

Formulation and Evaluation of Chewable Lozenges for Dental Caries

Rupali Prakash Dube, Priya Anil Chaudhari, Rishid Kamal Lonare, Rahul Bhaginath Mhaske

Prof. Khan Tooba (M.Pharm)

Department of Pharmaceutics

Gajanan Maharaj College of Pharmacy, Chh. Sambhajinagar.

rupalidube001@gmail.com

Abstract: Dental caries is a prevalent oral health issue worldwide. This study explores the potential of herbal lozenges as a novel approach to prevent dental caries. The lozenges are formulated using a combination of natural ingredients, including liquorice root extract, guava leaves extract, ginger extract, and piper betel leaves extract, which are known for their antimicrobial and anti-inflammatory properties. The lozenges also contain clove oil and peppermint oil for their analgesic and refreshing properties. The formulation is designed to provide a convenient and effective way to deliver these herbal ingredients to the oral cavity, promoting oral health and preventing dental caries. This study aims to evaluate the efficacy and safety of these herbal lozenges in preventing dental caries and promoting oral health. We developed herbal lozenges using natural ingredients like liquorice root, guava leaves, and ginger to promote oral health. The lozenges showed promising results in reducing *Streptococcus mutans* counts and preventing dental caries. This research explores the potential of herbal lozenges as a natural and effective way to prevent dental caries.

Keywords: Guava leaves, clove oil, oral health, antimicrobial activity, chewable lozenges

I. INTRODUCTION

Dental caries: dental caries (tooth decay) is a common oral infection affecting people of all ages, with a high prevalence in Thailand (66-90% in 2007).[1] The main cause is *Streptococcus mutans*, a bacterium that forms biofilms on tooth surfaces and produces acid from fermentable carbohydrates like sucrose. This acid dissolves tooth minerals, leading to demineralization and caries. Treatment options include fillings, root canals, and antibacterial therapy, but prevention through proper oral hygiene (brushing, mouthwash, flossing) is crucial. Chemicals like chlorhexidine and triclosan are used in oral care products, but their overuse can cause side effects like tooth discoloration and irritation. As a result, herbal products with anti-cariogenic properties are being explored as a potential alternative for caries [2]. When we eat sugary foods, bacteria in our mouth break them down and produce acids, mainly lactic acid. These acids lower the pH in the plaque on our teeth, causing the enamel to lose minerals and become softer [3]. If the acids continue, they can reach deeper layers of the tooth, leading to further damage. However, when the pH in the mouth goes back to normal, due to saliva, the minerals (calcium, phosphate, and fluoride) can help repair the enamel surface. If the pH stays low for too long, the damage becomes worse, forming a white spot on the tooth, which can still be fixed with proper care. Tooth pain, or toothache, is caused by irritation of the nerve in the tooth's root or surrounding tissues and can be either sudden and acute or chronic and persistent. It is often due to dental issues such as infections, decay, trauma, or tooth loss, and may also result from tooth extractions. In some cases, pain may feel like it originates in the teeth but is actually referred from areas like the ear, sinuses, or TMJ. Toothaches can significantly impact daily activities like eating and sleeping. According to the World Health Organization, reducing tooth pain should be a priority in global oral health initiatives, as dental issues, including caries, affect up to 90% of school-age children and adults worldwide, potentially hindering development and well-being. [4]



II. ADVANTAGES AND DISADVANTAGES

A. Advantages

- Simple to administer to elderly and paediatric patients.
- prolonged effect of the medication.
- Prevent the drug's first pass metabolism.
- Water is not necessary for medication use.

B. Disadvantages

- Some medications might not work well with aldehyde-based confectionery bases. For instance, benzocaine.
- Potential medication leakage from mouth to stomach, maybe accompanied by saliva.
- Hard candies, the preparation of lozenges requires a high temperature.
- Using a Gummy-style lozenge with kids has the drawback that they might think of it as candy rather than a serious dosing form.

2.1 Causes

Toothache can be caused by either non-dental (non-odontogenic) conditions.[5]

A. Dental

- Pulpitis
- Dentin hypersensitivity
- Periodontal
- Food impaction
- Periodontal abscess

B. Non-dental

- Myofascial pain
- Psychogenic toothache
- Acute and chronic sinusitis
- Angina pectoris [classical, refer to muscle pain]

2.2 Diagnosis

Diagnosing a toothache might be challenging. Dental pain can have a wide range of causes, including those that are not listed here, and it can come from or be directed towards the teeth. Dental discomfort can be used to replicate almost any type of facial pain syndrome. The diagnostic method for toothaches usually involves the following steps: obtaining a medical history, doing an examination, and conducting investigations. A differential diagnosis can be made if all of this information has been gathered to generate a clinical picture.

Dental discomfort can be diagnosed by an endodontist or dentist. They could tap on the tooth and look for indications of swelling, redness, or dental decay to determine what's causing the pain. The impacted tooth can get cold therapy to simulate the response. An oral examination combined with a thorough assessment of medical history may lead to a diagnosis. X-rays are often used to get a more accurate picture of the source of the pain.

2.3 Symptoms

- Pain in your jaw or teeth when you eat.
- Bleeding or discharge from the gums or surrounding tooth.
- Smelly breath.
- High temperature.



2.4 Lozenges

Lozenges are various-shaped, oral forms usually containing a flavoring substance and a medicinal agent [6]. They have become very widespread nowadays, both in food and pharmaceutical preparations, as a means of delivering different active substances [7]. They are premeditated to reduce both local and systemic symptoms as the medical agents are well absorbed via the buccal lining or when swallowed [8]. Lozenges provide various advantages as they are easy to administer to both pediatric and geriatric population and easy to prepare, with minimum amount of equipment and time [7]. Chewable lozenges are one of the most popular lozenges prepared by molding gelatin base which gives a distinctive rubber texture ranging from mild to very solid, depending on the amount of gelatin used [9,10]. Sugar is often added during the preparation of chewable lozenges for the flavor and consistency, but due to its undesirable effects, in terms of increasing glycemic index and high calories from simple sugars, some products are sugar-little or sugar-free.[11]lozenge is a combination solid medication made of both a flavouring and a chemical. It's made to dissolve gradually in the mouth and have effects that can be localised or systemic.[12] The French phrase for a diamond shape with four sides is where the name "lozenge" comes from. Moulded pastilles and troches, which are compressed lozenges, are two types of them that may be manufactured using these methods.[13]The oral cavity is the main entry for both the gastrointestinal and respiratory systems. Therefore, poor oral health could greatly impact many chronic conditions and systemic diseases [14]. Microorganisms found in the human oral cavity, referred to as the oral microflora [15], count for over than 700 bacterial species [16]. Streptococcus sp. is the most common oral microflora that plays an important role in the human microbial community and human health. Therefore, imbalance of microbial flora, known as dysbiosis, is linked to oral inflammation and could contribute to oral diseases and to systemic conditions through bacteremia [17-18]. A large number of synthetic drugs are currently considered to be effective for the remission of oral and throat inflammation and infection [19].

III. MATERIAL AND METHODS

3.1 DRUG PROFILE

1. Guava Leaves



Fig.3[A]Guava Leaves

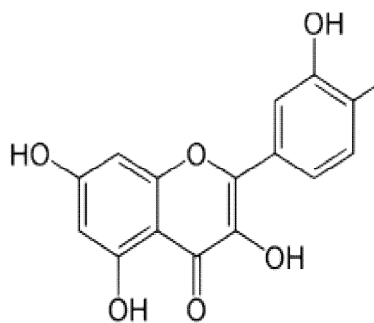


Fig.3[B]quercetine

Botanical Information

Scientific name: Psidium guajava

Family: Myrtaceae

Chemical Composition

Flavonoids: Exhibiting antioxidant and anti-inflammatory properties

Tannins: Known for their astringent and antimicrobial properties

Essential Oils: Contributing to fragrance and medicinal properties

Pharmacological Properties

Antimicrobial: Effective against various microorganisms

Antidiabetic: Potentially helping to regulate blood sugar levels

Gastroprotective: Soothing digestive issues



Traditional Uses

Culinary: Olive oil is a staple in Mediterranean cuisine.

Medicinal: Olive oil has been used to treat various conditions, including skin and digestive issues

Modern Applications

Dietary: Olive oil is a popular cooking oil and ingredient.

Cosmetics: Olive oil is used in skincare products for its moisturizing and antioxidant properties.

Pharmaceuticals: Olive oil is used as an excipient in some pharmaceutical products.

2. PEPPER BETAL LEAF



Fig 4[A]Peper betal leaf

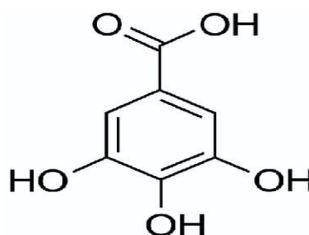


Fig 4[B]Phenol

Botanical Description:

Scientific name: Piper betle

Family: Piperaceae (Black Pepper family)

Chemical Constituents:

Phenols: Contributing to antimicrobial and antioxidant properties

Alkaloids: Exhibiting pharmacological activities

Tannins: Known for their astringent and antioxidant properties

Pharmacological Properties:

Antimicrobial: Effective against various microorganisms

Anti-inflammatory: Reducing inflammation and alleviating symptoms

Antioxidant: Protecting against cell damage

Digestive aid: Relieving symptoms of indigestion and promoting oral health.

Traditional Uses:

Digestive aid: Betel leaves may help aid digestion and relieve symptoms of indigestion.

Oral health: Betel leaves have been traditionally used to freshen breath and promote oral health.

Modern Applications:

Pharmaceuticals: Utilizing bioactive compounds for medicinal purposes

Food and Beverage Industry: Using extracts for flavor and preservation

Organic Synthesis: Exploring potential uses in chemical synthesis

Traditional Medicine: Continuing to be used in traditional remedies for various health issues.

3. GINGER (Zingiber officinale)



Fig 5[A]Ginger

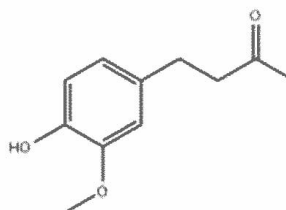


Fig 5[B]Gingerol



Botanical Information

Scientific name: Zingiber officinale

Family: Zingiberaceae

Chemical Composition

Gingerols: A group of compounds responsible for ginger's medicinal properties, including: A.Gingerol B.Shogaol

Volatile oils: Including zingiberene and bisabolol

Pharmacological Properties

Anti-inflammatory: Gingerols have anti-inflammatory activity.

Antiemetic: Ginger has been shown to have antiemetic effects.

Digestive benefits: Ginger may help alleviate nausea, bloating, and other digestive issues.

Traditional Use

Ayurvedic medicine: Ginger has been used for centuries in Ayurvedic medicine to treat various ailments.

Traditional Chinese medicine: Ginger is used in traditional Chinese medicine to treat digestive issues and other conditions.

Modern Applications

Dietary supplements: Ginger supplements are available in various forms, including capsules and extracts.

Pharmaceuticals: Ginger extracts and compounds are being investigated for their potential therapeutic applications.

4. Liquorice Root



Fig. 6[A] Liquorice Root

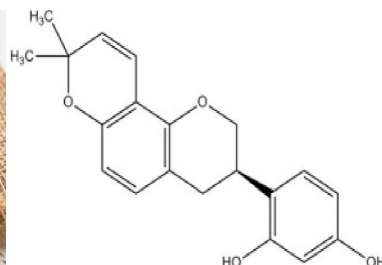


Fig.6[B] Comestans

Botanical Information

Scientific name: Glycyrrhiza glabra

Family: Fabaceae (Legume family)

Chemical Composition

Glycyrrhizin: A triterpenoid saponin responsible for its sweet taste and medicinal properties

Flavonoids: Exhibiting antioxidant and anti-inflammatory properties

Pharmacological Properties

Anti-inflammatory: Reducing inflammation and alleviating symptoms

Antimicrobial: Effective against various microorganisms

Expectorant: Relieving respiratory issues, such as coughs and bronchitis

Gastroprotective: Soothing digestive issues, such as ulcers and heartburn

Traditional Uses

Traditional medicine: Cinnamon has been used to treat digestive issues, respiratory problems, and other conditions.

Modern Applications

Pharmaceuticals: Utilizing bioactive compounds for medicinal purposes

Food and Beverage Industry: Using extracts for flavor and sweetness

Herbal Supplements: Continuing to be used in traditional remedies for various health issues

Skincare: Utilizing anti-inflammatory and antioxidant properties in skincare products



5. Clove Oil (*Syzygium aromaticum*)



Fig.7[A]Clove oil

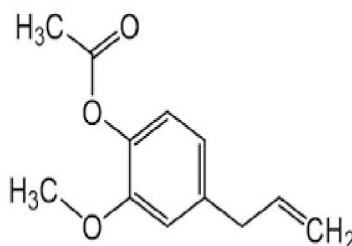


Fig.7[B]Eugenol

Botanical Information

Scientific name: *Syzygium aromaticum*

Family: Myrtaceae

Chemical Composition

Eugenol: A major compound responsible for clove's medicinal properties

Other compounds: Beta-caryophyllene, alpha-humulene, and eugenyl acetate.

Pharmacological Properties

Antimicrobial: Eugenol has antimicrobial activity against various bacteria and fungi.

Analgesic: Clove oil has been used as a local anesthetic and pain reliever.

Anti-inflammatory: Eugenol has anti-inflammatory properties.

Antioxidant: Clove has antioxidant properties, protecting against oxidative stress.

Traditional Uses

Dental care: Clove oil is used to relieve toothache pain and reduce inflammation.

Digestive issues: Clove has been used to treat digestive issues, such as nausea and vomiting.

Modern Applications

Dental products: Clove oil is used in some dental products, such as mouthwashes and toothache relief gels.

Pharmaceuticals: Eugenol is used in some pharmaceutical products, such as topical creams and ointments.

Food and beverages: Clove oil is used as a flavoring agent and ingredient in various food and beverage products.

6. Peppermint oil



Fig.8[A]. peppermint oil

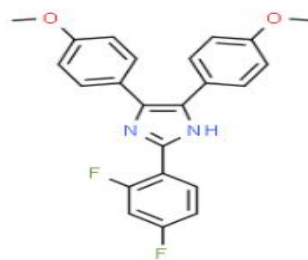


Fig.8[B]. Loratadine

Botanical Information

Scientific name: *Mentha piperita*

Family: Lamiaceae

Chemical Composition

Menthol: A major compound responsible for peppermint oil's medicinal properties

Pharmacological Properties



Digestive benefits: Peppermint oil may help alleviate digestive issues, such as IBS.

Analgesic: Menthol has analgesic properties, which may help relieve pain.

Antispasmodic: Peppermint oil may help relieve muscle spasms.

Antimicrobial: Peppermint oil has antimicrobial properties.

Traditional Uses

Digestive issues: Peppermint oil has been used to treat digestive issues, such as indigestion and nausea.

Headaches: Peppermint oil has been used to relieve headaches and migraines.

Modern Applications

Aromatherapy: Peppermint oil is used in aromatherapy for its invigorating and refreshing properties.

Digestive supplements: Peppermint oil is used in some digestive supplements.

Topical products: Peppermint oil is used in topical products, such as creams and ointments, for its analgesic and anti-inflammatory properties.

3.2 OTHER INGREDIENTS

• Glycerine:

Non-proprietary name: Ethylene glycol; 1,2 Ethanediol

IUPAC name: Ethane-1,2-diol

Molecular formula: C₂H₆O₂

Molecular weight: 62.07 g/mol

Melting point: 18.2 °C

Appearance : Odourless ,Colourless Viscous Hygroscopic Liquid.

Applications : As humectants agent

• Gelatin

Non-proprietary name: Gelatin, Gelatin foam,

Molecular formula: C₃₁H₂₇NO₄

Molecular weight: 733.9268

Melting point: 31.7–34.2 °C

Appearance : Colorless or slightly yellow transparent solid

Applications : as whipping agent

3.3 FORMULATION TABLE (For 8 Lozenges)

Ingredients	Formulation 1	Formulation 2	Formulation 3	Uses
Piper Betel Leaves Extract	0.5gm	1gm	1.5gm	Antioxidant and Aantimicrobial
Ginger Extract	0.5gm	1gm	1.5gm	Antiemetic and Antioxidant
Guava leaves Extract	1gm	2gm	3gm	Antidiabetic and Antimicrobial
Liquorice Root Extract	1gm	2gm	3gm	Expectorant and Gastroprotective
Gelatine	3gm	4gm	5gm	Whipping
Clove oil	1 -2 drops	3-4 drops	4-5 drops	Antibacterial and Anti-inflammatory
Glycerine	1ml	2ml	3ml	Humectant



Corn starch	2gm	3gm	4gm	Binding agent
Peppermint oil	1-2 drops	3-4 drops	4-5 drops	Flavouring agent
Distilled Water	15ml	20ml	25ml	Vehicle

Table 1. Formulation Table

3.4 Methods Of Preparation

1. Prepare Herbal Base

Mix liquorice root extract, guava leaf extract, ginger extract, and piper betle leaf extract together in a small bowl. Optionally, steep these in a small amount of hot water (5–10 mL) for 5–10 minutes, then strain if using fine extracts (optional for smoother texture). You can also use the extracts directly.

2. Incorporate Gelatin & Glycerine

Soften gelatine in a little cold water beforehand (blooming).
Add the bloomed gelatin to the extract and stir until fully dissolved.
Mix in glycerine — it adds smoothness and preserves moisture.

3. Add Herbal and Flavoring Agents

Stir in the prepared herbal extract mix (or extract), clove oil, and peppermint oil once the mixture has cooled slightly (not too hot to degrade oils).

4. Mold and Set

Lightly grease or dust candy molds or a flat tray with corn starch to prevent sticking.
Pour the mixture into molds or onto a tray and score to create 10 equal pieces.
Allow to cool and set at room temperature (or refrigerate for faster setting).

5. Unmold and Store

Once set, remove lozenges and dust lightly with corn starch if sticky.
Store in an airtight container away from moisture.

3.5 Evaluation Parameter

1. Appearance

The prepared chewable lozenges to check for color, clarity, and the presence of any suspected particles.

2. Stickiness and grittiness

By gently rubbing the prepared chewable lozenge sample between two fingers, the product's texture—specifically, its stickiness and grittiness—was assessed visually.

3. PH

The pH of the herbal lozenges was measured using a calibrated pH meter following the manufacturer's instructions, and the results showed a mean pH of 6.2 ± 0.3 (n=10) on the pH scale.

To determine the pH of a lozenge, weigh the lozenge and dissolve it in water and then measure the pH by following some steps:

Weight the lozenge

Dissolve it in 5 mL of water

Place the vial on a horizontal shaker until the lozenge dissolves

PH meter is use to measure the pH of a sample. A pH meter works by measuring the ion exchange between the sample and the glass electrode's inner solution, which generates an electrical voltage. The pH reading is based on the hydrogen ion concentration and the relation between the electric voltage and the pH reading.

The pH scale ranges from 0 to 14. A pH lower than 7 indicates an acidic substance, a pH of 7 indicates a neutral substance, and a pH greater than 7 indicates a basic substance.



4. Stability study

The stability study is currently in progress, the Chewable lozenges were tightly packed and stored at a cooling temperature (4°C) for three months, and the changes in the properties (appearance, stickiness and grittiness, pH, thickness and dissolution) has been evaluated.

5. Storage

It is advisable to keep these preparations out of children's reach and away from heat. They must to be shielded from excessive dampness. Either room temperature or chilled temperature is typically advised, depending on the drug's and the base's storage needs.

6. Alkaloids Detection (Dragendorff's Test):

A volume of 5 mL of the plant extract was transferred to a glass test tube. The chloroform-soluble layer of the extract was then subjected to extraction using 10 mL of acetic acid (CH₃COOH). Following this, a few drops of Dragendorff's reagent (a solution of potassium bismuth iodide) were added. The formation of an orange to reddish-brown precipitate indicated the presence of alkaloids.

7. Flavonoids Detection:

Five milliliters of the plant extract were heated with 10 mL of ethyl acetate (C₄H₈O₂) over a steam bath for approximately 3 minutes. The mixture was then filtered, and 4 mL of the resulting filtrate was shaken with 1 mL of dilute ammonia solution. The development of a yellow coloration suggested the presence of flavonoid compounds.

8. Test for Tannins

Lead Acetate test: To a few ml of extract, few drops of 1% Lead acetate is added. The mixture is shaken well. A yellowish precipitate indicates the presence of tannins.

9. Test for Total Phenols: To 2 ml of extract, 3% of FeCl₂ is added. Formation of deep blue colour indicates the presence of total phenol.

IV. RESULT AND DISCUSSION

In the results we perform the different types of test and process and the values comes out from that are entered in this observation table. The values of pH, type, shape, and other organoleptic properties are put in this observation table.

4.1 Physical Parameters Of Chewable lozenges:

Sr. No	Particular Observation	Observation F1	Observation F2	Observation F3
1.	Colour	Light Brownish	Brownish	Dark Brownish
2.	Odour	Minty	Minty	Minty
3.	PH	5.9	6.21	6.1
4.	Shape	Round	Round	Round
5.	Texture	Smooth	Smooth	Smooth
6.	Type	Chewable Lozenges	Chewable Lozenges	Chewable Lozenges

Table 2. Physical Parameters Of Chewable lozenges

5.2 Phytochemical Parameters Of Herbal Extract:

Tests	Name of tests	In methanol extract
Alkaloids	Wagners reagent	Positive
Flavonoids	Ferric chloride test	Positive
Tannins	Lead Acetate test	Positive
Phenol	Test for Total Phenols	Positive

Table 3. Phytochemical Parameters Of Herbal Extract

V. CONCLUSION

We conclude that, lozenges formulation containing guava leaves and clove oil could provide an effective natural remedy for preventing or managing dental caries. The antimicrobial properties of both guava leaves and clove oil could



help reduce harmful bacteria in the mouth, while the anti-inflammatory and soothing effects may promote healthier gums and teeth. Clove oil's antibacterial and analgesic effects may aid in relieving discomfort and preventing tooth decay. When combined in a lozenge, these ingredients could offer a natural and convenient way to enhance oral hygiene.

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