

FORMULATION AND EVALUATION OF HERBAL MOUTH GEL

Rudraksh B. Garad ,Amar A. Khose ,Aadinath sangale, Dr. Megha T Salve

Abstraction :

mouth ulcer is an ulcer that occurs on the mucous membrane of the oral cavity. Ulcers are consistently occur in the oral region. The ulcer show the symptoms are generally redness, warm sensation and pain. Mucormycosis (phycomycosis) is an opportunistic infection caused by a saprophytic fungus that lives in the soil or on decaying food. Patients with low host resistance, such as those with poorly controlled diabetes, hematologic malignancies, cancer treatment, or immunosuppressive therapy, are more susceptible to infection. The fungus infects arteries, causing thrombosis and ischemia, which leads to damage. In many cases, the fungus can travel from the mouth and nose to the brain, culminating in death. The oral lesions appear as ulcerations on the palate caused by necrosis caused by palatal vascular invasion. The ulcer is wide and deep, causing underlying bone denudation. The normally encountered thermal burns occurs when ingesting hot food substances or drink like coffee or tea or from a heated dental instrument during a dental procedure. Oral mucosal damage can result from accidental use of therapeutic agents during dental procedure such as eugenol, formocresol, sodium hypochlorite, and monomer. Alcoholic extract of Jasmine leaf was made by soxhlation Jasmine leaves were collected from Domestic backyard garden and washed with distilled water. Further these leaves are shade dried for a week and powdered in a mixer. This powder is passed through sieve number 6 to get desired sized powder. 100ml ethanol (70%) taken for 10 gm of Jasmine leaf powder. Soxhlation was carried out for 48 hours. Obtained extract was dried to get powder. In conclusion, the formulation and evaluation of a herbal gel for the treatment of mouth ulcers have demonstrated its potential as an effective and natural remedy. The development of the herbal gel involved selecting specific herbs known for their anti-inflammatory, analgesic, antimicrobial, and wound healing properties, which are essential for managing mouth ulcers.

Keywords :

Mouth ulcer , appetite, toothbrush, jasminum grandiflorum

INTRODUCTION:

Mouth ulcer is an ulcer that occurs on the mucous membrane of the oral cavity. Ulcers are consistently occur in the oral region. The ulcer show the symptoms are generally redness, warm sensation and pain. Although mouth ulcers can be miserable, particularly when you eat, drink or brush your teeth, they are generally harmless. Most of the time mouth ulcers will clear up by themselves within a week or two. You only need to look your dentist if the ulcer gets worse or lasts for longer than three weeks, or if you develop ulcer regularly.

1.1 Causes of mouth ulcers:

Single mouth ulcers are creating by damage to the mouth, for example by unintentionally biting the inside of your cheek while eating, or from a sharp tooth, food or filling. The cause of a periodic mouth ulcer is not always clear, but it's likely to be a combination of factors including a genetic vulnerability and a certain trigger. Possible triggers may include feeling concern or anxious, eating certain foods, hormonal changes and stopping smoking.

Symptoms of mouth ulcers:

- Loss of appetite
- Irritation of the sores by salty, spicy or sour foods.
- Swollen skin around the sores.
- Difficulty with chewing or tooth brushing because of the tenderness.



Fig:1 Mouth ulcer

1.2 Types of ulcer:

Based on the duration ulcers can mainly classified into acute (short term) or chronic (long term). Acute ulcers continue no more than three weeks and retreat automatically such as traumatic ulcers, aphthous ulcers, herpetic ulcer and chancres. Chronic ulcers continue for weeks and months such as major aphthous ulcers, ulcers from odontogenic infection, malignant ulcers, gummas ulcers.

The lone lesions may results from a trauma, infection or it could be a carcinoma and can present as a single ulcerative lesion. Numerous lesions may be seen in viral infections or autoimmune diseases and can present with numerous

ulcerations. Regular ulcers may present with a history of similar episodes along with intermittent healing. The size of the ulcers can differentiate from a few millimeters to centimeters and occur with fever and regional lymphadenopathy.

1.2.1 Acute ulcers:

Traumatic ulcers:

It is a quite common and acute in nature. The ulcers are caused typically by physical, thermal or chemical trauma to the oral mucosa causing tissue damage and ensuing ulceration. Physical trauma can be caused during regular activities like tooth brushing or flossing, sharp edges of denture or tooth brushing, mouth piercing and sometime can be self-inflicted by the patient when he/she is under local anesthesia during a dental procedure.

The normally encountered thermal burns occur when ingesting hot food substances or drink like coffee or tea or from a heated dental instrument during a dental procedure. Oral mucosal damage can result from accidental use of therapeutic agents during dental procedure such as eugenol, formocresol, sodium hypochlorite, and monomer.

When the cause of the traumatic ulcer is removed, it usually heals in 7-10 days. A biopsy should be conducted if the ulcers do not heal after two weeks to rule out a deep fungal infection or cancer. In the basic and tertiary phases of syphilis, these ulcers are frequently solitary; however, in the primary and tertiary stages, syphilis can show as single ulcers.

Necrotizing sialometaplasia:

The disease necrotizing sialometaplasia (NS) can be acute or chronic. It's a self-limiting, benign, nonneoplastic inflammatory condition of the salivary glands that, both clinically and histopathologically, looks like a cancer. It is more common among men in their forties and fifties.

The palate is the most commonly affected location, followed by the lower lip, retromolar area, sublingual region, tongue, and larynx. The lesion begins as a non-ulcerated swelling with pain, and the necrotic tissue eventually sloughs away, leaving a crater-like ulcer. The ulcer is inflamed and has well defined edges. The size of the lesion varies from 1 cm to more than 5 cm in most cases. Within 5 to 7 weeks, it resolves on its own.

1.2.2 Chronic ulcers:

Mucormycosis:

Mucormycosis (phycomycosis) is an opportunistic infection caused by a saprophytic fungus that lives in the soil or on decaying food. Patients with low host resistance, such as those with poorly controlled diabetes, hematologic malignancies, cancer treatment, or immunosuppressive therapy, are more susceptible to infection. The fungus infects arteries, causing thrombosis and ischemia, which leads to damage. In many cases, the fungus can travel from the mouth and nose to the brain, culminating in death. The oral lesions appear as ulcerations on the palate caused by necrosis caused by palatal vascular invasion. The ulcer is wide and deep, causing underlying bone denudation. The gingiva, lip, and alveolar ridge are the other oral areas that are affected.

Tuberculous ulcers:

Ulcerative lesions in the oral mucosa can be caused by granulomatous disorders. Oral symptoms of tuberculosis and leprosy can occur as a result of a systemic infection, but they are uncommon. Tuberculosis can affect the lungs or spread to other parts of the body. Primary, secondary, or military tuberculosis can affect the lungs. Primary tuberculosis is more commonly observed in children. It is usually asymptomatic, however it can be accompanied by a fever and a dry or productive cough. Oral lesions are uncommon and usually occur as a result of other illnesses. The organisms are most likely conveyed in the sputum and penetrate the mucosal tissue through a minor surface crack. Secondary

tuberculosis oral symptoms can occur anywhere in the mouth, with the tongue being the most usually afflicted location. The gingiva, mouth floor, palate, lips, and buccal mucosa are among the various regions affected. Oral ulcers are persistent, indurate.

Tuberculous ulcers are painless, persistent, and angular with overhanging or undermined margins. They are also irregular and might be unpleasant.

Prevention and control:

The accurate cause of most periodic mouth ulcers is unknown, there is no certain way to prevent them.

However, the following may help to reduce your risk of developing mouth ulcers.

- Avoid damaging the inside of your mouth by using a soft toothbrush and avoiding hard, crispy foods.
- Eat a healthy diet balanced, rich in vitamins.
- Make clearly you maintain good oral hygiene, including brushing your teeth at least twice a day. [2]

Taxonomy of *Jasmine grandiflorum*:

A kind of jasmine endemic to South Asia, the Arabian peninsula, East and Northeast Africa, and the Yunnan and Sichuan regions of China is called *Jasminum* Table.

Scientific classification	
Kingdom:	Plantae
Order:	Lamiales
Family:	Oleaceae
Genus:	<i>Jasminum</i>
Species:	<i>J. grandiflorum</i>

Table:1 Scientific Classification



Fig:3 *Jasminne Grandiflorum*

material and method:

Drug – Leaf extract of *Jasminum grandiflorum*

A :Chemical – Carbopol 940, Propylene glycol, Methyl paraben, Propyl paraben

B: Preparation Of Extract :-

Alcoholic extract of Jasmine leaf was made by soxhlation Jasmine leaves were collected from Domestic backyard garden and washed with distilled water. Further these leaves are shade dried for a week and powdered in a mixer. This powder is passed through sieve number 6 to get desired sized powder. 100ml ethanol (70%) taken for 10 gm of Jasmine leaf powder. Soxhlation was carried out for 48 hours. Obtained extract was dried to get powder.



Fig:6 Soxhlet Apparatus

C: Preparation of Gel –

Gel formulations were prepared using carbopol P940 as gelling agents and Propylene Glycol as penetration enhancer.

The carbopol P940 was mixed with Propylene Glycol in a beaker heated at 70 °C.

JDLE in a suitable solvent (ethanol) were added to this dispersion.

The preservative Methyl paraben, Propyl paraben was dissolved in water using heat the solution was left to cool and then warmed to about 70 °C with vigorously stirring using an electric stirrer.

Resulting solution added to the above solution with stirring until a gel was formed. [9]

Ingredients	(Concentration in Percentage)
JGLE	1%
Carbopol 940	1.25%
Propylene glycol	5%
Methyl paraben	0.2
Propyl paraben	0.1
Flavoring agent	0.1
Water (ml)	30

Table :2 Formulation of Gel

D: Evaluation of Gel:

- Odour
- pH
- Spreadability
- Appearance
- Viscosity

Appearance – The prepared gels were tested for color, clarity, texture, transparency and presence of any gritty particles.

Measurement of pH - The pH of herbal gel formulations were determined by using digital pH meter. 1 gm 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. pH of gel formulation was reported.

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. Spreadability is calculated by using the formula. $S = M * L / T$

Where M = weight tied to upper slide L = length of glass slides T = time taken to separate the slides

Viscosity- The viscosity of all the prepared formulations were analyzed by the

Brookfield's viscometer. ^[9]

Preliminary Phytochemical Investigation ^[18]

Test for Alkaloid

Stock solution: About 50 mg of solvent free extract is stirred add little quantity of HCl and filter it an perform various test for alkaloid.

- 1.Mayer's reagent:** To few ml of filtrate add two drop of Mayer's reagent if test is positive it give white/ creamy ppt.
- 2.Swagner's test:** To few ml of test solution add 2 drop of Wagner's reagent it gives reddish brown precipitate indicate test is positive
- 3.Hager's test:** To few ml of test solution add 1-2 ml of Hager's reagent if test is positive solution gives prominent yellow precipitate.



Fig: Hager's test

Test for phenolic compound and tannin

1.Ferric chloride test: About 50mg of extract is dissolved in distilled water and to this add few drop of neutral FeCl_2 solution. Formation of blue, green and violet colour indicate the presence of phenolic compound.



Fig: Ferric chloride test

2.Lead acetate test: A small quantity of extract is dissolved in Distilled water and to this 3ml of 10% lead acetate solution is added. A bulky white precipitate indicate the presence of phenolic compound

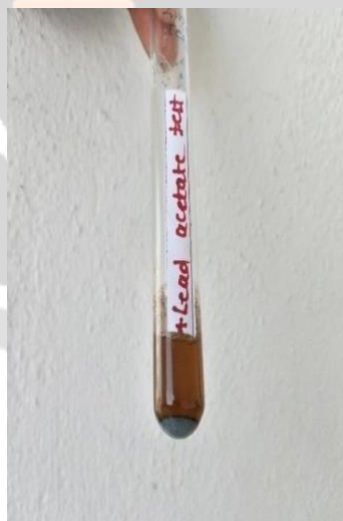


Fig: Lead acetate test

3.Foam test: A small quantity of extract is diluted with distilled water to 20ml. The suspension is shaken in graduated cylinder for 15 min. A two centimeter layer of foam or froth which is stable for 10 min indicate the presence of saponins.



Fig: Foam Test

Test for phytosterol

1. Salkowski test: Few drop of con. H₂SO₄ is added to the extract, shaken on standing, red colour in lower layer indicate the presence of steroid and golden yellow colour indicate the presence of triterpenoid.

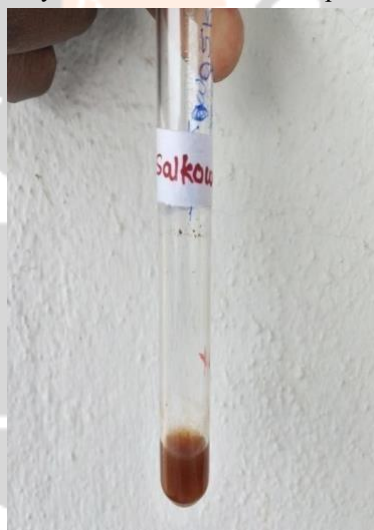


Fig: Salkowski test

Test for carbohydrates

Stock solution About 100mg of extract is dissolved in 5ml of distilled water and filtered. The filtrate is subjected to following test

1. Molish test : To 2ml of filtrate two drop of alc. Solution of α -naphthol is added. The mixture is shaken well and 1ml of concentrated H₂SO₄ added slowly .the tube is cooled .
violet ring at junction of two liquid indicate presence of carbohydrate.

2.Barfoed's test: To 1ml of Salkowski test solution add test few

3. Benedict test: To 0.5ml of drop of barfoed's filtrate 0.5ml of Benedict's reagent is heated on a boiling water bath for 2ml. reagent. I added. The A characteristics coloured mixture precipitate indicate the presence of sugar.

Result and Discussion:

1. Collection of plant and extraction: Leave are collected from plant of jasminum grandiflorum and get air dried for 2-3 days. After drying we perform maceration process for 2-3 day with ethanol use as solvent

2. Phytochemical screening: For evaluation and identification of phytochemical present in plat perform various test, which are describe in table

Test	Leaf extract
Test for alkaloid	
Mayer's test	+ve
Wagner's test:	+ve
Hager's test:	+ve
Dragendroff's test:	+ve
Test for phenolic compound and tannin	
Ferric chloride test:	+ve
Lead acetate test:	+ve
Detection of Saponin:	
Foam test:	+ve
Test for phytosterol	
Salkowski test	+ve

Test for carbohydrates	
Molish test	-ve
Barfoed's test	-ve
Benedict test	+ve

3. Formulation of herbal gel: Formulation of gel contain various excipient which are described in table. Every excipient have specific role in gel like gelling agent, polymer, preservatives. Formulation methods for gel also describe.

There is interaction between the leaf extract and excipient use in Formulation.

4. Evaluation test: Prepared gel were evaluated for various parameters such as physical appearance , pH, viscosity, spread ability. Observation reveals that gel were having smooth texture and elegant appearance. pH of gel having range between 6.7-6.9. In gel there is absence of lump. It having good spread ability.

Further observation given in table

Physical properties:

	Mean pH	S.D
1.	6.9	6.9±0.300

Evaluation test	Result
Appearance	Greenish brown
Odour	Minty

pH of gel:

Spreadability:

	Mean Diameter	S.D
1.	3.35	3.35±0.18

Viscosity		
RPM	Mean viscosity	S.D
50	10710	10710 ±114
100	5105	5105 ±20

Conclusion:

In conclusion, the formulation and evaluation of a herbal gel for the treatment of mouth ulcers have demonstrated its potential as an effective and natural remedy. The development of the herbal gel involved selecting specific herbs known for their anti-inflammatory, analgesic, antimicrobial, and wound healing properties, which are essential for managing mouth ulcers.

The formulation process focused on incorporating these herbal extracts into a gel base that provided a suitable consistency, ease of application, and enhanced bioavailability of the active constituents. The herbal gel exhibited desirable physical properties, such as smooth texture, good spreadability, and stability, making it convenient and practical for topical application.

The evaluation of the herbal gel demonstrated its efficacy in treating mouth ulcers. The herbal extracts present in the gel contributed to the reduction of inflammation, alleviation of pain, promotion of wound healing, and prevention of secondary infections. These effects were attributed to the synergistic actions of the bioactive compounds present in the herbs, which targeted the underlying causes and symptoms of mouth ulcers.

Furthermore, the herbal gel exhibited excellent tolerability and safety profiles, with no significant adverse effects reported during the evaluation process. This indicates that the herbal gel can be safely used as a topical treatment for mouth ulcers, offering a natural and gentle alternative to conventional medications.

It is important to note that further research is still necessary to explore the optimal dosage, frequency of application, and long-term effects of the herbal gel. Additionally, clinical trials involving a larger sample size would provide more comprehensive data on the efficacy and safety of the herbal gel in diverse populations.

Overall, the formulation and evaluation of the herbal gel for the treatment of mouth ulcers have highlighted its potential as a promising therapeutic option. By harnessing the healing properties of herbal extracts, the gel offers a natural and effective approach to managing mouth ulcers, providing relief from pain and promoting faster healing of the ulcers.

Reference:

- 1 Sivapatha sundaram, Preethi Sunnadaranam, S karthiga. Oral Ulcers - A Review. 2018;18
- 2 https://en.m.wikipedia.org/wiki/Jasminum_grandiflorum/

- 3 Yean Cheant Lim, Hemant laxman, Rob Mead, Ewen AB Camron. Oral gel choline salicylate induced refractory gastric ulceration. 2014;15 Hunasagi BS, Kalyane NV, Somashekhar M. Phyto chemical investigation & anti-ulcer activity of *Jasminum grandiflorum* . 2018;1 .
- 6 Sandeep, Padmaa M, Paarakh. *Jasminum grandiflorum* Linn (Chameli): Ethnobotany, Phytochemistry and Pharmacology-A review. Pharmacologyonline. 2009; 2:586-595
- 7 Crispian S and Rosemary S: Clinical review on Mouth ulcers and other causes of orofacial soreness and pain. BMJ 2000; 321
- 8 George S, Sathiamoorthy A, Sathiamoorthy S. Effect of alpha tocopherol on gastric ulcers induced by pylorus ligation in rats. Indian Journal of Pharmacology 1999; 31:431-433
- 9 Salunkhe Akshay Kumar Shivaji R. Vaidya Vaibhav. Formulation & development of Quercetin and monoammonium glycyrrhizinate loaded gel for the treatment of mouth ulcer. 2021;12:1789-1792
- 10 Upadhye et al. / Indian Journal of Pharmacy and Pharmacology 2021;8(3):226– 230
- 11 Umamaheswari M, Asok kumar K, Rathi devi R, Siva shanmugam AT, Subhadradevi V, Ravi TK. Antiulcer and invitro antioxidant activities of *Jasminum grandiflorum* L. J Ethno Pharmacol. 2007; 110(3): 464-70
- 12 Fenny Indah safitri, Desy Nawangsari, Dina debrina. Overview : application of carbopol 940gel. 2021;34:8081
- 13 Priyanka Srivastva, Mithilesh sing, Gatami Devi, Rakhi Chaturvedi 2013;593- 574 14 Abdullahi R Abubakar, Mainul Haque. Preparation of medicinal plant. Basic extraction & fractional procedure for experimental purpose.
- 15 P R Bharathi, S K Sripathi, A lakshami. *Jasminum Grandiflorum* li.. An update review 219;1:1996.
16. Practical handbook of herbal drug technology Nirali publication page no. 1 to 7.