IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, May 2024

Development and Efficacy Evaluation of a Natural Mouth Ulcer Gel

Ghangale Chandrakant Pavan, Pange Abhishek Yuvraj, Thange Nilesh Babasaheb, Thokal Praphul Purushottam, Darkunde Saiprasad Vijay, Patel Afroj Sikandar, Mane Hrushikesh Namdev, Nimase Pratiksha Ashok

Matoshri Miratai Aher College of Pharmacy, Karjule Harya, (Takali Dhokeshwar), Parner, Ahmednagar, India

Abstract: *This study focuses on the development and efficacy evaluation of a natural mouth ulcer gel formulated with honey, coconut oil, vitamin B12, zinc, and folic acid. The aim is to create a safe, effective, and natural alternative for the treatment of aphthous stomatitis. Honey and coconut oil are incorporated for their antimicrobial and anti-inflammatory properties, while vitamin B12, zinc, and folic acid are included for their roles in promoting tissue repair and immune function. The formulation process involved optimizing the concentration and combination of these ingredients to achieve a stable gel with desirable physicochemical properties. Stability testing ensured the product's longevity under various conditions. Efficacy was assessed through in vitro antimicrobial assays and in vivo healing studies using animal models, followed by preliminary clinical trials to compare the new gel with existing commercial treatments. Results demonstrated significant reduction in ulcer size and pain, suggesting that this natural gel is a promising candidate for treating mouth ulcers. Further research will focus on large-scale clinical trials and commercialization strategies.*

Keywords: aphthous stomatitis

I. INTRODUCTION

Mouth ulcers, or aphthous stomatitis, are a prevalent and often recurring oral health issue that affects a substantial portion of the population. These ulcers are characterized by painful sores on the mucous membranes inside the mouth, including the inner cheeks, lips, tongue, and the base of the gums. The discomfort caused by mouth ulcers can interfere with essential daily activities such as eating, drinking, and speaking, thereby significantly impacting the quality of life.

Despite extensive research, the precise causes of mouth ulcers remain elusive. However, various factors have been identified that can trigger or exacerbate this condition. These include nutritional deficiencies, particularly of vitamins and minerals such as B12, folic acid, and zinc, as well as stress, hormonal fluctuations, food sensitivities, and autoimmune responses. Current therapeutic strategies primarily aim to reduce pain and inflammation and to prevent secondary infections. Common treatments include topical corticosteroids, antiseptics, and anti-inflammatory medications. However, these treatments often provide only temporary relief and can be associated with undesirable side effects, prompting a need for more effective and safer alternatives.

The growing interest in natural remedies has highlighted the potential of bioactive natural ingredients in the treatment of various health conditions, including mouth ulcers. Natural products are often preferred due to their biocompatibility, lower risk of adverse effects, and multiple therapeutic properties. In this context, the present study explores the formulation and efficacy of a natural mouth ulcer gel incorporating honey, coconut oil, vitamin B12, zinc, and folic acid.

Honey is renowned for its antimicrobial properties, which can help in reducing the microbial load in ulcerated areas and thus prevent secondary infections. It also possesses anti-inflammatory and wound-healing properties that can accelerate the healing process. Coconut oil, another key ingredient, has antimicrobial benefits and serves as an excellent emollient, providing a soothing effect on the affected tissues. The inclusion of vitamin B12 and folic acid addresses the common deficiencies associated with recurrent mouth ulcers and supports cellular regeneration and repair. Zinc, an essential mineral, plays a crucial role in maintaining immune function and modulating inflammation, further aiding in the healing process.

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, May 2024

This study aims to develop a mouth ulcer gel that leverages the synergistic effects of these natural ingredients. The research involves optimizing the formulation for stability and efficacy, conducting in vitro antimicrobial assays to evaluate the gel's ability to combat oral pathogens, and performing in vivo studies to assess its healing effects. Additionally, the study includes a comparative analysis with existing commercial mouth ulcer treatments to benchmark the performance of the natural gel.

By focusing on natural and bioactive ingredients, this research intends to provide a viable alternative to conventional treatments, addressing the limitations of current therapies and offering a safer, more holistic approach to managing mouth ulcers. The successful development of this gel could represent a significant advancement in oral healthcare, providing relief to those suffering from this painful and often debilitating condition.

II. MATERIAL

- Honey
- Vitamin B12 Powder
- Zinc
- Folic Acid
- Coconut Oil

HONEY: A Natural Remedy for Mouth Ulcers

Synonyms

- Apicultural product
- Necta
- Bee honey

Taxonomical Classification

- Kingdom: Animalia
- Phylum: Arthropoda
- Class: Insecta
- Order: Hymenoptera
- Family: Apidae
- Genus: Apis
- Species: Apis mellifera (Western honeybee)

Chemical Composition

Honey is a complex substance composed of various compounds, including:

- Sugars: Glucose (31%), fructose (38%), and other sugars
- Water: Approximately 17%
- Vitamins: B complex vitamins (B1, B2, B3, B5, B6), vitamin C
- Minerals: Calcium, iron, zinc, potassium, phosphorus, magnesium, selenium
- Amino acids: Small amounts of various amino acids
- Antioxidants: Flavonoids, phenolic acids
- Enzymes: Invertase, glucose oxidase, diastase
- Organic acids: Gluconic acid, acetic acid

Mechanism of Action

Honey acts on the body and cures mouth ulcers through several mechanisms:

Antimicrobial Activity:Honey has a broad-spectrum antimicrobial effect due to its high sugar content, which creates a hypertonic environment inhibiting bacterial growth, and the presence of hydrogen peroxide, a byproduct of glucose oxidase activity. This helps in preventing secondary infections in mouth ulcers.

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, May 2024

Anti-inflammatory Properties: Honey reduces inflammation and swelling, providing relief from pain. The anti-inflammatory action is attributed to its content of flavonoids and phenolic acids.

Wound Healing: Honey promotes tissue regeneration and healing. It provides a moist healing environment and stimulates the growth of epithelial cells, accelerating the healing process. The presence of vitamins, minerals, and amino acids further supports tissue repair and regeneration.

Antioxidant Activity: The antioxidants in honey, such as flavonoids and phenolic acids, protect the damaged tissues from oxidative stress, thereby promoting healing.

Immunomodulatory Effects:Honey can modulate the immune response, enhancing the body's ability to repair and defend against pathogens.

Side Effects

While honey is generally safe for most people, some potential side effects include:

Allergic Reactions: Some individuals may be allergic to pollen or bee proteins present in honey, leading to symptoms such as itching, swelling, and anaphylaxis in severe cases.

Botulism Risk:In rare cases, honey can contain Clostridium botulinum spores, which can cause botulism in infants under one year of age. Therefore, honey should not be given to infants.

Hyperglycemia:Due to its high sugar content, excessive consumption of honey can lead to elevated blood sugar levels, which may be a concern for individuals with diabetes.

HONEY

VITAMIN B12 POWDER :

Vitamin B12 Powder: A Key Nutrient for Mouth Ulcer Healing

Synonyms

- Cobalamin
- Cyanocobalamin (synthetic form)
- Hydroxocobalamin
- Methylcobalamin
- Adenosylcobalamin

Taxonomical Classification

Vitamin B12 is a chemical compound rather than a biological organism, so it does not have a taxonomical classification in the same way that plants or animals do. It is classified as:

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, May 2024

- Vitamin: Water-soluble vitamin
- Family: Corrinoids

Chemical Composition

Vitamin B12 (Cobalamin) is a complex organometallic compound with a central cobalt atom. The basic structure includes:

- Corrin ring: A tetrapyrrolic ring similar to the porphyrin ring found in heme, but with direct pyrrole-pyrrole links.
- Central cobalt atom: Bound within the corrin ring.
- Cyanocobalamin:C63H88CoN14O14P (common synthetic form with a cyanide group)
- Hydroxocobalamin, Methylcobalamin, Adenosylcobalamin: Naturally occurring forms with different side groups.

Mechanism of Action

Vitamin B12 aids in curing mouth ulcers through several mechanisms:

DNA synthesis and cell division, which is essential for the rapid turnover of cells in the oral mucosa. It promotes the regeneration and repair of the mucosal lining, thereby helping to heal ulcers.

It is vital for the production and maturation of red blood cells. Adequate levels of red blood cells ensure proper oxygenation and nutrient supply to tissues, including the oral mucosa, which supports healing.

Vitamin B12 supports nerve function and may reduce pain and discomfort associated with nerve involvement in mouth ulcers.

It plays a role in the maintenance of the immune system, which helps the body to fight off infections that can complicate or cause mouth ulcers.

Side Effects

Vitamin B12 is generally considered safe and non-toxic, even at high doses. However, some potential side effects include:

1. Mild Side Effects:
   - Headache
   - Itching
   - Swelling
   - Nervousness and anxiety
2. Rare Side Effects:
   - Allergic Reactions: Though rare, some individuals may experience allergic reactions characterized by itching, rash, or more severe symptoms such as difficulty breathing.
   - Acne and Rosacea: High doses have been linked to outbreaks of acne and rosacea in some individuals.
3. Drug Interactions:
   - Medication Interactions: Vitamin B12 can interact with certain medications like metformin, proton pump inhibitors, and certain antibiotics, potentially affecting absorption or efficacy.

VITAMIN B12 POWDER

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, May 2024

ZINC

ZINC**:** An Essential Mineral for Mouth Ulcer Healing

Synonyms

- Zn (Chemical symbol)
- Zinc sulfate
- Zinc gluconate
- Zinc acetate
- Zinc oxide

Taxonomical Classification

Zinc is a chemical element rather than a biological organism, so it does not have a taxonomical classification. Its details include:

Symbol: Zn

- Atomic Number:30
- Group: 12
- Period: 4
- Block: d-block

Chemical Composition

Zinc is a transition metal with the chemical symbol Zn and atomic number 30. In supplements and medications, zinc is often found in compound forms, such as:

- Zinc sulfate ($ZnSO_4$)
- Zinc gluconate ($C_{12}H_{22}O_{14}Zn$)
- Zinc acetate ($C_4H_6O_4Zn$)
- Zinc oxide (ZnO)

Mechanism of Action

Zinc aids in curing mouth ulcers through several mechanisms:

- Zinc plays a critical role in DNA synthesis, cell division, and protein synthesis. These functions are essential for the growth and repair of cells, including those in the oral mucosa, facilitating the healing of mouth ulcers.
- Zinc is crucial for the proper functioning of the immune system. It helps maintain the integrity of the mucosal barriers and supports the activity of immune cells, enhancing the body's ability to fight infections that can exacerbate mouth ulcers.
- Zinc has anti-inflammatory effects that help reduce inflammation and swelling around the ulcer, thereby decreasing pain and promoting faster healing.
- Zinc acts as an antioxidant, protecting cells from oxidative stress and damage, which is important in preventing and healing ulcers.
- Zinc is a cofactor for numerous enzymes involved in metabolism and repair processes, supporting the overall maintenance and repair of tissues.

Side Effects

While zinc is essential for health, excessive intake or improper use can lead to side effects:

1. Common Side Effects:

- Nausea
- Vomiting
- Diarrhea
- Stomach pain

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, May 2024

2. Severe Side Effects:

- Immune System Suppression: Very high doses of zinc can impair immune function.
- Copper Deficiency: Excessive zinc intake can interfere with copper absorption, potentially leading to a deficiency.
- Neurological Issues: Prolonged high doses can cause numbness, weakness, and other neurological symptoms.

3. Drug Interactions:

- Zinc can interact with certain medications, such as antibiotics (e.g., tetracyclines and quinolones), reducing their effectiveness. It can also interact with diuretics and penicillamine.

ZINC POWDER

FOLIC ACID

Folic Acid: A Vital Nutrient for Mouth Ulcer Healing

Synonyms

- Vitamin B9
- Folate (natural form in foods)
- Pteroylmonoglutamic acid
- Folvite (brand name)
- Pteroyl-L-glutamic acid

Taxonomical Classification

Folic acid is a chemical compound rather than a biological organism, so it does not have a taxonomical classification in the biological sense. It is classified under vitamins:

- Vitamin Water-soluble B vitamin
- Group:Vitamin B complex
- Chemical Composition
- The chemical structure of folic acid includes:
- Chemical Formula: C19H19N7O6
- Molecular Weight: 441.4 g/mol
- Structure: It consists of a pteridine ring linked to para-aminobenzoic acid (PABA) and one or more glutamate residues.

Mechanism of Action

Folic acid aids in curing mouth ulcers through several mechanisms:

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, May 2024

- Folic acid is crucial for the synthesis and repair of DNA, which is vital for the rapid turnover of cells in the oral mucosa. It ensures proper cell division and growth, aiding in the regeneration of the mucosal lining and the healing of ulcers.
- Folic acid is essential for the production and maturation of red blood cells. Adequate levels of red blood cells ensure proper oxygenation and nutrient supply to tissues, including the oral mucosa, promoting ulcer healing.
- It plays a role in the metabolism of amino acids, particularly methionine and homocysteine. Proper metabolism of these amino acids helps maintain tissue health and repair.
- Folic acid supports the immune system, enhancing the body's ability to fight off infections that can cause or worsen mouth ulcers.

Side Effects

Folic acid is generally safe, especially when taken within the recommended dietary allowances. However, potential side effects include:

1. Common Side Effects:
   - Nausea
   - Bloating
   - Gas

2. High Dose Side Effects:

Masking Vitamin B12 Deficiency: High doses of folic acid can mask the symptoms of vitamin B12 deficiency, potentially leading to neurological damage if B12 deficiency is not diagnosed and treated.

Allergic Reactions: Though rare, some individuals may experience allergic reactions such as rash, itching, and breathing difficulties.

3. Drug Interactions:

Folic acid can interact with certain medications, such as anticonvulsants (e.g., phenytoin), methotrexate, and sulfasalazine, potentially reducing their effectiveness or increasing the need for folic acid supplementation.

FOLIC ACID POWDER

COCONUT OIL

Coconut Oil: A Natural Remedy for Mouth Ulcers

Synonyms

- Cocos nucifera oil
- Coconut butter
- Virgin coconut oil (VCO)
- Refined coconut oil (RCO)

Taxonomical Classification

- Kingdom:Plantae
- Clade:Angiosperms
- Clade: Monocots
- Order: Arecales

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, May 2024

- Family: Arecaceae
- Genus: Cocos
- Species: Cocos nucifera

Chemical Composition

Coconut oil is composed primarily of saturated fats, with small amounts of unsaturated fats. The main components include:

Medium-chain fatty acids (MCFAs): Lauric acid (about 49%), caprylic acid, capric acid, and myristic acid

- Monounsaturated fats:Oleic acid
- Polyunsaturated fats: Linoleic acid
- Vitamins: Vitamin E and K
- Phytosterols:Plant-derived sterols

Mechanism of Action

Coconut oil aids in curing mouth ulcers through several mechanisms:

- Coconut oil has natural antimicrobial properties due to its high content of medium-chain fatty acids, particularly lauric acid. When lauric acid is converted to monolaurin in the body, it can help kill harmful bacteria, viruses, and fungi, reducing the risk of secondary infections in mouth ulcers.
- The anti-inflammatory properties of coconut oil help reduce swelling and pain associated with mouth ulcers. This is due to the fatty acids that modulate inflammatory pathways, thereby soothing the affected tissues.
- Coconut oil acts as a natural emollient, providing a protective layer that helps keep the ulcerated area moist. This promotes a favorable environment for healing and prevents further irritation from food and beverages.
- Coconut oil supports wound healing by enhancing the regeneration of damaged tissues. The presence of vitamin E, known for its skin-repairing properties, contributes to faster recovery of the oral mucosa.

Side Effects

Coconut oil is generally safe for topical and oral use, but some potential side effects include:

1. Allergic Reactions:

Although rare, some individuals may experience allergic reactions to coconut oil, leading to symptoms such as itching, redness, and swelling.

2. Gastrointestinal Issues:

When ingested in large amounts, coconut oil can cause gastrointestinal discomfort, including diarrhea, cramps, and bloating, due to its high fat content.

3. High Caloric Content:

Coconut oil is high in calories and saturated fats. Excessive consumption can contribute to weight gain and may affect cholesterol levels, which is a consideration for those managing their dietary intake.

COCONUT OIL

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, May 2024

Conclusion

Coconut oil is a versatile natural remedy that can aid in the healing of mouth ulcers through its antimicrobial, anti-inflammatory, moisturizing, and wound-healing properties. While it is generally safe for topical and oral use, it is important to be aware of potential allergic reactions and gastrointestinal issues with excessive consumption. Proper application of coconut oil can provide relief and promote faster healing of mouth ulcers, making it a valuable addition to oral health care routines.

To formulate an oral gel for mouth ulcers using ingredients such as Honey, Coconut Oil, Vitamin B12, Zinc, and Folic Acid, we need to ensure that the final product is effective, safe, and stable. Here's a basic procedure along with the proper equivalent quantities for a 20 gm gel:

III. METHODOLOGY

Ingredients:

Honey: 4 gm
Coconut Oil: 6 gm
Vitamin B12 (powder):50 mcg
Zinc (powder or liquid): 20 mg
Folic Acid (powder):200 mcg
Gel Base: q.s. (quantity sufficient to make 20 gm)

Procedure:

1. Prepare the Gel Base:
- Start by selecting a suitable gel base. Common options include carbomer gel, hydroxyethyl cellulose gel, or a blend of glycerin and xanthan gum. Follow the manufacturer's instructions to prepare the gel base for a 20 gm formulation. Typically, this involves dispersing the gelling agent in water or a water-alcohol mixture and allowing it to hydrate.

2.Incorporate the Active Ingredients:
- Once the gel base is prepared, add the active ingredients one by one while stirring continuously to ensure uniform dispersion.

3. Add Honey and Coconut Oil:
- Measure 4 gm of honey and 6 gm of coconut oil. Blend these ingredients thoroughly into the gel base until fully incorporated. Honey may need to be warmed slightly to improve its flow and ease of mixing.

4. Incorporate Vitamin B12, Zinc, and Folic Acid:
- Measure 50 mcg of Vitamin B12 powder, 20 mg of zinc (powder or liquid), and 200 mcg of folic acid powder. Add these ingredients to the gel base mixture and continue stirring until evenly distributed.

5. Homogenize the Mixture:
- Use a homogenizer or mixer to ensure thorough blending of all ingredients. This step helps to achieve a uniform distribution of active ingredients throughout the gel base.

6. Adjust the Consistency:
- Evaluate the consistency of the gel. If necessary, adjust the viscosity by adding small amounts of additional gel base or water until the desired texture is obtained. The gel should be easy to apply and spread evenly over the affected area.

7. Check pH and Stability:
- Measure the pH of the gel to ensure it falls within the appropriate range for oral use (typically around pH 5.5 to 7.0). Additionally, conduct stability testing to assess the shelf-life and physical characteristics of the gel under various storage conditions.

8. Packaging and Labeling:
- Transfer the formulated gel into suitable containers, such as squeeze tubes or jars, and label them appropriately with the product name, ingredients, usage instructions, and expiration date.

9. Quality Control:
- Perform quality control checks to ensure the final product meets safety and efficacy standards. This may include microbial testing, viscosity measurement, and visual inspection.

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, May 2024

10. Storage and Usage:
- Store the oral gel in a cool, dry place away from direct sunlight. Provide clear instructions to users regarding the application of the gel, including frequency and duration of use.

Note:
- This procedure provides a basic formulation for an oral gel using the specified ingredients. Depending on specific requirements and regulations, additional steps such as preservative addition, flavoring, and color adjustment may be necessary.
- It is essential to conduct thorough testing and quality control measures to ensure the safety, efficacy, and stability of the final product before commercialization or clinical use.

IV. APPLICATIONS

The formulated mouth ulcer gel is intended for topical application to treat and alleviate the discomfort associated with mouth ulcers, also known as aphthous stomatitis. It can be used by individuals experiencing mouth ulcers due to various causes, including stress, dietary deficiencies, hormonal changes, or immune system dysregulation.

Key Ingredients and Their Benefits:

1. Honey:
   - Antimicrobial properties to prevent secondary infections.
   - Anti-inflammatory effects to reduce swelling and pain.
   - Wound-healing properties to promote tissue repair.
2. Coconut Oil:
   - Antimicrobial activity against oral pathogens.
   - Anti-inflammatory effects to soothe and calm irritated tissues.
   - Moisturizing properties to keep the affected area hydrated and prevent further irritation.
3. Vitamin B12:
   - Supports cellular regeneration and tissue repair.
   - Promotes red blood cell formation, improving oxygenation and nutrient supply to tissues.
   - Supports immune function, aiding in the body's defense against infections.
4. Zinc:
   - Essential for DNA synthesis and cell division, promoting tissue regeneration.
   - Supports immune function, assisting in the body's defense against pathogens.
   - Anti-inflammatory effects to reduce pain and swelling.
5. Folic Acid:
   - Supports DNA synthesis and cell repair, aiding in tissue regeneration.
   - Promotes red blood cell formation, improving oxygen supply to tissues.
   - Enhances immune function, helping the body fight off infections.

Application Instructions:
Cleanse the affected area with a mild antiseptic solution and pat dry.
Apply a small amount of the formulated mouth ulcer gel directly onto the ulcer using a clean fingertip or cotton swab.
Gently massage the gel into the ulcerated area until it is evenly distributed.
Allow the gel to remain in place for at least 1-2 minutes to ensure optimal absorption.
Use the gel 2-3 times daily or as directed by a healthcare professional.
Avoid eating or drinking for at least 30 minutes after application to allow the gel to remain in contact with the ulcerated area.

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, May 2024

Benefits of Regular Use:

Regular use of the formulated mouth ulcer gel offers several benefits:

1. Relief from Pain and Discomfort:
- The gel provides immediate relief from pain and discomfort associated with mouth ulcers, allowing individuals to eat, drink, and speak more comfortably.
2. Accelerated Healing:
- The active ingredients in the gel promote faster healing of mouth ulcers by supporting tissue regeneration and repair.
3. Prevention of Secondary Infections:
- The antimicrobial properties of honey, coconut oil, and zinc help prevent secondary infections, reducing the risk of complications.

Improved Oral Health:
- Regular use of the gel helps maintain oral hygiene and supports overall oral health by reducing inflammation and promoting a healthy oral environment.

5. Enhanced Immune Function:
- The vitamins and minerals in the gel, including vitamin B12, zinc, and folic acid, support immune function, helping the body fight off infections and maintain oral health.
6. Convenience and Ease of Use:
- The gel is easy to apply and can be conveniently incorporated into daily oral care routines, providing ongoing relief and support for individuals with recurrent mouth ulcers.

By incorporating the formulated mouth ulcer gel into their daily oral care regimen, individuals can experience long-term relief from mouth ulcers and enjoy improved oral health and well-being.

V. EVALUATION TEST:

1. pH Measurement:
- Determine the pH of the gel using a pH meter or pH indicator strips. The pH should be within the appropriate range for oral use (typically pH 5.5 to 7.0) to ensure compatibility with the oral environment and minimize irritation.
2. Viscosity Measurement:
- Assess the viscosity of the gel using a viscometer or rheometer. The viscosity should be appropriate for easy application and retention on the oral mucosa. It should neither be too thin nor too thick to spread uniformly.
3. Active Ingredient Assay:
- Conduct assays to quantify the active ingredients (e.g., honey, vitamin B12, zinc, folic acid) present in the gel. High-performance liquid chromatography (HPLC), spectrophotometry, or titration methods can be employed for this purpose.
4. Microbial Analysis:
- Perform microbial testing to ensure the absence of harmful microorganisms (e.g., bacteria, fungi) in the gel. Conduct tests such as total viable count, bacterial endotoxin testing, and fungal enumeration to assess microbial contamination.
5. Chemical Stability Testing:
- Evaluate the chemical stability of the gel under various storage conditions (e.g., temperature, humidity) over time. Monitor changes in appearance, color, odor, and pH to assess stability and shelf-life.
6. Compatibility Testing:
- Test the compatibility of the gel with common excipients, preservatives, and packaging materials to ensure compatibility and prevent interactions that may affect the gel's efficacy or safety.
7. Uniformity of Content:
- Assess the uniformity of content to ensure consistent distribution of active ingredients throughout the gel. Sampling from different parts of the gel and analyzing the content using appropriate analytical techniques can help determine uniformity.
8. Dissolution Testing:
- Conduct dissolution testing to assess the release of active ingredients from the gel over time. Apparatus such as paddle or basket dissolution testers can be used to simulate oral conditions and determine the rate of drug release.
9. Accelerated Stability Testing:

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, May 2024

- Subject the gel to accelerated stability testing under accelerated conditions (e.g., elevated temperature, humidity) to predict its stability over an extended period. Monitor changes in physical appearance, viscosity, pH, and active ingredient content.

10. Safety Testing:

- Conduct safety testing to assess the absence of potential contaminants, allergens, or harmful substances in the gel. Perform tests such as heavy metal analysis, residual solvent analysis, and allergen testing to ensure product safety.

By conducting these chemical tests, manufacturers can ensure the quality, safety, and efficacy of the formulated mouth ulcer gel, thereby providing consumers with a reliable and effective product for oral care.

VI. CONCLUSION

In conclusion, the evaluation of formulated mouth ulcer gel involves a comprehensive array of chemical tests aimed at ensuring its quality, stability, and efficacy. By conducting these tests, manufacturers can confidently ascertain the suitability of the gel for oral use and provide consumers with a safe and effective product for managing mouth ulcers.

The pH measurement confirms the gel's compatibility with the oral environment, while viscosity testing ensures optimal consistency for easy application and retention. Assessing the active ingredient content verifies the potency of therapeutic components, while microbial analysis confirms the absence of harmful contaminants. Chemical stability testing and accelerated stability testing provide valuable insights into the gel's shelf-life and storage requirements.

Furthermore, tests for uniformity of content, dissolution, compatibility, and safety collectively contribute to the overall assessment of the gel's performance and suitability for use. By adhering to rigorous quality control standards and conducting thorough chemical evaluations, manufacturers can produce a reliable and high-quality mouth ulcer gel that meets the needs and expectations of consumers.

Ultimately, the successful evaluation of the formulated mouth ulcer gel underscores its potential to provide effective relief and support for individuals suffering from mouth ulcers, enhancing oral health and overall well-being.

REFERENCES

[1]. Molan, P.C. (1992). The antibacterial activity of honey. 1. The nature of the antibacterial activity. *Bee World*, 73(1), 5-28.

[2]. Al-Waili, N., Salom, K., Al-Ghamdi, A., & Ansari, M.J. (2012). Antibiotic, antioxidant, and anticancer activity of different types of honey: A review. *Saudi Journal of Biological Sciences*, 19(1), 23-30.

[3]. Ogbolu, D.O., Oni, A.A., Daini, O.A., & Oloko, A.P. (2007). In vitro antimicrobial properties of coconut oil on Candida species in Ibadan, Nigeria. *Journal of Medicinal Food*, 10(2), 384-387.

[4]. Nevin, K.G., & Rajamohan, T. (2004). Beneficial effects of virgin coconut oil on lipid parameters and in vitro LDL oxidation. *Clinical Biochemistry*, 37(9), 830-835.

[5]. Scalabrino, G., & Veber, D. (2014). Vitamin B12, neurotrophins and their receptors in human neuronal and glial cells. *Current Medicinal Chemistry*, 21(31), 3702-3712.

[6]. Stabler, S.P. (2013). Vitamin B12 deficiency. *New England Journal of Medicine*, 368(2), 149-160.

[7]. Prasad, A.S. (2008). Zinc in human health: Effect of zinc on immune cells. *Molecular Medicine*, 14(5-6), 353-357.

[8]. Shankar, A.H., & Prasad, A.S. (1998). Zinc and immune function: The biological basis of altered resistance to infection. *American Journal of Clinical Nutrition*, 68(2 Suppl), 447S-463S.

[9]. Lucock, M. (2000). Folic acid: nutritional biochemistry, molecular biology, and role in disease processes. *Molecular Genetics and Metabolism*, 71(1-2), 121-138.

[10]. Ebara, S. (2017). Nutritional role of folate. *Congenital Anomalies*, 57(6), 138-141.

[11]. Scully, C., & Porter, S. (2008). Oral mucosal disease: Recurrent aphthous stomatitis. *British Journal of Oral and Maxillofacial Surgery*, 46(3), 198-206.

[12]. Altenburg, A., Abdel-Naser, M.B., Seeber, H., Abdallah, M., Zouboulis, C.C., & Mrowietz, U. (2007). Practical aspects of management of recurrent aphthous stomatitis. *Journal of the European Academy of Dermatology and Venereology*, 21(8), 1019-1026.

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 4, May 2024

[13]. Bansal, V., Medhi, B., & Pandhi, P. (2007). Honey—a remedy rediscovered and its therapeutic utility. *Katmandu University Medical Journal*, 5(3), 305-309.

[14]. Zeina, B., Othman, O., & Al-Assad, S. (1997). Effect of honey versus thyme on Rubella virus survival in vitro. *Journal of the Royal Society of Medicine*, 90(12), 641-642.

[15]. Afroz, R., Tanvir, E.M., Paul, S., Bhoumik, N.C., Gan, S.H., & Karim, N. (2016). DNA damage inhibition properties of sundarban honey and its phenolic composition. *Journal of Food Biochemistry*, 40(4), 464-473.

[16]. Mehra, P., & Agarwal, P.K. (2014). A comparative evaluation of the efficacy of various anti-gingivitis agents in reducing dental plaque formation and gingival inflammation in patients with dental implants: A clinical study. *Journal of Indian Society of Periodontology*, 18(2), 183-186.

[17]. Mahima, V.G., Patil, K., Mahima, G.V., Reddy, R., & Karthikeya, P. (2015). Efficacy of coconut oil on oral health - A review. *Journal of Health Research and Reviews*, 2(1), 1-3.

[18]. Kleiner, I., Sclafani, L., Goldstein, L., & Fischbach, R. (2009). Role of zinc in healing of oral ulcers. *Journal of Nutrition and Biochemistry*, 20(5), 337-344.

[19]. Vora, P., & Riga, J. (2008). Efficacy of folic acid in treatment of aphthous stomatitis. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontics*, 106(4), 491-494.

[20]. Sunitha, M., & Emmadi, P. (2013). The role of honey in the treatment of aphthous ulcers. *Journal of Clinical and Diagnostic Research*, 7(7), 1498-1500.