IJFANS INTERNATIONAL JOURNAL OF FOOD AND NUTRITIONAL SCIENCES
ISSN PRINT 2319 1775 Online 2320 7876
 UGC CARE Listed (Group -I) Journal Volume 11, Iss 3, 2022

FORMULATION AND EVALUATION OF HERBAL LOZENGES FOR MOUTH ULCERS

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ABSTRACT:
This study introduces the development and evaluation of herbal lozenges designed specifically for treating mouth ulcers, featuring Neem (*Azadirachta indica*) and Tulsi (*Ocimum sanctum* L) as key ingredients. Neem is well known for its diverse therapeutic compounds, providing strong anti-inflammatory, antimicrobial, and wound-healing properties. Tulsi, revered in traditional medicine for its anti-inflammatory and analgesic effects, complements Neem by enhancing its healing characteristics. The lozenges are formulated to dissolve slowly in the mouth, ensuring prolonged contact with ulcerated oral tissues to relieve pain and promote healing. The synergistic blend of Neem and Tulsi offers a promising natural approach to managing mouth ulcers, effectively addressing symptoms while supporting overall oral health and well-being.

Keywords: Mouth ulcer, Lozenges, Herbs, Medicinal Properties

INTRODUCTION

Mouth Ulcer: Mouth ulcers, also known as aphthous ulcers or canker sores, are small, painful lesions that form on the mucous membranes inside the mouth. These ulcers can cause discomfort while eating, drinking, and speaking, significantly affecting daily life. Factors such as stress, injury, or underlying health conditions can contribute to their development. Effective treatments are essential for managing symptoms and facilitating healing[1].

Types of Mouth Ulcers:

1. **Minor Aphthous Ulcers:**
   - Small, usually less than 1 cm in diameter.
   - Round or oval-shaped.
   - Typically heal within 1 to 2 weeks without scarring.
2. **Major Aphthous Ulcers:**
   - Larger than minor ulcers, often exceeding 1 cm in diameter.
   - Can have an irregular shape.
   - May take longer to heal, and scarring is possible[2].

ISSN PRINT 2319 1775 Online 2320 7876
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3. **Herpetiform Ulcers:**
    - Individual ulcers are usually 1 to 3 millimeters in diameter.
    - Small, round or oval-shaped.
    - Usually heal on their own within 1 to 2 weeks.

Causes of Mouth Ulcers:

1. **Mechanical Trauma:**
    - Accidental biting of the cheek, tongue, or lip.
    - Dental appliances, braces, or rough edges of teeth that cause irritation.
2. **Stress and Anxiety:**
    - Emotional stress and anxiety can weaken the immune system, increasing susceptibility to mouth ulcers.
3. **Nutritional Deficiencies:**
    - Insufficient intake of essential nutrients such as vitamin B12, iron, folic acid, and zinc can contribute to mouth ulcer formation.
4. **Food Sensitivities:**
    - Certain foods, especially acidic or spicy ones, may trigger mouth ulcers in sensitive individuals[3].
5. **Certain Medications:**
    - Side effects of medications like nonsteroidal anti-inflammatory drugs (NSAIDs), beta-blockers, and certain antibiotics can include mouth ulcers.
6. **Smoking and Tobacco Use:**
    - Smoking or using other tobacco products can irritate oral tissues and contribute to the development of mouth ulcers.

Symptoms of Mouth Ulcers:

1. **Pain:**
    - Mouth ulcers often cause pain or discomfort, particularly when eating, drinking, or brushing teeth[4].
2. **Difficulty Eating or Drinking:**
    - Due to the pain and sensitivity associated with mouth ulcers, individuals may find it uncomfortable or painful to eat or drink, especially when consuming acidic or spicy foods.
3. **Irritation or Burning Sensation:**
    - Some people may experience a burning or tingling sensation in the area surrounding the ulcer.
4. **Swelling:**
    - The tissues around the ulcer may appear slightly swollen or inflamed.
5. **Red or White Lesion:**
    - The ulcer itself may appear red or white, with a defined border[5].

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LOZENGES

Lozenges:

Lozenges are solid formulations containing medications in a sweet and flavored base. They are designed to dissolve slowly in the mouth, similar to medicated candies, providing relief to irritated throat tissues. Lozenges are widely used due to several advantages, including prolonging the medication's presence in the mouth, enhancing absorption, reducing stomach irritation, and bypassing initial liver metabolism[6].

Types of Lozenges:

1. **Medicated Lozenges:**
   - Contain active pharmaceutical ingredients intended for therapeutic use.
2. **Non-Medicated Lozenges:**
   - Do not contain active pharmaceutical ingredients and are used for soothing or refreshing purposes[7].

Classification of Lozenges:

I. According to Site of Action:

- **Local Effect:** Examples include antiseptics and decongestants.
- **Systemic Effect:** Examples include vitamins and nicotine.

II. According to Texture and Composition:

1. **Chewable Lozenges:**
   - Combine herbal ingredients with a chewable texture, providing a convenient way to deliver medicinal compounds to affected oral tissues.
   - *Example:* Vitamins.
2. **Hard Lozenges:**
   - Have a firm consistency and dissolve slowly, releasing herbal extracts that may soothe, reduce inflammation, and promote healing in oral tissues.
   - *Example:* Lollipops[8].
3. **Soft Lozenges:**
   - Designed to dissolve or disintegrate slowly, releasing herbal extracts with therapeutic properties to soothe and heal discomfort associated with conditions like mouth ulcers.
   - *Example:* Bentasil.
4. **Compressed Lozenges:**
   - Formulated for heat-sensitive ingredients using a compression method similar to compressed tablets, offering a non-disintegrating and slower dissolution profile.
   - *Example:* Troches.

These classifications provide varied options for delivering medicinal benefits tailored to specific oral health needs[9].

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MATERIALS AND METHODS

COMPOSITION

Table no. 1 : Formulation Table of herbal lozenges

Sr. No	Ingreedients	Quantity Taken
1.	Tulsi	280 mg
2.	Neem oil	2-5 drops
3.	Dextrose	7000 g
4.	Sugar	7000g
5.	Honey Flavour	QS
6.	Isomalt	QS

Ingredients Profile

1. Neem

Neem (Azadirachta indica), also known as margosa, nimtree, or Indian lilac, belongs to the mahogany family Meliaceae. It is native to tropical and semi-tropical regions and is renowned for its medicinal properties. Neem is a significant source of therapeutic agents deeply rooted in Indian traditional medicine[10].

- **Scientific Name:** Azadirachta indica
- **Family:** Meliaceae
- **Order:** Sapindales
- **Kingdom:** Plantae

Various parts of the neem tree, such as its fruits, seeds, oil, leaves, roots, and bark, have been utilized traditionally for treating inflammation, infections, mouth ulcers, fever, skin diseases, and dental disorders. These components play a vital role in Indian Ayurvedic and Unani medicinal systems and are integral to the production of modern pharmaceuticals, cosmetics, toiletries, and medicinal products.

According to Hindu beliefs, the neem tree is associated with Sithala, the goddess believed to govern diseases like chicken pox. Neem tea is used to alleviate headaches and fever, while its flowers are employed to treat intestinal issues. Neem bark acts as an analgesic and is traditionally used to alleviate high fevers such as those associated with malaria. Neem leaves are effective in treating skin diseases and mouth ulcers[11].

Aim, Need, and Objectives

Aim: The aim is to formulate herbal lozenges for the treatment of mouth ulcers.

Need: The need for developing herbal lozenges for mouth ulcers is to alleviate pain and inflammation, and combat oral infections effectively.

Objectives:

1. Develop a formula for herbal lozenges incorporating various herbs to enhance palatability and effectiveness.

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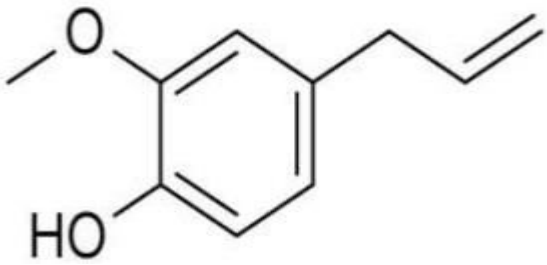
2. Study the neem tree (*Azadirachta indica*) and Tulsi (*Ocimum sanctum*), including their major and essential constituents, and explore their phytochemical and pharmaceutical significance.
3. Investigate Eugenol:

- **Molecular Formula:** C10H12O2
- **Molecular Weight:** 164.2 g/mol
- **Solubility:** Eugenol (4-allyl-2-ethoxyphenol) is the principal compound found in clove oil, comprising 83–95% of the oil. It is slightly soluble in water and highly soluble in organic solvents, appearing colorless or yellowish in color.



Methodology

1. **Preparation:**
   - Weigh powdered sugar and liquid glucose in a suitable beaker.
   - Heat the liquid glucose to reduce viscosity.
   - Slowly add sugar with continuous stirring to dissolve completely, maintaining temperature between 110 to 130°C.
   - After thorough mixing of sugar, add Tulsi powder and Neem oil, ensuring complete dissolution.
   - To adjust the intense dark color, add white colorant.
   - Incorporate desired colors and flavors, then pour the mixture into molds and allow it to air dry.
2. **Evaluation Parameters:**

- **Physical Parameters:** Evaluate clarity, texture, and consistency of the medicated lozenges. Assess texture for stickiness visually.
- **Weight Variation Test:** Weigh 6 lozenges from each batch individually using an analytical balance to measure average weight and standard deviations (Height: 1 cm, Width: 1.5 cm).
- **Diameter and Thickness:** Measure diameter and thickness using a vernier scale, crucial for tablet uniformity and patient acceptance (measured in mm).
- **Hardness Test:** Use a Pfizer tester to determine the hardness of the prepared lozenges.
- **Mouth Dissolving Time:** Place each lozenge in separate beakers with 100 ml phosphate buffer pH 6.8, stirring at 50 rpm using a mechanical stirrer at 37°C to record the time taken for complete dissolution.
- **Moisture Content:** Determine moisture content gravimetrically by weighing a 1 gram sample placed in a desiccator for 24 hours.
- **Stability Studies:** Subject the optimized formulations to stability studies at 40°C/75% RH for one month to assess their stability over time.

Conclusion:

- The formulation of herbal neem lozenges for treating mouth ulcers shows promise as a natural and potentially effective remedy.
- Careful ingredient selection, proportion optimization, and adherence to regulatory standards are crucial in the formulation process to ensure safety and efficacy.
- Laboratory testing helps refine the formulation to enhance taste, texture, and therapeutic benefits.
- Herbal neem lozenges offer potential benefits such as pain relief, inflammation reduction, infection control, and support for mouth ulcer healing.
- However, further research, particularly clinical studies, is necessary to validate their effectiveness and safety conclusively.
- In summary, herbal neem lozenges present a promising alternative for individuals seeking natural remedies for managing mouth ulcers.

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