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Preparation And Evaluation Of Herbal Lozenges From Betel Leaf.

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ABSTRACT :

Herbal lozenges derived from betel leaf offer a natural and traditional approach to addressing various health concerns. This paper examines the formulation, therapeutic properties, and potential applications of betel leaf lozenges in modern healthcare. Betel leaf, rich in bioactive compounds such as phenols, flavonoids, and tannins, exhibits antimicrobial, anti-inflammatory, and analgesic properties. The abstract delves into the methodologies used for the preparation of these lozenges, highlighting their efficacy in alleviating symptoms associated with respiratory conditions, oral ailments, and digestive issues. Furthermore, considerations regarding safety, dosage, and future research directions are discussed, emphasizing the potential of betel leaf lozenges as a valuable addition to complementary and alternative medicine practices.

The herbal based lozenges were formulated properly to provide proper relief from the cough symptoms by using natural herbal ingredients with potential and therapeutic properties. Lozenges also contain menthol or eucalyptus, which can help cool and sooth the throat. Others contain honey, which is known to have cough suppression properties.Some prescription lozenges have antibacterial and pain medications. The pain meds are usually non-steroidal anti-inflammatory drug

KEYWORDS : Herbal products, Betel Leaf, Lozenges, Herbal remedy, Oral hygiene, Traditional medicine, Antimicrobial properties, cultural significance, Natural ingredients

INTRODUCTION :

Herbal preparation :[1,2]

Herbal medicine has its origins in ancient cultures. It involves the medicinal use of plants to treat disease and enhance general health and wellbeing.Some herbs have potent (powerful) ingredients and should be taken with the same level of caution as pharmaceutical medications.[1] Herbal formulations means a dosage form consisting of one or more herbs or processed herbs in specified quantities to provide specific nutritional, cosmetic benefits meant for use to diagnose, treat, mitigate diseases of human beings or animals, alter the structure or physiology of human beings or animals.

Whether it's teas, tinctures, or extracts, herbal preparations harness the power of plants for wellness. They offer holistic alternatives to conventional medicine, often with fewer side effects. From calming chamomile to immune-boosting echinacea, there's a herbal remedy for almost every ailment.[2]

Benefits:[3,4]

1.Cost effective and accessible.

2.Natural healing.

3.Mitigated risk of side effects.

4.You can safely test and try different herbs.

5.Enhanced cognition.

6.Balanced hormones.

7.Natural pain management.

8.Earth connection.

Lozenges:[5,6,32]

Oral lozenge is the term used to define dosage forms that are intended to slowly dissolve in the mouth for local delivery primarily within the oral cavity. They may also be used for systemic absorption of drugs through the buccal and sublingual routes or swallowed for oral absorption.[5] Lozenges is a small usually sweetened solid piece of medicated material of any of various shapes that is designed to be held in the mouth for slow dissolution and often contains a demulcent. sore throat lozenges. called also pastille, troche.[6]

Lozenges are small, flavored medicated tablets typically designed to dissolve slowly in the mouth to soothe sore throats or alleviate coughs. They often contain ingredients like menthol, honey, or eucalyptus to provide relief.

Most lozenges can be bought over-the-counter and work by dissolving in the mouth gradually as you suck them, greasing up the throat coating, and decreasing the dryness and irritation and inflammation of the throat. Various brands of lozenges have different combinations of ingredients and various blends of fixings. They are used either for local or systematic action through the oral cavity. Lozenges are utilized for the delivery of

analgesics, sedatives, antimicrobials, antihistamines, cleaning agents, antitussives, aromatics, astringents, corticosteroids, decongestants, demulcents and different classes, and combinations of medications .[32]

For chesty coughs that are caused by infections, such as a cold, you can suck on throat lozenges to help fight the infection and numb the pain of a sore throat that's caused by a cough.[32]

Types of lozenges:[7,8]

· Medicated lozenges.

· Non-medicated lozenges.

Classification of lozenges:

I. According to its site of action:

a. Local Effect-

e.g Antiseptics, Decongestant.

b. Systemic Effect-

e.g Vitamins, Nicotine.

II. According to its texture and composition:

a. Chewable-

e.g Vitamins.

b. Hard-

e.g Lollipops.

c. Soft-

e.g Bentasil.

d. Compressed-

e.g Troches.

A) Chewable lozenges : Chewable lozenges are typically based on glycerinated gelatin; a base of glycerin, gelatin, and water.a preferred dosage form for children and adults who cannot swallow traditional tablets.[7]

B) Hard lozenges : Hard lozenges are generally formed using sucrose or other sugars similar to the process for hard candy confections that produce a hardened amorphous glassy material.[7]

C) Soft lozenges : Soft lozenges are a type of medicated candy-like dosage form designed to dissolve slowly in the mouth to release medication. They are often used for sore throat relief, cough suppression, or to deliver other medications like vitamins or throat numbing agents.[8]

D) Compressed lozenges : The heat liable ingredients i.e heat sensitive ingredients are not possible to formulate by procedure same as that of soft lozenges, hard lozenges. Simply the compression method is applicable for such type of ingredients, same as like compressed tablet.[8]

Advantages :[9]

Soothing Relief: They provide soothing relief for sore throats, coughs, and other throat irritations due to their soothing ingredients such as menthol or honey.

Localized Treatment: Lozenges deliver medication directly to the throat, providing targeted relief where it's needed most.

Convenience: They are convenient to carry and use, making them ideal for on-the-go relief whenever you need it.

Variety of Formulations: Lozenges come in various flavors and formulations, catering to different preferences and therapeutic needs.

Non-Invasive: Unlike some other forms of medication, lozenges are non-invasive and easy to administer, suitable for both adults and children.

Components of Lozenges

Ingredients	**Examples**
Candy base a. Sugar b. Sugar free Vehicle c. Fillers	Lactose, Maltose, Sucrose, Dextrose Mannitol, Sorbitol, Polyethylene Glycol Di - calcium phosphate, calcium sulphate, calcium carbonate, microcrystalline cellulose
Lubricants	Magnesium stearate, calcium stearate. Stearic acid, PEG, Vegetable oils, Fats
Binder	Acacia, Corn syrup, sugar syrup, Gelatin, Polyvinyl pyrrolidone, Tragacanth, Methyl cellulose
Coloring agent	Water soluble and lakolene dyes, Colors, Orange color paste, Red color cubes etc.

Flavoring agent	Methanol, Eucalyptus oil, Spearmint, Cherry flavor etc.
Whipping agent	Milk protein, Egg albumin Gelatin, Can't handle gum, Starch, Pectin, Algin, Carrageenan
Humectant	Glycerin, Propylene glycol.

Table no. 1 : Components of lozenges

Revisting The Benefits Of Betel :[10,11,31,33]

In India, Betel leaf (BL) plays an important role since ancient culture. Its use in India dates back to 400 BC. As per ancient books of Ayurveda, Charaka, Sushruta Samhitas, and Kashyapa Bhojanakalpa, the practice of chewing BL after meals became common between 75 AD and 300 AD.the leaf extract, fractions, and purified compounds are found to play a role in oral hygiene, and to have various properties including anti-diabetic, cardiovascular, anti-inflammatory/immunomodulatory, anti-ulcer, hepato-protective, anti-infective, etc.[10]

The betel plant is like a multi-purpose natural aid in traditional medicine! It has been known to possibly tackle a whole bunch of ailments, from colds and coughs to stubborn bronchial asthma and even stomach pain. Not only that, but it might also comes to your rescue in other conditions too, such as conjunctivitis, gum swelling, and those bother some boils.[31]

Fig. No. 1 : Betel Leaf

Taxonomical Classifications :

Kingdom: Plantae

Division: Magnoliophyta

Class: Magnoliopsida

Order: Piperales

Family: Piperaceae

Genus: Piper

Species: Piper betle L.

Vernacular Name :

Sanskrit: Tambool, Mukhbhushan, Nagavalli, Varnalata, Nagavallari

Hindi, Bengali, Urdu: Paan

Marathi: Vidyache pan

Distribution and Cultivation :

The betel vine is believed to have originated in Malaysia. The plant is widely grown in forests that are generally damp and also in hot and moist climatic conditions of India and many other countries in South and South East Asia, viz. China and Vietnam.[11]

The cultivation of betel, a vine whose leaves are commonly chewed for their stimulant effects, is widespread in tropical regions, especially in South and Southeast Asia. It's grown primarily for local consumption and cultural practices. The betel vine requires a warm, humid climate and well-drained soil. It's typically propagated through stem cuttings or air layering. Commercial cultivation for betel leaf production can be found in countries like India, Sri Lanka, Indonesia, Bangladesh, and Thailand. The distribution is mainly concentrated in regions where the climate and soil conditions are favorable for its growth.[11]

Chemical constituents of Betel leaf :

Chemical constituents	% Of Chemical Constituents
Allylpyrocatechol diacetate	0.71
Hydroxychavicol acetate	42.2
Chavibetol	53.1
Chavibetol acetate	15.5
Caryophyllene	3.71
Safrole	48.7
Chavibetol methyl ether	0.48
Eugene	0.32
a.- Pinene	0.21
f. -Pinene	0.21
1,8-Cineol	0.04

Table no. 2 : Chemical constituents of Betel Leaf

Activities Of Betel Leaf :

Betel leaf has a range of traditional uses, including being chewed for its stimulating effects and medicinal properties. It's also used in religious ceremonies, as a flavoring agent in dishes, and sometimes as a herbal remedy for various ailments.The betel leaf is often chewed with areca nut and slaked lime in many parts of Asia. This practice is known as betel chewing and is culturally significant in many societies. It's believed to have stimulating and medicinal properties, though excessive use can lead to health issues like oral cancer.

In throat infection :[12,13,14,15,16,17]

A sore throat is pain, scratchiness or irritation of the throat that often worsens when you swallow. The most common cause of a sore throat (pharyngitis) is a viral infection, such as a cold or the flu. A sore throat caused by a virus resolves on its own.[12]

Strep throat (streptococcal infection), a less common type of sore throat caused by bacteria, requires treatment with antibiotics to prevent complications. Other less common causes of sore throat might require more complex treatment.[13]

Sore throat lozenges and sprays provide some additional relief for the pain of sore throat, particularly those with anti-inflammatory or local anaesthetic ingredients. They are often combined with an antiseptic agent, which may or may not add any significant benefit.[13]

Provides quick relief from sore throat. Starts to work from 1st minute. Kills 99.9% bacteria and viruses in your throat.[14]

Some lozenges can contain other vitamins and minerals, such as zinc and vitamin C. As with any product containing supplementary vitamins and minerals, people should not take them in excess amounts without a doctor's approval. People should read the cough drop label before taking them to know what they are ingesting.[15]

Lozenges also contain menthol or eucalyptus, which can help cool and sooth the throat. Others contain honey, which is known to have cough suppression properties.[16]

Some prescription lozenges have antibacterial and pain medications. The pain meds are usually non-steroidal anti-inflammatory drugs.[16]

Betel leaves contain many chemical components such as betal-phenol, chavicol and other phenolic compounds. These components are known to have strong potentials in anti-fungi, anti-bacteria properties of betel Leaf.[17]

Coughing :[18,19,20]

Lozenges can help soothe a sore throat and alleviate coughing by providing a coating and sometimes containing ingredients like menthol or honey that have a soothing effect. Just be sure to follow the recommended dosage and instructions on the packaging. If your cough persists or worsens, it's best to consult a healthcare professional.

A throat lozenge (also known as a cough drop, sore throat sweet, troche, cachou, pastille or cough sweet) is a small, typically medicated tablet intended to be dissolved slowly in the mouth to temporarily stop coughs, lubricate, and soothe irritated tissues of the throat (usually due to a sore throat or strep throat),

Lozenges vary in pharmacological composition from those that contain analgesic ingredients (such as benzocaine and menthol) to those that are primarily effective due to their physiologic properties (such as the promotion of salivation).[18]

evaluation and proper manufacturing of the herbal based lozenges for cough by using combination of betel Leaf.[18]

The herbal based lozenges were formulated properly to provide proper relief from the cough symptoms by using natural herbal ingredients with potential and therapeutic properties.[19]

Lozenges provide a pleasant dosage form for patients who are unable to swallow other types of solid dosage form. [19]

they usually only provide temporary relief and may not address the underlying cause of the cough. It's important to use lozenges as directed and consult a healthcare professional if the cough persists or worsens.[20]

Drying of betel Leaf :[21,22]

The drying process constitutes an essential step in the ceramic sector, which aims at removing the water from the green ceramic material before firing takes place. This is a critical production step because if the material is inserted wet into the extreme environment conditions of the firing chamber, then the probability of moisture evaporation inside the pores of the material would be high.[21]

The drying process, which is a heat and mass transfer event that involves the transport of water in the product from the interior of the product to the surface and evaporating from the surface.[21]

By removing the moisture to a safe level, drying can prevent the growth and reproduction of microbial proliferation, mitigate moisture-mediated deteriorative biochemical reactions.[22]

Raw materials :

Local farmers supplied the betel Leaf(piper betel) , before drying the freshly collected betel Leaf were sorted and washed.

Prepration of leaves for drying :

The fresh betel Leaf were sorted by removing paste damage leaves, and Petioles were removed from leaves. Leaves are washed to remove dirt, after removing water drying was carried out.

Drying :

To dry betel leaves in an oven, follow these steps:

Preheat your oven to a low temperature, around 50-60°C (120-140°F). It's important not to use high heat to avoid burning or damaging the leaves.

wash the betel leaves thoroughly to remove any dirt or debris.

Pat the leaves dry with a paper towel to remove excess moisture.

Place the leaves in a single layer on a baking sheet lined with parchment paper. Make sure they are not overlapping to ensure even drying.

Place the baking sheet in the preheated oven and leave the door slightly ajar to allow moisture to escape.

Let the leaves dry in the oven for several hours, checking on them periodically. The exact time will depend on the thickness of the leaves and your oven's temperature.

Once the leaves are dry and brittle, remove them from the oven and let them cool completely.

Store the dried betel leaves in an airtight container away from moisture and light to maintain their freshness.

Fig. No. 2 : Dried Betel Leaf

Extraction of Betel Leaf :[23,24,25,26,27,28,29]

The extraction of betel leaves involves obtaining bioactive compounds from the leaves of the betel vine (Piper betle). Betel leaves have been utilized for centuries due to their medicinal properties and cultural significance in many Asian countries. The extraction process typically aims to isolate compounds such as phenols, tannins, flavonoids, and alkaloids, which contribute to the plant's therapeutic effects. These extracts have been studied for their potential pharmacological activities, including antioxidant, antimicrobial, anti-inflammatory, and anti-cancer properties. The extraction methods can vary, including techniques like solvent extraction, steam distillation, and supercritical fluid extraction, each offering unique advantages in obtaining specific compounds. Understanding the extraction process is crucial for harnessing the full therapeutic potential of betel leaves in various applications, ranging from traditional medicine to modern pharmaceuticals and herbal products.

Phyto-chemical compounds present in EO of plant materials are important components of human diet that can regulate the oxidation and stress related chronic diseases. To extract this EO from plant materials, several methods of extraction techniques such as hydro-distillation (HD), steam distillation, steam and water distillation, solvent extraction, super critical extraction etc.[23]

These techniques are widely used to enhance the extraction efficiency and to identify the chemical constitutes because of its simple and fast repeatability. However, HD method was widely used to extract EOs from most of the plant matrix that has gained much popularity in the present time with low cost and environmental friendliness.[23]

Betel leaves is one of the invaluable medicinal plants that has multipleuseful bioactivities found in Malaysia. In this work, the effect of extractiontemperature on the quality of the extract of betel leaves was investigated byquantifying the change of two active compounds, namely hydroxychavicol andeugenol. This is because the bioactivities depend on the content of the phy-tochemicals within the plant. The critical extraction temperature was deter-mined based on the findings.[24]

Solvent selection:[25]

The solvent is the key to a successful separation by liquid-liquid extraction. The several criteria are:

1. Distribution Coefficient

This is the ratio (at equilibrium) of the concentration of solute in the extract and raffinate phases. It gives a measure of the affinity of the solute for the two phases.

A distribution coefficient other than unity implies that the solute must have different affinity in the two phases. If only one solute is involved (such as in the recovery of an impurity from an effluent stream), only the distribution coefficient need be considered, and it is desirable for this to be as large as possible.

2. Selectivity (Separation Factor)

If there are more than one solutes (say two solutes A and B), then consideration should be given to the selectivity of the solvent for solute A as against B. The selectivity between the 2 solutes A and B is defined as the ratio of the distribution coefficient of A to the distribution coefficient of B. For all useful extraction operation the selectivity must exceed unity. If the selectivity is unity, no separation is possible.

3. Insolubility of Solvent

The solvent should have low solubility in the feed solution, otherwise the separation is not "clean". For example, if there is significant solubility of solvent in the raffinate stream, an additional separation step is required to recover the solvent.

4. Recoverability

It is always necessary to recover the solvent for re-use, and this must ordinarily be done by other means, eg. distillation. If distillation is to be used, the solvent should form no azeotrope with the extracted solute and mixtures should show high relative volatility. The solvent should also be thermally-stable under the distillation temperature.

5. Density

A large difference in density between extract and raffinate phases permits high capacities in equipment. This is especially important for extraction devices utilizing gravity for phase separation.

6. Chemical Reactivity

The solvent should be stable chemically and inert toward the other components of the system and toward the common materials of construction.

7. Viscosity, Vapour Pressure, Freezing Point

These should be low for ease in handling and storage, for example, a high viscosity leads to difficulties with pumping , dispersion and mass-transfer rate.

8. Availability and Cost

An excellent solvent may not be commercially available. Or it may represent a large initial cost for charging the system, and a heavy continuing expense for replacing inevitable operating losses.

Alchol : Typically, high-proof alcohols (190 and 200) have been used for extraction applications. Ethanol is emerging as one of the more popular solvents, because it is safe for infused edibles and compatible with any type of container. Ethanol also provides consistent results while being easily recoverable.[26]

Alcohol is indeed used as a solvent in various applications due to its ability to dissolve a wide range of substances, such as oils, fats, resins, and hydrocarbons. Its polarity and ability to mix with both polar and nonpolar compounds make it versatile in industries like pharmaceuticals, cosmetics, and cleaning products.[27]

ethanol is commonly used as an extraction solvent as it is considered a “green” and GRAS (generally recognized as safe) solvent, although other solvents such as hexane and butanol reportedly improve extraction yields.[27]

Water :

It is the safest and least expensive solvent. The fact that water is one of the few “green” solvents capable of tunable their properties by changing the temperature [1] has contributed to an increase in the number of publications using water as extraction solvent.[28]

Water is one of the most commonly used solvents due to its unique properties. Its polarity allows it to dissolve many substances, making it essential for biological processes, chemical reactions, and various industrial applications. Additionally, its abundance, safety, and environmental friendliness make it an ideal solvent for numerous purposes.[29]

Because of its polarity and ability to form hydrogen bonds, water makes an excellent solvent, meaning that it can dissolve many different kinds of molecules.[29]

Extraction process :[30]

By maceration: Maceration is one of the simplest extraction techniques in which coarse and powdered plant material is soaked in solvents such as methanol, ethanol, ethyl acetate, acetone, hexane etc. It is one of the popular and inexpensive techniques used for the extraction of different bioactive compounds from plant material.

Maceration is a common technique used for extracting compounds from plant materials like betel leaves. In this process, the leaves are soaked in a suitable solvent, such as ethanol or water, for a period of time to allow the solvent to dissolve the desired compounds. The resulting solution, known as a macerate, can then be filtered to separate the liquid extract from the solid plant material. This method is often used in herbal medicine and the production of natural extracts for various application.

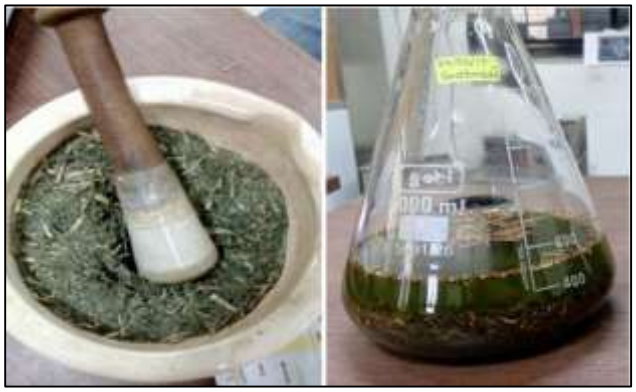

Fig. No. 3 : Maceration Process

Aim : To prepare and evaluate herbal lozenges - from Betel leaf.

METHODOLOGY :

The lozenges were prepared using the hand roll method.

The herbal lozenges composition formula is illustrated in table no.

All powdered constituent were passed through sieve number 40

The measured quantities of dried powder of herbs were then triturated with clove oil and mannitol.

Then added gelatin to the mixture, triturated well, added honey mixed consistently until the combination produce a soft mass of the required Consistentcy.

For prepration of individual lozenges, the mass was roled on a lozenge board to achieve consistent thickness and then cut equally to from circular flat peaces .

Then primary packaging was aluminum foil which prevented moisture uptake. This were then stored in sealed desiccators better storage conditions.

Formula of lozenges :

INGREDIENTS	QANTITY (14)
Piper betel leaves extract	2 gm
Ginger extract	1ml
Gelatin	30gm
Sucrose	40gm
Menthol	0.25gm
Glycerin	0.25gm
Honey	Q.S
Turneric powder	0.25gm

Table no. 03 : Formula for lozenges

Evaluation of Lozenges :

1.Thickness uniformity : Thickness uniformity Six lozenges were selected randomly from each batch and thickness was measured using Vernier calipers.lozengee thickness was almost uniform is 3.6mm .

2.Diameter : The diameter, size, and shape of lozenges depend on the molds selected. The lozenges of various sizes and shapes can be prepared. Diameter of the lozenges is ~ 1cm.

3.Moisture content : By the gravimetric method, 1 g sample was weighed and placed in an oven at 60–70°C for 12–16 h. Final weight was determined to utilize a delicate muslin fabric and its weight was rechecked. Percentage friability is given by the equation.

% F = (Initial weight−Final weight/Initial weight) × 100

% F = 1.1%

4.weight Variation : Ten lozenges were randomly selected from each batch and individually weighed. The average weight and standard deviation of 10 lozenges were calculated. The batch passes the test for weight variation test if not more than 2 of the individual lozenges weight deviates from the average weight.

5. pH Test : pH of the lozenges is determined to be 3.5 .

Results :The betal leaf lozenges was evaluated by thickness uniformity, diameter, moisture content, weight variation was performed .

CONCLUSION :

Betel leaf lozenges are often used for their medicinal properties, including their potential to aid in digestion, relieve throat irritation, and freshen breath. However, it's essential to use them in moderation due to potential side effects from prolonged use, such as oral health issues and addiction. As with any herbal remedy, it's best to consult with a healthcare professional before incorporating them into your routine. In the current investigation, Loratadine sweetened lozenges were prepared for the treatment of sore throat.Lozenges were successfully prepared by Piper betel leaves extract, Ginger extract,sucrose, gelatin, menthol, honey glycerin.

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