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Research Article

Formulation and Evaluation of Herbal Mouth Gel

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ABSTRACT

Ulcers are most common in the oral region, for which the patient seeks help from their Physician/dental surgeon. The presenting complaints are usually redness, burning, Sensation and/or pain. They can present in any part of the oral cavity but may be painful if it occurs in the movable area. Mouth ulcers cause pain and irritation from salty, spicy, and sour food items and may Cause discomfort while healing occurs due to the use of chemical formulations. This project Focuses on the preparation of an herbal mouth ulcer gel because it has fewer side effects. The gel was prepared by using guava leaf extract, jasmine leaf extract, and peppermint oil. Developed Formulations were transparent and homogeneous, and pH ranged from 6.8 to 7. Formulation Showed applicable spreadability. Therefore, developed formulations have the potential to treat mouth ulcers. However, further clinical studies are required to establish the clinical efficacy of prepared herbal gels. The present research has been undertaken with the objective to formulate and evaluate the polyherbal mucosal gel containing plant extracts (Calendula officinalis and Glycyrrhiza glabra) for the treatment of mouth ulcers. Calendula officinalis and Glycyrrhiza glabra are known to have anti-ulcer, anti-inflammatory, and antibacterial activities. Gels were prepared by using Carbopol. 940P as a gelling agent. Carbopol was used in different concentrations. All the prepared gel Formulations were evaluated for various properties such as pH, spreadability, extrudability, viscosity, in vitro release, etc. The formulation F4 containing a higher concentration (1.4%) of Carbopol 940P as a base showed good adhesion to oral mucosa. FTIR studies showed that there was no drug-excipient interaction. In-vitro drug release studies were carried out in phosphate buffer. (6.8 pH) using a Franz diffusion cell. The results of in vitro drug release and its permeation studies showed that the highest values were from F4, containing Calendula officinalis (91.3% of drug released after 3 hours), and F4 containing Glycyrrhiza Glabra (91.67% of drug released after 3 hour). Stability studies of the F4 formulation were also carried out as per ICH guidelines for 3 months. at different temperature and humidity conditions. Jasminum Officinale L.Keywords: Guava leaves, jasmine leaves, mouth ulcers, polyherbal, gel.

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INTRODUCTION

Ulcers are most common in the oral region, for which the patient seeks help from their Physician/dental surgeon. The presenting complaints are usually redness, burning, sensation And/or pain. They can present in any part of the oral cavity but may be painful. if it occurs in the movable area. Mouth ulcers are yellowish or whitish depressions with Red margination in the mucous lining of the mouth cavity, characterized by inflammation and pain. Based on clinical status, mouth ulcer patients can be categorized into three groups:minor, major, and herpetiform. Etiology is unknown or often misunderstood; its diagnosis is largely based on clinical signs (1). However, some factors like psychological stress topical trauma, microbial infections, genetics, nutritional derangements, immunological hormonal changes, allergies And medications are considered important factors asetiology of mouth ulcerations. Various synthetic and semi- synthetic medicaments are suggested to treat mouth ulcers with antibiotics and antiseptics, local anesthetics, local analgesics, steroidal and non-steroidal anti-inflammatory drugs. Topical steroids, viz. Triamcinolone and prednisolone are the most frequently used treatments, but they have some serious side effects on continuous application, like adrenal insufficiency, immuno-suppression, osteoporosis, hyperglycemia, gastrointestinal disturbance, etc. Moreover commercially available formulations containing synthetic and semi-synthetic active Agents have complained of local irritation, staining of teeth, burning sensation, etc., due Too high alcohol concentration and presence of some organic compounds (3). Considering These side effects and the demand for better patient compliance with the use of plant-based Medication is gaining popularity throughout the world. A number of selected herbs have been linked to astringent, antiseptic, and protective activity in burns and wounds (13). Hence, reported biological activities of all three selected herbs represent the same criteria provided by both topical and systemic drugs that have been reported for treatment of mouth ulcers. We prepare a stable mucoadhesive polyherbal formulation that can beUsed for the treatment of mouth ulcers. Mouth ulcers are yellowish or whitish depressions. with red margination in the mucus lining of the mouth cavity, characterized by inflammation and pain. Based on clinical status, mouth ulcer patients can be categorized into three groups: minor, major, and herpetiform. However, some factors, like psychological stress, topical trauma, microbial infections, genetics, nutritional derangements, immunological Hormonal changes, allergies, and medications are considered important factors as etiology of mouth ulcerations Various synthetic and semi-synthetic medicaments are suggested. to treat mouth ulcers with antibiotics and antiseptics, local anesthetics, local analgesics, steroidal and non-steroidal anti- inflammatory drugs. Topical steroids, viz., triamcinolone and prednisolone are most frequently used treatments, but they have some serious side effects on continuous application like adrenal insufficiency, immunosuppression, osteoporosis, hyperglycemia, gastrointestinal disturbance, etc. Considering these sides effects and demand for better patient compliance, the use of plant-based medication isgaining popularity throughout the world. A number of studies have reported the use of herbal plant's parts or extracts in the form of mouthwash, paste, or muco-adhesive gels for treatment of oral ulcers, namely Rosa damascena, Ruta graveolens, and Zingiber officinale, Cordia dichotoma, Glycerrhiza glabra, 2 Anthemis nobilis, Myrtus communis, Melissa officinalis, Hypericum perforatum, Zaharias mutiflora,

Curcuma longa, Punica granatum etc. (2-7). The present investigation deals with the use of Piper betle, Glycerrhiza glabra, and Psidium guajava leaf extract for the preparation of stable aqueous gel formulation which can be used as an alternative treatment for mouth ulcers. Jasmine can be either deciduous (leaves falling in autumn) or evergreen (green all year). round), and can be erect, spreading, or climbing shrubs and vines. Their leaves are borne in opposing or alternating arrangements and can be simple, trifoliate, or pinnate formation. The flowers are typically around 2.5 cm (0.98 in) in diameter. They are white or yellow, although in rare instances they can be slightly reddish. The flowers are borne in cymose clusters with a minimum of three flowers, though they can also be solitary on the ends of branches. The bracts are linear or ovate. The calyx is bell-shaped. We prepare a stable mucoadhesive polyherbal formulation that can be used for treatment of mouth ulcers.

Herbal Ingredient

1. **Honey:** Honey is natural product obtained from honey comb of bees Apis mallifera.

Family: Apidae

Chemical constituents:

* Carbohydrate
* Protein
* Vitamin
* Amino acid
* Minerals
* Organic salt
* Flavonoids

Mechanism of action: -Honey is antibacterial and anti-inflammatory properties so it apply on mouth ulcer so it decreases the inflammation and also kill bacteria in mouth so decrease inflammation in so automatically healing ulcer.

Uses:

* It shows antioxidant activity so it is used in the treatment of mouth ulcer.
* It shows antimicrobial activity, so it removes micro-organism in mouth.
* It shows apoptic activity, so it is also used in the treatment of cancer.

2. Mint:

Family: - Lamiaceae (Labiatae)

Kingdom: - PIantae

Order: - Tubiflorae

Botanical Name: -Menth

Chemical constituent:

* Vitamin A
* Vitamin C
* Iron
* Calcium
* Magnesium

Mechanism of action: The mint lives are applied on mouth ulcer so it gives cooling effect on ulcer, so decrease the pain due to the ulcer and give fragrance in mouth.

Uses: It gives antibacterial effect against cryogenic bacteria. It gives antimicrobial effect, so it is used in the treatment of ulcer.

3. **Indian Jasmine: -** It is also known Chameli in India.

Family: - Oleaceae
Botanical name: - Jasminum
Kingdom: PIantae
Order: - Oleales

Chemical constituents:

* Benzyl Alcohol
* Benzyl acetate
* Linolool

Mechanism of action: - Due to the anti-inflammatory, antibacterial activity the jasmine applied on ulcer so decrease the ulcer so automatically decrease the pain due to the ulcer.
Uses

* It gives anti- inflammatory action so it is used to decrease the inflammation due ulcer.
* It is used to healing of canker in mouth.
* It is also used in treat constipation so automatically treat mouth ulcer.

4. Euphorbia Thiamifolia

The euphorbia thiamifolia is also known as laghudhika or Choti-dudhi (milk hedge).

Family: - Euphorbiaceae

Chemical constituents:

* Flavonoids
* Glycosides
* Cardiac glycosides
* Terpenoids

Mechanism of action: - The mechanism of action of euphorbia is not clear but according to studies the euphorbia thaimifolia is a potent anti-inflammatory property so it is applied on ulcer in mouth so it decreases the inflammation in mouth.

The milk hadge is also act as antimicrobial agent, it is applied on ulcer so remove micro- organism present on in mouth and give freshness in mouth.

Uses: -

* The euphorbia thiamifolia is mainly used in blood purification.
* It is used in the treatment of constipation so the mouth ulcer is automatically healed.
* It is also used in the treatment of skin infection. It is used in the treatment of worm in intestine.

5. **Tridex Procumbenes: -** It is also known as coat buttons.

Family: - Asteraceae

Kingdom: - Plantae

Genus: - Tridex

Order: - Asterales

Chemical constituent;

* Alkyl esters
* Sterols
* Pentacyclictriterpene

Mechanism of action: -It applied on mouth ulcer so decrease the pain due to the ulcer because it mainly shows analgesic activity.

Uses

- It shows anti-inflammatory action so it is used to decrease the inflammation in mouth.
- The tridex procumbenes is also used in the treatment of malaria.
- It is also show antibacterial activity so it decreases the growth of bacteria in mouth.
- It acts as anti-oxidant so it decreases the oxidation of other components.
- It is also used in the treatment of cancer.

6. **Acacia Arabica:** It is commonl known as desi babul in India.

Family: - Leguminosae-Mimosaceae

Kingdom: - PIantae

Odour: - Odorless

Taste: - BIand and mucilaginous

Solubility: - lt is soluble in water and also soluble in alcohol, the watery solution is viscous and acidic.

Chemical constituents: -

* It consists arabin, which is complex mixture of calcium, magnesium and potassium salt of
* Arabic acid. L-arabinose
* D- galactose
* D- gluccuronic acid
* It also contains enzyme oxidase and peroxidase
* Polyphenols

Identification Test: -

* Solution of gum of {Pb(C2H302)2} lead acetate gelatinises the aqueous solution indin gum
* It is not producing the pink colour with the solution of ruthenium red
* But on addition of hydrogen peroxide solution and alcohol to aqueous solution of gum to produce blue colour due to the presence of oxidize enzyme.

Uses

* It applied on ulcer act as stimulant and astringent.
* It is used for brushing the teeth to remove fragrance micro-organism in mouth

Aloevera:

Kingdom: Plantae

Family: Asphodelaceae

Order: Asparagales

Botanical Name: Aloe vera (L.) Burm.f.

Chemical Constituents:

* Polysaccharides
* Salicylic Acid
* Lignin
* Vitamin- A, C, E, B1, B2

Uses:

* Aloevera can be quite beneficial for mouth ulcers due to its soothing , healing , and anti-inflammatory properties.
* Promotes healing.
* Anti-inflammatory.
* Soothes pain and irritation.

Review Of Literature

1) N. K. Jain et al., (2020) reveal the selected herb guava leaves and betel leaves can be used for amelioration of symptoms and decreasing mouth ulcer due to cumulative antioxidant, antimicrobial, anti-inflammatory, analgesic and antiulcer properties.

2) S. Shaikh etal., (2018) reveals that the Commercially available gels containing synthetic and semi synthetic active agents which have several disadvantages like staining on the teeth, irritation, and burning sensation only because presence of high degree of alcohol content and some organic compounds. The present investigation deals with use ofherbal powdered Guava Leaves in the treatment ofmouth ulcer in herbal gel.

3) V. Patil et al., (2022) have the Psidium gujava leaf extract micro particles loaded gel is a good mucoadhesive gel for mouth ulcer management. Therefore, herbal ingredients can be used for novel drug delivery and make it safe for administration with lesser risk of adverse reactions.

4) Miss. H.B. Tribhuvan et al., (2022) have the formulated gel was tested for different parameters such as physicochemical parameters such as pH, viscosity, distribution ability homogeneity, gel strength, clarity of gel ,etc. The gel is homogeneous mixture that shows the pH 6.8. This herbal gel was stable at room temperature protected from any germs and thus safe for use on mouth sores.

4) A. Pandit et al., (2022) have antioxidant and antimicrobial properties of betel leaves(piperbetle). Ethanolic compounds extracted from betel leaf showed excellent anti-microbial activity against gram negative and gram-positive pathogens. The anti-bacterial activity of betel leaf is due to the presence of polyphenols.

5) Ranathunja K. et al.,(2022) reveal medicinal value, ethnomedicinal uses scientifically validated biological activities, important phytochemicals, and Ayurveda properties regarding guava leaves (Psidium guajava). Survey of the literature revealed that Psidium guajava L. was a good source of health-promoting and contained secondary metabolites like Flavonoids, Tannins, glycosides, terpenoids, etc. The medicinal plant Psidium guajava L was re-ported to possess various pharmacological properties like antioxidant, anti-inflammatory, antimicrobial, ant cough.

6) V. Madaan et al., (2022) have detail information about mechanism of action ofhoney. Honey is antibacterial and anti-inflammatory properties so it apply on mouth ulcer so it decrease the inflammation and also kill bacteria in mouth so decrease inflammation in so automatically healing ulcer.

7) Ranathunja K. et al.,(2022) reveaI medicinal value, ethnomedicinal uses scientifically validated biological activities, important phytochemicals, and Ayurveda properties regarding guava leaves (Psidium guajava). Survey of the literature revealed that Psidium guajava L. was a good source of health-promoting and contained secondary metabolites like Flavonoids, Tannins, glycosides, terpenoids, etc. The medicinal plant Psidium guajava L was re-ported to possess various pharmacological properties like antioxidant, anti-inflammatory, antimicrobial, anticough.

8) R. sing et al., (2020) gives good antimicrobial, antifungal, anticancer activity of Guava. some essential phytoconstituents such as tannins, triterpenes, flavonoid, quercetin, pentacyclic triterpenoid, guajanoic acid, Saponin, carotenoids, lectins, leucocyanidin, ellagic acid, amritoside, beta-sitosterol, uvaol, oleanolic acid and ursolic acid.

9) N. Shahare et al., (2021) have prepared and evaluated mouth ulcer gel formulation using betel leaves as one of the ingredients. The leaves show various pharmacological activities like antiulcer, antibacterial, antifungal, anti- inflammatory, antioxidant activities.

2. Rational Of The study: - Need Of Work: -

- Understanding how mouthgel can help reduce plaque, gingivitis, and bad breath contributes to better oral hygiene practices.

- Evaluating how mouthgel contributes to reducing oral diseases, such as cavities and gum disease. Investigating the potential resistance development in oral bacteria to certain mouthgel ingredients, ensuring long-term effectiveness.

- Comporing the effectiveness of commercial mouthgel against home remedies, which can inform best practices for oral care.

Objectives: -

1. To formulate and evaluate an herbal mouth ulcer gel with guava leaves and jasmine Leaves.
2. The object of this study is to formulate Anti-ulcer gel that can lower the Ulcer effect.
3. To show that herbal product is safe.
4. To show that the herbal product is cheaper & easily available & easy to apply.

3. **Plan Of Work: -**

1. Selection of herbal drugs.
2. Selection of excipients.
3. Selection of method of preparation for herbal mouth ulcer gel.
4. Preparation of herbal mouth ulcer gel.
5. Evaluation of herbal mouth ulcer gel.
6. Extraction

• Identification Tests of Drug-

• Molish's Test: Molish's test is a general test for carbohydrates. This test is given by Almost all of the carbohydrates. In this test, concentrated sulfuric acid converts the given Carbohydrate into furfural or its derivatives, which react with α-naphthol to form a purple Coloured product.

• Fehling's Test: This test is given by reducing sugars. To the aqueous solution of Carbohydrate fehling's solution is added and heated in water bath. The formation of red Precipitate confirms the presence of reducing sugars. The copper ions present in fehling's Solution in +3 state is reduced to +2 oxidation stateand in alkaline medium it is precipitated as Red cuprous oxide.

• Identification test for Protein:

• Biuret Test: The compounds with peptide linkage undergoes this test. Proteins are Polypeptides of amino acids linked together by peptide bonds. An alkaline solution of protein is Treated with a drop of aqueous copper sulfate when a bluish violet colour is obtained.

• Xanthoproteic Test: Proteins on treatment with nitric acid gives a yellow or orange colour. Concentrated nitric acid is used for nitration. On the treatment of nitric acid, proteins give yellow Precipitate which turns to orange colour on treatment with alkali.

- **Preparation of reagents-**

Preparation of Distilled Water.

Preparation of reagent: In this project, distilled water , ethanol, chloroform used as a solvent. Distilled water was prepared in laboratory by using soxhlet apparatus. Tape water was taken in round bottom flask . later it was put on the soxhlet extraction . After 30 min.- 1 hr. distilled water was collected from process

- **Experimental design-**

Formulation and Evaluation of herbal mouth gel

- **Comparative study**
- **Result & Discussion**
- **Conclusion**

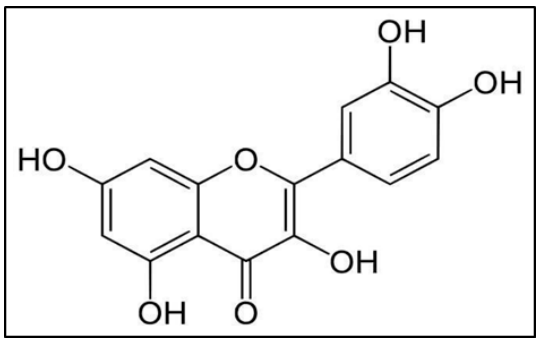
- **Reference**

4. Drug Profile: -

Description:

Name: Quercetin

Synonyms: 2-(3,4-Dihydroxyphenyl)-3,5,7-trihydroxy-4H-1-benzopyran-4-one



Structure of Quercetin

AS registry No: 117-39-5

Molecular formula: C15H10O7

Molecular weight: 302.23g/mol

Properties: Anti inflammatory

Uses: It helps to prevent bental caries.

Physicochemical properties

Melting point: 316 °C

Solubility: water soluble

Storage: Room Temreture

Side effects: - Headache and upset of stomach.

2. MATERIALS AND METHODS:

2.1 List of materials:

Table 6.1: List of materials

Sr. No.	Particular	Quantity
1.	Guava leaves	0.03
2.	Betel leaves	0.15
3.	Honey	2
4.	Peppermint oil	0.01
5.	Carbopo1934	0.3
6.	Methyl Paraben	0.06
7.	Propyl Paraben	0.03
8.	Propylene Glycol	1.5
9.	Triethanolamine	0.36
10.	Distilled Water	Up to 30

Drugs and chemicals:

Distilled Water, Triethanolamine, Propylene Glycol, Propyl Paraben, Methyl Paraben, Peppermint oil, Honey, Betel leaves, Guava leaves. Carbopo1934,

Glassware's and instruments:

Beaker, measuring cylinder, moter pastal, Funnel, Tripod Stand, Heating Mental.

METHODS:

* Carbopol 934 dispersed into distilled water.
* Add methyl paraben and propyl paraben in distilled water.

* Heating on water bath.
* Add propylene glycol aftercooling.
* Then add different concentration of leaves powder.
* At last full mixed ingredients added in Carbopol 934 gel with properly.
* Continuous stirring add triethanolamine drop wise for adjust pH (6.8-7).

Evaluation Test:

1.Physical Evaluation: Physical parameters such as color, odour and consistency were checked visually

Il. Measurement of pH: The pH of gel formulation were determined by using digital pH meter. Takelgm of gel and dissolved in10 ml of distilled water and keep apart for two hours. Then the measurement of pH of formulation was done by dipping the glass electrode completely into the gel system three times and the average values are reported [9]. The pH of gel formulation was reported

Ill. Homogeneity: All prepared gel formulation were tested for homogeneity by visual inspection after the gels have been set in to the container. They were tested for their presence and appearance of any aggregates. Homogeneity of gel formulation was reported. [7]

IV. Viscosity: The measurement of viscosity of the formulated gel was determined by Brookfield Viscometer with spindle no. I at 25 0C. The gels were rotated at speed 1.5 rotations per minute and at each speed, the corresponding dial reading was noted. Then viscosity of the prepared gels were obtained by multiplication of the dial reading with factor given in the Brookfield Viscometer catalogues [81Viscosity of gel formulation was reported.

V. Spreadability: Spreadability is expressed in terms of time in seconds taken by two slides to slip off from gel that is placed in between the slides under the direction of certain load. If the time taken for separation of two slides is less then better the spreadability [91. Spreadability is calculated by using the formula:Where M=weight of to upper slide

L = length of glass slides

T = Time taken to separate the slides Spreadabilty of gel Formulation were reported.

VI. Clarity: The clarity of formulation was determined by visual inspection. [101.

VIl. Gel strength: Gel strength was determined by the time in seconds required by the weight to penetrate in the gel. A 3.5 gm weight was placed on the surface of 5 gm formulated gel. Gel strength was determined by reporting the time in seconds required by the weight to penetrate 0.5cm in the gel [7] The gel strength was then reported.

VII. Anti-bacterial activity:

The anti-bacterial activity of preparation was performed against Gram-positive (Staphylococcus aureus NCIM5021,)and Gram-negative (E.coli NCIM 2832) bacteria by modified agar well diffusion method.[l,3] The suspension of test pathogens was prepared in sterile saline and used for further study. For the anti-bacterial activity test pathogens were inoculated on the surface of sterile nutrient agar plates and spread on plates by using a sterile spreader in an aseptic condition. After that agar well was prepared aseptically with the help of a sterilized glass cork borer having a 0.7 cm diameter. Then 100 gl volume of the test sample was added in the different wells of the respective test pathogens. Then plates were placed at 40C for

20 min for sample diffusion in a culture medium and transferred to an incubator at 37oc for 24 hrs. Furthermore, the obtained results were compared with the well containing 1000 pg /ml Streptomycin as a positive control.

VIII. Extrudability Test:

An extrudability test measures the ease with which a product, like a gel or ointment, can be pushed out of a container, reflecting its viscosity, consistency, and application characteristics.

IX. Stability Test:

Stability testing for an herbal mouth gel involves assessing its quality and properties under various storage conditions to ensure it remains effective and safe over time.

RESULT AND DISCUSSION:

Observation table:

Table 7.1: Prameter

parameters	observation
Nature	Semi- solid
Color	Greenish
Odour	Characteristics
pH	6.8
Texture	Smooth

7.2 Preliminary study:

7.2.1 Identification Test

Table7.2: Identification Test of Herbal Mouth gel

Sr. No.	Physical properties &test	Description
1.	Physical state	Semi-solid
2.	Color	Greenish
3.	Odor	Characteristics
4.	Solubility	Stable
5.	Homogeneity	Good
6.	Spreadability	5.18
7.	Viscosity	3.174

CONCLUSION

According to an old study, the mouth ulcer is mainly caused by acid secretion, and the main aim of this article to decrease the acid secretion and so automatically decrease the ulcer. This review gives clear information that the naturally occurring constituents of herbs are definitely able to resolve oral ulcers. This review provides the information on the treatment of ulcers by different herbal medicinal plants and Give information about its family, kingdom, chemical constituents, uses, etc. This review also provides This herb has introduced a good protocol for the treatment of various mouth ulcers. In present days the demand for herbal formulations in the market due to their cost-effectiveness and fewer side effects and the above experimental data, it is clear that the gel formulation with herbal ingredients such as honey Acacia Arabica, Indian Jasmine, Tridex procumbenes, Euphorbia Thiamifolia, and mint have good characteristic, viscosity, and also possesses good antimicrobial, anti-inflammatory, and antacid activity.activity that is necessary in the management of mouth ulcers.

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