

Formulation and Evaluation of Polyherbal Lozenges

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Abstract

Throat infections are most common disease in today's world. Chronic sore throat can lead to serious throat problems, like Pharyngitis. Common respiratory tract infections such as common cold and flu cause symptoms like headache, fever, runny nose, congestion, and cough. Lozenges are solid preparations that contain one or more medicaments, usually in a flavored, sweetened base, designed to dissolve slowly in the mouth to yield a constant level of drug in the oral cavity and calm the inflamed throat tissues. The primary goal of this study is to prepare extract-based lozenges using herbs like vasaka, ajwain, mint tulsii, ginger which are traditionally used to reduce cough and the other ingredients are honey and jaggery Which have soothing effect on the mucus membrane Of the respiratory tract. The fresh leaf juices of all the ingredients is used to prepare polyherbal lozenges. Although many Herbal and allopathic medicines are available, but they are not enough to treat all the Symptoms with a single formulation. The polyherbal lozenges Were evaluated for their physicochemical parameters such as weight Variation, thickness, hardness, moisture content, hardness friability, disintegration diameter and from the result it was revealed that all the physicochemical parameter for lozenges were within the monograph standard which are mentioned in GMP Guidelines. These polyherbal lozenges can be a useful, Affordable, and widely available treatment for minor throat infections.

Keywords: Polyherbal, lozenges, vasaka, formulation.

Introduction

In the modern world, throat infection is the most prevalent illness. Throat infections can lead to throat cancer and other throat infections, including pharyngitis. Sore throat is the most common symptom caused by the inflammatory process in the pharynx, tonsils or nasopharynx. Most of these diseases are of viral origin and are part of the common cold.

sore throat : a sore throat is pain and irritation in the throat that worsens when swallowing. The most common cause of a sore throat (pharyngitis) is an infection such as a cold or flu. Sore throats may be caused by viral infections, bacterial infections, irritants and injuries. Signs and symptoms may include a sore or itchy throat, severe pain when swallowing or speaking, difficulty swallowing, swelling in the neck or jaw, red tonsils, white patches or pus on the tonsils, and a hoarse or hoarse voice. Common infections causing a sore throat might result in other signs and symptoms, including fever, cough, sneezing, headache. To overcome these problems new dosage

forms that are lozenges were designed which dissolves and breaks up quickly in saliva without the need to swallow the whole dosage forms. Lozenges dissolves within 15 s to 2 min.^[1]

Lozenges : lozenges are solid dosage forms containing one or more medicaments, usually in a flavored, sweetened base, that are intended to dissolve or disintegrate slowly in the mouth. The development of lozenges dates back to the 20th century and they are still produced commercially. Most of the lozenge preparations are available as over the counter medications.^[2] lozenges are used by people who are unable to swallow solid oral dosage forms and for medications that need to be given slowly to provide a continuous dose of medication in the oral cavity or to coat the tissues of the throat with the medication.^[3] Lozenges have been used for the relief of minor sore throat pain and irritation.

Material and method

Vasaka: Vasaka is a potent ayurvedic herb that strengthens the respiratory system. The plant has many medicinal properties. It is the best medicine against many health problems such as shortness of breath, cough, and cold, nasal congestion, sore throat, asthma, bronchitis, other upper respiratory tract infections. Vasaka contains vasicine which has mucolytic properties and it is used in various herbal expectorant formulations. [4]



Fig.no.1: Vasaka Leaves

Ajwain: Ajwain can reduce cough and clear mucus from the nose; both of these can make breathing easier. It may also help to dilate the bronchi, which can be beneficial for people with asthma. Thymol in ajwain leaves is rich in anti-inflammatory, antibacterial and antifungal properties that help in instant recovery from cold, fever and flu. It helps to relieve nasal congestion. Ajwain has an expectorant effect. Ajwain contains thymol, which has expectorant properties. Therefore, it acts as a decongestant, helps to remove mucus, and help to breathe easily.

Fig.no.2: Ajwain Leaves



Mint Tulsi: Mint tulsi contains different chemicals as well as phytochemicals such as rosmarinic acid, Eugenol, carvacrol, linalool, oleanolic acid, β -caryophyllene etc. Utilized as Ayurveda practice and siddha practice. Mint tulsi has antioxidant, anti-inflammatory, anti-aging properties and can treat asthma, anxiety, pneumonia, colds and respiratory diseases.



Fig.no.3: Mint Tulsi Leaves

Ginger: Ginger is widely used in Ayurveda to treat many ailments such as indigestion, nausea, allergies, cough, cold, fever, sinusitis, bronchitis, respiratory problems, headaches, toothaches and swollen gums. Ginger is recommended in Siddha to relieve cough. Ginger is one of the most popular herbs for cough. The characteristic smell and taste of ginger root comes from the combination of zingerone, shogaol, gingerol and essential oil.



Fig no.4: Ginger

Honey: It is a saccharine fluid (from the nectar of flower) deposited in the honey comb by the hive bee, Apismal- Lifer, Apisdorsata and other species of Apis (Family Apidae). Honey has been used as a cough medicine from centuries and is believed to have antibacterial and anti-inflammatory properties that help soothe the throat and reduce coughing. Honey can be used as an herbal remedy for cough.



Fig.no.5: Honey

Jaggery: Jaggery is also called “healing sugar” as it is widely used in Ayurveda. Jaggery helps relieve cough and nasal congestion. Phlegm production can cause a feeling of congestion in the chest and lungs. Jaggery helps in removing phlegm and thus relieves cough and nasal congestion. Daily consumption of jaggery helps to prevent asthma cough & cold, congestion in the chest. It reduces throat irritation due to soothing and smoothening effects on soft tissues of throat. According to ayurveda, it produces warmth in the lungs and dilates the respiratory tract, so it helps in cough, asthma and breathing trouble.



Fig no. 6: Jaggery

Method of preparation [5, 6, 7]

The raw materials which are used in the polyherbal lozenges preparation vasaka, Ajwain, Mint tulsi, ginger, Jaggery and honey are added in required quantity.

- **Weighing and measuring the raw materials:** Measure and weigh the lozenges raw materials in given values: vasaka, ajwain, mint tulsi and ginger and lozenge base materials: Home made jaggery and honey.
- **Grinding and shifting:** Vasaka, Ajwain, Mint tulsi is rinse before grinding (with mortar and pestle) collectively with frequent addition of water (100 ml) to make juice of the formulation. Peel the ginger, crush it and extract the juice. Then menstrum is remove in the beaker with help of mesh and marc is discarded.
- **Preparing the base:** To prepare the base steel cooking vessel was selected, in which crushed jaggery (25gm) is subjected to heat at low flame on induction in order to melt it.
- **Adding the raw medicinal ingredients:** Mix ginger and leaf extract with powdered sugar before adding to the vessel containing Jaggery while giving continuously gentle stir to it.
- **Consistency:** Once the desired consistency is achieved, cool the mixture under a fan for a few minutes and then add 30 ml of honey to it.
- **Measuring and pouring in to the mould:** Use a pipette to pour 1 ml of the preparation into the star mold.
- **Cooling and refrigerating:** Cool lozenges for 20-30 minutes in room temperature of 15-20C before storing into refrigerator for hard formulation.

Storage [8, 9]

Lozenges should be stored away from heat and out of the reach of children. They must be protected from moisture. Room temperature or refrigeration is usually indicated, depending on the storage requirements of the drug and base.

Packaging

Lozenges are hygroscopic and frequently prone to absorption of atmospheric moisture. Considerations must include the hygroscopic nature of the candy base, storage conditions of the lozenges, length of time they are stored and the potential for drug interactions. These products should be stored in tight containers to prevent

drying if a disposable mould with a cardboard sleeve is used, it is best to slip this unit into a properly labelled, sealable plastic bag or container. Packaging should be proper and attractive.

Dispensing

The patient should receive counselling about the purpose of a hard lozenge which is to provide a slow, continual release of the drug over a prolonged period of time

Formulation Table

Table 1: Raw materials to be included in the Polyherbal hard lozenges composition.

Sr. No.	Name of ingredients	Scientific name	Quantity taken F1	F2	F3
1.	Vasaka	<i>Adhatoda vasica</i>	5gm	6gm	8gm
2.	Ajwain	<i>Trachyspermum ammi</i>	5gm	4gm	5gm
3.	Mint Tulsi	<i>Ocimum tenuiflorum</i>	1gm	3gm	2gm
4.	Ginger	<i>Zingiber officinale</i>	7gm	5gm	6gm
5.	Jaggery	<i>Saccharum officinarum L.</i>	25gm	27gm	25gm
6.	Honey	<i>Apis</i>	5gm	6gm	7gm
7.	Menthol crystals	-	2gm	1gm	0.5gm
	Total		50gm		

Evaluation of polyherbal Lozenges ^[10, 11]

Macroscopic Evaluation: The formulation developed were evaluated for its acceptability based on visual observation for various organoleptic properties like Colour, Odour, Taste, Texture, Shape.

Weight Variation: Twenty lozenges of the formulation were weighed using a digital balance and the test was performed according to the official method. Ten lozenges were selected from each group and weighed individually. Calculate the mean weight and standard deviation of 20 lozenges. The batch passes the test for weight variation test if the weight of a lozenges does not differ by more than 2 from the average weight. The yield value between 90- 110% of average weight. Calculation was done by using the following formula

$$\text{Average weight} = \frac{\text{Weight of 20 Lozenges}}{20}$$

$$\text{Weight variation} = \frac{\text{Individual Weight} - \text{Average Weight} \times 100 \%}{\text{Average Weight}}$$

Friability: The friability of tablets was determined using Roche Friabilator. It is expressed as a percentage (%). Ten lozenges were initially weighed and transferred to the friabilator. The friabilator was operated at 25 rpm for 4 minutes. The lozenges were weighed again after removing out lozenges from friabilator and dusting it. If tablets are found broken or cracked and the final value exceed the limit test is consider as failed. The value should not exceed 1% (0.5-1.0%). If exceed repeat three time for complete estimation. The percentage of friability is calculated using the following formula

$$\text{Friability} = \frac{\text{Initial Weight} - \text{Final Weight}}{\text{Initial Weight}} \times 100$$

Measurement of pH: The acidity or alkalinity of a lozenges was indicated by using laboratory pH meter, a scale from 1.0 to 14.0. 1% W/V Solution was prepared by dissolving 1 g lozenges in 100 ml distilled water and its pH was recorded.

Determination of moisture

Gravimetric analysis: Weigh approximately 1g of sample and note the initial weight. Then, it should be kept in a vacuum oven at 60-70 oC for 12-16 hours. After specific period of time, once again weigh the sample and moisture content can be calculated by subtraction of initial weight from final weight. Formula used for calculation moisture content is

$$\text{Moisture content} = \text{Initial weight} - \text{Final weight}$$

Disintegration time studies: Disintegration time is the interval required for complete disappearance of a lozenges or its particles from the tester. The prepared lozenges was tested according to USP30. By using a disintegration tester through the disintegration medium of phosphate buffer with pH 6.2 maintained at $37 \pm 0.5^\circ\text{C}$. The optimized batch of lozenges disintegrated in 90 Seconds which is acceptable for throat Lozenges. Disintegration time was also within acceptance criteria of 90 seconds to 1.5 minutes.

Hardness: Hardness indicates the ability of a lozenges to withstand mechanical shocks while handling. The hardness of the lozenges was determined using Monsanto hardness tester. It is expressed in Kg/cm². Three lozenges were randomly selected and hardness of the lozenges was determined.

Stability study: The stability study was performed to evaluate physical and chemical stability of the drug, which may affect the organoleptic properties of the lozenges. Accelerated stability study was conducted as per ICH guidelines at 45°C and 75% relative humidity over a period of seven weeks. Sufficient number of optimized formulations were packed in amber colored screw capped bottles and kept in incubator maintained at 37°C. Samples were taken in intervals of 15 days to estimate the drug content and to evaluate organoleptic properties.



Fig.no.7: prepared polyherbal Lozenges

Result

Organoleptic Evaluation: The prepared lozenges were evaluated for its organoleptic parameters like colour, odour, taste and texture, etc.

Table 2: Macroscopic Evaluation

Sr. No	Parameters	Observation		
		F1	F2	F3
1.	Colour	Brown	Brown	Brown
2.	Odour	Pleasant	Pleasant	Pleasant
3.	Taste	Sweet	Sweet	Sweet
4.	Texture	Smooth	Smooth	Smooth
5.	Shape	Star	Star	Star

Physicochemical Evaluation

The lozenges are evaluated for various quality parameters like hardness, friability, thickness, weight uniformity and disintegration time which comply with the standard mentioned in GMP guidelines.

Table 3: physicochemical evaluation

Formulation	Weight variation	Moisture content	Hardness (Kg/cm ²)	Friability %	Disintegration (min)	pH
F1	±0.20	0.4	9.2	0.9	8.10	8.0
F2	±0.23	0.5	8.9	0.8	8.30	7.8
F3	±0.19	0.3	9.1	0.7	8.15	7.5

Discussion

All medicated lozenges were brown in color. Taste of medicated lozenges was slightly sweet. The lozenges of third batch F3 showed smooth appearance and no cracks were found while inspecting using magnifying glass (5X and 10X) with very smooth flat surface and brown color with pleasant fragrance. It has mild sweet taste for using jaggery and colling effect. The hardness of each batch was recorded and found to be within satisfactory range of 9.2 to 9.0 kg /cm². Wetting time and absorption time is used as a marker from the ease of the lozenges disintegration in buccal cavity. It was observed that wetting time of final batch F3 of lozenges was as in the range of 90 seconds. The lozenge of optimized batch disintegrated in 90 Seconds which is acceptable for mouth dryness Lozenges. Disintegration time of lozenges was within acceptance criteria of 4 minute to 4.5 minutes. Moisture content was found within range of 0.4% w/w to 0.5 % w/w. The Stability Studies evaluation showed that Physical appearance of lozenges remains unchanged. Hardness, pH, Friability, Average Weight and Moisture Content of lozenges were within the satisfactory criteria. Disintegration time remains unchanged. From one month stability data, no Significant change in parameters were observed indicating no degradation of active ingredients.

Summary

Vasaka has proven bronchodilator activity. In Ayurveda, the swarasa or juice of Vasaka leaves are administered for respiratory conditions. The herbal lozenges are formulated from aqueous extract of Vasaka with bitter taste masked with jaggery and flavoured with ginger extract and menthol, easy for pediatric patients to administer. It can also be an ideal choice for travelling patients as it eliminates the need of water for its

administration. As Vasaka is a single component in the formulation, the standardization is easier. The cost of the formulation is reduced as it is easy to manufacture this formulation on a large scale. In this project attempt has been done to outline general formulation, evaluation and application of polyherbal lozenges. In this research work we studied what is polyherbal lozenges, brief introduction of lozenges, ideal properties of lozenges, collection and identification of herbs used in this Formulation, drug profile, material and method, various evaluation test are performed for prepared polyherbal lozenges.

Conclusion

The current research work is performed on development and evaluation of an herbal medicine as the herbal medicine are safe and effective with negligible side effects. Research work is based on the polyherbs which are used to make a polyherbal lozenges. We have formulated hard polyherbal lozenges with three different herbs Vasaka, ajwain, mint tulsii in addition it also contains honey and jaggery. The prepared polyherbal hard lozenges were evaluated for the physicochemical parameters and the finished products are in the standard limits which is mentioned in the GMP guidelines.

This study reveals that the polyherbal lozenges are suitable dosage form for symptomatic relief of cough sore throat and cold. The polyherbal lozenges pass all the parameters and it has been found that it is more effective in the treatment of cough minor throat infections hence this polyherbal lozenges it is one of its own kind which is formulated and it can be recommended for minor upper respiratory infections and in future further development of the formulation can be done. From the overall result it can be concluded that the polyherbal lozenges are therapeutically effective at lower doses with fewer side effects than the allopathic ones. They can be prescribed at a lower dose to accomplish the desired pharmacological action.

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