Formulation and Evaluation of Herbal Lozenges on Treatment of Candidiasis

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ABSTRACT

Trachyspermum Ammi is commonly known as Ajwain. The plant is used traditionally as stimulant, carminative, abdominal tumours, bronchial problem, lack of apetite, asthma. Medicinally, it has been proven to possess various pharmacological activities like antifungal, antioxidant, antimicrobial, antitussive, anthelmentics, antispasmodic, bronchodilating actions, diuretic. Studies reveal presence of various phytochemical constituents mainly carbohydrates, glycosides, saponins and volatile oils like thymol. Trachyspermum Ammishows action on fungal infection. The infection caused by species Candida can be treated with ajwain. Candidiasis is a fungal infection caused by yeast (a type of fungus). It affects the mouth and throat. Further studies, reveal the treatment of Candidiasis and formulation related to the disease.

Keywords - Ajwain, candidiasis, trachyspermum ammi, antifungal, thymol , lozenges

INTRODUCTION

Trachyspermum Ammi commonly known as " Ajwain" is distributed throughout Indiaand it is cultivated in Gujarat & Rajasthan .The use of plants and seeds in medicine isalmost as old as human civilisation .Trachyspermum Ammi, belonging to familyApiaceae is a highly valued medicinally important seed spice . The roots are diuretic innature & the seeds contain excellent properties.Candida species are currently the 4thleading cause of hospital acquired bloodstream infection. Ajwain oil, which is 2- 4.4%brown in colour, is found in seeds.The major ingredient in this oil is thymol, which isused to treat gastrointestinal issues appetite loss .Candidiasis is the most prevalent, with Candida albicans capable of causing more invasive infections than any other fungi. Fungi have become a major source of human disease. Candidiasis is most common of the disseminated mycoses. Oral Candidiasis is a superficial infection that affects the palate region . It is the infection produced by microorganism of the genus Candida; Candida Albicans is most common pathogenic species. More than 20 typesof Candida can cause infection with Candida Albicans being most common. Individuals at risk for invasive candidiasis include low birth weight babies, Oral Candidiasis is a superficial infection that affects the palate region .It is the infection produced by microorganism of the genus Candida; Candida Albicans is most common pathogenic species. More than 20 typesof Candida can cause infection with Candida Albicans being most common. Individuals at risk for invasive candidiasis include low birth weight babies, peoplerecovering from surgery, HIV, Cancer, & people admitted to an intensive care unit.The Candida species that survive on skin and on environmental surfaces may beexogenous or endogenous where in fungal infection are caused by Lozenges are solid dosage form which are intended to slowly dissolve in mouth for

therapuetic effect. A small usually sweetened and flavored medicated material that is designed to be held in the mouth.lozengesare manufactured by moulding and compression; when chewedgradually dissolve or disintegrate in mouth.The typically included one or more active ingredients in a foundation that is flavoured and sweetened and when sucked, they are meant to gently dissolve or disintegrate in mouth.Lozenges can be made by compressing or shaping sugar based tablets.lozenges are traditionally made to relieve minor irritation and coughs.The majority of lozenges composition are marketed over the counter medicines .Lozenges are used for people who are unable to swallow solid dosage form and for medication that need to be given slowly to provide a continuos dose of medication in oral cavity Or to coat the tissues of throat with medication. The medicine is usually added to a sugar basis for flavoured hard candies when making them. Lozenges are made to slowly erode or dissolve over a period of 30 minutes or less. Lozenges give easy administration, convenient for geriatric and Pediatric patient and improved drug effect . Overall, the lozenges offer a convenient and effective means of administration especially for patients with swallowing problem

Classification of Herbal Lozenges

1. **Hard Lozenges**

In order to create hard candy lozenges, a cooking technique is used to dissolve necessaryIn order to create hard candy lozenges, a cooking technique is used to dissolve necessary amount of sugar to create candy base. The hard candy might include upto 2-4% medication.

2. **Soft Lozenges**

Soft lozenges were easy to achieve because of they were easy to prepare on the spot and could be used with a variety of medication . They have a softer, chewier texture. They are often made with combination of sugar, honey, herbs , and they are used to treat sore throats

3. **Chewable Lozenges**

They are designed to chewed, rather than slowly dissolve .They are typically made with combination of sugar, honey, herbs,and they are used to treat sore throats. When choosing aherbal lozenge it is important to consider the specific health benefits you are looking for and the texture that you prefer.

REVIEW OF LITERATURE

Fatima S, Singh R, Malhotra A et al. 2024. The study focused on the synergistic effect of combining Allium sativum (garlic) and Ocimum sanctum (tulsi) in herbal lozenges. Extracts were formulated into sugar-based lozenges and tested for antifungal potency, stability, and release kinetics. The combined extract lozenges showed enhanced antifungal activity against Candida albicans compared to individual extracts, reinforcing the idea of multi-herb synergy in herbal dosage forms.

Nair P, Joshi H, Mehta R et al. 2023. In this study, herbal lozenges containing Glycyrrhiza glabra (licorice) extract were developed for patients with oral candidiasis. The lozenges were assessed for physical stability and antifungal activity. Results showed effective inhibition of Candida growth with good patient acceptability in terms of taste and mouthfeel. The findings suggest that licorice extract could be a beneficial component in lozenge formulations aimed at treating fungal infections of the oral cavity.

Sharma P, Kulkarni M, Deshmukh R et al. 2023. The study involved the formulation of herbal lozenges incorporating Syzygium aromaticum (clove) extract, known for its antifungal activity against Candida albicans.

The lozenges were evaluated for hardness, disintegration time, and in vitro antifungal activity. Results showed significant inhibition zones against C. albicans, indicating the effectiveness of clove extract as a natural antifungal agent suitable for oral formulations.

Kumar V, Rani S, Tripathi P et al. 2022. This research investigated the use of Curcuma longa (turmeric) in lozenge formulations for treating oral candidiasis. Curcumin-loaded lozenges were prepared using natural excipients. The lozenges exhibited satisfactory physicochemical properties and a sustained drug release profile. Antimicrobial tests confirmed curcumin's antifungal efficacy, supporting its role in managing candidiasis.

Amin M, Basir R, Ghazali F et al. 2021. The authors studied the incorporation of tea tree oil (Melaleuca alternifolia) in a lozenge base to treat fungal infections of the oral cavity. The essential oil was emulsified using a natural binder and incorporated into lozenges through the molding method. Evaluation included pH, microbial testing, and dissolution studies. The lozenges demonstrated prolonged antifungal activity, highlighting their potential as an alternative to synthetic antifungals.

NEED AND OBJECTIVE

NEED FOR THE STUDY

Candidiasis, primarily caused by *Candida albicans*, is a common fungal infection affecting the oral cavity, skin, and mucous membranes. The increasing resistance to conventional antifungal agents, their side effects, and the high cost of treatment have created a demand for safer, effective, and affordable alternatives. Herbal medicines have been traditionally used for their antimicrobial properties and offer a promising natural approach with minimal side effects.

Lozenges are an ideal dosage form for delivering active agents locally to the oral cavity, making them suitable for treating oral candidiasis. Combining this delivery form with herbal extracts known for antifungal activity can provide an effective, patient-friendly treatment option.

OBJECTIVES OF THE STUDY

1. To select and extract herbal ingredients with proven antifungal activity against *Candida albicans*.
2. To formulate herbal lozenges using the selected herbal extracts.
3. To evaluate the physicochemical properties of the prepared lozenges (e.g., hardness, weight variation, disintegration time).
4. To assess the antifungal efficacy of the herbal lozenges against *Candida albicans* using microbiological methods.
5. To perform stability studies to ensure the shelf-life and effectiveness of the lozenges over time.
6. To explore the potential of herbal lozenges as a natural, safe, and cost-effective treatment option for candidiasis.

PLAN OF WORK

I. Selection of crude drugs:

A) Active Pharmaceutical Ingredients:

1. Ajwain

B) Excipients:

1. Lemon
2. Tulsi
3. Jaggery
4. Clove

II. Collection of crude drugs:

The ajwain and other excipient such as jaggery, lemon, clove, are collected from marketed shop and tulsi collected from botanical garden and dried in hot air oven. Then converted into fine powder.

III. Preparation of materials:

Selection of effective method of preparation.

IV. Experimental Design:

Formulation of herbal lozenges

V. Comparative study

VI. Result & discussion

VII. Conclusion

VIII. Reference

DRUG PROFILE

Name :- **Ajwain Synonym** :- carom seeds **Structure** :-

Fig. no. 1 Geographical Source :- Indian subcontinent and the middle east. **Family** :- Apiaceae
Properties:- Antifungal, Antibacterial, Antioxidant

Macroscopic Characters :-

1) Colour :- Brown
2) Odour :- Strong, pungent, and characteristic; due to thymol (similar to oregano or thyme).
3) Taste :- Pungent, slightly bitter, and aromatic.

Chemical Constituent :- p-cymene, γ-terpinene, and various monoterpene **Solubility** :- soluble in organic solvents like alcohol and oils. Insoluble in water. **Storage** :- Store in air tight container in cool, dry place, away from sunlight.

Name :- **Tulsi**

Synonym :- Ocimum sanctum Linn. (Syn: *Ocimum tenuiflorum*)

Structure :-

Fig. no. 2

Geographical Source :- India is considered the native and primary source of *Ocimum sanctum* (Tulsi).

Family :- Lamiaceae (Mint family)

Properties:- Adaptogenic,Antioxidant,Immunomodulatory,Antimicrobial,Anti-inflammatory

Macroscopic Characters :-

1) Colour :- Fresh green to purple (depending on variety)
2) Odour :- Strong, aromatic (clove-like due to eugenol)
3) Taste :- Pungent, slightly bitter

Chemical Constituent :- essentials oils, flavonoids, phenolic compounds, alkaloids.

Solubility :- Partially soluble in water, Soluble in Alcohol.

Storage :- Store in air tight container in cool, dry place, away from sunlight.

Name :- **Lemon**

Synonym :- Citrus limon (L.) Osbeck

Structure :-

Fig. no. 3 Geographical Source :- Native to northeast India, Myanmar, and China **Family** :- Rutaceae

Properties:- Astringent, Anti-inflammatory, Antifungal, Antibacterial, Antioxidant

Macroscopic Characters :-

1) Colour :- Bright yellow (ripe fruit), greenish-yellow (unripe)
2) Odour :- Strong, fresh, citrus aroma
3) Taste :- Highly acidic, sour, tangy

Chemical Constituent :- Limonene, Citral (Neral + Geranial), β-Pinene

Solubility :- Citric Acid, Malic Acid, Sugars (Glucose, Fructose), Vitamin C (Ascorbic Acid)

Storage :- Protect from direct sunlight, Placed in cool and dry environment.

Name :- **Clove**

Synonym :- Syzygium aromaticum (L.) Merr. & L.M. Perry

Structure :-

Fig. no. 4

Geographical Source :- Native to Indonesia (Maluku Islands – Spice Islands),

Family :- Myrtaceae

Properties:- Analgesic,Anti-inflammatory,Antiseptic,Antioxidant

Macroscopic Characters :-

1) Colour :- Dark brown, reddish-brown
2) Odour :- Strong, spicy, aromatic
3) Taste :- Pungent, slightly bitter, warm sensation

Chemical Constituent :- Eugenol (70–90%), Eugenyl acetate, β-Caryophyllene, Tannins

Solubility :- Soluble in water and alcohol.

Storage :- Jaggery should be stored in a cool, dry place, away from direct sunlight.

Name :- Jaggery

Synonym :- Saccharum officinarum (Sugarcane) or Phoenix dactylifera (Date Palm)

Structure :-

Fig. no. 5

Geographical Source :- Jaggery is widely produced in tropical regions, especially in India, Pakistan.

Family :- Poaceae (Sugarcane) or Arecaceae (Date Palm)

Properties:- Rich in minerals ,Natural sweetener,Contains antioxidants.

Macroscopic Characters :-

1) Colour :- dark brown, depending on the source
2) Odour :- Sweet and Caramel-like.
3) Taste :- sweet with a slightly caramel-like flavor.

Chemical Constituent :- sucrose, glucose, fructose.

Solubility :- soluble in water.

Storage :- Jaggery should be stored in a cool, dry place, away from direct sunlight.

MATERIALS AND METHODS

Sr. No.	Ingredient	Quantity
1	Jaggery	90gm
2	Ajwain	6.5gm
3	Lemon juice	4-5 drops
4	Clove	0.4gm
5	Tulsi	2gm

Table no. 1

GLASSWARE AND INSTRUMENTS

Weighing balance, heating mantle, stirrer, hot air oven, rubber mould.

METHODS OF PREPARATION

1. Measure the raw material

2. Take ajwain, clove, tulsi and dry the ingredients through hot air oven to remove moisture content
3. After drying the ingredients powder them through mixer jar and then pass powder through seive to get finer particles to get dissolved
4. liquify jaggery on medium flame until it get melts
5. During melting add ajwain, clove, tulsi powder accordingly
6. Continue agitating mixture and add required quantity of lemon drops to it
7. Keep the mould ready
8. After mixing the entire ingredient transfer mixture into mould
9. Keep it at room temperature until it gets harder , then hard lozenges are stored for one to two days in refrigerator

Fig. no. 6 (Hard candy Lozenges)

EVALUATION PREPARED HERBAL FORMULATION

1. **Macroscopic Evaluation**

Refers to the assessment of sensory properties such as taste, odour , and appearance of product. Herbal lozenges can be evaluated using following parameters [7].

Appearance – The colour, size and shape of the lozenges should be assessed. The surface texture , presence of any speckles and uniformity of shape should be checked.

Taste – The taste should be evaluated for sweetness, sourness, bitterness, and saltiness.

Odour – The herbal aroma of lozenges should be assessed for intensity, quality and plesantness.

Texture – The texture of the lozenges should be assessed for hardness, chewiness, and stickiness.

2. **Weight Variation**

Weight variation refers to difference in weight between individual unit of product, such as herbal lozenges. It is important to evaluate weight variation in herbal lozenges to ensure that each lozenge contains correct amount of active ingredient and to ensure consistency in

product[7].

Average weight = (weight of 5 lozenges)/ 5

Weight variation = (Individual weight – average weight ×100%) / (average weight)

3. **Measurement of PH**

PH is an important parameter to evaluate in herbal lozenges. PH is a measure of the acidity or alkalinity of a solution and can have an impact on the stability, efficacy, and sensory properties of the product. The pH of herbal lozenges can be determined using a pH meter or pH paper. A small amount of the lozenge is dissolved in water, and the pH of the resulting solution is measured. The acceptable pH range for herbal lozenges depends on the specific product and Its intended use. Typically, a pH range of 5.5 to 7.5 is acceptable for most herbal lozenges. Dissolution Time Dissolution time is an important parameter to evaluate in herbal lozenges as it can affect the release of active ingredient and the efficacy of product. The dissolution time of herbal lozenges can be influenced by factors such as size, shape of lozenges and environmental conditions during storage. The dissolution time of herbal lozenges can be determined by placing a lozenges in beaker of water at specified temperature and measuring the time it takes for lozenges to dissolve.

RESULT AND DISCUSSION

PHYSICAL EVALUATION OF HERBAL LOZENGES

Sr. no	Parameters	Observation
1	Colour	Dark brown
2	Taste	Sweet
3	Texture	Smooth
4	Shape	Oval

Table no. 2

Weight Variation :-

Formulation	Average weight	%variation
Hard lozenges	4.5	2.4%

Table no. 3

Measurement of pH :-

Sr. no.	Dosage form	pH
1	Lozenges	5-6

Table no. 4

Dissolution Time :-

Sr. No	Dosage form	Dissolution time
1	lozenges	10-15min

Table no. 5

CONCLUSION

Herbal lozenges are natural remedies that offer several benefits for a variety of ailments such as sore throat, cough, cold, and allergies. With an increasing demand for natural and organic products, growing interest in traditional medicine, increased research and Development, and diverse applications, the future of herbal lozenges is promising. As Consumers become more health-conscious, the market for herbal lozenges is likely to grow significantly, providing a natural and effective alternative to conventional medications. Additionally, with on-going research, it is expected that more innovative and effective herbal lozenges will be developed to meet the growing demand for natural remedies. Herbal lozenges are a safe and effective option for those seeking natural relief from common ailments.

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