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Research Article

Formulation and Development of Dental Gel Enriched with Clove Oil

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ABSTRACT

Dental caries is a widely prevalent oral health condition that poses a significant global health challenge. Herbal extracts have shown considerable promise in improving oral hygiene within clinical practice. This research aimed to develop and evaluate a topical dental gel incorporating clove oil and natural Aloe vera gel, designed for the management of gingivitis, wound healing, plaque control, and oral mucosal disorders. Clove oil and Aloe vera gel, supported by evidence from previous studies, have demonstrated effectiveness in alleviating gum inflammation, enhancing oral protection, and promoting wound healing. The gel was formulated using Aloe vera as a natural polymer, combined with clove oil in optimized proportions. The formulation underwent thorough evaluation to assess properties such as transparency, pH, relative density, viscosity, spreadability, smoothness, and stability. The resulting formulation exhibited a brownish-yellow tint, a smooth and consistent texture, high transparency, a relative density of 10.2, a pH value of 7.2, viscosity measured at 3137 cP, and an extrudability rate of 93.34%. These findings highlight the potential of this formulation as a stable and effective dental gel for enhancing oral care.

INTRODUCTION

Periodontal disease is a global public health issue affecting people of all ages. Despite improvements in oral health, underprivileged populations in low- and middle-income countries, as well as some high-income regions, remain heavily impacted. Recent studies also show a rise in dental caries, affecting 2 billion people by 2010. Periodontal disease, including gingivitis and periodontitis, is characterized by bacterial buildup, inflammation, and tissue destruction. Gingivitis, the mildest form, causes swelling, redness, and bleeding, which can progress to severe damage if untreated.[1-4] Effective management of dental ailments requires sustained treatment, ensuring adequate antibacterial activity with minimal side effects. Natural products, particularly Aloe vera, are gaining attention as promising alternatives for oral disease prevention and treatment, especially in low-income communities.[5]

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Aloe vera is renowned for its remarkable medicinal properties and is widely used in cosmetics for treating burns, aiding wound healing, and combating signs of aging. The most popular species, Aloe barbadensis Miller, is cultivated globally. The gel, derived from the inner leaf, is known for its skin-healing properties by promoting cell growth and moisture retention. Consuming aloe vera can also protect and soothe the stomach's mucous membrane, especially when inflamed or damaged.[6-7]

Aloe vera, derived from the Arabic word "Alloeh," meaning "shiny," is widely recognized for its practical and patient-friendly gel form in the pharmaceutical industry. This gel is created by incorporating the medication into a semi-rigid polymer structure, offering excellent aesthetic appeal and spreadability. Research has demonstrated that aloe vera exhibits antiseptic, anti-inflammatory, antiviral, and antifungal properties, proving beneficial in various applications. Additionally, it is non-allergenic and supports immune function. Oral intake of aloe vera following acute radiation exposure has shown to improve early-stage wound healing, likely due to its ability to enhance inflammatory cell activity, fibroblast growth, angiogenesis, and growth factor production.[8-10]

Advancements in dentistry have increased the use of herbal remedies, including spices, for treating oral diseases. Traditional periodontal treatments often face issues like poor compliance, side effects, and high costs. Clove oil, with its growing clinical significance, is widely used in dental care for relieving toothaches, sore gums, and oral ulcers. It also helps with sore throats and bad breath when used in gargles.[11-12]

Clove oil is highly beneficial in dentistry due to its low toxicity and diverse therapeutic properties, including analgesic, antiseptic, antispasmodic, and disinfectant effects. This study focused on developing a clove oil-based dental gel to treat periodontal disorders and evaluating its physicochemical properties, such as drug concentration, spreadability, extrusion capacity, and antibacterial activity. By exploring the role of herbs and spices in managing dental infections, this research highlights natural alternatives to conventional treatments, offering a solution to issues associated with resistance to allopathic medicines.[13]

MATERIALS AND METHODS:

Chemicals:

Carbopol-940, Sodium Carboxymethyl Cellulose, Polyethylene Glycol-4000, Triethanolamine, Sodium Saccharin, and Sodium Benzoate were procured from the market.

Collection & Identification

Aloe vera leaves were collected from the medicinal garden of Shree Santkrupa College of Pharmacy, located in the Ghogaon neighborhood of Karad City, Maharashtra, India, ensuring they were free from disease and pest infestation. The plant was identified at the Department of Pharmacognosy, Shree Santkrupa College of Pharmacy, Ghogaon. [14]

Extraction

Fresh Aloe vera leaves were harvested and thoroughly rinsed with sterile distilled water followed by a mild chlorine solution after being washed under running water for 15 minutes. The leaves were then longitudinally incised, and the colorless parenchymatous tissue, known as Aloe gel, was meticulously scraped out using a sterile knife. The thick epidermis was carefully discarded, and the gel-like pulp was extracted

(Figure 1 and 2), minced, and homogenized using a mixer to obtain a uniform consistency.[15]

Figure 1: Aloe Vera Pulp

Figure 2: Pure Aloe Vera Extract

Formulation:

To prepare the gel, the gelling agents, Carbopol-940 and Sodium CMC, were dissolved in 50 mL of distilled water. The mixture was stirred thoroughly and allowed to hydrate for 30-45 minutes to form a uniform gel base, using a magnetic stirrer for improved consistency. In a separate step, the required amount of Sodium benzoate was dissolved in 5 mL of distilled water by boiling it in a water bath until fully dissolved. Once dissolved and cooled, Polyethylene glycol-400 (PEG-400) was added to the solution to serve as a humectant, ensuring proper integration into the gel base.

Next, surfactants such as Sodium lauryl sulfate (SLS) and stabilizers like Sodium saccharin, if a sweetening effect was desired, were incorporated. The mixture was stirred gently to ensure even dissolution of all ingredients. Sodium benzoate was then introduced to prevent microbial contamination, and the mixture was stirred until fully dissolved. The pH of the gel was adjusted to the optimal range of 6-7 using Triethanolamine, which also helped maintain skin or mucosal compatibility and aided in thickening the gel.

Gradually, the active ingredients, including Aloe vera extract and Clove oil, were added at the desired concentrations, with careful stirring to ensure even distribution. Finally, the remaining distilled water was used to adjust the volume of the mixture. The entire formulation was allowed to mix for an additional 15-20 minutes to ensure a consistent, smooth texture. Once the gel reached the desired uniformity, it was transferred into sterilized containers for storage and use, resulting in a stable and therapeutic gel suitable for topical or oral application.[16-18]

During the formulation trial phase, several issues, including homogeneity, spreadability, and viscosity, were encountered. To resolve these challenges, the concentrations of Carbopol and sodium CMC were adjusted. As a result, additional batches were discarded, and only one final batch was selected. The composition of the chemicals and plant extract is shown in Table 1 and Figure 3-7.

Table 1: Composition of Gel Formulation

Ingredients	Quantity Taken
Carbapol-940 (g)	1.5

Sodium CMC (g)	1
Sodium saccharin (g)	0.5
Sodium lauryl sulphate (SLS) (g)	2
Poly ethylene glycol-400 (g)	2
Sodium benzoate (0.05%) (g)	0.5
Tri-ethanolamine (ml)	q. s.
Aloe vera (ml)	Gradually dose increasing
Clove Oil	Gradually dose increasing
Distilled water (ml)	q. s.

Figure 3: Aloe Vera

Figure 4: Clove Oil

Figure 5: Chemicals

Figure 6: Formulated Gel

Figure7: Batches of Dental Gel

Evaluation Of Formulated Dental Gel:

Transparency:

The prepared individual and polyherbal gels were assessed for their physical appearance and homogeneity through visual inspection. Approximately 5 mL of the formulated gel was placed in a 10 mL test tube, and its transparency was evaluated visually (Fig. 8).[19, 20]

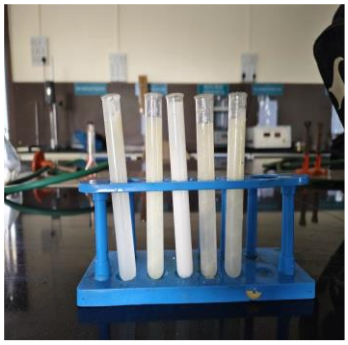

Figure 8: Transparency Test

Relative density

The relative density of the gel formulation was determined using a relative density bottle by measuring the weight of 10 mL of the formulation and 10 mL of distilled water (shown in Fig. 9). The relative density was calculated as the ratio of the formulation's weight to that of water, ensuring uniformity and consistency. Repeated measurements confirmed accuracy and reliability.[21,22]

Figure9: Relative density

pH

The pH of the formulated gel was determined using a calibrated pH meter (Fig.10). For the measurement, 1 g of gel was dispersed in 100 mL of purified water. The electrode was thoroughly rinsed with double-distilled water, dried with tissue paper, and calibrated using standard buffer solutions at pH 4.0, 7.0, and 9.0 to ensure accuracy. Measurements were performed in triplicate, and the average pH values were calculated. This evaluation is crucial for ensuring the gel's compatibility with skin and mucosal applications, as well as maintaining its stability and effectiveness[23,24]

Figue10: pH Determination

Viscosity

The viscosity of the gel was measured using a Brookfield viscometer at 25°C with spindle number 2 as shown in fig. 11. This assessment ensures the gel's optimal consistency for application, providing insights into its spreadability, stability, and ease of use [25,26]

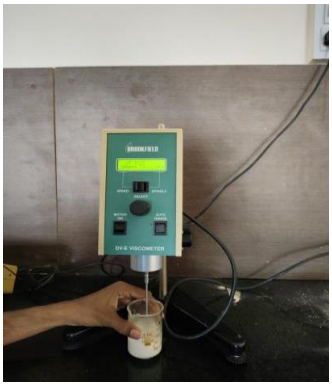

Figure 11: Viscosity Determination

Spreadability

The spreadability of the gel, which reflects its viscosity and ease of application, was evaluated using the slip and drag method. In this procedure, 2 g of the formulated gel was placed on a ground glass slide. A second glass slide was carefully positioned over the gel to form a sandwich-like arrangement. The assembly was left undisturbed

for 5 minutes to expel air bubbles and create a uniform gel layer between the slides. Excess gel was scraped off the edges.

The top slide was then subjected to a pull force of 80 g using a string attached to a hook, and the time (in seconds) required for the top slide to travel a distance of 7.5 cm was recorded. A shorter time indicated better spreadability, which is critical for ensuring ease of application and uniform distribution during use.[27,28]

The formula was used to calculate Spreadability: S=M × L /T

Where,

S= Spread ability

M= Weight in the pan (tied to the upper slide) L= Length moved by the glass slide

T= Time (sec) taken to separate the upper slide from the ground slide.

Smoothness

The smoothness of the gel formulation was assessed by gently rubbing a small amount of the gel between the fingers. The texture was observed to determine whether the gel was smooth, clumped, homogeneous, or rough. This evaluation ensures the formulation's consistency and user-friendliness, which are critical for effective application and patient comfort. [29].

Stability study

The stability study was conducted following ICH guidelines to assess the gel's durability under varying conditions. The formulated gel was packed in collapsible tubes and stored at controlled temperature and humidity settings: 25°C ± 2°C / 60% ± 5% RH, 30°C ± 2°C / 65% ± 5% RH, and 40°C ± 2°C / 75% ± 5% RH for three months. Periodic evaluations were performed to monitor changes in appearance, pH, and spreadability, ensuring the formulation's stability and effectiveness over time.[30]

RESULTS AND DISCUSSION:

Physicochemical evaluation: The physical and physicochemical properties of the formulated dental gel are depicted in table 2.

Table 2: Physical and Physicochemical Properties of the Formulated Dental Gel

Parameter	Observation/Value
Transparency	Translucent
Appearance	Homogeneous
Smoothness	Smooth
Colour	Yellowish brown
Relative Density	10.2
pH	7.2
Viscosity	3137 cp
Spreadability	6.5 cm/sec

The evaluation of the physical and physicochemical properties of the formulated dental gel highlights its suitability for oral health applications. The translucent appearance and homogeneous texture of the gel reflect its aesthetic quality and uniform composition, essential for patient acceptance and consistent therapeutic action.

The smoothness of the gel ensures ease of application, reducing irritation and promoting user comfort during use. The yellowish-brown color aligns with the natural ingredients used, indicating stability without significant discoloration.

The relative density of 10.2 confirms that the gel is adequately stable, preventing phase separation and ensuring a consistent dosage of active ingredients. The observed pH value of 7.2 is optimal for oral applications, avoiding irritation to

oral tissues while maintaining the stability of the formulation.

The viscosity of 3137 cp ensures effective retention at the site of application, preventing premature wash-off while allowing easy dispensing. Moreover, the spreadability value of 6.5 cm/sec demonstrates the gel's ability to be applied uniformly with minimal effort, enhancing its practicality for users.

Stability Evaluation at Various Conditions:

The stability of the formulated dental gel was assessed under different temperature and humidity conditions for three months, as per ICH guidelines. The key observations are as follows (table 3):

Table 3: Physical and Physicochemical Properties of the Formulated Dental Gel

Condition	Colour	Appearance	Spreadability (cm/sec)	pH
25ºC ± 2ºC / 60% ± 5% RH	Yellowish brown	Homogeneous	6.40	7.20
30ºC ± 2ºC / 65% ± 5% RH	Yellowish brown	Homogeneous	6.35	6.90
40ºC ± 2ºC / 75% ± 5% RH	Yellowish brown	Homogeneous	6.21	6.84

The stability study demonstrated that the dental gel maintained consistent physical and chemical properties across different storage conditions, with minor, acceptable variations observed in spreadability and pH at elevated temperatures and humidity levels.

The physical and physicochemical properties of the formulated dental gel affirm its suitability for oral applications. The pH and spreadability ensure patient comfort and ease of use, while the viscosity and smoothness enhance effective application and retention. The homogeneity and stability parameters further validate the formulation's readiness for extended use. These attributes collectively highlight the gel's potential as a therapeutic agent for managing oral health conditions. Future studies, including in vitro and in vivo evaluations, are recommended to further establish its efficacy and safety profile.

Stability studies revealed that the dental gel maintained its core physical and chemical properties under various tested conditions, with only minimal variations in spreadability and pH values. The gel retained its color and homogeneity across different temperatures and humidity levels, underscoring its robustness. Slight decreases in spreadability and pH at elevated stress conditions were observed but remained within acceptable ranges for such formulations.

In summary, the formulated dental gel demonstrated excellent stability and reliability, ensuring its effectiveness and usability over extended storage under diverse environmental conditions. These findings support its potential as a dependable therapeutic product for oral health care.

CONCLUSION:

The research concluded that natural remedies, such as the formulated dental gel, are safer and more acceptable alternatives to synthetic preparations, offering minimal side effects. The formulated gel demonstrated excellent potential for maintaining oral hygiene through its antimicrobial activity, effectively inhibiting the growth of pathogens within the oral cavity. With its favorable physicochemical properties, including optimal pH, viscosity, and spreadability,

the gel ensures ease of application and patient comfort. These findings highlight the gel's promise as a natural therapeutic agent, paving the way for future advancements in dental research focused on herbal and natural remedies.

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