Formulation & Evaluation of Aqueous Guava & Babul Leaves for the Treatment of Mouth Ulcer

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ABSTRACT

This study delved the development and evaluation of a new herbal gel for mouth ulcers using pulverized guava leaves. The gel incorporated colorful attention of the leaves with Carbopol 934 and Propylene glycol as a base. Evaluation included assessments of the gel's physical parcels and natural exertion. Infrared spectroscopy verified no adverse commerce between the leaves and the gelatinizing agent. The performing gel was transparent, invariant, and had a neutral pH range (7-7.5). also, it demonstrated good rheological parcels, spreading and banishing fluently. Anti-fungal tests revealed significant effectiveness against Candida albicans and Aspergillus aureus. In vitro analysis verified the presence of flavonoids in the guava leaves, contributing to their potent antioxidant exertion. This suggests implicit for combating oxidative stress associated with mouth ulcers. The formulated gel offered a stable, safe, and potentially superior volition to conventional synthetic treatments for mouth ulcers. Its overall parcels suggest a promising advancement in this area. In conclusion, the herbal gel displayed a range of desirable characteristics-translucency, unity, good rheology, potentanti-fungal exertion, and significant antioxidant parcels. These findings place it as a potentially safe and effective herbal remedy for mouth ulcers, potentially outperforming being synthetic options.

Keywords- Guava Leaves Powder, Gel, Mouth Ulcer, antioxidant, mucosal layer.
1. INTRODUCTION

1.1 Introduction:

Mouth ulcers, also known as oral aphthous ulcers, are a common condition characterized by painful sores that develop on the mucous membranes inside the mouth. The aim of this study was to formulate and evaluate a polyherbal emulgel for the treatment of mouth ulcers. The emulgel was prepared using a combination of natural plant extracts known for their anti-inflammatory, antimicrobial, and wound healing properties. The formulated emulgel was evaluated for its physical characteristics, rheological properties, drug content, in vitro release, and antimicrobial activity. The results of this study provide valuable insights into the development of an effective and safe treatment option for mouth ulcers.

1.2 MOUTH ULCER

Mouth ulcers are common and are usually due to trauma such as from ill fitting dentures, fractured teeth, or fillings. However, patients with an ulcer of over three weeks' duration should be referred for biopsy or other investigations to exclude malignancy or other serious conditions such as chronic infections. Ulcers related to trauma usually resolve in about a week after removal of the cause and use of benzylamine hydrochloride 0.15% mouthwash or spray (Difflam) to provide symptomatic relief and chlorhexidine 0.2% aqueous mouthwash to maintain good oral hygiene. A mouth ulcer is the loss or erosion of the delicate lining tissue of the mouth (mucous membrane). The most common cause is injury, such as accidentally biting the inside of your cheek. In most cases, mouth ulcers are harmless and resolve by themselves in 10 to 14 days without the need for treatment.

A mouth ulcer, also known as an oral ulcer or canker sore, is a common condition that affects the mucous membranes of the mouth. It is characterized by the formation of small, painful sores or lesions on the inside of the mouth, including the lips, cheeks, tongue, and gums. These ulcers can cause discomfort and difficulty in performing everyday activities such as eating, drinking, and speaking.

Mouth ulcers can vary in size, shape, and color, but they are typically round or oval with a white or yellowish center and a red border surrounding it. They can occur as single sores or in clusters and may last anywhere from a few days to several weeks before healing completely.

1.2.1 The exact cause of mouth ulcers is often unknown, but several factors are believed to contribute to their development. These factors include:

Trauma:

Accidental biting of the inside of the cheek, tongue, or lips, or injury from sharp food objects can lead to the formation of ulcers. The traumatic oral ulcer is very common and can be caused by acute or chronic trauma from sharp objects, accidental or intentional biting, or overzealous brushing. The ulcer is usually solitary and can range from less than 1 mm to more than 1 cm in diameter.

Oral hygiene:

Poor oral hygiene practices, such as infrequent brushing or using abrasive toothpaste, can irritate the delicate tissues in the mouth and trigger the development of ulcers.
Certain foods:

Spicy or acidic foods, such as citrus fruits, tomatoes, and chocolate, can irritate the mouth and increase the risk of developing ulcers.

Hormonal changes:

Some women may experience mouth ulcers during certain hormonal changes, such as menstruation.

1.3 STRESS AND EMOTIONAL FACTORS:

Emotional stress or anxiety can weaken the immune system and make individuals more susceptible to mouth ulcers.

Nutritional deficiencies:

A lack of certain vitamins and minerals, particularly vitamin B12, iron, and folic acid, can contribute to the formation of ulcers. Mouth ulcers are generally not contagious, but they can be painful and bothersome. Most ulcers heal on their own within 1-2 weeks without treatment. However, there are some over-the-counter gels, ointments, and mouthwashes available that can help alleviate the pain and promote healing. If the ulcers are large, persistent, or accompanied by other symptoms, it is advisable to consult a healthcare professional for further evaluation and management.

1.4 Types of mouth ulcer

Mouth ulcers are caused by many disorders. These include:

- Canker sores (Oral aphthous)
- Gingivostomatitis
- Herpes simplex (fever blister)
- Leukoplakia
- Oral cancer
- Oral lichen planus
- Oral thrush

1.4.1 Canker Sores (Oral aphthous):

Canker sores, also known as aphthous ulcers, are small, painful lesions that can form inside the mouth. They are not contagious and are quite common, affecting about 20% of the population. Canker sores typically appear as round or oval-shaped white or yellowish open sores with a red border. They can occur on the inside of the lips, cheeks, tongue, or the base of the gums. The exact cause of canker sores is not fully understood, but several factors are believed to contribute to their development. These factors include:

Stress: Emotional stress or anxiety can weaken the immune system and make you more susceptible to developing canker sores.

Certain foods: Spicy or acidic foods, such as citrus fruits, can trigger or worsen canker sores in some individuals.
Nutritional deficiencies: Lack of certain vitamins and minerals, such as vitamin B12, zinc, iron, or folic acid, may contribute to the development of canker sores.

Hormonal changes: Some women may experience canker sores during their menstrual cycle due to hormonal fluctuations.

Canker sores usually heal on their own within one to two weeks without leaving any scars. However, they can be quite uncomfortable and may interfere with eating, drinking, and talking. To alleviate the discomfort and promote healing, you can try the following remedies:

Over-the-counter treatments: Oral gels or creams containing benzocaine or hydrocortisone can provide temporary pain relief. They form a protective barrier over the sore and help reduce inflammation.

Saltwater rinses: Mix a teaspoon of salt in a glass of warm water and rinse your mouth several times a day. Saltwater helps cleanse the sore and promote healing.

Avoid irritants: Spicy, acidic, or rough foods can worsen the pain and prolong the healing process. Try to avoid these foods until the sore has healed.

Maintain good oral hygiene: Brush your teeth gently with a soft-bristle toothbrush and use a mild toothpaste. Avoid irritating the sore while brushing.

Topical medications: Your dentist or doctor may prescribe a corticosteroid ointment or antimicrobial mouthwash to help reduce pain and speed up healing.

If you frequently experience canker sores or they do not heal within two weeks, it’s advisable to consult a healthcare professional for further evaluation. They can

Figure No.1-Canker sores (Oral aphthous)
<table>
<thead>
<tr>
<th>S.No</th>
<th>COLD SORES</th>
<th>CANKER SORES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Cold sores are generally seen outside the mouth and around the lips.</td>
<td>Canker sores developed inside the mouth, at the base of gum and inner cheeks.</td>
</tr>
<tr>
<td>2.</td>
<td>Caused by herpes simplex virus.</td>
<td>There is no clear etiology.</td>
</tr>
<tr>
<td>3.</td>
<td>Appear in clusters, red in colour and fluid filled.</td>
<td>Comparatively smaller with a white-gray center and a red.</td>
</tr>
<tr>
<td>4.</td>
<td>Highly contagious</td>
<td>Not contagious</td>
</tr>
</tbody>
</table>

Table 1: Difference blw cold sore and canker sore.

1.4.2 Gingivostomatitis:

Gingivostomatitis is a common condition characterized by inflammation of the gums (gingiva) and the mucous membranes of the mouth (stomatitis). It is most commonly caused by the herpes simplex virus type 1 (HSV-1), although other viruses can also be responsible.

Causes: Herpes simplex virus type 1 (HSV-1): This is the most common cause of Gingivostomatitis, especially in children. HSV-1 is highly contagious and is typically transmitted through direct contact with an infected person's saliva or oral secretions.

Symptoms:

- Painful sores or ulcers: These can develop on the gum, tongue, inner cheeks, or other areas of the mouth.
- Swollen and red gums: The gums may appear inflamed and bleed easily.
- Difficulty eating and drinking: The presence of mouth sores can make it painful to eat or drink.
- Fever and general discomfort: Some individuals may experience fever, headache, and a general feeling of being unwell.

Treatment:

Symptom management: Over-the-counter pain relievers, such as acetaminophen or ibuprofen, can help alleviate pain and reduce fever.

Topical medications: Prescription or over-the-counter oral gels or creams containing anesthetic
## Table no.2: Difference b/w gingivitis and periodontitis

<table>
<thead>
<tr>
<th>S.No</th>
<th>Gingivitis</th>
<th>Periodontitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>Red, swollen, and bleeding gums.</td>
<td>Chronic inflammatory response leading to irreversible destruction of tissues and bone that support the teeth.</td>
</tr>
<tr>
<td>3.</td>
<td>Usually reversible through good oral hygiene and preventive care</td>
<td>Treatment requires more aggressive surgical care.</td>
</tr>
<tr>
<td>4.</td>
<td>Not uncommon in young adult and even youth</td>
<td></td>
</tr>
</tbody>
</table>

### 1.4.3 Herpes simplex (fever blister):

Herpes simplex refers to a viral infection caused by the herpes simplex virus (HSV). There are two types of herpes simplex viruses: herpes simplex virus type 1 (HSV-1) and herpes simplex virus type 2 (HSV-2). While there is currently no cure for herpes simplex, antiviral medications can help manage the symptoms and reduce the frequency and severity of outbreaks. These medications can also reduce the risk of transmission to others. It's important to consult a healthcare professional for an accurate diagnosis and appropriate treatment options if you suspect you have herpes simplex.

### 1.4.4 Leukoplakia

Leukoplakia is a condition characterized by the formation of white or grayish patches on the mucous membranes, particularly in the mouth. These patches cannot be easily scraped off and may have a rough or textured appearance. Leukoplakia can occur on the tongue, gums, inside of the cheeks, or the floor of the mouth.

### 1.4.5 Oral cancer

Oral cancer refers to cancer that develops in the mouth or oral cavity. It can occur in various parts of the mouth, including the lips, tongue, gums, lining of the cheeks, roof or floor of the mouth, and the tonsils. Like other types of cancer, oral cancer occurs when there is an uncontrolled growth of abnormal cells in the affected area.

### causes

The exact cause of oral cancer is not known, but certain risk factors increase the likelihood of developing the disease. These include tobacco use (cigarettes, cigars, pipes, chewing tobacco), excessive alcohol consumption, prolonged sun exposure to the lips, a family history of oral cancer, a weakened immune system, and infection with human papillomavirus (HPV).
1.4.6 Oral lichen planus

Oral lichen planus is a chronic inflammatory condition that affects the mucous membranes in the mouth, specifically the lining of the cheeks, gums, tongue, and other oral tissues. It is considered an autoimmune disorder, which means that the body's immune system mistakenly attacks and damages its own cells.

**Topical corticosteroids:** Medications in the form of creams, gels, or mouth rinses that help reduce inflammation and relieve symptoms.

**Immunosuppressants:** In more severe cases, medications that suppress the immune system may be prescribed to control the immune response.

**Oral hygiene measures:** Practicing good oral hygiene, including regular brushing and flossing, to maintain oral health and prevent secondary infections.

1.4.7 Oral thrush:

Oral thrush, also known as oral candidiasis, is a fungal infection that occurs in the mouth and throat. It is caused by an overgrowth of a fungus called Candida albicans, which is naturally present in the mouth in small amounts.

**Symptoms of oral thrush may include:**

- White, creamy lesions on the tongue, inner cheeks, gums, or roof of the mouth.
- Redness or soreness in the affected areas.
- Difficulty swallowing or a feeling of having something stuck in your throat.
- Loss of taste or an unpleasant taste in the mouth.
- Cracking or redness at the corners of the mouth (angular cheilitis) in severe cases.
2.1 Review of literature:

**Manthan M. Thawkare etc. (2023)** The study found that a herbal gel formulation with significant antimicrobial activity was stable, safe, effective, and suitable for treating mouth ulcer.

**Pooja Waghmare et al. (2023)** The study aimed to create and assess a fast-dissolving oral film using Ocimum sanctum and Glycyrrhiza glabra extracts for treating mouth ulcers.

**S. S. Chavan, V. D. Thombare, B. Shejul etc. (2023)** The study developed an herbal gel using Polyalthia longifolia leaf extract for treating mouth ulcers, demonstrating its effectiveness and low cost, highlighting the potential of herbal remedies.

**Shivani K. Dahihande etc. (2023)** The gel formulations showed good homogeneity, gelling properties, and pH compatibility for skin application. They had ideal viscosity and spreadability, with inverse relationship with viscosity. Extrusion and bioadhesive strength were within suitable range, indicating gel adhesion and effective topical application.

**Vaibhavi Shirke* et al. (2023)** The study reveals a new herbal gel with high potential for mouth ulcer treatment, offering a low-cost, therapeutically effective, and suitable drug delivery vehicle.

**D. Thombare, B. Shejul et al. (2023)** The study developed an herbal gel using Polyalthia longifolia leaf extract for treating mouth ulcers, demonstrating its effectiveness and low cost, highlighting the potential of herbal remedies.

**Vaishnavi Burley et al. (2021)** Herbal plants are highly effective in treating mouth ulcers due to their flavanoids, which have better computability, form, and less side effects, making them the most suitable option.

**Nam kumarjan* 1, Rituparna Roy et al. (2020)** The study shows a low-cost herbal gel formulation with high potential for mouth ulcer treatment, but clinical studies are ongoing to establish its clinical efficacy.

**Gu, Y., Huang, Y., Qiu, Z. et al. (2020)** Mouth ulcer is associated with inflammation and high risk of bacterial infection, which aggravates the patient's condition. Currently, there is no effective treatment for mouth ulcer. Herein, we report that vitamin-modified iron oxide activities. We discovered that vitamin B, (VB,) modified iron oxide nanoparticles performed enhanced peroxidase-like, catalase-like, and superoxide dismutase (SOD)-like activities, acting as typical iron oxide nanozymes (IONzymes) with triad activities. In particular, VB, modification significantly improved the SOD-like activity, thus providing a reactive oxygen species (ROS)-scavenging ability. Cellular antioxidant experiments showed that vitamin B,

**Huang, Y., et al. (2020)** ModifiedIONzymes (VB- IONzymes) protect human oral keratinocytes (HOK) and BALB/3T3 cells from hydrogen peroxide (H2O2), and these cells have high biocompatibility to eukaryotic cells. In addition, VB1-IONzymes exerted an antibacterial activity against Streptococcus mutans, Staphylococcus aureus, and Escherichia coli. Importantly, VB,-IONzymes accelerated the recovery of mouth ulcer and reduced the local secretion of inflammatory factors in mouse ulcer model via ROS scavenging and antibacterial activity.
Dalessandri D, et al (2019) Use of hyaluronic acid-based products has become a valuable alternative to drug-based approaches in the treatment of recurrent aphthous stomatitis (RAS). The presented study aimed to investigate the effect of a barrier forming hyaluronic acid containing mouth wash or a topical gel formulation on the healing of RAS and patient's quality of life. Methods: For this single-center retrospective study, medical records of the Dental School of

Sharma D1,2* and Garg R, et al (2018) Aphthous stomatitis is an inflammatory oral mucosa condition with unclear etiopathogenesis. Treatment options include local and systemic methods to manage pain, duration, and frequency of ulcer outbreaks. No single treatment is uniformly effective, and strategies should focus on symptomatic relief, ulcer-free periods, and healing. Future research should identify RAS etiology and develop standardized diagnostic criteria.

Bookman R, et al (2018) A case is reported of eosinophilic granuloma involving the calvarium, buccal mucosa and inguinal skin. The diagnosis was established by histologic study of each lesion. Radiologic examinations revealed presumed involvement of the lungs and pelvis. There was no laboratory or clinical evidence of diabetes insipidus. The present case is considered another example of the disease group called Histiocytosis X, which includes those disease entities formerly called eosinophilic granuloma of the bone, Hand-Schiiller-Christian disease and Letterer-Siwe disease. Division of Dermatology, Department of Medicine, University of California School of Medicine.

Vaillant L., et al (2016), Aphthous ulcers are painful ulcerations located on the mucous membrane, generally in the mouth, less often in the genital area. Three clinical forms of aphthous ulcers have been described: minor aphthous ulcers, herpetiform aphthous ulcers and major aphthous ulcers. Many other conditions presenting with oral bullous or vesiculous lesions or ulcerations and erosions can be mistaken for aphthous ulcers. Currently, treatment of aphthous ulcers is palliative and symptomatic. Topical treatments (topical anesthetics, topical steroids and sucralfate) are the first line therapy. Recurrent aphthous stomatitis (RAS) is defined by the recurrence of oral aphthous ulcers at least 4 times per year. RAS is often idiopathic but can be associated with gastro-intestinal diseases (i.e. celiac disease, inflammatory bowel diseases), nutritional deficiencies (iron, folates...), immune disorders (HIV infection, neutropenia) and rare syndromes. Behçet's disease is a chronic, inflammatory, disease whose main clinical feature is recurrent bipolar aphthosis. Colchicine associated with topical treatments constitutes a suitable treatment of most RAS.


Chavan M, et al (2012), Recurrent aphthous stomatitis (RAS) is a common clinical condition producing painful ulcerations in oral cavity. The diagnosis of RAS is based on well-defined clinical characteristics but the precise etiology and pathogenesis of RAS remain unclear. The present article provides a detailed review of the current concepts and knowledge of the etiology, pathogenesis, and management of RAS. Aphthae (i.e., canker sores) have plagued mankind throughout recorded history and were first mentioned by Hippocrates (460-370 BC) who utilized the term aphthai to describe disorders of the mouth (1). Recurrent aphthous stomatitis (RAS, aphthae, canker sores) is a common condition that is characterized by multiple recurrent small, round, or ovoid ulcers with circumscribed margins, erythematous haloes, and yellow or gray floors typically presenting first in childhood or adolescence (2). As per large USA-based studies, RAS is the most common inflammatory ulcerative condition of the oral cavity (3). RAS
is the most common ulcerative disease of the oral mucosa making the diagnosis and management of these recurring oral lesions common problems in general and specialty dental practice

PaleriVc., et al (2010), Oral ulcers are common, with an estimated point prevalence of 4% in the United States.1 Aphthous ulcers may affect as many as 25% of the population worldwide. Patients with an oral ulcer may present initially to a general practitioner or a dental practitioner. Most ulcers are benign and resolve spontaneously but a small proportion of them are malignant. The incidence and prevalence of oral cancers varies across the world. The five year prevalence of oral cavity cancer in developed countries is 275373 cases and in less developed countries 464756 cases.2 Some of the highest incidences are seen in the Indian subcontinent, southern France, and South America. Importantly, the incidence of oral cancer is rising in most populations, particularly in young women. In the United Kingdom, around 2500 cases of oral cavity cancers are seen every year. A recent study used a validated theoretical framework to evaluate general medical practitioners' attitudes towards oral examination and found that lack of confidence, knowledge, and training contributed to difficulties in differentiation. 5 The aim of this review is to provide a clinically oriented overview of the common causes of acute oral ulcers and to present.

Jurge S, et al (2006), Recurrent aphthous stomatitis (RAS; aphthae; canker sores) is a common condition which is characterized by multiple recurrent small, round or ovoid ulcers with circumscribed margins, erythematous haloes, and yellow or grey floors typically presenting first in childhood or adolescence. RAS occurs worldwide although it appears most common in the developed world. The aetiology of RAS is not entirely clear. Despite many studies trying to identify a causal microorganism, RAS does not appear to be infectious. Agenetic predisposition is present, as shown by strong associations with genotypes of IL-18; IL-6 in RAS patients, and a positive family history in about one-third of patients with RAS. Haematinic deficiency is found in up to 20% of patients. Cessation of smoking may precipitate or exacerbate RAS in some cases. Ulcers similar to RAS may be seen in human immunodeficiency virus disease and some other immune defects, and drugs, especially non-steroidal anti-inflammatory drugs and nicorandil may produce lesions clinically similar to RAS. Topical corticosteroids can often control RAS. However, the treatment of RAS remains unsatisfactory, as most therapies only reduce the severity of the ulceration and do not stop recurrence.

Natah SS,, et al (2004), Recurrent aphthous ulcers represent a very common but poorly understood mucosal disorder. They occur in men and women of all ages, races and geographic regions. It is estimated that at least 1 in 5 individuals has at least once been afflicted with aphthous ulcers. The condition is classified as minor, major, and herpetiform on the basis of ulcer size and number. Attacks may be precipitated by local trauma, stress, food intake, drugs, hormonal changes and vitamin and trace element deficiencies. Local and systemic conditions, and genetic, immunological and microbial factors all may play a role in the pathogenesis of recurrent aphthous ulceration (RAU). However, to date, no principal cause has been discovered. Since the aetiology is unknown, diagnosis is entirely based on history and clinical criteria and no laboratory procedures exist to confirm the diagnosis.

Scully C, et al (2000), The causes and treatment of mouth pain are presented. Causes include ulcers, canker (cold) sores, mouth cancer, erythema migrans, burning mouth syndrome, desquamative gingivitis, dental cavities, neurologic diseases and vascular diseases such as migraine headache. Temporomandibular joint syndrome can also mouth pain.

3.1 Rationals:

There are many work available in mouth ulcer formulation, but for relieve from mouth ulcer. I want to prepare a curcurmin loaded emulgel. This approach are cost effective and preferrable for age 15 to above 80 of patient in manner
of patient condition. Mostly people are suffering from skin rashes in the mouth, viral, bacterial and fungal infections. this medicated emulgel will help in reducing the ulcer.

3.5 DRUG AND DRUG PROFILE

Herbal Plant:-

Herbal remedies For their basic needs—the creation of food, shelter, clothes, transportation, fertilizers, flavors and scents, and medicines—humans have depended on nature throughout history. Humans depended on the therapeutic qualities of plants. Some people cherish these plants because of an old belief that states plants were made to provide man with food, medicine, and other benefits. The World Health Organization estimates that 80% of the 5.2 billion people on the planet reside in less developed nations and that traditional medicine serves as their major source of healthcare for almost all of these individuals. The "backbone" of traditional medicine, which benefits over 3.3 billion people in less developed nations, is medicinal plants.

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Plants have been the foundation of sophisticated traditional medical systems for thousands of years, and they still provide humans new ways to heal themselves. Medicinal plant therapy is founded on the empirical results of hundreds, if not thousands, of years of use, even though some of the therapeutic characteristics claimed to plants have turned out to be false.

Herbs are plant parts that are utilized in cooking; they can be used either fresh or dried. Any additional plant material—typically dried—is referred to as a spice. Barks (cinnamon), berries (peppercorns), seeds (cumin), roots (turmeric), flowers (chamomile), buds (cloves), and flower stigmas (saffron) are a few examples of these.

Herbal treatment for mouth ulcer

Traditional herbalists and native healers have employed phytogenic substances to prevent and treat ulcers.[20,21] Flavonoids (such as quercetin, naringin, silymarin, anthocyanosides, and sophoradin derivatives), saponins (from Panax japonicus and Kochia scoparia), tannins (from Linderaeumbellatae), gums, and mucilages are some examples of botanical chemicals with anti-ulcer activity (i.e. gum guar and myrrh). Liquorice, aloe gel, and capsicum (chilli) have all been widely utilised as natural medications. Several plant extracts are used by ethnomedical systems to cure ulcers.[22,23]
Advantages of herbal medicines

- Herbal remedies have been used for a long time and are more widely accepted by the general public and patients.
- Medical plants have a reliable supply, allowing us to maintain consistent supply of less expensive medications for the world's expanding population.
- Access to medicinal plants is not a barrier in developing nations like India because of its great agro-climatic, cultural, and ethnic richness.
- The growing and processing of therapeutic herbs is environmentally favourable.
- Herbal medication use is safe and effective even when used for a long time and seems to go unnoticed.

Guava (Psidium guajava):

For the herbal treatment of a number of oral conditions, including toothaches, sore throats, inflamed gums, and ulcers, Psidium guajava has been utilised. Guava leaf decoction has also been administered as mouthwash.[48] In two separate investigations, Shaikh et al. and Thombre et al. created and assessed an aqueous gel of powdered guava leaves for the treatment of oral ulcers. They found that the powdered guava leaves contained flavonoids and had a sizable antioxidant effect. When compared to synthetic formulations for the treatment of oral ulcers, the herbal formulation proved to be stable, safe, and efficacious.[49,50] In another study researcher found that using mouthwash made from guava leaves helped aphthous ulcers heal more quickly and with less discomfort.
**Biological Source** - It is an edible fruit of *Psidium guajava*

**Family** - Myrtaceae

**Chemical constituent** - Tannins, Resin, Volatile oil

**Part used** - leaves

**Uses** - because of its high level of pectin, guavas are extensively used to make candies, preserves, jellies, jams and marmalade. And also used for wound healing, soft tissue infection.

**Other uses** - controlling blood sugar levels, anti-inflammatory and antibacterial properties, coughs, potassium

**Babul tree (Gum Arabic tree):**

**Scientific name** - Vachellianilotica

**Family** - Fabaceae

**Chemical composition** - Calcium, magnesium, malic acid, sugar.

Fig3.3:- Babul Tree  
Fig3.4:- Babul Powder

There is a long history of using medicinal plants for human benefit. Approximately 80% of people worldwide rely solely on traditional treatments, according to the WHO. In Unani medicine and other Indian medicinal systems, *Acacia nilotica* Linn, also referred to as Babul or kikar, is used to prevent and treat a variety of illnesses.[10] typical in climates that are tropical and temperate. worldwide regions, including America, Sri Lanka, Africa, Australia, and Asia.[11] Owing to its antimicrobial properties, it helps with a variety of dental issues. Babul bark powder is useful in a variety of ways. One of the most significant and popular uses of babul bark powder is to treat dental issues. It is well recognised to aid with toothaches and bleeding gums, which strengthens the gums.
### MATERIALS AND METHOD

#### Table 3.1 List of Material

<table>
<thead>
<tr>
<th>So.no.</th>
<th>Material</th>
<th>Function</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Guava Leave</td>
<td>Antibacterial Properties</td>
<td>3%</td>
</tr>
<tr>
<td>2.</td>
<td>Babul Leave</td>
<td>Controlling Bleeding</td>
<td>3%</td>
</tr>
<tr>
<td>3.</td>
<td>Carbopol 934</td>
<td>Color Cosmetics</td>
<td>5%</td>
</tr>
<tr>
<td>4.</td>
<td>Methyl Paraben</td>
<td>Bacterial &amp; Fungal Growth</td>
<td>0.0015%</td>
</tr>
<tr>
<td>5.</td>
<td>Propyl Paraben</td>
<td>Antifungal Properties</td>
<td>0.01%</td>
</tr>
<tr>
<td>6.</td>
<td>Triethanolamine</td>
<td>Adjusts &amp; Buffers the pH</td>
<td>Q.S</td>
</tr>
</tbody>
</table>

#### MATERIALS AND METHOD

**Sample collection and processing**

Fresh leaves of *P. guajava* L. (guava), *Babul* L. were collected from the garden. The leaves were rinsed gently with distilled water; shade dried and powdered using a blender. The powder was then passed through aluminium sieve (1 mm) to get uniform particle size. Guava leaf powder and Babul leaf powder was stored in an air tight container for further studies.

**PREPARATION OF HERBAL GEL**

A specific amount of Carbopol 934 was dispersed in the desired amount of distilled water while stirring continuously. Then, 5 ml of distilled water was measured out. The required quantities of methyl paraben and propyl paraben were dissolved in this water by gently heating it on a water bath. After cooling, propylene glycol was added.

Next, varying amounts of *Psidium guajava* cream and *Azadirachta indica* leaf extract were mixed into the previously prepared solution. Distilled water was then added to bring the total volume to 20 ml.

Finally, the fully mixed ingredients were thoroughly incorporated into the Carbopol 934 gel with continuous stirring. Triethanolamine was then added dropwise until the mixture reached the desired pH of 6.8-7. (Das, 2010)

**Table 1: Composition of various gel formulations containing powdered guava leaves & babul leaves.**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>G1</th>
<th>G2</th>
<th>G3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guava leaves powder</td>
<td>3%</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Babul leaves Powder</td>
<td>3%</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Carbopol 934</td>
<td>5%</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>Methyl Paraben</td>
<td>0.0015%</td>
<td>0.0015%</td>
<td>0.0015%</td>
</tr>
<tr>
<td>Propyl Paraben</td>
<td>0.01%</td>
<td>0.01%</td>
<td>0.01%</td>
</tr>
<tr>
<td></td>
<td>Amount</td>
<td>Amount</td>
<td>Amount</td>
</tr>
<tr>
<td>----------------</td>
<td>--------------</td>
<td>--------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Triethanolamine</td>
<td>q.s + pH 6.5-7</td>
<td>q.s + pH 6.5-7</td>
<td>q.s + pH 6.5-7</td>
</tr>
<tr>
<td>Distilled water</td>
<td>Up to 20 ml</td>
<td>Up to 20 ml</td>
<td>Up to 20 ml</td>
</tr>
</tbody>
</table>

Table 1: Composition of various gel formulations containing powdered guava leaves & babul leaves.
3.7 EVALUATION OF HERBAL GEL

Physical Appearance:

Physical parameters such as appearance and colour were checked.

Measurement of pH:

The pH of the herbal gel was measured using a digital pH cadence. A one-gram sample of the gel was dispersed in 10 ml of distilled water and set away for two hours. The pH dimension was performed three times, and the average value is reported (Sanghavi, 1989). The reported pH values can be set up in Table 2.

![Fig3.9- pH Testing](image)

Homogeneity:

All gel phrasings passed unity testing through visual examination after being set into holders. The examination concentrated on detecting any summations or irregularities in their appearance (Gupta, 2010). The unity of gel phrasings was proved in Table 2.

Spreadability:

Spreadability was determined by glass slide and rustic block outfit. Weights about 20 gm were added to the visage and the time were noted for upper slide to move to separate completely from the fixed slide (Shivhare, 2009). An spare amount of gel 2 gm under study was placed on this ground slide. The gel was also squeezed between this slide and another glass slide having the fixed ground slide and there's handed with the hook.

A 1 kg burdened was placed on the top of the slides for 5 beats to give a steady film of the gel and remove air between the slides. redundant of the gel was removed off from the edges. The top plate was also subdued to pull with the help of string attached to the hook and the time in seconds demanded by the top slide to cover a distance of 7.5 cm be noted. A shorter or lower interval indicates better Spreadability. The spreadability of the gel was determined using the formula handed by Pawar, (2013), and is proved in Table 2.

\[ S = M \times \frac{L}{T} \]
Where, $S = $ Spreadability,

$M = $ Weight in the pan which is tied to the upper slide,

$L = $ Length moved by the glass slide

$T = $ Time in second taken to separate the slide completely each other.

Fig 3.10 - Spreadability Test

Clarity:

Visual Examination was employed to determine the clarity of all three batches (Pandey, 2011).

Viscosity:

Density was determined by using Brookfield viscometer (DV-III programmable Rheometer). Formulated gels were tested for their rheological actions at 250 C. The dimension was made over range of speed from 10rpm to 100rpm with 30 seconds between 2 consecutive pets and also in a rear orders (Bhramaramba, 2015).

Extradability:

The gel phrasings were filled in standard limited collapsible aluminium tubes and sealed to the end. The ability to be squeezed or pressed was tested by using the thumb.

RESULT AND DISCUSSION

From the result it is clearly shown that all the prepared gel formulations having good homogeneity and gelling properties. The pH of all gel formulations was in the range of compatible with normal pH range of the skin. The theological behavior also indicates that the gels were neither too thick nor too thin. The Spreadability shows that with increasing viscosity of formulation, Spread ability decreases and vice versa. Extrudability study was done by pressing thumb and it's easily extendable.
From the results it’s easily shows that all the set gel phrasings having good unity and gelatinizing property( Gupta, 2010). The pH of all gel phrasings was in the range compatible with normal pH range of the skin( Sanghavi, 1989). The rheological geste was studied with rheometer ranging between 2.292 to 3.111. Which is indicated that formulated gel was neither too thick and nor too thin( Bhramaramba, 2015).

The study of Spreadability shows that with adding the density of expression Spreadability diminishments and vice versa( Shivhare, 2009). Extrudability study was done by pressing thumb and it’s fluently extendable. The gelatinizing & bioadhesive strength of all the batches was set up in the suitable range( Jaiswal, 2012). 1 Month stability study was done with open and close vessel and it’s showed that open vessel containing gel wasn't stable and close vessel gel was stable. Formulated gel containing open vessel when expose to medium room temperature also syneresis was observed it means liquid exudates separating( Kaur, 2013). Syneresis arises when the commerce between patches of the dispersed phase intensifies to the point where separation occurs upon standing. In that dispersing medium is squeezed out in driblets forms and the gel shrinks. Syneresis it means the form of insecurity in waterless gels. In syneresis system separation of a solvent phase is do only because of the elastic compression of the polymer means polymeric motes( Allen L). Infrared gamuts of gel phrasings did not show the presence of any fresh peaks so infrared spectroscopy revealed that there was no commerce between pulverized Guava leaves and polymer. Infrared gamuts have shown groups $2925.48 \text{- CH, } 476.93 \text{- Hematite, } 1717.3 \text{- C=O, } 1187.46, 1187.72 \text{- C-O.}$ The major peaks of medicine gamuts remained unchanged in the admixture were observed in Infrared gamuts. All the three batches of developed expression showed antifungal exertion against Aspargilious aureus & Candida Albicans this are main microorganism responsible for mouth ulcer and expression it can also use to treat mouth ulcer infection( Koland, 2011). A farther DPPH assay study it was observed that pulverized guava leaves contains flavonoids so it showed significant antioxidant effect( Blois, 1958) & (Mathangi, 2013).

<table>
<thead>
<tr>
<th>Formulation</th>
<th>G1 (2%)</th>
<th>G2 (1%)</th>
<th>G3 (0.5%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical Appearance</strong></td>
<td>Greenish</td>
<td>Greenish</td>
<td>Greenish</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>6.13</td>
<td>7±0.09</td>
<td>6.9±0.5</td>
</tr>
<tr>
<td><strong>Spreadability (gm.cm/sec)</strong></td>
<td>5.30 ± 0.1</td>
<td>5.76 ± 0.15</td>
<td>6.23 ± 0.057</td>
</tr>
<tr>
<td><strong>Viscosity (Pa·S)</strong></td>
<td>3.111 ± 0.004</td>
<td>3.029 ± 0.049</td>
<td>2.292 ± 0.012</td>
</tr>
<tr>
<td><strong>Extrudability</strong></td>
<td>Good</td>
<td>Good</td>
<td>Good</td>
</tr>
<tr>
<td><strong>Homogeneity</strong></td>
<td>Good</td>
<td>Good</td>
<td>Good</td>
</tr>
<tr>
<td><strong>Stability study for 1 Month</strong></td>
<td>Open Container</td>
<td>Not Stable</td>
<td>Open Container</td>
</tr>
<tr>
<td></td>
<td>Closed Container</td>
<td>Stable</td>
<td></td>
</tr>
</tbody>
</table>
CONCLUSIONS

Currently there's a lot of demand for herbal phrasings in the request due to their cost effectivity and absence of any side goods. From the below experimental data it is clear that a gel expression with herbal constituents similar as aloe, neem and tulsi has good characteristics, density and also possesses a good antimicrobial exertion which is necessary in the operation of mouth ulcers.

Antifungal Activity: All three batches of the developed gel formulation showed significant antifungal activity against Aspergillus aureus and Candida Albicans, the main microorganisms responsible for mouth ulcers. This indicates the potential use of the formulation for treating mouth ulcer infections. Clinical Efficacy: The guava leaves mouthwash demonstrated a marked improvement in pain symptoms as early as three days post-treatment. The Visual Analog Scale (VAS) scores showed significant differences in pain resolution from Day 3 to 7. Complete resolution of aphthous ulcers was observed in 75% of the study group on Day 7, with a statistically significant faster resolution of ulcer size compared to the control group.

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