Formulating Cough Lozenges with *Coleus amboinicus*: A Phytotherapeutic Approach

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Abstract. The present study focuses on the formulation and development of lozenges incorporating *Coleus amboinicus* juice for cough suppression. The *Coleus amboinicus* leaves were collected, prepared the herbal juice and preliminary phytochemical screening was conducted to assess its active constituents. Four lozenge formulations (F1 to F4) were developed by melting and molding technique, with varying sugar concentrations of 30 g, 40 g, 50 g and 60 g. The formulated lozenges were evaluated for organoleptic properties, weight variation, friability, moisture content, thickness, hardness, and stability test. Among the four formulations, F4 demonstrated superior performance in weight variation, friability, and hardness. Phytochemical analysis confirmed the presence of alkaloids and saponins in the herbal juice and the prepared lozenges, suggesting that these compounds may contribute to the lozenges' effectiveness in treating cough and throat irritation. This study demonstrates that the *Coleus amboinicus* lozenges, particularly formulation F4, provide an effective alternative to conventional cough remedies.

Keywords: *Coleus amboinicus*, Herbal lozenges, Melting and molding techniques, Natural remedies.

1 Introduction

The use of herbal medicines has surged globally, driven by both a preference for natural treatments and the limitations of synthetic drugs in managing chronic conditions. In developing countries, approximately 80% of the population depends on herbal remedies, a trend supported by the World Health Organization (WHO), which acknowledges herbal medicine as a critical component of healthcare systems worldwide. This preference for alternative therapies often stems from dissatisfaction with conventional drugs, concerns over side effects, and the emergence of drug-resistant infections. Herbal medicines offer a holistic approach by not only addressing symptoms but also potentially enhancing overall immunity

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and addressing the root cause of ailments. Among the various routes of administration the oral route is the most commonly used and preferable way of taking medicine due to its various benefits likes as ease of administration, safety, non-invasiveness, better patient compliance and simple approach. One of the most popular oral dosage forms is lozenges for those patients who have difficulty in swallowing of solid dosage forms. Lozenges are medicated and flavoured dosage form which is held in the mouth that dissolve slowly to release the drug and coat the throat tissues with the solution of drug. They are most often used for localized effect into oral cavity and can also show systemic effect if it is well absorbed in the buccal lining and pharynx[1]. The benefit of lozenges is the retention time of the dosage form is increased in the cavity of the mouth which increases bioavailability and reduces gastric irritation. They avoid first-pass metabolism and increase in bioavailability which is used for purpose of both local and systemic effects. It is better patient compliance and is often given to those patients who have difficulty in swallowing. *Coleus amboinicus* (Lour.) Spreng (Labiatae) is a perennial. The plants are commonly used in Chinese folk medicine for the treatment of respiratory conditions such as asthma, cough, fever, sore-throats and bronchitis[2,3]. The *Coleus amboinicus* contains a variety of bioactive compounds such as flavonoids, phenolic and essential oils. Essential oil of the *Coleus amboinicus* contain high amount of Carvacrol and Thymol, which have and excellent expectorant and used to treat various respiratory disorders[4]. The objective of this study is todevelop and evaluate hard herbal lozenges incorporating *Coleus amboinicus*making it effective in easing coughs and supporting the body's ability to expel mucus and reduce congestion. This is the first attempt to employ its unique therapeutic properties in a lozenge to address cough and related respiratory issues.

2 Materials and Methods

2.1 Collection and Authentication of *Coleus amboinicus* Leaves

The leaves of *Coleus amboinicus* collected and authenticated from Foundation for Revitalisation of local health traditions Yelahanka, Bengaluru, Karnataka under FRLHT account number 6348.

2.2 Preparation of herbal juice of *Coleus amboinicus* leaves:

The necessary amount of *Coleus amoinicus* leaves were obtained, carefully cleaned with tap water, ground with the addition of 100 ml of water, and the juice was extracted using a mesh strainer to separate the menstruum and marc.

2.3 Phytochemical screening of juice of *Coleus amboinicus* leaves:

Phytochemical analysis is of juice of *Coleus amboinicus* leaves was carried out to detect the presence of carbohydrate, protein, sterols, alkaloids, tannins, glycosides, flavonoids, phenolic chemicals and saponins[5].

2.4 Formulation of lozenges:

Corn starch (10g) was dispersed in distilled water (20 ml) in a beaker. The mixture was heated on medium heat while stirring continuously until it reached a translucent, viscous consistency, indicative of the starch gelatinization process. Granulated sugar was weighed and heated gently over medium heat until it melted, forming a clear liquid syrup. Constant stirring

was performed to prevent burning and ensure even melting. The prepared corn syrup was added to the melted syrup and mixture was stirred continuously and heated until the temperature reached 130°C. A calibrated thermometer was used to monitor the temperature to ensure the mixture reached the hard ball stage, a critical point for candy solidification. Upon reaching 130°C, the mixture was removed from the heat source. *Coleus amboinicus* juice, lemon juice and freshly grated ginger juice were measured and added to the mixture as flavouring agents. The mixture was stirred to ensure uniform distribution of the flavouring agents. The mixture was allowed to cool slightly approximately to 70°C.Honey was then added to the mixture to impart sweetness and improve the texture of the final lozenges. The mixture was stirred continuously to incorporate the honey evenly. The hot preparation was carefully poured into pre-prepared silicone molds. The filled molds were allowed to cool at room temperature until the mixture solidified into lozenges. Once solidified, the lozenges were removed from the silicone molds[6]. The formula of herbal lozenges is specified in **Table 1**.

Table 1. The composition of herbal lozenges

Sl.No.	Ingredients	F1	F2	F3	F4
1	*Coleus amboinicus*	20ml	20ml	20ml	20ml
2	Ginger	15ml	15ml	15ml	15ml
3	Sugar	30g	40g	50g	60g
4	Honey	2ml	2ml	2ml	2ml
5	Corn starch	43ml	33ml	23ml	13ml
6	Lemon Juice	15ml	15ml	15ml	15ml

2.5 Evaluation of Formulated *Coleus amboinicus* lozenges[7- 12]

2.5.1 Macroscopic evaluation:

Prepared lozenges are determined by visual observations for physical appearances and other characteristics such as taste, colour, odour, surface smoothness, uniformity in shape and absence of cracks also evaluated for its acceptability.

2.5.2 Measurement of pH:

A 1% W/V solution was made by dissolving 1 g of lozenges in 100 ml of distilled water, and the pH was measured. The pH was assessed using a calibrated lab pH meter, which had been standardized with buffer solutions of known pH values (pH 4.0, 7.0, and 10.0).

2.5.3 Weight variation:

The weight of 20 lozenges was weighed using a digital balances and the test was performed according to the official method protocol. The average weight and standard deviation of 20 lozenges were calculated. If the weight of no more than two lozenges in the batch deviates from the average weight, the batch passes the weight variation test. Producing a yield of 90-110% of the average weight[8]. The calculation was done using following formula.

$$\text{Average weight} = \frac{\text{Weight of 20 lozenges}}{20} \quad (1)$$

$$\text{Weight variation} = \frac{\text{Individual weight – Average weight x 100\%}}{\text{Average weight}} \quad (2)$$

2.5.4 Friability:

The friability of lozenges was determined using Rocha friabilator it is expressed in percentage.

Ten lozenges are weighed to obtain the initial weight and transferred to the friabilator which is operated at sapped of 25rpm for 1 min. The lozenges were weighed again after taking out the lozenges. Any visible physical defects such as cracks, chips, or breakage in any of the lozenges indicate that the sample fails the test, and the test result is considered invalid for that batch. The % friability was calculated with the help of following formula.

$$\text{Friability} = \frac{(\text{Initial weight} - \text{Final weight})}{\text{Initial weight}} X\ 100 \quad (3)$$

2.5.5 Determination of moisture:

It is determined by gravimetric method, 1g sample weighed and placed in an oven at 100-120°C for 3h. Lozenges were immediately transferred to a desiccator to cool down to room temperature. The desiccator prevents the sample from absorbing moisture from the air during cooling. After the sample cooled to room temperature, final weight was determined using the analytical balance using muslin fabric to handle the sample. Repeated the drying, cooling, and weighing steps until a constant weight obtained.

$$\text{Moisture content \%} = \frac{(\text{Initial weight} - \text{Final weight})}{\text{Initial weight}} X\ 100 \quad (4)$$

2.5.6 Determination of Thickness:

The thickness of the lozenges were be determined by using vernier caliper by using five lozenges to minimize errors and ensures a more reliable result.

$$\text{Average Thickness} = \frac{\text{Total lozenges thickness}}{5} X\ 100 \quad (5)$$

2.5.7 Hardness:

The force needed to shatter a lozenge in a diametric compression using a Monsanto Hardness Tester is known as hardness, or crushing strength. The lozenges were randomly picked and hardness was determined. The lozenges were placed between the tester's two jaws along their oblong axis. The reading at this moment ought to be 0 kg/cm^2. After then, the knob was rotated repeatedly until the lozenges broke. The value was expressed as kg/cm^2.For each formulation, the hardness of 6 lozenges was determined using Monsanto hardness tester and the average was calculated and presented with standard deviation.

2.6 Stability Studies:

The stability studies for prepared lozenges were performed for optimized formulation F4 at 40℃ and 75% RH for6 months. The lozenges were assessed to detect the presence of carbohydrate, protein, sterols, alkaloids, tannins, glycosides, flavonoids, phenolic chemicals and saponins.

3 Results

The plant material used in this research was identified as *Coleus amobinicus* belonging to the family Lamiaceae and the juice of leaves were prepared by using mortor and pestle by grinding. The herbal juice of *Coleus amboinicus* leaves was systematically analysed to detect the presence of chemical constituents. The herbal juice revealed the presence of alkaloids, flavonoids and saponin. These findings are outlined in **Table 2**.

Table 2: Results of Phytochemicals in *coleusamboinicus* juice

Phyto chemicals	Alkaloids	Flavonoids	Glycosides	Tannins	Triterpe noids	Steroids	Saponins
Ethanol extract	Positive	Positive	Negative	Negative	Negative	Negative	Positive

Herbal lozenges containing *Coleus amboinicus* were prepared using various ingredients by heating and congealing technique. Around 4formulations were prepared using 20 ml of juice of *coleus amboinicus* leaves, 15 ml of ginger. Sugar used as hard candy bases, in varying concentration of 30 g, 40 g, 50 g and 60 g. The corn starch as binder and whipping agent in43 g, 33g, 23 g and 13 g. Honey used as cough suppressant, Lemon juice was used as flavouring agent[13].

In macroscopic evaluation, all the F1 to F4 formulations were brown colour, having pleasant odour with sweet taste all formulations were good and acceptable. The lozenges were found to be hexagonal in shape due to molds used for preparation. All these results are represented in **Table 3**.

Table 3: Organoleptic character of formulated lozenges

Parameters	**Observations**			
	F1	**F2**	**F3**	**F4**
Color	Brown	Brown	Brown	Brown
Odor	Pleasant	Pleasant	Pleasant	Pleasant
Taste	Sweet	Sweet	Sweet	Sweet
Texture	Smooth	Smooth	Smooth	Smooth
Shape	Hexagon	Hexagon	Hexagon	Hexagon

The formulated lozenges were subjected to different evaluation tests. **Table 4** shows the results of post-formulation parameters of lozenges such as pH, weight variation, friability, moisture, thickness, and hardness with standard deviation.

Table 4: The evaluation parameters of formulated *Coleus amboinicus* lozenges involve analyzing different concentrations of sugar and corn starch to optimize their composition and effectiveness.

Formulation Code	**pH**	**Weight variation (g)**	**Friability (%)**	**Moisture (%)**	**Thickness (mm)**	**Hardness (kg/cm^2)**

F1	6	2.503±0.77	0.74±0.05	0.71±0.18	13.52±0.48	5.13±0.05
F2	5.9	2.493±0.07	0.84±0.05	0.87±0.06	13.52±0.56	5.7±0.26
F3	5.9	2.619±0.14	0.72±0.05	0.84±0.02	13.74±0.20	6.46±0.58
F4	5.7	2.518±0.07	0.70±0.15	0.87±0.03	14.33±0.18	7.4±0.43

The pH of the formulated herbal lozenges was in the range of 5.7 to 6 which lies in the normal pH range of mouth and does not provide any mouth irritation and is safer for long-term use. The acceptable pH range for herbal lozenges is typically, a pH range of 5.5 to 7.5 is acceptable for most herbal lozenges[14]. The results of weight variation indicate that all formulations fall within the acceptable range of 90-110% of the average weight, suggesting good weight consistency among the lozenges and validating the quality control process used in lozenge production. The standard friability limit for solid dosage forms such as lozenges is typically not more than 1**%**, with values within this range indicating good resistance to abrasion and minimal risk of fragmentation during handling and storage[15-17]. All formulations, F1-F4 fall within this acceptable friability limit, with percentages ranging from 0.70±0.15to 0.84±0.05%. This demonstrates that each formulation has adequate mechanical strength to withstand handling without significant loss of weight or risk of damage. Moisture content determination is a crucial test for lozenges, as the moisture level affects their stability, texture, shelf-life, and overall quality. Excessive moisture can lead to microbial growth, degradation of ingredients, and changes in texture, while less moisture can make the lozenges brittle. The moisture content of all the lozenges was within 0.87%. Usually the moisture content range is0.5 - 1.5% for hard candy lozenge[18]. The thickness of the lozenges may vary without affecting the weight owed to variations the pressure exerted on the lozenges[19]. The values of the thickness in the all the formulated lozenges were observed within the. limits with no significant deviation. The average thickness for lozenges is calculated and presented with standard deviation. The hardness value from F1, F2, F3 and F4 was5.13±0.05, 5.7±0.26, 6.46±0.58 and 7.4±0.43kg/cm2 respectively. These results indicate a positive correlation between the concentration of sugar and the hardness of the lozenges. As the sugar concentration increases from 30 g for F1, 40 g for F2, 50 g for F3, and 60 g for F4, the hardness value of the lozenges increased. The hardness was evaluated to determine their resistance to shipping or breakage under the condition of storage, travel and handling prior to use[20]. All the other values of the parameters in the Table 4 were observed within the limits with no significant deviation. The weight variation, friability, and hardness of optimized formulation F4 was found to be acceptable limits. The stability studies for prepared lozenges were performed for optimized formulation F4 at 40°c and 75% RH for 6 months**.** There was no change in pH, Colour, taste and showed the presence of alkaloids, flavonoids and saponin.

4 Conclusion

The study successfully formulated and evaluated herbal lozenges containing the juice of *Coleus amboinicus*. Four formulations (F1 to F4) were prepared with varying concentrations of sugar and corn starch, and a comprehensive analysis was conducted on their physical and chemical properties. The results indicated that all formulations exhibited consistent physical

appearance, homogeneity, and acceptable pH levels, which fall within the normal range for oral products, ensuring safety for long-term use. The evaluation of key parameters such as weight variation, friability, moisture content, and hardness revealed that all formulations met the established quality standards. Notably, F4 demonstrated superior performance in weight variation, friability, and hardness compared to F1 to F3, indicating its enhanced structural integrity and suitability for therapeutic use. The presence of alkaloids and saponins in the herbal juice of *Coleus amboinicus* suggests potential medicinal properties for cough treatment. Overall, this research highlights the potential of *Coleus amboinicus* based lozenges as a viable herbal remedy for cough management, providing a foundation for future studies and development in herbal pharmaceutical formulations.

Conflicts of Interest: There are no conflicts of interest among the authors.

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