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FORMULATION AND EVALUATION OF HERBAL LOZENGES

Vidya Marwal*[1], Neha Sodiyal[2], SM Patil[3]

Student B Pharm IV Year, Shree Dev Bhoomi Institute of Education Science & Technology Veer Madho Singh Bhandari Uttarakhand Technical University, Dehradun, Uttarakhand, India.

Associate Professor, Shree Dev Bhoomi Institute of Education Science & Technology Veer Madho Singh Bhandari Uttarakhand Technical University, Dehradun, Uttarakhand, India.

Director, Shree Dev Bhoomi Institute of Education Science & Technology Veer Madho Singh Bhandari Uttarakhand Technical University, Dehradun, Uttarakhand, India.

Corresponding Address – Vidya Marwal
Student,
Shree Dev Bhoomi Institute of Education
Science & Technology Dehradun, Uttarakhand, India.

Abstract: Herbal lozenges are a type of oral dosage form that contains herbal extracts or other plant-based ingredients. They are designed to be dissolved slowly in the mouth, allowing the active ingredients to be absorbed through the mucous membranes. In this paper, we will provide an overview of herbal lozenges, including their definition, introduction, types, and evaluation parameters. Herbal lozenges are a popular choice for the treatment of sore throats, coughs, and other respiratory conditions. They are also commonly used for the management of digestive disorders, such as nausea, vomiting, and diarrhoea. There are several types of herbal lozenges available in the market, each with its own unique formulation and intended use. Some common types include immune-boosting lozenges, throat-soothing lozenges, and digestive support lozenges. The evaluation of herbal lozenges is crucial to ensure their safety and efficacy. Several parameters are used to assess the quality of herbal lozenges, including disintegration, thickness, friability, and weight variation. Disintegration is the time it takes for the lozenge to break down in the mouth. Thickness and friability determine the physical stability of the lozenge, while weight variation ensures consistency in dosing. herbal lozenges are a popular and effective form of herbal medicine. They offer a convenient and easy way to deliver therapeutic compounds to the body, and their efficacy can be evaluated through various parameters such as disintegration, thickness, friability, and weight variation. Further research is needed to explore the full potential of herbal lozenges in the treatment of various health conditions.

Keywords: **Diarrhoea, Lozenges, Friability, Disintegration, Potential.**

INTRODUCTION

Throat infections, including conditions like sore throat and tonsillitis, are common ailments that cause discomfort, pain, and difficulty in swallowing. While conventional treatments such as antibiotics are often prescribed, there is a growing interest in natural alternatives that can provide relief without the potential side effects associated with pharmaceutical drugs. Herbal lozenges have emerged as a popular and effective option for soothing throat infections, offering a natural and holistic approach to managing these conditions. Throat infections affect individuals of all ages, and their prevalence can be attributed to various factors, including viral or bacterial pathogens, environmental irritants, or weakened immune systems. These infections can significantly impact an individual's daily life, leading to discomfort, difficulty speaking, and reduced productivity. Traditional treatment options often focus on symptomatic relief, and herbal lozenges provide a natural alternative that targets the underlying causes while soothing the throat. Lozenges include one or more medications that have been dissolved or distributed in a sweetened base and are designed to be held in the mouth or pharynx.[1,2] Lozemges are used for both individuals who have trouble swallowing solid oral dosage forms and for medications that need to be given gradually to produce a steady level of medication in the oral cavity or to coat thoat tissues with the solution of medication.[3]

Herbal lozenges have been used for centuries as a natural remedy for a variety of ailments. The earliest recorded use of herbal lozenges dates back to ancient Egypt, where they were used to treat sore throats and coughs. The Eber papyrus which dates to around 1550 BC, comprises more than 700 chemicals, most of which are plant-derived.[4] The Greeks and Romans also used herbal lozenges, with the Greek physician Hippocrates prescribing them for respiratory problems. In the Middle Ages, herbal lozenges became even more popular, with many apothecaries selling them as a remedy for everything from coughs to toothaches. One of the most famous herbal lozenges from this time period was the "Pectoral of Syrup of Violets," which was used to treat coughs and sore throats.[(5)] During the 19th century, herbal lozenges continued to be a popular remedy, with many companies producing them commercially. One of the most well-known herbal lozenges from this time period was the "Fisherman's Friend," which was first produced in Fleetwood, England in 1865.[(6)]

Herbal lozenges are solid dosage forms that are designed to dissolve or disintegrate slowly in the mouth, providing a sustained release of active ingredients. They are commonly used for the treatment of sore throat, cough, and other respiratory ailments. The use of herbal ingredients in lozenges has gained popularity due to the growing demand for natural and safe remedies for these ailments. Herbal lozenges can be formulated using a variety of natural ingredients such as plant extracts, essential oils, and other natural substances. Herbal lozenges have gained popularity as a natural alternative to conventional medicine due to their perceived safety and efficacy. They are often preferred over pharmaceuticals due to their lower incidence of adverse effects and interactions with other medications. Herbal lozenges are also seen as a more sustainable option, as they are often made from locally sourced natural ingredients that are less harmful to the environment. Herbal lozenges are also regarded as a more environmentally friendly choice because they frequently contain natural, locally obtained ingredients that are less damaging to the environment. Lozenges are flavor-enhanced pharmaceutical dosage forms that are meant to be sucked and kept in the mouth or pharynx. They typically include one or more medications in a sweetened foundation.[7,8] Lozenges are most often used for localized effects in the mouth. The majority of the time, lozenges

are utilised for localised effects in the mouth. Vitamins, antibiotics, anaesthetics, antihistamines, decongestants, corticosteroids, astringents, analgesics, and other substances may be present.[9] Today, herbal lozenges are still used as a natural remedy for a variety of ailments, including sore throats, coughs, and even nausea. Many different herbs are used in these lozenges, including peppermint, ginger, and echinacea.

TYPES OF LOZENGES

There are three basic types of Lozenges.

Hard Lozenges:

Solid, compressed tablets called hard lozenges gently disintegrate in the mouth to release their active ingredients. Lozenges made of hard candy are composed of a glassy or amorphous mixture of sugar and other carbohydrates.[10] They typically include 0.5 to 1.5% moisture. Hard Lozenges should not disintegrate, deliver a slow, uniform disintegration or erosion over 5 to 10 minutes, have a smooth surface texture, and have a flavour that is pleasing to the palate while hiding the taste of the medication.[12] They are often used for medicinal purposes or as throat soothers. Hard lozenges typically have a longer dissolution time compared to soft and chewable lozenges.

Soft Lozenges:

Soft lozenges are made to dissolve more quickly in the mouth and have a consistency similar to gel. Soft lozenges are made with components like PEG (polyethylene glycol), chocolate, or acacia base and are intended for a delayed release of medication into the mouth. Some soft lozenges also include silica gel at its origin. The key ingredient in these lozenges that gives them their smoothness and texture is acacia.[13] They often contain a higher amount of active ingredients compared to hard lozenges and may have additional coating or moisture to provide soothing relief.

Chewable Lozenges:

The purpose of chewable lozenges is to be chewed, not slowly dissolved.Chewable lozenges often have a basis of glycerinated gelatin, which is a combination of gelatin, glycerin, and water.

You can combine this base with medication, acacia, and the appropriate flavouring and sweetening ingredients. They offer a different experience compared to hard and soft lozenges and provide a more immediate release of active ingredients. Chewable lozenges are popular among the pediatric and geriatric population.[13] Chewable lozenges are often used for medicinal purposes, such as cough or throat relief.

Advantages of lozenges

1. **Convenient and portable:** Lozenges are easy to carry and provide quick relief on the go.

2. **Targeted delivery:** They dissolve slowly in the mouth, allowing for targeted delivery of active ingredients to the throat and mouth.

3. **Soothing effect:** Lozenges often contain ingredients like menthol or honey that provide a soothing effect on the throat and alleviate discomfort.

4. **Localized action:** They work directly in the throat and mouth, providing localized relief for specific conditions.

5. **Versatile:** Lozenges can be used for various purposes, such as relieving sore throat, cough, or dry mouth.

6. **Non-invasive:** Lozenges are a non-invasive option for those who prefer not to swallow pillsuse sprays.

7. Easy to use: They require no preparation or administration, simply unwrap and consume.

8. It extend the time of drug in the oral cavity to elicit a specific effect.[14,15]

9. Cost of production is less, less production time.[11]

DISADVANTAGES OF LOZENGES:

1. **Limited effectiveness:** Lozenges may not provide as long-lasting or potent relief as other forms of medication.
2. **Temporary relief:** The effects of lozenges are usually temporary and may not address the underlying cause of the symptoms.
3. **Limited application:** Lozenges are primarily designed for throat and mouth conditions and may not be suitable for other ailments.
4. **Possible side effects:** Some individuals may experience allergic reactions or sensitivity to certain ingredients in lozenges.
5. **Restricted age groups:** Certain lozenges may have age restrictions, making them unsuitable for children or infants.
6. **Not suitable for all conditions:** Lozenges may not be appropriate for severe or chronic conditions that require stronger medications or alternative treatments.
7. **Taste and texture:** Some people may find the taste or texture of lozenges unpleasant or difficult to tolerate.

Ideal Properties of Lozenges

1. Lozenges should provide fast-acting relief, effectively delivering their active ingredients to the affected area.
2. They should have a pleasant taste to encourage compliance and make the experience enjoyable.
3. Lozenges should offer long-lasting relief, addressing symptoms such as sore throat, cough, or mouth dryness effectively over an extended period.
4. The formulation should ensure efficient dissolution or absorption for optimal delivery of the active ingredients.
5. Lozenges should be easy to consume and convenient for on-the-go use.
6. They should be safe, with minimal side effects or interactions with other medications.
7. Ideally, lozenges should be available in various strengths or formulations to cater to different needs and preferences.
8. They should be individually packaged and properly sealed for hygiene and convenience.
9. Lozenges should have a stable shelf life, maintaining their efficacy and quality throughout the recommended usage period.
10. They should be reasonably priced and accessible to a wide range of consumers.

AIM AND OBJECTIVE

The aim of this study is to formulate and evaluate herbal lozenges using natural ingredients for potential use in alleviating symptoms of throat discomfort and supporting respiratory health. The objective of this study:

1. To review existing literature on the therapeutic properties of herbal ingredients commonly used in lozenges and their potential benefits for throat and respiratory health.
2. To formulate herbal lozenges by selecting appropriate natural ingredients and determining their optimal concentrations for maximum efficacy.
3. To assess the physical and chemical characteristics of the formulated lozenges, including size, shape, weight variation, hardness, and disintegration time.
4. To conduct sensory evaluation tests to assess the taste, flavor, and overall acceptability of the herbal lozenges.
5. To discuss the results in light of the study objectives, drawing conclusions regarding the feasibility and effectiveness of the developed herbal lozenges.
6. To provide recommendations for further research and potential applications of the formulated lozenges in clinical practice or self-care for throat and respiratory health.

MATERIALS AND METHOD

Chemicals:

1. Peppermint leaves(dried or fresh)

2. Organic solvent (ethanol, methanol, hexane)

Equipment:

1. Soxhlet extractor

2. Heating mantle or hot plate

3. Glassware (round bottom flask, Condenser)

4. Glass wool or cotton

5. Filtration apparatus

Method

Sample collection and drying

Mentha piperita fresh green leaves were procured from Seemadwar on April 2023. After being thoroughly rinsed with water, the leaves were dried for two weeks in the shade. To make powder, these dried leaves were manually milled.

Fig.1- Extraction of Peppermint leaves by Soxhlet Appartaus

Extraction of Plant Materials

The dried leaves were ground into a powder weighing 90 grammes. The 50 grammes of powdered menthe piperita leaves were then extracted using the soxhlet extraction technique and methanol. As a solvent, 250 ml of methanol were utilised. A heating mantle was used to continuously heat the equipment. The specimen was put in an extraction thimble, which was then submerged in boiling point. The soxhlet extraction solvent, which went through numerous cycles over the course of around 6 to 7 hours, was collected.

Table 1: List of Ingredients used in the Herbal Lozenges

S.NO.	COMMON NAME	BOTANICAL NAME	PLANT PART USED	PROPERTIES	QUANTITY TAKEN
1	Honey 	*Apis Mellifera*	-	Sweetening agent, Binder, Moisturizing agent, Soothing agent, Antimicrobial agent.	170g
2	Peppermint 	*Mentha piperita*	Leaves	Soothing, Anti-inflammatory, Antimicrobial, Antioxidant, Decongestant.	2ml
3	Clove 	*Syzygium aromaticum*	-	Analgesic, Antiseptic, Antioxidant, Flavoring agent	2.5g
4	Ginger 	*Zingiber officinale*	Rhizome	Anti-inflammatory, Antioxidant, Digestive aid, Flavoring agent.	2.5ml
5	Lemon 	*Citrus limon*	-	Antimicrobial, Mucolytic, Vitamin-C, Flavoring agent.	2.5ml

6	Sugar 	*Saccharum officinarum*	-	Sweetening agent, Binder, Preservative, Cough Suppressant	40g

FORMULA OF HERBAL LOZENGES

Table 2: Raw materials to be included in the Herbal Lozenges.

S.NO.	INGREDIENTS	QUANTITY
1.	HONEY	170g
2.	PEPPERMINT EXTRACT	2ml
3.	CLOVE	2.5g
4.	GINGER JUICE	2.5ml
5.	LEMON JUICE	2.5ml
6.	POWDERED SUGAR	40g

METHOD OF PREPARATION OF HERBAL LOZENGES

Meltig and Molding technique was used for the preparation of Lozenges. In a beaker, combine the sugar, water, honey, lemon juice, ginger, cloves, peppermint extract. Heat the mixture over medium heat stirring constantly until the sugar has dissolved. Once the sugar has dissolved, increase the heat to medium-high and let the mixture boil for 10-15 minutes or until it reaches a temperature of 300 F (150 C)

Fig.1: Melting of Herbal Lozenges

Remove the mixture from the heat and let the mixture cool for a few minutes. If using molds, pour the mixture into the molds and let it cool and solidify for 30-45 minutes. If not using molds, pour the mixture onto a sheet of butter paper and let it cool until it is firm enough to handle. In a small beaker, sift the powdered sugar. Roll the lozenges in the powdered sugar until they are coated on all sides. If desired, add food coloring or flavoring extracts to the powdered sugar before coating the lozenges. Store the lozenges in an airtight container at room temperature for up to 2 weeks. If the lozenges stick together, you can coat them with more powdered sugar.

(a)

(b)

(c)

Fig.2: Herbal Lozenges

PHYTOCHEMICAL SCREENING

Through a series of qualitative tests, the presence of numerous types of secondary metabolites was identified. Using Dragendorff's and Mayer's reagents, alkaloids were found. Alkaline reagent assays and Shinoda's test were both used to identify flavonoids. Lead acetate and ferric chloride tests were used to identify phenolics. The Salkowski test was used to determine the terpenoids.

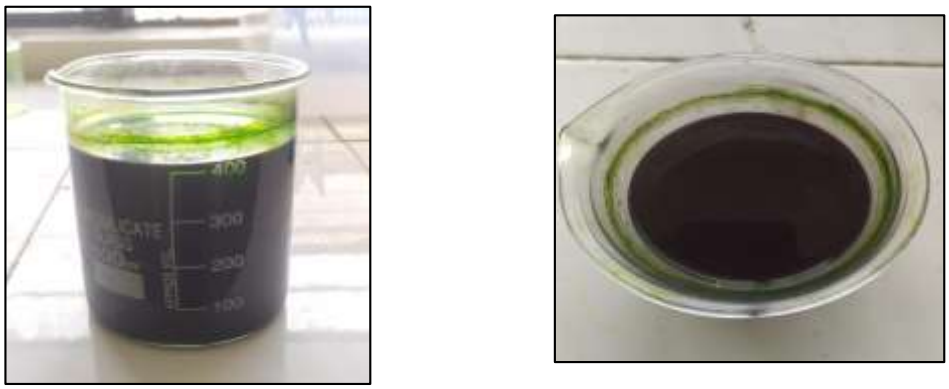

Fig.3: Extraction of Peppermint Leaves

- **Screening of Alkaloids:**

  In a test tube, place a small quantity of the extract.Drops of Dragendorff's reagent should be added.

  Alkaloids can be detected by the precipitate's orange-red colour.

- **Screening of Flavonoids:**

  In a test tube, place a small quantity of the extract.

  Add a couple of drops of weak hydrochloric acid (HCl), then a dash of magnesium oxide.

  Flavonoids are present when a red colour is formed or changes colour.

- **Screening of Phenols:**

  In a test tube, place a small quantity of the extract.Drops of 5% ferric chloride solution should be added.

  The presence of phenols is indicated by the development of a blue or green colour.

- **Screening of Tannins:**

  In a test tube, place a small quantity of the extract.Drops of 10% lead acetate solution should be added.

  Tannins are present when a white or cream-colored precipitate forms.

- **Screening of Terpenoids:**

  In a test tube, place a small quantity of the extract.

  Several drops of concentrated sulfuric acid (H2SO4) should be added.

  Terpenoids are present when a red colour forms or when the colour changes.

- **Wagner test:**

  Take a little peppermint essence and put it in a test tube.

  Wagner's reagent should be added in small amounts to the test tube containing the extract.

  Alkaloids can be detected in peppermint extract by the formation of a reddish-brown precipitate.

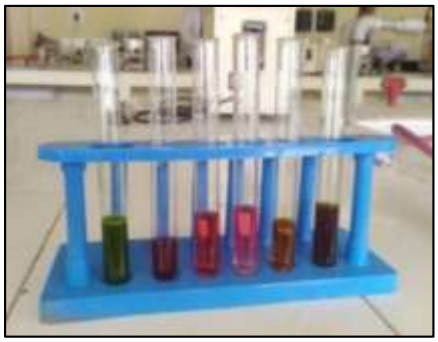

Fig.4: Phytochemical screening of extract of leaves of *Mentha piperita*

Table 1: Phytochemical screening of extract of leaves of *Mentha piperita*

S.NO.	PHYTOCHEMICALS	METHANOL EXTRACT
1.	Alkaloid	+
2.	Flavonoid	+
3.	Phenol	+
4.	Tannins	+
5.	Terpenoid	+
6.	Wagner	+

MACROSCOPICAL EVALUATION

On the basis of ocular observation. The formulations organoleptic qualities were determined.

Table 2: Macroscopical Evaluation

S.No.	Parameters	Observation
1	Colour	Dark Brown
2	Odour	Honey Flavour
3	Taste	Sweet & Bitter
4	Texture	Hard
5	Shape	Round

EVALUATION PARAMETER OF LOZENGES

Weight Uniformity test

The weight uniformity test was conducted on 20 randomly selected herbal lozenges from each batch. The average weight was calculated and the percentage variation of each tablet was determined.

$$\text{Average weight} = \frac{\text{Weight of 20 Lozenges}}{20}$$

$$\text{Weight variation} = \frac{\text{Individual Weight- Average Weight}}{\text{Average Weight}} \times 100\%$$

Hardness test

The resistance of lozenges to shipping, storage conditions, breakage, transportation and handling, depending upon the hardness.[16] The hardness test was conducted on 10 randomly selected herbal lozenges from each batch. The test was performed using a Monsanto hardness tester. The lozenges were individually placed in the tester and compressed until the required force was reached. The hardness of each lozenge was recorded.

Friability test

The friability test used to assess the physical strength and resistance of tablets or granules during handling, packaging and transportation. The friability test is done using a friability tester set at 25 rpm for 4 minutes.[16]

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

Thickness test

The thickness and diameter of the lozenge from production run is carefully controlled. Thickness can vary with no change in weight due to difference in the density of granulation and the pressure applied to the lozenges as well as the speed of the tablet compression machine.[17] The thickness test was conducted on 10 randomly selected herbal lozenges from each batch. The test was performed using a Vernier Calliper. The lozenges were placed between the jaws of the Vernier Calliper and the thickness of each lozenge was recorded.

$$\text{Average thickness} = \frac{\text{Total 5 lozenges thickness}}{5} \times 100$$

Table 3: Evaluation Parameters of Lozenges				
S.N.	**Weight Uniformity (mg)**	**Hardness Kg/cm**	**Friability(%)**	**Thickness (mm)**
1	870	19.05	0.70	11.34
2	760	17.08	0.68	11.67
3	850	17.09	0.50	12.43
4	650	18.04	0.48	12.75
5	770	17.06	0.56	12.67

COMPARATIVE STUDY OF STREPSILS AND LOZENGES

Disintegration test

The disintegration test determines the time it takes for a solid dosage form to break down into smaller particles or dissolve completely when placed in a liquid medium.The disintegration test was conducted on 5 randomly selected herbal lozenges and 5 selected Strepsils according to USP30. The test was performed using a disintegration tester with a basket rack assembly that rotates at 30 rpm through the disintegration medium of phosphate buffer with pH 6.2 maintained at 37°C. The time taken for each lozenge to disintegrate completely was recorded. The average disintegration time of the lozenges from batch A was 7 minute. The average disintegration time of the lozenges from batch B was 10 minute.The results of the disintegration test indicate that both batches of herbal lozenges have a consistent disintegration.

Table 4: Disintegration studies of Strepsils and Lozenges

Disintegration Time Strepsils (Min)	Disintegration Time Lozenges (Min)
10	7
10	7
10	7
10	7
10	7

DETERMINATION OF MOISTURE CONTENT

The mass of water divided by the mass of solids in a sample gives the moisture content, which is given as a percentage. The amount that was weighed was used to determine this attribute of the formulation was heated in hot air for one night at 110 degrees Celsius, and the moisture content was calculated.

S.No.	Dosage form	Moisture content
1.	Lozenges	3.2%

PH OF LOZENGES

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.

RESULT

The evaluation of prepared lozenges hardness (n=5), friability (n=5), thickness (n=5), weight uniformity (n=5), and disintegration time (n=5) produced the following results presented in Tables 3

CONCLUSION

In conclusion, our study suggests that herbal lozenges can be an effective and safe alternative to traditional cough drops for managing cough and sore throat symptoms. The use of herbal ingredients such as honey, ginger, and peppermint may provide additional health benefits beyond symptom relief, such as antioxidant and anti-inflammatory effects. Further research is needed to explore the mechanisms of action and optimal dosing of herbal lozenges, as well as their efficacy compared to other treatments. Overall, herbal lozenges represent a promising avenue for natural and holistic approaches to respiratory health.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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