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Formulation and Evaluation of Digestion Enhancer Soft Gel Lozenges

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Abstract
Digestive disorders such as dyspepsia, bloating, flatulence and indigestion account for a huge global health burden with millions of individuals suffering from them leading to decrease in quality of life. This study reports the design and characterization of soft gel lozenges incorporating bitter leaf (Vernonia amygdalina) extract as the active pharmaceutical ingredient, integrated with fennel oil (Foeniculum vulgare) and cardamom oil (Elettaria cardamomum) as a synergistic combination. Excipients used with these active components include gulkand (rose petal preserve), rose water, gelatine. Soft gel lozenges represent a novel and patient-friendly delivery system for herbal actives, offering advantages such as ease of administration, pleasant organoleptic properties, and enhanced mucosal absorption.
The formulations were characterized for physicochemical parameters including weight variation, hardness, friability, disintegration time, and in vitro drug release. The optimized formulation exhibited acceptable organoleptic properties, satisfactory stability, and effective digestive activity. These results support the potential of this herbal lozenge as a safe, effective, and palatable alternative for managing common digestive ailments.
Keywords: Soft gel lozenges, herbal formulation, digestive disorders, carminative, patient compliance

Introduction

Food is broken down mechanically and chemically into absorbable nutrients during digestion, a basic physiological process. An estimated 40% of persons experience gastrointestinal problems at any given time, making digestive system disorders one of the most common ailments in the world [1-4]. Common ailments including indigestion, bloating, gas, nausea, and dyspepsia severely hinder day-to-day functioning and are frequently poorly treated by traditional pharmaceutical treatments, which may have negative side effects with prolonged usage [5].

Plant-based treatments for digestive disorders have long been used in traditional herbal therapy. There are several ethnopharmacological records of plants including Elettaria cardamomum (cardamom), Foeniculum vulgare (fennel), and Vernonia amygdalina (bitter leaf) as carminatives, digestive tonics, and anti-spasmodic [6, 7]. There are chances to improve these ancient treatments' effectiveness, safety, palatability, and patient compliance by incorporating them into contemporary pharmaceutical dosage forms.

Lozenges are solid dosage forms designed to gradually dissolve or disintegrate in the mouth, releasing the medication for systemic or local action through the oral mucosal channel. Soft lozenges, which can include gelatine, glycerin, and other flexible excipients, offer a chewable or slowly dissolving matrix that is especially well-suited to herbal formulations that need to have a pleasing flavor and controlled release [8].

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The formulation's sensory qualities are further enhanced by the use of traditional substances like rose water and gulkand, which align it with Unani and Ayurvedic pharmaceutical traditions [9].

The goal of the current project is to create and assess a soft gel lozenge formulation for improving digestion by combining pharmaceutically approved excipients with herbal active ingredients that have been scientifically proven to be effective, stable, safe, and patient-acceptable.

Literature Review

Bitter Leaf (Vernonia amygdalina) — Primary Active

Bitter leaf, or Vernonia amygdalina, is a member of the Asteraceae family and is used extensively in Asian and African traditional medicine systems due to its hepatoprotective, anti-inflammatory, digestive, and antibacterial qualities [10]. Sesquiterpene lactones (vernodalin, vernolide), flavonoids, alkaloids, tannins, saponins, and phenolic acids are among the many bioactive components found in the plant [11]

Sesquiterpene lactones, which activate bitter taste receptors (TAS2Rs) in the gastrointestinal tract to induce gastric acid secretion, are the main cause of Vernonia amygdalina's bitter flavor. The generation of digestive enzymes, bile salts, and gastric hydrochloric acid is increased by this bitterness-induced secretagogue action, which promotes more effective macronutrient digestion [12]. Additionally, vernodalin and similar compounds have shown notable anti-inflammatory effects on the intestinal epithelium and gastric mucosa, lowering inflammation linked to gastritis and chronic dyspepsia [13].

Aqueous extracts of V. Amygdalina considerably enhanced gastrointestinal transit speed and decreased dyspepsia symptoms in human patients, according to a clinical investigation by Izevbigie (2003) [14]. The inhibitory effect of bitter leaf extracts against Helicobacter pylori, a prominent causative agent of chronic gastritis and peptic ulcer disease, was validated by later in vitro research [15].

Fennel Oil (Foeniculum vulgare)

For centuries, Ayurvedic, Chinese, and European traditional medicine have utilized fennel (Foeniculum vulgare Mill., family Apiaceous) and its essential oil as carminatives, antispasmodics, and digestive tonics [16]. Trans-anethole (50–80%), fenchone (10–15%), estragole, and limonene make up the majority of the essential oil, which together give it its distinctive anise-like scent and medicinal qualities [17].

The main bioactive component of fennel oil that gives it its carminative and antispasmodic properties is trans-anethole. It relieves intestinal cramps, colic, and flatulence by blocking smooth muscle contraction in the gastrointestinal tract via calcium channel antagonism [18]. Furthermore, fennel oil has been shown to have prokinetic activity via improving intestinal motility and stomach emptying, which further supports its function in controlling bloating and postprandial pain [19].

The antibacterial action of fennel oil against intestinal pathogens such as Salmonella spp., Candida albicans, and E. coli has been validated by pharmacological tests, indicating further advantages in preserving gastrointestinal microbial balance [20]. Fennel oil's usage in food and medicinal preparations is supported by the FDA's GRAS (Generally Recognized as Safe) certification [21].

Cardamom Oil (Elettaria cardamomum)

One of the most prized spices in the world, cardamom (Elettaria cardamomum Maton, family Zingiberaceae) is widely used in Ayurvedic medicine as a stomachic, carminative, and digestive agent [22]. The unique scent and biological activity of the essential oil are attributed to its abundance of 1,8-cineole (eucalyptol, 20–40%), α-terpinyl acetate (30–40%), linalool, and other monoterpenes [23].

Inhibition of gastric acid hypersecretion, relaxation of gastrointestinal smooth muscle (antispasmodic action), stimulation of salivary flow and secretion of digestive enzymes, and anti-inflammatory effects on the gastrointestinal mucosa are some of the ways that cardamom oil improves digestion [24]. Cardamom extracts greatly decreased gastrointestinal ulcers and enhanced mucosal integrity in experimental animals, according to a study by Jamal etc. al. (2006) [25].

The gastroprotective properties of cardamom oil have also been shown in in vitro and in vivo experiments, with notable prevention of stomach lesions caused by ethanol and indomethacin in mouse models [26]. In the lozenge formulation, the pleasant, fragrant flavor of cardamom oil also acts as a taste-masker, enhancing overall palatability and patient acceptance [27].

Soft Gel Lozenges as a Dosage Form

The United States Pharmacopeia (USP) defines lozenges as solid preparations meant to dissolve or disintegrate gradually in the oral cavity [28]. In contrast to hard candy lozenges, soft lozenges, also known as chewable lozenges or pastilles, are made with a foundation of gelatin, glycerin, sugar, and other plasticizers that give them a soft, flexible structure [29].

Lozenges' oral mucosal delivery provides a number of pharmacokinetic advantages over traditional tablets and capsules, including the avoidance of first-pass hepatic metabolism, quick onset of local action in the oropharyngeal region, increased bioavailability of active ingredients, and improved patient compliance (particularly in pediatric and geriatric populations) [30]. Particularly for herbal formulations, the slow-release matrix of soft lozenges permits bioactive phytochemicals to remain in contact with the oral and gastric mucosa for an extended period of time, which may improve their local therapeutic effects [31].

The formulation's use of rose water and gulkand, a traditional rose petal confection, is consistent with Unani and Ayurvedic pharmacy principles, where these components function independently as flavorings, demulcents, and mild digestive tonics [32]. The structural matrix is provided by gelatin, the humectant and plasticizer is glycerin, the acidulant and preservative is citric acid, and the antimicrobial preservative is sodium benzoate [33]. [Sources: 28, 29, 30, 31, 32, 33]

Excipients — Role and Rationale

Based on their proven safety profiles, functional qualities, compatibility with the active ingredients, and adherence to conventional pharmaceutical procedures, the excipients were chosen for this formulation. Each excipient's function is summarized in the following table:

Table 1: List of Excipients

Excipient	Category	Function in Formulation	Reference(s)
Gulkand	Traditional / Flavouring Agent	Natural sweetener, demulcent, mild digestive tonic; improves palatability and complements the digestive action	[32, 34]
Rose Water	Solvent / Flavoring	Natural flavoring and aroma agent; mild astringent and anti-inflammatory; aids in wetting and solubilizing actives	[35]
Gelatine	Gelling Agent / Matrix Former	Provides the structural framework of the soft lozenge; film-forming and binding properties	[36]
Glycerin	Humectant / Plasticizer	Prevents drying and cracking of the lozenge; improves flexibility and mouthfeel; mild sweet taste	[37]
Citric Acid	Acidulant / Preservative / pH Modifier	Adjusts pH for stability; enhances flavor profile; mild preservative action; chelates metal ions	[38]
Sodium Benzoate	Antimicrobial Preservative	Prevents microbial contamination and extends shelf life; active at pH 2.5–4.0	[39]
Purified Water	Solvent / Vehicle	Medium for dissolution and hydration of gelatin; preparation of solutions for incorporation	[40]

Gulkand

Fresh rose petals (Rosa damascena) are slowly cold-processed with sugar to create gulkand, a traditional Ayurvedic and Unani preparation. Its cooling, digestive, and adaptogenic qualities are well-established [34]. It lessens the harshness of the Vernonia amygdalina extract while adding natural sweetness, a lovely flowery scent, and a slight digestive aid. The formulation's digestive improvement profile is further enhanced by Gulkand's demonstrated antioxidant and anti-ulcer properties [32].

Rose Water

Rosa damascene petals are used to make rose water (Aqua rosae), which has long been used in culinary and medicinal preparations. In this formulation, it acts as a naturally occurring aromatic solvent, adding a pleasing flavor and scent. Citronellol, geraniol, and phenethyl alcohol are found in rose water and have modest antibacterial qualities [35]. Rose water is a suitable vehicle for this concoction because it is regarded in traditional medicine as a mild carminative and digestive system tonic.

Gelatin

Gelatin is a hydrolyzed collagen protein that is frequently employed as a gelling, binding, and film-forming ingredient in food and pharmaceutical applications. Gelatin creates the flexible matrix that provides soft lozenges their distinctive feel and regulated degradation profile [36]. According to BP/USP guidelines, pharmaceutical-grade gelatin (Type A or B) is utilized. Additionally, gelatin acts as a modest protective colloid that may lessen stomach irritation caused by bitter or acidic substances.

Glycerin

Glycerin, also known as propane-1,2,3-triol, is a plasticizer, humectant, and sweet-tasting polyol that is used in pharmaceuticals. Glycerin enhances mouthfeel, keeps the gelatine matrix flexible and soft, and stops moisture loss in soft lozenges [37]. All of the major pharmacopoeias recognize glycerin, which is categorized as GRAS. Its hygroscopic quality also helps to keep the formulation's water activity at the proper level to prevent microbial growth.

Citric Acid

Pharmaceuticals frequently employ citric acid, a naturally occurring organic acid, as an acidulant, pH modulator, flavor enhancer, and preservative adjunct [38]. Citric acid is used in this formulation to: (I) reduce the pH to the ideal range for sodium benzoate action; (ii) improve the lozenge's crisp, refreshing flavor character; and (iii) chelate metal ions that may otherwise catalyze the essential oil components' oxidative breakdown. At the amounts used in food and pharmaceutical goods, citric acid is regarded as safe and is listed in BP, USP, and the European Pharmacopoeia.

Sodium Benzoate

Sodium benzoate is a widely used antimicrobial preservative active against bacteria, yeasts, and molds [39]. Its mechanism of action involves the undissociated benzoic acid form penetrating microbial cell membranes and inhibiting respiratory enzymes and fatty acid biosynthesis. It is most effective at pH values below 4.5, which aligns with the acidic pH achieved through citric acid addition in this formulation. Sodium benzoate is used at concentrations up to 0.1% w/w in pharmaceutical preparations and is recognized as safe by regulatory authorities including the FDA, EFSA, and WHO.

Formulation Development

A soft, palatable lozenge that:
(I) delivers an effective dose of digestive actives; (ii) disintegrates/dissolves slowly in the mouth over 5–15 minutes; (iii) is free from microbial contamination; (iv) demonstrates acceptable stability over 24 months at ambient conditions; and
(v) masks the inherent bitterness of V. amygdalina extract through appropriate flavoring and sweetening agents was the target product profile (QbD) approach [41].

Composition (Per Lozenge)

The following table presents the optimized composition per lozenge unit (3 g target weight):

Table 2: Composition of Formulation

Ingredient	Category	Quantity (mg)	Reference
Bitter Leaf Extract (Vernonia amygdalina)	Active	200	[10, 14]
Fennel Oil (Foeniculum vulgare)	Active / Carminative	50	[18, 20]

Cardamom Oil (Elettaria cardamomum)	Active / Stomachic	30	[24, 26]
Gulkand	Sweetener / Demulcent	500	[32, 34]
Rose Water	Solvent / Flavoring	300	[35]
Gelatine (Pharmaceutical Grade)	Matrix Former / Binder	600	[36]
Glycerin	Humectant / Plasticizer	400	[37]
Citric Acid	Acidulant / Preservative	150	[38]
Sodium Benzoate	Antimicrobial Preservative	10	[39]
Purified Water (q.s.)	Vehicle / Solvent	q.s. to 3000	[40]

Manufacturing Process

The manufacturing procedure was created in compliance with WHO technical report series No. 996 (2016) [42] and GMP (Good Manufacturing Practice) guidelines:

Step 1: Bitter Leaf Extract Preparation: Using maceration for 72 hours, dried, powdered V. amygdalina leaves were extracted using aqueous-ethanolic extraction (70% ethanol). To create a standardized dry extract (yield: ~12% w/w), the extract was filtered, condensed under low pressure, and spray-dried.

Step 2: Gelatine Base Preparation: Pharmaceutical-grade gelatine was dissolved at 60°C with constant gentle stirring after being allowed to swell in purified water (1:3 w/v) for 30 minutes. The melted gelatine solution was mixed with glycerin.

Step 3: Incorporation of Actives: Rose water was heated to dissolve the bitter leaf dry extract. A tiny amount of glycerine was used to pre-mix and emulsify the fennel and cardamom oils. At 50–55°C, both solutions were added to the gelatine foundation while being constantly stirred.

Step 4: Excipient Addition: After thoroughly mixing the bulk mixture, Gulkand, citric acid, and sodium benzoate were added one after the other. Purified water was used to modify the mass to the necessary weight.

Step 5: Molding and Setting: The warm, uniform mass were poured into pre-lubricated lozenge molds with a 3 g capacity. It was then left to set for two hours at room temperature (25°C) before being refrigerated for thirty minutes at 4°C

Step 6: Demoulding, Inspection, and Packaging: The solidified lozenges were demolded, visually examined for homogeneity, packaged in moisture-resistant packaging, and kept for assessment at 25°C and 60% relative humidity.

Evaluation Parameters

According to Indian Pharmacopoeia (IP) 2022, British Pharmacopoeia (BP) 2023, and pertinent WHO guidelines [43, 44], the prepared soft gel lozenges were assessed for a wide range of physicochemical, organoleptic, microbiological, and stability criteria.

Table 3: Evaluation test results

Evaluation Test	Method / Standard	Acceptance Criteria	Reference
Organoleptic Properties	Visual, olfactory, taste assessment	Soft, uniform, pleasant taste and aroma	[43]
Weight Variation	20 lozenges weighed; % deviation calculated	NMT ±5% deviation	[43, 44]
Hardness / Texture	Texture analyzer (TA-XT Plus)	0.5–2.0 N (soft gel standard)	[29]
Moisture Content	Karl Fischer titration / Loss on drying	NMT 15% w/w	[43]
pH of Extract (1% solution)	Digital pH meter (calibrated)	4.0–5.5	[38]
Disintegration Time	Simulated saliva at 37°C	5–15 minutes	[28]
In Vitro Drug Release	Paddle apparatus, pH 6.8 PBS, 50 rpm	NLT 75% in 30 minutes	[43]

Microbial Limit Test	IP 2022 — TAMC, TYMC, pathogens	TAMC NMT 103 CFU/g	[43]
Preservative Efficacy (Sodium Benzoate)	Antimicrobial challenge test	Category 2 criteria (IP/BP)	[39, 44]
Stability Studies	ICH Q1A(R2): 40°C/75%RH, 6 months	No significant change in all parameters	[45]
Evaluation Test	Method / Standard	Acceptance Criteria	Reference
Assay of Active Marker	HPLC — Vernodalin (Bitter Leaf)	90–110% of label claim	[46]

Table 4: Results of Optimized Formulation

Parameter	Result	Inference
Color	Dark greenish-brown	Characteristic of bitter leaf extract
Odour	Pleasant, aromatic (fennel & cardamom dominant)	Acceptable
Taste	Mildly sweet with slight bitterness, pleasant finish	Acceptable; bitterness well-masked by gulkand
Average Weight	3.02 ± 0.08 g	Within ±5% limit — PASS
Hardness	1.2 ± 0.15 N	Within soft gel range — PASS
Moisture Content	8.5 ± 0.6%	Within limit (NMT 15%) — PASS
pH	4.3 ± 0.2	Optimal for sodium benzoate activity — PASS
Disintegration Time	9.5 ± 1.2 minutes	Within 5–15 min — PASS
In Vitro Drug Release (30 min)	82.4 ± 3.1%	NLT 75% — PASS
Microbial Limit (TAMC)	< 50 CFU/g	Complies with IP 2022 — PASS
Assay (Vernodalin)	97.8 ± 1.5%	Within 90–110% — PASS

Mechanism of Action

The digestion-enhancing effect of the formulated lozenge is mediated through complementary and synergistic mechanisms of the three active ingredients [47]:

Stimulation of Digestive Secretions (Bitter Leaf)

The oral cavity and gastrointestinal epithelium's TAS2R bitter taste receptors are activated by sesquiterpene lactones from V. amygdalina, primarily vernodalin and vernolide. This activation improves the chemical phase of digestion by reflexively increasing the secretion of bile, pepsin, and stomach acid (HCl) [12]. These receptors are stimulated for an extended period of time by the lozenge's protracted disintegration in the oral cavity.

Carminative and Antispasmodic Action (Fennel Oil)

Fennel oil's trans-anethole and fenchone prevent the gastrointestinal wall's smooth muscle from contracting in response to calcium. Gas pains, intestinal colic, and postprandial bloating are all relieved by this antispasmodic effect [18]. Furthermore, by relaxing the intestinal cardia and lower esophageal sphincter, fennel oil encourages the outflow of intestinal gas [19].

Gastroprotective and Stomachic Action (Cardamom Oil)

Cardamom oil's α-terpinyl acetate and 1,8-cineole promote the production of gastric mucus, which acts as a barrier against acid-induced mucosal damage [24]. By inhibiting pro-inflammatory cytokines and cyclooxygenase (COX) enzymes in the stomach and intestinal mucosa, these components also exhibit anti-inflammatory effect [26].

Synergistic Digestive Benefit of Gulkand and Rose Water

Additional demulcent and anti-inflammatory properties are offered by gulkand and rose water, which calm the stomach mucosa and lessen the burning feeling connected to acid dyspepsia [32, 35]. Rose petal extracts' polyphenols also support the gastrointestinal lumen's antioxidant milieu, shielding mucosal cells from oxidative damage.

Ingredient	Regulatory Status / Safety Data	Reference
Bitter Leaf Extract	Traditional use; LD50 (oral, rat) > 2000 mg/kg (aqueous extract); no mutagenicity in Ames test	[10, 13]
Fennel Oil	GRAS (FDA 21 CFR 182.20); FEMA No. 2483; ADI not limited (JECFA)	[16, 21]
Cardamom Oil	GRAS (FDA 21 CFR 182.20); FEMA No. 2241; widely used in food and pharma	[22, 27]
Gulkand	Traditional food ingredient; GRAS equivalent; extensive human use data	[34]
Gelatin	USP/NF; BP; GRAS; extensively used in pharmaceutical products	[36]
Glycerin	GRAS (FDA); USP/NF; oral ADI: not limited (WHO)	[37]
Citric Acid	GRAS; USP/NF; oral ADI: not limited (JECFA)	[38]
Sodium Benzoate	GRAS (FDA, NMT 0.1% w/v); WHO ADI: 0–5 mg/kg body weight	[39]

Stability Studies

In accordance with ICH Guideline Q1A(R2) [45], stability investigations were carried out under the following circumstances.

Accelerated conditions: 75% RH ± 5% RH and 40°C ± 2°C for six months. For six months, the intermediate conditions are 30°C ± 2°C and 65% RH ± 5%. Long-term conditions: 60% RH ± 5% RH and 25°C ± 2°C for 24 months (continuous)

Samples were taken out at 0, 1, 2, 3, and 6 months, and their physical characteristics, weight, pH, moisture content, assay, microbiological load, and release profile were assessed. The optimized formulation did not significantly degrade the active ingredients, change in color or texture, or rise in microbial count during the accelerated trial period, according to the results. Throughout the investigation, microbial growth was successfully prevented by the acidic pH that citric acid and sodium benzoate maintained [38, 39, 45].

Safety and Toxicological Profile

Each ingredient's known safety data supports the manufactured lozenge's safety.

Contraindications: People who are known to be hypersensitive to any of the substances indicated should take the product with caution. A healthcare provider should provide guidance for use during pregnancy and lactation. Because lozenges might cause choking, the product is not advised for children under the age of six without a doctor's consultation.

A major step forward in the conversion of ancient herbal medicines into contemporary, patient-acceptable pharmaceutical dose forms is the development and testing of soft gel lozenges for improved digestion. Both traditional use and current pharmacological evidence support the choice of V. amygdalina, F. vulgare oil, and E. cardamomum oil as major actives [10, 16, 22].

One particularly creative aspect of the recipe is the usage of gulkand. In addition to providing its own demulcent and digestive qualities, gulkand acts as a flavoring agent and a mild medicinal element, hiding the strong bitterness of V. amygdalina extract—a common problem when creating medicines from this plant [34]. This method is consistent with the idea of "synergistic formulation," which is supported by both contemporary combination drug theory and Ayurvedic pharmacopoeia.

The gelatin-glycerin technique produces the soft gel lozenge matrix, which offers these herbal actives the perfect delivery system. In order to maximize bitter receptor stimulation and start the cephalic phase of digestive secretion, the regulated disintegration profile (9.5 ± 1.2 minutes) guarantees extended contact of the actives with oral and oropharyngeal mucosa. The in vitro release data (82.4% in 30 minutes) confirms sufficient bioavailability of the active ingredients and is in line with the anticipated release profile for soft lozenges [30, 31].

The pH of 4.3 attained by adding citric acid is crucial for two reasons: it maximizes the antibacterial activity of sodium benzoate and preserves the stability of the essential oil components. The selected preservative system's effectiveness and compliance with pharmacopoeia standards are confirmed by the microbiological limit results (< 50 CFU/g) and preservative efficacy test results [38, 39].

Conclusion

Gulkand, rose water, gelatin, glycerin, citric acid, sodium benzoate, and purified water are among the carefully chosen excipients that support the soft gel lozenge formulation that contains bitter leaf extract, fennel oil, and cardamom oil. This formulation has been successfully developed and tested as a novel herbal digestive aid. Under ICH circumstances, the formulation showed excellent stability, strong microbiological purity, palatability, effective release of active ingredients, and satisfactory physicochemical qualities.

Gulkand and rose water are creatively incorporated into the formulation to bridge the gap between modern herbal product development and traditional Ayurvedic/Unani pharmaceutical techniques. A comprehensive strategy for treating common digestive issues is provided by the synergistic activity of the three herbal actives, which work through complimentary pathways combining bitter receptor stimulation, smooth muscle relaxation, gastroprotection, and anti-inflammatory action.

Additional research is advised, such as long-term stability studies (24 months), comprehensive pharmacokinetic profiling of important active indicators, and clinical evaluation in human subjects. This composition offers a safe, natural, and efficient substitute for traditional antacids and digestive enzyme supplements, and it has a great chance of being commercialized as an over-the-counter (OTC) herbal digestive health product.

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