



FORMULATION AND EVALUATION OF VASAKA TRADITIONAL MEDICINE BASED HERBAL LOZENGES

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ABSTRACT

Development of lozenges dating back to the 20th century and is still popular among consumers, and has therefore continued to produce commercially. Lozenges are administered in the oral cavity as a palatable solid unit dosing form. For its local or systemic effect they meant being dissolved in the mouth or pharynx. Lozenge tablets however offer several advantages with some disadvantages as pharmaceutical formulations. Lozenge as a dosage form can be adopted through buccal route, labial route, gingival route, and sublingual route for drug delivery. Multiple drugs for chronic illness treatments can also be incorporated into them. Lozenge allows for the loading of a wide range of active ingredients for the oral systemic drug delivery. Lozenges are available in the form of soft lozenges based on caramel, hard candy lozenges and compressed tablet lozenges containing drugs for sore throat, mouth infection and as mouth fresheners over the counter medications. The reasoning behind using medicated lozenges as one of the most preferred dosage type for antitussive drug delivery. This review focuses on various aspects of lozenge formulation providing an insight into the novel application of the lozenge drug delivery system to the formulating scientist.

Keywords: Vasaka lozenges, expectorants, buccal route, labial route, gingival route, and sublingual route for drug delivery.

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INTRODUCTION

Lozenges are solid, single dose preparation intended to be sucked to obtain, usually, a local effect in the oral cavity and the throat. They contain one or more active substances, usually in a flavored and sweetened base, and are intended to dissolve or disintegrate slowly in mouth when sucked [1]. Lozenges are used for patient who have difficulty in swallowing of solid oral dosage form as well as for the drugs which should be released slowly to yield a constant amount of drug in the oral cavity or to coat throat tissues with the solution of drug.

A lozenge in the throat includes a small medicated tablet to be slowly dissolved in the mouth to temporarily arrepentilate tobacco and lubricate and to soothe the irritated tissues of the throat infections (sore throat) caused due to common cold and influenza. Chewable lozenges are popular among the pediatric and geriatric population [2]. They are intended to treat local irritation or infection of mouth or pharynx and may also be used for systemic drug absorption. Lozenges are meant as softening and purging of the throat to produce local effects. Lozenges are also used for systemic effect provided the drug is well

absorbed through the buccal linings or when it is swallowed. Lozenges are placed in oral cavity. Because of the size of the sublingual lozenges, oral lozenges are made, commonly used and intended to lie between the cheek Although the length of lozenge dissolution is roughly 30 minutes, it depends on the user, who controls the rate of lozenge dissolution and absorption by suction to dissolution. Sucking and subsequent saliva production can also contribute to increased drug dilution and involuntary swallowing [3]. Lozenges can be prepared by molding (gelatin and/or fused sucrose and sorbitol base) or by compression of sugar-based tablets. Sometimes, molded lozenges are called pastilles whereas compressed lozenges can be called trocks.

They are used for patients who cannot swallow solid oral dosage forms as well as for medications designed to be released slowly to yield a constant level of drug in the oral cavity or to bath the throat tissues in a solution of the drug. Historically, lozenges have been used to treat mild irritant and sore throat symptoms and were widely used to provide topical anesthetics and antibacterials. Today they are used for of drugs like analgesics, anesthetics,

antimicrobials, antiseptics, antitussives, aromatics, astringents, corticosteroids, decongestants, and demulcents and other classes and combinations [4].

Advantages of Lozenges

1. It can be given to those patients who have difficulty in swallowing.
2. Easy to administer to geriatric and pediatric population.
3. It extends the time of drug in the oral cavity to elicit a specific effect.
4. Systemic absorption of drug can be possible through buccal cavity.
5. Taste of drug can be masked by sweeteners and flavors used in formulation
6. It can increase in bioavailability.
7. It can reduce dosing frequency.
8. No disintegration [5, 6].

Disadvantages of Lozenges

1. Some drug may not be suitable with aldehyde candy bases e.g. Benzocaine.
2. The non-ubiquitous distribution of drug within saliva for local therapy.
3. Possible draining of drug from oral cavity to stomach along with saliva.
4. The lozenges dosage form could be used as candy by children mistakenly.
5. The hard candy lozenges a high temperature required for their preparation [5, 6].

Types of Lozenges

According to Site of Action

1. Local effect. e.g. Antiseptic, Decongestants
2. Systemic effect. e.g. Vitamins, Nicotine

According to texture and Composition

1. Chewy or caramel based medicated lozenges
2. Compressed tablet lozenges
3. Soft lozenges
4. Hard candy lozenges

According to Site of Action

Lozenges are classified into various classes based on various methods such as according to the site of action which can either be local or systemic effect. Examples of local effect are antiseptic, decongestion, while vitamins, nicotine are example of systemic effect [3].

According to Texture and Composition

(1) Chewy or Caramel Based Medicated Lozenges

Such are the treatment type in which the drug is added to a caramel base chewed instead of absorbed in the mouth. These lozenges are especially used for pediatric patients and are a very effective means of administering medications for gastrointestinal absorption and systemic use. The chewable lozenge or "gum-like" candy lozenge is one of the most popular lozenges for pediatric use. Such gelatinous pastiles is created by pouring the melt into molds or out on a uniform thickness surface. The base of candy is cooked at 95-125°C and moved to the planetary mixer or sigma tank. Blended lozenge based on sugar and sweet food is used in sugar. The added whipper is below 105°C. This follows. Then, between 95-105°C the medications are added.

Color is dispersed in humectants and added to the above mass at a temperature above 90°C. Seeding crystals and flavor are then added below 85°C, followed by the addition of a lubricant above 80°C. Candies are then formed by rope forming [5, 7].

(2) Compressed Tablet Lozenges

The active component can be prepared by compression as thermally reactive. The granulation method is similar to that used for any compressed tablet. The tablets are different from regular tablets.

1. Organoleptic property
2. Non disintegrating characteristics and
3. Slower dissolution profiles.

The lozenge is made with strong compression to give a tablet that is easier to dissolve gradually in the mouth than normal. Commercially, the preparation of lozenges by tablet compression is less important [5].

Manufacturing Techniques for Compressed tablet:

Lozenges manufacturing of compressed tablet lozenges can either be direct compression and wet granulation. In direct compression, ingredients are thoroughly mixed and then compressed. In wet granulation, sugar content is pulverized by mechanical combination to a fine powder (40-80 mesh size). Medicament is added and thoroughly blended. The blended mass is subjected to granulation with sugar or corn syrup and screened through 2-8 mesh screens. This is followed by drying and milling to 10-30 mesh size. Flavor and lubricant are then added prior to compression [7].

(3) Soft Lozenges

The simplicity of extemporaneous preparation and use of a wide variety of medications has made soft lozenges popular. The bases usually consist of a mixture of various polyethylene glycols, acacia or similar materials. One form of these soft lozenges is the pastille, which is defined as a soft variety of lozenge, usually transparent, consisting of a medication in a gelatin, Glycerol-gelatin or acacia: sucrose base. They are easy to use, easy to transport, easy to store (room temp), and generally an enjoyable taste. Polyethylene glycol-based lozenges may have a tendency to be hygroscopic and may soften if exposed to high temperatures [5].

Manufacturing of soft lozenges:-

Due to their soft texture they can be rolled up by hand and then sliced into pieces or a plastic mold can be used for the warm weight. When PEG is used as PEG contract when it cools, the mold cavity will be overfilled. In the case of chocolate, this is not necessary as it does not shrink [7].

(4) Hard Candy Lozenges

Hard candy lozenges are mixtures of sugar and other carbohydrates in an amorphous (non-crystalline) or glassy state. They can also be regarded as solid syrups of sugars. Hard candy lozenge's moisture content and weight should range from 0,5% to 1,5% to 1.5% to 1.5-4,5%. It will be gradually and uniformly absorbed or depleted in excess of 5-10 minutes.

The preparation temperature requirements are usually high, therefore thermal labile substances cannot be included in the preparation. These pastilles were prepared by Heating and congealing method [5].

Manufacturing of hard Candy Lozenges:-

The basis of the sweets is cooked in a chocolate base cooker by dissolving the desired amount of sugar in one third of water. The temperature will continue until it reaches 110 °C. Remove the maize syrup and simmer until a temperature of 145-156°C is hit. The cooker removes the dough mass and then transfers the weight of the mass into a lubricated transfer container that is attached on a weight checking scale. The paint add-on is accompanied by alternatives, pastes or cubes. The weight then passes on to an inox steel cooling table with water jacket to mix and adds flavor, medicine and soil salvage. As the mass is refrigerated and then cut to the point it is either pushed into mould or drawn into a belt [7].

Lozenges are solid preparations aimed at dissolving in the pharynx of the mouth (or). Lozenges & pastille was produced in pharmacy since the 20th century, and is still under commercial development. These lozenges are tablets that gradually dissolve in the mouth, and release the drug into the saliva. They are used for dissolving local in the mouth (or) throat medicine.

MATERIALS AND METHODS**Table 1: Formulation of vasaka lozenges**

S.NO	INGREDIENT	QUANTITY TAKEN FOR 10 LOZENEGES
1.	VASAKA EXTRACT	1.5gm
2.	GINGER EXTRACT	3ml
3.	TULSI EXTRACT	3ml
4.	CLOVE POWDER	0.6gm
5.	HONEY	3ml
6.	SUGAR	30gm
7.	WATER	15ml
8.	MINT OIL	8-9 drops

Vasaka extract:

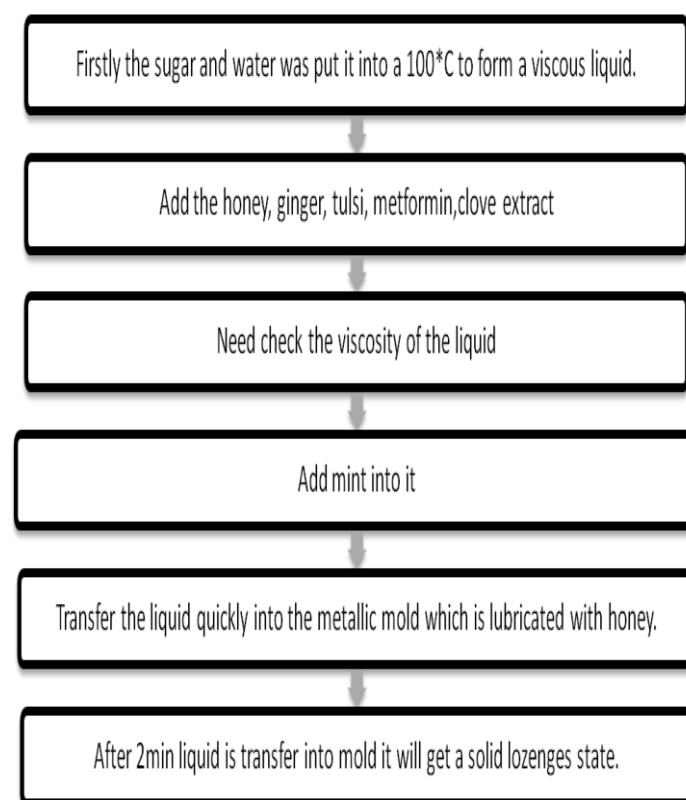
Vasaka leaves were collected and authenticated from Botanical Survey of India (BSI). Leaves were chopped and subjected to extraction using water as solvent as 60°C. Decoction was prepared by evaporating the extract to one third of its volume. Decoction was poured onto a glass tray and dried at 100°C. Dried extract was pulverized and stored in a desiccators [8].

Ginger:

The ginger extract was collected from a grate fresh ginger after peeling its upper scrub then the remaining part is used for ginger extract in this extract the juice is extracted by cheesecloth, wrap it properly and now squeeze it over an empty glass or bowl through which a liquid juice is extracted out which is further used as a ginger extract in formulation [9].

Tulsi:

Aqueous extract of tulsi leaves was obtained by grinding 200g of fresh leaves of the plant with 100ml of distilled water. The extract was sonicated and centrifuged at the rate of 10,000 rpm for 10 minutes then after the extract was collected and the residue of leaves was removed. Rest of the ingredients like honey, sugar, clove powder and mint oil are purchased from the market for the formulation of the herbal vasaka lozenges [10].

METHOD OF PREPARATION**Fig. 1: Process of Vasaka Lozenges Formulation****EVALUATION OF LOZENEGES****Physicochemical analysis study**

The prepared tablet lozenges will be subjected to various physico-chemical tests like, diameter, thickness, weight variation, and drug content evaluation [17].

Diameter and Thickness

Diameter and thickness of the lozenges were measured using vernier callipers. The test was performed for 10 lozenges and standard deviation was calculated [17].

Weight variations

Ten lozenges were weighed individually on an electronic balance. The average weight was calculated; each lozenge weight was then compared with average weight to assure whether it was within permissible limits or not.

Average weight= weight of 10 lozenges/10 [17].

RESULTS & DISCUSSION**Table 2: Evaluations of prepared lozenges**

Formulation	Weight of each lozenge (mg)	Hardness (kg/cm ²)	Thickness (mm)
FL1	3030.6±2.7	10.15±0.51	7.21±0.04
FL2	2999.3±2.65	10.3±0.46	7.19±0.08
FL3	3000.3±3.6	9.7±0.52	7.23±0.06
FL4	3000.2±2.3	10.76±0.53	7.21±0.03
FL5	3050.7±2.3	10.2±0.83	7.18±0.07
FL6	2999.6±2.65	11.3±0.50	7.20±0.01
FL7	2998.2±1.56	10.5±0.49	7.19±0.04
FL8	3100.1±0.49	10.3±0.43	7.18±0.05
FL9	3000.2±2.3	11.7±0.54	7.21±0.03
FL10	2999.3±2.65	10.39±0.50	7.22±0.12

In all formulations, tablets weight and thickness were in mean \pm 7.5% and mean \pm 5% respectively. The weight variation in all the formulations was found to be, 2999.4±1.56 mg to 3050.2mg which was in pharmaceutical limits. The thickness varies between mm. Hardness of all the tablets was maintained 9.86±0.40 to 11.07± 0.37.

PACKAGING OF LOZENGE

Lozenges are usually hygroscopic in nature hence an in volute and multiple packing systems should be used in order to maintain its stability during marketing. The single unit of lozenge is to be wrapped in a moisture impervious liner. These wrapped lozenges are placed in the glass, polyvinyl chloride or metal container that is tamper-proof or washable. Finally, these are over-wrapped using aluminum foil or by a cellophane sheet [11-15].

STORAGE

Lozenges from temperature or humidity extremes should be stored. The refrigerator or temperature of the room is generally specified in the product label according to both medication and the basis of the lozenge formulation requirements for storage. Lozenges should be kept out of reach by the children as per the label instruction [11-15].

DISPENSING

In order to ensure a gradual, steady release of the medication over long periods of time, a patient will undergo therapy. Strong and chewable lozenges should only be used as directed and not as snacks. They should be kept out of the reach [11-15].

DISCUSSION

The main objective of this study is to formulate and characterize VASAKA lozenges for Expectorant activity suitable for patient suffering from Expectorant and thought infection. Lozenges display many advantages over the other dosage form of these are; administer easy to geriatric and pediatric population, has good taste, it

prolongs the time of drug in the oral cavity to release a specific effect, prepared easily and no need water intake for administration, this study aimed to formulate vasaka as lozenges to improve delivery to treat oral thrush [18].

The prepared formulations were subjected to various physical and chemical tests like assay, weight variation and in-vitro release etc. All developed lozenge formulae were inspected for their color, and presence of lumps, no notable change was observed in the sample on visual observation. The prepared vasaka lozenges were translucent white. The result of weight variation indicating that all prepared vasaka lozenge has an average weight of 2999.4±1.56 mg to 3050.7±2.3 mg which is in accordance with requirement of British pharmacopeia [16]. In addition, the physicochemical characteristics revealed that the prepared VASAKA lozenges had an average thickness and hardness 5.295mm±0.23, 25.235mm \pm 0.18 respectively [18].

CONCLUSION

The present work is focused on the formulation of VASAKA as lozenges, which have various advantages over other dosage form one of which is the increase of bioavailability as it is a major factor responsible for the pharmacological activity of any drug. The lozenges are ease administered to children and elder patient in addition it masks bitterness of most drugs and has prolonged action. Moreover, it is preparation is ease and rapid in addition the less cost and equipment are required for their manufacture in comparing with other solid dosage forms. Lozenges as medicated confections both for systemic and local delivery of drugs are growing more popular. As innovative dosage forms for potent drugs which seem to be an ideal dosage form, they are expected to acquire more demand in pharmaceutical production. Lozenges include quick management, patient comfort, compliance with large patients and efficient treatment of low dose of medicinal products, rapid onset of action, reduced dose regimen and

cost effectiveness. In this field innovative product design also helps the consumer, physician and product industries. Lozenges will enjoy an important pharmacy position and will continue to remain at the same level in the future.

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