Phytopharmaceutical Innovations: Ensuring Standardized and Effective Herbal Lozenges for cold and cough relief by using Shankapushpi flower extract

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***Abstract*—Lozenges are palatable solid dosage forms that are used orally. Because of its natural composition, therapeutic benefits, and customer desire for plant-based therapies, herbal lozenges have drawn a lot of interest from the pharmaceutical and nutraceutical industries. These are herbaceous medicated dosage forms that include one or more medications and are intended to be swallowed and held in the mouth or pharynx. Several plant-based substances can be used to make herbal lozenges, depending on the intended purpose and desired outcome. However, differences in raw material quality, formulation methods, and regulatory compliance make it difficult to guarantee their efficacy, safety, and consistency. Medicated lozenges have the advantage of avoiding first-pass metabolism, reducing gastrointestinal discomfort, and increasing the dosage form's elution time in the oral cavity, all of which boost bioavailability. Minimizes first-pass metabolism and lessens stomach discomfort. Children are more likely than adults to approve lozenges as a dose form. There are three different kinds of lozenges on the market: compressed, firm, and soft. Their preparation techniques and ingredients are taken into consideration. The findings emphasize the need for a harmonized approach to quality control, ensuring safety and efficacy while meeting consumer demands for natural and sustainable healthcare solutions. This study investigates improvements in phytopharmaceuticals that improve the bioefficacy, quality control, and standardization of herbal lozenges.**

***Index Terms*—Shankapushpi petals, Ginger, Cinnamon, jaggery, evaluation, standardization, lozenges.**

I. INTRODUCTION

Lozenges are oral solid dosage formulations that are formulated to dissolve in the mouth [1]. Coughing is typically the result of the reflex arc being activated. This prevents foreign particles from entering the body. Coughing can occasionally be harmful to the body as well since it damages the mucosal layer of the airways [2]. These herbal lozenges aid in the treatment of throat infections and discomfort. They release the medication after gently dissolving [3]. Varieties of lozenges are usually used to treat cough and sore throat [4]. Patients who are unable to swallow solid dosage forms are also treated using lozenges [5]. Analgesic, antibacterial, antiseptic, antitussive, aromatic, astringent, corticosteroid, and calming qualities are all present in lozenges [6]. These are the prescription pills that are held in the mouth until they melt, dispersing the medication and causing the throat to relax [7]. These are the prescription pills that are held in the mouth until they melt, dispersing the medication and causing the throat to relax [8]. Lozenges are used as calming medications to treat coughs and bronchial issues quickly [9]. These are the preferred choice for people who have swallowing difficulties because they can also be used to administer medication straight to the throat [10]. A lozenge is often eaten by putting it in the mouth and allowing it to dissolve gradually over a few minutes [11]. The underlying idea behind the lozenges is that, depending on the herbs utilized, they can offer a variety of health advantages [12].

1.1. TYPES OF LOZENGES [13]

1.1.1. ACCORDING TO THE SITE OF ACTION:

a. Local effect Ex: Antiseptics, Decongestants
b. Systemic effect Ex: Vitamins, Nicotine

1.1.2. ACCORDING TO TEXTURE AND COMPOSITION:

a. Chewy or caramel based medicated lozenges
b. Compressed tablet lozenges
c. Soft lozenges
d. Hard candy lozenges

1.2. IDEAL PROPERTIES [14, 15]:

i. It shows slow release of the medicament.
ii. It is used to treat the mouth and throat for the slow administration in cough remedies.
iii. Some have medication that helps to fight with cold, and have anaesthetic property and helps to control pain.

1.3. ADVANTAGES [16]:

i. Easy to assess with minimum amount of time and equipment.
ii. Avoid first pass metabolism.
iii. Better patient adherence.
iv. Cost of production is less.
v. It has pleasant taste.
vi. Easy to supervise to both geriatric and paediatric.

DISADVANTAGES [17]:

i. Accidently taken by children as candy.
ii. Mistakenly swallowing of entire dosage.
iii. Hard lozenges change to grainy.

II. HERBS

Herbal materials: Shankapushpi flowers was collected from garden and shade dried and powdered. Cinnamon powder (Pure Tree foods, Mumbai, Maharashtra), Ginger powder (Crista farm fresh, Idukki, Kerala), jaggery and lemon were bought from local market.

Herbal tea ingredients morphology and its importance:

INGREDIENTS:

- Shankapushpi
- Ginger
- Jaggery
- Lemon
- Cinnamon

2.1. SHANKAPUSHPI:

Synonym: Vishnukranthi, Blue morning glory.

Convolvulus pluricaulis is a perennial plant. The branches are widely spread on the ground and long up to 30 cm. Roots are usually branched, cylindrical, ribbed having some rough stem nodules. Small roots are 1-5cm long, 0.1-04 cm thick. The color of the root changes from brown to light brown. Stems are cylindrical with hairy nodes and internodes. Leaves are shortly petiolate linear-lanceolate, acute, hairy on both surfaces. Leaves are 10.5-2 cm long and 0.1-0.5cm broad light green in color. Flowers are white or purple. It is solitary or in pairs sessile or sub-sessile in the leaf axis Fruits are capsuled, oblong globose with coriaceous, pale brown pericarp. Seed are minutely puberulous and brown in color.

Significance: Shankapushpi consists of various constituents such as D-glucose, maltose, rhamnose, sucrose, starch and other carbohydrates and also include fatty acids, hydrocarbons, and comprise of 30.9% myristic acid, 66.8% palmtic acid and 2.3% linoleic acid, hextriacontane [18]. Proteins and amino acids are also isolated from the plant. It has been studied that Shankapushpi has various pharmacological properties such as, Nootropic, anti-oxidant, analgesic, antiulcer and anti-catatonic and anti- helminthic activity [19].

2.2. GINGER:

Synonym: Allam, Adrak, Shunti.

Ginger consists of whole or cut, dried scrapped or unscraped rhizomes of Zingiber officinale Roscoe, family Zingiberaceae. It contains not less than 0.8% of total gingerols on dried basis. Ginger needs warm humid climate and is cultivated in areas with heavy rainfall. It is cultivated even at sea level, but still it thrives best at an altitude of 1000 - 1500 m. If no sufficient rainfall is available, proper arrangements for irrigation are necessary. Sandy or clay or red loamy soils are suitable for ginger. Ginger is cultivated by sowing rhizomes in the month of June.

Significance: Ginger is composed of various bioactive compounds that contribute to its medicinal and nutritional value. It contains approximately 1-4% volatile oil, 40-60% starch, 10% fat, 5% fiber, 6% inorganic material, 10% residual moisture, and 5-8% acrid resinous matter [20]. The volatile oil that is present in ginger comprises a range of monoterpene and sesquiterpene hydrocarbons, oxygenated mono- and sesquiterpenes, and phenylpropanoids. The sesquiterpene hydrocarbons that are found in ginger are α-zingiberene, β-bisabolene, α-farnesene, β-sesquiphellandrene, and α-curcumene [21]. Ginger

oleoresins contain phenolic ketones include gingerols, shogaols, zingerone, hexahydrocurcumin, and their o-methyl ether derivatives [22].

Ginger found in various forms that includes fresh, dried, powdered, and oil extracts, each exhibiting unique chemical and pharmacological properties. Ginger is used as a stomachic, aromatic, carminative, stimulant, and flavouring agent [23]. Ginger oil is most commonly used in mouthwashes, beverages, and liquors, while ginger powder has been found to be effective in alleviating motion sickness [24]. Additionally, ginger is known to stimulate digestion, reduce bloating, and alleviate gastrointestinal discomfort, demonstrating potent anti-inflammatory properties [25]. Ginger extract also possess antioxidant, antimicrobial, and anticancer properties, making it a valuable natural remedy in modern medicine [26].

2.3. CINNAMON:

Synonym: Dalchini, Karuva, Lavangapattai

Cinnamon consists of the dried inner bark of the shoots of coppiced trees of Cinnamomum zeylanicum, belonging to family Lauraceae. It should not contain less than 1.0 per cent of volatile oil. Cinnamon is a crop of tropical countries. It needs sandy soils with an admixture of humus. The altitude at which it grows favourably is 800 to 1000meters.The seeds are sown in well prepared nursery beds located at suitable places in June and July. The seeds are sown at a distance of 10cm and covered with small layer of soil and watered properly. It takes approximately 20days for germination of seeds.

Significance: Cinnamon bark consists about 0.5-1.0% of volatile oil, 1.2% of tannins, mucilage, calcium oxalate, starch and sweet substance known as mannitol also 49.9% of cinnamaldehyde, 87.3% eugenol, benzaldehyde, cuminaldehyde and also other terpenes like phellandrene, pinene, cymene, caryophyllene etc [27]. Cinnamon is fragrant and delicious spices with high antioxidant content. It also provides antibacterial, anti-fungal, anti-oxidant, anti-tumour activity and may help fight throat pain and infection due to cold and cough. It has various essential oils, particularly cinnamaldehyde, have natural antimicrobial properties [28].

2.4. LEMON:

Synonym: Nimbu, nimmakaaya, nimbe

Lemon peel is the outer part of the pericarp of the ripe or nearly ripe fruits of Citrus limonia, family Rutaceae. It contains not less than 2.5% of volatile oils. The leaves are linear, sharp - edged and emit a lemony fragrance when crushed.

Significance: Flavour of lemon oil is due to neral and geraniol only. Lemon peel contains 2-4% of volatile oil. The other constituents of the peels are hesperidin, pectin, calcium oxalate and bitter substances. Lemon has various properties such as carminative and stimulant and oil is used as perfuming and flavouring agent. It is also used for extraction of pectin and volatile oil. And also contains antioxidants, which may help protect cells from oxidative damage [29].

2.5. JAGGERY:

Synonym: Gur, medicinal sugar

India is the largest producer and consumer of Jaggery. Jaggery is prepared by concentrating the sweet juices of sugar cane to a solid or semisolid state. It is golden yellow in color, hard in nature and crystalline in structure and sweet in taste. It is natural sweetener and has winy fragrance.

Significance: Jaggery contains proteins, minerals and vitamins. When compared to refined sugar it has potent source of iron and copper. It helps to purify blood, regulate liver function and keep body healthy [30]. It contains 70% sucrose, less than 5% sucrose and fructose [31]. More than 70% jaggery is produced in India [32].

III. IMPORTANCE OF INGREDIENTS USED IN HERBAL LOZENGES

The importance of each ingredient used in the preparation of herbal lozenges are tabulated in table no.1

Table no.:1 Importance of ingredients of herbal lozenges

Name of the ingredients	Biological source	Chemical constituents	Uses
Shankhpushpi	The *Convolvulus pluricaulis* of Leaves and flowers are used for its medicinal properties. Family: Convolvulaceae	Alkaloids, flavonoids, glycosides, phenolic acids, terpenoids, saponins, resins, volatile oils.	Enhance memory, boosts immunity, regulate menstrual cycles, treats epilepsy and constipation.
Ginger	Obtained from rhizomes of *Zingiber officinale.* Family: Zingiberaceae	Gingerol, shogaols, zingiberene, alpha- curcumene, zingerone.	It has anti-inflammatory, antioxidant and digestive properties. Treat motion sickness, stomach upset, boosts immune system.
Jaggery	Obtained from the juices of palm trees or sugarcane.	Sucrose, calcium, iron, protein.	Helps in digestion, prevents anaemia, Boosts immunity, hypertension, premenstrual syndrome, nourishes skin
Lemon	Obtained from *Citrus limon* belongs to the family Rutaceae.	Citric acid, vitamin C, flavonoids, potassium, calcium.	Boosts immunity, provide antioxidant, protection, soothe throat irritation aid digestion
Cinnamon	Obtained from the barks of *Cinnamomum zeylanicum.* Family: Lauraceae	Cinnamaldehyde, Cinnamic acid, Eugenol, Polyphenols and essential oils.	It has anti-oxidant, anti-inflammatory and antimicrobial properties. Used for blood sugar regulation and heart health.

Fig:1 Ingredients of herbal lozenges

IV. MATERIAL AND METHODS:

4.1. Collection of plant materials: All these herbs were collected from different sources and dried in hot air oven at 60˚C to remove the moisture.

4.2. Method of preparation:

Take 40gm of jaggery and add 20ml of water

↓

Melt the jaggery until it attains thick consistency.

↓

To the melted jaggery, add 0.2g of shankapushpi powder, 0.5g of Zinger powder, 0.4g of lemon powder, 0.2g of cinnamon powder.

↓

Mix all the contents.

↓

Now add the mixture into the moulds.

↓

Leave the moulds until they dry.

↓

Pack and label them.

4.3. Evaluation and standardization methods

Standardization and evaluation are essential for determining and validating the quality, potency, purity, and authenticity of herbal extracts, raw materials, and final goods. modifying and managing the production process to guarantee a constant level of quality and potency, which will ensure that particular bioactive chemicals or markers are present in a specified quantity and that pharmacopoeial and regulatory standards are met. As per Indian Pharmacopoeia (IP), evaluation refers to the process of assessing the quality of herbal material or preparation based on its physical, chemical, biological & microbiological characteristics ensuring purity & strength of the herbal preparation. Various parameters to evaluate and standardize the formulations are as follows:

4.3.1. *Organoleptic evaluation*

The lozenges by using above formulation prepared in the laboratory were evaluated based on the visual observation for various organoleptic properties like color, odour, shape, taste, texture [12, 33].

4.3.2. Physical evaluation:

4.3.2.1. Weight Variation: Studied weight variation of twenty tablets by weighing them using the digital balance and test was performed. Weighing 20 lozenges individually, calculating the average weight and individual weights to the average.

$$\text{Weight variation} = \frac{\text{Average weight - Initial weight}}{\text{Average weight}}$$

4.3.2.2. Disintegration Time: Disintegration time is the time interval required for complete disappearance of the lozenges. Test of the prepared lozenges was conducted according to USP30. By using a disintegration tester through the disintegration medium of phosphate buffer with pH 6.2 maintained at 37 ± 0.5℃. The lozenge of improved batch disintegrated in 90 seconds which is acceptable for throat lozenges.

4.3.2.3. Friability**:** The friability of tablets was determined using Roche Friabilator. Ten tablets were weighed initially and transferred into friabilator. The friabilator was operated at 25rpm for 4minutes. After taking out the tablets are weighed again and brushing the dust away. If the tablets are found broken and the final value exceed the limit test is considered as failed. The value should be more than 1‰. The percentage friability was then calculated by using the formula:[34]

$$\text{Friability} = \frac{\text{(Initial weight - Final weight)}}{\text{Initial weight}} * 100$$

4.3.2.4. Measurement of pH: By using pH meter the acidity of the lozenges was recorded a Scale from 1 to 14.0. 1% W/V Solution was prepared by dissolving 1g lozenges in 100ml distilled water and its pH was recorded [35].

4.3.2.5. Moisture analysis

a) Karl Fisher titration - measuring the water content in substances, utilizing a chemical reaction between water and Karl Fischer reagent, consisting of iodine, Sulphur oxide.

b) Azeotropic distillation method:

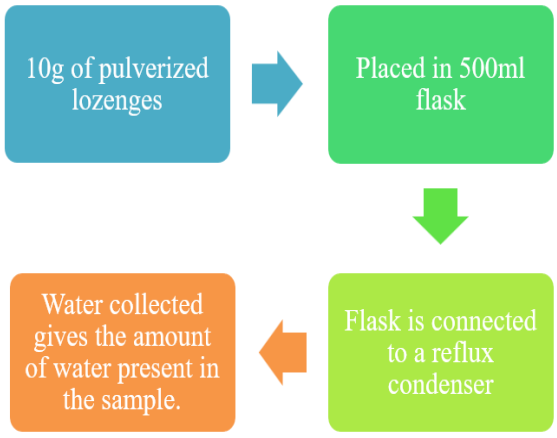

Fig:2 Flow chart of Azeotropic distillation

4.3.2.6. Moisture content: In the formulated lozenges, the presence of any bacterial, molds or spore contents is checked in the raw materials, finished products, machinery, environmental conditions and storage drums. Laboratory

microbial testing should include the following counts:

- Total plate
- Total coliform
- Yeast and molds

INGREDIENTS	QUANTITY
Jaggery	40g
Shankapushpi	0.2g
Zinger	0.5g
Cinnamon	0.2g
Lemon	0.4g

- *E. coli*
- Salmonella [36].

4.3.2.7. Stability testing: Lozenges are subjected to stability testing under following conditions-

- 1-2 months at 60℃
- 3-6 months at 45℃
- 9-12 months at 37℃ [37].

V. RESULT AND DISCUSSION:

5.1. Methods and materials:

5.1.1. As per the table no.2, weigh all the ingredient then prepared and packed as per the given steps below

Table no.:2 Formulation of herbal lozenges

Preparation of herbal lozenges:

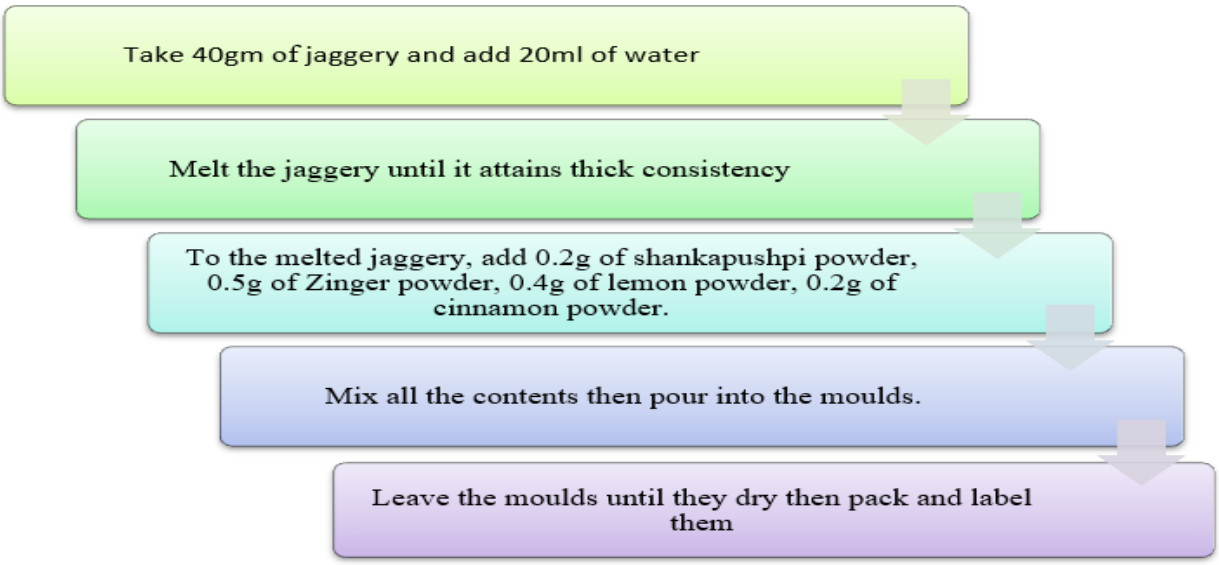

Fig:3 Flow chart of method of preparation of lozenges

5.1.2. By using various evaluation parameters, the prepared herbal lozenges were evaluated and compared with marketed lozenges (Panchatulasi)

5.1.2.1. Organoleptic evaluation**:** The results of organic evaluation parameters were tabulated in table no. 3.

Table no.3 Comparison of organic evaluation of test and standard

EVALUATION	TEST	STANDARD (compared to Panchatulasi)
Color	Brown	Orange
Odour	Pleasant	Pleasant
Taste	Sweet	Sweet
Texture	Smooth	Smooth

Shape	Round	Round

5.1.2.2.Physical evaluation: The results of physical evaluation parameters were tabulated in table no. 4.

Table no.4 Comparison of Physical evaluation of test and standard

EVALUATION	TEST	STANDARD (compared to Panchatulasi)
Weight variation	Average weight= 1.45 % Variation= 0.35	Average weight=1.79 % Variation=0.20
Disintegration time	1.8 min	1.5 min
Friability	0.8%	0.9%
Moisture content	0.5%	0.38%

VI. CONCLUSION

Herbal lozenges are natural and effective alternative to conventional medications for treating common ailments like sore throat, cough, cold and allergies. Day by day the consumers are becoming more health conscious, the market for herbal lozenges is likely to grow significantly. These are the form of tablets that slowly dissolve in the mouth and show their action. So that it provides cooling effect in the mouth. Herbal lozenges are safe and effective without any side effects. They show both local and systemic therapy.

VII. DECLARATIONS OF INTEREST

None

VIII. ACKNOWLEDGEMENT

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