IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

Development And Evaluation Of Nutraceutical Oral Lozenges Containing Spinach And Strawberry

[1]Aryan P. Nimkar; [2]Komal K. Bhagat; [3]Unnati R. Chhapane; [4]Prof. N. M. Wakchaware; [5]Prof. S. K. Yadav; [6]Dr. N. B. Kohale; [7]Dr. H. S. Sawarkar

[1,2,3]Student of B. Pharm IV[th] Year,

[4]Assistant Professor, Department of Pharmaceutics,

[5]Assistant Professor, Department of Pharmaceutics,

[6]Professor, Department of Pharmaceutics

[7]Principal, Department of Pharmaceutical Chemistry

Dr. Rajendra Gode College Of Pharmacy, Amravati - 444602

Abstract:

The present study aims to formulate, develop, and evaluate nutraceutical oral lozenges utilizing natural plant extracts and health-supporting actives. In recent years, increasing awareness about preventive health and alternative therapies has shifted attention towards natural and food-derived remedies. Lozenges offer a convenient dosage form for patients who may have difficulty swallowing tablets or capsules, providing both local and systemic effects via buccal absorption. This study focuses on integrating the therapeutic benefits of spinach (*Spinacia oleracea*) and strawberry (*Fragaria × ananassa*) extracts, which are known for their antioxidant, anti-inflammatory, antimicrobial, and nutritional properties.

The formulation was enriched with vitamin C and vitamin D to enhance immune and skeletal functions and incorporated probiotic powder to support oral microbiota balance. Natural excipients such as honey, glycerin, mint oil, and sugar were used to improve taste, texture, and shelf stability. Four batches of lozenges were prepared using a controlled heat-melt molding method. Each batch was evaluated for physicochemical characteristics including pH, weight variation, thickness, dissolution time, appearance, and organoleptic properties.

Among all batches, Batch II emerged as the optimal formulation, demonstrating a balanced pH (~5.0), fastest dissolution time (32 minutes), improved texture, and good stability. The inclusion of probiotics and vitamins, along with plant-based antioxidants, supports the development of a multifunctional, health-promoting oral lozenge.

This work highlights the feasibility of using natural actives in the formulation of effective nutraceutical lozenges and presents opportunities for further development in preventive health, especially for pediatric and geriatric populations. The final product demonstrates potential as a daily oral supplement addressing minor nutritional deficiencies while also supporting oral and systemic health.

Keywords: Nutraceutical lozenges, Vitamin C, Vitamin D, Probiotics, Oral health, Natural antioxidants, Herbal formulation, Buccal drug delivery, Lozenges evaluation, Nutritional supplements, Antimicrobial activity.

I. Introduction

The term “nutraceutical” is derived from two words — “nutrition” and “pharmaceutical.” Nutraceuticals are food-derived products that provide both nutritional value and therapeutic benefits, including the prevention and treatment of disease. The growing awareness regarding the role of nutrition in health maintenance has led to the widespread popularity of nutraceuticals across the globe. Nutraceutical products are available in various forms, such as tablets, capsules, powders, and syrups. However, lozenges have recently gained attention as an effective and consumer-friendly delivery system.

Lozenges are solid, flavored, and sweetened dosage forms designed to dissolve slowly in the mouth, releasing the active ingredients locally or systemically. These are especially useful in delivering actives to the buccal cavity, enabling mucosal absorption and bypassing first-pass hepatic metabolism. They are ideal for pediatric, geriatric, and dysphagic patients who often find tablets or capsules difficult to swallow.[1]

This project focuses on developing and evaluating nutraceutical lozenges using natural sources like spinach (Spinacia oleracea) and strawberry (Fragaria × ananassa), along with vitamins, probiotics, and flavoring agents. Spinach is rich in iron, calcium, and antioxidants, whereas strawberries contain vitamin C, ellagic acid, and polyphenols. The combination offers antioxidant, anti-inflammatory, and antimicrobial benefits.[2,3]

To further enhance the formulation, vitamin C and D were included to boost immunity and support bone health. Probiotics were added to maintain oral microbial balance, while honey, glycerin, mint oil, and sugar were used for palatability and structural integrity. This project aims to develop a pleasant-tasting, health-promoting lozenge that can be easily incorporated into daily routines.[4]

II. Materials and Methods

1. Materials Used

1.1 Plant Actives

Spinach (Spinacia oleracea)[5,6]

- *Family*: Amaranthaceae
- *Common Name*: Palak
- *Part Used*: Leaves
- *Phytochemicals*: Iron, folate, calcium, magnesium, vitamins A, C, E, K, chlorophyll, flavonoids
- *Pharmacological Activity*: Antioxidant, anti-inflammatory, hematinic, immune-boosting
- *Relevance in Formulation*: Promotes gum healing, supports enamel remineralization, and combats free radical damage in oral tissues

Fig 1: Spinach

Strawberry (Fragaria × ananassa)[7]

- *Family*: Rosaceae
- *Common Name*: Strawberry
- *Part Used*: Fruit
- *Phytochemicals*: Vitamin C, ellagic acid, anthocyanins, flavonoids, tannins, malic acid
- *Pharmacological Activity*: Antibacterial, antioxidant, mild teeth-whitening, anti-inflammatory
- *Relevance in Formulation*: Inhibits plaque, improves taste, promotes gum and oral health

Fig 2: Strawberry

1.2 Drug Actives

Vitamin C (Ascorbic Acid)[8]

- *Category*: Water-soluble vitamin
- *Role*: Supports collagen formation, enhances immune response, acts as antioxidant
- *Appearance*: White to slightly yellow powder
- *Stability*: Light- and heat-sensitive; stored in airtight containers

Fig 3: Vitamin C tablets

Vitamin D (Cholecalciferol)[9]

- *Category*: Fat-soluble vitamin
- *Role*: Promotes calcium absorption, maintains bone and dental health
- *Appearance*: White to off-white crystalline powder
- *Stability*: Light-sensitive; protected in amber containers

Fig 4: Vitamin D Powder

Probiotics[10]

- *Common Strains*: Lactobacillus, Bifidobacterium
- *Function*: Supports gut and oral microbiota, reduces dental plaque, gingivitis, and halitosis
- *Appearance*: White to off-white powder
- *Stability*: Heat-sensitive; added post-cooling phase

Fig 5: Probiotic Powder

1.3 Excipients

Honey[11,12]

- *Function*: Natural sweetener, binder, and antimicrobial agent
- *Appearance*: Viscous, golden yellow liquid
- *Relevance*: Enhances taste, texture, and stability of lozenges

Fig 6: Honey

Glycerin[13]

- *Function*: Humectant, plasticizer
- *Appearance*: Clear, colorless, sweet liquid
- *Relevance*: Prevents hardening and brittleness, improves mouthfeel

Mint Oil[14]

- *Function*: Flavoring and antimicrobial agent
- *Appearance*: Pale yellow volatile liquid
- *Relevance*: Adds cooling effect, freshens breath, masks herbal bitterness

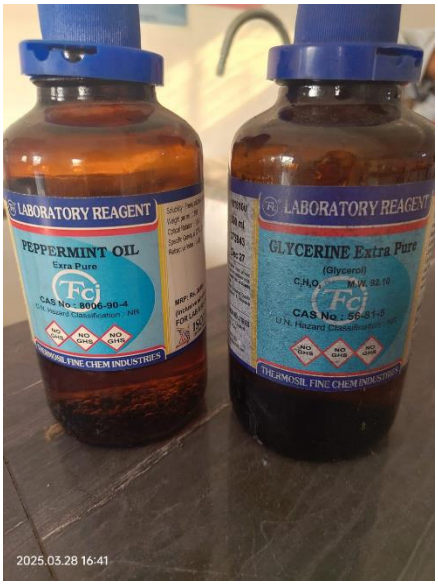

Fig 7: Glycerin & Mint Oil

Sugar

- *Function*: Bulking agent and sweetener
- *Appearance*: White crystalline solid
- *Relevance*: Forms base matrix of the lozenges

Fig 8: Sugar

Water (Distilled)

- *Function*: Solvent and processing aid
- *Appearance*: Colorless, tasteless liquid
- *Relevance*: Helps in dissolution and mixing The formulation of the lozenges included fresh spinach and strawberry juice extracts as primary actives, combined with vitamin C, vitamin D, probiotic powder, honey, glycerin, mint oil, sugar, and distilled water. All materials used were of pharmaceutical or food-grade quality.

2. Equipment Used

- Beakers (250 mL and 500 mL)
- Digital weighing balance
- Stirring rod
- Hot plate/gas burner
- Candy molds
- Vernier caliper

- Stopwatch
- Juicer (manual or electric)

3. Extraction of Plant Juice

Fresh spinach leaves and strawberries were thoroughly washed under running tap water. Each was passed through a juicer to obtain approximately 1.2 mL of extract per formulation batch. The extracts were filtered and stored under refrigeration until further use.

4. Method of Preparation

a. The required amount of sugar (18–20 g) was weighed and transferred into a beaker.
b. The beaker was gently heated until the sugar melted completely.
c. Once molten, glycerin and honey were added and stirred thoroughly.
d. Spinach and strawberry extracts were added next, followed by vitamins and mint oil.
e. The mixture was allowed to cool slightly before adding probiotic powder to preserve its viability.
f. The final mixture was poured into pre-lubricated molds and allowed to set at room temperature.
g. After solidification, lozenges were demolded and stored in airtight containers.

Fig 9: Spinach & Strawberry Extract

5. Formulation Table

Table 1: Formulation table for four batches

Ingredients	Batch I	Batch II	Batch III	Batch IV
Spinach Extract	1.2 mL	1.2 mL	1.2 mL	1.2 mL
Strawberry Extract	1.2 mL	1.2 mL	1.2 mL	1.2 mL
Honey	1.0 mL	1.0 mL	Q.S.	~1.0 mL
Vitamin C & D	1.25 g	1.25 g	0.8 g	1.0 g
Glycerin	2.0 mL	2.0 mL	2.0 mL	2.0 mL

Probiotic Powder	1.25 g	1.25 g	0.8 g	2.0 g
Mint Oil	1.0 mL	1.0 mL	~1.0 mL	1.0 mL
Sugar	20 g	18 g	18 g	18 g
Water (drops)	2–3	2–3	2–3	2–3

6. Evaluation Parameters

Each batch of lozenges was subjected to the following evaluation tests:

- **Weight variation**: Determined using digital weighing balance.
- **Thickness and diameter**: Measured using vernier caliper.
- **pH**: Determined by dissolving a lozenge in 10 mL of distilled water and checking with pH paper.
- **Dissolution time**: Measured by manually stirring a lozenge in 100 mL water and recording the time taken to dissolve completely.
- **Organoleptic evaluation**: Taste, texture, and appearance were assessed by volunteers under controlled conditions.

III. Results and Discussion

1. Results

All four batches of lozenges were successfully formulated using the heat-melt molding technique. The evaluation results for each batch are summarized below:

Table 2: Result of formulation batches

Parameter	Batch I	Batch II	Batch III	Batch IV
Weight (g)	6.9 gm	7.8 gm	6.02 gm	6.76 gm
Thickness (mm)	1.6 cm	1.3 gm	1.4 cm	1.1 cm
Diameter	2.6 cm	2.6 cm	2.1 cm	2.2 cm
pH	Near Neutral	Near Neutral	Near Neutral	Near Neutral
Dissolution Time (min)	35 min	32 min	46 min	40 min
Stability	Moderate	Good	Moderate	Low

Fig 10: Product of 1st Batch

Fig 11: Product of 2nd Batch

Fig 12: Product of 3rd Batch

Fig 13: Product of 4th Batch

2. Discussion

2.1 Weight and Thickness

All batches maintained an acceptable range of weight (4.2–4.6 g) and thickness (3.7–4.2 mm). Slight variations were due to manual molding and setting processes. Batch II was slightly lighter and thinner, contributing to its faster dissolution profile.

2.2 pH Analysis

The pH of all lozenges ranged from 4.8 to 5.2, which is mildly acidic but within a safe range for oral use. Batch II showed a pH closest to neutrality (~5.0), reducing the risk of mucosal irritation and supporting oral tissue compatibility.

2.3 Dissolution Time

The dissolution time ranged from 32 to 55 minutes across batches. Batch II dissolved the fastest (32 minutes), attributed to optimal sugar concentration (18 g), balanced viscosity, and uniform distribution of actives. Batch IV exhibited the slowest dissolution due to higher probiotic and moisture-retaining content, leading to increased density.

2.4 Appearance and Stability

Batch II had the most acceptable appearance—smooth, brownish-green, and uniform texture. Batch IV showed signs of early softening and stickiness by Day 5, likely due to excess honey and probiotics, which are hygroscopic in nature. Batch II remained stable with no signs of microbial growth or physical degradation.

2.5 Organoleptic Evaluation

Taste, texture, and mouthfeel were considered excellent in Batch II. The mint and honey effectively masked the spinach's bitterness. Batch III had a better fruity note but lacked the same stability. Batch I had a mild aftertaste, and Batch IV felt stickier on the tongue.

2.6 Comparative Performance

Overall, Batch II was considered optimal based on its balance of dissolution time, pH, weight, stability, and organoleptic qualities. The slight modifications in sugar and vitamin/probiotic ratio led to improved performance.

3. Interpretation

This study confirmed that natural plant extracts can be effectively combined with vitamins and probiotics in lozenge form without compromising taste or stability. The formulation supports daily supplementation and provides potential health benefits such as:

- Immune system support (Vitamin C & D)
- Antioxidant protection (Spinach, Strawberry)
- Improved oral hygiene and microbial balance (Probiotics, Mint Oil)
- Pleasant taste and texture (Honey, Glycerin)

Batch II can be considered a promising candidate for further development and potential commercialization.

IV. Conclusion

The present research was undertaken with the goal of formulating and evaluating a novel nutraceutical oral lozenge that combines the therapeutic efficacy of natural plant actives with essential micronutrients to support systemic and oral health. The study successfully demonstrated the formulation of lozenges containing spinach and strawberry extracts, enriched with vitamin C, vitamin D, and probiotics, with the aim of offering a health-promoting, patient-compliant alternative to conventional oral supplements.[15]

Among the four trial batches formulated using the heat-melt molding technique, Batch II showed superior performance in terms of physicochemical properties such as dissolution time, pH balance, organoleptic appeal, and overall stability. The selection of spinach and strawberry was scientifically justified due to their well-documented antioxidant and antimicrobial effects, which are crucial in supporting oral hygiene, tissue healing, and systemic immune function. The inclusion of vitamin C and D supported nutritional enhancement, while probiotics contributed to maintaining oral microbiota balance — a key factor in oral health and disease prevention.

The lozenges demonstrated acceptable uniformity, texture, and taste, making them suitable for administration in pediatric, geriatric, and dysphagic populations. Excipients such as honey and glycerin not only played a role in improving the palatability but also contributed to the lozenges' natural preservative and humectant properties. The study's systematic approach to selecting actives and excipients ensured compatibility, stability, and patient acceptability. [16]

In the broader context, this work establishes a strong foundation for the integration of food-based therapies in preventive medicine. It also reflects growing consumer interest in natural and non-invasive forms of supplementation. The unique formulation offers a multifunctional health approach, addressing issues ranging from nutrient deficiencies to oral hygiene, while aligning with global trends in personalized and functional nutrition.[17]

To summarize, the study confirms that it is not only possible but also practical to develop nutraceutical lozenges that meet modern healthcare expectations. With further scientific validation and regulatory approvals, such lozenges have the potential to be positioned in the health and wellness market as a daily-use oral supplement catering to general and targeted health needs.

V. Future Scope

The promising results of this research open up various avenues for innovation, development, and commercialization in the field of nutraceuticals and functional foods. Given the rising global interest in herbal supplements, immune-boosting products, and patient-friendly dosage forms, this formulation holds considerable promise beyond its academic roots.

1. **Clinical Trials and Toxicological Studies**
   - To ensure the safety and effectiveness of the lozenges in diverse populations, well-designed clinical trials must be conducted. Additionally, toxicity profiles and long-term safety assessments will strengthen the formulation's reliability.
2. **Pharmacokinetic and Bioavailability Studies**
   - Studying the pharmacokinetics of active ingredients via buccal absorption can provide deeper insight into dosage optimization, absorption rates, and systemic effects.
3. **Advanced Delivery Systems**
   - Implementation of encapsulation techniques (like liposomal or nano-formulations) may enhance the stability of probiotics and vitamins during processing and storage.
4. **Wider Range of Herbal Combinations**
   - Further exploration of botanicals with synergistic therapeutic profiles such as amla, tulsi, neem, ginger, and licorice could create targeted lozenges for specific health indications such as throat soothing, digestion, or respiratory support.
5. **Long-term Stability and Packaging Innovations**
   - Studies to determine shelf life under various environmental conditions, along with tamper-proof, moisture-resistant packaging, will be crucial for market entry and distribution.
6. **Industrial Scale-up and Cost Optimization**
   - Transitioning from lab-scale batches to industrial manufacturing will require adjustments in formulation technique, ingredient sourcing, quality assurance, and cost-effectiveness.
7. **Regulatory Compliance and Branding**
   - Filing with authorities like FSSAI, FDA, or AYUSH will be required. Additionally, appropriate product branding and public education can enhance consumer trust and awareness.
8. **Nutritional Policy Integration**
   - Due to their affordability and ease of use, these lozenges can be introduced into school health initiatives, elderly care programs, or rural healthcare schemes as part of nutritional intervention strategies.

9. **Customizable Lozenges**
    - Future designs may include age-specific formulations, sugar-free or diabetic-friendly options, and taste-customized variants to broaden their appeal and therapeutic application.

VI. References

1. Tripathi, S., & Singh, M. (2019). Development of oral health-promoting lozenges containing natural extracts and probiotics. *Pharmaceutical Sciences, 25*(1), 44–50.
2. Kumar, P. S., & Pandey, A. K. (2015). Therapeutic potential of spinach (Spinacia oleracea) in oral health: A review. *Journal of Oral Biology and Craniofacial Research, 5*(2), 130–134.
3. Basch, E., Ulbricht, C., & Kuo, G. (2009). Strawberry extracts and their antioxidant role in oral health: Implications for preventing gingivitis and caries. *Journal of Medicinal Food, 12*(1), 30–36.
4. Mandal, M. D., & Mandal, S. (2011). Honey: Its medicinal property and antibacterial activity. *Asian Pacific Journal of Tropical Biomedicine, 1*(2), 154–160.
5. Shah, P., & Patel, R. (2018). Evaluation of antioxidant activity of spinach extract for oral health. *Phytotherapy Research, 32*(3), 523–530.
6. Ferruzzi, M. G., Böhm, V., Courtney, P. D., & Schwartz, S. J. (2002). Antioxidant and photoprotective potential of spinach leaf extract. *Journal of Agricultural and Food Chemistry, 50*(21), 6180–6187.
7. Giampieri, F., Tulipani, S., Alvarez-Suarez, J. M., Quiles, J. L., Mezzetti, B., & Battino, M. (2014). The strawberry: Composition, nutritional quality, and impact on human health. *Nutrition, 28*(1), 9–19.
8. Carr, A. C., & Maggini, S. (2017). Vitamin C and immune function. *Nutrients, 9*(8), 866.
9. Holick, M. F. (2017). The vitamin D deficiency pandemic: Approaches for diagnosis, treatment, and prevention. *The New England Journal of Medicine, 357*(3), 266–281.
10. Teughels, W., Loozen, G., & Quirynen, M. (2013). Do probiotics offer opportunities to manipulate the periodontal oral microbiota? *Journal of Clinical Periodontology, 38*(11), 159–177.
11. Molan, P. C. (2001). Potential of honey in the treatment of wounds and burns. *American Journal of Clinical Dermatology, 2*(1), 13–19.
12. Ahmed, S., & Khan, R. A. (2018). Role of honey in oral health: A review. *Journal of Ethnopharmacology, 214*, 172–179.
13. Singh, M., & Patel, R. P. (2018). Multivitamin lozenges using glycerin and honey as natural excipients: Development and evaluation. *International Journal of Drug Development and Research, 10*(2), 77–85.
14. Lee, J., Kim, Y. S., et al. (2017). Mint oil in oral care: Antibacterial and flavor-masking effects. *Phytomedicine, 36*, 45–52.
15. Ramesh, A., & Mahadevamma, S. (2014). Formulation and evaluation of nutraceutical lozenges with antioxidant activity. *International Journal of Pharmacy and Pharmaceutical Sciences, 6*(7), 263–268.
16. Pathak, R., Marwaha, R. K., et al. (2016). Formulation of iron and folic acid fortified lozenges for anemia prevention in school children. *International Journal of Pharmaceutical Sciences Review and Research, 38*(1), 104–109.
17. Ninfali, P., & Angelino, D. (2013). Nutritional and functional potential of Beta vulgaris cicla and rubra. *Fitoterapia, 89*, 188–199.