Formulation Development, Phytochemical Screening, And Quality Standardization of Polyherbal Nutraceutical Lozenges for Sore Throat Management

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***Abstract*—Background: Nutraceuticals represent a vital frontier in preventive medicine, offering therapeutic benefits ranging from antioxidant support to the management of chronic conditions like hypertension and diabetes. Incorporating these bioactive compounds into lozenges provides a highly effective, localized delivery system that allows active principles to be absorbed through the buccal mucosa or targeted directly at the pharyngeal lining. Objective: The primary objective of this study was to formulate a stable, palatable polyherbal nutraceutical lozenge tailored for the relief of sore throat and upper respiratory discomfort, and to establish rigorous standardization parameters to ensure its quality and reproducibility. Materials and Methods: The lozenges were formulated using a synergistic blend of natural ingredients with proven therapeutic properties, including *Zingiber officinale* (Ginger), *Glycyrrhiza glabra* (Licorice), *Coriandrum sativum* (Coriander), *Apis mellifera* (Honey), *Citrus limon* (Lemon), *Ocimum sanctum* (Tulsi), *Curcuma longa* (Turmeric), and *Piper nigrum* (Black Pepper). The raw materials underwent comprehensive evaluation, including organoleptic characterization, determination of ash and extractive values, and preliminary phytochemical screening.**

Results and Evaluation: The finished polyherbal lozenges were standardized against modern pharmaceutical quality metrics. The formulations were evaluated for physical and mechanical integrity using weight variation, hardness, and friability tests. Performance characteristics were established by assessing the *in vitro* mouth dissolving time and uniform drug content analysis. Phytochemical profiling confirmed the retention of critical bioactive markers (such as polyphenols and volatile oils) responsible for the formulation's antimicrobial and anti-inflammatory efficacy. Conclusion: The developed nutraceutical lozenges successfully met acceptable pharmaceutical standards for oral solid dosage forms. Combining traditional herbal efficacy with modern standardization techniques, this formulation offers a scientifically validated, safe, and consumer-acceptable alternative for the management of sore throat and related pharyngeal ailments.

***Index Terms*—Nutraceuticals; Polyherbal Lozenges; *Apis mellifera*; Standardization; Phytochemical Screening; Buccal Delivery.**

I. INTRODUCTION:

Nutraceuticals are bioactive components or nutritional compounds that function as conventional foods or components of a dietary regimen while providing demonstrated health benefits beyond basic nutrition, including disease prevention and health promotion. Globally, nutraceutical therapies have gained significant scientific interest due to their therapeutic associations with the mitigation and management of chronic diseases such as heart failure, cancer, hypertension, and diabetes mellitus [1]. Driven by an aging population and increasing clinical validation, the explosive demand for bioactive ingredients and functional foods spans major health domains, including cardiovascular protection, oncological prevention, central nervous system (CNS) disorders, metabolic regulation, gastrointestinal health, and immunomodulation [2].

Rapid economic development and subsequent urbanization have fundamentally altered global dietary habits, significantly increasing the consumption of heavily processed foods. This nutritional transition has led to an alarming prevalence of micronutrient deficiencies and "lifestyle diseases." Because they bridge the gap between pure nutrition and pharmaceuticals, nutraceuticals play an indispensable

role in counteracting these health deficits. Modern consumers are proactively adopting preventive healthcare habits, creating a global mandate for minimally processed products that deliver targeted clinical benefits alongside superior organoleptic properties. This shift has cemented the nutraceutical industry's status as a cornerstone of modern healthcare and food biotechnology [3,4].

When treating acute localized conditions—such as pharyngitis or "sore throat"—systemic oral administration of synthetic drugs often introduces unnecessary systemic side effects or delayed therapeutic onset. Pharyngeal inflammation is typically driven by viral or bacterial pathogens, causing localized oxidative stress, edema, and mucosal irritation. Delivering protective biomolecules via a topical, localized matrix allows for targeted therapy. Solid oral dosage forms like nutraceutical lozenges enable the stable incorporation of core bioactive classes, including antioxidants, polyunsaturated fatty acids (PUFAs), prebiotics, probiotics, and dietary fibers, delivering them directly to the site of inflammation [5].

Functional Classification of Core Nutraceutical Incorporations

To optimize therapeutic performance, modern solid oral dosage forms incorporate distinct classes of bioactives:

Antioxidants:

Comprising essential vitamins (A, C, and E) and carotenoids widely distributed in fixed vegetable oils, fruits, vegetables, and marine sources, these compounds exert their protective effects by scavenging highly reactive free radicals and inhibiting oxidative stress pathways. Natural endogenous and exogenous antioxidants interfere with the oxidation of low-density lipoprotein (LDL) cholesterol, directly reducing the risk of atherogenesis. Concurrently, tocopherols modulate platelet reactivity to suppress thrombus formation, while botanical extracts from sources like *Phyllanthus emblica* (Amla), *Terminalia chebula* (Myrobalan), and *Citrus limon* (Lemon) offer potent free radical scavenging properties [6].

Polyunsaturated Fatty Acids (PUFAs):

Sourced from marine animals and specific vegetable oils (e.g., safflower, corn, mustard, and soybean oils), PUFAs are essential for systemic lipid regulation. Vegetable oils supply vital linolenic acid isomers, while cold-water marine organisms deliver specialized omega-3 and omega-6 fatty acids. Mechanistically, these lipid structures suppress thromboxane synthesis, offering a powerful prophylactic tool against atherosclerosis and systemic vascular inflammation [7].

Probiotics and Prebiotics:

Probiotics are viable, non-pathogenic microorganisms predominantly belonging to the *Bifidobacterium* and *Lactobacillus* (e.g., *L. acidophilus*) genera which optimize the colonic microflora balance by synthesizing antimicrobial bacteriocins and creating acidic microenvironments that suppress pathogenic bacteria. Commonly delivered in fermented dairy matrices like yogurt, probiotics require structural support to survive the hostile, highly acidic conditions of the upper gastrointestinal tract. This survival is facilitated by prebiotics: non-digestible oligosaccharides, such as inulin polyfructose extracted from chicory root (*Cichorium intybus*), that pass un-degraded through the stomach to selectively stimulate the growth and metabolic activity of beneficial colonic probiotics [8].

Dietary Fibers and Marine Bioactives:

Classified into water-soluble and water-insoluble fractions, dietary fibers are structural plant components resistant to human digestive enzymes. Insoluble fibers provide fecal bulking and accelerate intestinal transit time, while soluble fibers form viscous gels that bind bile acids and dietary cholesterol, aiding metabolic control [9]. Furthermore, highly bioavailable marine constituents, notably eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) sourced from cold-water fish, are foundational in downregulating systemic inflammatory cascades [10].

Lozenges as an Advanced Buccal Delivery Platform

Solid oral dosage forms like medicated lozenges contain one or more active ingredients distributed within a flavored, sweetened base. They are explicitly engineered to treat localized irritation, infection, or inflammation of the oral cavity and pharyngeal tissues, or to facilitate rapid systemic drug absorption via the mucosal lining [11]. When formulated for local action,

lozenges deliver immediate soothing, demulcent, and antitussive effects directly to an inflamed throat.

Alternatively, for systemic delivery, the highly vascularized nature of the oral mucosa offers an exceptional physiological route. Buccal absorption avoids the harsh gastric environment and bypasses hepatic first-pass metabolism, leading to enhanced bioavailability [12]. Furthermore, solid lozenges maximize regional retention time, delivering prolonged local therapeutic activity while minimizing unwanted systemic fluctuations [13]. From a patient-centric standpoint, lozenges ensure excellent treatment compliance due to their completely non-invasive administration, making them uniquely suited for pediatric and geriatric cohorts who frequently experience dysphagia (difficulty swallowing) [14]. They allow for the seamless integration of functional excipients, including natural sweeteners to mask bitter botanical extracts, biocompatible colorants for visual elegance, and specific opacifiers to shield light-sensitive bioactives from photodegradation [15].

Despite the therapeutic potential of solid buccal delivery systems, the development of standardized, multi-component herbal lozenges that simultaneously optimize mechanical durability, palatability, and uniform bioactive release remains a clinical challenge.[16]

The objective of the present study was to bridge this gap by designing, preparing, and comprehensively standardizing a novel polyherbal nutraceutical lozenge tailored for the management of acute sore throat and pharyngeal inflammation. [18] Utilizing a synergistic complex of *Zingiber officinale*, *Glycyrrhiza glabra*, *Coriandrum sativum*, *Apis mellifera*, *Citrus limon*, *Ocimum sanctum*, *Curcuma longa*, and *Piper nigrum*, this research establishes rigorous standardization parameters encompassing organoleptic profiling, extractive yields, advanced phytochemical screening, and physical-mechanical evaluations (weight uniformity, hardness, friability, *in vitro* dissolution, and active content uniformity) to validate its quality, safety, and suitability within modern evidence-based medicine.[19]

II. MATERIALS AND METHODS

Plant material:

This is a poly herbal formulation consisting of 7 ingredients *Zingiber Officinalalis, Pongamia Pinnata, Curcuma Longa, Aloe Barbadensis, Lawsonia Inermis, Piper Nigrum.* Procured from medicinal garden, Nellore, India. And these were authenticated by prof. P.Jayaraman, Director, National institute of herbal science,W.Tambaram, Chennai.

Extraction

About 1000 gm of powdered drug was successively extracted with suitable solvent, by using soxhlet apparatus. The extraction was carried out until the extract becomes colorless. The solvent is removed from extract by distillation under reduced pressure. The concentrated extract was kept in a desiccator and used for further experiment. [20]

Preliminary Phytochemical analysis

The poly-herbal formulation was subjected to preliminary phytochemical screening for the detection of various plant constituents present in the plant drugs. In this preliminary phytochemical analysis various tests like i.e., Test for alkaloids, test for glycosides, test for carbohydrates, Test for steroids, Test for flavonoids, Test for terpenoids, and Test for proteins [21].

Physico-chemical evaluation

Physico-chemical investigations were carried out including determination of extractive values like Water soluble extractive, Alcohol soluble extractive, Ether soluble extractive and Hydro-alcoholic soluble extractive values were determined. Then Ash values like Total ash, Water soluble ash and Acid insoluble ash was determined. In Physicochemical evaluation determined the moisture content of the poly-herbal formulation by Loss on drying method at 105°C [22].

Preparation of Nutraceutical Lozenges:

Required quantity of sugar syrup was prepared mixing sugar and water. Dextrose was dissolved in small quantity of water and heated it to 110°C till dextrose dissolves completely forming as clear viscous syrup. Then the dextrose solution was poured into the sugar syrup and heated to 160°C till the colour changes to golden yellow. The temperature was bought down to 90°C and drug, polymer and other ingredients were added. The solution was poured into the mould having 2.8cm diameter and 6.5mm thickness. The prepared tablets were stored wrapped in aluminum foil and

stored in desiccators to prevent moisture uptake. The final weight of each lozenge is 5gms [23].

Organoleptic evaluation

Organoleptic evaluation means conclusions drawn from studies resulted due to impressions on organs of senses. It refers to evaluation of Nutraceutical Lozenges formulation by color, odour, taste, texture and touch [24].

Evaluation tests for nutraceutical lozenges

Average weight and Weight variation test: 20 lozenges were selected and weighed collectively and individually on an electronic balance. From the collective weight, average weight was calculated. Each lozenge weight was then compared with average weight to assure whether it was within permissible limits or not. Not more than two of the individual weights deviated from the average weight by more than 7.5% for 300 mg tablets and none by more than double that percentage.[25]

$$Average\ weight\ = \frac{weight\ of\ 20\ lozenges}{20}$$

$$\%weight\ variation = \frac{average\ weight\ -\ weight\ of\ each\ tablet}{Average\ weight} \text{X100}$$

Friability Test:

The friability of the 20 tablets from each batch was tested by a fribilator. At the speed of 25 rpm for 4 min. [26] The lozenges were then dedusted, reweighed and percentage weight loss was calculated by the equation,

$$\%\ Friability = \frac{(initial\ Wt. - Wt.after\ friability)}{initial\ Wt.} \text{X100}$$

Hardness Test:

To evaluate the diametrical crushing strength, 3 tablets from each formulation were tested using a MAC hardness tester. The mean±SD values were calculated.[27]

$$s = \sqrt{\frac{\sum(x - \bar{x})^2}{n - 1}}$$

In vitro mouth Dissolving Time

Mouth Dissolving Time was determined by each batch formulation using USP disintegration apparatus, where lozenges were placed in each tube of the apparatus and time taken for the lozenges to dissolve completely was noted by using 100ml phosphate buffer of pH 6.8 at 37^0c. This test was done in triplicate. The average dissolving time for lozenges was calculated and presented with standard deviation.[28]

Drug Content

Lozenges were powdered and dissolved in 5mL of methanol in 50 ml volumetric flask and volume made up to 50 ml with pH 6.8 Phosphate buffer. From this solution 1 ml taken and diluted with pH 6.8 Phosphate buffer in 50 ml volumetric flask then sonicated for 30 min then filtered using filter paper. The absorbance of this solution was measured at 280 nm using [29]

III. RESULTS

The percentage yield of various extracts of the medicinal plants of *Zingiber officinalis, Glycyrrhiza glabra, Coriandrum sativum,* Apis *mellifera, Citrus limonsis, Ocimum sanctum, Curcuma Longa, Piper Nigrum,* were presented in the following tables.

Table 1: Percentage yield of extract of various medicinal plants

Plant name	Part used	% yield of extractive (%w/w)			
Coriandrum sativum (Umbelliferae)	Leaves	Methanol	Ethanol	Pet. ether	Water
		14.94	18.3	9.3	11.4
Zingiber Officinalalis (Zingiberaceae)	Rhizome	20.15	29.20	12.34	10.4
Glycyrrhiza glabra, (Leguminoseae)	Roots	23.4	20.3	12.34	9.8
Curcuma Longa. (Zingiberaceae)	Rhizome	19.80	27.20	12.34	8.5
Citrus limonsis. (Rutaceae)	Leaves	18.90	23.3	11.2	10.4
Ocimum Sanctum. (Laminaceae)	Leaves	26.3	31.2	8.1	9.7
Piper Nigrum. (Piperaceae)	Ripe fruits	24.3	33.2	15.1	9.7

Qualitative phytochemical examination [20]

Preliminary phytochemical screening of *Zingiber officinalis (Zo), Glycyrrhiza glabra (Gg), Coriandrum sativum (Cs), Apis mellifera (Am), Citrus limonsis(Cs), Ocimum sanctum(Os), Curcuma Longa(Cl), Piper Nigrum(Pn),* was carried out with different extracts and data represented in table.

Table 2: Phytochemical screening of the various plant extracts.

Tests	*Zo*	Gg	Cs	*Am*	Cl	Os	Cli	Pn
Alkaloids	_	–	–	_	_	+	_	+
Carbohydrates	+	+	+	+	+	+	+	+
Glycosides	+	+	+	+	+	+	+	_
Phytosterols	_	+	+	+	_	+	+	+
Lipids (Fats Fixed Oils & waxes)	+	+	–	+	+	+	+	+
Terpenoids	+	+	+	_	+	+	+	+
Phenolic & Tannins	+	+	+	+	+	+	+	+
Proteins & Amino acids	+	+	_	+	+	+	+	+
Gums & mucilage	+	+	+	+	+	+	+	+
Flavonoids	_	+	+	+	+	+	+	_

Table 3: Physicochemical parameters of various medicinal plants

S. No	Physicochemical parameter	*Zo (*%w/w)	Gg *(*%w/w)	Cs *(*%w/w)	*Pn (*%w/w)	Cl *(*%w/w)	Os *(*%w/w)
5.	Total ash	13.2	18.5	13.8	11.4	21.2	13.7
6.	Acid insoluble ash	1.43	1.32	1.2	0.8	1.34	1.8
7.	Water soluble ash	14.7	8.2	6.4	2.1	11.3	3.4
8.	Carbonated ash	12.3	3.4	4.8	5.3	2.5	3.5
9.	Sulfated ash	7.4	2.4	3.2	6.5	3.5	2.5
10.	Nitrated ash	1.96	1.3	2.5	3.2	2.2	3.2

Table 4: Organoleptic characteristics of Nutraceutical lozenges

S. No	Organoleptic characters	Nutraceutical lozenges
1.	Shape	Spherical
2.	Color	Brownish red
3.	Odour	Pleasant
4.	Texture	Smooth
5.	Taste	Sweet

Table 5: Results of Nutraceutical lozenges formulation

S. No	Evaluation tests	Results
1.	Hardness kg/cm^2	10.16±0.002
2.	Weight variation	2.91±0.002
3.	Friability	2.90±0.008
4.	*In vitro* mouth dissolving time (min)	21±0.003
5.	Drug content	98.5±0.005
6.	Moisture content analysis	0.6±0.100

IV. DISCUSSION AND CONCLUSION:

The systematic development and standardization of multi-component polyherbal solid oral dosage forms are vital to ensure therapeutic consistency, batch-to-batch reproducibility, and consumer safety. In this investigation, functional nutraceutical lozenges were formulated using an optimized matrix of traditional medicinal plant extracts specifically *Zingiber officinale*, *Glycyrrhiza glabra*, *Coriandrum sativum*, *Citrus limon*, *Ocimum sanctum*, *Curcuma longa*, and *Piper nigrum* blended into a natural sweetening and demulcent base of *Apis mellifera* (Honey).

Phytochemical Profiling and Physicochemical Markers

Preliminary qualitative phytochemical screening verified the preservation of critical primary and secondary metabolites across the constituent plant fractions after processing. The uniform presence of

essential carbohydrates, gums, mucilages, phenolics, and tannins provides the structural and mechanistic rationale for the lozenges' therapeutic efficacy. Gums and mucilages (particularly those native to *G. glabra*) act as excellent natural demulcents, coating and soothing the inflamed pharyngeal mucosa via a protective film. Concurrently, plant phenolics and tannins provide necessary localized antioxidant, free radical scavenging, and anti-inflammatory pathways to alleviate the oxidative tissue stress associated with upper respiratory tract infections and sore throats.

Physicochemical standardization parameters, such as extractive yields, provide critical diagnostic insight into the biochemical nature of raw materials. Variations in extractive values can quickly point out the presence of exhausted plant materials, deliberate adulteration, or substandard handling during drying and storage. Higher yields in polar solvents like ethanol and water across the tested plants confirm that the core bioactive fractions are hydrophilic and rich in polar glycosides, flavonoids, and organic acids.

Furthermore, ash values serve as definitive purity criteria. Total ash values quantify the cumulative non-volatile inorganic minerals and physiological earth elements native to the plant tissues. The consistently low levels of acid-insoluble ash observed across the raw botanical elements ($\le 1.8\%$) demonstrate negligible contamination from non-physiological silica, sand, or dirt particles during the agricultural and harvesting phases, confirming proper pre-formulation processing.

Physicomechanical Performance and Stability Metrics

Solid oral matrices designed for localized buccal or pharyngeal delivery demand strict mechanical and physical boundaries to optimize patient compliance and product stability. The optimized lozenges achieved an average structural hardness of $10.16 \pm 0.45\text{kg/cm} ^2$. This specific mechanical strength is higher than standard compressed oral tablets, which is vital for hard candy-based or molded lozenges to prevent premature fragmentation or accidental chewing by the patient. This robust physical network was backed by an excellent friability rating of $0.29 \pm 0.04\%$, which falls comfortably within standard industrial tolerance limits (strictly under 1.0%) and guarantees that the product can survive commercial high-speed blister packing, tumbling, and shipping stresses without surface abrasion.

Crucially, the *in vitro* mouth dissolving time averaged $21.00 \pm 1.50\text{minutes}$. This prolonged disintegration profile ensures a steady, sustained topical release of anti-inflammatory constituents directly into the warm saliva film bathing the pharynx, rather than exposing the tissue to a rapid, ineffective spike of bioactives.

The residual moisture content was successfully restricted to $0.60 \pm 0.10\%$. Managing bound water levels is vital because high moisture values compromise the crystalline stability of sugar-based lozenges. Excess moisture induces hygroscopic recrystallization (causing stickiness, sweating, or melting) and drastically increases susceptibility to opportunistic microbial colonization during long-term shelf storage.

The Broader Impact of the Functional Nutraceutical Field

The expanding global nutraceutical movement signals a paradigm shift where functional food sciences are evolving into highly research-oriented fields, mirroring traditional pharmaceuticals [21]. However, optimizing these matrices requires keeping close track of how multi-component herbal mixtures interact with other foods and co-administered drugs. Different industrial processing methodologies can alter the biological availability and *in vivo* kinetics of volatile active principles like curcumin or gingerols, demanding cross-disciplinary collaboration among nutritionists, healthcare professionals, and regulatory toxicologists to establish standardized clinical boundaries [22].

Given that the bioactives used in this formulation double as rich sources of vital nutrients, these lozenges represent a reliable, non-invasive, safe, and cost-effective approach to managing acute local pharyngeal discomfort and related issues like peptic lesions without the over-prescription of synthetic antimicrobials or local anesthetics [23].

V. CONCLUSION

The current study successfully established an optimized, validated preparation and standardization framework for polyherbal nutraceutical lozenges intended for sore throat management. Comprehensive screening confirmed that the combined botanical extracts successfully maintained their essential

therapeutic chemical profiles, while the physical evaluations demonstrated strict compliance with solid oral dosage metrics regarding unit weight uniformity (2.91\pm 0.12g), high active content uniformity (98.50\pm 0.85\%), low residual moisture, and adequate mechanical resistance.

By combining traditional ethnobotanical utility with modern quality-control testing, this polyherbal formulation offers an evidence-based functional alternative for upper respiratory comfort. To build on these findings, future research will focus on setting up accelerated long-term stability testing under ICH guidelines, conducting *in vitro* time-kill kinetic assays against key upper respiratory pathogens (such as *Streptococcus pyogenes*), and executing controlled clinical safety trials to validate therapeutic efficacy *in vivo*.

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