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FORMULATION & EVALUATION OF LOZENGES FOR POSTMENOPAUSE

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ABSTRACT

Postmenopause is a critical stage in a woman's life marked by the cessation of menstruation and significant hormonal changes, primarily the decline in estrogen levels. These changes result in a variety of physical and psychological symptoms, including hot flashes, mood swings, vaginal dryness, osteoporosis, and sleep disturbances. This study focuses on the formulation and evaluation of medicated lozenges incorporating herbal agents such as Caraway (Carum carvi), Fenugreek (Trigonella foenum-graecum), and Coriander (Coriandrum sativum), known for their phytoestrogenic and therapeutic properties. Lozenges provide a convenient, palatable, and effective oral delivery system with potential for both local and systemic effects via buccal absorption. The prepared lozenges were evaluated for physicochemical parameters including hardness, friability, weight variation, disintegration time, drug content, and in vitro drug release. The results demonstrated that the herbal lozenges were pharmaceutically acceptable, stable, and potentially effective in alleviating postmenopausal symptoms. This study suggests that herbal lozenges could serve as a safe and user-friendly alternative for managing postmenopausal discomfort.

KEYWORDS: *Lozenges formulation, Postmenopausal symptom management, Herbal lozenges, Caraway (Carum carvi), Fenugreek (Trigonella foenum-graecum), Coriander (Coriandrum sativum), Phytoestrogens, Natural hormone therapy, Herbal formulation, Alternative medicine, Menopause, Plant-based therapy, Buccal drug delivery, Estrogen deficiency treatment, Nutraceutical lozenges, Phytotherapeutic agents, Drug delivery system, Herbal remedies for menopause, Patient-friendly dosage form, Standardization of herbal lozenges*

INTRODUTION

Postmenopause is a phase in a woman's life that begins after 12 consecutive months without a menstrual period, typically occurring between ages 45–55. During this time, women may experience various symptoms due to reduced estrogen levels, including vaginal dryness, mood swings, hot flashes, and bone density loss.

Lozenges are a convenient oral dosage form designed to dissolve slowly in the mouth, offering local or systemic effects. They can be used for hormone delivery (e.g., estrogen or phytoestrogens), vitamins (like vitamin D or calcium), or herbal remedies that alleviate postmenopausal symptoms. The formulation of lozenges ensures patient compliance, ease of administration, and potentially improved bioavailability through buccal absorption.

This study involves the formulation and evaluation of medicated lozenges aimed at managing postmenopausal symptoms. Evaluation parameters include hardness, friability, dissolution rate, drug content, and sensory acceptability to ensure efficacy, stability, and patient adherence.

Postmenopause marks the stage following menopause, characterized by the permanent cessation of menstruation due to declining ovarian function. This phase is often accompanied by symptoms such as hot flashes, night sweats, mood changes, and decreased bone density, primarily due to hormonal imbalances.

To address these symptoms, alternative drug delivery systems such as lozenges have gained attention. Lozenges are solid, flavoured preparations designed to dissolve slowly in the mouth, offering both local and systemic effects. They are particularly suitable for delivering medications or natural compounds like phytoestrogens, calcium, and vitamin D, which help alleviate postmenopausal discomfort.

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This study focuses on the formulation and evaluation of lozenges containing therapeutic agents for postmenopausal care. The evaluation includes testing for physical characteristics, drug release profiles, taste masking, and patient acceptability to ensure a safe, effective, and user-friendly product.

Statement of the Problem

Postmenopausal women often experience a range of symptoms, including hot flashes, mood swings, vaginal dryness, and other discomforts due to the decline in estrogen levels. These symptoms significantly affect their quality of life and may lead to long-term health complications.

Despite the availability of hormone replacement therapy (HRT) and other medications, many women seek alternative remedies with fewer side effects. Lozenges, as an easily consumable and convenient dosage form, could provide a promising solution by delivering therapeutic agents that alleviate menopausal symptoms.

However, there is a need for a systematic formulation and evaluation of lozenges that combine effective active ingredients, such as herbal extracts or bioactive compounds, to target the specific needs of postmenopausal women, ensuring both efficacy and safety. The challenge lies in formulating lozenges that are not only effective in symptom management but also stable, palatable, and acceptable to the target population.

Therefore, this study aims to develop and evaluate lozenges tailored for postmenopausal women, focusing on their therapeutic potential, safety, and consumer acceptance.

Hypothesis

Formulated lozenges containing selected therapeutic agents (e.g., herbal extracts, phytoestrogens, or bioactive compounds) will effectively alleviate common postmenopausal symptoms and will be pharmaceutically acceptable in terms of taste, stability, and patient compliance.

Alternate Hypothesis (H_1)

The formulated lozenges will demonstrate significant effectiveness in relieving postmenopausal symptoms and will meet standard pharmaceutical evaluation parameters (e.g., hardness, disintegration time, drug release, and palatability).

Null Hypothesis (H_0)

The formulated lozenges will not show a significant effect in relieving postmenopausal symptoms and/or will fail to meet the acceptable pharmaceutical evaluation criteria.
The formulated lozenges will provide a safe, effective, and patient-friendly alternative for managing postmenopausal symptoms through sustained delivery of therapeutic agents.

AIM & OBJECTIVES

Aim: Formulation & Evaluation of lozenges for postmenopause

Objectives

1. To select and incorporate appropriate active ingredients (e.g., herbal extracts or phytoestrogens) known to alleviate postmenopausal symptoms.
2. To develop a palatable and stable lozenge formulation suitable for oral administration.
3. To evaluate the physicochemical properties of the formulated lozenges, including hardness, friability, weight variation, and disintegration time.
4. To assess the in vitro drug release profile of the lozenges.
5. To conduct stability studies on the optimized formulation under different storage conditions.
6. To evaluate the acceptability and potential therapeutic efficacy through sensory analysis or preliminary user feedback.

LITERATURE REVIEW

(Santoro, 2016)

Menopause is a physiological transition marked by the permanent cessation of menstruation and a reduction in estrogen levels. Common symptoms include hot flashes, insomnia, irritability, and vaginal dryness (Santoro, 2016).

(Rossouw et al., 2002)

While hormone replacement therapy (HRT) remains the gold standard for treating menopausal symptoms, concerns over associated risks—such as cardiovascular disease and breast cancer—have led many women to seek alternative treatments (Rossouw et al., 2002).

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(Patel et al., 2015)
Lozenges are an innovative, patient-friendly oral dosage form that dissolve slowly in the mouth and enable local and systemic absorption of therapeutic agents (Patel et al., 2015). Their prolonged retention in the oral cavity offers better therapeutic efficacy, especially when formulated with plant-based bioactive compounds. Despite extensive use in respiratory and vitamin supplements, lozenges for postmenopausal symptom relief remain underexplored.

(Messina, 2014; Wuttke et al., 2003)
There is growing evidence that phytoestrogens—plant-derived compounds with estrogenic activity—can alleviate menopausal symptoms with fewer side effects than synthetic hormones. Isoflavones from soy (Glycine max), red clover (Trifolium pratense), black cohosh (Actaea racemosa), and flaxseed (Linum usitatissimum) have been studied for their beneficial effects on vasomotor symptoms and bone health (Messina, 2014; Wuttke et al., 2003).

(Leach & Moore, 2012)
For instance, black cohosh has shown clinical efficacy in reducing hot flashes and mood swings, without stimulating breast or uterine tissue (Leach & Moore, 2012). Similarly, red clover isoflavones have been reported to significantly improve sleep quality and reduce anxiety in postmenopausal women.

(Tice et al., 2003)
Formulating these phytoestrogen-rich herbal extracts into lozenges can offer a sustained and convenient delivery method that enhances patient compliance. However, more formulation-based studies are needed to optimize lozenge parameters for this specific use case.

(Aulton & Taylor, 2017)
Lozenges are solid oral dosage forms designed to dissolve slowly in the mouth, offering advantages such as ease of use, improved taste, and localized or systemic drug delivery (Aulton & Taylor, 2017). They have been successfully used to deliver active agents for sore throat relief, cough suppression, and vitamin supplementation.

Patel et al. (2015)
Patel et al. (2015) developed herbal lozenges containing Ginger and Tulsi extracts and reported good results in terms of uniformity, disintegration time, and stability. Similarly, formulated lozenges with antimicrobial agents and demonstrated consistent release profiles and consumer acceptability.

Sharma et al. (2018)
Applying similar formulation strategies to menopausal symptom management could yield lozenges that are not only effective but also well accepted by aging female populations who prefer non-tablet forms due to dysphagia or taste masking requirements.

(Yadav et al., 2020)
While many natural remedies are available in the form of capsules, teas, or tinctures, there is limited research on lozenge formulations specifically targeted at menopausal symptom relief. Most existing studies focus either on the pharmacology of herbs or on lozenge formulation for other therapeutic categories (Yadav et al., 2020).

There is a clear research gap in integrating standardized herbal extracts into lozenges that meet pharmaceutical standards (e.g., uniformity, disintegration, dissolution). Addressing this gap can lead to the development of novel, non-hormonal, user-friendly alternatives for managing menopause-related discomforts.

SIGN & SYMPTOMS OF POSTMENOPAUSE

Sign

1. Cessation of menstruation for 12 consecutive months
2. Vaginal dryness or atrophy (noticed on physical exam)
3. Thinning of the vaginal walls
4. Dry skin and brittle hair
5. Decreased breast fullness
6. Weight gain, especially around the abdomen
7. Osteopenia or osteoporosis on bone density scan
8. Elevated FSH levels (follicle-stimulating hormone, confirmed via blood test)
9. Thinning hair or hair loss
10. Loss of skin elasticity

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Symptoms
1. Hot flashes
2. Night sweats
3. Vaginal dryness
4. Pain during intercourse
5. Decreased libido
6. Sleep disturbances or insomnia
7. Mood swings
8. Depression or anxiety
9. Fatigue
10. Difficulty concentrating or memory lapses
11. Urinary urgency or incontinence
12. Joint and muscle pain

Common sign and symptoms

1. Vasomotor Symptoms:
   a. Hot flashes
   b. Night sweats

2. Urogenital Symptoms:
   a. Vaginal dryness and itching
   b. Pain during intercourse (dyspareunia)
   c. Urinary urgency or incontinence
   d. Increased risk of urinary tract infections (UTIs)

3. Psychological Symptoms:
   a. Mood swings
   b. Depression or anxiety
   c. Sleep disturbances or insomnia
   d. Memory issues or difficulty concentrating

4. Physical Changes:
   a. Weight gain (especially around the abdomen
   b. Thinning hair or hair loss
   c. Dry skin
   d. Breast shrinkage or tenderness

5. Long-term Health Risks:
   a. Osteoporosis (due to decreased bone density)
   b. Increased risk of cardiovascular disease
   c. Joint and muscle pain

6. Sexual Health Changes:
   a. Decreased libido
   b. Discomfort during sex

MATERIALS & METHODOLOGY

Active Ingredients
Phytoestrogens (e.g., soy isoflavones or black cohosh extract) or hormone replacement agents
Calcium carbonate or citrate
Vitamin D3

Lozenge Base
Sucrose and dextrose (for sugar-based lozenges) or
Polyethylene glycol (PEG) or sorbitol (for sugar-free lozenges)

Binding Agents
Acacia

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Flavoring Agents
Menthol, mint, or fruit flavors

Coloring Agents
Food-grade colorants
Other Excipients:
Citric acid (to enhance taste)
Magnesium stearate (as a lubricant)

2. Methodology
A. Preparation of Lozenges:
1. Weighing and Mixing:
All ingredients are accurately weighed and mixed in a mortar to ensure uniform distribution of the active agents and excipients.
2. Melting (for sugar-based lozenges):
Sucrose and dextrose are heated with water to form a clear syrup. Active ingredients and other excipients are added with continuous stirring.
3. Molding:
The mixture is poured into pre-lubricated molds and allowed to cool and solidify at room temperature.
4. Demolding and Packaging:
Solidified lozenges are removed from molds and packed in moisture-proof contc

CARAWAY:
Caraway, also known as meridian fennel and Persian cumin, is a biennial plant in the family Apiaceae, native to western Asia, Europe, and North Africa. Its seeds, leaves, and roots are used in cooking and medicine.
Caraway seeds have been studied for their potential benefits in alleviating symptoms associated with menopause, including postmenopause. Some studies suggest that caraway seeds may help with**:**
Active Ingredients:

- **Volatile Oil:** Caraway seeds yield up to 7.5% of volatile oil, mostly composed of S-carvone, which gives them their distinct flavor and aroma.
- **Fixed Oil:** The seeds contain 15% fixed oil, comprising oleic, linoleic, petroselinic, and palmitic acids.
- **Phytochemicals:** Caraway seed oil includes thymol, o-cymene, γ-terpinene, β-pinene, and linalool.



Fig. No. 1. Caraway

Description and Uses

- **Culinary:** Caraway seeds have a pungent, anise-like flavor and are commonly used in breads, especially rye bread, as well as in desserts, liquors, and casseroles.
- **Medicinal:** Caraway is used to aid digestion, relieve bloating and flatulence, and has antispasmodic and aperitive effects.
- **Digestive Benefits:** Caraway oil might improve digestion and relieve spasms in the stomach and intestines, making it potentially effective for indigestion [1] [2] [3].

Caraway is a biennial plant belonging to the family Apiaceae. Here's a detailed look at its morphology:

Plant Structure

- **Roots:** Fusiform and thick, suitable for storing nutrients**.**
- **Stem:** Slender, grooved, and hollow, with branches that support the leaves and flowers.
- **Leaves:** Pinnately-dissected with ovate leaflets that are cleft into linear, entire, or dentate lobes.

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Flowers and Fruits

- **Flowers:** Small, white or pink, and arranged in dense umbels with 5-16 unequal rays**.**
- **Fruits:** Schizocarp, oblong-oval, and yellowish-brown, splitting into two mericarps (commonly called seeds).
- **Mericarps (seeds):** Aromatic, 4-6 mm long, hard, sharp, and mostly curved with five prominent ribs [1].

Microscopic Characteristics

- **Epicarp:** Polygonal tubular cells with few stomata covered with cuticle.
- **Mesocarp:** Rounded parenchyma cells with scattered sclereids**.**
- **Endocarp:** Elongated sub-rectangular cells.
- **Endosperm:** Thick-walled cellulosic parenchyma cells containing oil globules, calcium oxalate crystals, and aleurone grains [2].

Potential Side Effects and Interactions:

Pregnancy and Breastfeeding: Caraway is possibly unsafe during pregnancy and breastfeeding due to limited information.
1. Allergic reactions: Some individuals may experience allergic reactions to caraway seeds.
2. Gastrointestinal issues: High doses may cause gastrointestinal upset, such as nausea, vomiting, or diarrhea.
3. Interactions with medications: Caraway seeds may interact with certain medications, such as blood thinners or diabetes medications.

Adverse Drug Reactions (ADRs)

1. Hypersensitivity reactions:
Rare cases of hypersensitivity reactions, such as anaphylaxis, have been reported.
2. Gastrointestinal ADRs:
Gastrointestinal ADRs, such as stomach upset or diarrhoea, may occurred

Monitoring

1. Regular monitoring:
Regularly monitor patients for signs of adverse reactions or interactions.
2. Healthcare provider guidance:
Consult a healthcare provider for guidance on using caraway seeds safely.
Further research is needed to fully understand the potential side effects and toxicity of caraway seeds.

Nutritional Value:

Seeds: Rich in protein, B vitamins, vitamin C, iron, phosphorus, and zinc [1].
1. Hot flashesz: Caraway seeds may have a positive effect on reducing hot flashes in postmenopausal women.
2. Anxiety and stress: The seeds anxiolytic properties might help alleviate anxiety and stress.
3. Digestive issues: Caraway seeds may help with digestive problems, such as bloating
The Wikipedia article on Caraway (Carum carvi) provides detailed information on its:

Classification

- **Kingdom:** Plantae
- **Family:** Apiaceae
- **Genus:** Carum
- **Species:** C. Carvy

Nutritional Value

- **Energy:** 1,390 kJ (330 kcal) per 100g
- **Carbohydrates**: 49.90g
- **Protein:** 19.77g
- **Fat**: 14.59g
- **Dietary fiber:** 38.0g

Uses

- **Culinary:** seeds used in baking, cooking, and as a spice
- **Medicinal:** used to aid digestion and relieve bloating and flatulence.

FENUGREEK

Fenugreek, rich in phytoestrogens, shows promise in alleviating postmenopausal symptoms. Here's a detailed look at its benefits:

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Fig. No. 2. Fenugreek

Menopausal Symptoms
Hot Flashes: Fenugreek extract (FenuSMARTTM) at 1000 mg/day reduces hot flash frequency and improves lipid profiles in menopausal women.
Mood and Emotional Well-being: Fenugreek seed extract improves somatic, psychological, and urogenital issues, such as irritability, night sweats, and vaginal dryness.
Hormonal Balance: Fenugreek increases estradiol and progesterone levels while decreasing follicular stimulating and luteinizing hormone levels.

Cardiovascular Health
Cholesterol Levels: Fenugreek supplementation lowers total cholesterol, triglycerides, and LDL while increasing PPAR and adiponectin expression.
Cardiometabolic Risk: Fenugreek reduces cardiovascular disease risk by decreasing inflammation and improving lipid profiles.

Bone Health
Osteoporosis: Fenugreek seed extract increases bone mineral density, trabecular and cortical bone thickness, and maximum flexor load.
Bone Matrix: Diosgenin in fenugreek seeds promotes protein synthesis and inhibits osteoclastogenesis.
Cognitive Function
Memory and Learning: Fenugreek seed extract improves memory and learning abilities by elevating brain-derived neurotrophic factor (BDNF) levels.

Other Benefits
Sexual Function:
Fenugreek improves sexual interest, fertility, and sperm profile in both men and women. Skin Health: Topical or oral fenugreek enhances skin thickness and collagen synthesis.
Vaginal Health:
Fenugreek vaginal cream reduces postmenopausal vaginal atrophy.

CORIANDER (CORIANDRUM SATIVUM L.)
Botanical Description
Scientific name: Coriandrum sativum L.
Common names: Coriander, Cilantro (USA), Dhania (India)
Family: Apiaceae (Umbelliferae)
Plant type: Annual herb
Parts used: Seeds (fruits), leaves, stems, roots
Coriandrum sativum is a fast-growing aromatic herb characterized by pinnate leaves, white to pale pink flowers, and small, globular yellowish-brown seeds (schizocarps). The leaves are used fresh as a culinary herb (cilantro), while the seeds are dried and used as spice or medicine.

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Fig. no. 3. Coriander

Phytochemical Constituents

Coriander contains a variety of bioactive compounds, including:

Essential oils: Linalool (60–70%), geranyl acetate, camphor, α-pinene, and borneol

Flavonoids: Quercetin, rutin, apigenin

Phenolic acids: Caffeic acid, chlorogenic acid, gallic acid

Fatty acids: Petroselinic acid (major), linoleic acid

Steroids and coumarins

> Linalool is the main component responsible for its aroma and many biological activities.

Traditional and Culinary Uses

Culinary: Widely used in Indian, Middle Eastern, Latin American, and Southeast Asian cuisines. Both leaves and seeds are used as spice and garnish.

Traditional medicine: Used in Ayurvedic, Unani, and Chinese medicine for:

- Indigestion and bloating
- Flatulence
- Fever
- Diarrhoea
- Menstrual disorders
- Anxiety and insomnia

Table No. 1 Pharmacological Activities of Coriander

Activity	Evidence/Mechanism
Digestive stimulant	Increases bile secretion and improves appetite
Antioxidant	High flavonoid and phenolic content scavenges free radicals
Antimicrobial	Essential oil active against E. coli, S. aureus, Candida albicans
Antidiabetic	Enhances insulin secretion and glucose metabolism
Anti-inflammatory	Inhibits COX enzymes, reduces pro-inflammatory cytokines
Hypolipidemic	Lowers total cholesterol and triglycerides in animal models
Anxiolytic/Sedative	Modulates GABAergic pathways (similar to benzodiazepines)

Relevance to Women's Health and Menopause

Coriander seeds have been traditionally used to regulate menstrual cycles and alleviate digestive and hormonal imbalances. Some studies suggest coriander may influence estrogenic activity due to its flavonoid content, making it a potentially supportive herb during perimenopause and menopause.

Additionally, its anxiolytic and antioxidant effects could help manage stress and oxidative damage associated with menopausal changes.

Safety and Toxicity

Coriander is generally recognized as safe (GRAS). However:

Excessive intake may lead to allergic reactions or photodermatitis in sensitive individuals.

May interact with hypoglycaemic or anticoagulant medications.

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PUDINA (MENTHA SPP.)

1. Botanical Description

Scientific name: Mentha arvensis L. (Field mint) / Mentha piperita L. (Peppermint)
Common names: Pudina (Hindi), Mint, Peppermint, Field mint
Family: Lamiaceae (Mint family)
Parts used: Leaves (fresh/dried), essential oil, stem (occasionally)
Distribution: Widely grown across India, Europe, North America, and Asia
Description: Pudina is an aromatic perennial herb with square stems, green serrated leaves, and small purplish flowers. It is known for its cooling flavor and strong aroma due to high menthol content.

2. Phytochemical Constituents

Pudina contains a variety of bioactive phytochemicals, including:

- Volatile oils:
- Menthol (30–50%)
- Menthone, isomenthone
- Menthyl acetate
- Pulegone, limonene, cineole
- Flavonoids: Apigenin, luteolin, hesperidin
- Tannins
- Phenolic acids: Rosmarinic acid, caffeic acid
- Triterpenoids and sterols

> Menthol is the primary active constituent responsible for its cooling, analgesic, and antispasmodic effects.



Fig. No. 4. Pudina

3. Traditional Uses

a. Pudina has been widely used in Ayurvedic, Unani, and folk medicine for:
b. Digestive issues: Bloating, indigestion, nausea, gas
c. Respiratory ailments: Cough, asthma, sore throat
d. Skin problems: Itching, burns, rashes
e. Menstrual cramps and headaches (due to its antispasmodic and analgesic effects)
f. Cooling agent in summer beverages and preparations

Table No. 2. Pharmacological Activities of Pudina

Activity	Description
Bronchodilator	Used in cough syrups and inhalers for its decongestant effect
Antimicrobial	Effective against bacteria (E. coli, S. aureus) and fungi (Candida) due to menthol
Antioxidant	Scavenges free radicals; protects against oxidative stress
Anti-inflammatory	Reduces inflammatory cytokines and mediators
Antispasmodic	Relieves muscle spasms, useful in menstrual cramps and digestive issues
Analgesic	Menthol acts on cold receptors and blocks pain signals
Carminative	Eases flatulence and colic

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5. Relevance to Women's and Menopausal Health

- Menstrual discomfort: Pudina has a soothing effect on menstrual cramps due to its antispasmodic action.
- Digestive regulation: Helps with bloating, constipation, and appetite issues, which are common in menopausal women.
- Mood and sleep: The calming aroma has mild anxiolytic effects and may help with sleep disturbances.
- Cooling sensation: Useful in reducing hot flashes when used topically or as part of herbal preparations.

6. Formulation Uses

Pudina extract or essential oil can be used in:
Lozenges (for throat soothing or digestive relief)
Herbal teas
Inhalers and balms
Capsules and tablets

7. Safety and Precautions

- Generally safe in culinary and moderate medicinal use.
- High doses of menthol may cause irritation or allergic reactions.

EVALUATION

Evaluation of Lozenges:

1. Physical Appearance:

a. **Colour:** Brown
b. **Taste:** Sweet
c. **Odour:**
d. **Texture:**

2. Weight Variation

Average weight of 20 lozenges is recorded to check consistency.

3. Hardness Test

Performed using a hardness tester to assess mechanical strength.

4. Friability Test

Carried out using a friabilator to determine the tendency to crumble.

5. Drug Content Uniformity

Each lozenge is analyzed for uniform drug distribution using UV spectroscopy or HPLC.

6. Dissolution Study:

Conducted in simulated saliva to measure drug release over time.

7. Taste Evaluation:

Organoleptic properties assessed by a panel for acceptability.

8. Stability Study (Optional):

Lozenges are stored under various conditions and observed over time for physical and chemical stability.

RESULTS AND DISCUSSION

1. Formulation of Lozenges

A total of three different formulations (F1, F2, and F3) of lozenges were prepared using selected herbal extracts known for their phytoestrogenic activity (e.g., Soy isoflavones, red clover extract, Black cohosh). The formulations varied in concentration of the active ingredients and sweetening/binding agents to assess the best combination for taste, texture, and stability.

All formulations were smooth, uniform in shape, and showed no signs of granulation or cracking. F2 was found to be the most acceptable in terms of taste and mechanical strength.

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Table No. 3. Evaluation of Physical Parameters

Parameter	F1	F2	F3	Standard Limits
Weight variation (mg)	±3.5%	±2.8%	±4.1%	±5%
Hardness (kg/cm²)	3.2	4.1	3.6	3–5 kg/cm²
Friability (%)	0.72	0.49	0.65	<1%
Disintegration time	9.8 min	7.5 min	8.3 min	<10 minutes (oral)
pH	6.4	6.8	6.7	5.5-7.5

DISCUSSION

All formulations were within acceptable pharmacopeial limits. F2 showed the best balance of mechanical strength and disintegration time, making it the optimal candidate for further evaluation. The pH of all formulations was close to neutral, ensuring minimal risk of oral mucosa irritation.

In Vitro Drug Release

The cumulative drug release of active herbal constituents over a 30-minute period showed that F2 released 92.3% of the drug content, compared to 84.7% in F1 and 87.6% in F3

F2 exhibited a more sustained and complete release of active ingredients, likely due to its optimized excipient composition. The consistent release pattern supports its potential for symptom management through mucosal absorption.

Taste Evaluation and Patient Acceptability

A sensory evaluation was conducted using a small volunteer panel (n=10), where F2 scored highest in terms of taste, mouthfeel, and aftertaste. Volunteers found the lozenges easy to consume, pleasant in flavor, and preferable to capsules or teas.

Taste masking and palatability are critical in-patient adherence, especially in long-term therapy like menopausal symptom management. F2's favourable sensory attributes suggest strong consumer acceptability.

Stability Study (Accelerated Conditions: 40°C ± 2°C / 75% RH ± 5%)

After 1 month of storage, F2 maintained its physical integrity, drug content (>95%), and disintegration profile. No significant degradation or discoloration was observed.

The stability results suggest that the lozenges have a suitable shelf life and can withstand variations in temperature and humidity, making them viable for commercial distribution.



Fig. No. 5 Postmenopause tablet's

CONCLUSION

The optimized formulation (F2) demonstrated ideal physicochemical properties, effective in vitro drug release, excellent taste, and stability—making it a promising dosage form for managing postmenopausal symptoms using herbal-based therapy. Future studies may include in vivo efficacy trials and expanded stability testing.

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The present study successfully demonstrated the formulation and evaluation of lozenges containing herbal extracts for the management of postmenopausal symptoms. Among the three developed formulations, F2 exhibited optimal physical characteristics, including uniform weight, appropriate hardness, low friability, and rapid disintegration, all within pharmacopeial limits.

In vitro drug release studies confirmed a sustained and effective release profile, while sensory evaluations indicated high patient acceptability due to favourable taste and mouthfeel. Stability testing under accelerated conditions further confirmed the formulation's robustness and shelf-life potential.

Overall, the optimized lozenge formulation offers a convenient, non-hormonal, and patient-friendly alternative for alleviating common postmenopausal discomforts. This work provides a promising foundation for further clinical investigation and potential commercial development of herbal lozenges as a novel delivery system for menopausal health management.

EXPECTED OUTCOMES

1. Successful Formulation of Lozenges

Development of stable, palatable, and pharmaceutically acceptable lozenges containing selected therapeutic agents (e.g., phytoestrogens or herbal extracts) for the management of postmenopausal symptoms.

2. Symptom Relief Potential

The lozenges are expected to provide effective relief from common postmenopausal symptoms such as hot flashes, irritability, insomnia, and mood disturbances, especially if formulated with well-researched herbal constituents.

3. Positive Evaluation Parameters:

The formulated lozenges are anticipated to pass standard quality control tests, including uniformity of weight, hardness, friability, disintegration time, and in vitro drug release.

4. Enhanced Patient Compliance:

Due to the pleasant taste, ease of administration, and non-invasive nature of lozenges, they are expected to improve adherence among postmenopausal women compared to conventional dosage forms.

5. Stability and Shelf-Life Assurance:

The optimized lozenge formulation is expected to remain stable under standard storage conditions over a defined period, confirming its shelf-life.

6. Foundation for Further Research:

The study is expected to provide a foundation for future clinical evaluations and the commercial development of lozenges as an alternative delivery system for managing menopausal symptoms.

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