

Formulation and Evaluation of Chewable Beetroot Lozenges for Multipurpose Health Benefits.

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Abstract

The present study was carried out to formulate and evaluate chewable lozenges prepared from fresh beetroot juice. Beetroot (*Beta vulgaris*) is a nutritious vegetable rich in betalains, nitrates, polyphenols, vitamins, and minerals. These bioactive compounds possess antioxidant and health-promoting properties. The aim of this study was to develop a convenient, palatable, and stable chewable lozenge formulation containing beetroot juice and to evaluate its quality using standard pharmaceutical tests. The chewable lozenges were prepared using fresh beetroot juice along with suitable excipients such as sweeteners and binding agents. The prepared lozenges were evaluated for organoleptic properties, weight variation, thickness, hardness, disintegration time, dissolution behavior, moisture content, and chewability. Organoleptic evaluation showed that the lozenges had an attractive reddish-purple color, pleasant taste, smooth texture, and acceptable appearance. The weight variation test indicated uniformity among the prepared lozenges, showing that each lozenge contained nearly the same amount of ingredients. Thickness measurements showed only minor variations, confirming uniform size and shape.

Disintegration testing showed that the lozenges disintegrated within an acceptable time suitable for chewable dosage forms. Dissolution studies were performed using USP Dissolution Apparatus II in 0.1 N hydrochloric acid at $37 \pm 0.5^\circ\text{C}$. The results showed satisfactory release of beetroot constituents from the lozenges, indicating good dissolution characteristics. Moisture content was determined by the loss-on-drying method and was found to be within acceptable limits, suggesting good product stability and reduced chances of microbial growth. The chewability test revealed that the lozenges were soft, easy to chew, and had a pleasant mouthfeel without sticking to the teeth. Overall, the results demonstrated that fresh beetroot juice can be successfully incorporated into chewable lozenges. The formulated lozenges showed satisfactory physical properties, stability, and release characteristics. Therefore, beetroot juice-based chewable lozenges may be considered a promising nutraceutical formulation with good consumer acceptability. Further studies on long-term stability and health benefits can be conducted to support their future therapeutic and commercial applications. **Keywords:** Beetroot Juice, Chewable Lozenges, Nutraceutical, Antioxidant, Dissolution Study, Evaluation Parameter

INTRODUCTION

In recent years, awareness regarding health, nutrition, and disease prevention has increased significantly due to unhealthy lifestyles, stress, poor dietary habits, and environmental pollution. These factors contribute to various health problems such as anemia, fatigue, cardiovascular diseases, obesity, and weakened immunity. As a result, people are increasingly preferring natural and herbal products that provide both nutritional and therapeutic benefits. This growing interest has promoted the development of nutraceuticals and functional foods, which are considered safer and associated with fewer side effects than synthetic drugs.

Among various natural products, beetroot (*Beta vulgaris*) is recognized as a highly nutritious vegetable with several medicinal properties. Beetroot contains essential nutrients such as iron, folic acid, potassium, magnesium, calcium, vitamins A, B-complex, and C, along with dietary fiber and carbohydrates. It is also rich in betalains, flavonoids, and polyphenols, which possess strong antioxidant and anti-inflammatory activities. These bioactive compounds help reduce oxidative stress and protect the body from chronic diseases such as cardiovascular disorders, diabetes, and cancer.

One of the major therapeutic benefits of beetroot is its role in improving hemoglobin levels due to its high iron and folic acid content. Iron is essential for red blood cell formation and oxygen transportation in the body. Regular consumption of beetroot may help reduce symptoms of anemia such as weakness, dizziness, and fatigue. Beetroot is also rich in dietary nitrates, which are converted into nitric oxide in the body. Nitric oxide helps relax blood vessels, improves blood circulation, and lowers blood pressure, thereby supporting cardiovascular health and enhancing physical performance.

Despite its nutritional and medicinal importance, fresh beetroot has limited acceptability because of its earthy taste and odor. In addition, fresh beetroot juice is highly perishable and prone to microbial spoilage, reducing its shelf life and convenience. Therefore, there is a need to develop a suitable dosage form that can improve stability, palatability, and patient compliance while preserving the beneficial properties of beetroot.

Chewable lozenges are considered an effective and patient-friendly dosage form. They are easy to administer, convenient to carry, and suitable for pediatric and geriatric patients who may experience difficulty swallowing tablets or capsules. Chewable lozenges also provide accurate dosing and improved stability compared to liquid formulations. The addition of sweeteners, flavors, and gelling agents improves taste, texture, and overall acceptability of the formulation.

The formulation of chewable beetroot lozenges offers a novel approach for delivering the nutritional and therapeutic benefits of beetroot in a stable and convenient form. The prepared lozenges may help improve hemoglobin levels, reduce fatigue, provide antioxidant protection, and support cardiovascular health. Evaluation parameters such as hardness, weight variation, thickness, friability, and organoleptic properties are essential to ensure the quality, safety, and stability of the formulation. Thus, chewable beetroot lozenges can be considered a promising nutraceutical product with improved patient compliance and multiple health benefits.

Objectives

- To formulate chewable lozenges containing beetroot extract or powder using suitable excipients.
- To evaluate the prepared lozenges for physicochemical parameters such as hardness, friability, weight variation, thickness, and disintegration time.
- To assess organoleptic properties like taste, color, and texture for better patient acceptability.

- To study the stability of the formulated lozenges under different storage conditions.
- To analyze the potential multipurpose benefits such as antioxidant activity, hemoglobin improvement, and energy enhancement.
- To develop a safe, effective, and patient-friendly +nutraceutical dosage form.

List Of Ingredient In Chewable Beetroot Lozenges:

Sr.No	Common Name	Properties	Quantity taken
1	Beetroot juice	Active /Therapeutic ingredient	10ml
2	Glycerin	Humectant,sweetening agent, softing agent	2ml
3	Gelatin	Binding agent	4g
4	Methlyparabeam	Preservative, Antimicrobial agent	0.04g
5	Sucrose	Sweetening Agent	8g
6	Papermint oil	Flavouring agent	2-3 drops

Active chemical constituent	Type of compound	Major phaemacological / therapeutic use
Betainin	Betallain pigment (betacyanin)	Powerful antioxidant, anti-inflammatory activity, protects cells from oxidative stress, provides natural red color to lozenges
Betacyanins	Pigment Compounds	Antioxidant activity, supports liver protection, reduces free radical damage
Betaxanthins	Pigment Compound	Antioxidant effect, supports detoxification and immune function
Dietary Nitrate	Inorganic Bioactive Compound	Converts to nitric oxide in the body, improves blood circulation, helps reduce blood pressure, enhances exercise performance
polyphenol	Phenolic compound	Antioxidant and anti-inflammatory activities, protects against cardiovascular disorders
flovoinoid	Secondary Metabolite	Free radical scavenging, antimicrobial and cardioprotective effects
Ascorbic Acid (vit c)	Vitamin	Enhances immunity, antioxidant effect, improves iron absorption
Rutin	Amino Acid Derivative	Maintains electrolyte balance and supports heart function
Potassium	Mineral	strengthens blood vessels, antioxidant activity

Betaine (Trimethylglycine)	Mineral	Supports liver function, reduces homocysteine levels, osmoprotective action
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Table No.2 : List of chemical constituent present in beetroot and there therapeutic use

Method of Preparation

Step-wise Method of Preparation of Chewable Beetroot Lozenges

Step 1: Collection and Preparation of Beetroot Juice

Fresh beetroot was collected and washed thoroughly with distilled water to remove dirt and impurities. The outer peel was removed carefully using a clean knife. The beetroot was then cut into small pieces and crushed using a mixer grinder to obtain the juice. The extracted juice was filtered through muslin cloth to remove fibrous particles and obtain clear beetroot juice for formulation.



Fig No.1 : Steps of Collection and Preparation of Beetroot Juice

Step 2: Weighing of Ingredients

All the ingredients required for the preparation of chewable beetroot lozenges were weighed accurately using a digital balance according to the formulation composition.

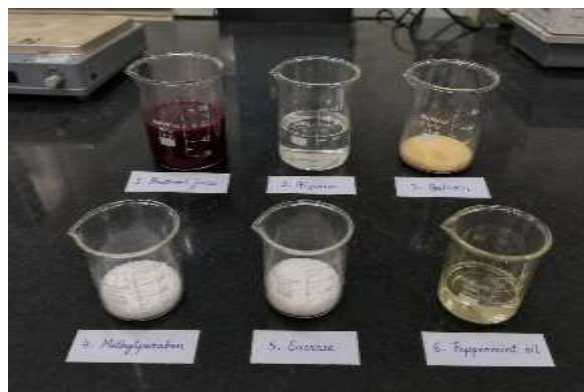


Fig No 2: Weighing of Ingredients

Step 3: Hydration of Gelatin

Gelatin was taken in a clean beaker containing a small quantity of purified water and allowed to soak for about 10–15 minutes. This process was carried out to ensure proper swelling and hydration of gelatin.



Fig No.3 : Hydration of Gelatin

Step 4: Preparation of Sugar Syrup

In a separate beaker, glycerin and powdered sugar were mixed together. The mixture was heated gently on a water bath with continuous stirring until the sugar dissolved completely and a clear syrup was formed.



Fig No 4: Preparation of Sugar Syrup

Step 5: Addition of Hydrated Gelatin

The hydrated gelatin was added slowly into the prepared sugar syrup with continuous stirring. Stirring was continued until a uniform viscous mixture was obtained without the formation of lumps.



Fig No 5: Addition of Hydrated Gelatin

Step 6: Incorporation of Beetroot Juice

Freshly prepared beetroot juice was added slowly to the viscous gelatin mixture with continuous stirring to ensure uniform distribution throughout the formulation. The temperature was maintained carefully to avoid degradation of the natural pigments and active constituents present in beetroot juice.



Fig No 6: Incorporation of Beetroot Juice

Step 7: Heating of the Final Mixture

The complete formulation was heated gently with continuous stirring until a smooth, homogeneous, and bubble-free mass was obtained. Excessive heating was avoided to prevent degradation of the natural color and phytoconstituents of beetroot.

Step 8: Molding of Lozenges

The prepared viscous mass was poured carefully into previously lubricated lozenge molds. Proper lubrication of molds was ensured to facilitate easy removal of the lozenges after setting.



Fig No 7 : Molding of Lozenges

Step 9: Cooling and Solidification

The filled molds were allowed to cool at room temperature until the lozenges solidified completely and attained the desired shape and consistency.

Step 10: Removal and Packaging

After complete setting, the chewable beetroot lozenges were removed carefully from the molds. The prepared lozenges were wrapped individually in butter paper or aluminium foil to protect them from moisture and environmental contamination.



Fig No 8: Removal and Packaging

Step 11: Storage of Prepared Lozenges

The prepared chewable beetroot lozenges were stored in airtight containers at room temperature .

Precautions During Preparation

Fresh beetroot juice should be filtered properly to remove fibrous particles.

Continuous stirring should be maintained during heating to avoid lump formation.

Excessive heating should be avoided because it may degrade the natural pigments and active constituents of beetroot.

The molds should be properly lubricated for easy removal of lozenges.

Prepared lozenges should be stored in airtight containers to prevent moisture absorption.

Principle of Preparation

Chewable beetroot lozenges were prepared based on the principle of the melting and molding technique. In this method, gelatin acts as a gelling agent and glycerin provides softness and chewability to the formulation. Fresh beetroot juice serves as a natural active ingredient containing antioxidants and natural coloring compounds. The prepared formulation provides prolonged retention in the oral cavity and improves patient acceptability due to its pleasant taste and chewable nature

Evaluation Parameter and Result

1) Organoleptic evaluation

Organoleptic evaluation is an important quality control parameter used to assess the sensory characteristics of beetroot lozenges, including color, odor, taste, texture, appearance, and mouthfeel. This test is based on the response of human sense organs to the formulation and helps determine the acceptability and palatability of the lozenges. organoleptic properties greatly influence patient compliance and consumer acceptance.

Result: The prepared beetroot lozenges were dark reddish-purple in color, with a pleasant beetroot odor and sweet taste. The lozenges showed a smooth texture, uniform appearance, and acceptable mouthfeel, indicating good organoleptic properties.

color – Dark reddish color

Odor –Characteristics Pleasant Beetroot Odour

Taste – sweet with mild beetroot Flavor
 Appearances _ uniform , glossy , and attractive
 Texture – Smooth
 Mouthfeel- Pleasant and Acceptable



Fig No 9: chewable Beetroot Lozenges

2) Weight Variation Test for Beetroot Lozenges

The weight variation test is an important quality control parameter used to evaluate the uniformity of dosage units in beetroot lozenges.

In this test, twenty lozenges are selected randomly from each batch and weighed individually using a calibrated digital analytical balance. The average weight is calculated, and the percentage deviation of each individual lozenge from the average weight is determined using the following formula:

Formula: % Deviation = (Individual weight – Average weight) / Average weight × 100

Acceptances Criteria: As per pharmacopeial limits (±5% for lozenges >250 mg).

Result:

Lozenges No.	Weight (mg)	Deviation From Average (mg)	% Deviation
1	1995	+5	-0.25
2	2965	+8	+0.40
3	1998	-2	-0.10
4	2005	+5	+0.25
5	1994	-6	-0.30
Average Weight	2000	-	-

Calculation

$$\% \text{ Deviation} = \frac{1995 - 2000}{2000} \times 100$$

$$= -0.25\%$$

All five lozenges showed weight variations within the acceptable pharmacopoeial limit of ±5%. Therefore, the prepared beetroot lozenges passed the weight variation test, indicating good uniformity of weight.



Fig No.10 : Measuring Weight of Beetroot lozenges

3) Thickness

This test ensures uniform size and shape.

Procedure: Measured using a Vernier calliper for 10 lozenges.

Acceptance Criteria: Minimal variation indicates uniform compression.

Result: The average thickness of the lozenges was found to be 4.2 ± 0.1 mm, indicating uniform size and thickness with minimal variation.



Fig no 11: Measurement of lozenge thickness using a Vernier caliper.

4) Hardness Test

Determines the mechanical strength of lozenges.

Procedure: Measured using a Monsanto or Pfizer hardness tester.

Acceptance Range: Typically 3–6 kg/cm² for chewable lozenges (should not be too hard)

Result: The average hardness of the lozenges was found to be 4.5 ± 0.2 kg/cm², indicating adequate mechanical strength and good chewability.

5) Disintegration Test for Chewable Beetroot Lozenges

Disintegration testing is an essential quality control parameter used to evaluate the ability of chewable lozenges to break down into smaller fragments under simulated physiological conditions. Although chewable lozenges are intended to be masticated, this test ensures product safety, uniformity, and performance in cases of incomplete chewing or accidental swallowing.

Apparatus APP DT 1000 Disintegration Test Apparatus

Basket-rack assembly (6 tubes with mesh screen)

Beaker (1000 mL capacity)

Thermostatically controlled water bath

Stopwatch-The APP DT 1000 apparatus operates with a controlled up-and-down movement of the basket assembly, ensuring uniform testing conditions.

Medium Dilute Hydrochloric Acid (0.1 N HCl)

Preparation: Dilute concentrated hydrochloric acid with distilled water to obtain 0.1 N HCl, simulating gastric fluid conditions.

Test Conditions: Temperature: $37 \pm 0.5^{\circ}\text{C}$

Volume of medium: 800–1000 mL

Number of units tested: 2 lozenges

Frequency of movement: 28–32 cycles per minute

Time duration: Up to 60 minutes

Procedure: Fill the beaker with 0.1 N dilute HCl and maintain the temperature at $37 \pm 0.5^{\circ}\text{C}$.

Place one lozenge in each tube of the basket-rack assembly.

Insert the assembly into the APP DT 1000 disintegration test apparatus.

Operate the apparatus, allowing the basket to move vertically in the medium.

Observe each lozenge and record the time required for complete disintegration.

Endpoint Determination

A lozenge is considered completely disintegrated when:

It breaks into soft, uniform fragments.

Result: The prepared chewable beetroot lozenges showed satisfactory disintegration in 0.1 N HCl at $37 \pm 0.5^{\circ}\text{C}$, with complete disintegration occurring within 32 ± 2 minutes. The formulation remained intact initially and gradually disintegrated without leaving a hard core, indicating acceptable quality and uniformity.



Fig No 12 : Disintegration test Apparatus

6) Dissolution Evaluation of Chewable Beetroot Lozenges

The dissolution study of chewable beetroot lozenges was carried out to determine the release profile of active phytoconstituents under simulated physiological conditions.

Apparatus

Dissolution testing was performed using USP Dissolution Apparatus II (Paddle type).

Dissolution Medium Medium: 900 mL of dilute hydrochloric acid (0.1 N HCl)

PH: 1.2 (to simulate gastric fluid conditions)

Temperature: $37 \pm 0.5^{\circ}\text{C}$

Paddle rotation speed: 70 rpm

Procedure

One lozenge was placed in the dissolution vessel containing 900 mL of preheated dissolution medium. The apparatus was operated at 70 rpm and maintained at 37°C throughout the experiment.

At predetermined time intervals (5, 10, 15, 20, 30, 45, and 60 minutes), 2 mL samples were withdrawn. The withdrawn samples were filtered using Whatman filter paper.

An equal volume of fresh dissolution medium was added to maintain sink conditions.

Analysis of Samples

The filtered samples were analysed using a UV-Visible spectrophotometer.

The absorbance was measured at the λ_{max} of beetroot extract (commonly around 538 nm for betalains). The concentration of released constituents was calculated using a previously prepared calibration curve.

Result

The dissolution profile of the prepared chewable beetroot lozenges was evaluated in 0.1 N HCl (pH 1.2) using USP Dissolution Apparatus II. UV-visible spectrophotometric analysis at 538 nm showed absorbance values ranging from 0.0034 to 0.0488, indicating the release of beetroot phytoconstituents into the dissolution medium. The formulation exhibited satisfactory dissolution behavior and consistent release characteristics under simulated physiological conditions.



Fig No.13; Dissolution Test apparatus

7) Moisture Content Determination

To determine the moisture content of chewable beetroot lozenges, which is critical for ensuring product stability, texture, microbial safety, and shelf life.

Method: The moisture content of the prepared lozenges was determined using the loss on drying (LOD) method.

Apparatus: Hot air oven

Procedure; Accurately weigh about 2–5 lozenge sample and transfer it into a previously dried and weighed moisture dish Record the initial weight (W_1).

Place the dish in a hot air oven maintained at 105°C.

Dry the sample for 3 hours or until a constant weight is obtained.

Remove the dish and allow it to cool to avoid moisture absorption from the environment.

Weigh the dish again and record the final weight (W_2).

Repeat drying and weighing if necessary until a constant weight is achieved.

Calculation: Moisture Content (%) = $\frac{W_1 - W_2}{W_1} \times 100$

Where: W_1 = Initial weight of sample (before drying)

W_2 = Final weight of sample (after drying)

Evaluation Parameters

The moisture content of chewable lozenges should typically be within the range of 1–5% w/w.

Higher moisture content may lead to:

Microbial growth Stickiness or deformation

Reduced shelf life

Lower moisture content may cause:

Excess hardness

Poor mouthfeel

Result:

Parameter	Value
Number of lozenges	5
Initial weight (w_1)	10.00 g
Final weight After dry w_2	9.75 g
Weight Loss	0.25g

Calculation:

Moiture Content: $\frac{W_1 - W_2}{W_1} \times 100$

$$= \frac{10.00 - 9.75}{10.00} \times 100$$

=2.5%

Result :

The moisture content of the prepared beetroot chewable lozenges was found to be 2.5% w/w. The value was within the acceptable limit (1–5% w/w), indicating good stability, texture, and storage characteristics of the formulation.

8) Chewability Test

The chewability of prepared beetroot lozenges was evaluated by chewing the lozenges manually to check texture, softness, and mouthfeel.

Result: The lozenges showed good chewability with a soft and pleasant texture and were easy to chew without sticking to teeth.

Result

The prepared beetroot chewable lozenges were evaluated for various quality parameters. The lozenges showed uniform appearance, acceptable weight variation, satisfactory thickness and hardness, rapid disintegration, and good dissolution characteristics. The moisture content (2.5% w/w) was within acceptable limits, indicating good stability and storage properties. The lozenges also exhibited good chewability with a soft texture, pleasant mouthfeel, and no sticking to teeth. Overall, the formulation complied with the desired quality requirements and was found suitable for oral administration.

Conclusion

Chewable beetroot lozenges were successfully formulated and evaluated for various quality control parameters. The prepared lozenges showed satisfactory organoleptic properties, uniform weight distribution, consistent thickness, and adequate hardness. Disintegration and dissolution studies demonstrated effective release of beetroot phytoconstituents, while moisture content remained within acceptable limits, indicating good product stability. The chewability assessment confirmed a pleasant texture and good patient acceptability. Overall, the developed chewable beetroot lozenges proved to be a stable, palatable, and effective nutraceutical formulation that may provide the health benefits associated with beetroot bioactive constituents such as betalains, dietary nitrates, polyphenols, vitamins, and minerals. Further studies on long-term stability and clinical efficacy may be carried out to establish their therapeutic potential.

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