

Formulation and Evaluation of Polyherbal Cough Lozenges

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ABSTRACT

One of the most popular oral solid dose forms is lozenges. They slowly disintegrated in the mouth to lubricate and calm the inflamed throat tissues. They are the simplest and most natural method of drug administration. Common respiratory tract infections like the common cold and flu typically cause symptoms like head and body aches, fever, tiredness, runny nose, congestion, and cough. The primary goal of the study is to create and assess a polyherbal lozenge cure for cold, sore throat, and cough suppression. The polyherbal extract-based lozenge contains historically used ingredients such as prickly pear fruit, Guduchi, mint tulsi, ginger, and cinnamon as well as other herbs. Both soft herbal lozenges and hard lozenges made of polyherbal components were manufactured using the fresh leaf juices of each ingredient. The current research project was successfully completed by gathering feedback and responses from 100 volunteers, including both children and adults of either sex. It was discovered from the survey that both soft and hard polyherbal lozenges were effective in treating cough and sore throat conditions and had a tolerable taste.² From the mentioned research, it was possible to create a polyherbal lozenge that contained both soft and hard herbal lozenges, and it was only an attempt to do so. These polyherbal lozenges can be a useful, affordable, and widely accessible treatment for minor throat infections because they contain mint, tulsi, and guduchi leaves. Both the soft and hard polyherbal lozenges' physicochemical parameters—such as weight variation, thickness, hardness, moisture content, hardness friability, and disintegration diameter—were assessed, and the results showed that they all fell within the monograph standard that is outlined in GMP Guidelines

Keyword: Polyherbal lozenges, Prickly pear fruit, Guduchi, Mint tulsi, Crystal menthol.

1. INTRODUCTION :-

There are a number of lozenges of this type on the market, but herbal lozenges are usually made with natural ingredients such as eucalyptus, chamomile, fruit extracts and honey. 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.^[25] Throat lozenges include cough lozenges, trochees, cashews or cough drops, which are small medicated lozenges designed to dissolve slowly in the mouth to temporarily stop a cough, lubricate and soothe irritated throat tissues such as cold and flu. Oral administration of drugs is the preferred route of administration for a wide variety of drugs, with tablets being the most common dosage form. Solid dosage forms are popular for their ease of administration, precise dosing, self-medication, pain avoidance, and most importantly, patient compliance. At least 90% of drugs may be administered by the oral route. Lozenges are used for patients who have difficulty swallowing solid oral medicines, for administering a fixed amount of medicine in the oral cavity, or for medicines that need to be released slowly to coat the pharyngeal tissue increase.¹



Fig No 1- Digramatic representation of lozenges.

Herbal preparations:- There are many forms in which herbs can be administered, the most common of which is a liquid consumed as an herbal tea or a (possibly diluted) plant extract. Herbal teas, or tisanes, are the resultant liquid of extracting herbs into water, though they are made in a few different ways.

- *Infusions are hot water extracts of herbs, such as chamomile or mint, through steeping.*
- *Decoctions are the long-term boiled extracts, usually of harder substances like roots or bark.*
- *Maceration is the cold infusion of plants with high mucilage content, such as sage or thyme. To make macerates, plants are chopped and added to cold water. They are then left to stand for 7 to 12 hours (depending on herb used). For most macerates, 10 hours is used. Tinctures are alcoholic extracts of herbs, which are generally stronger than herbal teas.*



- *Tinctures are usually obtained by combining pure ethanol (or a mixture of pure ethanol with water) with the herb. A completed tincture has an ethanol percentage of at least 25% (sometimes up to 90%). Non-alcoholic tinctures can be made with glycerin but it is believed to be less absorbed by the body than alcohol-based tinctures and has a shorter shelf life. Herbal wine and elixirs are alcoholic extract of herbs, usually with an ethanol percentage of 12–38%.*
- *Extracts include liquid extracts, dry extracts, and nebulizes. Liquid extracts are liquids with a lower ethanol percentage than tinctures. They are usually made by vacuum distilling tinctures. Dry extracts are extracts of plant material that are evaporated into a dry mass. They can then be further refined to a capsule or tablet. The exact composition of an herbal product is influenced by the method of extraction.*

- A tea will be rich in polar components because water is a polar solvent. Oil on the other hand is a non-polar solvent and it will absorb non-polar compounds. Alcohol lies somewhere in between. Many herbs are applied topically to the skin in a variety of forms.
- Essential oil extracts can be applied to the skin, usually diluted in a carrier oil. Many essential oils can burn the skin or are simply too high dose used straight; diluting them in olive oil or another food grade oil such as almond oil can allow these to be used safely as a topical. Salves, oils, balms, creams and lotions are other forms of topical delivery mechanisms. Most topical applications are oil extractions of herbs.
- Taking a food grade oil and soaking herbs in it for anywhere from weeks to months allows certain phytochemicals to be extracted into the oil. This oil can then be made into salves, creams, lotions, or simply used as an oil for topical application.
- Many massage oils, antibacterial salves, and wound healing compounds are made this way. Inhalation, as in aromatherapy, can be used as a treatment.

IDEAL PROPERTIES OF LOZENGES[2]

- Is a solid preparation consisting of sugar and gum, the latter giving strength and cohesiveness to the lozenge.
- Facilitating slow release of the medicament.
- It is used to medicate the mouth and throat for the slow administration in digestion or cough remedies.
- It is intended to dissolve slowly in the mouth to temporarily suppress the cough and lubricate and soothe irritated tissues of the throat.
- Some have medications that help fight colds, and most have anesthetic to help ease the pain.
- Lozenges also contain menthol or eucalyptus, which can help cool and soothe the throat.

TYPES OF LOZENGES

There are three basic types of lozenges:

- **Hard**
 - **Soft**
 - **Chewable**
- **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.5
 - **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 molded cavities.
 - **Chewable lozenges:**- Chewable are typically based on glycerinated gelatin; a base of glycerin, gelatin, and water. This base can be mixed with drug, acacia, and suitable flavoring and sweetening agents.

SHAPES OF LOZENGES[19]

- Flat
- Circular
- Bi convex
- Cylindrical
- Octagonal

ADVANTAGE OF LOZENGES[4][13]

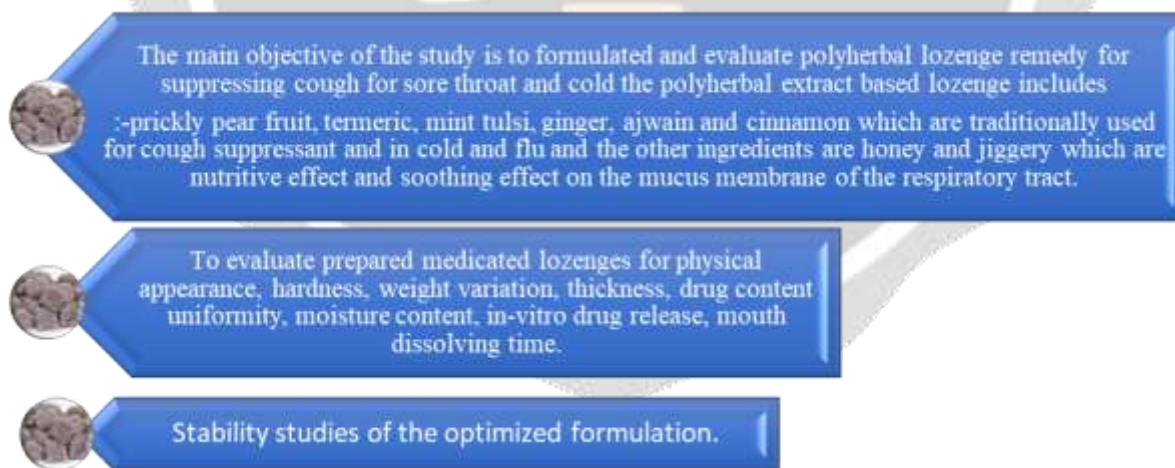
- 1) It is easy to administer to both pediatric and geriatric patients.

- 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) *It can be prepared with minimal equipment.*
- 5) *Taste of the drugs can be masked by sweeteners and flavours used in the formulation.*
- 6) *Increase the contact time of drug.*
- 7) *Prolong drug action.*
- 8) *Do not require water intake form administration.*
- 9) *It can increase in bioavailability.*
- 10) *It can reduce dosing frequency.*
- 11) *It can reduce gastric irritation.*
- 12) *Avoid first pass metabolism of drugs.*
- 13) *Lozenges can be withdrawn if dose is not needed.*
- 14) *Can be given to those patients who have difficulty in swallowing.*
- 15) *Do not require water intake for administration.*
- 16) *Technique is non invasive, as is the case with parenteral.*
- 17) *It extends the time of drug in the oral cavity to elicit a specific effect.*

DISADVANTAGE OF LOZENGES[20][24]

- Heat stable drugs are suitable.*
- Children having above 6 years of age can use lozenges safely.*
- Drugs having minimum bitter taste are suitable.*
- Hard candy lozenges the high temperature required for their preparation.*
- Hard lozenges become grainy.*
- Possible draining of drug into the stomach.*
- The non ubiquitous distribution of drug within saliva for local therapy.*
- Accidental swallowing of entire dosage form.*

OBJECTIVES



HYPOTHESIS





- H1**:-It may use to medicate the mouth and throat for the slow administration in digestion or cough remedies.
- H2**:-Gives quick relief from sore throat, cough, and irritation.
- H3**:-Along with the soothing effect on the respiratory symptoms, its pleasant taste, zero side effects, and extremely low cost, are making it popular at an accelerated pace.
- H4**:-It can be used by both children & adults.
- H5**:-It is made purely with natural ingredients that have proven medicinal properties and does not have any chemical additives.






PLAN OF STUDY

- Collection of raw materials that is polyherbs that are to be involved in preparation they are Prickly pear fruit, guduchi, Mint tulsi, ginger, Jaggery and honey are added in required quantity. The mentioned plant powder were collected from the herbal store which is located in the premises of Samarth institute of pharmacy, Belhe, Pune. This study was performed to expedite a new formulation and evaluation of a polyherbal lozenges of both types hard and soft lozenges were developed to know their effectiveness against the minor throat problems.
- Preparation of polyherbal lozenge
- Fresh powder of plant leaf are extracted.
- Both soft and hard lozenges are formed in moulds.
- Evaluation of polyherbal lozenges Physical chemical properties such as diameter, weight variation, thickness, disintegration, hardness or determination of moisture content or friability or pH.

METHODOLOGY

- **FORMULA OF POLYHERBAL LOZENGES :-**

Sr No	COMMON NAME	BOTANICAL NAME	PLANT PART USED	ETHNOBOTANICAL USES
1	Prickly pear 	<i>Opuntia basilaris</i>	Fruit Powder	Antidiabetes, Improve haemoglobin, reduces inflammation, Anti-aging properties, protects gut.
2	Guduchi 	<i>Tinospora cordifolia</i>	Leaves	Anti-pyretic, Anti-spasmodic, Anti-diabetic, Anti-oxidant.
3	Mint Tulsi 	<i>Ocimum tenuiflorum</i>	Leaves	Antidepressant, Antianxiety, Antiasthmatic, Antifatigue, Antithyroid, Anthelmintic, etc.,
4	 Ginger	<i>Zingiber officinale</i>	Rhizome	Colds, nausea, arthritis, migraines, and hypertension.

5	 Honey	<i>Apis</i>	-	Anti-inflammatory, antibacterial, antimicrobial, treat burns topically, treat cold, cough and heal wound
6	 Jaggery	<i>Saccharum officinarum L</i>	-	Digestion, immunity booster, infection and beauty treatment, water retention. Etc.
7	 Sugar	<i>Saccharum officinarum L</i>	-	Glucose syrup is used to bind the mixture together and solidify the final product
8	 Cinnamon	<i>Cinnamomum zeylanicum</i>	Bark Powder	Anti-bacterial, May support gut health, Lower Blood sugar, Anti-Inflammatory.
9	 Crystal Menthol	<i>Mentha arvensis</i>	Natural menthol flakes	Use in Aromatherapy, Promote easier breathing, Relieve nasal congestion, soothe sore throats, coughs, headaches. Support immunity and stabilize the emotions.

QUALITY CONTROL OF LOZENGES

Evaluation of Polyherbal Lozenges[14][18]

1. Macroscopic 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.

2. Weight Variation:- 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.7 Calculation was done by using the following formula;

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

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

3. 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 $37 \pm 0.5^\circ\text{C}$. The lozenge of optimized batch disintegrated in 90 Seconds 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.

4. 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.8

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

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

6. 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 $100-120^\circ\text{C}$ for 3hrs. Cool to room temperature. Repeat until constant weight observed. Percentage friability is given by the equation.9

$$\% F = \frac{(\text{Initial Weight} - \text{Final weight})}{\text{Initial weight}} \times 100.$$

7. Determination of Thickness- The thickness of the tablets was determined by using vernier caliper. Five tablets were used. The average values were calculated.

$$\text{Average thickness} = \frac{\text{Total 5 lozenges thickness}}{5}$$

8. 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.

9. Swelling Index- Swelling rate is evaluated by using p.H6.4 phosphate buffer. The initial weight is determined. Then placed in petri dish coating phosphate buffer placed in incubator at $37 \pm 1^\circ\text{C}$ a d tablet is removed at different time interval (0,1,2, 3.etc) Blotted with filter paper and reweight.

$$\text{Swelling index} = \frac{\text{Initial Weight} - \text{Final Weight}}{\text{Initial Weight}}$$

10. 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 diameters should not exceed $\pm 5\%$ for tablets with diameter of less than 12.5 and $\pm 3\%$ for diameter of 12.55mm or more.

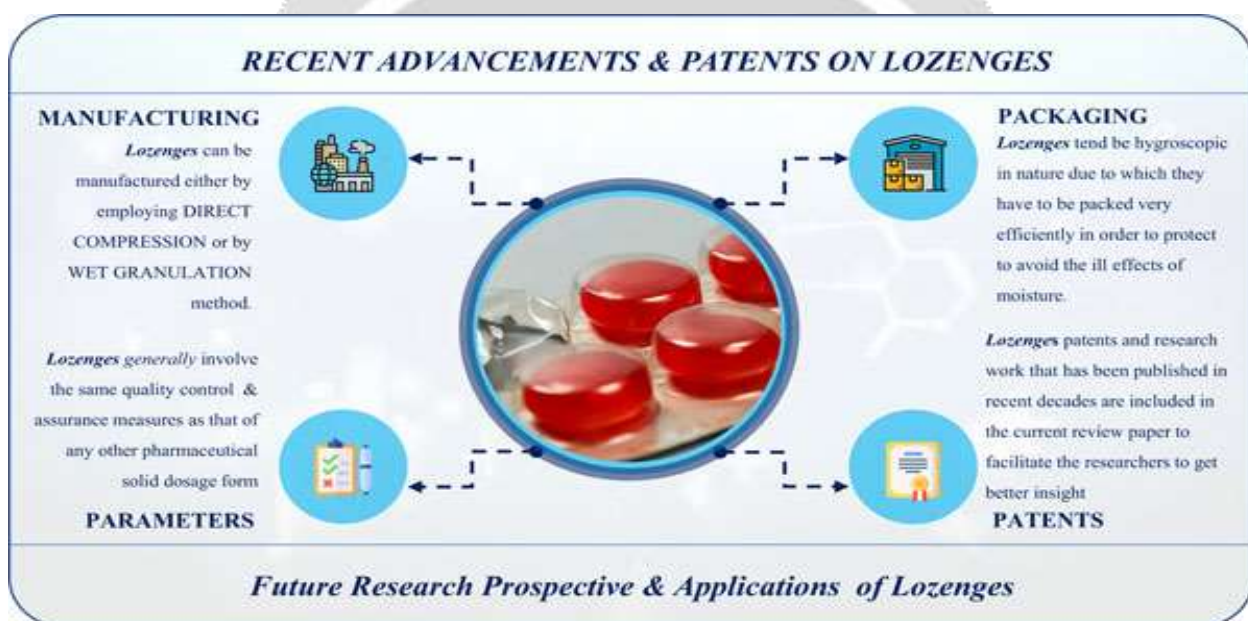
11. Microbial Check on Lozenges- In this microbial check, the presence of any bacterial, mold or spore contamination is checked in raw materials, finished products, machinery, cooling tunnels, environmental conditions and storage drums. Laboratory microbial testing should include the following counts: total plate, total coliform, yeast and mold, E.coli, Staphylococcus, Salmonella.[19]

12. Stability Testing for Lozenges- Lozenges are subjected to stability testing under following conditions: 2 months at 60 °C, 3-6 months at 45°C, 9-12 months at 37 °C, 36-60 months at 25 ° C. Lozenges in their final packs are subjected to the following conditions for stability testing: 25 °C at 80% relative humidity (RH) for 6-12 months, 3 °C at 80% RH for 3 months, and 25 ° C at 70% RH for 6-12 months.[19]

PACKAGING OF LOZENGES

The lozenges are hygroscopic in nature, a complex and multiple packaging is adopted. The individual unit is wrapped in polymeric moisture barrier material which are then placed in tight or moisture resistant glass, polyvinyl chloride or metal container that is over wrapped by aluminum foil or cellophane membrane^[3]

RECENT ADVANCEMENTS & PATENTS ON LOZENGES



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CONCLUSION

The polyherbal lozenges were developed by systematic and thorough study of all the herbs which are included in the formula followed by optimization of the polyherbal formulation dosage and evaluation of qualitative and quantitative parameters which were performed by précised advanced analytical instruments.

The therapeutic effectiveness of both the formulation were done by conducting a survey through questionnaire and feedback from the patients. This study reveals that the polyherbal lozenges of both formula 1 soft and formula 2 hard are suitable dosage form for symptomatic relief of cough sore throat and cold which can be used for geriatrics and for pediatric purpose hence polyherbal lozenges passes all the parameters and 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 for the first time and it can be recommended for minor upper respiratory infections and in future further development of the formulation can be done.

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