



## Formulation and Evaluation of Polyherbal Lozenges by Using Natural Ingredients

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### ABSTRACT

Herbal lozenges are widely used for the treatment of cough, sore throat, and other respiratory disorders due to their soothing and therapeutic effects. The present study aimed to formulate and evaluate herbal lozenges using natural ingredients such as *Clitoria ternatea*, Giloy, turmeric, ginger juice, honey, and jaggery. The lozenges were prepared by melting jaggery and mixing it with herbal extracts to obtain a homogeneous mixture, which was then poured into molds and allowed to solidify. The prepared formulations were evaluated for various parameters including organoleptic properties, hardness, friability, weight variation, pH, disintegration time, and dissolution studies. The results showed that all formulations possessed acceptable physical characteristics with hardness ranging from 2.4–3.3 kg/cm<sup>2</sup> and friability within acceptable limits. The disintegration time ranged from 36–43 seconds, and the drug release was found to be 84–95% within 30 minutes. Among the formulations, F3 showed comparatively better performance in terms of disintegration and drug release. The study concluded that the developed herbal lozenges are stable, effective, and may provide relief from cough and sore throat while supporting respiratory health.

**Keyword:** Ingredient, method of preparation, post formulation studies, Result.

### 1. INTRODUCTION

As an advanced method of medication delivery for both local and systemic effects, lozenges have an excellent future. Both adults and children accept lozenges as an effective dose form. Typically designed to be held in the oral cavity and moistened with saliva before being completely dissolved. Lozenges can be categorized according to their texture and makeup, including chewy, caramel, compressed tablet lozenges, soft lozenges, and hard boiled lozenges. The most frequent and popular items among customers are hard boiled lozenges (HBL), also known as hard boiled candies (HBC). In a flavoured and sweetened base, and when sucked, are meant to gently dissolve or disintegrate in the buccal cavity. Lozenges are used for patients who have trouble swallowing solid oral dosage forms and for medications that need to be given gradually to maintain a steady level of medication in the oral cavity.

Different classifications that experience issues in using customary oral measurement structures incorporate the intellectually sick, uncooperative and patients experiencing queasiness, movement affliction, unexpected scenes of hypersensitive assault or hacking. Now and then it very well might be hard to swallow conventional items because of non accessibility of water. These issues prompted the advancement of a novel sort of solid oral dose structure consequently, an appealing, taste veiling plans are the need of great importance.<sup>[1]</sup>

#### 1.1 TYPES AND DEFINATION

Lozenges are various-shaped, solid dosage forms usually containing a medicinal agent and a flavoring substance, intended to be dissolved slowly in the oral cavity for localized or systemic effect. They are also called troches or pastilles. Pastilles have a softer texture and a high percentage of a sugar or a combination of a gelatin and sugar. Many lozenges have hard candy bases of sugar and syrup and often incorporate an adhesive substance such as acacia. Commercial lozenges (troches) may be made on a tableting machine using high compression pressures. Lozenges are designed to dissolve slowly in the mouth. They are designed to dissolve and not to disintegrate. Ingredients should be heat-stable if they are to be incorporated into extemporaneously-prepared lozenges. Soft and chewable lozenges have just been reintroduced into pharmacies and are becoming more and more popular. The soft lozenges generally have a polyethylene glycol base and the chewable lozenges have a glycerinated gelatin base. These usually are chewed and are a means of delivering the product to the gastrointestinal tract for systemic absorption.



## 1.2 ADVANTAGES

- It might be administered to people who have trouble swallowing.
- Simple to regulate to geriatric and paediatric populace.
- It broadens the hour of medication in the oral cavity to evoke a particular impact.
- Foundational assimilation of medication can be conceivable through buccal cavity.
- Taste of medication can be vealed by sugars and flavors utilized in definition.
- It can increment in bioavailability.
- It can decrease dosing recurrence.
- No disintegration.
- Do not require water for intake.
- Less production time.
- Less production cost.
- If the dosage is not required, Lozenge can be stopped.

## 1.3 DISADVANTAGES

- Some drug may not be suitable with aldehyde candy bases e.g. Benzocaine.
- The drug's non-universal dispersion in saliva for local treatment.
- Drug and saliva may flow from the mouth cavity and enter the stomach.
- The lozenges dosage form could be used as candy by children mistakenly.<sup>[2]</sup>

## 1.4 CLASSIFICATION OF LOZENGES:

### →According to the site of action

- (a) Local effect Ex. Germicides, Decongestants.
- (b) Systemic impact Ex. Nutrients, Nicotine.

### →According to texture and composition

- (a) Chewy or caramel based medicated lozenges
- (b) Compressed tablet lozenges
- (c) Soft lozenges
- (d) Hard sweets lozenges.<sup>[3]</sup>

## 1.5 IDEAL PROPERTIES OF LOZENGES

1. Lozenges should provide fast-acting relief, effectively delivering their active ingredients to the affected area.



2. To promote compliance and enhance the experience, they ought to taste good.
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 ought to be affordable and available to a variety of customers.

## 1.6 PURPOSES

In the form of a little tablet that gradually dissolves in the mouth, Objective Herbal tablets are intended to offer a number of health advantages. Herbal tablets are intended to relieve a variety of illnesses by directly delivering herbal active components to the mouth, throat, and respiratory system.

1. Relief of symptoms of cough and sore throat
2. Promote respiratory health
3. Strengthen the immune system
4. Supporting digestion and intestinal health
5. Relaxation and tension
6. Alleviation of allergy symptoms
7. Preserving dental hygiene and wellness. It is crucial to remember that utilizing herbal supplements to address a medical issue should only be done after seeing a physician, since they are not meant to substitute medical diagnosis or therapy.<sup>[4]</sup>

## 2. INGREDIENTS

### 2.1 *Clitoria Ternatea*

Butterfly pea, or *Clitoria ternatea*, is a perennial herbaceous plant belonging to the Fabaceae family. It has garnered a lot of attention lately due to its potential uses in agriculture, modern medicine, and as a natural source of antioxidants and food coloring. Early research evaluated *C. ternatea* for these uses because it has long been grown as a crop for fodder and forage. After several field tests in Queensland, Australia, *C. ternatea* cv. "Milgarra," the sole cultivar in Australia released for grazing, was eventually registered.<sup>[5]</sup>



**Fig.1** *Clitoria ternatea*

## 2.2 Giloy

Scientific name: *Tinospora cordifolia*.

Family: Menispermaceae.

Biological source: It is a fairly common plant of deciduous & dry forests, growing over hedges & small trees. The plant grows up to 1,200 meters above sea level in India's tropical regions, from Kumaon to Assam and in the north via West Bengal, Bihar, and the Deccan.



**Fig.2** Giloy

The plant is quite stiff and likes a warm temperature, but it may be cultivated almost anywhere. Typically, planting takes place during the wet season. Tinospora has been used for ages to treat a variety of illnesses in Ayurveda. One of the primary plants having a bitter flavor is gulevl. Over the past 20 years, the medication has been the subject of extensive phytochemical, pharmacological, and clinical research, with many intriguing findings in the areas of immunomodulation, anticancer activity, liver disorders, and corona virus infection. It also helps alleviate vata and kapha dosha.

## 4.3 Turmeric Powder

Scientific name: *Curcuma longa*

Family: Zingiberaceae

Biological source: Turmeric is grown for trade in Southeast Asia, primarily in India. both culinary uses and conventional medicine.



**Fig.3 Turmeric Powder**

Turmeric has potent antioxidant qualities and is used in food preparation and home remedies. As a nutritional supplement, turmeric is being recommended these days for a wide range of ailment, such as melancholy, liver illness, allergies, lung infections, arthritic pain, digestive issues.

#### **4.4 Ginger**

Scientific name: *Zingiber officinale*

Family: Zingiberaceae

Biological source: Despite being cultivated in the Caribbean, Africa, Australia, and India. Ginger is originally from South East Asia. India accounts for the production.



**Fig.4 Ginger**

Ginger is widely used in folk medicine. More specifically, ginger's rhizomes gained popularity due to their potent flavor as well as their health-promoting qualities. It was thought that adding honey to fresh roots would effectively stop coughing. Furthermore, *Zingiber officinale* plays a protective role against fever, common cold, respiratory problem like bronchitis and sinusitis.

#### **4.5 Honey**

Scientific name: *Hexose sugars*

Family: *Apidae*

Biological source: Honey can be obtained from both wild and domesticated bee colonies. A hive may generate about 29 kilograms (65 pounds) of honey per year. Sometimes wild bee colonies can be found using a honey guide bird.

**Fig.no.5**

Honey's high concentration of sugar, the most common element, is responsible for its sweetness. Every species of honey has a distinct concentration of active ingredients. It relies on a number of characteristics, including the production technique, geographic region, and plant source. However, the primary constituents include sugar (fructose and glucose, making nearly 75% of the total sugar content), mineral (potassium, magnesium, calcium, iron, phosphorus, sodium), vitamin (in particular, those in the B series), enzymes (glucose oxidase and catalase), and acids (amino and organic).<sup>[6]</sup>

#### 4.6 Jaggery:

Made from the juice or sap of Palmyra, date, or coconut palms (*Phoenix dactylifera*, *Borassus flabellifer*, or *Cocos nucifera* L.). Jaggery is a sweet substance that is high in sugar. It is used in foods and medications. It serves as both a sweetener and a preservative. Soft lozenges were made by melting and using molds. To make a homogenous mixture, jaggery was mixed with the powder and other ingredients that had been melted over a water bath. The liquid was then poured into the stainless steel mold.<sup>[7]</sup>

**Fig.6 Jaggery**

### 3. METHOD OF PREPARATION

To create a homogenous mixture, jaggery was melted in a water bath and combined with the other ingredients (powder). The slurry was then poured into the plastic mold.

After adding a small amount of water to another container, all the herbs were added, well combined, and then filtered. They added honey. The mixture was heated to 150°C while being continuously stirred. After turning off the heat, the mixture was poured onto a lozenge mold to create perfectly sized lozenges. At room temperature, the mold was let to cool and solidify. *Clitoria ternatea*, giloy, turmeric, ginger juice, and honey were among the herbs included in the composition to have a calming effect on the throat.<sup>[8]</sup>



Fig.7 Melted Jaggery



Fig.8 Clitoria powder

#### 4. FORMULA OF HERBAL LOZENGES Table No.[1]

Sr.NO.	INGREDIENTS	QUANTITY
1	<i>Clitoria ternatea</i>	1g
2	Giloy	1g
3	Turmeric	0.5g
4	Ginger Juice	1g
5	Honey	5g
6	Jaggery	21.5g



Fig.9 Herbal Lozenges

#### 5. POST FORMULATION STUDIES:

##### 5.1 Organoleptic Evaluation

The sensory attributes of the lozenge, such as color, taste, odor, form, and texture, are referred to as organoleptic qualities. When it comes to long-term use in chronic illnesses like diabetes, these characteristics are particularly important for consumer acceptance and compliance. The taste should be appetizing (sometimes covered up with tastes or sweets), the odor should be pleasant or neutral, and the color should be consistent and aesthetically pleasing. The user experience is also influenced by texture and mouth feel; smooth, non-gritty formulations are preferred. For herbal lozenges containing bitter ingredients like Giloy, organoleptic optimization through flavouring agents and sweeteners is essential to ensure continued patient use and adherence.<sup>[9]</sup>

##### 5.2 Diameter :

The diameter, size, and shape of lozenges depend on the molds selected. The lozenges of various sizes and shapes can be prepared, but generally, they are circular with either flat or biconvex faces.<sup>[10]</sup>



### 5.3 Weight variation:

Weight variation ten lozenges were chosen at a random rate from each batch and weighed one by one. Ten lozenges were weighed, and the average weight and standard deviation were obtained. If no more than two of the individual lozenges depart from the average weight, the batch passes the weight variation test.

### 5.4 Thickness:

Thickness consistency, Vernier callipers were used to measure the thickness of the six lozenges that were randomly chosen from each batch.

### 5.5 Hardness:

The force needed to shatter a lozenge in a diametric compression using the Monsanto Hardness tester is known as hardness or crushing strength (F<sub>0</sub>). Six lozenges were tested for hardness for each batch. The tester's two jaws were used to hold the lozenges between them along their oblong axis. Reading should be 0 kg/cm<sup>2</sup> at this moment. After then, the knob was rotated continuously until the lozenges broke. At this stage, the value was indicated as kg/cm<sup>2</sup>.

### 5.6 Moisture content:

A sample weighing 1 g was kept in a desiccator at room temperature for 24 hours. After specified period of time, weigh the sample and moisture content is calculated by subtraction of final weight from initial weight. The moisture content and the weight of hard boiled lozenges should range in between 0.5 – 1.5% and 1.5 – 4.5g respectively.

$$MC = \frac{W_1 - W_2}{W_1} \times 100$$

### 5.7 Friability:

The friability was tested using Roche Friabilator. The apparatus treats the tablet to abrasion and shock in a plastic chamber that rotates at 25rpm and drops a tablet from a height of six inches with each rotation. In the friabilator, a pre-weighted sample of tablets were put and subjected to hundred rotations. The tablets were reweighed after being dusted with a white muslin towel. The USP limit is 0.5% to 1% the formula for friability (F) is as follows: %

$$\% F = \frac{W_i - W_f}{W_i} \times 100$$

### 7.8 Dissolution test

Dissolution is the process in which a substance forms a solution. Dissolution testing measures the extent and rate of solution formation from a dosage form. The dissolution of a drug is important for its bioavailability and therapeutic effectiveness. This study is carried out by using USP II Dissolution type apparatus (paddle type). Dissolution study was carried out in 900 ml of buffer pH 6.4 by USP II paddle method at 100 rpm. Samples were withdrawn at 5 min time interval and replaced immediately with an equal volume of fresh buffer and were analyzed spectrophotometrically. Temperature 37°C ± 2°C maintained between dissolution studies.<sup>[11]</sup>

### 7.9 Disintegration time studies :

Disintegration time is the interval required for complete disappearance of a lozenges or its particles from the tester net. Disintegration test of the prepared lozenges was performed according to USP30, using a disintegration tester through the disintegration medium of phosphate buffer with pH 6.2 maintained at 37 ± 0.5°C.<sup>[12]</sup>

### 7.10 PH

The pH of the herbal lozenges was measured using a calibrated pH meter following the manufacturer's instructions. Measures the pH of the lozenge formulation to ensure it is within the desired range for stability and efficacy.<sup>[13,14]</sup>



## 6. RESULT AND DISCUSSION

The prepared herbal lozenges showed good organoleptic properties with acceptable color, taste, odor, and shape. All formulations had uniform weight (2000 mg) and hard consistency. The hardness (2.4–3.3 kg/cm<sup>2</sup>) and friability (0.4–0.8%) were within acceptable limits, indicating good mechanical strength. The pH (5.2–6.1) was suitable for the oral cavity. The disintegration time ranged from 36–43 seconds, and the drug release was 84–95% within 30 minutes. Among all formulations, F3 showed better disintegration and drug release, indicating good performance of the herbal lozenges.

Table no. 2. Evaluation Parameters-Results

Sr. no.	Parameters	Formulation			
		F1	F2	F3	
1.	Organoleptic evaluation	Colour	Brown	Brown	Brown
		Odour	Sweetish	Sweetish	Sweetish
		Taste	Sweet	Sweet	Sweet
		Shape	Round	Square	Oval
2.	Consistency	Hard	Hard	Hard	
3.	Hardness	3.3 kg/cm <sup>2</sup>	2.8 kg/cm <sup>2</sup>	2.4 kg/cm <sup>2</sup>	
4.	Friability	0.8 %	0.4 %	0.6 %	
5.	PH	5.2	6.1	5.8	
6.	Weight variation	2000mg	2000mg	2000mg	

### 6.1 Disintegration Time:

Table no.3

Formula	Disintegration time (sec)
F1	43±3
F2	39±4
F3	36±2

### 6.2 Dissolution Study:

Table no.4

Sampling time (minutes)	Drug release profile (% drug release)		
	F1	F2	F3
10	85±0.24	87±0.22	84±0.27
15	87±0.52	90±0.27	89±0.35
20	91±0.72	93±0.35	90±0.53
30	94±0.07	93±0.22	95±0.31

## 7. CONCLUSION

The herbal lozenges were successfully formulated using *Clitoria ternatea*, Giloy, turmeric, ginger, honey, and jaggery. The prepared formulations showed acceptable organoleptic properties, good hardness, low friability, and uniform weight variation. Disintegration and dissolution studies indicated effective release of herbal ingredients. Among the formulations, F3 showed better performance with faster disintegration and higher drug release. Therefore, the developed herbal lozenges may be useful for relieving cough, sore throat, and supporting respiratory health.

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