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Research Article

Formulation and Evaluation of a Polyherbal Local Anesthetic Gel for Dental Application

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ABSTRACT

The clinical management of odontalgia primarily relies on the administration of synthetic local anesthetics. Although these agents provide rapid relief, their use is frequently complicated by concerns regarding systemic toxicity and localized tissue irritation, which can limit their suitability for certain patient populations or frequent applications. This study investigated the development and characterization of a polyherbal anesthetic gel as a safer, plant-derived alternative intended for targeted dental use. The formulation utilized standardized extracts of Acmella oleracea at a concentration of 10%, Zingiber officinale at 2%, and Salvia officinalis at 0.1. These active constituents were integrated into a Carbopol 940 polymeric gel matrix, chosen for its ability to provide a stable delivery vehicle that adheres effectively to the oral mucosa. Physicochemical analysis revealed that the polyherbal gel possessed high homogeneity and maintained a pH of 6.0. This pH level is particularly significant because it is compatible with human skin and mucosal surfaces, reducing the likelihood of chemical irritation upon application. Rheological testing established a viscosity of 4850 ± 120 cps and a spreadability of 16.24 ± 0.35 g.cm/sec. These parameters are essential for ensuring that the gel can be easily applied to the affected area while remaining localized long enough to facilitate drug absorption. In vitro release models indicated that the active ingredients diffused from the matrix within 10–15 min. Within this profile, spilanthol, a bioactive alkylamide derived from Acmella oleracea, was identified as the primary contributor to localized anesthetic efficacy, likely due to its known ability to penetrate mucosal layers and interact with sensory nerve endings. The therapeutic potential of the gel extended beyond pain relief, as evidenced by the antimicrobial and anti-inflammatory assays. Preliminary tests showed zones of inhibition greater than 15 mm against common oral pathogens, suggesting that the formulation may help mitigate the microbial load associated with dental caries or gingival inflammation. The interaction between gingerols from Zingiber officinale and

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rosmarinic acid from Salvia officinalis significantly decreased inflammatory markers in simulated cell lines. This suggests a synergistic effect, where the formulation simultaneously addresses pain sensation and the underlying inflammatory response. Safety profiles were established through cytotoxicity and human patch tests. The formulation exhibited minimal cytotoxicity, with an IC50 ≥ 500 µg/mL, indicating a high threshold for cellular safety. In vivo performance was characterized by the absence of erythema or adverse reactions during human patch testing, although clinicians should advise against excessive application to prevent potential sensitivity in particularly delicate mucosal areas. Stability testing over 30-day period showed no evidence of phase separation, grittiness, or loss of physical integrity. These results support the conclusion that the developed polyherbal gel is a stable and effective natural alternative for managing dental pain, with the potential to serve as a significant component in the development of next-generation, over-the-counter dental products.

INTRODUCTION

Odontalgia: Definition and Nature Odontalgia, widely recognized as toothache, is defined as pain originating from a tooth or its immediate supporting structures. Rather than being a standalone disease, it is a clinical symptom that indicates an underlying pathology within dental tissues, such as the enamel, dentin, pulp, periodontal ligament, or alveolar bone. It is one of the most frequent causes of dental visits, presenting with symptoms ranging from mild, temporary discomfort to severe, continuous pain that can disrupt daily functions such as eating and speaking. Clinically, this is significant because it often serves as the first sign of conditions such as dental caries, pulpitis, or periodontal disease.

Anatomy of the tooth: Pain can arise from various structures. While the enamel itself lacks innervation, its loss, often due to erosion or caries, exposes the underlying dentin. Dentin contains microscopic tubules that connect directly to the pulp, rendering it sensitive to mechanical and thermal stimuli. The dental pulp is the most sensitive structure, containing blood vessels, connective tissue, and nerves; consequently, inflammation typically results in intense pain. Pain may also originate from the periodontal ligament, particularly during chewing, or be referred from non-dental areas, such as the maxillary sinus or temporomandibular joint.

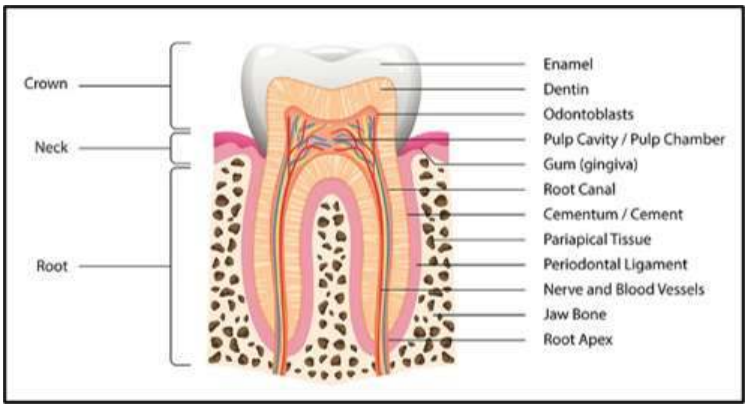


Figure 1 Anatomy of tooth

Pain Mechanism: The mechanism underlying odontalgia varies based on the affected tissue. The “hydrodynamic theory" is the prevailing explanation for dentin-related sensitivity. This theory posits that stimuli such as cold, heat, or sugar cause the fluid within the dentinal tubules to move, stimulating mechanoreceptors near the pulp and producing sharp, sudden pain. Dental pain is initiated when noxious stimuli, including dental caries, trauma, or infection, induce tissue damage and activate nociceptors primarily situated in the dental pulp and dentin. This process involves the release of inflammatory mediators, such as prostaglandins, bradykinin, histamine, and

substance P, which decrease the activation threshold and sensitize these sensory nerve endings. According to hydrodynamic theory, external factors such as temperature fluctuations or osmotic changes cause fluid displacement within the dentinal tubules, thereby stimulating nerve fibers at the pulp-dentin interface. The resulting impulses are conducted via A-delta fibers, which transmit rapid and localized sharp pain, and C fibers, which are responsible for dull, lingering, and throbbing sensations. These signals are relayed through the trigeminal nerve to the brain for sensory processing. Persistent inflammation can further enhance nerve sensitivity, leading to prolonged pain and increased responsiveness to stimuli that are typically nonpainful.

Classification of Odontalgia:

- Reversible Pulpal Odontalgia: Characterized by brief pain triggered by specific stimuli (such as cold or sweets) that vanishes once the trigger is removed, often indicating early caries.
- Irreversible Pulpal Odontalgia: This condition manifests as spontaneous, lingering pain that may intensify at night, signalling severe inflammation that requires intervention.
- Periapical Odontalgia: Involves inflammation around the tooth root, often causing pain during biting.
- Other Forms: This includes referred pain (e.g., from sinusitis) and neuropathic odontalgia, which stems from nerve injury rather than dental pathology.

Gaps in research: Odontalgia, commonly referred to as dental pain, can be effectively managed using herbal anesthetic agents as natural substitutes for conventional local anesthetics. These herbal alternatives provide safe and efficient pain relief by directly targeting nerve endings and reducing inflammation in affected dental tissues. Unlike synthetic options, herbal agents are generally well tolerated, presenting minimal side effects and a significantly lower risk of systemic toxicity or allergic reactions. In addition to providing pain relief, these agents often possess antiseptic and anti-inflammatory properties that contribute to improved oral health during treatment. While their efficiency depends on factors such as concentration and application method, appropriate use can provide effective analgesia for mild-to-moderate dental pain.

Rationale for Using Herbal Anesthetics The shift toward exploring herbal anesthesia for odontalgia is driven by several distinct advantages over synthetic local anesthetics.

Key benefits include:

- Analgesic Efficacy: Specific plant extracts contain bioactive compounds that act on nerve endings to effectively reduce pain sensations, similar to conventional anesthetics.
- Anti-inflammatory Action: Since dental pain often involves inflammation of the pulp or surrounding tissues, herbs such as ginger and clove help reduce tissue swelling alongside pain.
- Biocompatibility: Herbal compounds are biodegradable and compatible with body tissues, minimizing the risk of long-term complications associated with synthetic substances.
- Safety and Tolerability: Synthetic anesthetics carry the risk of allergies and systemic side effects. In contrast, herbal alternatives are

safer and better tolerated, making them an excellent option for sensitive patients.

Synthetic drugs available in the market, such as lidocaine, show anesthetic effects with side effects such as local tissue irritation, allergic reactions, CNS toxicity. Therefore, herbal formulations are more preferable than synthetic formulations, as they have negligible side effects. Key herbal agents and mechanisms of various herbs have been identified for their efficacy in treating dental pain. The table below outlines common plants, their active compounds, and their specific therapeutic effects. Conclusion: Herbal anesthesia represents a promising natural approach to dental pain management. When used appropriately, these agents not only alleviate pain but also support broader oral health with fewer risks than synthetic counterparts.

Table 1 Herbs and their uses

Herb/ plant	Active compounds	Therapeutic action in odontalgia
Acmella olerecea	Spilanthol	Acts as a strong local anaesthetic that reduces nerve pain sensation
Clove (Syzygium aromaticum)	Eugenol	It provides analgesic, anti-inflammatory, and antiseptic benefits.
Ginger (Zingiber officinale)	Gingerols, Shogaols	Offers anti-inflammatory effects and mild analgesia.
Salvia (Salvia officinalis)	Rosmarinic acid, Thujone	It functions as an analgesic and anti-inflammatory agent.
Peppermint (Mentha piperita)	Menthol	It provides a cooling effect and acts as a mild local anesthetic.
Turmeric (Curcuma longa)	Curcumin	Reduces pain and swelling through anti-inflammatory properties, antiseptic property.

Role of acmella: Spilanthes acmella is the first herb used in polyherbal gel formulation. Acmella has recently emerged as a subject of significant scientific interest, largely because of its unique biological profile and potential for therapeutic use. A member of the Asteraceae family, the Acmella genus has a long history of traditional use in pain relief, with a specific reputation for treating oral and dental issues. Today, it is viewed as a valuable natural reservoir for developing plant-based alternatives to synthetic analgesics and anesthetics. The combination of its historical use in ethnopharmacology and the growing experimental data positions Acmella as a strong candidate for translational research across the pharmaceutical, dental, and biomedical fields.

The scientific importance of Acmella stems from its rich chemical composition, particularly its high concentration of alkamides, such as spilanthol. This compound acts as a potent local anesthetic and analgesic. Unlike conventional synthetic anesthetics, which can carry risks of side effects or toxicity, compounds derived from Acmella offer a pathway toward safer, biodegradable, and cost-effective pain management. This potential has sparked increased research into understanding how it works, how it can be formulated, and its clinical applications. Furthermore, Acmella serves as an excellent model for multidisciplinary research, bridging the gaps between pharmacognosy, phytochemistry, and drug development. It is easy to cultivate and offers sustainable availability, making it highly suitable for use in experimental studies. As the global medical community shifts its focus toward nature-derived therapeutics, Acmella provides a scientifically robust platform to validate traditional knowledge through modern research.

Traditionally, Acmella oleracea has been a go-to remedy for managing dental pain, and modern science has validated its effectiveness for specific types of odontalgia. It is particularly useful for

peripheral, reversible types of pain, where the primary issues are inflammation and nerve sensitization, rather than deep, irreversible tissue damage. The plant's ability to manage pain is largely attributed to spilanthol, which provides the necessary analgesic and anesthetic effects.

Pharmacological indications: Dentinal Hypersensitivity: Acmella exhibits remarkable efficacy in treating sharp, fleeting pain caused by exposed dentin (hypersensitivity). Spilanthol interacts with peripheral sensory nerve endings and modulates voltage-gated sodium channels and transient receptor potential (TRP) channels. This results in reduced nerve excitability and desensitization of the dentinal tubules, making it highly effective against pain triggered by temperature changes, touch, or sweet or acidic stimuli.

The plant is also therapeutically relevant for reversible pulpitis, an early stage of inflammation in which the pulp tissue is not yet permanently damaged. In these cases, Acmella offers symptomatic relief by inhibiting inflammatory mediators, such as cytokines and prostaglandins, and by blocking pain signals at the nerve level. However, it is important to note that its role is palliative; it manages symptoms but cannot reverse the pathology if the condition progresses to irreversible pulpitis.

Gingival and Periodontal Pain: Acmella alleviates mild periodontal issues through a dual mechanism of anti-inflammatory and antimicrobial action. This helps control inflammation in the gingival tissues caused by microbes, thereby reducing tenderness and discomfort associated with gum pain. Postoperative Relief: Acmella can also be beneficial following minor dental procedures, such as scaling, or in cases of minor trauma to the oral mucosa. Its local anesthetic properties facilitate faster symptom relief and improved comfort during the healing process.

Mechanism of action of Spilanthes Acmella:

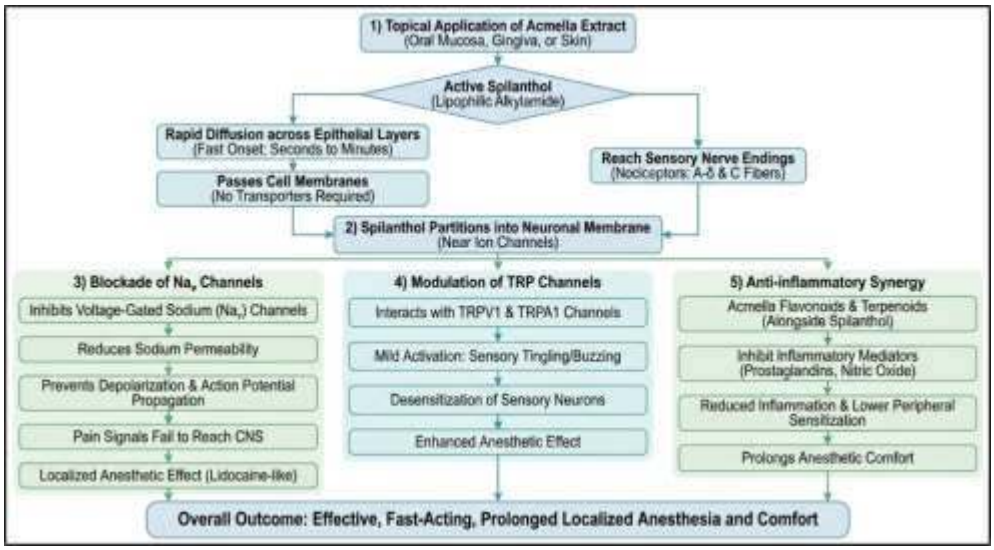


Figure 2 Mechanism of action of Spilanthes Acmella

Role of ginger (Zingiber officinale): Zingiber officinale Roscoe (ginger) is one of the most thoroughly investigated plants in phytotherapy, bridging the gap between traditional medicine and modern pharmacology. Its value lies primarily in its potent analgesic and anti-inflammatory properties, which are increasingly relevant for the development of herbal anesthetics. While historical records have long documented the use of ginger for pain and swelling, contemporary

research spanning molecular, pharmacological, and clinical studies has validated these applications. In the context of anesthesia, ginger serves a distinct purpose by suppressing the inflammatory pathways that heighten pain sensitivity. This action effectively complements plant-based local anesthetics that directly block nerve conduction. Furthermore, ginger offers a distinct safety advantage over synthetic anti-inflammatory agents. It modulates multiple biological targets without the significant gastric, renal, or cardiovascular risks associated with conventional drugs. This favorable safety profile makes it an ideal candidate for local anesthetic formulations, particularly those designed for dental, oral, and soft-tissue procedures.

Mechanism of Action of Gingerols

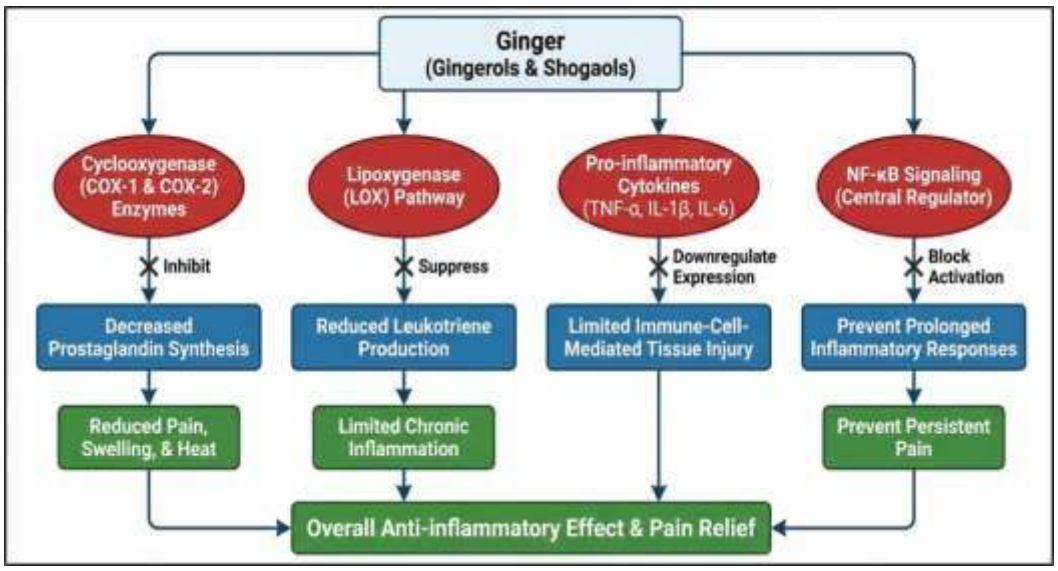


Figure 3 Mechanism of Action of Gingerols

Role of Salvia: For centuries, traditional medicine in Europe and the Middle East has relied on a specific genus of plants to handle everything from infections to deep tissue pain: Salvia. Belonging to the mint family (Lamiaceae), this genus is incredibly diverse, with over 900 species worldwide. However, two stars have emerged in the scientific community: common sage (Salvia officinalis) and Chinese herb Danshen (Salvia miltiorrhiza). What is the reason for the interest in these plants? This is due to their complex chemistry. They are rich in secondary metabolites, specifically diterpenoids, flavonoids, and essential oils, which offer a potent combination of antioxidant and anti-inflammatory benefits.

However, the real advantage lies in their interaction with the body. Synthetic drugs often come with heavy costs, such as gastrointestinal damage. In contrast, salvia-derived compounds offer a multi-targeted approach to healing with significantly lower toxicity. This distinct advantage positions them as a promising natural alternative, or strictly as adjunct therapy, for safely treating long-term inflammatory conditions.

Mechanism of action of salvia officinale:

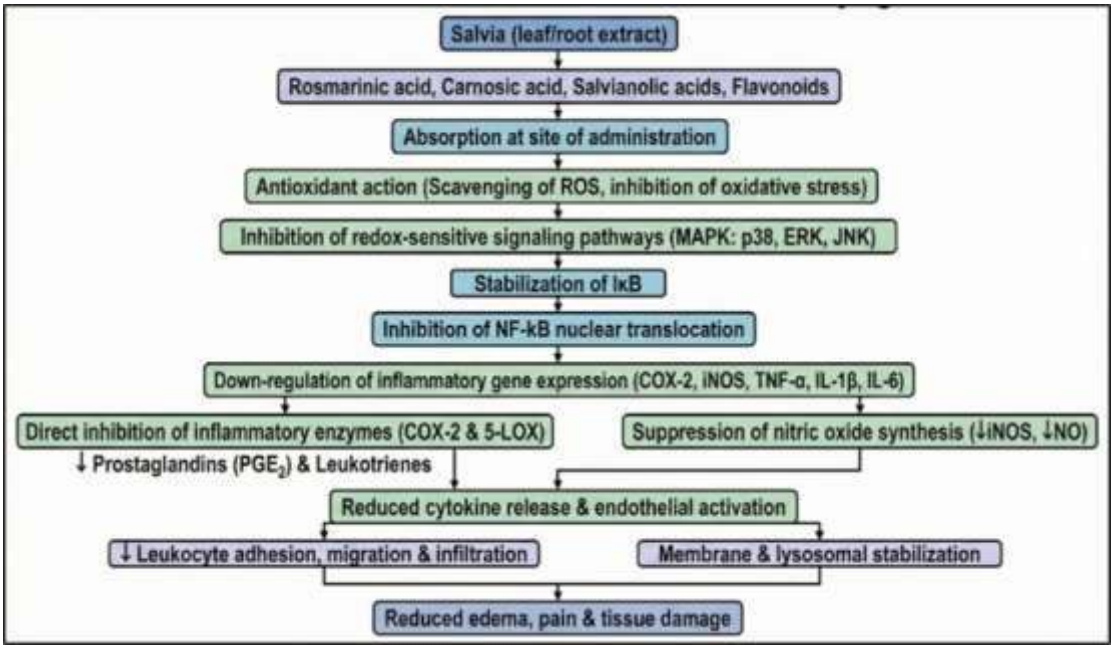


Figure 4 Mechanism of action of salvia

Objectives:

- To select a suitable drug/extract and excipients based on therapeutic relevance, physicochemical properties, and literature support.
- To perform preformulation studies to find out presence essential phytochemicals
- To develop a stable and effective pharmaceutical formulation using suitable excipients and processing techniques.
- The formulated product was evaluated for physicochemical, performance, and quality parameters according to pharmacopeial guidelines.
- The stability of the optimized formulation was assessed under specified conditions.

Etiology and clinical significance: The primary cause of odontalgia is dental caries, in which bacteria demineralize the tooth structure and progressively invade the enamel and dentin until they reach the dental pulp. Other common causes include pulpitis, periodontal diseases such as gingivitis and periodontitis, and dental trauma, including cracks, fractures and tooth wear. In addition, recent dental procedures, defective restorations, exposed dentin, impacted teeth, sinus infections, and parafunctional habits, such as bruxism, can contribute to the development of odontalgia. The intensity of pain may vary from mild sensitivity to severe throbbing discomfort, depending on the extent of tissue damage and pulpal involvement. Understanding the nature of pain, its quality, duration, location, and triggering factors, such as thermal stimuli, chewing, or spontaneous onset, is essential for clinicians to distinguish between reversible and irreversible conditions. An accurate diagnosis is achieved through a combination of clinical examination, pulp vitality tests, percussion and palpation, and radiographic evaluation. Early identification of the underlying cause allows timely intervention, preventing further disease progression and preserving the tooth structure. Appropriate treatment may range from preventive measures and desensitizing agents to restorative procedures,

periodontal therapy, root canal treatment, or tooth extraction in cases where the tooth is beyond restoration.

MATERIALS AND METHODS:

1. SPILANTHES ACMELLA:

Botanical Name: Acmella oleracea (frequently referred to in older pharmacological literature by its synonym, Spilanthes acmella)

Family: Asteraceae

Biological Source: Consists of the fresh or dried flower heads and leaves of the plant

Active Constituent: Spilanthol

Uses:

- Provides local anesthetic action for rapid relief of dental pain and toothache.
- It exhibits analgesic activity by reducing pain and discomfort in the oral cavity.
- It possesses anti-inflammatory properties that help reduce gingival inflammation and swelling.
- It demonstrates antimicrobial activity against oral pathogens, supporting oral hygiene.

Figure 5 Flower of spilanthes acmella

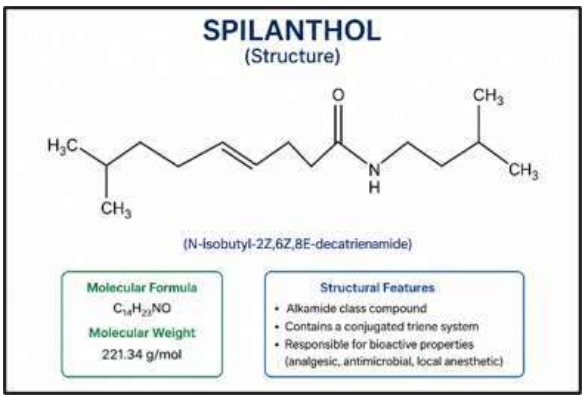


Figure 6 Structure of spilanthol

2. GINGER (ZINGIBER OFFICINALE):

Botanical Name: Zingiber officinale

Family: Zingiberaceae

Active Constituent: Gingerols & Shogaols.

Uses:

- It exhibits analgesic activity by reducing pain through the inhibition of inflammatory mediators.
- It possesses anti-inflammatory properties that help reduce swelling and gingival inflammation.
- It exhibits antioxidant activity by scavenging free radicals and protecting oral tissues from oxidative stress.
- It demonstrates antimicrobial activity against several oral microorganisms, supporting oral health.
- It promotes wound healing by reducing inflammation and aiding the repair of damaged oral mucosal tissues.

Figure 7 Source of ginger

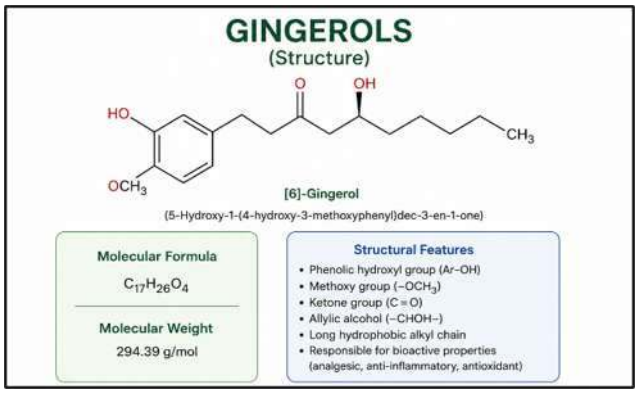


Figure 8 Structure of gingerols

3. SALVIA

Botanical Name: Salvia officinalis

Family: Lamiaceae

Active Constituent: Rosmarinic Acid & Carnosol.

Biological Source: Consists of the fresh or dried leaves, and occasionally the flowering tops, of the plant.

Uses:

- It exhibits anti-inflammatory activity by reducing gingival inflammation and oral tissue swelling.
- It possesses antimicrobial properties against oral pathogens, helping to prevent dental plaque and infections.
- Provides antioxidant activity by protecting oral tissues from oxidative stress and free radical damage.
- Promotes wound healing by accelerating the repair of damaged oral mucosa and gingival tissues.
- Supports oral hygiene by reducing bad breath and maintaining a healthy oral microbial balance.

Figure 9 Salvia flower

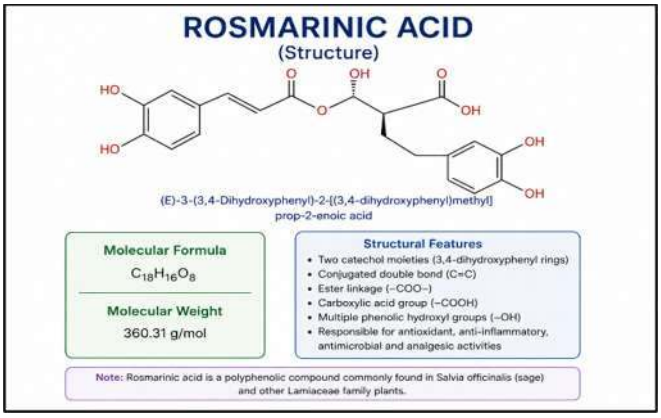


Figure 10 Structure of rosmarinic acid

4. CARBOPOL 940

Chemical Name: Carbomer homopolymer type C

Uses:

- Acts as a gelling agent to produce a clear, stable, and smooth gel formulation.

- Enhances viscosity and improves the consistency and spreadability of the dental gel.
- Provides mucoadhesive properties, increasing the residence time of the gel on the oral mucosa.

5. PROPYLENE GLYCOL

Chemical Name: 1,2-propanediol and 1,2-dihydroxypropane

Uses:

- Acts as a co-solvent to enhance the solubility of hydrophobic ingredients such as menthol and herbal extracts.
- Functions as a humectant to retain moisture and prevent the gel from drying out during storage.
- Enhances the penetration of active ingredients through the oral mucosa, improving their therapeutic effectiveness.

6. SODIUM BENZOATE

Chemical Name: $C_7H_5NaO_2$ or sodium salt of benzoic acid.

Uses:

- Acts as an antimicrobial preservative to inhibit the growth of bacteria, yeasts, and molds in the gel formulation.
- Enhances the shelf life of the dental gel by preventing microbial contamination during storage.
- Maintains the stability and quality of the formulation by protecting it from spoilage and degradation.

7. TRIETHANOLAMINNE

Chemical Name: $C_6H_{15}NO_3$ or TEA or TEOA

Uses:

- Acts as a pH-adjusting agent to achieve the optimum pH for oral gel formulations.
- Neutralizes Carbopol 940 to form a clear, stable gel with the desired viscosity.
- Improves the consistency and stability of the gel by facilitating proper gel network formation.

PHYTOCHEMICAL SCREENING

1. SPILANTHES ACMELLA:

Table 2 phytochemical screening of spilanthes acmella

Phytochemical Class	Test	Observation	Inference
Alkaloids	Mayer's test (Extract + 2-3 drops Mayer's reagent)	Creamy white precipitate	Alkaloids may be Present
Flavonoids	Alkaline Reagent Test (Extract + 10% NaOH Solution)	Intense Yellow Color	Flavonoids may be Present
Tannis	Feric chloride test (Extract + 5% $FeCl_3$ Solution)	Greenish-black color	Tannis may be Present

2. ZINGIBER OFFICINALE

Table 3 phytochemical screening of zingiber officinale

Phytochemical Class	Test	Observation	Inference
Alkaloids	Hager's test (Extract + Hager's Reagent)	Yellow ppt	Alkaloids may be Present
Flavonoids	Lead acetate test (Extract + 10% lead acetate solution)	Yellow ppt	Flavonoids may be Present
Tannins	Gelatin Test (Extract + 1% gelatin solution + NaCl)	White ppt	Tannins may be Present

3. SALVIA OFFICINALIS

Table 4 phytochemical screening of salvia officinalis

Phytochemical Class	Test	Observation	Inference
Alkaloids	Dragendroff's Test (Extract + dragendroff reagent)	Orange-red Precipitate	Alkaloids may be Present
Flavonoids	Shinoda Test (Extract + Mg ribbon + conc. HCl)	Pink to Magenta color	Flavonoids may be Present
Phenols	Lead actetate test (Extract + 10% lead acetate solution)	White to bulky Precipitate	Phenols may be Present

FORMULATION TABLE:

Table 4

INGREDIENTS	QUANTITY (gm)	USES
Amcella extract	10g	Local anaesthetic, analgesic
Salvia extract	0.1g	Anti-inflammatory, antimicrobial
Ginger extract	2g	Analgesic, anti-inflammatory
Carbopol 940	1g	Gelling agent
Propylene glycol	5g	Humectant
Sodium benzoate	0.2g	Preservative
Triethanolaminne	Until becomes basic	pH adjuster
Peppermint oil	q.s.	Fragrance
Purified water	q.s.	Vehicle

Formulation Development of the Polyherbal Gel: The polyherbal gel formulation (100 g batch) was prepared utilizing Carbopol 934/940 as the primary gelling agent, incorporating active herbal extracts alongside necessary excipients. The step-wise procedure for the preparation of the gel is detailed below:

1. **Preparation of Carbopol Dispersion (Aqueous Phase):** An accurately weighed quantity of Carbopol 934/940 (1 g) was carefully sprinkled into 80 mL of purified water under continuous mechanical stirring. To prevent the formation of lumps and ensure complete hydration, the dispersion was allowed to stand and swell for 30 to 60 minutes. This process yielded a clear, uniform, and viscous polymeric solution.

2. **Preparation of the Drug Phase:** The active herbal constituents comprising 10 g of Acmella extract, 2 g of Ginger extract, and 0.1 g of Salvia extract were accurately weighed and triturated thoroughly to ensure uniform mixing. To this extract blend, 5 g of Propylene glycol was added and mixed until a homogenous mixture was obtained. In this formulation, Propylene glycol served a dual purpose as both a co-solvent for the extracts and a penetration enhancer for topical delivery.

3. **Addition of Preservative:** To ensure the microbial stability of the formulation, Sodium benzoate (0.2 g) was utilized as a preservative. It was accurately weighed and dissolved in a minimal quantity of warm purified water (alternatively, it can be dissolved in a portion of the propylene glycol). This preservative solution was then seamlessly incorporated into the prepared drug phase under continuous stirring.

4. **Incorporation of Drug Phase into Gel Base:** The uniform, preservative-containing drug mixture was then introduced slowly into the fully hydrated Carbopol dispersion. Continuous and careful stirring was maintained throughout this addition to guarantee a homogenous distribution of all active constituents and excipients within the gel base.

5. **Neutralization and Gel Formation:** To initiate the gelling mechanism, Triethanolamine (TEA) was added dropwise to the mixture under gentle stirring. The neutralization of the acidic Carbopol polymer induced the uncoiling and swelling of the polymer chains, transitioning the mixture into a transparent, smooth gel. The addition of TEA was carefully monitored to adjust the final pH of the formulation to a range of 5.5–6.5, which is highly compatible with the physiological pH of the skin, thereby ensuring suitability for topical application.

6. **Removal of Entrapped Air**: To eliminate any air bubbles that may have been entrapped within the viscous matrix during the vigorous stirring phases, the formulated gel was allowed to stand undisturbed for a sufficient period. This deaeration step ensured the final product possessed a clear, aesthetically pleasing, air-free appearance.

7. **Packaging and Storage:** The finalized herbal gel formulation was carefully transferred into clean, dry, and airtight wide-mouth containers (or collapsible tubes). The packaged gel was then stored at room temperature, securely maintained for subsequent physical, chemical, and pharmacological evaluation studies.

Methods of Evaluation: formulation of the polyherbal local anesthetic gel, the preparation was subjected to a series of physicochemical, pharmaceutical, and safety evaluation parameters to ascertain its quality, efficacy, and suitability for topical application.

1. **Physical Appearance:** The formulated gel was carefully examined visually to assess its physical state. The preparation was evaluated for clarity, texture, consistency, and homogeneity. It was also inspected for the presence of any grittiness, lumps, or phase separation by rubbing a small quantity of the gel between the thumb and index finger.

2. **PH Determination:** The pH of the topical formulation is a critical factor governing skin compatibility, stability, and drug release characteristics. In the absence of a digital pH meter, the pH of the polyherbal gel was

determined using standardized narrow-range pH indicator papers. An accurately weighed quantity of 1 g of the gel was uniformly dispersed in 100 mL of freshly prepared distilled water. A clean glass rod was dipped into the dispersion, and a drop was applied onto the pH indicator strip. The immediate colour change developed on the strip was visually compared against the standard colour reference chart provided by the manufacturer to determine the exact pH value. The test was repeated in triplicate to ensure accuracy.

3. **Colour and Odour:** The colour of the gel was determined by visual inspection against a clear background, noting the specific hue imparted by the herbal extracts. The organoleptic property of odour was evaluated manually through sensory observation to detect the characteristic aromatic scent of the active ingredients and to ensure no objectionable or rancid odour had developed.

4. **Viscosity:** Viscosity, which dictates the flow properties and extrudability of the gel, was determined using a Brookfield Viscometer. The gel sample was placed in a beaker, and the appropriate spindle was lowered perpendicularly into the centre of the gel without touching the container's bottom or sides. The spindle was rotated at a specified speed at room temperature, and the viscosity was recorded to ensure the polymer concentration provided optimal rheological properties.

5. **Spreadability:** Spreadability indicates the extent to which the topical gel readily spreads upon application. It was determined using the parallel plate method. An accurately weighed amount of gel (0.5 g) was placed between two horizontal glass slides of standard dimensions. A standardized weight was allowed to rest on the upper slide for a specified time to yield a uniform film. The time taken by the upper slide to travel a specific distance under the influence of a standard weight tied to it was noted. Spreadability was calculated using the equation: $S = \frac{M\,X\,L}{T}$ (where S is spreadability, M is weight tied to the upper slide, L is length of the glass slide, and T is time taken).

6. **Stability Studies:** To evaluate the immediate physical integrity and shelf-life stability of the polyherbal gel under accelerated environmental conditions, stability studies were conducted over a 30-day period. The finalized formulation was packed into airtight, containers and stored under controlled room temperature conditions 25^0C $\pm$ 20^0C. The samples were withdrawn at specified intervals specifically at Day 0(Initial), 24 Hours, 15 Days, and 30 Days and systematically re-evaluated for any acute alterations in organoleptic properties (colour, odour, appearance), pH values, and phase homogenesity.

7. **Safety Studies (Skin Irritation Test):** To ensure the dermatological safety of the formulation, a primary skin irritation test (Patch Test) was conducted on healthy human volunteers. An area of approximately 1 sq. cm on the dorsal surface of the hand (or volar forearm) of the volunteers was marked. A precise quantity of the formulated polyherbal gel was applied to the designated area and covered. The application site was continuously observed for any signs of erythema (redness) or edema (swelling) at intervals of 12, 24, and 48 hours post-application.

OBSERVATION AND RESULTS

Phytochemical tests:

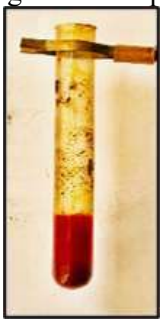
1. Spilanthes Acmella:

Table 5

Phytochemical Class	Test	Observation	Inference
Alkaloids	Dragendroff's Test (Extract + dragendroff reagent)	Orange-red Precipitate  Figure 11	Alkaloids are Present
Flavonoids	Shinoda Test (Extract + Mg ribbon + conc. HCl)	Pink to Magenta color  Figure 12	Flavonoids are Present
Phenols	Lead actetate test (Extract + 10% lead acetate solution)	White to bulky Precipitate  Figure 13	Phenols are Present

2. Salvia Officinalis:

Table 6

Phytochemical Class	Test	Observation	Inference
Alkaloids	Dragendroff's Test (Extract + dragendroff reagent)	Orange-red Precipitate  Figure 14	Alkaloids are Present

Flavonoids	Shinoda Test (Extract + Mg ribbon + conc. HCl)	Pink to Magenta color  Figure 15	Flavonoids are Present
Phenols	Lead actetate test (Extract + 10% lead acetate solution)	White to bulky Precipitate  Figure 16	Phenols are Present

3. Zingiber Officinale:

Table 7

Phytochemical Class	Test	Observation	Inference
Alkaloids	**Hager's test** (Extract + Hager's Reagent)	Yellow ppt  Figure 17	Alkaloids are Present
Flavonoids	**Lead acetate test** (Extract + 10% lead acetate solution)	Yellow ppt  Figure 18	Flavonoids are Present

Tannins	**Gelatin Test** (Extract + 1% gelatin solution + NaCl)	White ppt  Figure 19	Tannins are Present

Evaluation parameters for physical test:

Table 8

Evaluation parameters	Observation/ result
Physical Appearance	Smooth, viscous, opaque gel
Colour	Dark brown/ Herbal brown
Odour	Aromatic herbal Odor
Homogenesity	Excellent
Phase Separation	None
Grittiness	Absent

Figure 20

Physicochemical Evaluation:

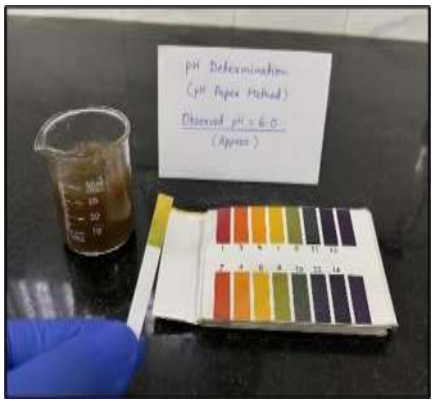


Fig 21 PH Measurement

Fig 22 Viscosity Measurement

Fig 23 Spreadability

Table 9

Parameter	Result	Acceptable range
pH	6.0	5.5 – 7.5 Compatible for oral use
Viscosity	4850 ± 120 cps	Sufficient viscosity for topical application
Spreadability	16.24 ± 0.35 g.cm/sec	Should be easily Spreadable on skin

Stability Studies:

Table 10

Time interval	Color & appearance	pH	Phase separation / homogeneity	Grittiness
Initial day	Dark brown, smooth	6.0	None (Highly uniform)	Absent
24 Hours	Dark brown, smooth	6.0	None (Highly uniform)	Absent
15 days	Dark brown, smooth	6.0	None (Highly uniform)	Absent
30 days	Dark brown, smooth	6.0	None (Highly uniform)	Absent

Safety Studies (Preliminary Skin Irritation Observation):

Table 11

Volunteer No.	Observation At 12 Hour	Observation At 24 Hours	Observation At 48 Hours	Result
Volunteer 1	No Erythema / Edema	No Erythema / Edema	No Erythema / Edema	Non-Irritant
Volunteer 2	No Erythema / Edema	No Erythema / Edema	No Erythema / Edema	Non-Irritant
Volunteer 3	No Erythema / Edema	No Erythema / Edema	No Erythema / Edema	Non-Irritant

Packaging and Storage: The prepared polyherbal dental gel was packed in a clean, airtight container to protect it from moisture and contamination. The formulation was stored at room temperature (25 ± 2°C) in a cool, dry place, away from direct sunlight. The container was kept tightly closed after each use to maintain the stability and quality of the formulation throughout the study period.

Figure 24

RESULTS AND DISCUSSION

Preliminary phytochemical screening of the hydroalcoholic extracts of Spilanthes acmella, Salvia officinalis, and Zingiber officinale confirmed the presence of important bioactive constituents, including alkaloids, flavonoids, phenolic compounds, tannins, terpenoids, glycosides, and saponins. These phytochemicals are known for their analgesic, anti-inflammatory, antimicrobial, antioxidant, and wound-healing properties, which may collectively contribute to the local anesthetic activity and overall therapeutic potential of the formulated polyherbal dental gel. The prepared polyherbal dental gel exhibited satisfactory physical characteristics. The formulation was smooth, homogeneous, and free from lumps, coarse particles, and phase separation. It possessed a characteristic herbal brown colour with a pleasant herbal odour and showed no evidence of grittiness. These observations indicate that the gel had good physical stability and acceptable aesthetic properties for topical dental application.

The physicochemical evaluation demonstrated that the formulated gel possessed desirable characteristics for topical use. The pH of the formulation was found to be 6.0 ± 0.1, which is compatible with the oral mucosa and is unlikely to

cause irritation. The spreadability value was 16.25 g·cm/sec, indicating that the gel spread easily and uniformly over the application site. The viscosity of the formulation was 4850 cps, providing suitable consistency for easy application, adequate retention at the site of action, and convenient extrusion from the container. The stability study was carried out for 24 hours, 15 days, and 30 days under room temperature storage conditions. Throughout the study period, no significant changes were observed in colour, odour, homogeneity, pH, viscosity, spreadability, or physical appearance. No evidence of phase separation or degradation was detected, indicating that the formulation remained physically and chemically stable during the storage period.

The safety evaluation of the prepared gel was performed by observing the application site for signs of erythema (redness) and edema (swelling). No redness, edema, irritation, or other adverse reactions were observed during the study, suggesting that the formulation is safe and well tolerated for topical application on the oral mucosa. Microbial evaluation demonstrated that the prepared gel remained free from visible microbial contamination throughout the study period. The incorporation of sodium benzoate as a preservative, along with storage in an airtight container under appropriate conditions, effectively maintained the microbiological quality of the formulation. The absence of bacterial and fungal growth indicates that the gel possesses satisfactory microbial stability and is suitable for topical dental use.

CONCLUSION

The present study successfully achieved its objective of formulating and evaluating a polyherbal dental gel intended to provide a local anesthetic effect. The formulation containing Spilanthes acmella, Salvia officinalis, and Zingiber officinale exhibited satisfactory physical and physicochemical characteristics, including acceptable pH, appropriate viscosity, good spreadability, excellent homogeneity, and the absence of phase separation or grittiness. The gel also remained stable during the study period and showed no signs of redness, edema, or microbial contamination, indicating that the formulation is safe, stable, and suitable for topical dental application.

The findings of the study suggest that the formulated polyherbal dental gel has promising potential as a natural alternative to conventional topical anesthetic preparations. The presence of bioactive phytoconstituents with analgesic, anti-inflammatory, and antimicrobial properties may provide multiple therapeutic benefits while minimizing the adverse effects commonly associated with synthetic anesthetic agents. Overall, the developed formulation demonstrated desirable pharmaceutical characteristics and may serve as a suitable herbal dental gel for local anesthetic applications.

Further research should focus on comprehensive pharmacological evaluation through in vivo studies to confirm the local anesthetic efficacy and determine the duration of action. Clinical trials involving human subjects are necessary to establish the safety, effectiveness, and patient acceptability of the formulation. Future studies may also include optimization of the formulation, long-term stability testing as per ICH guidelines, standardization of herbal extracts, advanced drug-release studies, and large-scale manufacturing. These investigations could facilitate the development of the formulation into a commercially viable herbal dental product for routine clinical use.

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