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Research Article

FORMULATION AND EVALUATION OF HERBAL ORAL GEL CONTAINING EXTRACTS OF POWDERED *VITEX NEGUNDO* LEAVES WITH *ANACYCLUS PYRETHRUM* TO TREAT MOUTH ULCER

***[1]Kalyani Kakad, [1]Vikas Gore, [2]Sneha Nawale**

*[1]Department of Pharmacognosy, P. E. Society's Modern College of Pharmacy, Nigdi, Pune Maharashtra- 411044.
[2]Department of Pharmacognosy, Gokaraju Rangaraju College of Pharmacy, Bachupally, Hyderabad-500090 (Osmania University).

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ABSTRACT

Mouth ulcers, known as canker sores or aphthous ulcers, are common painful lesions within the oral cavity, often resulting from factors like nutritional deficiencies, stress, hormonal changes, or physical trauma. This study investigates the development of a topical gel incorporating natural therapeutic agents extracted from *Vitex negundo* and *Anacyclus pyrethrum* to alleviate symptoms associated with mouth ulcers. These botanical extracts exhibit anti-inflammatory, analgesic, and antimicrobial properties that can reduce pain and promote oral ulcer healing. The gel formulations, formulated with appropriate gelling agents and excipients, underwent evaluation based on appearance and consistency to identify the optimal formulation. The selected formulation will undergo further antimicrobial studies to assess its effectiveness in managing mouth ulcers. In conclusion, the development of a topical gel containing bioactive compounds from *Vitex negundo and Anacyclus pyrethrum* represents a promising approach for treating mouth ulcers. This research contributes to the understanding of natural remedies for oral health conditions and highlights the potential of botanical extracts in topical formulations for managing oral ulcers.

Keywords: Anti-ulcer activity, Wound healing, Gel formulation, Oral health, Evaluation.

INTRODUCTION

Gels are mostly semi-solid combinations including a liquid phase that has been augmented with additional components to harden it. Topical gel forms are placed locally on particular mucosal surfaces when trying to spread the drug or generate an immediate effect (Singh, 2014). Small sores or scratching that develop inside the mouth or at the base of the teeth are known as mouth ulcers. Apthopus ulcers as canker sores are various names to mouth ulcers. A mouth ulcer may also be referred to as a break or breach in the membrane that lines inside of the mouth. typically, it starts out as a white-colored or pale depression in your mouth. Mouth ulcers may occur by nutritional shortages, poor oral hygiene, infections, stress, indigestion, mechanical injury, food allergies, hormonal imbalance, skin disease etc. Mouth ulcers, also known as aphthous ulcers, can be painful while eating, drinking or brushing teeth (Indhumathi, 2020).

Topical gel formulations are consistent, semisolid preparations which are simple to remove from the epidermis and are less oily compared to other drug delivery strategies. They are comprised of solutions or dispersions of one or more medication in acceptable hydrophilic or hydrophobic bases. They are applied externally to the skin or certain mucous membranes for beneficial prevention, or defensive purposes (Mhaske S. D., 2022). Several excipients are utilized in the gel-making technique: propylparaben, triethanolamine, methylparaben, carbopol 934, disodium edeate, and propylene glycol. The gelling element carbopol 934 was utilized in three distinct levels to make the gel formulation. One batch is picked according to its appearance that displays the majority of the gel-like qualities (Mhaske S. D., 2022).

*Corresponding Author: Dr. Kalyani Kakad, Department of Pharmacognosy, P. E. Society's Modern College of Pharmacy, Nigdi, Pune Maharashtra- 411044. Email: kk_pharma20@rediffmail.com.

Oral ulcers

An ulcer is a defect in the integrity of the epithelium resulting from molecular necrosis. Ulcers are frequently noticed near the cavities in the mouth, and patients typically seek neither dental or medical therapy for such conditions. Redness, suffering, and/or a burning feeling all typical warning signs. They can arise anywhere in the oral cavity, but they can lead to difficulty if they do so in the area that's flexible (Mhaske S. D., 2022). A mouth ulcer, frequently referred to as an oral ulcer or a mucosal ulcer, is an injury of the oral cavity's membrane. Usually, those are painful round or oval sores that arise on the inside of the cheeks or lips behind the mouth. Mouth ulcers are fairly prevalent and may develop from a number of diseases and their therapies. despite the fact these usually have not any significant underlying causes underlying it. Mouth ulcers tend to be triggered by nutritional deficiencies such as iron deficiency, vitamin a lack (particularly B12 and C), infections, stress, indigestion, mechanical harm, food allergies, hormonal imbalances, issues with the skin, etc. Mouth ulcers, additionally known as aphthous ulcers, might discomfort when you eat, drink, or brushing your teeth (Mhaske S. D., 2022).

Mouth ulcers can be described as moderate, at deeper, or herpetiform depending on the severity and amount. Mouth ulcer forms that are typical are: Moderate ulcers: These typically go entirely in 10 days to 2 weeks with a diameter for 2 to 8 mm. Deeper ulcers: These usually have an unequal or irregular border. This type of ulcer may leave a scar in the mouth and take a long time to heal. Herpetiform ulcers: these kinds of ulcers are the result by multiple small pinhead-sized infections packed close (Raghvendr K. Y., 2021).

Vitex negundo is a verbenaceae family tree which climbs to a height if 4.5 feet and is native to India. Anti-inflammatory, antibacterial, anti-fertility, antispasmodic, analgesic, hepato-protective, estrogenic, anticonvulsant, antiarthritic, diuretic, antimicrobial, anti-parkinsonian, antipsychotic, antidepressant, antihistamine-releasing activity, mosquito repellent activity, anti-feedant, anti-filarial, juvenomimetic, and anti-androgenic are only some among its numerous medicinal uses. The leaves can be helpful in rheumatism, arthritis, catarrhal fever, cephalagia, sprains, orchitis, syphilis, inflammations, and ulcers. It also serves as warm, tonic, and vermifuge (Sharma P.C., 2005).

Anacyclus pyrethrum (L) is commonly known as African pyrethrum, akarkara, tigendesste, and igendess. It is a species belonging to the family Asteraceae, which is indigenous to Morocco, Algeria, and Spain. This species includes the two varieties *Anacyclus pyrethrum* var. pyrethrum (L) and *Anacyclus pyrethrum* var. depressus (Ball) Maire. The roots of A. pyrethrum (L) are used to cure toothaches, salivary production, angina, digestive issues, lethargy, female infertility, and even tongue and limb paralysis in traditional medicine. They are used to treat gout and sciatica and to keep disease at bay in the form of cream-based animal fats. Anesthetic, anti-inflammatory, anticonvulsant, antioxidant, antidiabetic, and memory enhancer effects of Anacyclus pyrethrum (L) roots have been documented in the literature (Neha R. Jumde., 2022).

MATERIAL AND METHODS

Collection and authentication of plant materials

The leaves of plant powder *Vitex negundo* and rhizomes of *Anacyclus pyrethrum* we procured from the local area of PCMC, Pune, India in month of December 2023 and the plant specimens are authenticated by “Manakarnika Aushadhayala”. Chinchwad -33 respectively.

Chemicals

Ethanol, carbopol 940, methyl paraben, propyl paraben, propylene glycol 400, disodium edetate, triethanolamine, distilled water.

Equipment’s

Digital balance, pH meter, Magnetic stirrer, water bath, Ultra sonicator, Brookfield viscometer, spredability apparatus.

Preparation of plant extract

A total of 20 g of powder of leaves parts of *Vitex negundo* and *Anacyclus pyrethrum* was extracted by maceration with 200 mL of 90% ethanol at room temperature for 48 h. Then mixtures were filtered and evaporated at 40 °C, and the residue obtained was then kept a until further use. Then extraction yield for leaves powder was 16% w/w and 10% w/w, respectively. (Sharma, P. K., 2018 and Sharma, P. K., 2012).

Preparation of herbal gel

Carbopol 934 was dissolved slowly with stirring in 60 mL of demineralized water for 1 hrs to avoid agglomeration Then disodium edetate and triethanolamine were dissolved in 10 mL of demineralized water separately and stirred for 10 min. Mixed 4.83 mL of propylene glycol in 12 mL of demineralized water with stirring for 10 min. Disodium edetate and triethanolamine solution were added to carbopol solution and the pH was then adjusted to 7.4 by stirring the solution for 10 min. Then propylene glycol solution was added with stirring for 10 min until a clear consistent gel base was obtained (Nappinnai., 2006). Further required quantity of extract was added to the above mixture and this solution was mixed properly to the Carbopol 940 gel with continuous stirring (Das S., 2011).

Table 1. Ingredients of herbal mucosal gel.

Ingredients	Quantity (gm)	Role	%w/w
Basil oil	1	Reduce mouth Ulcer, antibacterial activity.	0.3
Nirgundi	0.5	Antibacterial, Laxative, Antioxidant, Anti-inflammatory.	0.15
Akarkara	0.5	Anti-inflammatory, Antibacterial used	0.15
Apple cider	0.5	Destroy bacteria in mouth	0.15
Carbopol 934	1.5	Mucoadhesive polymer used as gelling agent	0.45
Methyl paraben	0.00015	Preservative	0.000045
Propyl paraben	0.01	Preservative	0.03
Propylene glycol	5	Co-solvent	1.5
Triethanolamine	1.5	For adjust pH	0.45
Disodium edeate	0.005	Chelating agent	0.0015
Distilled water	q. s	-	Up to 30ml

Evaluation parameters

Physical evaluation

Physical parameters such as color, odour and consistency were checked visually. The color of the formulations was checked by visual inspection. The consistency of formulations was checked by applying on skin. The odour of the formulations was checked by mixing the gel in water and observing the smell (Table 2).

Percentage yield

Weigh the empty container in which the gel formulation was stored then again weigh the container with gel formulation. To obtain the practical yield subtract the weight of empty container with the container with gel formulation. Then the percentage yield was calculated by the formula given below: Percentage yield = (practical yield/theoretical yield) × 100 (Table 3).

Measurement of pH

The pH of gel formulations was determined by using digital pH meter. Take 1 gm of gel and dissolved in 10 ml of distilled water and keep apart for two hours (Table 4). Then the measurement of pH of formulations was done by dipping the glass electrode completely into the gel system three times and the average values are reported (Mokashi M., 2015).

Homogeneity

All prepared 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 (Table 5).

Viscosity

The measurement of viscosity of the formulated gel was determined by Brookfield Viscometer with spindle no. 1 at 25°C. The gels were rotated at speed 0.3, 0.6 and 1.5 rotations per minute and at each speed, the corresponding dial reading was noted. Then viscosity of the prepared gels was obtained by multiplication of the dial reading with factor given in the Brookfield Viscometer catalogues (11). Viscosity of gel formulation was reported in Table 6.

Spread ability

Spread ability 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 spread ability (Kaur LP., 2010) 12). Spread ability is calculated by using the formula:

$S = M \times L / T$

Where M = weight tied to upper slide

L = length of glass slides

T = time taken to separate the slides

Spread ability of gel formulations were reported in Table 7.

Extrudability

The formulated gel was filled in standard capped collapsible aluminum tubes and sealed by crimping to the end. The weight of filled tubes was recorded and the tubes were sandwiched between two glass slides and were clamped. 500gm weight was placed over the slides and then the cap was removed to extrude (Table 8). The amount of extruded gel was collected and weighed. Extrudability was

determined by calculating the percentage of extruded gel (Mendhekar SY., 2017).

Clarity

The clarity of herbal batch was determined by visual inspection (Pandey N., 2011).

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 (Tables 9). Gel strength was determined by reporting the time in seconds required by the weight to penetrate 0.5 cm in the gel (Thombre KP., 2018).

Anti-fungal activity

The antifungal and antibacterial activity of formulation and blank formulation were carried out by Cup-plate method in comparison with marketed antifungal formulation (Hiora sg oral gel). The antifungal and antibacterial activity test was performed by using *Candida albicans* and *Staphylococcus aureus*. Prepared nutrient brought and poured in to sterile petri plates and kept aside for drying and cooling. After that *Candida albican* culture were spread by micron wire loop. A sterile cork borer 6 mm diameter was used to drill holes 4 mm deep. Then place 0.5 gm of gel from each formulation in to these holes. Plates were then incubated at 27°C for 48 hr. Then the zone of inhibition (diameter in mm) was measured (Koland M., 2011, Satish Kumar A, 2016) (Table 10).

Stability study

Stability studies were done with open and close container. Here, by subjecting the product to room temperature for 1 month. (Table 11).

RESULTS AND DISCUSSION

From the above results it is clearly shows that all the prepared gel formulations were yellowish green in color and having good homogeneity and gelling property. The pH of all gel formulations was in the range compatible with normal pH range of oral cavity. The rheological behaviors of gel formulations were studied with Brookfield viscometer which indicated that the viscosity of gel formulation was consistent neither too thick nor too thin. The study of spreadability shows that with increasing the viscosity of formulation spreadabilty decrease and its vice-versa. The gelling strength and extrudability is found in the suitable range. Thus overall, the gel formulation complies with all parameters of an marketed ideal gel. Accelerated stability studies indicated that the physical appearance, rheological properties, extrudability, spreadability in the optimized formulation remain unchanged upon storage for 3 months. This optimized herbal mucosal gel showed good antifungal and antibacterial activity against *Candida albicans* and *Staphylococcus aureus* that is main microorganism responsible for mouth ulcer.

Table 2. Physical evaluation of gel formulations and Marketed gel (Hiora-Sg oral gel).

Formulation	**Herbal gel**	**Marketed gel**
Color	Yellowish green	Dark brown
Consistency	Good	Good
Odor	Characteristic	Odorless

Table 3. Percentage yield of gel formulations and Marketed gel (Hiora-Sg oral gel).

Formulation	**Herbal gel**	**Marketed gel**
Percentage yield (%)	93.32	98.4

Table 4. pH of gel formulations and Marketed gel (Hiora-Sg oral gel).

Formulation		**Herbal gel**	**Marketed gel**
pH	**Day**		
	1	7.0	7.2
	2	6.8	6.9
	3	6.4	6.7
	Avg =	6.7	6.9

Table 5. Homogeneity of gel formulations and Marketed gel (Hiora-Sg oral gel).

Formulation	**Herbal gel**	**Marketed gel**
Homogeneity	Good	Good

Table 6. Viscosity of gel formulations and Marketed gel (Hiora-Sg oral gel).

Formulation			**Herbal gel**	**Marketed gel**
Viscosity(cps)	**Rpm**	**10**	4100	5200
	Rpm	**20**	5300	6400
	Rpm	**30**	6200	6900

Table 7. Spreadability of gel formulations and Marketed gel (Hiora-Sg oral gel).

Formulation		**Herbal gel**	**Marketed gel**
Spreadabilty (gm.cm/sec)	**Wt.(gm)**		
	5	9.19	14.16
	10	12.31	11.17

Table 8. Extrudability of gel formulations and Marketed gel (Hiora-Sg oral gel).

Formulation	**Herbal gel**	**Marketed gel**
Extrudability (%)	86.3	89.5

Table 9. Gelling strength of gel formulations and Marketed gel (Hiora-Sg oral gel).

Formulation		**Herbal gel**	**Marketed gel**
Gelling strength	**Wt.(gm)**		
	5	39.11	37.16
	10	28.87	27.19

Table 10. Antifungal studies of gel formulations and Marketed gel (Hiora-Sg oral gel).

Formulation	**Zone of inhibition (mm)**		**Zone of inhibition (mm)**	
	Candida albicans		*Staphylococcus aureus*	
Standard drug	ciprofloxacin	47	ciprofloxacin	45
Herbal gel	0.25 gm =	23	0.25 gm =	25
	0.5 gm =	21	0.5 gm	30
Marketed (Hiora-Sg oral gel)	0.25 gm =	25	0.25 gm =	15
	0.5 gm =	28	0.5 gm =	26

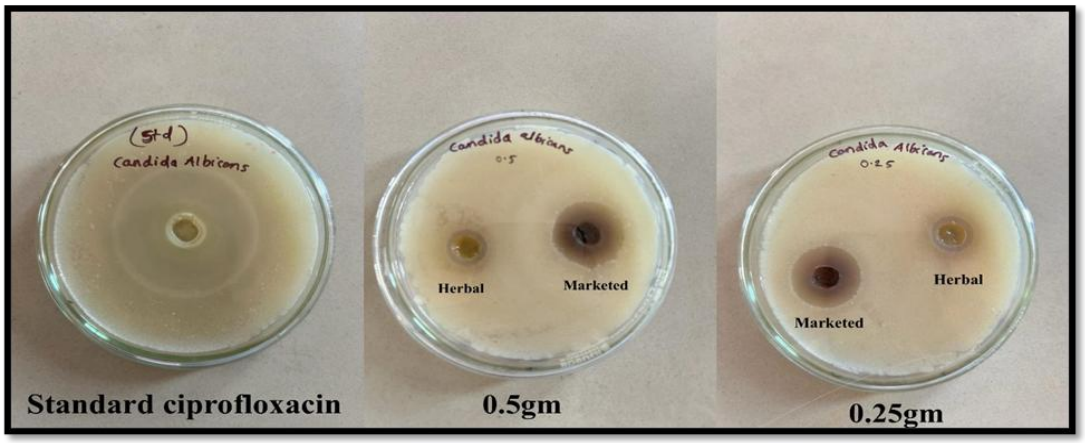

Figure 1. Zone of Inhibition *Candida albicans.*

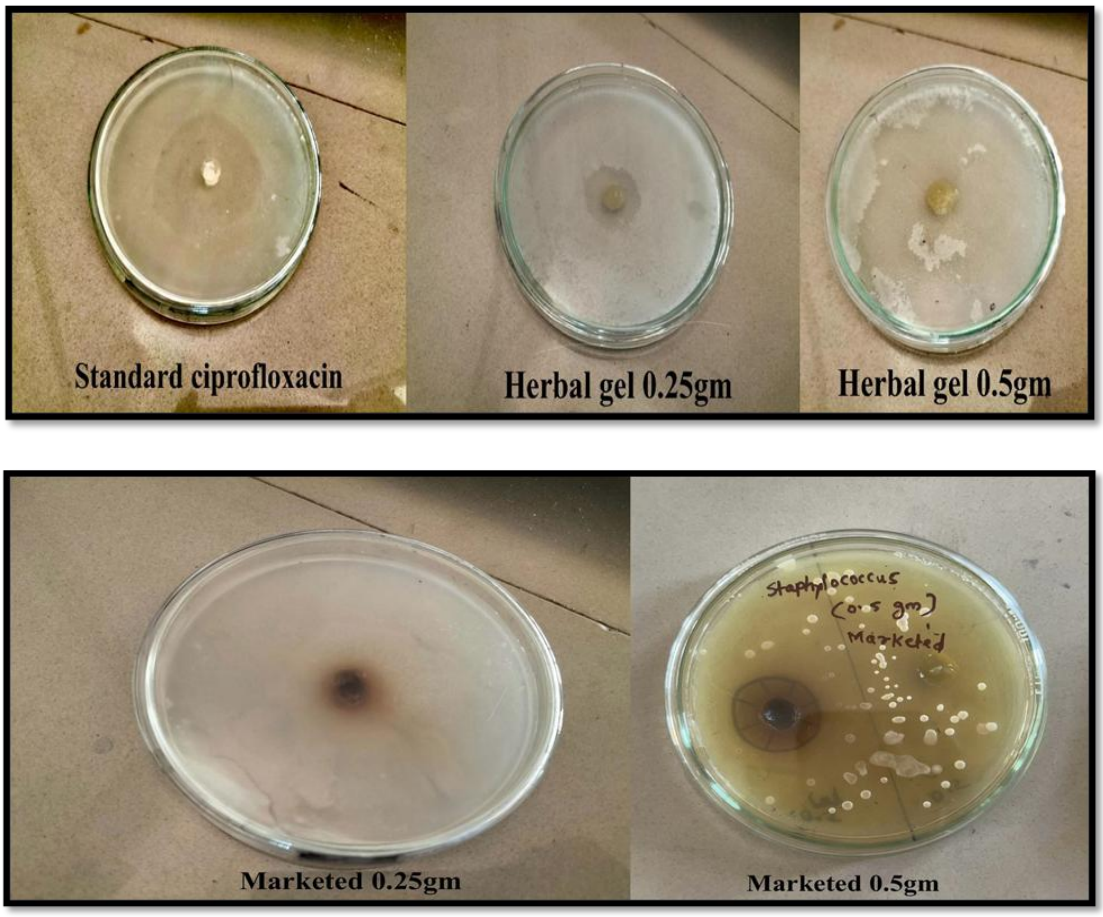

Figure 2. Zone of Inhibition *Staphylococcus aureus.*

Table 11. Stability studies of gel formulations and Marketed gel (Hiora-Sg oral gel).

Formulation	**Herbal gel**		**Marketed gel**	
Stability	Open container	Closed container	Open container	Closed container
	Not stable	Stable	Not stable	Stable

Optimization of batches

After analysis of formulations for their extrudability and gelling strength it is observed that the formulation containing equal amount of *Vitex negundo* extract and *Anacyclus pyrethrum* extract showed good result. The batch F (mixed) optimized with good pH, viscosity, spreadability, extrudability and gelling strength, hence this formulation is further used for anti-fungal study.

Table 12. Optimization of batches.

Parameters	Optimized batch F (Herbal gel)	Optimized batch F (Marketed gel)
Color	Yellowish green	Dark brown
Odor	Characteristics	Odorless
pH	6.7	6.9
Viscosity	6200	7100
Spredability	12.31	11.17
Extrudability	86.3	89.5
Gelling strength	28.87	27.19

CONCLUSION

From the mentioned results, it was concluded that the prepared gel formulations are in good appearance with suitable pH range. Formulated gel have good homogeneity, proper gel strength & spread ability. The gel is neither too thick nor too thin. The all-formulated gels are found to be stable in closed container as compared to open container. The formulation showed the antibacterial and antifungal activities against Staphylococcus aureus and Candida albicans. It is very good attempt to establish herbal gel of Vitex negundo extract and Anacyclus pyrethrum extract. The data presented in this study, it was demonstrated that the developed herbal gel formulation possess significant, therapeutically efficacious, suitable vehicle for drug delivery in low cost but definitely with high potential. The result showed that due to combination dosage form developed new herbal gel formulation having good activity so it is safe, stable and good for mouth ulcer treatment.

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CONFLICT OF INTERESTS

The authors declare no conflict of interest

ETHICS APPROVAL

Not applicable

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AI TOOL DECLARATION

The authors declares that no AI and related tools are used to write the scientific content of this manuscript.

DATA AVAILABILITY

Data will be available on request

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