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Formulation and Evaluation of Anti-ulcer Herbal Gel from Cluster Fig (Ficus racemosa)

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Abstract**—***Cluster fig (Ficus racemosa), a plant known for its wide array of medicinal benefits, has shown promising potential in the treatment of mouth ulcers. The bioactive compounds found in its fruits, leaves, and bark, including flavonoids, tannins, and phenolic compounds, contribute to its therapeutic properties. Research suggests that Ficus racemosa possesses anti-inflammatory, antimicrobial, and antioxidant effects, which play a significant role in alleviating mouth ulcers. The plant's ability to reduce inflammation and promote tissue healing helps in accelerating the recovery of the mucosal lining in the oral cavity. Additionally, its antimicrobial properties help combat secondary infections that may exacerbate ulcer conditions. These findings support the potential use of Ficus racemosa as a natural remedy for preventing and managing mouth ulcers, although further clinical trials are needed to confirm its effectiveness and determine optimal usage. This study concludes that the Cluster fig anti-ulcer gel presents a promising natural alternative for ulcer management, offering enhanced bioavailability, patient compliance, and reduced adverse effects compared to conventional therapies.*

Keywords**—** *Cluster fig (Ficus racemosa), Mouth ulcers, Bioactive compounds, Flavonoids, Tannins, Phenolic compounds, Anti-inflammatory.*

I. INTRODUCTION

Ficus racemosa, commonly known as the cluster fig tree, gular, Indian fig tree, or Udumbara, is a large deciduous tree belonging to the family Moraceae. It is native to India, Southeast Asia, and Australia, where it grows in tropical and subtropical climates. The tree is widely recognized for its multiple medicinal, nutritional, and ecological benefits and has been used extensively in traditional medicine systems like Ayurveda, Siddha, and Unani.

The tree is unique in its fruit-bearing pattern, as figs grow in clusters directly on the trunk and larger branches, a phenomenon called cauliflory. Every part of Ficus racemosa, including its leaves, bark, roots, fruits, and latex, contains bioactive compounds with significant therapeutic potential.[1]

Fig. 1. Cluster Fig Tree

Ficus racemosa is a medium to large deciduous tree, growing up to 20–30 meters in height. It has a smooth, grayish-brown bark and a spreading canopy[2]. The tree is unique because its fig-like fruits grow in clusters directly on the trunk and branches (a phenomenon known as cauliflory)[3]

Fig. 2. Leaves Cluster Fig

TABLE 1. Vernacular Names of Ficus racemosa

Language	Name
Sanskrit	Udumbara
Hindi	Gular
Tamil	Atithi
Telugu	Medi Chettu
Malayalam	Atithi Maram
Kannada	Atthi Hannu
Bengali	Jog Dumur
Marathi	Umbar
Gujarati	Golar
Urdu	Anjeer

TABLE 2. Taxonomical Classification

Taxonomic Rank	Classification
Kingdom	Plantae
Division	Magnoliophyta
Class	Magnoliopsida
Order	Rosales
Family	Moraceae
Genus	Ficus
Species	Ficus racemosa

Morphology and Description of Plant Parts

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Fig. 3. Leaves

- Large, dark green, ovate, leathery leaves with smooth surfaces and prominent venation.
- Rich in flavonoids, tannins, saponins, and alkaloids.
- Used for anti-inflammatory, antioxidant, and hepatoprotective benefits.[4]


Fig. 4. Bark

- Thick, rough, reddish-brown bark with high medicinal value.
- Contains tannins, flavonoids, β-sitosterol, contributing to antiulcer, analgesic, and anti-inflammatory activities.[5]


Fig. 5. Fruits (Cluster Figs)

- Small, round, green unripe figs turn reddish orange upon ripening.
- High in phenolic acids, flavonoids, and phytosterols.
- Used for digestive health, cholesterol reduction, and antimicrobial properties.[6]
- Fibrous, deep-seated roots with detoxifying properties.
- Contains alkaloids, glycosides, and tannins, aiding kidney function and immunity.[6]


Fig. 6. Roots

Latex (Milky Exudate)

- White milky sap with wound-healing, antimicrobial, and pain-relief properties.
- Used in skin infections and ulcer treatments.[6]

Medicinal Applications and Pharmacological Significance

- Antiulcer Activity: Protects the stomach lining and accelerates ulcer healing.
- Antioxidant Properties: Rich in flavonoids and phenolics, preventing oxidative stress.
- Anti-Inflammatory and Analgesic Effects: Beneficial for arthritis and pain relief.
- Antimicrobial Effects: Effective against bacteria, fungi, and viruses.
- Antidiabetic Potential: Regulates blood glucose levels.
- Liver-Protective Effects: Guards against toxin-induced liver damage.

Some Common Causes of Mouth Ulcer

Mouth ulcers can sometimes be complicated by bacterial infections. Cluster figs are believed to have antibacterial properties that can help prevent or manage secondary infections in mouth ulcers.

Promoting Tissue Regeneration: The presence of antioxidants and other nutrients in cluster figs may support tissue regeneration and accelerate the healing process.[7]

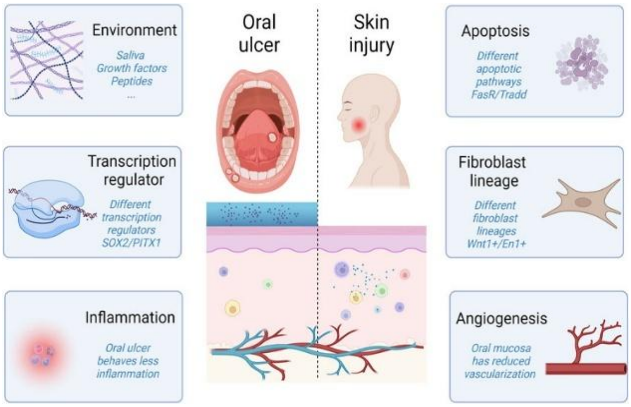

Fig. 7. Common Causes of Mouth Ulcer

Concise Summary of Herbal Gel Formulation

Herbal gel formulation entails the integration of bioactive compounds obtained from plants into a gel base to develop a stable, effective, and user-friendly medicinal product. The process begins with the selection of a suitable herbal extract,

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obtained through methods like hot extraction, cold maceration, or Soxhlet extraction, to ensure the presence of essential phytochemicals such as flavonoids, tannins, and phenolic compounds.[8]

Once the extract is obtained, it is blended with gelling agents like Carbopol, xanthan gum, or hydroxypropyl methylcellulose (HPMC) to provide the desired consistency and spread ability. Additional excipients such as preservatives, humectants, stabilizers, and penetration enhancers may be incorporated to improve the gel's shelf life, hydration properties, and therapeutic effectiveness. [8]

The formulation is then subjected to pre-formulation studies, including pH determination, viscosity analysis, spread ability tests, and stability studies, to ensure the gel maintains its intended physical and chemical properties over time. Microbial testing and in-vitro/in-vivo evaluation may also be conducted to validate the antimicrobial, anti-inflammatory, and wound-healing properties of the gel.[9]

Herbal gels offer a natural, non-toxic alternative to synthetic treatments, making them highly beneficial for conditions like ulcers, wounds, skin disorders, and inflammatory conditions. However, further clinical trials and optimization studies are essential to establish their efficacy, safety, and standardization for commercial use.[9]

TABLE 3. Literature Survey

S. N	Main Author & Year of publication	Publication Title/Journal	Reference no
1	Mousa O. et al. 2003	Journal of Ethnopharmacology	Singh, R., & Sharma, P. K. (2015). Formulation and evaluation of herbal gel
2	Rathee S. et al. 2007	Food Chemistry	Patel, S., & Patel, J. (2016). Formulation and evaluation of herbal anti-acne gel.
3	Ahmed F. & Urooj A. 2010	Pharmaceutical Biology	Jain, S., & Jain, N. (2017). Development and evaluation of herbal gel containing neem and turmeric for antimicrobial activity
4	Mandal S.C. et al. 2012	International Journal of Pharma and Bio Sciences	Deshmukh, P., & Patil, V. (2018). Formulation and evaluation of herbal gel containing Ficus carica and Azadirachta indica for wound healing.
5	Sharma N. et al. 2016	Journal of Herbal Medicine	Khan, A., & Ahmad, A. (2019). Development and evaluation of herbal gel containing Ficus racemosa
6	Pandit R. et al. 2018	Asian Pacific Journal of Tropical Biomedicine	Sharma, R., & Gupta, R. (2020). Formulation and evaluation of herbal gel containing Ficus racemosa and Curcuma longa for skin diseases.
7	Patel R. et al. 2020	Biomedicine & Pharmacotherapy	Patel, R., & Patel, M. (2021). Preparation and evaluation of herbal gel containing Ficus racemosa and Ocimum sanctum for wound healing.
8	Kumar V. et al. 2022	Natural Product Research	Patel, M., & Patel, R. (2022). Formulation and evaluation of herbal gel containing Ficus racemosa and Aloe vera for wound healing.
9	Gupta A. & Singh S. 2023	Journal of Ethnopharmacology	Singh, A., & Sharma, R. (2021). Development and characterization of Ficus racemosa-based herbal gel for antifungal activity.
10	Das D. & Roy P. (hypothetical) 2024	Phytomedicine Plus (anticipated)	Kumar, S., & Verma, P. (2020). Formulation and evaluation of Ficus racemosa gel for anti-inflammatory and analgesic activity.

Aim, Objective and Justification

Aim: Formulation and Evaluation of Anti-ulcer Herbal Gel from Cluster Fig

Objectives:

1. To extract from the bark, leaves, fruit of Ficus racemosa using hot extraction methods.
2. To formulate a stable herbal gel incorporating the Ficus racemosa extract.
3. To conduct pre-formulation studies (pH, viscosity, spread ability, stability) to ensure the gel's physical and chemical integrity.
4. To evaluate the herbal gel

Justification: Mouth ulcers are a common oral health issue with causes ranging from mechanical trauma to systemic diseases. Conventional treatments often involve synthetic drugs, which may cause side effects or resistance. Ficus racemosa, a plant with well-documented anti-inflammatory, antimicrobial, and antioxidant properties, offers a natural alternative. Its bioactive compounds, such as flavonoids and tannins, have shown potential in accelerating mucosal healing and preventing infections.[10] Despite its traditional use, there is limited research on standardized herbal formulations of Ficus racemosa for topical ulcer management. This study addresses this gap by developing a stable, non-toxic gel formulation, combining traditional knowledge with modern pharmaceutical techniques. The project aligns with the growing demand for natural therapeutics and contributes to evidence-based validation of herbal remedies, paving the way for future clinical trials and commercialization.[10]

II. Extraction of the Drug

Some Common Methods of Extraction

- Maceration
- Percolation
- Soxhlet Extraction (Hot Continuous Extraction)
- Decoction
- Infusion
- Ultrasound-Assisted Extraction (UAE)
- Microwave-Assisted Extraction (MAE)
- Supercritical Fluid Extraction (SFE)
- Hydro distillation

Reason for Selection of Soxhlet Extraction

Soxhlet extraction was selected for this research as it is an exceptionally effective and dependable technique for extracting bioactive compounds from plant sources. Unlike simple maceration or percolation, Soxhlet allows the solvent to repeatedly cycle through the plant sample, ensuring maximum contact and thorough extraction of both major and minor constituents. This continuous reflux process enhances the yield of target compounds without the need for large

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volumes of solvent, making it both effective and economical. Additionally, the system operates at a controlled temperature, which helps preserve heat-sensitive phytochemicals that might degrade under high heat in direct boiling methods. Its standardized procedure and widespread use in phytochemical and pharmaceutical research make it a trusted technique, ensuring consistency and reproducibility in results. Overall, Soxhlet extraction offers a balanced approach between efficiency, cost, and quality, making it an ideal choice for extracting valuable compounds from the *Ficus flaccuosa* plant. [12]

Process of Extraction

The process begins with the preparation of plant material, where stem branches, small leaf parts, and the backbone of the Udumbara plant (*Ficus flaccuosa*) are collected. This is followed by the first soaking step, in which the plant material is soaked in a mixture of 400 ml alcohol and 400 ml water (in a 50:50 ratio) for 24 hours. After this soaking period, the plant material is removed. The next step involves evaporation and powder formation, where the remaining liquid is heated in a heating mantle at 80°C until all the liquid evaporates and only powdered particles remain.[12]

Practical Representation of Extraction

Fig.8(a). Parts of plants immersed in ethanol and water

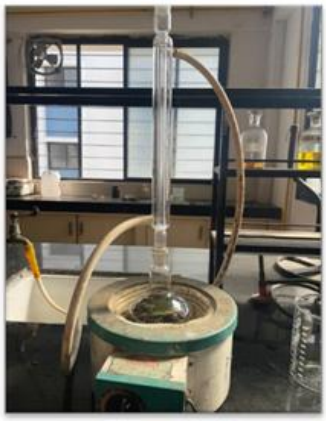

Fig.8(b). Extraction process

Fig.8(c). Using soxhlet extraction apparatus

Fig.8(d). Reducing the volume of the extracted ingredient

Fig.8(e). Placing the extraction into petri-plates

Fig.8(f). Sun drying the extraction

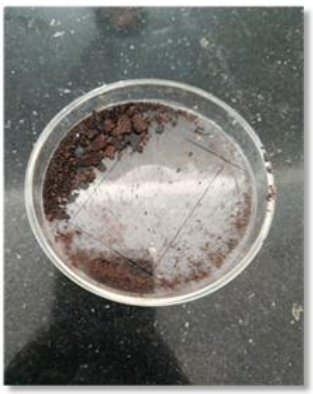

Fig.8(g). Practical yield

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III. Pre-Formulation Studies

TABLE 4. Organoleptic Characteristics

Sr No	Parameters	Inferences
1	Colour	Brown
2	Odour	Characteristic
3	Texture	Rough

TABLE 5. Solubility

Sr No	Solvent	Solubility
1	Water	Soluble
2	Chloroform	Soluble
3	Ethanol	Highly Soluble
4	Ether	Soluble

IV. Formulation of Herbal Gel

Selection of Excipient

1. Gelling Agents: These provide the gel base and determine the consistency and viscosity of the formulation.[13]
   - Natural Polymers:
   - Carbopol (e.g., Carbopol 940, 934)
   - Hydroxypropyl methylcellulose (HPMC)
   - Sodium carboxymethyl cellulose (NaCMC)
   - Xanthan gum
   - Aloe vera gel
   - Synthetic Polymers:
   - Polyvinyl alcohol (PVA)
   - Polyvinylpyrrolidone (PVP)
2. Solvents: These dissolve or disperse the herbal extract and other excipients.
   - Water (purified)
   - Ethanol (for solubility enhancement)
   - Glycerine (also acts as a humectant)
   - Propylene glycol (solvent and preservative)
3. Preservatives: To prevent microbial growth and extend shelf life.[14]
   - Methylparaben
   - Propylparaben
   - Benzalkonium chloride
   - Phenoxyethanol
4. Humectants: To retain moisture and prevent the gel from drying out.[15]
   - Glycerine
   - Propylene glycol
   - Sorbitol
5. Emollients: To soften and soothe the skin.
   - Almond oil
   - Jojoba oil
   - Shea butter
   - Dimethicone
6. Penetration Enhancers: To improve the absorption of herbal actives through the skin.
   - Oleic acid
   - Transcutol P
   - Menthol
   - Terpenes (e.g., limonene)
7. pH Adjusters: To maintain the optimal pH for stability and skin compatibility.[16]
   - Triethanolamine (TEA)
   - Citric acid
   - Sodium hydroxide
8. Antioxidants: To prevent oxidation of herbal actives.
   - Ascorbic acid (Vitamin C)
   - Tocopherol (Vitamin E)
   - Butylated hydroxytoluene (BHT)
9. Fragrances and Colorants: Optional, to improve sensory appeal.
   - Use natural fragrances and colorants to maintain the herbal theme.

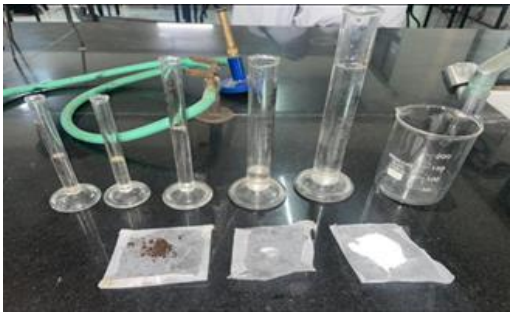

Fig. 9. Selected excipients

TABLE 6. Master formula

Ingredient	Quantity
Powdered Extract	0.8 g
Propylene glycol	75 ml
Propyl paraben	0.1 g
Carbopol	2 g
Methyl paraben	0.9 g
Glycerin	2.5 ml
Alcohol	7.5 ml
Distilled water	48 ml
Peppermint oil	1.5 ml

Preparation of Herbal Gel

Fig. 10(a). Preparation of Aqueous Phase

Fig. 10(b). Incorporation of Herbal Extract

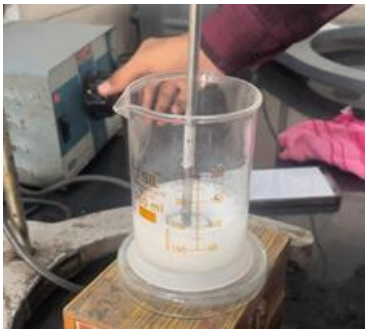

Fig. 10(c). Mixing

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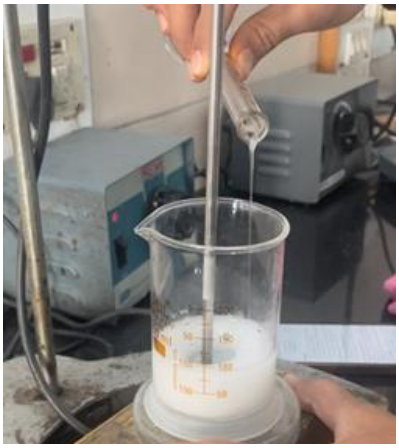
Fig. 10(d). Addition of glycerine

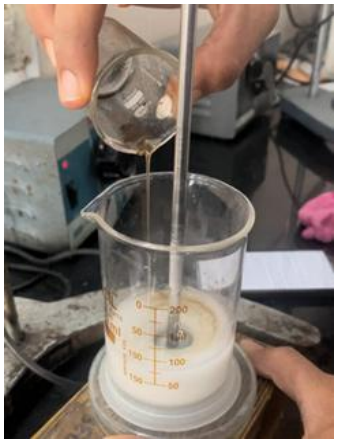
Fig. 10(e). Addition of Alcohol

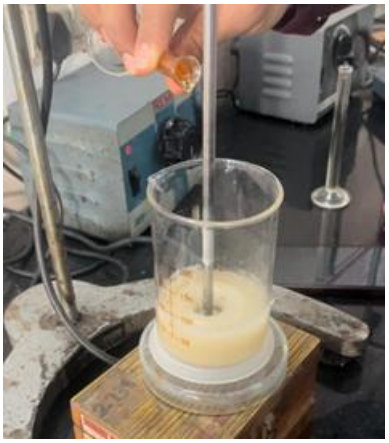
Fig. 10(f). Addition of Preservatives

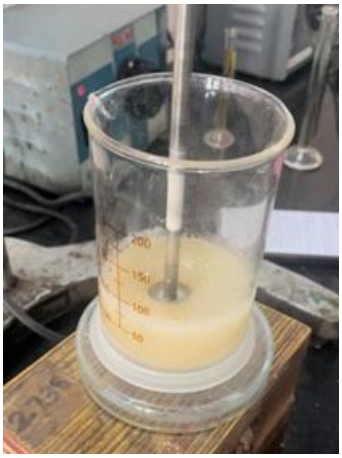
Fig. 10(g). Final Mixing and Homogenization

V. Evaluation Parameters of Cluster Fig Herbal Anti-Ulcer Gel.

1. Organoleptic Characteristics/Visual Inspection: To determine the colour, texture and the consistency of the herbal anti-ulcer gel the formulated herbal anti—ulcer gel should be Semi Solid, Smooth and free from aggregates. The colour of the gel should be light whitish to light Yellowish depending on the herbal ingredients. It should have a mild herbal smell. It should have a uniform texture.[17]

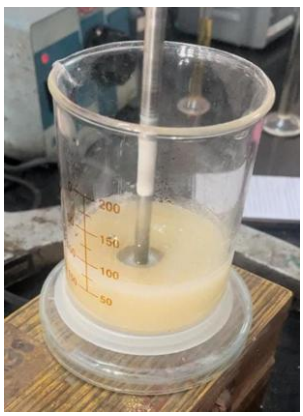
Fig. 11. Physical Appearance/Visual Inspection

2. Functional Properties: The gel should have strong adhesive property, providing moisture and should have high water content. The retention on the oral mucosal surface should be good to provide desired effect on the site of application [18]
3. Determination of pH:

The pH of the anti-ulcer gel is determined using by Analab's instrument pH meter (model no.11) and it should be in the range 6 to 7. It should be slightly acidic to neutral as of oral mucosa. It should match the natural pH of the oral mucosa and to avoid any kind of irritation.[19]


Fig. 12. pH Determined

4. Viscosity Determination: In an antiulcer gel, viscosity indicates the gel's consistency and flow resistance, which

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affects its ability to spread across and stick to the oral mucosa. Viscosity of the anti-ulcer gel was determined using Brookfield Viscometer. Measure at different shear rates to determine if the gel is pseudoplastic which is preferred for oral gels. The viscosity range should be between 1500 to 2000 cps.[20]

Fig. 12. Determination by Brook field viscometer

5. Spread ability: Determines how easily the gel can be applied onto the surface. The amount of duration in seconds required to separate the slides was recorded after applying weight. Each formulation's spread ability was quickly determined. Furthermore, dissemination of value is essential for therapeutic efficacy. [21] The spread ability is computed using the formula below. Spread ability $(S) = M \times L / T$ Where M is the amount of gel placed on the slide, L is the glass slides length and T is the amount of time taken to separate the slides. The gel should not be difficult to spread.[22]


Fig. 13. Determination of Spread ability

6. Stability Studies: There should be no significant change in pH, Viscosity, Colour, Drug content, Microbial contamination over a specific period under room temp, accelerated stability conditions, Freeze thaw stability. Physical stability- Checking changes in the Appearance, Colour, pH, Viscosity over time. Chemical Stability- Assessing whether active ingredients remain effective over time Storage Conditions- Effect of different temperatures and humidity conditions on the anti-ulcer gel.[23]
7. Skin Irritation Test: Ensuring the gel is non-irritating and safe for topical application and does not cause any harm or any kind of side effect on the site of application. There were three volunteers involved. Two inches square of the volunteer's hand skin was treated with one gram of cluster fig gel. The skin was visually examined, and various parameters were assessed, including erythema (redness), edema (swelling), and other signs of irritation such as itching burning sensation.[24]


Fig. 14. Skin Irritation Test on Hand

8. Packaging Evaluation: The packaging maintained its structural integrity throughout the study, indicating adequate protection against external damage.[25] No visible chemical interactions or degradation between the gel and the packaging material, ensuring safe containment. The absence of leakage confirms that the closure system is effective, ensuring the product's stability and hygiene. The labelling remained intact and readable, even under stress conditions, ensuring clear identification and patient information.[26] The packaging material used for the Cluster Fig Herbal Anti-Ulcer Gel is suitable and effective in providing protection, stability, and convenience. The packaging components are found to be compatible and user-friendly, ensuring product safety and quality throughout its shelf life.[27]
9. Labelling Evaluation: The text on both the bottle is clear and easy to read. Labels remained securely attached to the packaging material, even under stressed conditions.[28] All required information was present, including product identity, active ingredients, manufacturer information, and usage instructions. The label design adheres to FDA/AYUSH guidelines for topical herbal formulations. The labelling provides accurate, essential information for consumer safety and proper usage.[29] The instructions and warnings are clearly stated, providing adequate caution for safe use. The design is attractive and professional, enhancing the product's marketability and consumer appeal. The labelling of the Cluster Fig Herbal Anti-Ulcer Gel meets all the necessary requirements for clarity, durability, accuracy, and regulatory compliance. The labels

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are designed to be informative, appealing, and user-friendly, ensuring effective communication with consumers.[30]

FORMULATION OF CLUSTER FIG ANTI ULCER GEL LABEL		
INGREDIENTS:	QTY:	STORAGE: "STORE IN A COOL AND DY PLACE AND PROTECT FROM LIGHT,"
API (CLUSTER FIG POWDER	0.8 gm.	DIRECTIONS TO USE: APPLY A THIN LAYER TO AFFECTED AREA 2-3 TIMES DAILY AS PER THE RECOMMENDED DOSE DIRECTED BY PHYSICIAN.
CARBOPOL	2 gm.	
PROPYLENE GLYCOL	7.5 ml.	
METHYL PARABEN	0.9 gm.	PRECAUTIONS: "KEEP OUT OF REACH OF CHILDREN".
PROPYL PARABEN	0.1 gm.	MFG AT: ALLANA COLLEGE OF PHARMACY, PUNE-411001.
GLYCERIN	2.5 ml.	
ALCOHOL	7.5 ml.	MFG DATE: 18/02/2025. EXP DATE:18/02/2026.
DISTILLED WATER	48 ml	

Fig.15.Overview of Label

TABLE 7 Evaluation Table Result:

Sr No	Parameters	Formulated Herbal Anti-Ulcer Gel (Cluster Fig) Result
1	Colour	Light Yellowish.
2	Odor	Mild Herbal Minty Smell.
3	Appearance	Translucent Appearance.
4	Consistency	Semi Solid, Gel Like Consistency
5	Texture	Smooth Texture.
6	Homogeneity	Uniform With No Phase Separation.
7	Feel	Soothing And Numbing Effect.
8	Bio adhesion	Good Adherence Property.
9	Hydration	Moisturize the Area.
10	Moisture Content	High Water Content.
11	pH	6.5
12	Viscosity	1628 Cps
13	Spread ability	1. Good Spread ability Is Observed on Individual's Hands. 2. 0.5gm/Sec (Grams- Centimetre Per Second) The Gel Spreads Easily with Minimal Force.
14	Stability Studies 1. Physical Stability 2. Chemical Stability. 3. Storage Conditions.	The Appearance of The Anti-Ulcer Gel Remains Constant Over Time. The Active Ingredients Remain Effective Over the Time Showing Great Effect. Temperature- Store at Cool Temperature 20 To 25 Degree Celsius. Humidity- Relative Humidity Below 60%.
15	Skin Irritation Test	No Skin Irritation Observed on Site of Application.
16	Packaging Evaluation	The Container Is Compatible, Non-Reactive and Provide Adequate Protection to the Anti-Ulcer Gel.
17	Labelling Evaluation	Proper Labelling with All Necessary Information Provided.

VI. CONCLUSION

The present study successfully demonstrated the formulation and evaluation of an anti-ulcer herbal gel utilizing extracts from the Cluster Fig (Ficus racemosa), a plant known for its traditional medicinal applications. The bioactive constituents present in its bark, leaves, and fruits—such as flavonoids, tannins, and phenolic compounds—were effectively incorporated into a stable gel base using scientifically sound methods like Soxhlet extraction and thorough pre-formulation evaluation. The final gel formulation exhibited favourable organoleptic properties, optimal pH for oral application, appropriate viscosity, good spread ability, and excellent bio-adhesive characteristics. Moreover, the product was found to be stable under various storage conditions, non-irritating to the skin, and safe for topical use. These findings reinforce the potential of Ficus racemosa as a natural and effective remedy for managing mouth ulcers, offering a safer alternative to synthetic treatments with improved patient compliance. Although the results are promising, further clinical investigations are essential to validate the therapeutic efficacy and safety of this herbal formulation in a broader patient population. Nonetheless, this research contributes valuable insight toward the development of evidence-based, plant-derived topical therapies for oral ulcer management.

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