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Formulation And Evaluation Of Poly Herbal Mouth Ulcer Gel.

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ABSTRACT

Mouth ulcers, also known as aphthous ulcers or canker sores, are a common oral mucosal disorder characterized by painful lesions in the mouth. They can be caused by various factors such as trauma, hormonal changes, stress, or certain underlying medical conditions. Traditional herbal remedies have been used for centuries to alleviate the discomfort associated with mouth ulcers and promote healing. This abstract review the efficacy of several herbal remedies commonly used for treating mouth ulcers, including turmeric, guava leave and coccinea grandis. These herbs possess anti-inflammatory, antimicrobial, and wound-healing properties, which may help to reduce pain, inflammation, and promote faster healing of mouth ulcers. Clinical studies evaluating the effectiveness of these herbal remedies have shown promising results in reducing the duration and severity of mouth ulcers. However, further research is needed to fully understand their mechanisms of action and establish standardized protocols for their use in clinical practice. Herbal remedies can be considered as alternative or adjunctive therapies for managing mouth ulcers, but patients should consult with healthcare professionals before using them, especially if they have underlying medical conditions or are taking medications that may interact with these herbal remedies.

Mouth ulcer gel can help alleviate discomfort and promote healing for mouth ulcers. They create a protective barrier over the ulcer, reducing irritation from food and drink, and often contain ingredients to reduce inflammation and pain. If you're experiencing discomfort from mouth ulcers, using a gel could provide relief and support healing. However, for persistent or severe ulcers, it's advisable to consult a healthcare professional for further evaluation and treatment.

KEYWORDS: Mouth ulcer, Polyherbal gel, Anti-inflammatory, Antimicrobial.

INTRODUCTION

Mouth ulcers, also known as canker sores, are small, painful lesions that can develop on the gums, inner cheeks, tongue, or roof of the mouth. They can be caused by various factors including injury, stress, hormonal changes, certain foods, or underlying health conditions. Over-the-counter topical treatments or mouth rinses can help alleviate symptoms and promote healing. If mouth ulcers persist or are accompanied by other symptoms, it's advisable to consult a healthcare professional for further evaluation.

Mouth ulcers can be caused by various factors, including:

1. Minor injury: Accidental biting of the inside of the mouth or injury from sharp or hard foods can lead to the formation of ulcers.

2. Certain foods: Spicy, acidic, or rough-textured foods can irritate the mucous membranes and trigger ulcer formation.

3. Stress or hormonal changes: Emotional stress or hormonal fluctuations, such as those occurring during menstruation, can increase the likelihood of developing mouth ulcers.

4. Nutritional deficiencies: Deficiencies in vitamins, particularly B vitamins, iron, and zinc, can contribute to the development of mouth ulcers.

5. Underlying medical conditions: Conditions such as autoimmune diseases, gastrointestinal disorders, and viral infections can cause recurrent mouth ulcers. Most mouth ulcers heal on their own within 1-2 weeks without scarring. However, they can be painful and uncomfortable during this time.

Over-the-counter remedies like mouth ulcer creams, as well as home remedies like saltwater rinses and honey, can help alleviate pain and promote healing. If mouth ulcers persist, recur frequently, or are accompanied by other symptoms such as fever or difficulty swallowing, it's important to consult a healthcare professional for further evaluation and treatment.

MOUTH ULCER

Mouth ulcers are small sores that form on your gums, lips, tongue, inner cheeks or roof of your mouth. Lots of different things can cause them, including minor injuries, hormonal changes and emotional stress. Many mouth ulcers go away on their own. Others may require treatment.

What is a mouth ulcer?

A mouth ulcer is a sore that appears anywhere inside your mouth. These sores are usually red, yellow or white, and you might have one or several.

You can get mouth ulcers on your:

Gums. Tongue.

Roof of mouth (palate). Inner cheeks.

Inner lips.

These sores are often painful and can make eating, drinking and speaking uncomfortable.

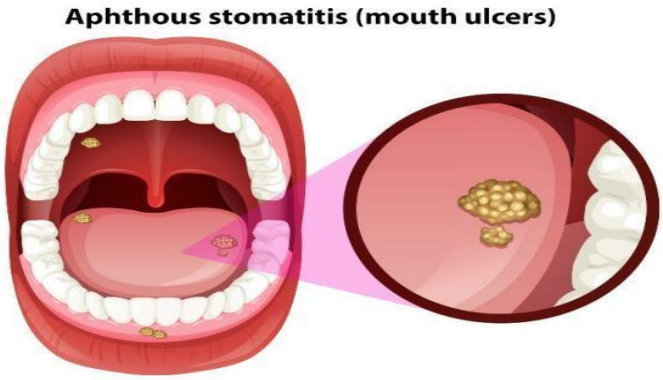

Fig. 1

Types of mouth ulcers:

There are three main types of mouth ulcers. These include:

1. **Herpetiform ulceration (HU)**

Herpetiform ulcers are a subtype of aphthous ulcers and get their name because they resemble the sores associated with herpes. Unlike herpes, HU is not contagious. HU ulcers recur very quickly, and it may appear that the condition never gets better.

Fig.2

2. Minor ulcers

This type can range in size from about 2 millimeters (mm) up to 8 mm across. These ulcers typically take up to 2 weeks to get better and will cause minor pain.(Minor ulcer have a diameter of less than a centimeter and heal in one to two weeks.)

Fig.3

3. Major ulcers

Bigger than minor ulcers, major ulcers are often irregular in shape, may be raised, and penetrate deeper into the tissue than minor ulcers. They can take several weeks to go away and are likely to leave scar tissue when they clear (Major ulcer have a diameter of two to three centimeters,are deeper and take longer time to heal.)

Fig.4 Symptoms of minor and major ulcers include:

- one or more painful sores that may appear on the cheeks, the roof of the mouth, or the tongue.
- The appearance of round lesions that have red edges and are yellow, white, or gray in the middle.

During more extreme outbreaks of mouth ulcers, some people may experience fever, sluggishness, and swollen glands.

Common Causes of Mouth Ulcer

Although there is no recognized an etiology or pathophysiology for mouth ulcers, some factors are thought to be significant, such as iron and vitamin deficiencies, particularly B12 and C, poor dental hygiene, infections, stress, indigestion, mechanical injury, skin disease etc.

1) **Hereditary factors**: About 30%-40% of patients with aphthous ulcers have a family history, indicating that there is a genetic component to this condition. In certain cases, a family history of recurrent aphthous ulcers is evident. Young age of onset and symptoms of greater severity are two common connections.

2) **Physical or psychological stress:** Aphthous ulcer incidence are strongly correlated with stressful living circumstances. Psychological stress may act as a trigger or a moderating element in the development of recurrent aphthous stomatitis. Stress has not been conclusively shown to be the cause of or a contributing factor in investigations to recurrent aphthous stomatitis.

3) **Nutritional deficiencies**, including those affecting iron, folic acid, vitamin B12, B1, and B2 and B6, have been linked to a subset of aphthous ulcer patients. Depending on diet and dietary supplementation, different regions' contributions of nutritional deficits to aphthous ulcers are likely to differ.

4) **Trauma:** Stress and localized trauma are the most common causes of aphthous ulcers. Accidental self- biting, dental work, sharp-edged foods (like potato chips), anesthetic injections, and tooth brush bristles can all cause damage to the oral mucosa. In addition to this, stress from the surroundings and your emotions might cause an aphthous ulcer.

5) **Food sensitivities:** Numerous foods have the potential to trigger allergies. Patients with recurrent aphthous stomatitis exhibit anti-cow milk and anti- wheat protein antibodies (celiac illness). As a result, several typically allergenic foods (such as strawberries, tomatoes, and nuts) haven't been directly linked to recurrent aphthous stomatitis.

6) **Immunological diseases:** Aphthous ulcers are more prevalent and more severe in people with immune disorders, such as cyclic neutropenia, inflammatory bowel disease, Behçet's illness, and HIV disease.

The most common topical treatments for mouth ulcers in Western medicine include corticosteroids, antibiotics, and analgesics. But when used for a longer time and more frequently, they all run the risk of having negative side effects, Gels are mainly semi-solids that have a liquid phase that has been thickened with additional chemicals. Topical gels are applied to specific mucosal surfaces or to the skin as a topical or percutaneous medicine.

MARKETED PRODUCTS

Fig 5: ORASORE

Fig 6: HiOrA - K

Fig 7: AMRIT MOUTH PAINT

DRUG PROFILE

1. Guava

Biological Source: -

Guava, (Psidium guajava) is obtained from small tropical tree or shrub.

Family:- Myrtaceae

Fig.8 Part used in formulation – Dried leaves **Chemical constituents:-**

β-sitosterol Guaijavarin Oleanolic acid **USES -**

Guava leaves have anti-inflammatory action and antibacterial ability that fights infections and kills germs and people consuming guava leaves at home will help curb toothaches. The juice from the guava leaves is also said to provide relief from swollen gums and oral ulcers.

2. Coccinia Grandis

Biological source:- is a perennial herbaceous vine .

Family:- cucurbitaceae

Fig.9

Parts used - Fruits

Chemical Constituents

- β amyrin
- Lupeol
- β Sitosterol
- Oleic and palmitic acids

Uses

It is a rapidly growing, perennial climber or trailing vine. Traditionally different parts of this plant namely the roots, leaves and fruits are used in folklore medicine for several purposes like jaundice, diabetes, wound healing, ulcers, stomach ache, skin disease, fever, asthma, cough. The Fruit powder showed a significant dose related decrease in ulcer index, with significant increase in mucus secretion.

3. Turmeric

Bilogical Source – Obtained from dried rhizomes of curcuma longa linn.

Family- Zingiberaceae

Part Used – Rhizomes

Fig.10

Chemical Constituents

- Curcumin
- Curcumin oil
- Zingiberene

Uses

Turmeric, due to its medicinal properties can heal any kind of internal wound in no time. This Indian spice has the power to fight infections and can also help in soothing down the ulcers inside the mouth.

MATERIALS AND METHOD

Materials

- Psidium guava leaf extract
- coccinia grandis fruit extract.
- Curcumin extract
- Carbapol 934
- Propylene glycol
- Methyl Paraben
- Glycerol
- Peppermint oil

Equipments

- Brookfield Viscometer
- Incubator
- Distillation Apparatus
- Mechanical stirrer

FORMULATION METHOD

Collection of Material

- Guava leaves were collected from the campus & coccinia grandis fruit & curcumin purchased from local market.
- Leaves & fruits were dried at room temperature in shade.
- The plant material were then powdered & prepared for extracting.

Extraction method- Cold maceration method.

1. Harvest and clean fresh guava leaves.
2. Crush or chop the leaves.
3. Place them in a container.
4. Add cold water/ethanol to cover the leaves.
5. Seal and store in a cool, dark place for 24-48 hours.
6. Strain the liquid from the leaves.
7. Store the extract for various uses.

Formulation of polyherbal mouth ulcer gel

1. Specified Amount of carbapol 934 dispersed in required amount of distilled water with Continuous stirring. (0.5 gm in 50ml) Methyl paraben dissolve in hot distilled water over a water bath in beaker
2. After heating, allow the solution to cool before adding another ingredient.
3. Add propylene glycol 400 & after adding coccinia grandis and psidium guava leaf extract Turmeric extract added sequentially.
4. Finally, full mixed ingredient was mixed properly to the carbapol -934 swell gel with continuous stirring.
5. Volume was made up to 30-50 ml with. distilled water.
6. Few drops of peppermint oil were added as flavorant.

OBSERVATION TABLE

Table 1 :

Sr.no	Ingredients (gm/ml)	F1	F2	F3	Role
1.	Guava leaves extract	0.3	0.5	0.5	Anti-ulcer and anti-microbial agent
2.	Coccinia grandis extract	_	0.3	0.5	Wound healing and anti-inflammatory agent
3.	Turmeic extract	0.5	0.3	0.3	Anti-bacterial
4.	Carbapol 934	0.3	0.3	0.5	Gelling agent
5.	Propylene glycol	1	1.5	1.5	Humectant
6.	Methyl paraben	0.3	0.5	0.5	Preservative
7.	Peppermint oil	0.2	0.2	0.2	Cooling agent,flavorant
8.	Glycerine	0.2	0.2	0.2	Smoothing agent
9.	Distilled water	Q.S	Q.S	Q.S	Vehicle

Fig10. Formulated Gel

EVALUATION PARAMETERS

1) Physical Evaluation

Physical parameters such as color, odor and consistency were checked visually.

Color – The color of the formulations was checked by visual inspection.

Consistency – The consistency of the formulations was checked by applying on skin.

Odour – The odor of the formulations was checked by mixing the cream in water and observing the smell.

2) Measurement of pH

The pH of the gel formulation were determined by using digital pH meter.1gm of gel was taken and dispersed in 10 ml of distilled water and keep aside for two hours . The measurement of pH of formulation was carried out in three times and the average values are reported.

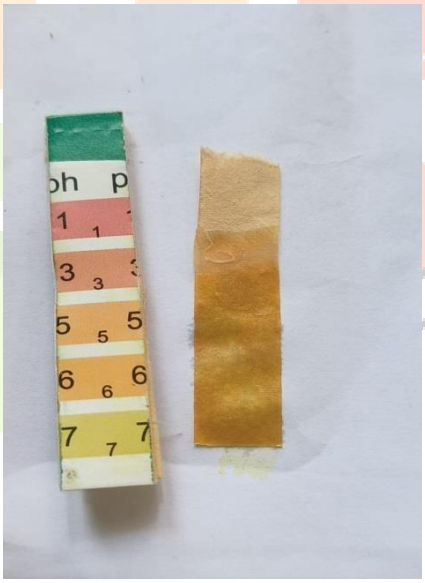

Fig.12

3) Spread ability

A glass plate with a circle that was already marked with a 1 cm diameter was coated with 0.5 g of gel to test the spreadability. 250g of weight was placed on the top glass plate and left there for five minutes.

The formula was used to calculate it is,

$$S = M \times L/T$$

L = Length of glass slide

T = Time required to separate the slides M = weight fastened to upper slide

Fig.13

4) Homogeneity:

All developed cream formulations were tested for homogeneity by visual inspection after the cream have been set into the container. They were tested for their presence and appearance of any aggregates. Homogeneity of gel formulation was reported.

5) Centrifugation Test –

All 3 batches of gel were put into centrifuged equipment for centrifugation testing. The centrifuge was turned on for an hour at 1000 rpm to evaluate the separation of the two phases.

Fig.14

6) Grittiness Test -

It was tested manually by pressing a small quantity of the formulated cream between the thumb and index finger. Immediate skin feel was evaluated.

7) Extrudability Test -

Extrudability test is the measure of the force required to extrude the material from a collapsible tube when certain amount of force has been applied on it in the form of weight. In the present study the quantity in percentage of ointment extruded from the tube in application of certain load was determined.

The Extrudability of prepared mouth ulcer cream formulation was calculated by -

$$\text{Extrudability (\%)} = \frac{\text{Amount of cream extruded from the tube}}{\text{Total amount of ointment filled in the tube}} \times 100$$

8) Antimicrobial Activity

- Agar well diffusion method

Nutrient agar medium was prepared and sterilized by autoclaving at 121◦C for 15 minutes. The three to four agar plates were prepared and labeled. The nutrient agar after sterilization was poured into the two plates and allowed to solidify. After solidification the culture, lactobacillus were applied on each plate. Then the wells were prepared using cork borer. Then the samples were poured in respective wells using micropipette. The plates were incubated at 37◦C for 24 hours.

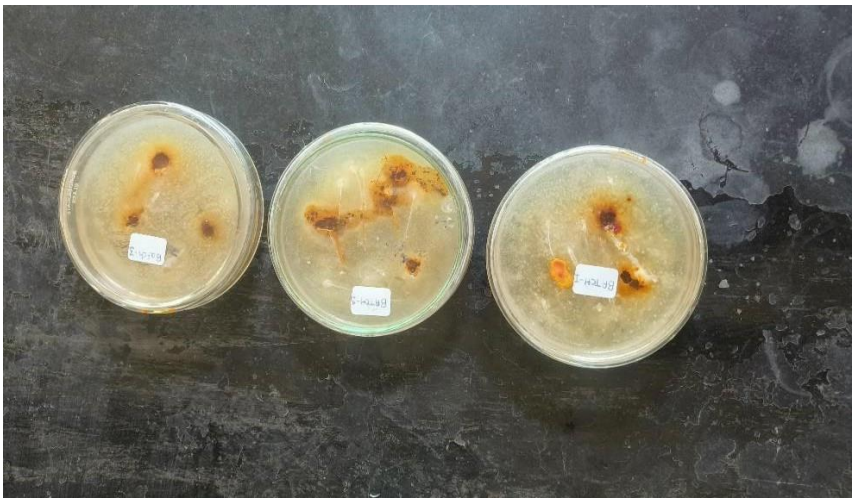

Fig 14: Antibacterial activity

RESULT AND DISCUSSION

- **Result**

❖ **Physical Evaluation**

Table 2: physical evalution of Gel formulation

Formulation	**Colour**	**consistency**	**Odour**
F1	Brownish Yellow	Smooth	Characteristic
F2	Yellow	Smooth	Characteristic
F3	Yellow	Smooth	Characteristic

❖ **pH**

Table 3: pH of gel formulation

Formulation	**pH**
F1	6
F2	5.8
F3	6.3

❖ **Spredablity**

Table 4: Spredablity of gel formulation

Formulation	**Spredablity(gm.cm/sec)**
F1	5.3
F2	6.5
F3	7

❖ **Homogeneity**

Table 5: Homogeneity of gel formulation

Formulation	**Homogeneity**
F1	Good
F2	Good
F3	Good

❖ **Centrifugation test**

Table 6: Centrifugation test of gel formulation

Formulation	**Centrifugation test**
F1	Phase seperated
F2	No phase seperated
F3	No phase seperated

❖ **Extrudability test**

Table 7: Extrudability test of gel formulation

Formulation	**Extrudability (%)**
F1	80 %
F2	79.2 %
F3	84.8 %

❖ **Grittiness studies**

Table 8: Grittiness test of gel formulation

Formulation	**Result**
F1	Grittiness upon application on skin
F2	No grittiness upon application on skin
F3	No grittiness upon application on skin

❖ **Antibacterial studies**

Table 9: Antibacterial studies of gel formulation

Formulation	**Antibacterial studies (mm)**
	Lactobacilli
Standard	27
Formulation -3	24
Blank	14

➢ **Discussion**

The result it is clearly shown that 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 spreadability shows that with increasing viscosity of formulation, spreadability decreases & vice versa. The gelling strength of the batch was found in the suitable range. The batch of developed formulation showed anti-bacterial activity against Staphylococcus aureus and Esherichia coli this are main microorganism rom responsible for mouth ulcer and formulation it can also use to treat mouth ulcer infection.

The combination of curcuma longa, Psidium guajava, Coccinia grandis provided synergistic mouth ulcer

CONCLUSION

Natural remedies are more acceptable in the belief that they are safer with lesser side effects than the synthetic medicines. Nowadays herbal formulation have increasing demand in the sworld market. The presented study of coccinia grandis extract and Psidium guajava leaf extract for the effective management of mouth ulcers may boost drug penetration from the affected area, indicating antifungal and antibacterial action. The presence of propylene glycol may boost the cream stability. Coccinia grandis extract has antiulcer properties. It also possesses antioxidant properties, which aid in the protection of the mouth's surface from oxidative damage. The leaf extract of Psidium guajava contains phenolic acids, flavonoids, terpenoids, glycosides, and saponins, which have antibacterial and antiulcer activity. As a result, a polyherbal combination of coccinia grandis extract and Psidium guajava leaf extract has been added into the cream used to treat mouth ulcers. The F3 formulation had higher viscosity due to its higher carbapol934 content. Since F1 and F2 had no significant variation in evaluating parameters, the F3 formulation was chosen as the superior formulation because of proper appearance and uniformity. According to in vitro studies, polyherbal gel made of Coccinia grandis extract and Psidium guajava leaf extract is useful to heal mouth ulcers. The result showed that due to combination dosage form developed new herbal gel formulation having good anti -inflammatory activity so it is safe, stable and good for mouth ulcer treatment.

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