FORMULATION AND EVALUATION OF POLYHERBAL LOZENGES

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ABSTRACT

The main objective of the study is to formulated and evaluate polyherbal lozenge remedy for suppressing cough for sore throat and cold the polyherbal extract based lozenge includes vasaka [Adhatoda vasica], ajwain [Trachyspermum ammi], mint tulsi [Ocimum tenuiflorum], ginger which are traditionally used for cough suppressant and in cold and flu and the other ingredients are honey and jaggery which are nutritive effect and soothing effect on the mucus membrane of the respiratory tract. The fresh leaf juices of all the ingredients were used for the preparation of polyherbal lozenges of both soft herbal lozenge and hard lozenge were prepared. Both the polyherbal lozenges were evaluated for their physicochemical parameters such as weight variation, thickness, hardness, moisture content, hardness friability, disintegration diameter were identified and there results were revealed as all the physicochemical parameter for both soft and hard lozenges were within the monograph standard which are mentioned in GMP Guidelines. The present research work was successfully concluded by taking feedback and responses from a hundred volunteers which includes both children and adults of either sex from the survey it was found that the polyherbal lozenges of both the types of soft and hard were effective in cough and sore throat conditions and with a acceptable taste. From the above investigations it was expertise to develop a polyherbal lozenge of both soft and hard herbal lozenges and it was just an attempt to make a polyherbal lozenges in which the leaves of mint tulsi and ajwain were incorporated for the first time and these polyherbal lozenges can be an effective, economical and easily available remedy for minor throat infections.
KEYWORDS: Polyherbal lozenges, Vasaka, Ajwain, Mint tulsi, physio chemical.

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.

In ancient Egypt, the Ebers papyrus dates from about 1550 BC, and covers more than 700 compounds, mainly of plant origin. The earliest known Greek herbals came from Theophrastus of Eresos who, in the 4th century BC, wrote in Greek Historia Plantarum, from Diocles of Carystus who wrote during the 3rd century BC, and from Krateuas who wrote in the 1st century BC. Only a few fragments of these works have survived intact, but from what remains, scholars noted overlap with the Egyptian herbals. Seeds likely used for herbalism were found in archaeological sites of Bronze Age China dating from the Shang dynasty (1600–1046 BC). Over a hundred of the 224 compounds mentioned in the Huangdi Neijing, an early Chinese medical text, are herbs. Herbs were also commonly used in the traditional medicine of ancient India, where the principal treatment for diseases was diet. De Materia Medica, originally written in G.

Herbal lozenges are similar in size, and sometimes in flavor, to hard candies but are intended to ease sore throats and help people recover from colds, influenza, and similar illnesses. There are a number of such lozenges on the market, but herbal lozenges are usually made with primarily natural ingredients such as eucalyptus, 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, herbal lozenge.

**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.[16]

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.

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.

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 sweeting agents.[20]

ADVANTAGE OF LOZENGES
1. Ease of pediatric and geriatric patients.
2. Local and systematic effect
3. Increase contact time of drug
4. Prolong drug action
5. Cost of production is less.

DISADVANTAGE OF LOZENGES
1) Possible draining of drug into the stomach
2) Accidental swallowing of entire dosage form
3) Non-ubiquitous distribution of drug in the saliva for local administration.

**IDEAL PROPERTIES OF LOZENGE**

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. Some have medications that help fight colds, and most have anesthetic to help ease the pain.
6. Lozenges also contain menthol or eucalyptus, which can help cool and soothe the throat.

**AIM AND OBJECTIVE**

The main objective of the study is to formulated and evaluate polyherbal lozenge remedy for suppressing cough for sore throat and cold the polyherbal extract based lozenge includes Vasaka [Adhatoda vasica], Ajwain [Trachyspermum ammi], Mint tulsi [Ocimum tenuiflorum], ginger which are traditionally used for cough suppressant and in cold and flu and the other ingredients are honey and jiggery which are nutritive effect and soothing effect on the mucus membrane of the respiratory tract.

**PLAN OF STUDY**

1) **Collection and authentication** of raw materials that is polyherbs that are to be involved in preparation they are Vasaka, Ajwain, Mint tulsi, ginger, Jaggery and honey are added in required quantity. The mentioned plant leaves were collected from the herbal garden which is located in the premises of Shadan college of pharmacy, Peerancheru, Hyderabad. These plants were authenticated by Telangana medicinal plant board Tilak Nagar, Abids, Hyderabad. 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 there effectiveness against the minor throat problems.

2) **Preparation of polyherbal lozenge**

0 Fresh juice of plant leaf are extracted.
Both soft and hard lozenges are formed in moulds.

3) Evaluation of polyherbal lozenges
Physic chemical properties such as diameter, weight variation, thickness, disintegration, hardness, determination of moisture content, friability, pH.

MATERIALS AND METHODS
Collection and Authentication: The raw materials which are used in the polyherbal lozenge preparation turis, ginger, Jaggery and honey are added in required quantity. are Vasaka, Ajwain, Mint. The mentioned plant leaf were collected from the herbal garden which is located in the premises of Shadan college of pharmacy, Peerancheru, Hyderabad and these plants were authenticate by Telangana Medicinal Plant B Tilak Nagar, Abids, Hyderabad. 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 there effectiveness against the minor throat problems.

Table 1: List of Polyherbal Ingredients used in the Polyherbal Ghrita.

<table>
<thead>
<tr>
<th>S.no</th>
<th>COMMON NAME</th>
<th>BOTANICAL NAME</th>
<th>PLANT PART USED</th>
<th>ETHNOBOTANICAL USES</th>
<th>QUANTITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mint Tulsi</td>
<td>Ocimum tenuiflorum</td>
<td>Leaves</td>
<td>Antidepressant, Antianxiety, Antiasthmatic, Antifatigue, Antithyroid, Anthelmintic, etc.</td>
<td>4g</td>
</tr>
<tr>
<td>2</td>
<td>Vasaka</td>
<td>Adhatoda vasica</td>
<td>Leaves</td>
<td>Treating bronchitis, asthma and dental ailments. It relieves cough, cold and breathlessness.</td>
<td>30g</td>
</tr>
<tr>
<td>3</td>
<td>Ajwain</td>
<td>Trachyspermum ammi</td>
<td>Leaves</td>
<td>Antineoplastic, Wound Healing, Diuretic Activity, Respiratory Disorders, Analgesic antiplatelet Activity, Antimicrobial Activity, Antifungal Activity, Skin Care, Antidiabetic Activity, Anxiolytics</td>
<td>30g</td>
</tr>
<tr>
<td>4</td>
<td>Ginger</td>
<td>Zingiber officinale</td>
<td>Rhizome</td>
<td>Colds, nausea, arthritis, migraines, and hypertension.</td>
<td>40g</td>
</tr>
</tbody>
</table>
Honey 
Apis
- 
Anti-inflammatory, antibacterial, antimicrobial, treat burns topically, treat cold, coughul and heal wound
30g

Jaggery
Saccharum officinarum L.
- 
Digestion, immunity booster, infection and beauty treatment, water retention. Etc.,
150g

**METHOD OF PREPARATION OF POLYHERBAL FRESH JUICE[^3,^5]**

1) The leaves of Vasaka ajwain and mint tulsi are taken in required quantity as mentioned in formula.

2) They were rinsed thoroughly with tap water.

3) All the three herbs were grinded by adding 100 ml of water and the juice is extracted with a mesh.

4) Marc and menstruum were separated.

5) Ginger juice was also extracted and added to the formulation.

**FORMULA OF POLYHERBAL LOZENGES**

Table 2: Raw materials to be included in the Polyherbal soft lozenges composition.

<table>
<thead>
<tr>
<th>S.NO</th>
<th>INGREDIENTS</th>
<th>QUANTITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>VASAKA</td>
<td>30 g</td>
</tr>
<tr>
<td>2.</td>
<td>MINT TULSI</td>
<td>4g</td>
</tr>
<tr>
<td>3.</td>
<td>AJWAIN</td>
<td>30g</td>
</tr>
<tr>
<td>4.</td>
<td>GINGER</td>
<td>40g</td>
</tr>
<tr>
<td>5.</td>
<td>HONEY</td>
<td>30ml</td>
</tr>
<tr>
<td>6.</td>
<td>JAGGERY</td>
<td>150g</td>
</tr>
<tr>
<td>7.</td>
<td>SUGAR</td>
<td>42gm</td>
</tr>
<tr>
<td></td>
<td>TOTAL</td>
<td>300g</td>
</tr>
</tbody>
</table>
Table 3: Raw materials to be included in the Polyherbal hard lozenges composition.

<table>
<thead>
<tr>
<th>S.NO</th>
<th>INGREDIENTS</th>
<th>QUANTITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>VASAKA</td>
<td>30 g</td>
</tr>
<tr>
<td>2</td>
<td>MINT TULSI</td>
<td>4 g</td>
</tr>
<tr>
<td>3</td>
<td>AJWAIN</td>
<td>30 g</td>
</tr>
<tr>
<td>4</td>
<td>GINGER</td>
<td>40 g</td>
</tr>
<tr>
<td>5</td>
<td>HONEY</td>
<td>30 ml</td>
</tr>
<tr>
<td>6</td>
<td>JAGGERY</td>
<td>150 g</td>
</tr>
<tr>
<td>7</td>
<td>SUGAR</td>
<td>42 g</td>
</tr>
<tr>
<td>8</td>
<td>CORN SYRUP</td>
<td>16 g</td>
</tr>
<tr>
<td>9</td>
<td>CRYSTAL MENTHOL</td>
<td>2-3 g</td>
</tr>
<tr>
<td></td>
<td>TOTAL</td>
<td>395 g</td>
</tr>
</tbody>
</table>

Flowchart Illustrates The PROCEDURE OF PREPARING LOZENGES\(^3\)[5]

- The following flowchart illustrates the start to end steps involved in making of polyherbal lozenges;

1. Measure the raw materials
   
2. Rinse the raw material prior grinding (vasaka+Mint tulsi+ajwain+ 100ml water and ginger)
   
3. After grinding extract the juice with help of mesh.
   
4. Marc and menstrum is obtained
   
5. Menstrum includes ginger juice and leafs extract is mixed thoroughly.
   
6. Liquify Jaggery at low flame
   
7. Menstrum is added to the vessel containing jaggery
   
8. Contineously stirr at low flame until the desire density is
THE PROCESS OF PREPARING POLYHERBAL LOZENGE[5][12][3]

1) Weighing and measuring the raw materials: Measure and weigh the lozenge raw materials: clove,
2) ginger and licorice, and lozenge base materials:sugar, molasses and concentrated sea buckthorn juice.

1. Weighing and measuring the raw materials: Measure and weigh the lozenge raw materials in above given values: vasaka, ajwain, mint tulsi and ginger and lozenge base materials: Home made jaggery, honey and sugar.
2. **Grinding and shifting:** Vasaka, Ajwain, Mint tulsi is rinse thoroughly prior grinding (with mortar and pestle) collectively with frequent addition of water (100 ml) to make juice of the formulation. Ginger skin is pilled off and crush to extract its juice separately. Once done menstrum is extracted in the beaker with help of mesh. And marc is discarded.

3. **Preparing the base:** To prepare the base steel cooking vessel was selected, in which crushed jaggery (150g) is subjected to heat at low flame on induction in order to melt it.

4. **Adding he raw medicinal ingredients:** Ginger and leaf extract is mixed together with finely powdered sugar before adding to the vessel containing jiggery while giving continuously gentle stir to it.

5. **Consistency:** Once desire consistency is obtain, the preparation is cooled under the fan for few minutes before adding 30ml of honey to it.

6. **Measuring and pouring in to the mould:** For formulation-1, 1 ml of preparation is poured into oval/semi oval shape mould with the help of pipette. Where as for formulation-2, the preparation is made into semisolid consistency and mounded it to tablet forms manually.

7. **Cooling and refrigerating:** Cool lozenges for 20-30 minutes in room temperature of 15-200C before storing into refrigerator for hard formulation.

8. **Storage and packaging:** The preparation in stored in glass container coated with fine sugar, at room temperature, away from moisture.
Figure. 3: A. Formulation, B. cooling the preparation. C. Adding honey.

Fig no. 4: Glass container containing Soft lozenges.

**COMPOSITION:**
- Vasaaka .......... 30gm
- Mint Tulsi .......... 4gm
- Ajwain ............ 30gm
- Ginger ............ 40gm
- Honey ............ 30ml
- Jaggery .......... 150gm
- Sugar .......... 92gm
- Corn syrup ........ 16gm
- Crystal menthol ...... 2-3gm

**Hard lozenges**

**Direction to use:**
One lozenge to be dissolved slowly in the mouth every 2-3 hours up to a maximum of 12 lozenges in 24 hours. Only for Adults and Children (over 6 years)

**Storage condition:** Stored away from heat and out of reach of children.

**Mfg:**
**Exp date:**
**Batch no:**
**Lic No:**

Fig no. 5: Label for Formula: 1 Hard Lozenge.

**COMPOSITION:**
- Vasaaka .......... 30gm
- Mint Tulsi .......... 4gm
- Ajwain ............ 30gm
- Ginger ............ 40gm
- Honey ............ 30ml
- Jaggery .......... 150gm
- Sugar .......... 50gm

**Soft lozenges**

**Direction to use:**
One lozenge to be dissolved slowly in the mouth every 2-3 hours up to a maximum of 12 lozenges in 24 hours. Only for Adults and Children (over 6 years)

**Storage condition:** Stored away from heat and out of reach of children.

**Mfg:**
**Exp date:**
**Batch no:**
**Lic No:**

Fig. no. 6: Label for Formula: 2 Soft Lozenge.
EVALUATION OF POLYHERBAL LOZENGES\textsuperscript{[13][9]}

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. Calculation was done by using the following formula.

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

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

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 ± 0.5°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 upon type of lozenges.

4. Friability
The friability of tablets was determined using Roche Friabulator. It is expressed in percentage (%). Ten tablets were initially weighed and transferred into friabulator. The friabulator 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:

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

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°C for 3hrs.Cool to room temperature. Repeat until constant weight observed. Percentage friability is given by the equation.

\[
\% F = \frac{\text{Initial Weight} - \text{Final weight}}{\text{Initial weight}} \times 100.
\]

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

\[
\text{Average thickness} = \frac{\text{Total 5 lozenges thickness}}{5} \times 100
\]

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.

![Testing hardness with Monsanto tester.](image)

Fig no. 8: testing hardness with Monsanto tester.

9. Swelling Index

Swelling rate is evaluated by using pH 6.4 phosphate buffer. The initial weight is determined. Then placed in petri dish coating phosphate buffer placed in incubator at 37+/− 1°C tablet is removed at different time interval 0, 1, 2, 3, etc. Blotted with filter paper and re-weighed.

\[
\text{Swelling index} = \frac{\text{Initial Weight} - \text{Final Weight}}{\text{Initial Weight}} \times 100
\]

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 diameter should not exceed ± 5% for tablets with diameter of less than 12.5 and ± 3% for diameter of 12.55 mm or more.

RESULTS

1) Collection And Authentication

The phytoconstituents properties of leaves of vasaka, tulsi mint, ajwain, were studied and collected. The mentioned plant leaf were collected from the herbal garden which is located in the premises of Shadan college of pharmacy, Peerancheru, Hyderabad and these plants were authenticated by Telangana medicinal plant board Tilak Nagar, Abids Hyderabad.
2) Experiment
Soft and hard lozenge lozenges were prepared according to the given parameter.

3) Organoleptic Evaluation

Table 4: Macroscopic Evaluation.

<table>
<thead>
<tr>
<th>S.NO</th>
<th>PARAMETER</th>
<th>OBSERVATION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td><strong>Soft lozenges</strong></td>
</tr>
<tr>
<td>1</td>
<td>Colour</td>
<td>Brown</td>
</tr>
<tr>
<td>2</td>
<td>Odour</td>
<td>Pleasant</td>
</tr>
<tr>
<td>3</td>
<td>Taste</td>
<td>Sweet</td>
</tr>
<tr>
<td>4</td>
<td>Texture</td>
<td>Smooth</td>
</tr>
<tr>
<td>5</td>
<td>Shape</td>
<td>Round</td>
</tr>
</tbody>
</table>

A. Physico Chemical Evaluation

1) Weight variation

Table 5: Weight variation.

<table>
<thead>
<tr>
<th>FORMULATION</th>
<th>Average weight</th>
<th>% Variation observed</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1-HARD LOZENGES</td>
<td>1.29</td>
<td>±0.20</td>
</tr>
<tr>
<td>F2-SOFT LOZENGES</td>
<td>1.27</td>
<td>±0.14</td>
</tr>
</tbody>
</table>

GRAPH: 01: Weight Variation.

- **Average Weight**
- **Limit Of Variation**
- **% Variation Observe**
2) Disintegration time

Table 6: Disintegration time.

<table>
<thead>
<tr>
<th>DOSAGE FORM</th>
<th>DISINTEGRATION TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1-HARD LOZENGES</td>
<td>1.5 min</td>
</tr>
<tr>
<td>F2-SOFT LOZENGES</td>
<td>1 min</td>
</tr>
</tbody>
</table>

Graph: 02 Disintegration Time.

3) Friability

Table 7: Friability.

<table>
<thead>
<tr>
<th>S.NO.</th>
<th>DOSAGE FORM</th>
<th>FRIABILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>F1-HARD LOZENGES</td>
<td>0.9 %</td>
</tr>
<tr>
<td>2.</td>
<td>F2-SOFT LOZENGES</td>
<td>0.6%</td>
</tr>
</tbody>
</table>

Graph 03: Friability.

4) Measurement of pH

Table 8: Measurement of pH.

<table>
<thead>
<tr>
<th>S. No</th>
<th>DOSAGE FORM</th>
<th>pH</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>F1-HARD LOZENGES</td>
<td>8.0 %</td>
</tr>
<tr>
<td>2.</td>
<td>F2-SOFT LOZENGES</td>
<td>8.45 %</td>
</tr>
</tbody>
</table>
5) Moisture content

Table 9: Moisture content.

<table>
<thead>
<tr>
<th>S. No</th>
<th>DOSAGE FORM</th>
<th>MOISTURE CONTENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>F1-HARD LOZENGES</td>
<td>0.4 %</td>
</tr>
<tr>
<td>2.</td>
<td>F2-SOFT LOZENGES</td>
<td>0.5 %</td>
</tr>
</tbody>
</table>

Graph 04: pH of Lozenges.

6) Determination of Thickness

Table 10: Determination of Thickness.

<table>
<thead>
<tr>
<th>S.NO.</th>
<th>DOSAGE FORM</th>
<th>THICKNESS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>F1-HARD LOZENGES</td>
<td>195.6 mm</td>
</tr>
<tr>
<td>2.</td>
<td>F2-SOFT LOZENGES</td>
<td>212.8 mm</td>
</tr>
</tbody>
</table>

Graph 05: Moisture Content.
7) Determination of hardness

Table 11: Determination of hardness.

<table>
<thead>
<tr>
<th>S.NO.</th>
<th>DOSAGE FORM</th>
<th>Hardness</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>F1-HARD LOZENGES</td>
<td>9.2 Kg/cm</td>
</tr>
<tr>
<td>2.</td>
<td>F2-SOFT LOZENGES</td>
<td>7.8 Kg/cm</td>
</tr>
</tbody>
</table>

8) Diameter

Table 12: Diameter.

<table>
<thead>
<tr>
<th>S.NO.</th>
<th>DOSAGE FORM</th>
<th>DIAMETER</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>F1-HARD LOZENGES</td>
<td>2.35mm</td>
</tr>
<tr>
<td>2.</td>
<td>F2-SOFT LOZENGES</td>
<td>2.30 mm</td>
</tr>
</tbody>
</table>
Table 13: Physicochemical Evaluation of Hard Lozenge.

<table>
<thead>
<tr>
<th>S.No</th>
<th>Weight Variation</th>
<th>Disintegration [min]</th>
<th>Friability [%]</th>
<th>pH</th>
<th>Moisture Content</th>
<th>Thickness [mm]</th>
<th>Hardness [Kg/cm]</th>
<th>Diameter [mm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>±0.20</td>
<td>8.10</td>
<td>0.9</td>
<td>80</td>
<td>0.4</td>
<td>195.6</td>
<td>9.2</td>
<td>2.35</td>
</tr>
<tr>
<td>2.</td>
<td>±0.19</td>
<td>8.90</td>
<td>0.8</td>
<td>8.2</td>
<td>0.5</td>
<td>192.3</td>
<td>10.1</td>
<td>2.34</td>
</tr>
<tr>
<td>3.</td>
<td>±0.21</td>
<td>7.90</td>
<td>0.10</td>
<td>8.3</td>
<td>0.3</td>
<td>187.3</td>
<td>11.3</td>
<td>2.36</td>
</tr>
<tr>
<td>4.</td>
<td>±0.23</td>
<td>8.30</td>
<td>0.6</td>
<td>8.1</td>
<td>0.5</td>
<td>190.6</td>
<td>9.1</td>
<td>2.33</td>
</tr>
<tr>
<td>5.</td>
<td>±0.28</td>
<td>7.90</td>
<td>0.7</td>
<td>8.4</td>
<td>0.2</td>
<td>194.6</td>
<td>8.9</td>
<td>2.35</td>
</tr>
</tbody>
</table>

Table 14: Physicochemical Evaluation of Soft Lozenge.

<table>
<thead>
<tr>
<th>S.No</th>
<th>Weight Variation</th>
<th>Disintegration [min]</th>
<th>Friability [%]</th>
<th>pH</th>
<th>Moisture Content</th>
<th>Thickness [mm]</th>
<th>Hardness [Kg/cm]</th>
<th>Diameter [mm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>±0.14</td>
<td>9.0</td>
<td>0.9</td>
<td>8.0</td>
<td>0.4</td>
<td>195.6</td>
<td>7.8</td>
<td>2.30</td>
</tr>
<tr>
<td>2.</td>
<td>±0.15</td>
<td>10.1</td>
<td>0.8</td>
<td>8.2</td>
<td>0.5</td>
<td>192.3</td>
<td>7.1</td>
<td>2.9</td>
</tr>
<tr>
<td>3.</td>
<td>±0.18</td>
<td>9.9</td>
<td>0.10</td>
<td>8.3</td>
<td>0.3</td>
<td>187.3</td>
<td>6.3</td>
<td>2.6</td>
</tr>
<tr>
<td>4.</td>
<td>±0.19</td>
<td>8.70</td>
<td>0.6</td>
<td>8.1</td>
<td>0.5</td>
<td>190.6</td>
<td>7.4</td>
<td>2.33</td>
</tr>
<tr>
<td>5.</td>
<td>±0.20</td>
<td>9.30</td>
<td>0.7</td>
<td>8.4</td>
<td>0.2</td>
<td>194.6</td>
<td>8.0</td>
<td>2.34</td>
</tr>
</tbody>
</table>

Table 15: Physicochemical evaluation parameters of Hard Lozenge and Soft Lozenge.

<table>
<thead>
<tr>
<th>Evaluation parameters</th>
<th>Hard lozenge</th>
<th>Soft lozenge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight variation</td>
<td>±0.20</td>
<td>±0.14</td>
</tr>
<tr>
<td>Disintegration time</td>
<td>1.5 min</td>
<td>1 min</td>
</tr>
<tr>
<td>Friability</td>
<td>0.9</td>
<td>0.6</td>
</tr>
<tr>
<td>Measurement of Ph.</td>
<td>8.0 %</td>
<td>8.45 %</td>
</tr>
<tr>
<td>Moisture content</td>
<td>0.4 %</td>
<td>0.5 %</td>
</tr>
<tr>
<td>Determination of Thickness</td>
<td>195.6mm</td>
<td>212.8</td>
</tr>
<tr>
<td>Determination of hardness</td>
<td>9.2Kg/cm</td>
<td>7.8 Kg/cm</td>
</tr>
<tr>
<td>Diameter</td>
<td>2.35 mm</td>
<td>2.30 mm</td>
</tr>
</tbody>
</table>
FEEDBACK FORM[11]  

<table>
<thead>
<tr>
<th>S.No</th>
<th>Different criteria</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Color acceptability of lozenge</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Taste and palatability - Too sweet - Too bitter - Acceptable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Dissolution in mouth is easy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Safety and sterility concern</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Duration of action is quick and satisfactory</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Would you like to recommend it to flu patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Did you find it better compared to other marketed drugs and dosage form.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Directions:** Please indicate your level of agreement or disagreement and score (1-5) against each of these statement regarding "herbal lozenge". Place a "X" mark in the box of your Answer.

![Pie Chart](chart.png)

PIE CHART REPRESENTING ACCEPTANCE CRITERIA FOR HARD LOZENGE
DISCUSSION

Lozenges are used to treat the symptoms like sore throat and congestion of throat which are the common in cold and flu. The developed lozenges includes polyherbs like.

Vasaka [Adhatoda vasica]: 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 like breathing trouble, cough, and cold, nasal congestion, sore throat, asthma, bronchitis, other upper respiratory tract infections, bleeding disorders, etc. which is antitussive.

Ajwain [Trachyspermum ammi]: Ajwain can provide relief from coughing as well as clear mucus from your nose, both of which make breathing easier. It may also help to widen the bronchial tubes, which can help those with asthma.

Mint tulsi [Ocimum tenuiflorum]: it 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. Tulsi is characterized by antioxidant, anti-inflammatory, anti-aging properties, etc. that provides the treatment of asthma, anxiety, bronchitis, flu, respiratory infections, high sugar and cholesterol level, etc.

Ginger [Zingiber officinale]: Zingiber officinale which belongs to the family Zingiberaceae. Z. officinalis is one of the natural remedies for swine flu prevention. Traditional medicine practitioners often used ginger to boost the body's immunity level, relief gastrointestinal
illness, cure cough and flu, anti-nausea, anti-inflammatory, and also aid digestion. The characteristic odor and flavor of the ginger root comes from the mixture of zingerone, shogaols and gingerols, and volatile oils. Ginger contains gingerol, a pungent ingredient of ginger volatile oil with Sulphur-containing compounds (allicin, allii, and ajoene), and enzymes (allinase, peroxidase, and myrosinase), which exhibited antibiotic properties.

In addition jaggery, honey flavors and their antitussive property works wonder for the formulation. Both the soft and hard polyherbal lozenges were evaluated for its quality and therapeutic efficacy by various organoleptic and physicochemical parameters and feed-back of people having symptoms of cold and flu were recorded. The developed formulations comply with all the standards mentioned in GMP and can be used safely without any side effects.

**CONCLUSION**

The present research work is performed on development and evaluation of an herbal medicine as the herbal medicine are safe and effective with negligible side effects. Our work is based on the polyherbs which are used to make a polyherbal lozenges. We have formulated both soft and hard polyherbal lozenges with three different herbs Vasaka, ajwain, mint tulsi in addition it also contains honey and jaggery. Both the polyherbal soft and hard lozenges which were given the name formula 1 and formula 2 were evaluated for the physiochemical qualitative and quantitative parameters and the finished products are in the standard limits which is mentioned in the GMP guidelines. And which can support and recommend to compete with the marketed lozenge.

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.
ACKNOWLEDGEMENT
The authors are grateful to Dr. Shaik Mohd Khasim the Director of Shadan College of Pharmacy, and Dr. R. Sridhar Babu, Principal of Shadan College Of Pharmacy, Peerancheeru, Hyderabad. For providing their valuable suggestions, infrastructure and facilities to carry out our research work.

REFERENCES