

Translating Herbal Potency into Dosage Form: Development and Evaluation of *Moringa oleifera* Enriched Lozenges

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Abstract: *The present investigation focuses on the development of a multifunctional Moringa oleifera lozenge designed not only as a conventional throat soothing preparation but also as a localized phytochemical delivery platform for oral mucosal therapy. The study uniquely emphasizes the natural isothiocyanates, flavonoids, and enzyme-activated bioactive compounds present in Moringa oleifera, which upon gradual dissolution in saliva may create a sustained antimicrobial and antioxidant microenvironment within the oral cavity. In addition, the mucilage-like nature of Moringa phytoconstituents was explored for its potential to enhance mucosal residence time by forming a thin protective bio adhesive layer over irritated oral tissues.*

The optimized lozenge formulation demonstrated excellent physicochemical stability with uniform drug distribution and controlled release behaviour, achieving nearly complete phytoconstituent release within 30 minutes while maintaining structural integrity and acceptable mechanical strength. The formulation further addressed one of the major formulation challenges associated with Moringa oleifera—its inherent bitterness—through successful taste balancing, improving palatability and patient compliance.

The developed system highlights the untapped potential of Moringa oleifera as a modern orotransmucosal phytopharmaceutical capable of delivering both therapeutic and nutritional benefits simultaneously. The study establishes a novel approach toward integrating bio adhesive herbal delivery with sustained phytochemical activation, offering promising applications in oral infections, throat irritation, mucosal inflammation, and supportive immune care..

Keywords: *phytochemical delivery platform*

I. INTRODUCTION

Oral drug delivery remains the most preferred route due to its simplicity, patient compliance, and extensive absorptive surface area (Meghwal M et al.,2012) (Paul M et al.,2012). Lozenges are medicated, flavoured solid dosage forms designed for slow dissolution in the oral cavity, enabling both local and systemic therapeutic effects. They are particularly advantageous for paediatric and geriatric patients, offering improved bioavailability, avoidance of first-pass metabolism, and ease of administration without water. Oral infections, affecting various regions of the oral cavity, are a significant health concern.

Oral infections represent a significant public health concern, impacting multiple regions within the oral cavity. These infections may involve the dorsum and lateral surfaces of the tongue(Shinde Satish G et al.,2014) (Pundir Suchitra et al.,2014) buccal epithelium, hard and soft palate, as well as both supragingival and subgingival plaque on tooth surfaces.

Moringa oleifera commonly referred to as the “Miracle Tree,” is widely distributed across tropical and subtropical regions, with its origin traced to Afghanistan, Bangladesh, India, and Pakistan. It is highly valued for its drought tolerance and exceptional nutritional profile, making it an economical and reliable source of nourishment(Kasolo



J.M., et al 2010) al Nearly all parts of the plant possess therapeutic and nutritional significance. The leaves are particularly rich in β -carotene, calcium, potassium, and other essential minerals, while their dried form contains a high proportion of oleic acid. Various plant parts, including bark, roots, and flowers, are traditionally utilized for managing conditions such as ulcers, toothache, hypertension, helminthiasis, and paralysis. Additionally, the plant plays a crucial role in combating malnutrition. This study focuses on its phytochemical composition, pharmacological activities, and ethnomedicinal relevance.

lozenges offer a distinctive and relatively underexplored advantage in buccal drug delivery due to the presence of naturally occurring isothiocyanates and enzyme-activated phytoconstituents. When the lozenge slowly dissolves in saliva, enzymatic interactions can enhance the release of these bioactive compounds, leading to a sustained antimicrobial microenvironment within the oral cavity. Additionally, the mucilage-like properties of Moringa leaf constituents may contribute to the formation of a thin protective bioadhesive layer over the oral mucosa, prolonging drug residence time and providing soothing effects on irritated tissues.

This dual functionality—combining bio adhesion with controlled phytochemical release— positions Moringa oleifera lozenges as a unique, multifunctional system with potential advantages over conventional synthetic formulations in oral healthcare applications commonly known as Shajna and referred to by names such as the drumstick tree, horseradish tree, ben oil tree, and “miracle tree,” is widely recognized for its adaptability, ease of cultivation, and exceptional nutritional and medicinal value.(Fakir et al., 2017) Rich in essential nutrients, its leaves, pods, and flowers serve as valuable resources for combating malnutrition in both humans and animals. It is particularly noted for its high content of vitamins, minerals, proteins, and bioactive compounds, including flavonoids, carotenoids, and ascorbic acid. The plant exhibits diverse pharmacological activities such as antibacterial, anti-inflammatory, antioxidant, antihyperglycemic, and cardioprotective effects. Traditionally, it has been used to manage gastrointestinal disorders, skin conditions, and overall health maintenance. Modern studies further support its role in conditions like diabetes, anaemia, and metabolic disorders. Despite its vast therapeutic potential, Moringa oleifera remains underutilized, highlighting the need for further research into its pharmacological applications and clinical relevance.

Millions of patients are hospitalized each year due to adverse drug reactions throughout the world. In contrast, when it comes to natural herbal products, despite their long history of use, there have been very few reported instances of such adverse reactions. Plants stand out as one of the most valuable resources for medications, food supplements, and nutraceuticals (Tiwari et al., 2011). Therefore, in traditional medicine, historical guidelines have recommended the use of Moringa oleifera leaves for their advantageous effects on mental well-being and maintaining healthy skin. Furthermore, Moringa oleifera has been associated with a wide range of therapeutic uses in both laboratory and living organism experiments, including antibacterial, antifungal, antiviral, cytotoxic, antihyperglycemic, antioxidant, anti-inflammatory, antiparasitic, and heart-protective properties (Dhakad et al., 2019). Additionally, numerous clinical investigations have explored the pharmacological impact of Moringa oleifera in the treatment of conditions such as metabolic syndrome, type 2 diabetes mellitus, osteoporosis, anaemia, and dyslipidaemias. Nevertheless, despite its significant nutritional and therapeutic benefits, Moringa oleifera leaves have not gained as much popularity as other leafy greens, and there remains untapped potential in exploring its pharmacological properties, especially regarding its potential as a neuroprotective agent.

It exhibits notable effects in lowering blood lipid levels, reducing blood pressure, promoting weight loss, aiding in digestive regulation, safeguarding the liver against the effects of alcohol, and boosting overall immune system function (Liang et al., 2019). This remarkable plant possesses extraordinary medicinal attributes that have the potential to address healthcare requirements in various scenarios. Its ability to thrive in challenging environmental conditions and its widespread accessibility make it a noteworthy candidate for both economic and health-related opportunities in resource-constrained developing nations. This review focuses on the pharmacological properties of Moringa oleifera and its medicinal applications in traditional and modern healthcare systems.

It is referred to be a miracle tree due to its many health benefits, such as having 15 times more potassium than bananas and 15 times more calcium than milk. It also has 7 times more vitamin C than oranges and 10 times more vitamin A



than carrots, 4 times more protein than found in eggs, and 9 times more protein than contained in yogurt (Islam et al., 2021).

M. oleifera demonstrates the ability to grow under a wide range of soil conditions, with optimal growth observed in well-drained sandy or loamy soils exhibiting slightly alkaline characteristics. Notably, almost all parts of the plant possess significant economic and nutritional value, being utilized both as a food source for human consumption and as forage for livestock.

The *Moringa oleifera* tree was introduced to Africa from India in the early twentieth century, where it was primarily utilized as a nutritional and health supplement. Traditionally, it has been employed in the management of various ailments, including its use as a fomentation to alleviate spasms, as well as in the treatment of diarrhoea. Additionally, it has been reported to function as a diuretic and central nervous system stimulant in conditions such as paralytic disorders, epilepsy, and hysteria.

Historical and ethnopharmacological evidence indicates that, for centuries, populations across numerous countries have relied on *Moringa* leaves as a form of traditional medicine for the management of common health conditions.

OROTRANSMUCOSAL DRUG DELIVERY

Oral mucosal drug delivery is an alternative method of systemic drug delivery that offers several advantages over both injectable and enteral methods and also enhances drug bioavailability because the mucosal surfaces are usually rich in blood supply, providing the means for rapid drug transport to the systemic circulation and avoiding, in most cases, degradation by first-pass hepatic metabolism. The systems contact with the absorption surface resulting in a better absorption, and also prolong residence time at the site of application to permit once or twice daily dosing. For some drugs, this results in rapid onset of action via a more comfortable and convenient delivery route than the intravenous route. Not all drugs, however, can be administered through the oral mucosa because of the characteristics of the oral mucosa and the physicochemical properties of the drug. Although many drugs have been evaluated for oral transmucosal delivery, few are commercially available.

The clinical need for oral transmucosal delivery of a drug must be high enough to offset the high costs associated with developing this type of product. Transmucosal products are a relatively new drug delivery strategy. Transmucosal drug delivery promises four times the absorption rate of skin. Drugs considered for oral transmucosal delivery are limited to existing products, and until there is a change in the selection and development process for new drugs, candidates for oral transmucosal delivery will be limited. The present papers intend to overview a wide range of orotransmucosal routes being potentially useful for transmucosal drug delivery and remind us of the success achieved with these systems and the latest advancement in the field.

SUBLINGUAL ROUTE

The sublingual mucosa is considered a suitable site for rapid onset drug delivery due to its high permeability, thin membrane, extensive surface area, and rich blood supply (Chiappin et al., 2007). However, the sublingual route may not always be effective for the treatment of acute conditions because maintaining the dosage form in close contact with the mucosal surface is difficult. Continuous saliva secretion and tongue movement can easily dislodge the formulation (Giannola et al., 2007). Despite these limitations, this route offers significant advantages, including avoidance of first-pass metabolism and protection of the drug from degradation by gastrointestinal fluids. Furthermore, the membrane sites allow easy application, localization, and removal of the drug delivery system (Madhav et al., 2009).

TYPES OF OROTRANSMUCOSAL DRUG DELIVERY ROUTE

A. Buccal route

The buccal mucosa is useful for the treatment of either local or systemic therapies. It is overcoming the drawbacks of conventional administration routes. It is more tolerant to potential allergens and resilient compared to other mucosal tissues (Patel et al., 2011). When it is used as less of a tendency to cause irreversible irritation or injury. As a result, it is



a prospective site for the regulated orotransmucosal drug delivery system in a variety of chronic systemic therapy (Giannola et al., 2007). However, certain medications may synthesis and composition. Additionally, unintentional swallowing may cause drugs to be lost from the site of absorption (Madhav et al., 2009). The small absorption area and the barrier property of the buccal mucosa contribute to the limitations of this route. Furthermore, due to the constant intake of saliva in the oral cavity, long-term storage of dosage forms to improve absorption at this point is a major challenge (Giannola et al., 2007). Easy access to the membrane sites makes it possible to apply, locate and remove the delivery system quickly. Additionally, there is a good chance that the transmucosal membrane in the oral cavity will allow for longer delivery (Madhav et al., 2009).

B. Sublingual route

The sublingual mucosa is considered a suitable site for rapid onset drug delivery due to its high permeability, thin membrane, extensive surface area, and rich blood supply (Chiappin et al., 2007). However, the sublingual route may not always be effective for the treatment of acute conditions because maintaining the dosage form in close contact with the mucosal surface is difficult. Continuous saliva secretion and tongue movement can easily dislodge the formulation (Giannola et al., 2007). Despite these limitations, this route offers significant advantages, including avoidance of first-pass metabolism and protection of the drug from degradation by gastrointestinal fluids. Furthermore, the membrane sites allow easy application, localization, and removal of the drug delivery system (Madhav et al., 2009).

C. Palatal route

The parenteral route is a well-established method of drug administration that overcomes the limitations associated with the poor effectiveness of certain medications when administered orally. Nevertheless, parenteral formulations are costly, require repeated administration, and often result in low patient compliance (Shakya et al., 2011). The palatal mucosa possesses a keratinized epithelium with moderate thickness, leading to comparatively lower permeability. These epithelial surfaces are covered with a mucus layer. Among the palatal regions, the soft palate has been identified as the most practical and easily accessible novel site for drug delivery (Madhav et al., 2009). It is commonly utilized as a retention site for dosage forms intended for systemic delivery of therapeutic agents. To minimize mechanical irritation and discomfort, dosage forms designed for the soft palate should possess a smooth and flexible surface (Shakya et al., 2011).

Structure of oral cavity

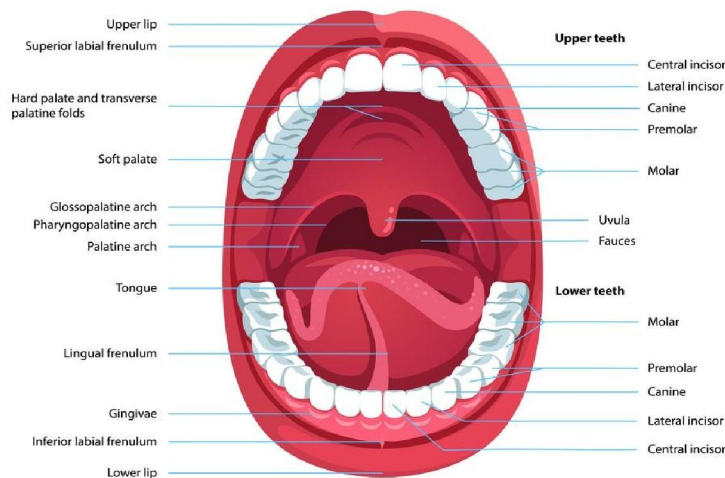


Figure 1. Graphical representation of various mucosa in oral cavity



D. Gingival

Mucoadhesion refers to the ability of mucus or mucosal membranes to remain attached to each other for an extended period. In drug delivery, the term describes the adhesion of drug carriers to the mucus layer present on specific biological surfaces to enhance drug retention and absorption (Shaikh et al., 2011). For successful mucoadhesion to occur, a sequence of events takes place, the nature of which depends on the properties of the mucoadhesive material. Bone marrow transplantation and radiation therapy to the head and neck region, particularly conditioning regimens used in the treatment of oral cancer, are associated with several complications (Chowdary and Srinivas, 2000). One major complication is mucositis, an inflammatory condition affecting the oral mucosa. Dose-dependent damage to the mucosal tissues can result in painful ulcerations, difficulty in swallowing, and discomfort in the oral cavity.

GI TRACT BARRIERS IN OROTRANS-MUCOSAL DRUG DELIVERY SYSTEM

A. Physiochemical barrier

Orally administered pharmaceuticals pass through both the upper and lower regions of the gastrointestinal (GI) tract, with the lower GI tract serving as the primary site for drug absorption while also presenting several barriers to effective oral delivery. Drug efficacy may be significantly reduced if the drug undergoes degradation before reaching the small intestine due to the acidic pH and increased proteolytic activity present in the upper GI tract (El-Kattan and Varma, 2012).

As drugs travel through the upper GI tract, they are exposed to the harsh gastric environment and powerful proteolytic enzymes of the stomach, which can lead to substantial degradation. In addition, oral formulations must withstand mechanical stresses within the GI tract that may interfere with drug stability and development. Large biomolecules such as proteins and biologics are particularly susceptible to rapid degradation in the gastrointestinal environment (Gavhane and Yadav, 2012).

A study demonstrated that when bovine milk immunoglobulin was incubated with pepsin at pH 2, its *in vitro* rotavirus-neutralizing activity decreased by approximately 96%, highlighting the detrimental impact of the GI environment on large biologic molecules

(Petschow and Talbott, 1994). Therefore, biologics often require specific modifications to enhance their stability and enable them to withstand the natural conditions of the gastrointestinal tract (Le et al., 2022).

Furthermore, oral drug administration is associated with reduced systemic bioavailability because of the first-pass metabolism phenomenon, unlike intravenous or intranasal administration routes. This effect was demonstrated in a study involving cyclosporin administration to the small intestine of liver transplant patients, where extensive enzymatic degradation of the drug was observed (Pond and Tozer, 1984). First-pass metabolism refers to the reduction in drug concentration before it reaches systemic circulation, primarily due to metabolic activity and decreased gastric residence time. After 60 minutes of administration, portal blood samples contained 25%–51% of cyclosporin metabolites, indicating rapid

B. Intestinal Microbiota

The term microbiota refers to the diverse population of microorganisms residing within the gastrointestinal tract, which play a vital role in maintaining immune homeostasis (Rooks and Garret, 2016). The gut microbiota and the host function together through various microbiota-dependent pathways to strengthen the immune system, support epithelial integrity, and promote the growth of beneficial bacteria within the mucus layer. However, in individuals with compromised immune function, these microorganisms may become potentially harmful (Cerf-Bensussan and Gaboriau-Routhiau, 2010).

Although the gastrointestinal tract is essential for digestion due to its unique physiological characteristics, dynamic environment, and complex regulatory mechanisms, these same factors can negatively affect the efficacy of orally administered drugs (Rooks and Garret, 2016). Interestingly, the intestinal microbiota that often acts as a barrier to drug



absorption can also be utilized therapeutically in immunotherapy applications (Cerf-Bensussan and Gaboriau-Routhiau, 2010)

In one study, *Escherichia coli* Nissle 1917 (EcN) was coated with a yeast membrane to specifically target M cells through β -glucan molecules embedded within the yeast membrane (Lin et al., 2021). This investigation demonstrated that orally administered yeast membrane-coated EcN could localize within Peyer's patches, where it may stimulate an immune response capable of preventing disruption of the intestinal barrier (Le et al., 2022).

C. Epithelial barrier

Tight junctions present in the epithelial layer of the gastrointestinal tract regulate the movement of substances across the mucosal surface and function as the body's first immune defense barrier. Molecules entering systemic circulation must pass through active or passive transport pathways (Keselowski et al., 2020). These junctions influence both paracellular and transcellular transport across epithelial tissues (Tscheik et al., 2013). Such barriers reduce gastric residence time and limit the sustained action of orally administered drugs. However, the same epithelial structures can also be utilized for targeted drug delivery. Studies demonstrated successful in vitro epithelial transcytosis using IgG Fc-linked nanoparticles (Pridgen et al., 2013).

D. Mucosal immune system of the gut

The mucosal layer covering the epithelial surface acts as one of the primary immune defence mechanisms of the gastrointestinal tract. This layer is produced by goblet cells in the intestine, which secrete a gel-like substance composed mainly of glycoproteins (Hansson, 2012). Continuous mucus secretion within the GI tract can reduce the availability of orally administered drugs at their target site (James, 1993). The mucosal system functions as a specialized immune barrier by identifying and eliminating or neutralizing foreign substances present in the intestinal lumen, thereby protecting the body's normal microbial flora (Johansson et al., 2013). The glycoprotein-rich mucosal surface varies in thickness throughout the GI tract, and drugs must penetrate this barrier before reaching systemic circulation (Ensign et al., 2012).

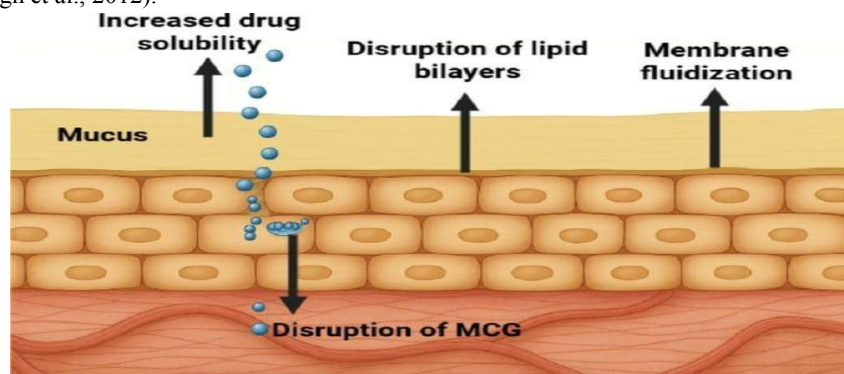


Figure 2. Drug molecules by passing the various membranes in mucosal membrane

CHARACTERISTICS OF ORO-TRANSMUCOSAL DRUG DELIVERY

A. Permeability of oral mucosa

The epithelial layer of the oral mucosa acts as a protective barrier that prevents fluid loss from underlying tissues and regulates drug permeability (Shimono and Clementi, 1976). This barrier is mainly attributed to the lipid-rich upper epithelial layers (Kulkarni et al., 2009). As suprabasal cells mature, they develop strong desmosomal junctions and membrane-coated granules (MCGs), which release lipophilic substances into intercellular spaces to maintain epithelial integrity and restrict the movement of hydrophilic molecules across the epithelium (Shojaei, 1998; Salamat-Miller et al., 2005). Variations in epithelial thickness and keratinization significantly influence permeability within different



regions of the oral mucosa (Sankar et al., 2011). Keratinized tissues exhibit lower permeability than non-keratinized tissues due to their lipid composition (Ganem-Quintanarc et al., 1997). Among oral regions, the sublingual mucosa is the most permeable, whereas the buccal mucosa and hard palate show comparatively lower permeability (Squier and Hall, 1985)

B. Increased permeability in disease state

Drug diffusion through the orotransmucosal route occurs more readily in ulcerated or eroded tissues due to the disruption of the normal permeability barrier (Harsanyi et al., 1986). Conditions such as lichen planus can significantly increase mucosal permeability, although reduced barrier integrity may also lead to rapid drug loss from ulcerated sites (Sankar et al., 2011). Consequently, diseased mucosal regions may show enhanced drug penetration compared to healthy tissues. Similarly, malignant and oral lesions can alter mucosal permeability. Studies on nitrosornicotine demonstrated significantly higher permeability in non-lesional tissues surrounding leukoplakic areas compared to normal oral mucosa and leukoplakic regions themselves (Banoczy et al., 2003).

CHALLENGES IN ORO-TRANSMUCOSAL DRUG DELIVERY SYSTEM

The gastrointestinal (GI) tract serves as a highly complex pathway for the transport and absorption of orally administered medications. While many drugs are intended to reach systemic circulation and exert effects throughout the body, some formulations are specifically designed to produce localized therapeutic action within the stomach and intestinal regions (Dimmitt et al., 2012). Anatomically, the GI tract is divided into upper and lower sections. The upper GI tract includes the mouth, pharynx, esophagus, stomach, and duodenum, whereas the lower GI tract comprises the remaining portions of the small intestine along with the cecum, colon, and rectum (Treuting et al., 2018; Cheng, 1974). Despite regional differences in function, the GI tract maintains a relatively uniform structural organization consisting of a mucosal lining, submucosal tissues, mucus layers, and surrounding smooth muscle components (Dimmitt et al., 2012). The mucosal surface, formed by epithelial cells, lamina propria, and muscularis mucosae, plays a dual role in nutrient transport and gastrointestinal immune protection (Treuting et al., 2018). Among all regions, the small intestine acts as the principal site for drug absorption because of its extensive surface area, prolonged residence time, and highly specialized absorptive regions such as the jejunum and ileum (Lennernas, 1998; Rubin and Langer, 2016).

However, efficient oral drug delivery remains challenging due to the constantly changing physiological environment of the GI tract. Factors including pH variation, mucus thickness, bacterial population, intestinal transit time, and segmental absorption characteristics significantly influence drug stability and bioavailability (Ensign et al., 2012). These obstacles are generally categorized into biological and technical barriers. Biological barriers include physiological conditions that degrade drug molecules or restrict their absorption at the target site (Rouge et al., 1996). In contrast, technical challenges arise during the design and development of delivery systems capable of overcoming these biological limitations, as well as during scale-up and commercialization processes (Homayun et al., 2019). Thus, successful orotransmucosal drug delivery requires a strategic balance between biological compatibility, formulation stability, and advanced delivery system engineering.

MECHANISM OF ACTION IN ORAL TRANSMUCOSAL DRUG DELIVERY SYSTEMS.

The mechanism of orotransmucosal delivery of fentanyl citrate (OTFC) has been extensively investigated using a mathematical modelling approach. The developed model incorporated several transport processes, including dissolution of the fentanyl citrate lozenge, equilibrium between adjacent layers, saliva interaction, and diffusion across the oral mucosal membrane. Governing equations and boundary conditions were discretized using an orthogonal collocation-based method, while time-dependent integration was performed using the built-in NDSolve function in Mathematica. Simulations were carried out using a 200µg dose of fentanyl citrate (Kim and Simon, 2011).



The oral mucosa offers several advantages as a drug delivery site, including easy accessibility, rich vascularization, avoidance of hepatic first-pass metabolism, rapid healing capacity, and favourable permeability characteristics for both local and systemic drug delivery applications (Hearnden et al., 2012).

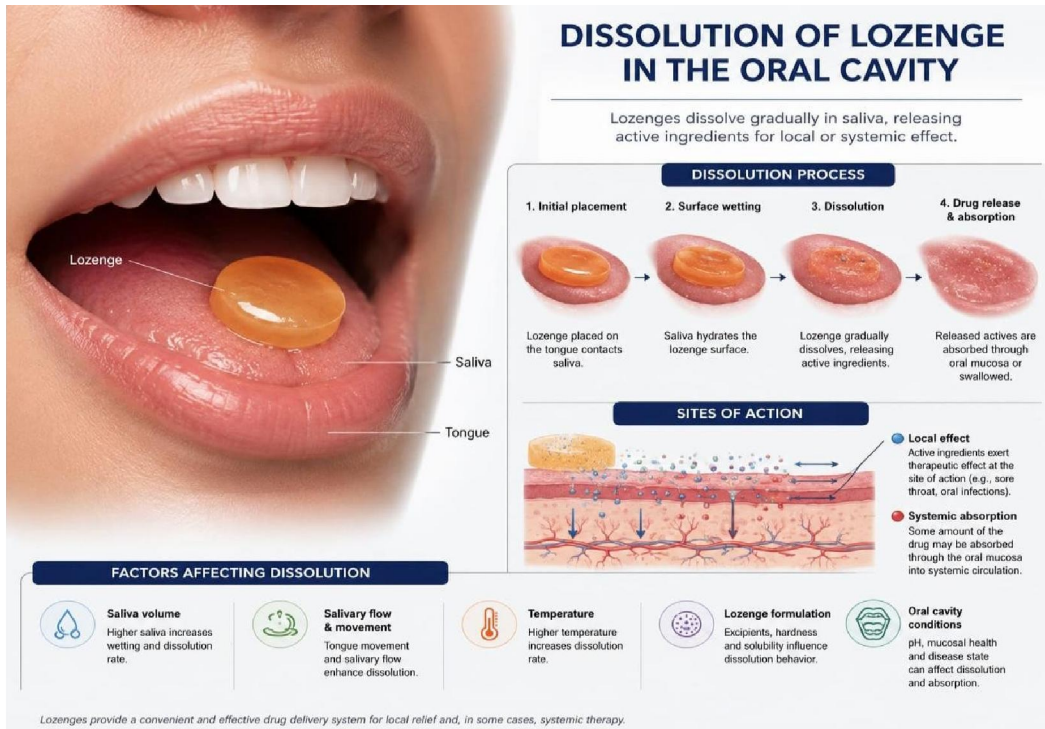
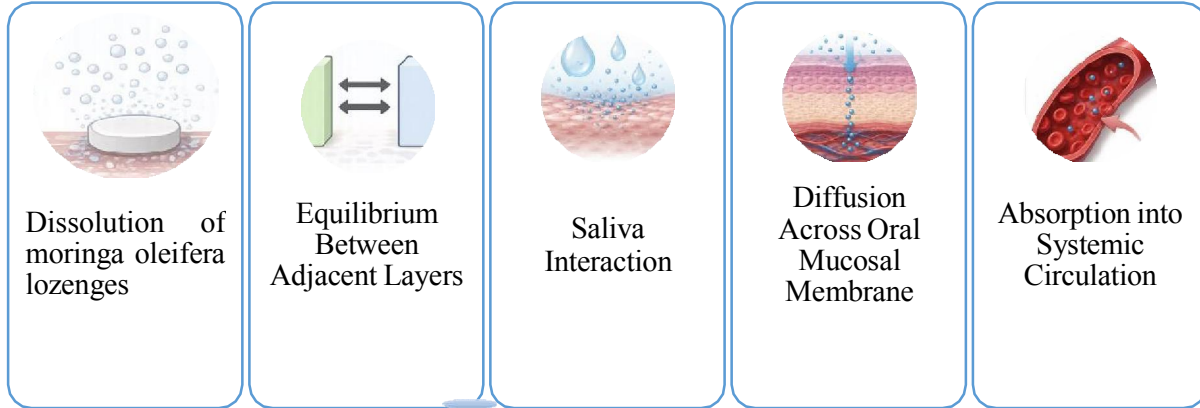


Figure 3. Dissolution of lozenges in oral cavity

APPLICATION OF OROTRANSMUCOSAL DRUG DELIVERY SYSTEM

A paediatric formulation must be in a dosage form that the intended age group can handle and allow accurate dose administration. For this susceptible age group, it is especially crucial to consider the types and quantities of excipients employed in the formulation (Lam et al., 2014). There are several barriers that need to be overcome in the development of transmucosal delivery.



TYPES OF LOZENGES

A. Chewable Lozenges:

In chewable lozenges, the active ingredients are incorporated into a caramel-based matrix, so they are chewed rather than allowed to dissolve in the mouth. These formulations typically contain glycerine, gelatine, and water. They are highly flavoured, often with fruit Flavors, and may have a slightly acidic taste to mask the unpleasant taste of glycerine. Chewable lozenges are mainly intended for paediatric use, enabling drug absorption through the gastrointestinal tract to achieve systemic effects. The glycerine base used is similar to that in glycerine or glycerinated gelatine suppositories, usually composed of 70% glycerine, 20% gelatine, and 10% purified water. [Mendes RW., et al.,2006]

B. Hard Lozenges:

Hard lozenges consist of a mixture of sugars and carbohydrates in a non-crystalline, amorphous, or glassy state and are sometimes referred to as sugar syrups. Their weight typically ranges from 1.5 to 4.5 g, [Batheja P, et al., 2006] with a moisture content of about 0.5–1.5%. These lozenges dissolve directly in the mouth rather than disintegrating. Since their preparation involves high temperatures, heat-sensitive ingredients cannot be incorporated. They are commonly used for relieving sore throat, treating throat infections, and reducing irritation by delivering drugs with topical aesthetic or antibacterial properties.

C. Soft Lozenges:

Soft lozenges are designed for the gradual release of drugs in the oral cavity. They are prepared using bases such as polyethylene glycol (PEG), chocolate, or acacia, with some formulations also containing silica gel. Acacia plays a key role in providing desirable texture and smoothness. PEG-based lozenges may soften at elevated temperatures and are hygroscopic, so they should be stored in a cool and dry environment.

D. Compressed Lozenges:

Compressed lozenges are suitable for formulating heat-sensitive ingredients that cannot withstand the high temperatures used in hard or soft lozenge preparation. These are produced using a compression technique similar to tablet manufacturing. Unlike conventional tablets, they are formulated to dissolve slowly and do not disintegrate rapidly. Granulation methods are commonly employed in their preparation. [James M Diet al.,2006]

CHRONOLOGICAL DEVELOPMENT OF LOZENGES

In the early first millennium BC, the Egyptians prepared primitive candies using honey combined with various herbs. Later, during the 19th century, certain medications derived from morphine and heroin were developed and widely used to suppress cough by acting directly at its source. Lozenges are also known by several names, including cough drops, throat sweets, troches, cachous, pastilles, and cough sweets. [Banas JA, et al.,2013]

Lozenges are commonly used in the treatment of conditions such as the common cold and influenza. The term “lozenge” is associated with a diamond-like shape, [Parasol cough lozenges. Et al.,] which reflects its traditional appearance. Unlike liquid medicines that are taken with a spoon or measuring device, lozenges are designed to be placed in the mouth and allowed to dissolve slowly. This slow dissolution enables a prolonged release of medication, making them particularly effective for conditions like sore throat, cough, and oral thrush.

The word “lozenge” originates from a French term referring to a diamond-shaped figure with four equal sides. To make these preparations more palatable, the active drug is incorporated into a flavoured and sweetened base, often referred to as pastilles or jujubes. As the lozenge dissolves, the drug is gradually released in the oral cavity.

Historically, lozenges and pastilles were compounded in pharmacies well into the 20th century, but today they are manufactured on a commercial scale. In general, lozenges are solid dosage forms specifically intended to dissolve slowly in the mouth or throat, delivering medication over an extended period.



II. LITERATURE REVIEW

1.[Ben Bassat N, et al.,2013]

Herbal lozenge formulations are increasingly utilized among the Thai population in contemporary practice. Lozenges are solid dosage forms designed to dissolve slowly in the mouth or pharynx, allowing for localized as well as systemic therapeutic effects. Additionally, lozenges may facilitate systemic drug absorption. Their effectiveness largely depends on their ability to dissolve readily within the oral cavity. Various herbal lozenge formulations, including those containing marshmallow root extract and *Salvia officinalis*, have been developed to improve therapeutic efficacy and patient acceptability.

2.[Fahey J W. et al2005]

Moringa oleifera Lam. (commonly known as Marum) is one of the most extensively cultivated species of the Moringaceae family, valued both as a dietary vegetable and a medicinal plant. The leaves of *M. oleifera* serve as a rich source of essential nutrients, including vitamins and minerals such as calcium.

3.[Sreelatha S, et al.,2009]

Moringa oleifera leaf preparations are commercially available in dosage forms such as capsules, tea bags, and boluses. Therefore, the present study aims to develop a lozenge formulation containing *M. oleifera* leaf extract, offering a novel and effective alternative for herbal drug delivery.

4.[Rong Liu, et al.,2022]

Moringa oleifera provides four major edible parts including leaves, pods, flowers, and seeds. The leaves are considered highly nutritious as they contain proteins, β -carotene, vitamins A, B, C, and E, riboflavin, folic acid, pyridoxine, amino acids, minerals, phenolic compounds, phytochemicals, and omega-3 and omega-6 fatty acids. *Moringa* leaves mainly contain palmitic and linolenic acids, while the seeds are rich in oleic acid.

5. [Ashutosh Pareek, et al.,2023]

Moringa oleifera grows quickly in sandy, well-drained loamy soil and commonly thrives at elevations around 500 m above sea level. The plant is generally small to medium in height with naturally tripinnate leaves. Its flowers develop on inflorescences measuring about 10–25 cm in length, while the fruits are elongated pods that are usually three-sided. The trunk is mostly straight, although it may sometimes develop irregularly. The branches are arranged unevenly, forming an umbrella-like canopy. The brown seeds possess a semi-permeable seed coat, and a single tree can produce nearly 15,000–25,000 seeds annually.

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7. [Swetha Yoganadan]

Various advanced technologies have been developed to improve conventional lozenge formulations. These advancements involve the use of novel ingredients and improved manufacturing techniques to enhance taste, reduce calorie content, accelerate production, and optimize drug release characteristics. Pharmaceutical lozenges offer the



advantage of extending the retention time of the dosage form in the oral cavity, thereby improving bioavailability, reducing gastrointestinal irritation, and minimizing first-pass metabolism.

8. [Xinyue Su, et al.,2023]

Literature reports that the bitter taste of *Moringa oleifera* extract is one of the major difficulties encountered during formulation development. Hence, recent research suggests incorporating taste-masking techniques, sweetening agents, and flavouring substances to enhance palatability, patient acceptance, and compliance in herbal lozenge formulations.

9. [A.K. Singhal, et al.,2012]

Research on *Moringa oleifera* has primarily concentrated on its leaves and seeds, while comparatively little attention has been given to its stems. Using methanol reflux extraction and column chromatography techniques, four compounds—cholest-5-en-3-ol, stigmasterol, gamma-sitosterol, and tricosanoic acid—were isolated from the stem of *M. oleifera*. Both the methanolic extract and the isolated fractions demonstrated significant antifungal activity against *Rhizoctonia solani* and *Fusarium oxysporum*. Additionally, fractions obtained using various solvents including hexane, benzene, chloroform, ethyl acetate, acetone, and water also exhibited antifungal effects against these pathogens. Furthermore, the flowers and fruits of *M. oleifera* are reported to contain high amounts of carbohydrates, proteins, organic acids, flavonoids, and phenolic compounds. According to Singhal et al., antioxidants such as tocopherols, ascorbic acid, carotenoids, and flavonoids present in the plant possess the ability to neutralize reactive oxygen species (ROS).

10.[Muazu, J., et al.,2014]

Evaluation of herbal lozenges commonly involves parameters such as hardness, friability, thickness, weight variation, drug content uniformity, disintegration time, and dissolution profile. Researchers have reported that these quality control tests are essential for maintaining the consistency, stability, and efficacy of the dosage form. In addition, stability studies conducted under varying temperature and humidity conditions help determine the shelf life and appropriate storage conditions of the formulation.

III. AIM AND OBJECTIVE

Aim of the Study

To design, formulate, and systematically evaluate lozenges incorporating *Moringa oleifera* leaf extract, with the objective of developing a pharmaceutically stable, therapeutically effective, and patient-compliant herbal dosage form for the management of oral and pharyngeal disorders.

Objectives of the Study

- To formulate lozenges containing *Moringa oleifera* leaf extract using suitable pharmaceutical excipients and standardized formulation techniques.
- To optimize the formulation for physicochemical and organoleptic characteristics to ensure product acceptability and uniformity.
- To evaluate the formulated lozenges for parameters such as:Hardness Friability Weight variation Thickness Disintegration profile
- To conduct stability studies under defined environmental conditions to determine shelf- life and formulation integrity.
- To qualitatively and quantitatively analyze phytoconstituents present in the formulation for quality control and efficacy.
- To evaluate the microbial quality of the prepared lozenges for safety and compliance with microbiological standards.



- To develop a patient-friendly herbal dosage form for treating: Throat irritation, Oral infections, Related oral/pharyngeal conditions
- To investigate drug–excipient compatibility of Moringa oleifera extract with formulation components using analytical techniques.
- To evaluate the in vitro release profile of active phytoconstituents and study drug release kinetics.
- To assess palatability, mouthfeel, and taste-masking efficiency to improve patient compliance.

IV. PLAN OF WORK

The present investigation will be carried out in a systematic and sequential manner to ensure the successful development and evaluation of Moringa oleifera leaf extract lozenges. The study will be executed through the following stages:

1. Literature Review

An extensive and critical review of the available scientific literature will be conducted to gather relevant information on Moringa oleifera, its phytochemical constituents, pharmacological activities, and its application in novel dosage forms, particularly lozenges.

2. Procurement and Authentication of Plant Material

Fresh leaves of Moringa oleifera will be procured from a reliable source and authenticated by a qualified botanist to ensure the accuracy and quality of the plant material.

3. Preparation of Plant Extract

The collected leaves will be cleaned, dried under controlled conditions, and subjected to suitable extraction methods (such as solvent extraction) to obtain the crude extract rich in active phytoconstituents.

4. Preformulation Studies

Preliminary studies including organoleptic evaluation, solubility analysis, and drug– excipient compatibility studies will be performed to establish the physicochemical characteristics of the extract.

5. Formulation of Lozenges

Lozenges will be formulated using appropriate excipients by suitable techniques (e.g., moulding or compression method) to obtain a uniform and stable dosage form.

6. Optimization of Formulation

Different formulation batches will be prepared by varying excipient composition to achieve optimal physicochemical properties and acceptable organoleptic characteristics.

7. Evaluation of Lozenges

The prepared lozenges will be evaluated for various quality control parameters, including hardness, friability, weight variation, thickness, disintegration time, and uniformity, in accordance with standard pharmacopeial guidelines.

8. Phytochemical and Analytical Evaluation

Qualitative and quantitative analysis of active constituents (such as flavonoids) will be carried out using appropriate analytical techniques to ensure consistency and efficacy.



9. In Vitro Release Studies

Dissolution studies will be performed to evaluate the release profile of active constituents and to understand the drug release kinetics.

10. Stability Studies

The optimized formulation will be subjected to stability studies under specified environmental conditions to assess its shelf-life and stability over time.

11. Data Analysis and Interpretation

All experimental data will be systematically recorded, statistically analysed, and interpreted to draw valid conclusions regarding the formulation's performance.

V. MATERIALS AND INSTRUMENT

Materials

- Moringa oleifera leaf extract
- Sucrose (sweetening agent)
- Citric acid (antioxidant)
- Gum acacia (binder)
- Magnesium stearate (lubricant)
- Peppermint (flavouring agent)
- Tartrazine

Glassware

- Beakers (100ml,250ml,500ml)
- Measuring cylinder (25ml,50ml,100ml)
- Funnel
- Petri dishes
- Round bottom flask
- Filter paper
- Glass rod
- Watch glass

Instruments

- Analytical balance (for accurate weighing of ingredients)
- Hot air oven (for drying of plant material)
- Mechanical grinder or pulveriser (for size reduction)
- Sieve set (for particle size uniformity)
- Heating mantle or water bath (for preparation of base)
- Mortar and pestle (for mixing)
- Molds (for lozenge preparation)
- Monsanto hardness tester (for hardness evaluation)
- Roche friabilator (for friability testing)
- Vernier caliper (for thickness measurement)
- Disintegration test apparatus
- Dissolution test apparatus (for in vitro release studies)



VI. DRUG AND EXCIPIENT PROFILE PLANT DOSSIER

MORINGA OLEIFERA

Over the past few decades, the field of herbal medicine has grown rapidly, leading to increased popularity of *Moringa oleifera* in developed countries due to its natural origin and minimal side effects. Herbal medicines and their constituents play a vital role in various traditional systems such as Unani medicine, Siddha medicine, Yoga, Homeopathy, Naturopathy, and Ayurveda, with more than 70% of the population relying on these non-allopathic approaches. *Moringa oleifera*, commonly referred to as the horseradish tree or drumstick tree, belongs to the Marantaceae family and is native to the sub-Himalayan regions of India, Pakistan, Bangladesh, and Afghanistan. It is a small, fast-growing tree that can be evergreen or deciduous, typically reaching a height of 10–12 meters. [Basu BD, et al., 2005]

This plant is valued for its unique combination of bioactive compounds, including zeatin, quercetin, beta-sitosterol, kaempferol, and caffeoylquinic acid. It is also rich in essential minerals such as iron, potassium, calcium, copper, zinc, magnesium, and manganese. Several species of the *Moringa* genus exist, including *M. arborea*, *M. Drouhard*, *M. ovalifolia*, *M. long tuba*, *M. rive*, *M. borazine*, *M. concanensis*, *M. hildebrandtii*, *M. ruspoliana*, *M. stenopetala*, *M. peregrina*, and *M. pygmaea*.

Various parts of the plant—such as the bark, leaves, seeds, flowers, roots, and immature pods— *Moringa oleifera* leaves are exceptionally nutrient-dense, containing significantly higher levels of key nutrients compared to common foods—about nine times more vitamin A than carrot, fifteen times more potassium than banana, seventeen times more calcium than milk, twelve times more vitamin C than orange, and twenty-five times more iron than spinach. The leaves are also a rich source of antioxidants, including beta-carotene, vitamin C, quercetin, and chlorogenic acid. Notably, chlorogenic acid has been reported to help reduce blood glucose levels. [Vaidya ADB, et al., 2007] Additionally, both the leaves and seeds of *Moringa oleifera* may offer protection against arsenic toxicity, which is a significant global public health issue due to groundwater contamination. The seeds are particularly effective in water purification applications. [Gupta RK, et al., 2010]

From a digestive health perspective, the plant is high in dietary fibre, which helps cleanse the intestines by removing residual waste from unhealthy diets. Furthermore, it contains isothiocyanates with antibacterial properties that may help eliminate *Helicobacter pylori*, a microorganism associated with gastritis, peptic ulcers, and gastric cancer.

It contains important phytochemicals like terpenoids, alkaloids, tannins, steroidal aglycones, and reducing sugars. The leaves are particularly rich in essential amino acids, making them beneficial for maintaining a healthy body. Traditionally, *Moringa* leaves have been widely used in Ayurvedic medicine for disease prevention and treatment, as well as for their water-purifying properties and high nutritional value. However, the small size of the leaves makes them somewhat difficult to harvest and utilize, despite their rich content of vitamins, minerals, and essential nutrients.





Figure 4 . Moringa oliefera

SYNONYMS OF MORINGA OLEIFERA

Synonyms: The plant Moringa oleifera is known by Several names throughout the world. The synonyms are give below

Sr no	Language	Name
1	Latin	<i>Moringa oleifera</i>
2	Sanskrit	Subhanjana,
3	Hindi	Saguna, Sainjna
4	Gujarati	Suragavo
5	Tamil	Mulaga , Munaga
6	Malayalam	Murinna, Sigru
7	Punjabi	Sainjna, Soanjna
8	Unani	Sahajan
9	Ayurvedic	Haritashaaka, Raktaka, Akshiva
10	Arabian	Rawag
11	French	Morungue
12	Spanish	Angela, Ben, Moringa
13	Chinese	La ken
14	English	Drumstick tree, Horseradish tree

Table 1. Synonym of moringa olifera



BIOLOGICAL SOURCE :

The dried leaves, seeds, pods, flowers, and roots of *Moringa oleifera* Lam., belonging to the family Moringaceae.”

GEOGRAPHICAL SOURCE:

Moringa oleifera is native to the sub-Himalayan tracts of northern India, Pakistan, Nepal, and parts of Bangladesh. While originating in these regions around 2000 BC, it is now cultivated worldwide in tropical and subtropical regions, including Africa, Asia, and Latin America.

TAXONOMICAL CLASSIFICATION:

Sr no	Taxonomical Rank	Classification
1	Kingdom	Plantae
2	Division	Magnoliophyta
3	Class	Magnoliopsida
4	Order	Brassicales
5	Family	Moringaceae
6	Genus	Moringa
7	species	Moringa oleifera

Table 2. Taxonomical classification of moringa oleifera

Moringa Nutrition content

Nutritional analysis	Pods (per 100 g)	Fresh leaves (per 100 g)	Dried leaves (per 100 g)
Moisture %	86.9	75	7.5
calories	26	92	205
Protein (g)	2.5	6.7	27.1
Fat (g)	0.1	1.7	2.30
Carbohydrate (g)	3.7	13.4	38.2
Fibre (g)	4.8	0.9	19.2
Minerals (g)	2	2.3	-
Calcium (mg)	30	440	2003
Magnesium (mg)	24	24	368.0
Phosphorous (mg)	110	70	204.0

Table 3: moringa nutrition content [Abarams et al.,1993]

Topographical sources and distribution of moringa oleifera

Oleifera is widely distributed worldwide, but its indigenous origin is in India, Arabia and the East Indies. It is common in Asia, Africa, the Caribbean, Latin America, the Pacific Islands, Florida, Madagascar, Central America, Cuba, the Philippines, Ethiopia, and Nigeria. The history of the plant explains that *M. oleifera* was introduced from India to Africa, Southeast Africa, and the Philippines in ancient times [Vimala, G. et al.,2014 Popoola, J.O.et al.,2013] (Figure 3). It requires tropical and subtropical regions and grows at a temperature of about 25– 35 °C.M. *oleifera* is a deciduous



type of tree typically grown in tropical and subtropical regions across the globe. It grows best in indirect sunlight and without waterlogging, and the soil should be slightly acidic to alkaline. The tree begins to bear fruit at 6 to 8 months of age. Commercially, it is grown in different countries such as Africa, Mexico, Hawaii, and South America, but due to different soil conditions, the nutrient content varies from country to country

Many households prefer to grow a small number of moringa trees around their homes. These trees are also frequently planted along roadsides, in backyards, and on unused land that is not utilized for rice farming (Fakir et al., 2017). *Moringa oleifera* (MO) is native to the Himalayan region of northwestern India, particularly the sub-Himalayan belt stretching from the Chenab River to the Sarada River and extending into Uttar Pradesh. Over time, it has been widely introduced and cultivated in several regions across the globe, including Bangladesh, Malaysia, the Philippines, Singapore, Sri Lanka, Cuba, Myanmar (Burma), and various parts of Africa (Swati et al., 2018).



Figure 5. Topographical distribution of *moringa oleifera*

Traditional uses of *moringa oleifera*

1. Internal System Support

- Supports Immune System: Boosts white blood cells, fights infections, and accelerates recovery.
- Supports Heart Health: Lowers cholesterol, improves circulation, and reduces cardiovascular disease risk.
- Regulates Blood Sugar Levels: Improves insulin sensitivity, stabilizes blood glucose, and aids diabetes control.
- Liver Wellness: Protects liver cells, aids detoxification, and restores enzyme balance.
- Digestive Health: High fiber eases digestion, prevents constipation, and soothes the gut.
- Diuretic Support: Increases urine output, reduces water retention, and supports kidney health.

2. Physical & Protective Benefits

- Anti-Inflammatory Properties: Reduces inflammation, alleviates arthritis, and supports chronic disease management.
- Bone & Joint Support: Provides minerals, reduces joint inflammation, and strengthens bones.
- Skin and Hair Health: Nourishes skin and hair, reduces ageing signs, and fights damage.
- Vitality and Energy: Enhances libido, improves sexual health and vitality.

3. Cellular Health

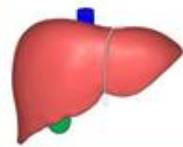
- Rich in Antioxidants: Protects cells from oxidative stress and damage, promotes longevity.
- Antioxidant Protection: Contains bioactives that suppress tumor growth and oxidative damage.





Boosts immunity

Rich in vitamins, minerals and antioxidants that strength the immune system



Detoxifies the body

supports liver function and helps in the elimination of toxins



supports heart health

helps reduce cholesterol and triglycerides level, supporting a healthy heart.

Figure 6. Health benefits of moringa olifera



Various Parts Of Moringa oleifera Used In Traditional Systems

1. Seeds are traditionally used for water purification due to natural coagulating proteins.
2. Twigs are used as natural toothbrush (chewing sticks) for oral hygiene.
3. Leaf paste is applied as a wound healing poultice for cuts, burns, and ulcers.
4. Seed oil (ben oil) is used for skin protection and anti-aging purposes.
5. Leaves and roots are used in folk medicine as supportive remedy in snake and insect bites.
6. Leaves are consumed to enhance lactation in nursing mothers.
7. Decoction of leaves and bark is used to reduce fever and support malaria treatment.
8. Traditionally used as a brain tonic to improve memory and mental clarity.
9. Extracts are used for food preservation due to antimicrobial properties.
10. Leaves are used as nutritional supplement in livestock feed to improve health and milk production.

Excipients used in moringa Enriched lozenges

Sr no	Excipients	Compatibility profile	Roles
1	Sucrose	compatible	Bulking agent sweetening agent Binder dissolution control preservative effect crystallization behaviour
2	Citric acid	compatible	antioxidant pH modifier saliva stimulation effervescent
3	Gum acacia	compatible	binder Dem esculent viscosity enhancer decontrolled drug release
4	Magnesium stearate	compatible	lubricant antiadherent flow promoter enhance product uniformity
5	Peppermint/menthol	compatible	flavouring agent cool & soothing effect fleshing effect

Table 4. Excipients used in moringa oleifera lozenges

Structural characterization of excipients

Excipient Profile:

1. Sucrose
 1. Nonproprietary Names BP: Sucrose
 - IP: Sucrose
 - USP–NF: Sucrose Ph.Eur.: Saccharose JP: Sucrose
 2. Synonyms Saccharose Cane sugar Beet sugar Table sugar Sugar



3. Chemical Name

β -D-Fructofuranosyl- α -D-glucopyranoside

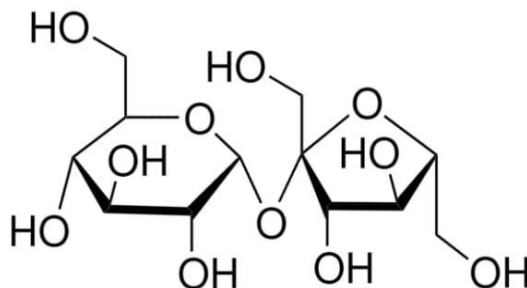
4. Empirical Formula & Molecular Weight

Molecular Formula: $C_{12}H_{22}O_{11}$ Molecular Weight: 342.30 g/mol

Sucrose is a naturally occurring disaccharide composed of glucose and fructose units linked through an α,β -glycosidic bond (Mathlouthi and Reiser, 1995)

5. Structural Formula

Sucrose contains one α -D-glucose molecule and one β -D-fructose molecule joined through a glycosidic linkage between C1 of glucose and C2 of fructose (Shallenberger and Birch, 1975).



6. Functional Category

- Sweetening agent
- Tablet binder
- Flavoring agent
- Stabilizing agent
- Coating agent
- Cryoprotectant
- Lyoprotectant

7. Applications in Pharmaceutical Formulation or Technology

Sucrose is extensively used in pharmaceutical formulations due to its excellent sweetness, stability, and compatibility with many active pharmaceutical ingredients. It is widely employed in syrups, lozenges, chewable tablets, oral suspensions, and sugar-coated tablets as a sweetening and flavor-masking agent (Rowe et al., Handbook of Pharmaceutical Excipients, 2009).

In tablet manufacturing, sucrose acts as a binder and improves granule cohesiveness during wet granulation processes. Sucrose-based coatings also enhance the appearance, elegance, and patient acceptability of dosage forms (Aulton and Taylor, 2018).

Research has shown that pharmaceutical-grade sucrose significantly improves the stability of proteins and vaccines during freeze-drying and storage by preventing protein denaturation and aggregation (Allison et al., 1999).

Sucrose is also used as a cryoprotective and lyoprotective excipient in biologics and parenteral formulations because it stabilizes biomolecular structures during freezing and dehydration processes (Carpenter and Crowe, 1989).

Recent studies on sucrose esters demonstrated their utility in enhancing drug solubility and improving controlled drug delivery systems (Garti and Aserin, 1996).

8. Description

Sucrose occurs as colorless crystals, white crystalline powder, or transparent lustrous masses with a sweet taste and odorless nature. It is obtained commercially from sugar cane and sugar beet (Mathlouthi and Reiser, 1995).

It is highly soluble in water and forms viscous aqueous solutions. Under acidic conditions or prolonged heating, sucrose undergoes hydrolysis to form glucose and fructose, commonly known as invert sugar (Rowe et al., 2009).



Pharmaceutical-grade sucrose complies with pharmacopeial specifications and is characterized by high purity, excellent stability, and low toxicity (Aulton and Taylor, 2018)

9. Typical properties

APPEARANCE –white crystalline powder

MOLECULAR WEIGHT- 342.30g/mol

MELTING POINT - ~185°C (decomposes)

DENSITY-1.58 g/cm³

The physicochemical properties of sucrose contribute significantly to its utility as a pharmaceutical excipient and stabilizer (Rowe et al., 2009).

10. Solubility

- Freely soluble in water
- Slightly soluble in ethanol
- Practically insoluble in chloroform and ether

Its high aqueous solubility makes sucrose particularly suitable for oral liquid dosage formulations (Aulton and Taylor, 2018).

11. Stability and Storage Conditions

Sucrose is stable under normal storage conditions when stored in a tightly closed container in a cool and dry place. However, exposure to moisture may lead to clumping and microbial contamination (Rowe et al., 2009).

At elevated temperatures, sucrose undergoes caramelization and degradation. In acidic environments, hydrolysis may occur resulting in the formation of reducing sugars (Mathlouthi and Reiser, 1995).

12. Incompatibilities

Sucrose may be incompatible with:

- Strong oxidizing agents
- Strong acids
- Alkaline substances
- Amines

Hydrolysis of sucrose under acidic conditions may affect formulation stability and drug compatibility (Aulton and Taylor, 2018).

13. Safety

Sucrose is generally regarded as a safe and nontoxic excipient for pharmaceutical and food applications. It is widely accepted for oral administration and has low irritancy potential (Rowe et al., 2009).

However, excessive intake of sucrose-containing products may contribute to dental caries, obesity, and hyperglycemia in diabetic patients (WHO Technical Report Series, 2015).

2. citric acid

1. Nonproprietary Names

BP: Citric Acid IP: Citric Acid

USP–NF: Citric Acid Ph.Eur.: Citric Acid JP: Citric Acid

2. Synonyms

2-Hydroxypropane-1,2,3-tricarboxylic acid Citrate acid

Sour salt Acidum citricum

3. Chemical Name

2-Hydroxypropane-1,2,3-tricarboxylic acid

4. Empirical Formula & Molecular Weight

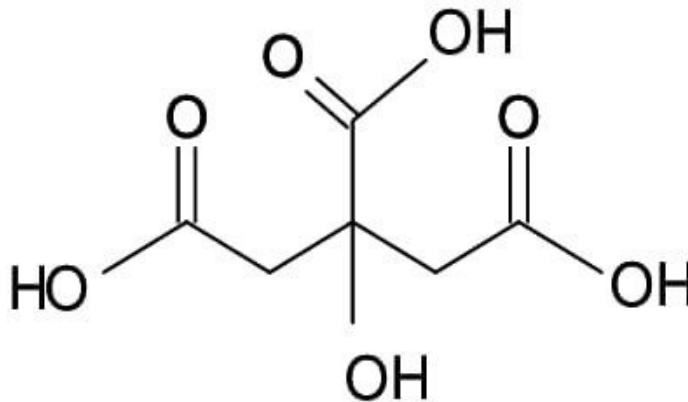
Molecular Formula: C₆H₈O₇ Molecular Weight: 192.12 g/mol

Citric acid is a weak organic tricarboxylic acid naturally present in citrus fruits and extensively used in pharmaceutical and food formulations (Rowe et al., 2009).



5. Structural Formula

Citric acid contains three carboxylic acid groups and one hydroxyl group, which contribute to its acidic nature and buffering capacity (Aulton and Taylor, 2018).



6. Functional Category

- Acidifying agent
- Buffering agent
- Chelating agent
- Flavoring agent
- Antioxidant synergist
- Effervescent agent
- pH-adjusting agent

7. Applications in Pharmaceutical Formulation or Technology

Citric acid is widely used in pharmaceutical formulations because of its excellent acidifying and buffering properties. It is commonly employed in effervescent tablets, oral solutions, syrups, lozenges, and parenteral preparations to adjust and maintain pH stability (Rowe et al., 2009).

In effervescent formulations, citric acid reacts with carbonates and bicarbonates to release carbon dioxide, thereby improving tablet disintegration and patient acceptability (Aulton and Taylor, 2018).

Research studies have demonstrated that citric acid acts as an effective chelating agent by binding metal ions, thereby improving formulation stability and preventing oxidation of active pharmaceutical ingredients (Datta et al., 2012).

Citric acid is also used as an antioxidant synergist in pharmaceutical and food products because it enhances the effectiveness of antioxidants such as ascorbic acid and sodium metabisulfite (Allen, 2013).

Several studies reported that citric acid improves the solubility and dissolution profile of poorly soluble drugs through pH modification and salt formation mechanisms (Serajuddin, 2007).

8. Description

Citric acid occurs as colorless translucent crystals or as a white crystalline powder with a strongly acidic taste and odorless nature. It is freely soluble in water and alcohol (Rowe et al., 2009).

It is commercially obtained by fermentation of carbohydrate sources such as molasses using *Aspergillus niger* microorganisms (Soccol et al., 2006).

Citric acid exhibits excellent buffering capacity and high chemical stability under normal storage conditions, making it highly suitable for pharmaceutical applications (Aulton and Taylor, 2018).

9. Typical properties

APPEARANCE: Colorless crystals or white crystalline powder

ODOR: Odorless

TASTE: Strongly acidic taste

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MOLECULAR WEIGHT: 192.12 g/mol

MELTING POINT: Approximately 153°C

DENSITY: Approximately 1.66 g/cm³

SOLUBILITY: Freely soluble in water and ethanol

PH: Acidic

NATURE: Weak organic tricarboxylic acid

HYGROSCOPICITY: Slightly hygroscopic

BUFFERING CAPACITY: Excellent buffering property CHELATING PROPERTY: Strong metal ion chelation ability

STABILITY: Stable under normal storage conditions

The physicochemical properties of citric acid make it an effective acidifying and buffering excipient in pharmaceutical formulations (Datta et al., 2012).

10. Solubility

- Freely soluble in water
- Freely soluble in ethanol
- Slightly soluble in ether

Its high aqueous solubility contributes significantly to its widespread use in oral liquid and effervescent formulations (Rowe et al., 2009).

11. Stability and Storage Conditions

Citric acid is stable in air under normal environmental conditions. It should be stored in a well- closed container in a cool and dry place protected from excessive moisture (Aulton and Taylor, 2018).

Exposure to high humidity may lead to caking due to its slightly hygroscopic nature. On heating, citric acid decomposes and may form aconitic acid derivatives (Rowe et al., 2009).

- Incompatibilities
- Citric acid may be incompatible with:
 - Strong oxidizing agents
 - Alkaline substances
 - Metal nitrates
 - Sulfides
 - Tartrates

It may react with carbonates and bicarbonates in the presence of moisture causing premature effervescence (Allen, 2013).

13. Safety

Citric acid is generally regarded as a safe and nontoxic pharmaceutical excipient when used within recommended concentrations. It is extensively used in oral, topical, and parenteral formulations (Rowe et al., 2009).

Excessive exposure may cause mild irritation to the skin, eyes, or gastrointestinal tract due to its acidic nature (WHO, 2000).

3. Gum Acaia

1. Nonproprietary Names

BP: Acacia IP: Acacia

USP–NF: Acacia Ph.Eur.: Acacia JP: Acacia

2. Synonyms Gum Arabic Acacia Gum Gum Acacia Arabic Gum Senegal Gum

3. Chemical Name

Dried gummy exudation obtained from the stems and branches of Acacia senegal and related species

4. Empirical Formula & Molecular Weight

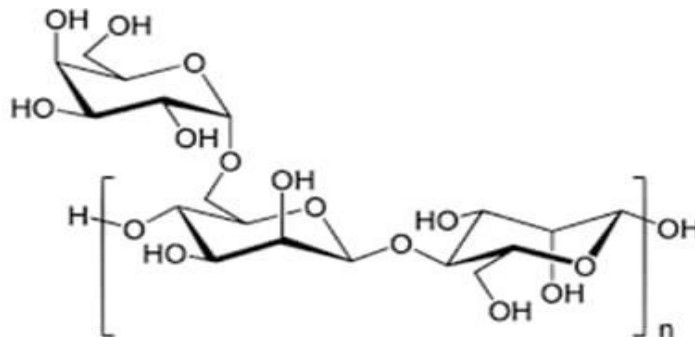
Gum acacia is a complex polysaccharide composed mainly of arabinose, galactose, rhamnose, and glucuronic acid residues. It does not possess a fixed molecular formula due to its natural polymeric nature (Rowe et al., 2009).



The average molecular weight ranges from approximately 240,000 to 580,000 Da depending on source and composition (Phillips and Williams, 2009).

5. Structural Formula

Gum acacia is a branched-chain natural polysaccharide containing calcium, magnesium, and potassium salts of arabic acid. Its structure consists mainly of galactopyranose units with side chains of arabinose and rhamnose residues (Verbeken et al., 2003).



6. Functional Category

- Suspending agent
- Emulsifying agent
- Binder
- Thickening agent
- Stabilizing agent
- Demulcent
- Film-forming agent

7. Applications in Pharmaceutical Formulation or Technology

Gum acacia is extensively used in pharmaceutical formulations because of its excellent emulsifying, suspending, and binding properties. It is widely utilized in oral suspensions, emulsions, tablets, lozenges, and topical preparations (Rowe et al., 2009).

In tablet formulations, gum acacia acts as an effective binder by improving granule cohesiveness and tablet hardness during wet granulation processes (Aulton and Taylor, 2018).

Research studies have demonstrated that gum acacia forms stable oil-in-water emulsions because of its protective colloidal properties and high water solubility (Dickinson, 2003).

Gum acacia is also employed as a suspending agent in liquid dosage forms because it increases viscosity and reduces sedimentation of insoluble particles (Allen, 2013).

Several investigations reported that gum acacia possesses excellent biocompatibility and low toxicity, making it suitable for controlled drug delivery and microencapsulation systems (Verbeken et al., 2003).

Recent pharmaceutical research has explored gum acacia as a natural polymer for sustained-release drug delivery formulations due to its biodegradable and mucoadhesive characteristics (Patel and Goyal, 2011).

8. Description

Gum acacia occurs as white to yellowish-white tears, flakes, granules, or powder with a bland taste and odorless nature. It is a natural dried gummy exudate obtained mainly from *Acacia senegal* and *Acacia seyal* trees (Rowe et al., 2009).

It is readily soluble in water forming a viscous mucilaginous solution but is practically insoluble in ethanol. Gum acacia exhibits excellent emulsifying and film-forming properties because of its complex polysaccharide structure (Phillips and Williams, 2009).

Due to its natural origin, biodegradability, and safety profile, gum acacia is widely accepted as a pharmaceutical and food excipient (Aulton and Taylor, 2018).



9. Typical properties

APPEARANCE: White to yellowish-white powder or tears

ODOR: Odorless

TASTE: Bland and mucilaginous

NATURE: Natural branched polysaccharide

MOLECULAR WEIGHT: Approximately 240,000–580,000 Da

SOLUBILITY: Freely soluble in water; insoluble in ethanol

VISCOSITY: Forms viscous mucilage in water PH: Approximately 4.5–5.5 (aqueous solution) DENSITY: Approximately 1.35 g/cm³

EMULSIFYING PROPERTY: Excellent oil-in-water emulsifier BINDING PROPERTY: Good tablet binding ability

STABILITY: Stable under dry conditions

FILM-FORMING PROPERTY: Excellent film-forming capability

HYGROSCOPICITY: Slightly hygroscopic

The physicochemical characteristics of gum acacia contribute significantly to its pharmaceutical applications as a stabilizer, emulsifier, and binder (Dickinson, 2003).

10. Solubility

- Freely soluble in water
- Practically insoluble in ethanol
- Insoluble in ether and oils

Its high aqueous solubility allows the formation of viscous colloidal dispersions suitable for pharmaceutical suspensions and emulsions (Rowe et al., 2009).

11. Stability and Storage Conditions

Gum acacia is stable under normal environmental conditions when stored in airtight containers in a cool and dry place (Aulton and Taylor, 2018).

Exposure to excessive moisture may lead to microbial contamination and viscosity changes because of its hygroscopic nature. Aqueous solutions are susceptible to microbial growth and may require preservatives (Allen, 2013).

12. Incompatibilities

Gum acacia may be incompatible with:

- Strong oxidizing agents
- Alcohol in high concentration
- Ferric salts
- Borax

1. Nonproprietary Names BP: Magnesium Stearate IP: Magnesium Stearate

USP–NF: Magnesium Stearate Ph.Eur.: Magnesium Stearate JP: Magnesium Stearate

2. Synonyms

Magnesium Octadecanoate Dibasic Magnesium Stearate Stearic Acid Magnesium Salt Vegetable Magnesium Stearate

3. Chemical Name

Magnesium octadecanoate

4. Empirical Formula & Molecular Weight

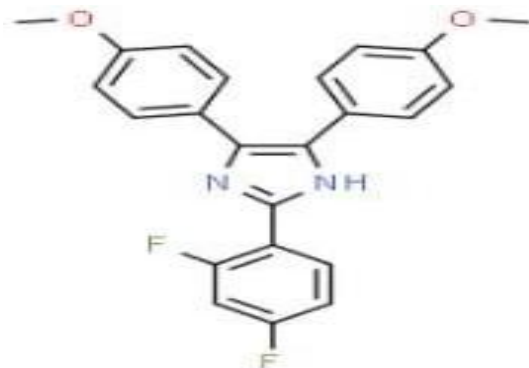
Molecular Formula: C₃₆H₇₀MgO₄ Molecular Weight: 591.24 g/mol

Magnesium stearate is a metallic soap composed mainly of magnesium salts of stearic acid and palmitic acid and is extensively used as a pharmaceutical lubricant (Rowe et al., 2009).

5. Structural Formula

Magnesium stearate consists of two stearate molecules attached to one magnesium ion, producing a hydrophobic metallic soap structure responsible for its lubricating properties (Aulton and Taylor, 2018).





6. Functional Category

Lubricant Antiadherent Glidant

Tablet manufacturing aid Capsule lubricant

7. Applications in Pharmaceutical Formulation or Technology

Magnesium stearate is one of the most widely used excipients in tablet and capsule manufacturing because of its excellent lubrication efficiency. It reduces friction between formulation particles and tablet punches during compression processes (Rowe et al., 2009).

It is commonly used in concentrations ranging from 0.25% to 5% w/w in solid dosage forms. Research studies have demonstrated that magnesium stearate significantly improves powder flowability and enhances manufacturing efficiency during direct compression tableting (Bolhuis and Chowhan, 1996).

Magnesium stearate also acts as an antiadherent by preventing sticking of granules to punches and dies during tablet compression (Aulton and Taylor, 2018).

Several investigations reported that excessive blending with magnesium stearate may decrease tablet hardness and delay tablet disintegration because of hydrophobic film formation around powder particles (Shah et al., 1986).

Research studies have shown that magnesium stearate can influence drug dissolution profiles by reducing wettability and water penetration into compressed tablets (Mollan and Celik, 1993).

In capsule formulations, magnesium stearate improves powder filling properties and enhances uniformity of low-dose formulations (Staniforth, 1988).

8. Description

Magnesium stearate occurs as a very fine, light white powder with a faint characteristic odor and greasy texture. It is practically insoluble in water, ethanol, and ether (Rowe et al., 2009).

It is produced by the reaction of magnesium salts with stearic acid or sodium stearate. Commercial magnesium stearate may contain variable proportions of magnesium palmitate and magnesium stearate (Aulton and Taylor, 2018).

Due to its hydrophobic nature and low surface energy, magnesium stearate exhibits excellent lubrication and antiadherent properties in pharmaceutical processing (Bolhuis and Chowhan, 1996).

9. TYPICAL PROPERTIES

APPEARANCE: Fine, white, light powder

ODOR: Faint characteristic odor

TASTE: Bland taste

NATURE: Hydrophobic metallic soap

MOLECULAR WEIGHT: 591.24 g/mol

MELTING POINT: Approximately 117–150°C

DENSITY: Approximately 1.03 g/cm³

SOLUBILITY: Practically insoluble in water, ethanol, and ether

PH: Neutral



LUBRICANT CONCENTRATION: Commonly used at 0.25–5% w/w

FLOW PROPERTY: Excellent flow-enhancing property

COMPRESSIBILITY: Improves tablet compression efficiency PARTICLE CHARACTER: Very fine and greasy powder STABILITY: Stable under normal storage conditions

HYGROSCOPICITY: Slightly hygroscopic

The hydrophobic and lubricating properties of magnesium stearate greatly influence tablet manufacturing efficiency and dissolution behavior (Shah et al., 1986).

10. Solubility

Practically insoluble in water Insoluble in ethanol and ether

Slightly soluble in warm benzene and warm alcohol

Its poor aqueous solubility contributes to its effectiveness as a pharmaceutical lubricant and moisture-resistant excipient (Rowe et al., 2009).

11. Stability and Storage Conditions

Magnesium stearate is stable under normal environmental conditions and should be stored in a tightly closed container in a cool and dry place protected from moisture and strong oxidizing agents (Aulton and Taylor, 2018).

Exposure to excessive humidity may affect powder flowability and lubricant performance. Prolonged storage may also alter compressibility characteristics (Bolhuis and Chowhan, 1996).

12. Incompatibilities

Magnesium stearate may be incompatible with:

Strong acids

Strong oxidizing agents Iron salts

Alkalis

Excessive concentrations may retard drug dissolution because of hydrophobic coating formation around particles (Mollan and Celik, 1993).

13. Safety

Magnesium stearate is generally regarded as a safe and nontoxic pharmaceutical excipient when used within approved concentrations. It is extensively utilized in oral solid dosage forms because of its low systemic toxicity (Rowe et al., 2009).

Research studies indicate that excessive quantities may affect dissolution and bioavailability of poorly soluble drugs; however, normal pharmaceutical levels are considered safe for human use (FDA Inactive Ingredient Database). Lead salts

Acidic or alkaline conditions may alter viscosity and emulsifying properties of gum acacia dispersions (Verbeken et al., 2003).

5. peppermint

1. Nonproprietary Names BP: Peppermint Oil USP–NF: Peppermint Oil Ph.Eur.: Peppermint Oil

2. Synonyms Mentha Oil Peppermint Essence Mint Oil

3. Chemical Name

Volatile oil obtained from the fresh aerial parts of *Mentha piperita*

4. Empirical Formula & Molecular Weight

Peppermint oil is a mixture of volatile compounds mainly containing menthol, menthone, and menthyl acetate (Rowe et al., 2009).

Major constituent:

Menthol Molecular Formula: $C_{10}H_{20}O$

Molecular Weight: 156.27 g/mol

5. Functional Category

• Flavoring agent



- Cooling agent
- Perfuming agent
- Sweetening enhancer

6. Applications in Pharmaceutical Formulation or Technology

Peppermint is widely used in pharmaceutical preparations as a flavoring and cooling agent in lozenges, syrups, mouthwashes, chewable tablets, and oral formulations because of its pleasant taste and aroma (Aulton and Taylor, 2018).

Research studies have demonstrated that peppermint oil possesses mild antimicrobial, soothing, and cooling properties due to the presence of menthol (McKay and Blumberg, 2006).

Peppermint is also commonly used in herbal and cough preparations to improve patient acceptability and mask unpleasant drug taste (Rowe et al., 2009).

7. Description

Peppermint oil occurs as a clear, colorless to pale yellow liquid with a strong characteristic mint odor and cooling taste. It is obtained mainly from *Mentha piperita* leaves by steam distillation (Aulton and Taylor, 2018).

8. TYPICAL PROPERTIES

APPEARANCE: Clear colorless to pale yellow liquid

ODOR: Strong characteristic mint odor TASTE: Cooling and refreshing taste NATURE: Volatile aromatic oil

MAIN CONSTITUENT: Menthol

SOLUBILITY: Slightly soluble in water; soluble in alcohol

VOLATILITY: Highly volatile

STABILITY: Sensitive to light and air

COOLING PROPERTY: Excellent cooling sensation

The cooling and flavoring properties of peppermint improve palatability and patient compliance in oral pharmaceutical formulations (McKay and Blumberg, 2006).

9. Solubility

- Slightly soluble in water
- Freely soluble in alcohol and oils

10. Stability and Storage Conditions

Peppermint oil should be stored in well-filled, airtight, light-resistant containers in a cool place protected from heat and light to prevent oxidation and loss of volatile constituents (Rowe et al., 2009).

11. Incompatibilities

- Peppermint oil may be incompatible with:
- Strong oxidizing agents
- Strong acids
- Alkalis

12. Safety

Peppermint is generally regarded as safe when used in pharmaceutical and food products within recommended concentrations. Excessive amounts may cause irritation or hypersensitivity reactions in sensitive individuals (McKay and Blumberg, 2006).



VII. EXPERIMENTAL WORK AND METHODOLOGY

1. Preparation of Moringa oleifera Leaf Extract

Fresh leaves of Moringa oleifera were collected, washed thoroughly, and shade-dried to preserve thermolabile constituents. The dried material was pulverized using a mechanical grinder and passed through a suitable sieve to obtain uniform particle size. The powdered drug was subjected to solvent extraction using a suitable solvent system. The extract was concentrated and dried to obtain a semisolid mass, which was stored in an airtight container for further use.

2. Formulation of Lozenges

1. Preparation of Lozenges (Heating and Congealing Method)

a. Weighing of Ingredients

Accurately weigh the required quantity of sucrose and other excipients required

b. Heating of Sucrose

Heat sucrose in a suitable vessel with continuous stirring. Continue heating until a clear, viscous syrup is formed. preparation of syrup base was prepared by dissolving required amount of sucrose in distilled water at 140°C and continuously stirring for 30 -40 mins.

2. Temperature Control

Maintain proper temperature to prevent decomposition or caramelization of sugar upto 140°C-150°C c until it the syrup breaks.

3. Incorporation of Active Ingredient

Add the prepared Moringa oleifera extract to the syrup. Mix continuously to ensure uniform distribution.

4. Addition of Binding Agent

Add gum acacia to improve cohesiveness and binding of the formulation.

5. Addition of Acidulant

Add citric acid to enhance taste and provide a slight acidic flavour.

6. Mixing

Stir the mixture thoroughly to obtain a homogeneous mass.

7. Molding

Pour the prepared mass into pre-lubricated Molds of desired shape.

8. Cooling and Solidification

Allow the Molds to cool at room temperature until the lozenges solidify.

9. Removal from Molds

Carefully remove the solidified lozenges from the Molds.

10. Drying

Dry the lozenges in a hot air oven to remove excess moisture.

11. Packaging

Pack the lozenges in suitable moisture-resistant packaging





Figure 7. stages of conversion of sucrose to syrup base

3. Formulas of preparation of moringa oleifera lozenges:

Sr no	Ingredients	F1	F2	F3	F4	F5	F6
1	Moringa	750 mg	750 mg	750 mg	750 mg	750 mg	750 mg
2	Sucrose	1700 mg	1700 mg	1800 mg	1800 mg	1900 mg	1900 mg
3	Citric acid	60 mg	65 mg	70 mg	65 mg	70 mg	75 mg
4	Acacia	90 mg	110 mg	130 mg	90 mg	110 mg	130 mg
5	Magnesium stearate	60 mg	60 mg	65 mg	65 mg	70 mg	70 mg
6	Menthol	q.s	q.s	q.s	q.s	q.s	q.s
7	distilled water	q.s	q.s	q.s	q.s	q.s	q.s
8	Total weight	2660 mg	2685 mg	2815 mg	2770 mg	2900 mg	2925 mg

Table 5. composition of moringa oleifera lozenges





Figure 8. Formulated moringa olifera lozenges

4. Optimized formula

Sr no	ingredients	F1
1	moringa	750 mg
2	sucrose	1700 mg
3	Citric acid	60 mg
4	Acacia	90 mg
5	Magnesium stearate	60 mg
6	menthol	q.s
7	distilled water	q.s
8	Total weight	2660 mg

Table 6. optimized formula for moringa olefera lozenges

Evaluation parameters

1. Genral Appearance

Colour- Light green to yellowish-green

(due to presence of Moringa oleifera extract and slight heating effect)

Odour- Characteristic herbal odour, Slight sweet smell due to sucrose

Taste- Sweet with a mild bitter aftertaste (bitterness from moringa, balanced by sugar and citric acid)

Touch (Texture)- Hard and smooth surface, slightly sticky

2. weight variation:

Lozenges were randomly checked for the uniform weight of lozenges. were 5 lozenges is selected to perform weight variation test, then average weight of lozenges for each batch is calculated and also deviation.

2 lozenges from average weight are greater than acceptance limit shall be accepted.



Sr no	Weight of lozenges	Average weight
1	2.60 g	3.08g
2	3.47g	
3	3.07 g	
4	3.36 ga	
5	2.93 g	

a) Acceptance criteria:

1. individual weight should not more than $\pm 5\%$ from average weight.
2. maximum 2 lozenges can be deviated but it should not more than $\pm 10\%$

b) formula

$$\% \text{ Deviation} = \frac{\text{Individual weight} - \text{average weight}}{\text{Average weight}} \times 100$$

Average weight

3. Hardness:

5 lozenges are randomly taken .it is based on principal of ordinary plier. Monsanto hardness tester is used for checking the hardness of lozenges. The lozenges are placed between the jaw of plier and pressure is applied by pressing the handle with hand unit until the lozenge's breaks. The reading of the dial indicates pressure needed to break the lozenges

Sr no	Hardness (kg/cm2)
1	15.7
2	15.6
3	15.3
4	15.4
5	15.6



Figure 9. Monsanto hardness tester



4. Friability test

Normally during the course of compression of lozenges a sufficient pressure is applied on the granules, so that the lozenges can withstand the wear and tear during transportation and handling. friability test is performed to evaluate the ability of the lozenges to withstand wear and tear in packing, handling and transporting. The appearance used to perform this test is known as friabilator.



Figure 10. Roches friabilator

Sr no	Initial weight	Final weight
1	2.60	2.57
2	3.47	3.44
3	3.07	3.04
4	3.36	3.33
5	2.93	2.90
Total weight	15.43	15.28

Formula:

$$\begin{aligned}
 \% \text{ friability} &= \frac{\text{initial weight} - \text{final weight}}{\text{Initial weight}} \times 100 \\
 &= \frac{15.43 - 15.28}{15.43} \times 100 \\
 &= 0.97
 \end{aligned}$$

The friability test of the prepared lozenges shows acceptable mechanical strength. The % friability was within the official limit of not more than 1%, indicating that the lozenges possess sufficient resistance to abrasion and handling during packing and transportation.

5. thickness:

the thickness of lozenges is the only dimensional variable related to the process. The thickness of individual lozenges may be measured by vernier capillary.



Sr no	Thickness (mm)
1	4.8
2	5.2
3	5.0
4	5.1
5	4.9
Average thickness	5.0

The thickness of prepared lozenges was found to be uniform and within acceptable limit. The average thickness was approximately 5.0 mm, which indicates proper compression and uniformity of the formulation.

6. Dissolution test

Place 1000 ml of phosphate buffer and previously warm temperature 37.5°C into the vessels. place the lozenges in the basket. Start the motor and adjust the rotation speed to 50-100 rpm. withdraw the volume of solution from the vessels after 5 mins. filter and determine the amount of active ingredient present in it by uv spectroscopy. repeat the complete operation 5 times upto 30 mins.

Time(min)	% of drug release
5	22%
10	41%
15	58%
20	72%
25	84%
30	92%

The dissolution study of the prepared lozenges showed gradual and uniform drug release. Approximately 92% of the drug was released within 30 minutes, indicating satisfactory dissolution characteristics of the formulation.



Figure 11. dissolution apparatus

7. Drug content

The drug content of the prepared lozenges was determined by the UV spectrophotometric method. One lozenge was accurately weighed and crushed into a fine powder using a mortar and pestle. An amount of powder equivalent to the



required drug quantity was transferred into a 100 mL volumetric flask containing a suitable solvent such as phosphate buffer or distilled water. The mixture was shaken thoroughly and sonicated to ensure complete dissolution of the drug. The volume was then made up to 100 mL with the same solvent and filtered using Whatman filter paper. An appropriate dilution of the filtrate was prepared and the absorbance was measured using a UV-visible spectrophotometer at the selected wavelength. A standard drug solution was prepared similarly and its absorbance was recorded. The percentage drug content of the lozenges was calculated using the ratio of sample absorbance to standard absorbance multiplied by 100. .

Drug Content Calculation of Individual Lozenges Assume standard absorbance = 0.500

% Drug content = Absorbance of test sample × 100

Absorbance of test standard

Sr no	Sample absorbance	Drug content (%)
1	0.492	98.4%
2	0.496	99.2%
3	0.489	97.85%
4	0.503	100.6%
5	0.495	99.0%



Figure 12. uv visible spectroscopy

VIII. RESULT AND DISCUSSION

A) weight variation Test

Sr no	Weight of lozenges	Average weight
1	2.60 g	
2	3.47g	



3	3.07 g	3.08g
4	3.36 ga	
5	2.93 g	

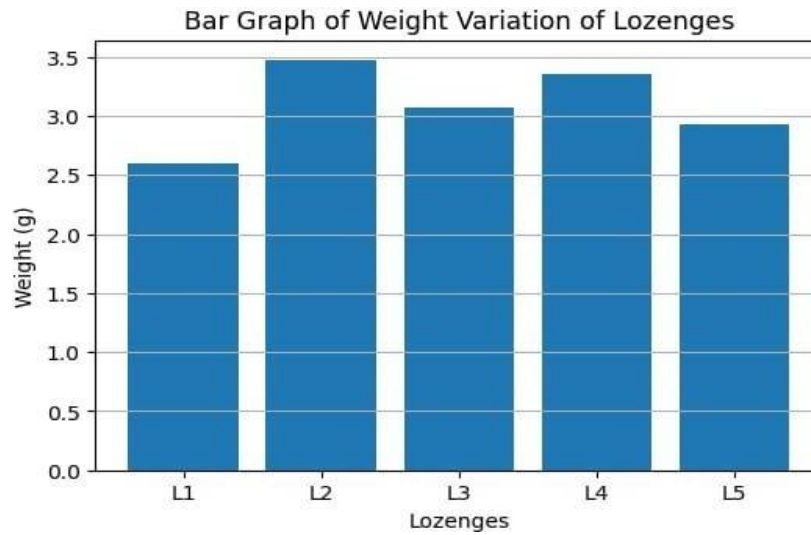
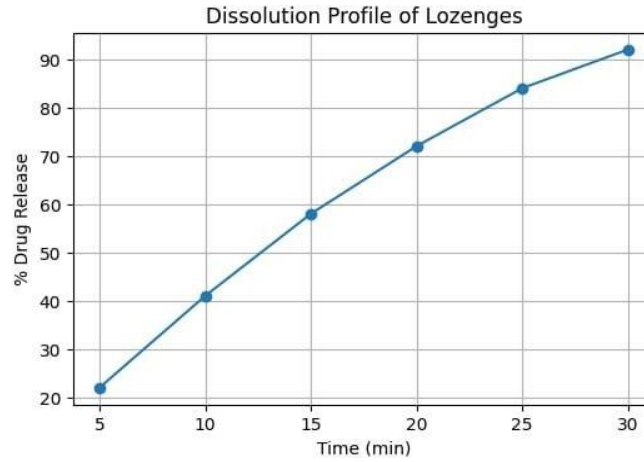


Figure 13. Weight variation

B) Drug content:

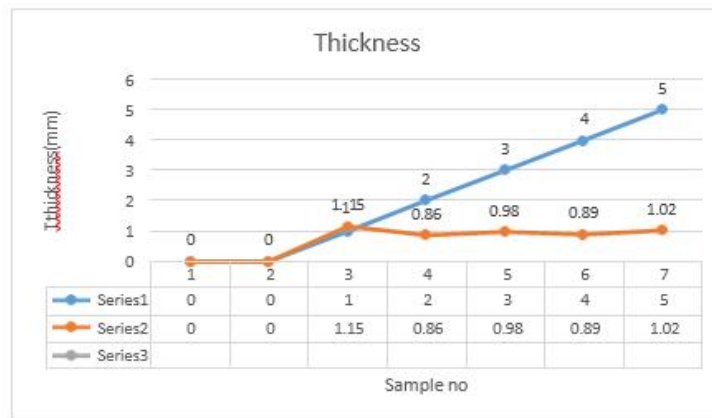
Sr no	Sample absorbance	Drug content (%)
1	0.492	98.4%
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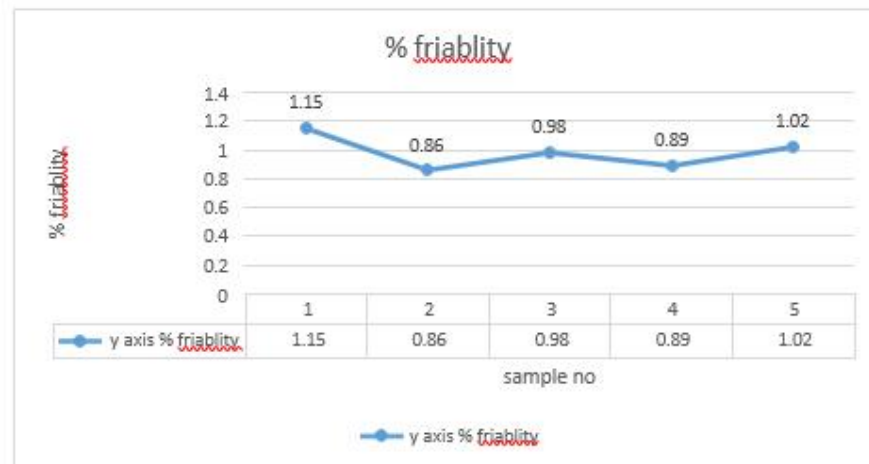


Result: Average drug content = 99% The values are within the acceptable limit of 90– 110%.

C) Thickness:



D) Friability:



Result: % friability of total lozenges is found to be 0.97% and %friability of individual lozenges is found to be 0.86 to 1.15%.

IX. THERAPEUTIC EFFECT OF MORINGA OLEIFERA LOZENGES

1. Anti-diabetic activity

The aqueous extract of *Moringa oleifera* leaves has demonstrated significant antidiabetic activity and helps in maintaining glycaemic control. A study was conducted to evaluate the in- vitro antioxidant potential and in-vivo antidiabetic activity of methanolic extracts obtained from *Moringa oleifera* pods using streptozotocin (STZ)-induced diabetic albino rats as the experimental model. The diabetic rats received extract doses of 150 mg/kg and 300 mg/kg for a duration of 21 days. Antidiabetic efficacy was assessed by analyzing various biochemical parameters in serum and pancreatic tissues. The findings revealed that treatment with the extract markedly slowed the progression of diabetes. Both administered doses significantly lowered serum glucose and nitric oxide levels, while simultaneously increasing serum insulin and protein concentrations.

Various pharmacological activities of *Moringa oleifera* have been reported using different plant parts and extracts. Aqueous and alcoholic extracts of leaves and roots exhibited antioxidant and free radical scavenging properties. Methanolic leaf extracts showed antiepileptic and anticonvulsant activities in pentylenetetrazole-induced models. Aqueous leaf extracts demonstrated antidiabetic effects in streptozotocin-induced diabetic models. Ethanolic leaf extracts displayed cardiovascular and antihypertensive activities, while aqueous root extracts showed antifertility effects. Bark extracts exhibited antiurolithiatic activity against ethylene glycol-induced urolithiasis. Alcoholic seed kernel extracts demonstrated anti-asthmatic activity in human studies. Ethanolic extracts of leaves and seeds showed hepatoprotective and anticancer properties. Methanolic and aqueous extracts prepared from roots, bark, leaves, flowers, seeds, and stalks exhibited anti-inflammatory activity in carrageenan-induced models. Macerated, infused aqueous, and ethanolic leaf extracts demonstrated anthelmintic activity using piperazine citrate as the standard. In addition, aqueous leaf extracts also showed central nervous system activity in penicillin-induced models.

2. Cardiovascular Activity

The ethanolic extract of *Moringa oleifera* leaves exhibited significant antihypertensive and hypotensive effects. In-vivo studies conducted on animal hearts demonstrated that thiocarbamate and isothiocyanate glycosides present in the extract were mainly responsible for its potent blood pressure-lowering activity.

3. Anti-Fertility Activity

The ethanolic extract of *Moringa oleifera* leaves exhibited significant antihypertensive and hypotensive effects. In-vivo studies conducted on animal hearts demonstrated that thiocarbamate and isothiocyanate glycosides present in the extract were mainly responsible for its potent blood pressure-lowering activity.

4. Anti-Asthmatic Activity

A study was conducted to evaluate the therapeutic potential of *Moringa oleifera* seed kernels in patients suffering from bronchial asthma. Male and female patients with mild to moderate asthma were administered 3 g of finely powdered dried seed kernels daily for a period of three weeks. Clinical effectiveness was determined using spirometry before and after the treatment period. Most patients exhibited increased haemoglobin (Hb) levels along with a reduction in erythrocyte sedimentation rate (ESR). Improvements were also noted in symptom scores and in the severity of asthmatic episodes. Following three weeks of treatment, significant enhancement was observed in forced vital capacity (FVC), forced expiratory volume in one second (FEV1), and peak expiratory flow rate (PEFR), which increased by $32.97 \pm 6.03\%$, $30.05 \pm 8.12\%$, and $32.09 \pm 11.75\%$, respectively.



5. Anti-Cancer Activity

Ethanollic extracts obtained from the leaves and seeds of *Moringa oleifera* exhibited significant antitumor activity. Thiocarbamate and isothiocyanate-related compounds isolated from the plant were identified as tumour promoter inhibitors. The in-vivo antitumor effect was mainly attributed to the presence of three known thiocarbamate and isothiocyanate derivatives, which inhibited teleocidin B-4-induced Epstein–Barr virus activation associated with tumour promotion.

6. Anti-microbial Activity

The leaves, roots, bark, and seeds of *Moringa oleifera* possess notable antimicrobial activity against various bacteria and fungi. In-vitro studies using the disc diffusion method demonstrated activity against bacteria, yeasts, dermatophytes, and helminths. Fresh leaves as well as aqueous seed extracts were found to inhibit the growth of *Pseudomonas aeruginosa* and *Staphylococcus aureus*

7. Anti-Inflammatory Activity

Methanolic extracts of the leaves and flowers, along with ethanolic seed extracts of *Moringa oleifera*, exhibited significant anti-inflammatory activity. In-vitro anti-inflammatory effects were also observed with hot water infusions prepared from the flowers, leaves, roots, seeds, stalks, and bark of the plant. These extracts were pharmacologically evaluated using carrageenan-induced inflammatory models.

8. CNS Activity

Extracts of *Moringa oleifera* leaves were found to restore brain monoamine levels, indicating possible therapeutic benefits in Alzheimer’s disease. The anticonvulsant potential of aqueous root extracts and ethanolic leaf extracts was investigated in-vitro using penicillin-induced seizure models. The evaluation also included locomotor activity and the measurement of neurotransmitters such as serotonin (5-HT), dopamine, and norepinephrine in the brain [22].

9. Dental Caries

Dental caries is strongly associated with cariogenic biofilms, which are oral biofilms containing a high proportion of *Streptococcus mutans*. Oral biofilms are generally well-organized structures composed of a balanced population of normal microbial flora and pathogenic bacteria such as *S. mutans*. Su-Kyung Jwa investigated the antimicrobial activity of *Moringa oleifera* leaf extracts against *S. mutans* and evaluated their inhibitory effect on the formation of cariogenic biofilms.

1. Suspending Agent

A comparative study was conducted to evaluate the suspending properties of gums obtained from *Moringa oleifera* and tragacanth. Zinc oxide suspensions were formulated using both *Moringa* gum and tragacanth gum as suspending agents. The prepared suspensions were assessed based on parameters such as sedimentation profile, dispersibility, degree of flocculation, and rheological behaviour. The findings of the study indicated that the suspending properties of *Moringa oleifera* gum are comparable to those of gum tragacanth.

2. Surfactant Behaviour

A study was conducted to investigate the interfacial properties and fluorescence characteristics of a coagulating protein isolated from *Moringa oleifera* seeds, along with its interaction with sodium dodecyl sulphate (SDS). The findings of the study revealed that:

- a) The protein extracted from *Moringa* seeds exhibits significant surfactant-like behaviour.
- b) The coagulant protein demonstrates strong interactions with SDS, suggesting the presence of specific binding sites for the surfactant molecule.



c) The interaction between the protein and SDS leads to the formation of a stable protein–SDS complex.

3. Film forming property

Studies reported that gum of *M. oleifera* has enormous potential for use in the preparation of polymeric films as drug delivery systems.

4. As stabilizer

Plant phenolics have gained considerable interest in recent years for their potential effects against food related microorganisms. Phenolic extract obtained from the leaves of *M. oleifera* and *M. druidical* showed stabilizing activity. In the present study effect of addition of phenolic extract from leaves of *M. oleifera* and *M. indicator* the shelf life of pineapple juice stored at 40 °C was investigated by monitoring the changes in titrable acidity and sensory parameters for 8 w. Results observed that the extracts of natural phenolics can be used to improve the quality and safety of foods.

X. CONCLUSION

The present study was carried out to formulate and evaluate *Moringa oleifera* lozenges. The prepared lozenges were evaluated for various physicochemical parameters such as weight variation, thickness, hardness, friability, drug content, and dissolution study. The weight variation test showed uniformity in the weight of the lozenges, indicating proper mixing and compression of the formulation. The thickness and hardness values were found to be within acceptable limits, demonstrating adequate mechanical strength and uniformity of the lozenges. The friability study indicated satisfactory resistance to abrasion when maintained within the pharmacopeial limit. Drug content analysis confirmed uniform distribution of the active constituent in the formulation with an average drug content of approximately 99%. The dissolution study showed satisfactory drug release, with about 92% drug release within 30 minutes, indicating effective release characteristics of the prepared lozenges.

Moringa oleifera possesses various pharmacological activities such as antioxidant, antimicrobial, anti-inflammatory, and immunomodulatory effects due to the presence of flavonoids, phenolic compounds, vitamins, and minerals. The formulated lozenges may help in soothing throat irritation, reducing microbial growth in the oral cavity, and providing nutritional as well as therapeutic benefits. Overall, the formulated *Moringa oleifera* lozenges exhibited acceptable quality control parameters and can be considered a stable, effective, and patient-friendly herbal lozenge formulation.

XI. FUTURE PROSPECTS

Moringa oleifera lozenges possess significant future potential in the field of herbal and nutraceutical formulations due to their therapeutic and nutritional benefits. In the future, these lozenges may be developed as an effective herbal alternative for the management of throat infections, cough, sore throat, and oral microbial conditions. Because *Moringa oleifera* contains antioxidants, vitamins, minerals, and bioactive compounds, the formulation may also be useful in improving immunity and general health.

Further studies can be carried out to enhance the stability, taste masking, and patient acceptability of the formulation. Advanced formulation techniques may be used to improve drug release and shelf life. Clinical studies and pharmacological evaluations can be performed to establish the efficacy and safety of the lozenges in human subjects. The formulation also has scope for commercialization as a natural, economical, and patient-friendly herbal product in the pharmaceutical and nutraceutical industries.

The incorporation of *Moringa oleifera* into lozenge formulations also offers promising applications in respiratory care, throat infections, oral health management, and immune- supportive therapies due to its antimicrobial and soothing effects. Recent reviews suggest that moringa-derived products may emerge as valuable nutraceutical and phytopharmaceutical preparations for chronic disease prevention and supportive healthcare management (Azlan et al., 2022)



In future pharmaceutical research, development of sugar-free moringa lozenges using alternative sweeteners such as isomalt and xylitol may improve suitability for diabetic and pediatric patients. Furthermore, incorporation of herbal synergistic agents such as peppermint, ginger, tulsi, and honey may enhance therapeutic effectiveness and market value of moringa lozenges.

Advanced clinical studies and toxicity evaluations are still required to establish standardized dosage regimens, long-term safety, and therapeutic efficacy of moringa-based lozenges in human subjects. Current literature strongly supports the potential of *Moringa oleifera* as a future phytopharmaceutical and functional medicinal product with wide industrial and therapeutic applications (Pareek et al., 2023).

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