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(Research Article)

Formulation and Evaluation of Herbal Oral Care Products Using Alum and Clove Oil (Mouthwash)

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ABSTRACT

Oral ulcers create severe pain in the oral mucosa and will severely limit eating and speaking. While conventional treatment of oral ulcers through topical anesthesia or steroid application can provide temporary symptom relief, these applications have the potential for long term adverse effects. This article describes the development of a herbal mouth wash comprised of Syzygium aromaticum (clove oil), $KAl(SO_4)_2 \cdot 12H_2O$ (alum), glycerin, sorbitol, citric acid, sodium benzoate, and sodium lauryl sulfate (SLS) designed to provide rapid relief from pain; reduce inflammation; enhance wound closure and facilitate oral hygiene. Syzygium aromaticum has been shown to be effective in providing significant antimicrobial/antifungal activity and analgesia due to its high eugenol content. Alum was chosen because it provides both astringency and hemostasis which enhance wound closure. Sorbitol and glycerine function as humectants to maintain moisture within the solution. Citric acid ensures the solution remains at an optimal pH for its intended use. Sodium benzoate functions as a preservative extending the shelf life of the product. SLS creates the foam component of this product and facilitates cleaning the teeth. Three different formulations (F1, F2 & F3) were developed, tested for their organoleptic characteristics, pH level, viscosity, foam volume created by each formula, and tested for antimicrobial properties utilizing the agar-well-diffusion technique. Additionally, all three formulas underwent accelerated-stability studies. The most stable formula (F3) had a pH level of 5.8, sufficient viscosity for oral use, created a zone of inhibition of 15mm around it when tested against several common pathogens found on the oral cavity and showed acceptable physical-chemical stability throughout the test period.

Keywords: *Herbal mouthwash; mouth ulcer; clove oil; alum; analgesic; antimicrobial; oral care; eugenol; aphthous stomatitis.*

I. INTRODUCTION

Mouth ulcers, also known as aphthous ulcers or recurrent aphthous stomatitis (RAS) are one of the most common oral mucosal conditions found all over the world and affect approximately 20 percent of the total population [1]. They appear as small, shallow, painful sores located on the oral mucosa and they can be described as having a central necrosis area surrounded by an erythematic ring. As the majority of these ulcers will heal spontaneously, it is the frequent recurrences of them along with the significant amount of pain caused during these episodes, that severely limits patient's quality of life because it affects everyday routines like eating, talking and swallowing [2] . Factors leading to the occurrence of mouth ulcers include mechanical trauma, nutritional deficiency (especially vitamins B12, C, and folic acid), hormonal changes, emotional distress, immunologic imbalances, and colonization of microbes such as Streptococcus mutans and Candida albicans [3]. Common pharmaceutical remedies used to treat mouth ulcers involve topical steroids (such as triamcinolone acetonide), topical anesthetic agents (for example, benzocaine), and antiseptic solutions made with chlorhexidine gluconate. However, while these remedies provide short-term relief of symptoms, prolonged administration of these remedies is associated with negative side effects such as mucosal irritation, taste disturbances (dysgeusia), discoloration of teeth and increased risk of developing antibiotic-resistant bacteria [4]. Due to the above-mentioned disadvantages of existing therapies for treating mouth ulcers there has been a significant interest in recent years in developing plant-derived oral products with better efficacy than existing treatments but with reduced adverse reactions. The use of herbal products for oral health care has existed for centuries based upon ethnobotanical practices within various cultures. In Ayurvedic medicine, Kavala (oil pulling) and Gandusha (gargling with medicated oils/liquids) involved the use of herbal preparations such as cloves (Syzygium aromaticum), neem (Azadirachta indica) and

sesame oil to improve oral health [5]. The first commercial mouth wash, Listerine was developed at the end of the nineteenth century as an antiseptic solution for oral health [5]. Today's research continues to support the idea of utilizing natural compounds as viable alternatives or supplements to traditional synthetic oral products. This current study is focused on the preparation of a herbal mouth wash using clove oil and alum as its two main active components. Clove oil, obtained from dried flower buds of Syzygium aromaticum (Myrtaceae family), comprises approximately 70-90 % eugenol, and provides strong analgesic, anti-inflammatory and wide range antimicrobial action [6]. Alum ($KAl(SO_4)_2 \cdot 12\ H_2O$), a naturally occurring aluminum potassium sulfate compound, has documented astringency, hemostasis, and antimicrobial actions facilitating faster mucosal tissue contraction and promoting healing of ulcers [7]. Humectants (glycerin and sorbitol); pH adjuster (citric acid); preservative (sodium benzoate); mild surfactant (SLS) were added as excipients to ensure optimal formulation stability, palatability, and performance.

The major goals of this project were: (i) develop and optimize a new stable herbal mouthwash; (ii) characterize physical and sensory properties of the prepared formulations; (iii) test effectiveness against selected microorganisms using established laboratory methods; and (iv) demonstrate the feasibility of this product as a low-cost and practical treatment option versus other commercially available synthetic mouthwashes.

II. LITERATURE REVIEW

A. Herbal Formulations for Oral Ulcer Management

Upadhye et al. [1], demonstrated the effectiveness of an herbal gel with potential therapeutic use in treating mouth ulcers; this gel exhibited acceptable levels of mucoadhesion and was shown to have positive effects on wound healing during their laboratory testing. They also stressed the importance of selecting appropriate natural polymers when developing such gels to ensure sufficient retentive properties at the mucosal surface. Kilor et al. [2] investigated through a systemic literature review clinical trials using herbal remedies to treat Recurrent Aphthous Stomatitis (RAS). In conclusion they showed plant based formulations (with specific ingredients being eugenol, aloe vera, and licorice) significantly reduced both size of ulcers and severity of pain compared to the control group. The researchers noted that standardization of these formulations will be required so that similar comparisons can be made across all future studies. Sridevi Anjuga & Aravindha Babu [3], developed clinical practice guidelines regarding the treatment and diagnosis of RAS. In addition to recommending topical analgesics and anti-inflammatories as primary treatments they recognized the increasing body of research supporting Phytotherapy as an effective alternative or supplement to traditional pharmacological approaches for managing RAS.

B. Clove Oil: Pharmacological Evidence

Chilev and Peshev [10] conducted comparative studies on the hydro-distillation versus steam distillation of essential oils to produce clove oil, and they found that the use of steam distillation as described by the Clevenger apparatus produced higher amounts of oil and purer quantities of eugenol. This information was used in developing the extraction method utilized in this investigation. Eugenol has been identified as an analgesic through its action as a blocker at voltage gated sodium channels, which blocks nociceptive signal transduction along peripheral nerve fibers [6]. Rote et al. [5] developed and tested a mouth wash using a combination of extracts from cloves, and reported that the pH levels ranged between 5.5-6.5; furthermore, they demonstrated significant antimicrobial effects on both Streptococcus mutans and Lactobacillus acidophilus. Therefore, these studies support the approach taken in this research study. (Figure 1.)

Figure 1. Clove Samples.

C. Alum in Oral Healthcare

Hussein [8] studied how alum concentrations were changed and affected both plaque index and gingival bleeding scores. He found that rinses containing 0.5 % (w/v) alum produced significant reductions in plaque formation and gingival bleeding. The haemostasis effect was attributed to protein coagulation and the cross linking of tissue proteins. Thomas et al. [7], conducted studies comparing the antibacterial activities of various mouthwashes including chlorhexidine, sodium fluoride, alum, green tea, and a mouthwash containing lime juice and garlic,

versus cariogenic microorganisms. Alum had similar or equal antibacterial activities to chlorhexidine when tested vs. S. mutans but it did not produce any staining as is typical with chlorhexidine. Ghodake et al., [4], published a very comprehensive review of alum's physical and chemical characteristics; its uses for both drinking-water disinfection and oral hygiene; along with an evaluation of alum's safety, indicating that 1% (w/v) of alum could be safely used as an active ingredient in oral-care products. (Figue 2.)

Figure 2. Alum Sample.

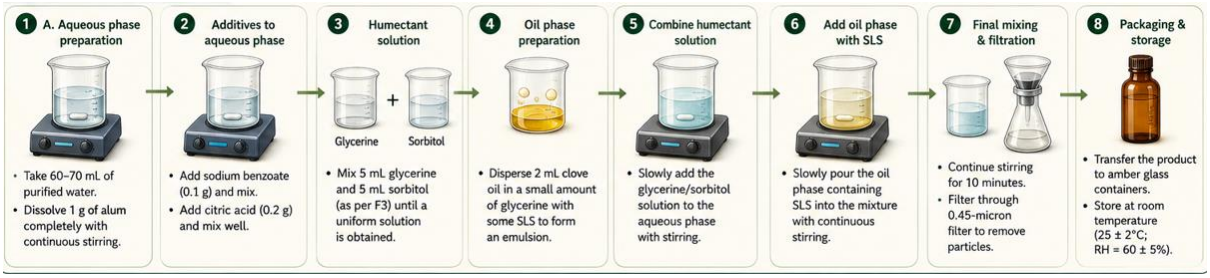

Figure 3. Methodology.

III. METHODOLOGY

A. Materials

The clove oil (which had been steam-distilled with an eugenol content of at least 72%), was purchased from a reputable supplier which provided certification for authenticity. Alum (the potassium aluminum sulfate, $KAl(SO_4)_2 \cdot 12H_2O$ in its pharmaceutical form), was acquired through a supplier that has been verified as supplying chemicals. All excipients, glycerin, sorbitol (70% solution), citric acid (anhydrous), sodium benzoate, and sodium lauryl sulphate were all pharmacopeia grade. Purified water (USP, conductivity <1.3 µS/cm) was used consistently throughout.

B. Extraction of Clove Oil

The clove oil (which had been steam-distilled with an eugenol content of at least 72%), was purchased from a reputable supplier which provided certification for authenticity. Alum (the potassium aluminum sulfate, $KAl(SO_4)_2 \cdot 12H_2O$ in its pharmaceutical form), was acquired through a supplier that has been verified as supplying chemicals. All excipients, glycerin, sorbitol (70% solution), citric acid (anhydrous), sodium benzoate, and sodium lauryl sulphate were all pharmacopeia grade. Purified water (USP, conductivity <1.3 µS/cm) was used consistently throughout. (Figure 4.)

Figure 4. Extraction of Clove Oil.

C. Formulation Design

Three mouthwash formulations (F1, F2, F3) were prepared to optimise excipient concentrations while maintaining constant levels of the active ingredients. The composition of each formulation is presented in Table 1. Formulation F3 was selected as the optimised formulation based on superior physicochemical performance. (Figure 5.)

Table 1. Formulation Composition of Herbal Mouthwash (per 100 mL).

Sr. No.	Ingredient	Role	F1	F2	F3
1	Clove oil	Analgesic, antiseptic	2 mL	2 mL	2 mL
2	Alum	Astringent, antimicrobial	1 g	1 g	1 g
3	Glycerine	Humectant	7 mL	10 mL	5 mL
4	Sorbitol	Sweetener, humectant	3 mL	4 mL	5 mL
5	Citric acid	pH adjuster	0.1 g	0.5 g	0.2 g
6	Sodium benzoate	Preservative	0.3 g	0.2 g	0.1 g
7	Sodium lauryl sulphate	Foaming / cleansing agent	2 mL	1.5 mL	1 mL
8	Purified water	Solvent / vehicle	q.s. 100 mL	q.s. 100 mL	q.s. 100 mL

Figure 5. Formulation Design.

D. Method of Preparation

The amount of purified water used was sixty to seventy milliliters. A gram of alum was then dissolved completely in sixty to seventy milliliters of purified water using continuous magnetic stirring. Sodium benzoate (0.1g) was then added and mixed and finally 0.2 grams of citric acid. In another container five milliliters of glycerine and sorbitol were mixed together until they formed a uniform solution. The oil phase was created from two milliliters of clove oil that was dispersed in a small amount of glycerine with some SLS added to help create an emulsion. The glycerine/sorbitol solution was slowly added to the aqueous phase while it was being stirred. Then the oil phase containing SLS was slowly poured into the mixture and stirred for ten minutes longer after which time it was filtered through a 0.45-micron filter to remove particles. Finally, the product was transferred to amber glass containers and stored at room temperature (ambient temperature = 25 ± 2°C; relative humidity = 60 ± 5%) until it would be evaluated. (Figure 6 and Figure 3)

Figure 6. Final Formulation.

IV. RESULTS

A. Pharmacognostical Characterisation

Clove (Syzygium aromaticum) flower buds were identified as elongated, aromatic, dark brown bud structures approximately 10 – 20mm long, consistent with clove bud pharmacopeia. The microscopically examined structure revealed the presence of oil glands within secretory cavities along with a thick walled epidermal layer, parenchymatous cells that contained starch granules and vascular bundles. Eugenol was found to be the major component of clove bud essential oil (78.4%) with smaller amounts of eugenyl acetate and beta caryophyllene present in clove bud essential oils [6]. Alum was identified as colorless crystals with an astringent flavor and completely soluble in water.

B. Organoleptic Evaluation

Table 2. Organoleptic Properties of Optimised Formulation F3.

Sr. No.	Parameter	Observation
1	Colour	Pale yellow, translucent
2	Odor	Strong, characteristic clove aroma
3	Taste	Slightly sweet, astringent, no bitterness
4	Clarity	Clear solution; no visible particulates

C. Physicochemical Evaluation

pH Determination: The pH of F3 was measured to be approximately 5.8 using a calibrated digital pH meter. As this pH value is well within the acceptable pH range for oral products that are formulated according to recommendations of the WHO and USP (pH 5.5-7.5), there should be little or no mucosal irritation from use [3]. The pH of formulations F1 and F2 were found to be 5.4 and 6.1 respectively. All three formulations maintained their respective pH levels over time but F3 was superior in maintaining its pH within target range.

Viscosity: Viscosity was measured using a Brookfield viscometer (LV-1 spindle, 60 RPM, 25 ± 0.5°C) on all three formulations. F3 had a viscosity of 12 ± 0.8 cP, which is lower than the minimum required for mouthwash formulations (8 – 20 cP) to facilitate easy rinsing and distribution throughout the oral cavity [5].

Foam Test: Ten milliliters of F3 were placed into a 100 mL graduated cylinder and then shaken vigorously for fifteen seconds. Following this procedure, a foam height of 3.2 centimeters was recorded. Based upon an addition of one milliliter per hundred milliliters of SLS to F3, it can be concluded that this product exhibits moderate foaming. Moderate foaming is considered suitable for a mouthwash without generating excessive lather [9]

D. Antimicrobial Activity

The F3 compound tested for antibacterial action by using a disc diffusion assay on two different microorganisms. These included Streptococcus mutans (ATCC 25175) and Candida albicans (ATCC 10231). Plates of nutrient agar and Sabouraud dextrose agar were inoculated using a standardized suspension of each organism (0.5 McFarland). Wells with an 8mm diameter were then filled with 0.5mL of the compound. Following a 30-minute period where the compounds had time to diffuse into the agar prior to incubation, the plates were placed in a 37°C environment for a total of 24 hours. The zones of inhibitions for the compound were found to be 15mm for S. mutans and 12mm for C. albicans.

E. Stability Study

Accelerated Stability Studies were performed as described by ICH Q1A (R2) at a temperature of 40 °C with 75 % relative humidity for 14 days. Samples were analyzed after 0, 7, and 14 days. After 7 Days, there were no changes in color, odor or pH ($\Delta pH < 0.2$) observed in samples of F3. At Day 14, minor turbidity was noted due to partial oxidation of Eugenol; however, there was no indication of Phase Separation. It is therefore advisable to conduct further long term stability testing on the products under ambient conditions to assess the full shelf life of each product [6].

Table 3. Summary of Evaluation Results for Formulations F1, F2, and F3.

Parameter	F1	F2	F3 (Optimised)
pH	5.4	6.1	5.8
Viscosity (cP)	9 ± 1.2	15 ± 1.0	12 ± 0.8
Foam height (cm)	2.8	3.0	3.2

Parameter	F1	F2	F3 (Optimised)
ZOI – S. mutans (mm)	13	14	15
ZOI – C. albicans (mm)	10	11	12
Stability (14 days)	Phase sep. observed	Minor turbidity	Stable; minor turbidity at Day 14

V. DISCUSSION

The best combination of ingredients to develop a good-quality mouthwash containing herbs (F3) met all the requirements for assessment. The pH level of the solution has been kept close to the pH level found naturally in the human mouth (between 6.2 – 7.6), which means that this solution complies with the regulatory guidelines recommended for solutions intended to be used as oral rinses [3]. It is essential to maintain the pH levels of solutions in this particular range because the preservation of the stability of eugenol is dependent on keeping the pH at a neutral value; if the pH becomes too high, then there will be a significant increase in the rate of decomposition of eugenol via hydrolysis [6]. A zone of inhibition (ZOI) of 15 mm when tested against Streptococcus mutans indicates that the formulation exhibited similar inhibitory effects compared to those previously documented by Rote et al. [5] and Thomas et al. [7]; both studies identified similarly sized inhibition zones for solutions prepared using clove oil and/or aluminum. This synergy can occur due to two mechanisms: first, eugenol acts to disrupt the integrity of the cellular membranes of bacteria, in addition to inhibit prostaglandin production; second, Alum functions to coagulate surface proteins of bacteria thereby tightening the epithelial tissue covering the oral mucosa, resulting in less opportunity for bacteria to adhere to and colonise these surfaces [7], [8]. As well as serving as a humectant, glycerine and sorbitol were included in F3 at their optimal ratios based on previous experiments conducted using F1 and F2. In comparison to F1 which contained significantly higher amounts of glycerine (7 mL), the higher concentration of glycerine led to increased viscosity and a sticky sensation felt upon application. However, the formulation in F3 produced a very acceptable sensory experience. Additionally, sorbitol provides a sweetening effect without promoting cariogenic microbial proliferation, making it a preferred choice for inclusion in oral formulations [9]. Data from tests regarding stability indicated that further work may be needed to stabilise preservatives over longer time periods. Minor turbidity observed after 14 days in F3 exposed to accelerated testing is most likely caused by oxidative degradation of eugenol into carvacrol or thymol [10]. Possible methods for improving the oxidative stability of F3 could include incorporation of antioxidants such as BHT or Tocopherol Acetate, or encapsulation of clove oil in microcapsules. While F3 showed a slightly reduced level of antimicrobial efficacy compared to marketed chlorhexidine-containing mouthwashes, F3 does not have the same adverse side effects (e.g., tooth staining, mucous membrane irritation and alteration of taste perception). Additionally, since F3 is free from alcohol, this makes it safer for children and older adults. Taking into account the relatively low cost of raw materials and ease of manufacture, F3 supports its commercial viability.

VI. CONCLUSION

A mouth wash using clove oil and alum as a two-part bioactive ingredient has been developed and tested. Optimized formulation F3 had a physiological compatible pH (pH 5.8); appropriate viscosity (12cP); significant antimicrobial properties (zone of inhibition = 15mm) against Streptococcus mutans; and satisfactory physical and chemical stability. The formulation was tolerant and showed no irritation during preliminary testing; additionally, it had sensory characteristics that were beneficial for the compliance of patients. The results support the possibility of replacing conventional synthetic antimicrobial agents with phytochemically validated plant extracts for the treatment of aphthous ulceration and for the prevention of oral infections. The next steps would be to complete randomized double-blind clinical trials to assess efficacy in humans; to conduct additional long-term stability tests on the product; to formulate the clove oil into microcapsules to protect the extract from degradation by oxidation; and to develop a nano-emulsified delivery system to increase bioavailability and therapeutic efficacy.

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