FORMULATION AND EVALUATION OF POLYHERBAL GEL FROM PSIDIUM GUAJAVA EXTRACT FOR MOUTH ULCER

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***Abstract*—Herbal medicines is still the mainstay of about 75-80% of the world's population, mainly in developing countries, for primary health care because of better cultural acceptability, better compatibility with human body and lesser side effects. Herbal medicines consist of plant or its part to treat injuries, disease or illnesses and are used to prevent and treat diseases and ailments or to promote health and healing.**

It is a drug or preparation made from a plant or plants and used for any to such purpose. Herbal medicines are the oldest form of health care known to mankind. A gel is a soft, solid or solid-like material which consists of at least two components, one of them being a liquid, present in substantial quantity. There are number of synthetic gels in the market as compared to herbal or natural gel, but synthetic gels has some harmful effects on skin like irritation and dryness of skin.

Now a day's peoples are more aware about side effects and each and every ingredient using formulation of gel or any other formulation. Hencedue to this reason there is increasing demand for natural ingredient containing formulation.

The aim of this project was to formulate and evaluate herbal mouth ulcer gel. Therefore, developed formulations have potential to treat mouth ulcers. However, further clinical studies are required to establish clinical efficacy of prepared herbal gels.

Herbal gel was prepared by using different concentration of powdered guava leaves and Carbopol 934, Propylene glycol as a gel base.

From the experimental evidence of investor studies it was observed that powdered guava leaves contain flavonoids so it showed significant antioxidant effect. Developed herbal formulation was stable, safe and effective over to synthetic formulations for the treatment of mouth ulcer.

***Index Terms*—Herbal medicine, mouth ulcer gel, betel leaves, guava leaves.**

I. Introduction

Gel are typically semi-solid formulations having a liquid phase that has been Thickened with other components. Uses of topical gel preparations are for skin application or percutaneous penetration of medicament or local action to certain mucosal surfaces. A mouth ulcer is a break or breach in the mucous membrane, which is lines the inside of the mouth. It usually has yellow or white color and usually looks like a depression in mouth that is the mucous membrane. [1] 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. [2]

1.1 Definition of mouth ulcer: -

Mouth ulcers are painful, shallow lesions that develop on the soft tissues lining the mouth, including the gums, tongue, inner cheeks, and lips. They typically appear as white, yellow, or grey spots with a red border and are often called canker sores. Most are non-contagious and heal on their own within one to two weeks. it is called as mouth ulcer. [3]

1.2 Types of mouth ulcer: -

1.Minor

2. Major

1.3 Various Dosage Form used for the Treatment of Mouth Ulcers: -

- Pastes
- Mouthwashes
- Buccal tablet
- Buccal patch
- Medicated chewing gum
- Pharmaceutical Gel

1.4 Mouth ulcer treatments

SELF-TREATMENT:- Allowing ice chips to melt over the ulcers or rinsing your mouth with salt water or baking soda and water may help to lessen pain. Avoiding spicy, acidic and abrasive foods may also help. Using anti-ulcer gels may provide some relief.[4]

FIG NO:01 MOUTH ULCER

1.5 Mouthwash

Mouthwash is an aqueous solution which is most often used for control of plaque and is a medicated liquid which is held in mouth and swished by the action of perioral musculature to eliminate the oral pathogens.[5]

1.6 Herbal Mouthwash

Herbal mouthwashes are mouthwashes which are prepared from natural plant extracts. The natural extract present in the herbal mouthwashes are obtained from various plant leaves, fruits, seeds and various tree oils.[6]

1.7 Causes mouth ulcers:-

- Minor tissue injury from dental work, such as having a cavity filled.
- Accidentally biting your cheek or tongue.
- Allergic reaction to certain bacteria.
- Wearing orthodontic braces or retainers.
- Vitamin deficiencies.
- Using harsh or abrasive toothpaste.
- Eating a lot of acidic foods, such as oranges, pineapples and strawberries.
- Hormonal changes during your period.
- Stress.
- Lack of sleep.
- Viral, bacterial or fungal infections.

- Genetic factor.[7]

1.8 Pharmaceutical Gel:-

A gel is a solid or semisolid system made up of at least two components that contains a condensed mass and is interpenetrated by a liquid. Gels and jellies are made up of a tiny quantity of solids scattered in a big amount of liquid, however they have a solid-like rather than a liquid-like consistency. The presence of some type of epidermal structure, which gives jelly and gel their solid-like qualities, is a distinguishing feature.[8]

1.9 Advantages:-

- Early Warning Sign
- Encourages better oral care and diet habits.
- Self-limiting Condition

1.10 Disadvantages:-

- Pain and Discomfort
- Difficulty in Eating
- Speech Problems
- Risk of Infection
- Nutritional Deficiency
- Stress and Irritation
- Recurring Nature

1.11 Symptoms of mouth ulcer:-

- stinging pain (worse while eating or talking)
- Swelling,
- Burning sensation before the sore appears.
- Pain and Discomfort
- Physical Irritation
- Inflammation
- Visible Sores

1.12 Use of Herbal mouthwash

The use of mouthwashes requires a correct diagnosis of the oral condition and through knowledge of the product to achieve an effective treatment.

Use of herbal mouthwash is to improve oral hygiene.

It help to control dental plaque.It can be use in gum diseases.

Used for killing germs in oral cavity.It freshen breath and covers bad breath.Using a mouthwash for gum disease prevention is very important.

It is use to clean septic sockets.It relieve pain and inflammation. In treatment of Mucositis and Halitosis.[9]

1.13 Benefits of mouthwash:-

Using a mouthrinse does not take the place of optimal brushing and flossing. Mouthrinses may offer additional benefit in terms of reducing the risk of bad breath, cavities, or gum disease; or for relief of dry mouth or pain from oral sores.[10]

*** Plant profile:-**

1) Guava Leaves :-

Family:- *Myrtaceae*

Synonyms:- *yellow cattley guava.Psidium littorale.Psidium.strawberry guava.fruit tree.*

Biological source:-*uercetin,avicularin,apigenin,guaijaverin,kaempferol,hyperin, myricetin, gallic acid, catechin,epicatechin, chlorogenic acid, epigallocatechin gallate, and caffeic acid*

Guava is a tree that grows in Central and South America.

The Guava leaves is commonly eaten fresh or made into beverages, jams, and other foods. Various parts of the plant,

Including the leaf and the fruit, are used as medicine.People use guava leaf for stomach and intestinal conditions,pain, diabetes, and wound healing.

The fruit is used for high blood pressure. But there is no good scientific evidence to support any uses of guava.

Guava Leaves Description/Taste:-

Guava leaves are oblong to oval in shape and average 7-15 centimeters long and 3-5 centimeters wide. The leaves grow in an opposite arrangement, which means two leaves grow at the same point on either side of the stem, and have short petioles, or stalks that join the leaf to the stem. The surface of the deep green Guava leaf is wide and leathery with faint white veins and some light brown patches.[11-12]

Current Facts:-

Guava leaves, botanically classified as Psidium guajava, are members of the Myrtaceae, or myrtle family along with eucalyptus, allspice, and clove. Guava leaves have been used in traditional Eastern medicine since ancient times and have recently gained in notoriety as an alternative natural medicine.[13-14]

2) Betel Leaves :-

Family:- *piperaceae*

Synonyms:- *Paan, penang, pinang*

Biological source:- *The betel nut is the seed of the areca, or betel, palm (Areca catechu), family Arecaceae, and the betel leaf is from the betel pepper, or pan plant (Piper betle), family Piperaceae.*

The betel, Piper betle, is a species of flowering plant in the pepper family Piperaceae, native to Southeast Asia.

It is an evergreen, dioecious vine, with glossy heart-shaped leaves and white catkins.

Betel plants are cultivated for their leaves which are mostcommonly used as flavoring in chewing areca nut.

Betel leaves are used as a stimulant, an antiseptic, and a breath-freshener

3) Tulsi Leaves:-

Family: *Lamiaceae (formerly Labiatae).*

Synonyms: *Holy Basil, Sacred Basil, Indian Basil.*

Biological Source: *Consists of the fresh and dried leaves of Ocimum sanctum Linn. (synonym: Ocimum tenuiflorum L.).*

II. LITERATURE REVIEW

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12.Kanchan Upadhye1,*, Kirti Charde1 Gouri Dixit1 Suparna Bakhle. 1Dept. of Pharmaceutics, Priyadarshini J. L. 30-08-2021Available online 04-09-2021 Keywords: Aphthous stomatitis Aloe barbedensis Ocimum tenuiflorum Azadirachta indica Carbopol 940.

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III. AIM AND OBJECTIVES

3.1 Aim: -

Formulation and evaluation of polyherbal gel from psidium gujava and betel leaves extract for mouth ulcer.

3.2 Objective: -

1. To prepare a polyherbal gel formulation
2. To study the medicinal properties of Psidium guajava
3. To select suitable herbal ingredients
4. To prepare plant extract using an extraction method
5. To evaluate physical characteristics of the gel
6. To determine pH of the gel
7. To evaluate spreadability
8. To study viscosity of the formulation
9. To evaluate extrudability
10. To perform stability studies
11. To evaluate antimicrobial activity
12. To evaluate skin irritation and safety
13. To assess overall effectiveness of the formulation.

IV. PLAN OF WORK

Literature Review

⬇

Searching Matter Having Potential to Prepare Polyherbal Preparations

⬇

Collection of All Ingredients Required for The Preparation

⬇

Formulation of Polyherbal Mouth Ulcer Gel Preparation

⬇

Evaluation of Polyherbal Mouth Ulcer Gel Preparation

⬇

Complication Of Data

⬇

Future Scope

⬇

Conclusion

⬇

Summary

⬇

Result

⬇

Reference

V. MATERIALS AND METHODS

5.1 Materials: The following chemicals were used for the present project work shown in table 1

Table.1

Ingredient
Carbapol
Propyl Paraben
Methyl Paraben
Triethanolamine
Peppermint oil

5.2 Methodology

Identification and collection of herbs : For the present work Aloe vera, Curcuma longa ,blue pea (Asian pigeonwings). Green tea (Lipton) was procured from the local market of badnapur. Table 2. represent common name, botanical name and family of herbs**.**

Table.2

Sr.No	**Common Name**	***Botanical Name***	***Family***
1	Guava Leaves	*Psidium Gujava*	*Myrtaceae*
2	Betel Leaves	*Piper Betel*	*piperaceae*
3	Tulsi Leaves	*Ocimum Tenuiflorum*	*Lamiaceae*

Excipients and herbal ingredients with their roles: -

Table.3

Sr.No	Ingredients	Roles
1	Guava Leaves	Anti-inflammatory, anti-microbial abd wound-healing properties.
2	Tulsi	Creating a protective layer over the ulcer which speed up healing and reduce discomfort.
3	Betel Leaves	Natural anti-microbial and anti- inflammatory properties.
4	Carbapol	Acts as a mucoadhesive gelling agents in mouth ulcer gel
5	Propyl paraben	Used as a preservative
6	Triethanolamine	Thickener, pH balancer, emulsifier.
7	Methylparaben	Preservative
8	Peppermint oil	Cooling and soothing effects.

Morphological characterstics of leaves of all plants have been done using WHO guidelines .

5.3 Collection of Plant material:-

All the ingredients are collected various plant source then the leaves were dried at room temperature in shade. The plant material were then powdered and prepared for extracting.

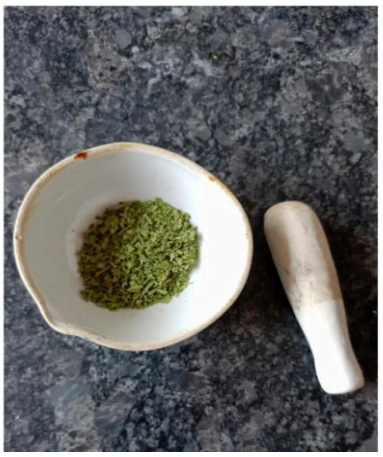

FIG NO:02 HYDRALCOHOLIC EXTRACT

5.4 Preparation of herbal Gel:-

A specified amount of Carbopol was dispersed in required amount of distilled water with continuous stirring.

5ml of distilled water was taken and required quantity of methyl paraben and propyl paraben were dissolved by heating on water bath.

Further varying concentration of Guava leaves ethanolic extract, betel leaves ethanolic extract and liquorice root aqueous extract were mixed to the above mixture.

Finally full mixed properly to the Carbopol gel with continuous stirring and triethanolamine was added drop wiseamount of Carbopol was dispersed in required amount of distilled water with continuous stirring.

5ml of distilled water was taken and required quantity of methyl paraben and propyl paraben were dissolved by heating on water bath.

Further varying concentration of Guava leaves ethanolic extract, betel leaves ethanolic extract and

liquorice root aqueous extract were mixed to the above mixture.

Finally full mixed properly to the Carbopol gel with continuous stirring andriethanolamine was added drop wise to the formulation for adjustment of required pH (6.8-7).

Volume was made up to 100 ml with distilled water and few drops of Peppermint oil was added as flavouran.

Transfer the gel into clean, airtight containers or collapsible tubes.

Ingredients	Quantity
Guava Leaves	2 gm
Beetle leaves	2 gm
Liquorice root	1 gm
Carbopol	2 gm
Methyl Paraben	0.025 gm
Propyl Paraben	0.02 gm
Triethanolamine	0.01 ml
Peppermint oi1	0.01 ml
Distilled water	q.s to 10 ml

5.5 Formulation and Evaluation:-

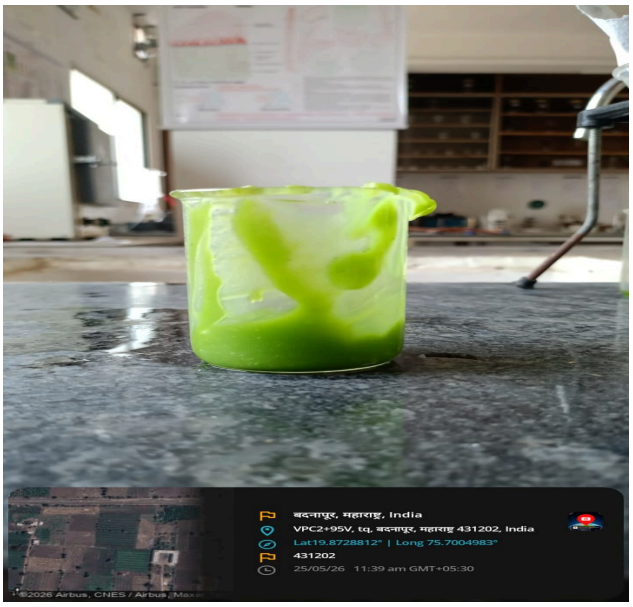

FIG NO:04 MOUTH ULCER GEL

Physical Appearance:-

Color : Greenish

Odor : Characterstic

Texture : Semi – Solid

Appearance : Smooth, Homogeneity

Smooth, greenish gel with pleasant peppermint odor.

pH Determination:-

Measure using a digital pH meter.

Expected Result

pH: 6.5 – 7.0

Extrudability:-

Determine ease of gel extrusion from tube.

Homogeneity:-

All developed gel formulations 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.

Spreadability:-

Spreadability was determined by glass slide and wooden block apparatus. Weights about 20gm were added to the pan and the time were noted for upper slide to move to separate completely from the fixed slide. An excess amount of gel 2gm under study was placed on this ground slide.

Viscosity:-

Viscosity was determined by using Brookfield viscometer (DV-III programmable Rheometer). Formulated gels were tested for their rheological behaviors at 250C. The measurement was made over range of speed from areverse orders.

Gel strength:-

Gel strength was determined by the time in seconds required by the weight to penetrate in the gel. A Sample amount of 5gm of each of the optimize batches was taken and 3.5gm weight was placed on the surface of gel. The time in seconds required by the weight to penetrate 0.5cm in the gel.

Bioadhesive Strength:-

Bioadhesive strength was determined by using glass slide and wooden block apparatus. Bioadhesive strength used to measuring the force required to detach the formulation from cellophane membrane.

Stability study:-

Stability studies were done with open and close container. Here, by subjecting the product to roomtemperature for 1 month.

Antifungal activity:-

The antifungal activity of all developed batches of formulation and without drug containing gel formulation i.e. blank formulation were carried out by Cup-plate method in comparison with marketed antifungal formulation (Zo1ef1.)

There are two different bacteria cultures used were Aspargilious aureusand Candida Albicans.

The antifungal test was performed using the agar well diffusion Prepared nutrient brought and poured in to sterile petri plates and kept for drying and cooling.

VI. RESULTS AND DISCUSSION

All formulated gels showed good homogeneity and gelling properties.

The pH of all formulations was within the acceptable range for oral application.

The gels exhibited suitable viscosity, spreadability, and extrudability.

Good bioadhesive strength was observed in all batches.

Stability studies indicated that gels stored in closed containers remained stable, while open containers showed syneresis.

The formulations demonstrated significant antimicrobial and antifungal activity against Candida albicans and other oral microorganisms.

The developed Psidium guajava gel was found to be stable, effective, and suitable for mouth ulcer treatment.

a) Colour: The colour of the gel observed was greenish.

b) Odour: The odour of gel was characteristic.

c) State: The state of gel was semi-solid in nature.

d) pH: According to the results, the pH of all the formulation was found to be 6.5– 7.0

Result of Stability Studies:-

Formulaition	Physical appearance	pH	Spread ability (gm.cm/sec)	Viscosity (Pa.S)	Extrudability
F1	Greenish	6.8A0.9	5.70z0.1	3.174z0.01	Good
F2	Greenish	7+0.9	5.86z0.15	3.073+0.049	Good
F3	Greenish	6.9+0.5	6.52z0.05	2.334z0.01	Good

VII. CONCLUSION

The formulated Psidium guajava herbal gel showed good stability, compatibility, and satisfactory physicochemical properties. The optimized formulation exhibited significant antibacterial activity and was found suitable for effective mouth ulcer treatment. Therefore, Psidium guajava gel can be considered a safe, effective, and economical herbal alternative for the management of oral ulcers.

Sr.no	Parameters	Results
1	Colour	Greenish
2	Odour	Characterstic
3	State	Semi – Solid
4	Appearance	Smooth, homogeneous
5	pH	6.5 – 7.0

VIII. EXPECTED OUTCOME

1. Successful Formulation of Polyherbal Gel:-

A stable polyherbal gel containing Psidium guajava leaf extract and other selected herbal ingredients is expected to be successfully formulated. The gel should possess good consistency, smooth texture, and uniform distribution of active constituents without phase separation or grittiness.

2. Acceptable Physicochemical Properties:-

The formulated gel is expected to meet the required quality parameters:

Appearance: Smooth, homogeneous, and free from lumps.

pH: Between 6.0–7.0, suitable for oral mucosal application and non-irritating to ulcerated tissues.

Viscosity: Adequate viscosity to ensure proper retention at the ulcer site.

Spreadability: Easy application and uniform spreading over the affected area.

Extrudability: Easy extrusion from the tube without excessive force.

Stability: No significant changes in color, odor, pH, or consistency during storage.

3. Enhanced Antimicrobial Activity:-

The polyherbal gel is expected to inhibit the growth of common oral pathogens such as Streptococcus mutans, Staphylococcus aureus, and Candida albicans. The antimicrobial action of phytochemicals like flavonoids, tannins, and phenolic compounds present in Psidium guajava leaves may help prevent secondary infections at the ulcer site.

4. Anti-inflammatory Effect:-

The formulation is expected to reduce inflammation and swelling associated with mouth ulcers. Bioactive compounds present in guava leaves are known to inhibit inflammatory mediators, thereby decreasing redness, irritation, and discomfort.

5. Faster Wound Healing:-

The gel is anticipated to accelerate the healing process by promoting tissue regeneration and collagen synthesis. Antioxidants present in the herbal extracts may protect damaged oral tissues from oxidative stress and support rapid recovery.

6. Reduction in Pain and Discomfort:-

Application of the gel is expected to provide soothing effects and reduce pain, burning sensation, and irritation caused by mouth ulcers. This may improve the patient's ability to eat, drink, and speak comfortably.

7. Safe and Economical Herbal Alternative:-

The formulated polyherbal gel is expected to be safe for local oral use with minimal side effects. Being derived from natural plant sources, it may serve as a cost-effective alternative to conventional synthetic medications used for mouth ulcer treatment.

8. Improved Patient Compliance:-

Due to its ease of application, pleasant texture, and effective therapeutic action, the gel is expected to improve patient acceptance and compliance, leading to better treatment outcomes.

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