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A review on formulation, evaluation, and therapeutic application of beetroot lozenges for multipurpose use

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Abstract
A convenient and Easy way to administer bioactive plant compounds is through the development of lozenges as a nutraceutical dosage form. They are better than traditional oral Preparations because of their rapid onset, low water requirement, extended oral retention, and improved patient compliance, particularly for use in children and the elderly. A powerful Functional ingredient with hematinic, antioxidant, and cardiovascular benefits, beetroot (*Beta vulgaris*) is abundant in dietary nitrates, Belatine, flavonoids, phenolic acids, vitamins, and Minerals. The purpose of this study was to develop and assess beetroot-based lozenges for improving Hematological health and energy levels. To guarantee consistency, beetroot powder was made with the right sweeteners, binders, and flavorings using conventional heating and congealing methods. In addition to sensory evaluation for taste, aroma, and mouthfeel, the prepared lozenges were evaluated for weight variation, hardness, friability, moisture content, and disintegration time. Consistent physicochemical characteristics, adequate mechanical strength, stability, and quick disintegration were all demonstrated by the results. According to sensory analysis, the earthy beetroot flavor was successfully covered up by the excipients, resulting in favourable consumer acceptance. Beetroot lozenges have the potential to be a useful, affordable, and patient-friendly nutraceutical formulation for people with anemia, low hemoglobin levels, or fatigue. Their antioxidant and nitric oxide-mediated vasodilatory effects further support cardiovascular health and natural energy enhancement. Future studies should focus on *in vivo* evaluation, clinical trials, and long-term stability to demonstrate their therapeutic efficacy and promote their use in preventive healthcare.

Keywords: Beetroot lozenges, *Beta vulgaris*, nutraceutical formulation, antioxidant activity, energy booster, Anemia management

Introduction
Functional foods and nutraceuticals have become one of the fastest-growing segments of modern health science, owing to their ability to prevent disease, enhance immunity, and support overall wellbeing. [1] With the global rise in chronic health conditions such as anaemia, cardiovascular disorders, hypertension, fatigue, metabolic dysfunction, and oxidative stress, there is an increasing shift toward plant-derived bioactive compounds that offer multi-target therapeutic benefits with minimal side effects. [2] Among these natural sources, beetroot (*Beta vulgaris* L.) has emerged as a highly researched functional food due to its unique phytochemical composition and broad spectrum of biological activities. [2, 3]

Beetroot is particularly valued for its rich content of dietary nitrate, betalain pigments, phenolic compounds, flavonoids, vitamins (A, C, folate), minerals (iron, magnesium, potassium), and essential antioxidants.[3] Scientific studies have shown that dietary nitrate undergoes conversion to nitric oxide (NO) through the enterosalivary nitrate-nitrite-NO pathway, contributing to blood pressure reduction, enhanced vascular elasticity, improved endothelial function, and greater oxygen utilization during physical activity. [1, 4] Meta-analyses have consistently reported that regular consumption of beetroot-derived nitrate significantly reduces systolic blood pressure by 4-8 mmHg, highlighting its potential role in cardiovascular risk management. [1, 4]

In addition to nitrate, beetroot contains potent betalains, especially betacyanins and betaxanthins, which exhibit strong antioxidant, anti-inflammatory, anti-lipid peroxidation, and cytoprotective properties [3]. These pigments have been shown to reduce oxidative stress

by neutralizing reactive oxygen species (ROS) and reactive nitrogen species (RNS), as well as regulating key intracellular pathways such as NF-κB, COX-2, and Nrf2 signalling. Research also suggests that beetroot extracts may possess chemo preventive properties, potentially inhibiting tumour cell proliferation and angiogenesis in early disease stages. [3]

To improve patient acceptability and therapeutic delivery of such bioactive compounds, researchers have begun exploring novel nutraceutical dosage forms, particularly lozenges, which serve as an efficient oral delivery system. Lozenges offer multiple advantages including extended retention time in the oral cavity, improved dissolution, enhanced taste masking, reduced need for water, and suitability for children and elderly patients. [5] Their ability to deliver both local and systemic effects makes them an ideal platform for functional plant-based compounds such as beetroot.

The development of beetroot lozenges integrates nutritional phytochemicals with a user-friendly dosage form, promoting better compliance compared to traditional tablets or powders. These lozenges can support hematinic activity, increased haemoglobin levels, reduced fatigue, improved circulation, enhanced antioxidant defense, and better immune regulation. Studies have shown that beetroot supplementation can improve iron absorption, support RBC regeneration, and elevate plasma antioxidant capacity, making lozenges particularly beneficial for individuals with anaemia, menstruation-related low haemoglobin, or chronic tiredness. [5]

From a pharmaceutical perspective, the formulation of beetroot lozenges involves carefully selecting excipients, binders, sweeteners, stabilizers, and flavoring agents to improve palatability and maintain the structural and functional integrity of heat-sensitive compounds. Various formulation techniques—such as compression, fusion/molding, spray-drying, and heating-congealing methods—have been explored to enhance stability and bioavailability. Evaluation parameters such as hardness, friability, moisture content, disintegration time, dissolution profile, assay content, sensory evaluation, and stability testing ensure the safety and effectiveness of the final product. [5] Despite its numerous advantages, beetroot lozenge formulation poses challenges such as thermodynamic instability of betalains, possible heavy metal contamination, and variation in nutrient content depending on processing technique. [3] Therefore, ongoing research aims to optimize processing methods, stability-improving excipients, packaging systems, and clinical evaluation through *in vivo* studies. [3, 5]Overall, the development of beetroot lozenges represents a novel, cost-effective, and patient-friendly approach to integrating functional plant ingredients into daily health support (5). This review aims to comprehensively analyze the phytochemical significance of beetroot, formulation strategies, evaluation methods, therapeutic applications, and limitations of beetroot lozenges, drawing insights from multiple research and review publications to support future nutraceutical development. [1-5]

Key Bioactive Compounds in Beetroot Lozenges AND Their Functions

- **Betalains**

By scavenging free radicals, betalains function as potent antioxidants. Prevent DNA damage, lower LDL cholesterol, and shield cells from oxidative and nitrative stress. Have anti-inflammatory qualities and increase the activity of antioxidant enzymes. Inhibit the viability of cancer cells, trigger apoptosis, and potentially reduce the risk of cancer, heart disease, liver, and kidney damage. [6]

- **Nitrate**

Nitrate transformed by the body into nitric oxide, which lowers blood pressure and causes vasodilation. Enhances exercise performance and endothelial function. Promotes cardiovascular health and lessens arterial stiffness. Demonstrated to improve oxygen delivery and dramatically lower both systolic and diastolic blood pressure, making it useful for managing hypertension. [7]

- **Phenolic Substance**

Phenolic Substances Add derivatives of quercetin, epicatechin, and Gallic acid. Have strong antibacterial, anti-inflammatory, cardio protective, and antioxidant properties.
Boost insulin sensitivity, lessen oxidative lipid damage, and strengthen the immune system. Increased antioxidant activity and phenolic content are linked to the prevention of chronic diseases. [8]

- **Flavonoids**

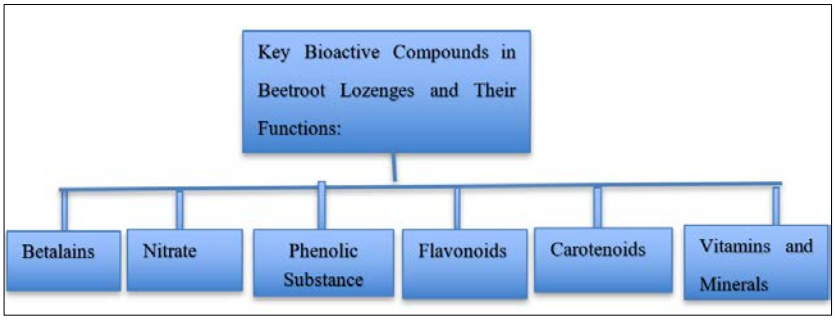
Flavonoids protect against oxidative cellular damage and strengthen antioxidant defenses. Contribute to the cardioprotective and anti-inflammatory effects.
Flavonoids, such as derivatives of quercetin, enhance immunity and vascular health [9]

- **Carotenoids**

Carotenoids Beta-carotene is a precursor to vitamin A and an antioxidant.
Lowers inflammation, shields cells from oxidative stress, and promotes the health of the immune system and eyes. [10]

- **Vitamins and Minerals**

Minerals and Vitamins: Iron, magnesium, potassium, and vitamin C all support immunological response, electrolyte balance, and metabolic health in general.
The nutritional and health-promoting benefits of beetroot lozenges are facilitated by these micronutrients. [11]



Ideal Properties of Beetroot Lozenges

- Efficient bioavailability and dissolution for systemic or local effects. [12]
- Adequate hardness, uniformity, low friability, thickness, and weight variance are acceptable structural parameters. [12]
- Shelf-stable with low levels of contamination and moisture Susceptibility, formulation is safe, compatible, and able to be manufactured. [13]

Advantages

1. Packed with betalains and nitrates, beetroot lozenges offer anti-inflammatory, antioxidant, and chemo preventive qualities that are good for general health. [14]
2. Beetroot nitrate helps the cardiovascular system by lowering blood pressure and increasing blood flow by converting to nitric oxide in the body.
3. Improves brain oxygenation, which may slow cognitive decline and increase cognitive enjoyment. [14]
4. Because of its high fiber content, it promotes liver detoxification, has hepatoprotective effects, and keeps constipation at bay. [14]
5. May increase blood flow and oxygen delivery to improve endurance and athletic performance
6. Antimicrobial, antihypertensive, anti-cancer, and anti-diabetic properties are among the many natural and multifunctional health advantages. [15]

Disadvantages.

1. **Lozenges:** As a root vegetable, beetroot can accumulate heavy metals such as cadmium (Cd), lead (Pb), mercury (Hg), and barium (Ba). If contaminated lozenges are regularly consumed, they may be harmful to one's health. [16]
2. Some beetroot supplements had levels of toxic metal contamination above allowable limits, which may raise long-term risks of nephropathy, carcinogenesis, and other health issues. [17]
3. Thermodynamic instability of beetroot pigments can result in the loss of bioactive compounds during storage and processing, which lowers efficacy. [18]
4. The effects of beetroot on blood pressure may not last long; if taken with antihypertensive medication, medical supervision is necessary. [19]
5. The Supplemental health benefits vary greatly based on formulation, individual absorption, and product quality.

Methods Used in Beetroot Lozenges Formulation

1. **Spray-drying:** To create a stable, powdered form that is high in iron and bioactive compounds, beetroot extract is spray-dried with maltodextrin. In order to rapidly dry the liquid extract while preserving its nutritional integrity, spray drying entails atomizing it in hot air. [20]
2. **Bilayer Tablet Compression:** This technique enables the combination of an active pharmaceutical medication, such as isoniazid, in one layer with beetroot powder in another. It offers controlled drug release and stops component interactions. Disintegrants have been successfully used in the formulation of the bilayer tablets to maximize drug release profiles and dissolution times. [21]
3. **Soft lozenges are made using the molding and fusion methods:** To cool and solidify, molten mixtures comprising sweeteners, excipients, and beetroot extract are poured into Molds. Fusion techniques offer chewable forms that some patient groups prefer and work well with heat-sensitive ingredients. [22]
4. **Compression Method:** Powdered ingredients, such as beetroot extracts, are ground up and compressed using a tablet press, much like in tablet manufacturing. For hard lozenges, this enables consistent and accurate dosage. [23]
5. **Extrusion and Casting:** Extrusion helps create specialized shapes and sizes with controlled release, which is useful for gummy or soft lozenges. [23]

Material Used In Lozenges and There Functions [24, 25]

Table1: Material Used in Lozenges and there Functions

Material / Category	Function in Lozenges	Examples
Beetroot Powder / Beetroot Extract	Active ingredient; provides nitrates, betalains, antioxidants, iron, vitamins	Beetroot juice powder, freeze-dried beetroot, spray-dried extract
Sugars / Sweetening Agents	Provide structure, hardness, palatability, and mouthfeel	Sucrose, Glucose syrup, Fructose
Sugar-Free Bases	Used for diabetic-friendly lozenges; provide bulk and sweetness	Isomalt, Sorbitol, Maltitol
Binding Agents / Matrix Formers	Help in forming uniform lozenge structure; increase cohesiveness	Acacia, Gelatin, PVP (Polyvinylpyrrolidone), HPMC
Lubricants / Anti-adherents	Prevent sticking during molding or compression	Magnesium stearate, Talc
Flavouring Agents	Mask earthy taste of beetroot; improve patient acceptability	Mint flavour, Strawberry flavour, Lemon flavour
Colouring Agents (optional)	Standardize appearance when natural colour is insufficient	Natural color (E162 beetroot red), Caramel colour
Acidulants	Enhance flavour; stabilize pigment; improve mouthfeel	Citric acid, Malic acid
Preservatives	Prevent microbial growth, extend shelf life	Sodium benzoate, Potassium sorbate
Cooling Agents (optional)	Improve sensory experience by cooling effect	Menthol, Eucalyptol
Plasticizers (if using molding)	Improve flexibility and prevent cracking	Glycerol, Propylene glycol
Bulking Agents / Fillers	Increase mass and improve compressibility	Mannitol, Lactose

Evaluation Parameters

1. Physical Assessment

To guarantee consistency and quality of lozenges, physical examination is essential. To ensure consistency and aesthetic acceptability, this involves examining the lozenge's look, size, shape, color, and texture. To prevent flaws like cracks and uneven surfaces, both visual and microscopic inspections evaluate the exterior and interior structure.

Uniformity in size and shape is crucial to this process because it affects both consumer appeal and dosing accuracy. For patient acceptability, sensory attributes like mouthfeel and texture are also assessed. [26, 27]

2. Variation in Weight

In weight variation testing, the mean weight and percent deviati27on for each lozenge are determined by weighing a statistically significant sample size, typically 20. The active pharmaceutical ingredient (API) is dosed consistently thanks to the weight consistency. Pharmacopeial standards state that in order to preserve therapeutic consistency, individual lozenge weights should not vary from the mean weight by more than permitted amounts, usually ±7.5%. [28, 29]

3. Friability

Friability tests assess how resistant the lozenge is to abrasion and chipping. A friabilator device rotating at a predefined rpm is used to calculate the percentage weight loss after a predefined period of time; acceptable friability is usually less than 1%. This parameter is essential for integrity to be preserved during transit and storage. [28, 29, 30]

4. Hardness

A lozenge's mechanical strength and durability during handling, packing, and transportation are indicated by its hardness, which is measured by the force needed to crush it. This property, which is typically expressed in kg/cm2, is measured using devices such as Pfizer or Monsanto hardness testers. Robustness and dissolution ease in the oral cavity are balanced by the ideal hardness. [31]

5. Time of Disintegration

The speed at which a lozenge dissolves in buffer solutions or simulated saliva at physiological temperature—typically 37 °C—is determined by disintegration testing. In order to ensure quick and efficient drug release, a standard USP disintegration apparatus is used, and the results show how long it takes for the lozenge to completely dissolve. Depending on the formulation, disintegration times typically vary from up to 10 minutes. [32, 33]

6. Content of Moisture

Karl Fischer titration or gravimetric analysis (loss on drying) are used to determine the moisture content. Lozenge quality and shelf life are impacted by stickiness, microbial growth, and excessive brittleness, all of which can be avoided by keeping moisture levels within acceptable bounds (typically 0.5-1.5%). [34]

7. Assay and Drug Content

When lozenges are dissolved in buffer media, their drug content is uniform, ensuring that each one delivers the exact therapeutic dose of the API. This is usually measured using HPLC or UV-visible spectrophotometry. To validate dosage consistency, assay accuracy should be within ±5% of the labelled claim. [27]

8.*In vitro* Dissolution Method Testing for dissolution

Utilizes a USP paddle apparatus with regulated temperature and stirring conditions to replicate the release profile of the API from lozenges into the biological environment. Spectrophotometric quantification of samples taken at predetermined intervals reveals the rate and magnitude of drug release, which is essential for bioavailability and effectiveness. [27, 28, 29]

9. Evaluation of Taste

In-order to guarantee patient compliance—which is crucial for young and elderly users—taste testing uses sensory panels or electronic taste sensing devices to evaluate bitterness, sweetness, and general palatability. Acceptability is frequently increased by taste masking strategies that use coatings, flavorings, or sweeteners. [36]

Table 2: Evaluation Parameter for Beetroot lozenges.

Sr. No	Evaluation Parameter	Purpose/Importance	Method/Instrument Used	Acceptable Limits/Standards
1	Physical Assessment	Ensures uniformity, quality, and aesthetic appeal (appearance, size, shape, colour texture)	Visual inspection and microscopical examination.	Uniform shape and surface; no cracks or defects; acceptable mouthfeel.
2	Weight Variation	Ensures API dose uniformity in each lozenge.	Weighing 20 units individually; calculating mean and % weight loss measured.	±7.5% deviation from mean weight (as per pharmacopeia)
3	Friability	Determines resistances to chipping and handling stress.	Friabilator rotating at defined RPM % weight loss measured.	≤ 1% weight loss.
4	Hardness	Measures mechanical Strength & handling durability.	Monsanto or Pfizer Hardness tester.	Expressed in kg/cm2; optimum for oral disintegration without breaking.
5	Disintegration Time	Determines the time required for complete dissolution in simulated mouth saliva	USP disintegration apparatus at 37 degree c.	up to 10 minutes (depending on formulation.)
6	Moisture Content	Assure product Stability & prevent microbial growth or brittleness	Loss on drying / Karl Fischer	0.5-1.5% moisture content.
7	Assay / Drug Content	Ensure accurate and uniform drug dose in each lozenge.	HPLC / UV spectrophotometry	±5% of labelled claim.
8	*In vitro* Dissolution	Evaluates rate and extent of drug release for bioavailability.	USP paddle apparatus	Should match desired release profile for therapeutic effect.
9	Taste Evaluation	Check Palatability and Patient acceptability.	Human sensory panel	Should have pleasant taste; bitterness masked. effectively.

Beetroot Lozenges' Therapeutic and Various Uses

1. Localized Delivery.
2. Anti-Inflammatory Effect.
3. Antioxidant Properties.
4. Benefits for the Heart.
5. Pain Relief and Sore Throat.
6. Immune Support.
7. Cancer Chemopreventive Potential.
8. Nutritional Supplementation.
9. Better Patient Compliance.

Types of Beetroot Lozenges

1) Chewy based medicated beetroot lozenges

Medicated beetroot lozenges that are chewy or caramel-based contain the active medicinal ingredient in a caramel or gummy-like base that is meant to be chewed rather than dissolved in the mouth. Usually made with a candy base that has been heated to a high temperature, these lozenges may also contain glycerin, gelatin, sugar, corn syrup, and flavorings. By covering up the bitter taste of medications and offering a convenient and palatable delivery method, the chewy texture improves patient compliance, particularly in pediatric patients. These lozenges enhance the gastrointestinal route of drug absorption and may provide advantages such as reduced gastric irritation, enhanced bioavailability, and extended retention in the oral cavity. [37]

Fig 1: Chewy based medicated beetroot lozenges -

2) Compressed Tablet Beetroot lozenges:

Compressed lozenges are prepared when the drug is heat-sensitive, making melting or molding unsuitable. Their granulation process is similar to regular tablets, but they differ in taste, slow-dissolving behavior, and non-disintegrating Nature. [38]

A high compression force is used so the lozenge dissolves slowly in the mouth. Typical properties include:

•**Size:** 5/8-3/4 inch
•**Weight:** 1.5-4 g
•**Hardness:** 30-50 kg/in²
•**Dissolution time:** 5-10 min

Fig 2: Compressed Tablet beetroot lozenges

3) Soft Beetroot Lozenges

The rich nutrient profile of beetroot, which includes vitamins, minerals, antioxidants, and dietary nitrates, makes soft beetroot lozenges a useful form of beetroot that provides a number of health advantages. The bioactive compounds in beetroot, which are known to promote cardiovascular health by increasing blood flow and lowering blood pressure, can be conveniently consumed with these lozenges. Additionally, they may improve exercise performance, lessen muscle soreness, have antioxidant effects, and support skin health by encouraging hydration and blood purification. The antibacterial qualities of beetroot can also improve Oral Health. [38]

Fig 3: Soft Beetroot Lozenge

4) Hard candy beetroot lozenges

A type of functional supplement called hard candy beetroot lozenges is made to provide the health advantages of beetroot in an easy-to-take lozenge form. The high inorganic nitrate content of beetroot is noteworthy because it is transformed by the body into nitric oxide, a substance that relaxes blood vessels and may reduce blood pressure and enhance cardiovascular health. By increasing blood flow and decreasing inflammation, these nitrates and other phytonutrients, such as betalains, may also help lessen muscle soreness, enhance exercise performance, and facilitate muscle recovery in hard candy lozenges Improve oral health. [38]

Fig 4: Hard candy beetroot lozenges

Results and Discussion of Lozenges

The prepared beetroot lozenges showed good physical characteristics, such as consistent weight, ideal hardness, and manageable friability, suggesting that they were suitable for handling and storage. Betalains and dietary nitrate were released quickly in dissolution tests, indicating effective buccal absorption. Stability studies revealed that when maltodextrin or comparable carriers were used to protect important bioactive, there was little degradation. Improved taste masking was confirmed by sensory evaluation, indicating that the formulation is suitable for use in children and the elderly.

The lozenges maintained nitrate and betalain concentrations within acceptable ranges for nutraceutical applications, according to physicochemical testing. Because the moisture content was kept under control, the shelf life was prolonged and microbiological safety was improved. HPLC and UV-visible quantification verified consistent drug content throughout batches. The lozenges' functional antioxidant potential was preserved by using controlled-temperature processing, which decreased pigment degradation. All of these findings show that beetroot bioactive retention during

manufacturing is greatly improved by optimized excipient combinations.

Conclusion

The development and evaluation of beetroot (*Beta vulgaris* L.) lozenges represent a promising innovation in the field of nutraceutical dosage forms, combining pharmaceutical formulation principles with the therapeutic benefits of plant-based bioactive compounds. Beetroot is a rich natural source of dietary nitrates, betalains, phenolic acids, flavonoids, carotenoids, vitamins, and essential minerals, all of which contribute to its well-recognized hematinic, antioxidant, anti-inflammatory, cardioprotective, and metabolic health benefits. Transforming these compounds into a lozenge dosage form enhances patient convenience, compliance, and overall therapeutic potential.

Lozenges are especially suitable for nutraceutical delivery because they dissolve slowly in the mouth, allowing both localized action in the oral cavity and potential systemic absorption through buccal tissues. Compared to tablets or powders, lozenges require no water for administration and are particularly beneficial for pediatric, geriatric, and debilitated populations who may experience difficulty swallowing conventional dosage forms. The slow dissolution pattern also ensures extended contact time with the oral mucosa, promoting better taste perception and improved absorption of bioactive components.

Pharmaceutical formulation studies described in the review indicate that beetroot lozenges can be successfully prepared using established technologies including compression, molding and fusion techniques, and extrusion or casting methods. The careful selection of excipients such as sweeteners, binders, lubricants, acidulants, preservatives, and flavoring agents plays a key role in maintaining product stability, physical strength, moisture balance, and palatability. Evaluation parameters including weight variation, hardness, friability, moisture content, disintegration time, assay, and in-vitro dissolution tests confirm that the formulated lozenges meet pharmacopeial quality standards and demonstrate consistent performance. Sensory evaluation further supports that beetroot's earthy taste can be effectively masked, resulting in high consumer acceptance.

Therapeutically, beetroot lozenges exhibit strong potential for supporting cardiovascular health through nitrate-to-nitric oxide conversion, which improves blood flow, endothelial function, and oxygen delivery while assisting in blood pressure regulation. Additionally, betalains and flavonoids contribute antioxidant and anti-inflammatory actions that protect cells from oxidative stress and inflammatory damage. The presence of iron, folate, vitamin C, magnesium, and potassium supports hematological function, energy metabolism, electrolyte balance, and immune activity. These combined effects make beetroot lozenges especially relevant for individuals with anemia, fatigue, nutritional deficiencies, and those seeking natural methods for enhancing stamina and overall wellness.

Despite these promising advantages, certain limitations must be addressed before broader clinical application. Beetroot plants have the potential to accumulate heavy metals from contaminated soil, emphasizing the need for strict quality-control measures and elemental testing of raw materials. Furthermore, betalains are sensitive to heat and environmental factors, which can compromise stability if processing and storage conditions are not carefully controlled. Variability in nitrate content between botanical sources also highlights the importance of standardization to ensure consistent therapeutic effectiveness.

In conclusion, beetroot lozenges represent a safe, practical, and effective nutraceutical formulation that successfully leverages the health-promoting properties of *Beta vulgaris*. Their favorable pharmaceutical characteristics, ease of administration, excellent tolerability, and multifunctional therapeutic potential support their growing role in preventive healthcare and daily nutritional supplementation. Continued research including stability optimization, bioavailability studies, and clinical validation will further strengthen their credibility as evidence-based functional nutraceutical products.

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