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FORMULATION AND EVALUATION OF POLYHERBAL LOZENGES

T. Srivallika[1], M. Himaja Trivedi[1*], M. Srinadh[1], Maram Chinnaeswaraiah[1]

[1]Department of Pharmacognosy, Anurag Pharmacy College, Ananthagiri, Kodad-508206, Suryapet District, Telangana

*Corresponding author E-mail: himajatrivedi1141@gmail.com

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ABSTRACT

The main objective of the study is to formulate and evaluate polyherbal lozenges for sore throat. The polyherbal based lozenges includes clove oil, liquorice *[Glycyrrhiza glabra]*, Cinnamomum *[Cinnamomum cassia]*, cardamom *[Elettaria cardamon*], sugar *[Sucrose]*, ginger *[Zingiber officinalis]*, Jaggery *[Saccharum officinarum]* which are traditionally used for cough suppressant and for sore throat and the other ingredients which are nutritive effect and gives soothing effect on mucus membrane of the respiratory tract. The powdered mixture of all ingredients was used in the preparation for formulation of hard lozenge. The polyherbal lozenges were evaluated for their physiochemical parameters such as thickness, hardness, disintegration, friability and pH. The results of all physiochemical parameter of hard polyherbal lozenge were within the monograph standard which are mentioned in GMP Guidelines. The present research work was successfully concluded by taking feedback and responses from volunteers which include adults and children of either sex. From the survey it was found that the polyherbal lozenges were effective in cough and for sore throat conditions and with an acceptable taste. From the above investigations it was expertise to develop a polyherbal lozenge of hard herbal lozenges and it was just an attempt to make a polyherbal lozenges in which the powders of liquorice roots cinnamon, cardamon and clove oil were incorporated for the first time and these polyherbal lozenges can be effective, economical and easily available remedy for the minor throat infections as well as used to cure sore throat infections.

INTRODUCTION

Among the various routes of administration, the oral route is the most favoured route because of different points of the interest including simplicity of ingestion, flexibility, and in particular patient compliance. The significance disadvantage of this route is for paediatric and geriatric patients who face difficulty in swallowing[1]. Sore throat or pharyngitis is inflammation of the throat which exhibits symptoms such as the runny nose, cough, headache, difficulty swallowing, swollen lymph nodes, and a hoarse voice. It is typically caused by a viral, bacterial, or fungal infection. The microscopic organism that most normally causes sore throat is streptococci. A sore throat can also occur by aggravation, smoking, air contamination, unnecessary shouting, and postnasal trickle brought about by hypersensitivities and breathing through the mouth[2]. To conquer these issues such as difficulty in swallowing and conditions such as sore throat, formulators have significantly devoted their push to build up a novel kind of tablet dosage form for the oral route, that is

one which deteriorates and break up quickly in salivation without the requirement of swallowing the dosage form as a whole. These tablets are lozenges that break down from 15 seconds to 2 minutes. The quicker the medication breaks, the faster the assimilation and beginning of clinical impact[3]. Lozenges are solid dosage preparations that contain one or more medications, usually in a flavoured, sweetened base, that are intended to dissolve or disintegrate slowly in the mouth[4]. Lozenges are intended to be held in the mouth or pharynx[5]. Lozenges are used for the patients who have difficulty swallowing of solid dosage forms as well as the drugs which should be released slowly to yield a constant amount of drug in the oral cavity or to coat the throat tissues with the solution of drug[6,7]. The lozenges tablets are differ from conventional tablets in terms of organoleptic, non-disintegrating characteristics and with slower dissolution profiles. Commercially lozenges are made by moulding or by compression they slowly dissolve or disintegrate in the mouth sometime they are chewed. A throat lozenge includes cough drop, torche, cachou, or cough sweet which is small, medicated tablet intended to be dissolved in the mouth to temporarily arrest coughs, to lubricate and to soothe the irritated tissues of the throat infections caused due to common cold or influenza[8]. 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 the ingredients and various blends of fixing. They are used either for local or systemic action through the oralcavity. 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 medication[9].

Herbal lozenges are similar in size, and sometimes in flavour, to hard candies but are intended to ease sore throats and help people recover from colds, influenza, and similar illness. There are a number of such lozenges in the market, but herbal lozenges are usually made with primarily natural ingredients such as chamomile, fruit extracts and honey. In addition to herbal lozenges for cold and flu season, there are also lozenges that are intended to help people who are trying to quit smoking[10].

MATERIALS AND METHODS

Collection of Herbs: The raw materials which are used in the polyherbal lozenge preparation are cinnamon, cardamom, ginger, jaggery, sucrose and liquorice were purchased from Sri Ganesh Ayurvedic store, Kodada. Clove oil was collected from Research-Lab Chem Industries. This study was performed to evaluate a new formulation and evaluation of polyherbal hard lozenge was developed to know its effectiveness.

Method of Preparation of Polyherbal Mixture: Liquorice, cinnamon, and cardamom were ground to a fine powder as per sufficient quantity. Jaggery was converted into a fine thick solution on a hot iron plate. Ginger juice was extracted from *Zingiber officinalis*. Sugar was ground to a fine powder.

Storage and Packing: The preparation was stored in a glass container at room temp away from moisture [3, 11-12].

EVALUATION OF POLYHERBAL LOZENGES

Organoleptic Evaluation

Organoleptic properties were examined by visual inspection of lozenges for appearance, colour, odour, taste, and texture.

Disintegration Time Studies

Disintegration time lozenges was determined by using Disintegration apparatus. Potassium dihydrogen phosphate bufferwas used as disintegration medium

Table No.1: List of Polyherbal Ingredients Used in the Polyherbal Lozenges

S.No	Common Name	Botanical Name	Plant Part Used	Quantity
1	Liquorice 	*Glycyrrhizaglabra*	Roots	20gm
2	Cinnamon 	*Cinnamomumcassia*	Bark	5gm
3	Cardamom 	*Elettariacardamom*	Seeds	0.5gm
4	Ginger 	*zingiberofficinale*	Rhizome	1 inch
6	Clove oil 	*Eugenia caryophyllus*	Seeds	2-3 drops
7	Sugar 	Sucrose	-	30gm

Formula of Polyherbal Lozenges

Table No. 2: Raw Materials to Be Included in the Polyherbal Hard Lozenges Composition

S.no	Ingredients	Quantity
1	Liquorice	20gm
2	Cinnamon	5gm
3	Cardamom	0.5gm
4	Ginger	1 inch
5	Jaggery	50 gm
6	Sugar	30gm
7	Water	100ml
8	Clove oil	2-3 drops

The lozenges were cooled for 20-30 minutes at a room temperature of 15-20^0 C before storing in the refrigerator for hard formation.

Figure No. 1: Disintegration studies for Polyherbal Lozenges

Friability: The friability of lozenges was determined by using Roche friabilator. It is expressed in % . 10 lozenges were initially weighed and transferred into Friabilator. The Friabilator was operated at 25 rpm for4 mins. The lozenges were weighed again after taking out and brushing the dust away. If the lozenges are found broken or cracked or the final value exceed the limit, test was considered as fail.The values should not be more than 1% (0.5-1.0) The %friability was then calculated using following formula. Friability = initial wt - final wt x 100 / initial wt

Measurement of pH: The acidity or alkalinity of a lozenge was determined by using pH meter. 1% w/v solution was prepared by dissolving 1gm candy in 100ml distilled water and its pH was recorded by dipping the pH meter in the solution.

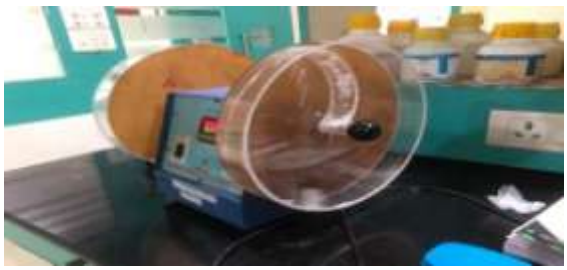

Figure No.2: Friability studies for Polyherbal Lozenges

Figure No.3: Digital pH Meter

Hardness

This indicated the ability of a lozenges to with stand mechanical shocks while handling. The hardness of the lozenges was determined by using hardness tester it is expressed in kg/cm^2. 3 lozenges were randomly picked and hardness was determined [13-14].

Figure No.4: Hardness Test for Polyherbal Lozenge

Figure No. 5: Polyherbal Lozenges

RESULTS AND DISCUSSION

The primary goal of this study was to formulate and evaluate polyherbal lozenges contain liquorice, ginger, cinnamon, cardamom, jaggary, sugar and clove oil for patients suffering from sore throat. The determination in appearance, weight, thickness, hardness, friability and pH were analyzed.

Organoleptic Evaluation

Table No.3: Macroscopic Evaluation

S.No	Parameter	Observation
1	Colour	Brown
2	Odour	Pleasant
3	Taste	Sweet
4	Texture	Smooth

Physicochemical Evaluation

Table No. 4: Physicochemical Evaluation

SI.No	Parameter	Observation
1	Disintegration Time	10 min 4 sec
2	Friability	0.52%
3	Hardness	8.9 Kg/cm
4	pH	9.0

Table No. 5: Feedback Form

S.No	Different Criteria	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1	Colour acceptability of lozenges					
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 sore throat/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[]* *4. Price [ ]* *Specify any other*					

Directions: Please indicate your level of agreement or disagreement and score (1-5) against each of these statements regarding "herbal lozenges". Place a "X" mark in the box of your answer [15].

DISCUSSION

Lozenges are used to treat the symptoms like sore throat and congestion of the throat which are common in cold and flu. The formulated lozenges include polyherbal like

Liquorice [*Glycyrrhiza glabra*]: Liquorice is a potent ayurvedic plant that enhances the respiratory system. The plant has manifold curative properties and is an ultimate remedial measure for a lot of health abnormalities including lung, liver, and circulatory diseases. Liquorice root is promoted as a dietary supplement for conditions such as digestive problems, menopausal symptoms, cough, and bacterial and viral infections.

Cinnamon [*Cinnamon cassia*]: Cinnamon is a spice obtained from the inner bark of Cinnamomum. It enhances the antimicrobial, antioxidant, anti-inflammatory properties. Cinnamon is mainly as an aromatic condiment and flavouring additive in a wide variety of cuisines, sweet and savoury dishes etc.

Cardamom [*Elettaria cardamomum*]: Cardamom is a potent ayurvedic plant. It contains anti-inflammatory and antioxidant properties. Also helps in digestion problems including heartburn, intestinal spasms, irritable bowel syndrome, intestinal gas, constipation, liver and gallbladder complaints, and loss of appetite and also used as a flavouring agent.

Ginger [*Zingiber officinale*]: Gingeris a potent ayurvedic plant. It contains antioxidant and anticancer properties. It also helps to treat numerous ailments, such as colds, nausea, arthritis, migraines, and hypertension. It is also used as a flavouring agent and improves digestion. *Zingiber officinale* is rich in zinc compounds.

Jaggery [*Saccharum officinarum*]: Jaggery contains antioxidant and anticarcinogenic properties. It is also known as a medicinal sugar. It aids in digestion and also detoxes the liver and blood. Used to treat lung and bronchial infections, and relieve constipation.

Cloveoil [E*ugenia caryophyllus*]: it contains antioxidant and analgesic properties. It aids in digestion and also acts as a dental analgesic. Used as a stimulant and also used as a flavouring agent [16-22].

Polyherbal lozenges have been developed with 5 different herbs which are envisioned for cough and sore throat. The various measure taken for the qualitative, quantitative, and physical parameters of the finished product is in compliance with the standard mentioned in GMP guidelines and requirements simultaneously supporting the impression of the polyherbal lozenges can compete with the standard lozenges available in the market. The herbal lozenges were designed and developed after extensive study of herbs, formulation dosage optimization, manufacturing techniques of lozenges and evaluation of qualitative, quantitative by precise and modern methods for assessment.

CONCLUSION

The present study was an attempt to formulate and evaluate polyherbal lozenges for sore throat. Based on the extensive review of the literature, five herbs were selected for the formulation and evaluation of polyherbal lozenges for sore throat. The polyherbal lozenges contain historically used ingredients such as liquorice, cinnamon, cardamom, ginger, jaggery, sugar, and clove oil The polyherbal lozenges were developed by a systemic and thorough study of all the herbs which are included in the formula. The effectiveness has been analyzed by a survey through a questionnaire. The present research work was successfully concluded by taking feedback and responses from volunteers which include adults of either sex. From the survey it was found that the polyherbal lozenge of hard type was effective in cough and for sore throat conditions and with an acceptable taste. The study carried out has endorsed the quality and effectiveness of the polyherbal lozenges. This study reveals that lozenges are a suitable dosage form for the symptomatic relief of sore throat, cold, and, flu. Hence the lozenges pass all the parameters and were found to be more effective in the treatment of sore throat. Hence this formation can be recommended for patients having a sore throat, cold and flu symptoms.

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