated hard lozenges hold an important place in pharmacy and are likely to remain significant in the future.

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