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FORMULATION AND EVALUATION OF POLYHERBAL LOZENGES FOR THE TREATMENT OF SORE THROAT

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ABSTRACT

Lozenges are solid dosage forms that are intended to be dissolved or disintegrated slowly in the mouth. They contain one or more active ingredients and are flavoured and sweetened so as to be pleasant tasting. It is generally used for their topical effect, but may also have ingredients that produce a systemic effect. Minimum side effects make the herbal and alternative medication more attractive for the end users. This poly-herbal extract-based lozenges have proven the quality. The polyherbal extract based lozenges include Zingiber officinale Roscoe, Justicia adhatoda, Rosa Rubiginosa, Punica granatum, Psidium guajava, Piper Longum which is envisioned for cough and sore throat. 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. The aim of herbal lozenges is to deliver the active herbal ingredients directly to the throat, mouth and respiratory system to provide relief from various conditions. Herbal lozenges can be formulated with a variety of herbs and natural ingredients, each of which may have different therapeutic properties.

KEYWORDS: Polyherbal, Lozenges, Sore throat.

INTRODUCTION

Herbal medicine

Herbal medicine (also herbalism) is the study of pharmacognosy and the use of medicinal plants, which are a basis of traditional medicine. There is limited scientific evidence for the safety and efficacy of plants used in 21st century herbalism, which generally does not provide standards for purity or dosage. The scope of herbal medicine commonly includes fungal and bee products, as well as minerals, shells and certain animal parts. Herbal medicine is also called phytomedicine or phototherapy.

History of herbal medicine archaeological evidence indicates that the use of medicinal plants dates back to the paleolithic age, approximately 60,000 years ago. Written evidence of herbal remedies dates back over 5,000 years to the sumerians, who compiled lists of plants. Some ancient cultures wrote about plants and their medical uses in books called herbals. In ancient egypt, herbs are mentioned in egyptian medical papyri, depicted in tomb illustrations, or on rare occasions found in medical jars containing trace amounts of herbs.[1]

Sore throat

A respiratory tract infection often begins with throat discomfort, inflammation, and pain in the pharynx. Bradykinin and prostaglandins influence on sensory nerve terminals in the upper respiratory tract are most likely create a painful throat.

Influenza viruses is a pathogen responsible for cause of respiratory infections(sore throat). one of the most prominent symptoms of sore throat including pain, dryness, or irritation in a throat.[2]

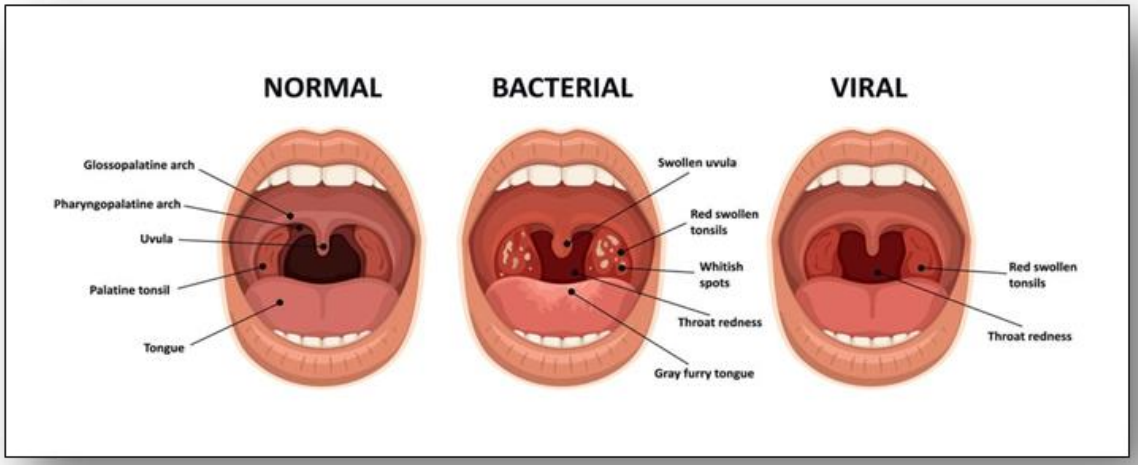

Figure 1: Normal and Bacterial, Viral throat infection.

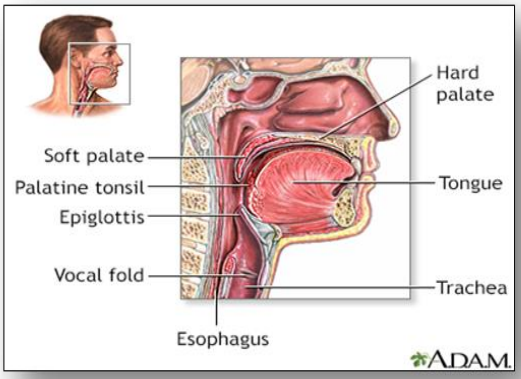

Figure 2: Sorethroat infection.

Sore throats are divided into types, based on the part of the throat they affect. The types of sore throat include:

1. Tonsillitis, which is swelling and redness of the tonsils, the soft tissue in the back of the mouth.
2. Pharyngitis, which causes swelling and soreness in the throat.
3. Laryngitis, which is swelling and redness of the voice box, or larynx.

Upper respiratory infections that can cause sore throat include common cold, epiglottitis, laryngitis, and pharyngitis.[3]

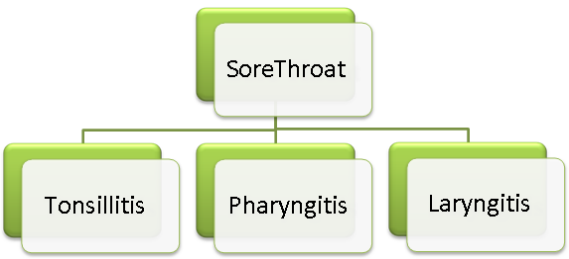

Figure 3: Types of sore throat.

Treatment of sore throat includes antibiotics, syrups, lozenges, cool mist vaporizer, gargles etc.

Lozenges

Lozenges are medicinal dose forms with tastes which are meant to be swallowed and held onto the throat or oral cavity. They include one or more drugs, typically in the sweetener base. Medicated lozenges which containing one or multiple herbs are known as polyherbal lozenges, and it maximize the therapeutic beneficial effects of the dosage form.[4]

There are a number of lozenges of this type on the market, but herbal lozenges are usually made with natural ingredients. Lozenges are used for patients who have difficulty in swallowing the solid oral form of the drug, as well as drugs that need to be released slowly in order to get a constant amount of the drug into the oral cavity or to coat the tissues of the throat with a solution of the drug.[5]

Types of lozenges

There are three basic types of lozenges:

Hard lozenges

Hard lozenge is generally formed using sucrose or other sugars similar to the process for hard candy confections that produce a hardened amorphous glassy material. To slow the rate of dissolution, polymers such as PEGs and HPMC may be added. Another type of hard lozenge may be made of compressed powders. An example of this is clotrimazole troches (lozenges) made as a large compressed tablet that is slowly dissolved in the mouth. The tablet base material is made of dextrose, MCC, and povidone.

Soft lozenges

Soft lozenge is often made using PEGs of sufficient molecular weight to provide slow dissolution in the

saliva. Additionally, hydrocolloids such as acacia may also be added as an adhesive agent. Soft clotrimazole troches can be made this way by adding drug and acacia to melted PEG 1450 base and pouring into troche moulded cavities.

Chewable lozenges

Chewable are typically based on glycerinated gelatine, a base of glycerine, gelatine, and water. This base can be mixed with drug, acacia, and suitable flavouring and sweetening agents.[6]

Advantage of lozenges[7]

1. It is easy in Delivering to both paediatric as well as geriatric patients.
2. It has a pleasant taste and will extend the time a quantity of drug remains in the oral cavity to elicit local activity.
3. Systemic absorption of drugs can be possible through buccal cavity.
4. Taste of the medicine can be masked by sweetening and flavouring agents used in the formulation.
5. Do not require water intake form administration.
6. Avoid first pass metabolism of drugs.
7. Increase contact time of drug so gives prolong drug action.
8. Cost of production is less.

Disadvantage of lozenges[8]

1. Heat stable drugs are suitable.
2. Drugs having minimum bitter taste are suitable.
3. Hard candy lozenges the high temperature required for their preparation.
4. Hard lozenges become grainy.
5. The non ubiquitous distribution of drug within saliva for local therapy.
6. Accidental swallowing of entire dosage form.

Ideal properties of lozenges[9]

1. Is a solid preparation consisting of sugar and gum, the latter giving strength and cohesiveness to the lozenge.
2. Facilitating slow release of the medicament.
3. It is used to medicate the mouth and throat for the slow administration in digestion or cough remedies.
4. It is intended to dissolve slowly in the mouth to temporarily suppress the cough, and lubricate and soothe irritated tissues of the throat.
5. Lozenges also contain menthol or eucalyptus, which can help cool and sooth the throat.

AIM AND OBJECTIVE

The main objective of the study is to formulated and evaluates polyherbal lozenges remedy for suppressing cough for sore throat and cold. The polyherbal extract based lozenges includes guava leaves, vasaka leaves, pomegranate peel, ginger which are traditionally used for cough suppressant and in cold and flu and the other ingredients are honey, rose petals and lemon which are nutritive effect and soothing effect on the mucus membrane of the respiratory tract.

MATERIALS AND METHODS

Collection and authentication of herbal plants

The plant materials of guava,vasaka, pomegranate ,ginger, rose were collected from college and home premises .The plants were authenticated from L. B. S. college of art and science and commerce satara. The collected leaves of vasaka, leaves of guava, rose petals and peels of pomegranate were washed and dried under shade. Powder of pippali was collected from nearby ayurvedic shop, sugar and lemon premix prepared at home and used as sweetener and antioxidant and honey from ayurvedic shop as well. After proper drying, all materials were grinded using mixer and the powders were passed through sieve no.120 to get a fine powder. This study was performed to expedite a new formulation and evaluation of formulated polyherbal lozenges to know their effectiveness against the minor throat problems.

Image no. 1: Vasaka leaves.

Image no. 2: Gauva leaves.

Image no. 3: Pomegranate peel.

Image no. 4: Rose petals.

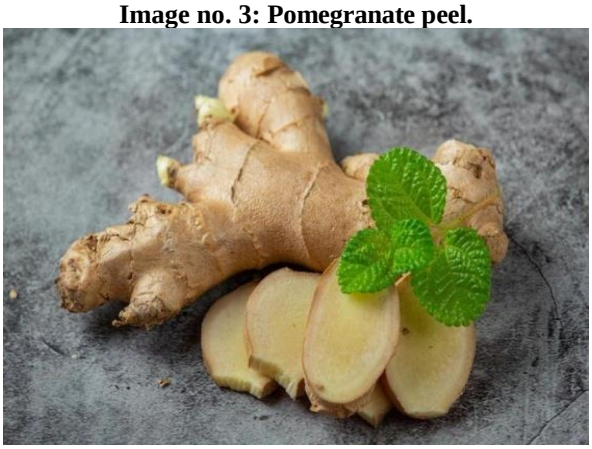

Image no. 5: Ginger.

Image no. 6: honey.

Image no. 7: Pippali.

Image no. 8: Sugar and lemon premix.

Image no. 1-8: Showing List of herbal Ingredients used in preparation of lozenges.

Table no. 1: Information of polyherbal Ingredients used in preparation of lozenges.

Sr. No.	Common Name	Botanical name	Plant part used	Uses /Activity
1	Vasaka	*Justicia adhatoda*	Leaves	Treating cold cough
2	Guava	*Psidium guajava*	Leaves	Antimicrobial, inflammatory, antiallergic, antihyperglycemic
3	Pomegranate	*Punica granatum L.*	Peel	Coughing, Sore throat
4	Rose powder	*Rose indica*	Petals	Reduce inflammation, Rich in mineral, soothe a sore throat
5	Ginger	*Zingiber officinale*	Rhizomes	Colds, Arthritis, Migraines, Hypertension
6	Honey	-	-	Anti-inflammatory, Antibacterial, Antimicrobial, Treat cold
7	Long pepper or pippali	*Piper longum*	Seed	Asthma, Sore throat, Diarrhoea, Indigestion
8	Sugar and lemon premix	-	-	Sweetener, Antioxidant

Formulation table

Table no. 2: Formulation table.

Sr. no.	Ingredients	Quantity
1	Vasaka Leaves powder	4gm
2	Guava leaves powder	3gm
3	Pomogranate peel powder	3gm
4	Rose petals powder	2gm
5	Fresh Ginger juice	25ml
6	Honey	q.s.
7	Pippali powder	2gm
8	Sugar and lemon premix	q.s

Image no. 9 **Image no. 10** **Image no. 11**

Image no. 9, 10, and 11 showing Preparation of polyherbal lozenges.

Image no. 12: Prepared polyherbal lozenges.

Preparation of polyherbal lozenges

Measure and weighed the lozenge raw material including all the fine powders of vasaka, guava, pomegranate peel, rose petals and pippali as given in the formulation table. After weighing, the ginger was crushed and fresh juice was prepared. Taken the given quantity of water and ginger juice in vessel, add all weighed powders in it and boiled the mixture for 15 minutes. After boiling, cool the mixture and filter it. The filtrate was again taken in a vessel and premix of lemon, sugar and honey was added to it. This mixture heated until the desired consistency was obtained. Once desire consistency is obtained the preparation was poured in a silicon moulds. Cool lozenges for 20-30 minutes in room temperature before storing into refrigerator to form a hard formulation, after proper drying, the lozenges were removed from the moulds. The preparation was stored in glass container coated with fine sugar, at room temperature, away from moisture.[10-11]

Evaluation of polyherbal lozenges[12-13]

Organoleptic evaluation

The formulation developed in the laboratory were evaluated for its acceptance based on visual observation for various organoleptic properties like Colour, Odour, Taste, Texture, Shape.

Uniformity of weight

Study weight variation twenty tablets of the formulation were weighed using a digital balance and the test was performed according to the official method. Ten lozenges were randomly selected from each batch and individually weighed. To The average weight and standard deviation of 20 lozenges were calculated. The batch passes the test for weight variation test if not more than 2 of the individuals lozenges weight deviates from the average weight. Yielding value between 90- 110% of

average weight. Calculation was done by using the following formula.
Average weight = Weight of 20 Lozenges /20
Weight variation= Individual Wright- Average Weight x 100% /Average Weight

Disintegration time studies
Disintegration time is the interval required for complete disappearance of a lozenges or its particles from the tester. Test of the prepared lozenges was performed according to USP30. By using a disintegration tester through the disintegration medium of phosphate buffer with pH 6.2 maintained at 37 ± 0.5°C. The lozenge of optimized batch disintegrated in 90Seconds which is acceptable for throat Lozenges. Disintegration time was also within acceptance criteria of 90 seconds to 1.5 minutes depending up on type of lozenges.

Friability
The friability of tablets was determined using Roche Friabilator. It is expressed in percentage (%). Ten tablets were initially weighed and transferred into friabilator. The friabilator was operated at 25 rpm for 4 minutes. The tablets were weighed again after taking out tables and brushing the dust away. If tablets are found broken or cracked and the final value exceed the limit test is consider failed. The value should be no more than 1% (0.5-1.0%). If exceed repeat three time for overall estimation. The % friability was then calculated with help of following formula:
Friability= (Initial Weight -Final Weight) X 100/
Initial Weight

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

Determination of moisture
This test is used to determine the water content of a material by drying a sample to constant mass at a specified temperature. By the gravimetric method, 1 g sample was weighed and placed in an oven at 100-120°C for 3hrs. Cool to room temperature. Repeat until constant weight observed. Percentage friability is given by the equation.
% F = (Initial Weight−Final weight/Initial weight) ×100.

Determination of Thickness
The thickness of the tablets was determined by using vernier calliper. Five tablets were used. The average values were calculated.
Average thickness = Total 5 lozenges thickness ×100/5

Hardness
Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablets was determined using Monsanto hardness tester. It is expressed in kg/cm2. Three tablets were randomly picked and hardness of the tablets was determined.

Diameter
Ten tablets for diameter uniformity are carried out. Then the value of the diameter is taken.The deviation of each is calculated and the deviation of individual unit from the mean diameter should not exceed ± 5% for tablets with diameter of less than 12.5 and ± 3% for diameter of 12.55mm or more.

RESULT AND DISCUSSION

Organoleptic Parameters of lozenges

Table no. 3: Organoleptic Parameters of prepared polyherbal lozenges.

Sr no.	Parameters	Observations
1	Colour	Brownish Green
2	Odour	Pleasant
3	Taste	Sweet
4	Texture	Rough
5	Shape	square

The lozenges were found to be square in shape with rough texture. This square shape was due to moulds used for preparation. The taste of the lozenges was determined using human volunteer and was sweet in taste. The sweet taste could be attributed to the use of sugar as base. The odour of prepared lozenges was pleasant; it can be attributed to the presence of rose petals powder and other crude drugs. Colour of lozenges was brownish green due to honey sugar base and crude drugs which were dark coloured. All these results are represented in Table no. 3.

Evaluation of Formulated Lozenges

Table no. 4: Evaluation of Formulated Lozenges.

Formulation	Evaluation parameter	Result
Polyherbal Hard lozenges	Uniformity of weight	503.55 mg
	Disintegration time	5min
	Friability	0.59 %
	Measurement of pH	7.5
	Moisture content	0.48%
	Thickness	197mm
	Hardness	8kg/cm^2
	Diameter	2.25mm

Average weight for twenty lozenges was found to be 503.55 mg. The no. of lozenges deviating from the average weight was within limit of 5% specified in the monograph. The uniformity in weight can be correlated with uniformity in dosing. The result is given in Table no. 4.

Ideally Disintegration time test is not official for the formulation expected to be dissolved slowly in the mouth and hence the limits are not specific. Still the test was performed to find whether the lozenge dissolves in mouth and how much time it takes to dissolve completely so that the faster and localized onset of action

can be obtained. The test was performed as per the procedure given in the monograph for uncoated tablets. The medium used was phosphate buffer pH 6.2 to simulate the pH of oral fluid. Sampled six lozenges revealed average disintegration time of 5 min (Table no. 4.).

The Friability test to confirm the impact resistance of the formulation, friability testing was performed on the twenty lozenges. The % loss in weight estimated was found to be 0.59 % which indicates that the formulation passes the test as the limits specified in Pharmacopoeia indicates that the value should be not more than 1.0% (Table no. 4.).

The hardness determination is one of the required parameters in quality assessment for lozenges. This indicates thestrength of the formulation and ability to withstand the impacts during transportation and handling. The transport and handling may cause chipping of the lozenges. Hence to determine the ability of the formulation to prevent fracturing, hardness testing was performed using Pfizer hardness tester. The average hardness for twenty lozenges was found to be 8kg/cm^2.

FEEDBACK FORM 1

Patient name: Shanta Gaikwad Age: 70

S.No	Different criteria	Strongly Agree	Agree	Neutral	Disagree	Strongly disagree
1.	Color acceptability of lozenge			□		
2.	Taste and palatability -Too sweet -Too bitter -Acceptable	□				
3.	Dissolution in mouth is easy	□				
4.	Safety and sterility concern		□			
5.	Duration of action is quick and satisfactory	□				
6.	Would you like to recommend it To flu patients		□			
7.	Did you find it better compared Too the marketed drugs and dosage form.		□			
8.	What factor mostly affect your choice in selection of any lozenge from market 1.Formulation 2.Availability 3.packaging	□ □ □				

FEEDBACKFORM 2

Patient name: Sayli Panhale Age : 12

S. No	Different criteria	Strongly Agree	Agree	Neutral	Disagree	Strongly disagree
1.	Color acceptability of lozenge		□			
2.	Taste and palatability -Too sweet -Too bitter -Acceptable	□				
3.	Dissolution in mouth is easy		□			
4.	Safety and sterility concern		□			
5.	Duration of action is quick and Satisfactory	□				
6.	Would you like to recommend it To flu patients	□				
7.	Did you find it better compared to other marketed drugs and Dosage form.			□		
8.	What factor mostly affect your choice in selection of any lozenge from market 1.Formulation 2.Availability 3.Packaging	□ □ □				

CONCLUSION

The present research work is performed for development and evaluation of a polyherbal lozenges to treat sore throat as the herbal medicine are safe and effective with negligible side effects. Present work is based on the multiple herbs. We have formulated hard polyherbal lozenges with different herbs like Vasaka, pippli, ginger, dried pomegranate peels, dried rose petals, dried guava leaves in addition it also contains honey and sugar lemon premix. polyherbal hard lozenges were evaluated for the different parameters by précised advanced analytical instrumental Methods for assessment. The study reveals that the polyherbal lozenges are suitable dosage form for relief from cough, sore throat and cold which can be used for special population (geriatrics, pediatric) purpose hence polyherbal lozenges passes all the parametersand it was found with the feedback responses 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 with combination of multiple herbs and it can be recommended for minor upper respiratory infections and in future furtherdevelopment of the formulation can be done.

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