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“Formulation and Evaluation of Topical Herbal Gel Incorporated with *Ficus Racemosa* Bark Extract for Anti-Inflammatory Activity”

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Abstract: The ethanolic extract of *Ficus racemosa* bark was investigated for its potential anti-inflammatory activity. Preformulation studies confirmed the presence of important phytoconstituents such as polyphenols, flavonoids, tannins, and terpenoids, which are known to inhibit inflammatory mediators and contribute to therapeutic activity.

A topical gel was formulated using the ethanolic bark extract as the active ingredient and Carbopol 934 as the gelling agent. Other excipients included propylene glycol (penetration enhancer), polyethylene glycol 200 (solvent and humectant), methyl paraben (preservative), and distilled water. Triethanolamine was added dropwise to neutralize the formulation and maintain a skin-friendly pH. The formulation process ensured uniform dispersion of the extract, resulting in a smooth and stable gel.

The prepared gel was evaluated for physical appearance, pH, viscosity, and spreadability. It exhibited a smooth texture, good consistency, attractive appearance, and no phase separation. The pH was within the acceptable range for topical application, indicating minimal risk of skin irritation. Spread ability studies showed that the gel could be easily applied over the skin surface. Viscosity measurements confirmed suitable rheological properties, ensuring ease of application and adequate retention at the site of action. By performing in-vitro anti-inflammatory studies the extract containing gel showed notable anti-inflammatory activity when compared with the standard drug.

Overall, the study demonstrated that *Ficus racemosa* bark extract can be successfully incorporated into a topical gel formulation, offering a promising herbal alternative for the management of inflammatory conditions through localized action while meeting the growing demand for natural therapeutic products.

Keywords: Anti-inflammatory activity, *Ficus racemosa* bark, Herbal gel, Phytoconstituents

Introduction:

In recent years, significant attention has been focused on the development of safe, biocompatible, and environmentally sustainable pharmaceutical dosage forms derived from natural sources. Conventional synthetic drugs and topical formulations, although effective, are often associated with drawbacks such as skin irritation, toxicity, high cost, and limited biocompatibility. These limitations have encouraged the exploration of plant-based formulations as safer and more economical alternatives [1, 2, 5]. Among them, herbal topical gels have gained importance due to their ease of application, improved patient compliance, and ability to deliver active constituents directly to the affected site.

Topical gels are semi-solid preparations that provide localized therapeutic action and enhance drug penetration through the skin. Their non-greasy nature, good spread ability, and controlled drug release properties make them suitable for the management of inflammation, pain, and various skin disorders [5, 6, 7, 8]. Incorporation of herbal extracts into gel formulations offers the additional advantages of reduced side effects and multiple pharmacological activities [5, 6]

Ficus racemosa (Cluster Fig) is a well-known medicinal plant widely used in traditional medicine. The bark contains various bioactive phytoconstituents, including flavonoids, tannins, phenolic compounds, saponins, and terpenoids, which possess significant anti-inflammatory, antioxidant, and wound-healing properties [1, 2, 12, 15]. The ethanolic extract of *Ficus racemosa* bark has been reported to inhibit inflammatory mediators and reduce oxidative stress, making it a promising candidate for topical therapeutic applications.

The selection of suitable excipients plays a vital role in the effectiveness and stability of herbal gels. Carbopol 934 is used as a gelling agent because of its excellent thickening and gel-forming properties. Polyethylene glycol 200 acts as a solvent and enhances the solubility of active constituents, while propylene glycol functions as a penetration enhancer and humectant. Methyl paraben and propyl paraben are incorporated as preservatives to prevent microbial contamination and improve shelf life [5, 6, 7, 8].

Therefore, the present study focuses on the formulation and evaluation of an anti-inflammatory topical gel containing ethanolic extract of *Ficus racemosa* bark, aiming to develop an effective, safe, stable, and patient-friendly herbal formulation for the management of inflammatory conditions.

Materials and Methods:

List of materials with their use and sources:

Table 1: List of materials with their use and sources

Sr.No.	Material	Use	Sources
1.	Ethanolic Extract of <i>Ficus racemosa</i> bark	It Shows anti-inflammatory activity	<i>Ficus racemosa</i> plant
2.	Carbopol 934	Used as polymer/swelling agent	SIGMA-ALDRICH LTD.
3.	Triethanolamine	Emulsifying agent and pH modifier	RESEARCH-LAB FINE CHEM INDUSTRIES
4.	Propylene glycol	Humectant	UNICHEM KOLHAPUR
5.	PEG 400	Plasticizer	S.D.LAB CHEMICAL CENTRE MUMBAI
6.	Methyl paraben	Preservative	S.D.LAB CHEMICAL CENTRE MUMBAI

Experimental methods:

Collection and Authentication:

The bark of *Ficus racemosa* used in the present study was collected from the Ajara region of Kolhapur district, Maharashtra. Botanical authentication of the plant material was carried out by the Head of the Department of Botany at Shivraj College of Science, Gadhinglaj, an institution affiliated with Shivaji University [4, 11].

Drying and Extraction of Herb:

The bark of *Ficus racemosa* was shade-dried and subsequently milled into a coarse powder using an electric grinder. A quantity of 100 g of the powdered material was transferred into a Soxhlet thimble for extraction. Ethanol (500 mL) served as the extraction medium and was placed in a round-bottom flask connected to the Soxhlet apparatus. Upon heating with an isomantle, the solvent vaporized, condensed, and repeatedly passed through the plant material. When the extraction chamber reached its maximum level, the solvent containing dissolved constituents returned to the flask through the siphon tube, allowing continuous extraction. The process was maintained for nearly 60 h and completed approximately 32–33 extraction cycles. After removal of the solvent, 15.5 g of concentrated bark extract was obtained and retained for subsequent experimental work. [4, 11, 12]

Organoleptic Evaluation of *Ficus racemosa* bark extract:

Organoleptic assessment of the *Ficus racemosa* bark extract was carried out by examining its physical attributes, including color, odor, consistency, and overall appearance. [3, 4, 11]

Solubility Study of *Ficus racemosa* bark extract:

The solubility profile of the *Ficus racemosa* bark extract was determined by evaluating its ability to dissolve in different solvents. A known quantity of the extract was treated with selected solvents, and the extent of dissolution was observed and recorded to assess its solubility characteristics. [3, 12]

Phytochemical screening:

The phytochemical screening of the *Ficus racemosa* bark extract was carried out to identify the presence of various bioactive constituents such as Alkaloids, Glycosides, Flavonoids, Saponins, Tannins and phenolic compounds. Standard qualitative tests were performed to detect different classes of phytochemicals, and the results were recorded based on the characteristic reactions observed during the analysis [3, 4, 11, 12]

Compatibility study:

Extract–excipient compatibility was evaluated using FTIR spectroscopy to investigate possible interactions between the *Ficus racemosa* bark extract and formulation excipients. Comparative analysis of the FTIR spectra was performed, and the results were used to assess the compatibility of the formulation ingredients. [9, 10]

Formulation Table of Herbal Gel:**Table 2:** Formulation table of Herbal Gel

Batch	<i>Ficus racemosa</i> bark extract(g)	Carbopo 1934 (g)	Triethanolamine (mL)	Propylene glycol (mL)	PEG 400 (mL)	Methyl paraben (g)	Distilled water (mL)
F1	0.5	0.25	0.5	3	0.45	0.25	Up to 50
F2	0.5	0.5	0.5	3	0.67	0.25	Up to 50
F3	0.5	0.75	0.5	3	0.89	0.25	Up to 50
F4	0.5	1	0.5	3	0.89	0.25	Up to 50

Formulation of Herbal Gel:

Carbopol 934 was gradually dispersed in a measured quantity of distilled water with continuous stirring to ensure uniform wetting and to avoid the formation of lumps. The dispersion was then allowed to hydrate and swell for approximately 30 minutes. After complete swelling, the mixture was stirred mechanically at 1200 rpm for 30 minutes to obtain a homogeneous gel base. In a separate beaker, methyl paraben was dissolved in propylene glycol with constant stirring until a clear solution was formed. Subsequently, 1 g of *Ficus racemosa* bark extract was incorporated into the Carbopol gel base. Polyethylene Glycol 400 (PEG 400) was then added as a co-solvent and spreadability-enhancing agent, followed by continuous stirring to ensure uniform mixing. The preservative solution was slowly added to the gel base, and the formulation was mixed thoroughly. Distilled water was added to make up the final volume to 50 mL. Triethanolamine was then added dropwise with continuous stirring until the pH was adjusted to 6.8–7.0, resulting in the formation of a smooth and consistent gel. The prepared herbal gel was packed in a suitable container and stored at 4°C for subsequent evaluation studies [5,6,7,8]

Evaluation of Topical Herbal Gel:**Physical appearance:**

The physical appearance of the formulated herbal gel was evaluated by visual inspection. Parameters such as color, odour, homogeneity, consistency, transparency, and the presence of any particulate matter were observed and recorded to assess the overall quality and aesthetic characteristics of the formulation. [5, 6]

pH Determination:

For pH determination, 1 g of the formulated herbal gel was dispersed in 100 mL of distilled water and allowed to stand for 2 h to obtain a uniform dispersion. Following equilibration, the glass electrode of a calibrated digital pH meter was immersed in the prepared sample, and the pH was recorded after stabilization of the reading. Each formulation was analyzed in triplicate, and the mean pH value was calculated and reported. [5, 6]

Spreadability:

The spreadability of the formulated *Ficus racemosa* herbal gel was evaluated using the glass slide method. Approximately 1 g of the gel formulation was placed within a pre-marked circular area (1 cm diameter) on a glass slide. A second glass slide of known weight was carefully positioned over the sample, and an additional weight of 100 g was applied for 5 min to facilitate uniform spreading of the gel. After removal of the load, the extent of spreading was assessed by measuring the increase in the diameter of the gel film. For determination of spreadability, a weight of 10 g was attached to the upper slide, and the time required for the two slides to separate was recorded. The spreadability coefficient was calculated using the following equation: Spreadability (S) = $M \times L / T$

Where: M = Weight attached to the upper slide (10 g), L = Length of the glass slide (6.8 cm), T = Time taken for complete separation of the slides (s) [5,6]

Viscosity:

The viscosity of the formulated *Ficus racemosa* herbal gel was determined using a Brookfield viscometer. An adequate quantity of the gel was transferred into a clean sample container, ensuring the absence of air bubbles. The appropriate spindle was immersed in the formulation, and the measurement was carried out at room temperature. The spindle was rotated at a predetermined speed until a stable reading was obtained. Viscosity values were recorded in centipoise (cP), and each formulation was analyzed in triplicate to ensure reproducibility. The mean viscosity value was calculated and reported. [5, 6]

In-Vitro Anti-inflammatory Activity:

The anti-inflammatory activity of the formulated *Ficus racemosa* herbal gel was evaluated using the egg albumin protein denaturation assay. The reaction mixture (10 mL) consisted of 0.4 mL of fresh hen's egg albumin, 5.6 mL of phosphate-buffered saline (PBS, pH 6.4), and 100 μ L of the test sample. The control was prepared using an equal volume of double-distilled water in place of the test sample. The reaction mixtures were incubated at $37 \pm 2^\circ\text{C}$ for 15 min and subsequently heated at 70°C for 5 min. After cooling to room temperature, the absorbance was measured at 660 nm using a UV-Visible spectrophotometer, with the vehicle serving as the blank. Diclofenac sodium was used as the reference standard and was subjected to the same experimental conditions. The percentage inhibition of protein denaturation was calculated using the following equation:

$$\% \text{ Inhibition} = [(C - T) / C] \times 100$$

Where C represents the absorbance of the control and T represents the absorbance of the test sample. [13, 14]

Result and Discussions:**Percentage Yield:**

Table 3: Percentage yield of *Ficus racemosa* bark extract

Plant	Percentage yield
<i>Ficus racemosa</i> bark extract	15.5%

Organoleptic characteristics of *Ficus racemosa* bark extract:

Table 4: Organoleptic characteristics of *Ficus racemosa* bark extract

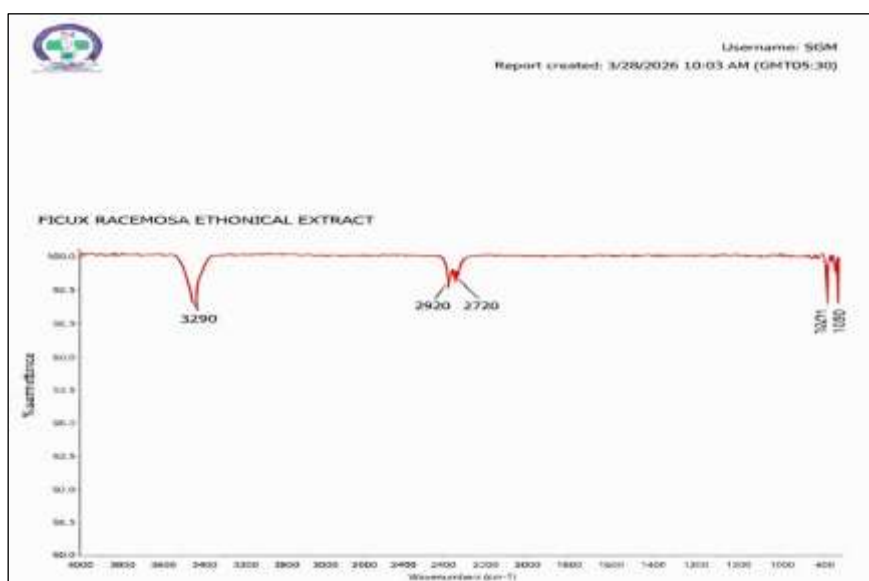
Sr. No.	Parameter	Method	Observation
1.	Physical state	Visual observation	Semi-solid
2.	Colour	Visual observation	Dark brown
3.	Odour	By smelling	Astringent

Solubility study of *Ficus racemosa* bark extract:**Table 5:** Solubility study of *Ficus racemosa* bark extract

Sr. No.	Solvent	Observation
1.	Distilled water	Sparingly to moderately soluble
2.	Ethanol	Freely soluble
3.	Methanol	Freely soluble
4.	Chloroform	Insoluble
5.	Acetone	Moderately soluble

Phytochemical screening of *Ficus racemosa* bark extract:**Table 6:** Phytochemical screening of *Ficus racemosa* bark extract

Sr. No.	Phytochemical test	Observation	Inference
1.	Foam Test	Persistent foam formed	Saponins present
2.	Ferric chloride Test	Greenish black coloration appeared	Tannins/Phenols present
3.	Shinoda Test	Pink coloration Developed	Flavonoids present
4.	Zinc HCL acid reduction Test	Red coloration appeared	Flavonoids present
5.	Keller-Killiani Test	Reddish-brown ring at interface	Cardiac glycosides present
6.	Benedict's Test	Brick-red ppt formed	Reducing sugars present
7.	Wagner's Test	Reddish-brown ppt formed	Alkaloids present
8.	Salkowski reaction	Reddish-brown coloration	Steroids/terpenoids present
9.	Dragendroff's Test	Orange-Red ppt	Alkaloids present
10.	Million's Test	White ppt turn red on heating	Proteins present
11.	Million's Test	White ppt	Tannins present

Compatibility study:**Fig.1:** FTIR of *Ficus racemosa* bark extract

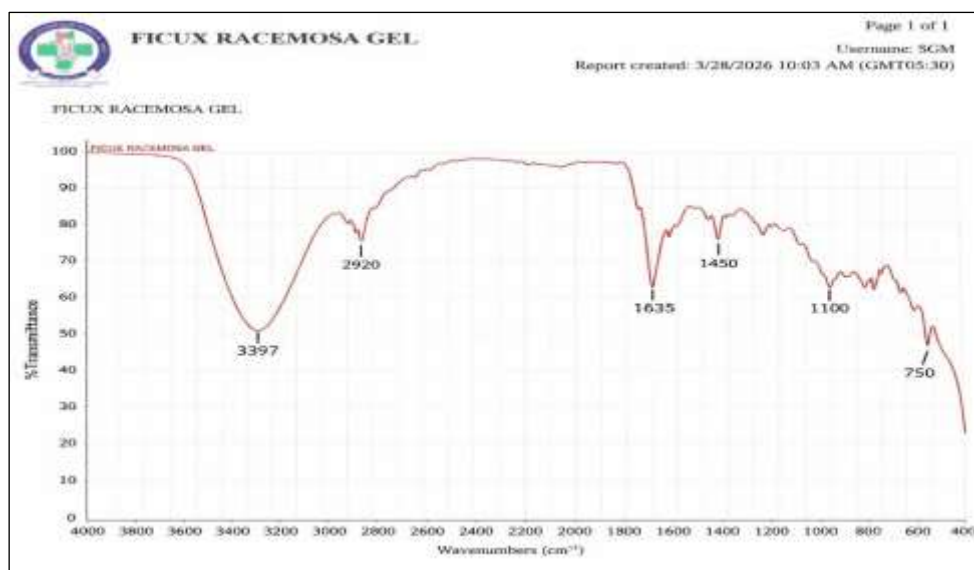


Fig. 2: FTIR of physical mixture

Formulation of Herbal Gel:



Fig.3: Formulation of Herbal Gel

Evaluation of Herbal Gel:

Physical appearance

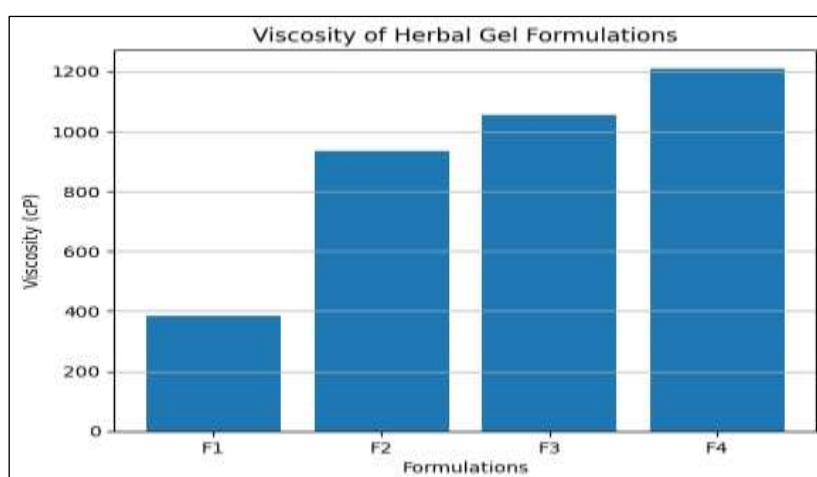
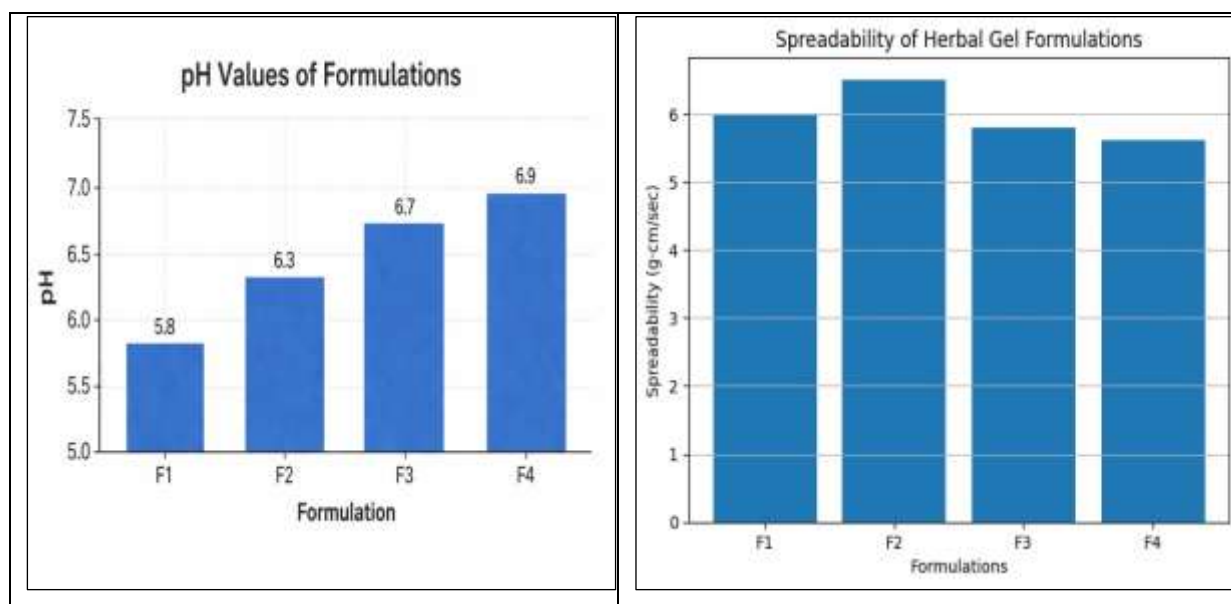
Table 7: Physical appearance of Herbal Gel

Formulation	F1	F2	F3	F4
Colour	Reddish-Brown	Reddish-Brown	Reddish-Brown	Reddish-Brown
Odour	Astringent	Astringent	Astringent	Astringent
Appearance	Opaque	Opaque	Opaque	Opaque
Consistency	Excellent	Excellent	Good	Good

pH, Spreadability, Viscosity:

Table 8: pH, Spreadability, Viscosity of Herbal Gel

Batch	pH	Spreadability(gm.cm/sec)	Viscosity(cps)
F1	5.8	6	384
F2	6.3	6.1	934
F3	6.7	5.8	1056
F4	6.9	5.6	1210



Graph 1: Graphical representation of pH, Spreadability and Viscosity

In-Vitro Anti-inflammatory activity By PDA Method:

Sr. No.	Sample Code	Concentration (µg/ml)	Protein Denaturation Assay					
			Absorbance at 660 nm					
			Test 1	Test 2	Test 3	Mean	% Inhibition	IC50 (µ/ml)
1	Control	-	1.54	1.54	1.54	1.54	-	-
2	Standard (Diclofenac Sodium)	20	1.40	1.37	1.39	1.39	9.74	72.21 %
		40	1.20	1.20	1.22	1.21	21.43	
		60	0.91	0.89	0.93	0.91	40.91	
		80	0.67	0.65	0.63	0.65	57.79	
		100	0.18	0.18	0.23	0.20	86.36	
3	Formulation 2	20	1.41	1.42	1.37	1.40	8.74	80.77 %
		40	1.26	1.27	1.24	1.26	19.40	
		60	0.98	1.00	0.95	0.98	35.91	
		80	0.79	0.80	0.78	0.79	48.70	
		100	0.27	0.28	0.26	0.27	82.30	

Fig. 4: In-Vitro Anti-inflammatory activity By PDA Method result**Summary and Conclusion:**

The present study was undertaken to formulate and evaluate an anti-inflammatory herbal gel containing ethanolic extract of *Ficus racemosa* bark. The bark was collected, authenticated, shade-dried, powdered, and extracted using the Soxhlet extraction technique with ethanol as the extraction solvent. The obtained extract was subjected to organoleptic evaluation, solubility studies, and preliminary phytochemical screening, which confirmed the presence of important bioactive constituents including flavonoids, tannins, phenolic compounds, and terpenoids. Compatibility between the extract and formulation excipients was assessed using FTIR spectroscopy, indicating the absence of significant interactions.

A topical herbal gel was successfully prepared using Carbopol 934 as the gelling polymer along with PEG 400, propylene glycol, methyl paraben, and triethanolamine. The formulated gel was evaluated for various physicochemical parameters such as appearance, pH, viscosity, and spreadability. The formulation exhibited a smooth texture, uniform consistency, satisfactory spreadability, appropriate viscosity, and a pH suitable for topical administration. No evidence of phase separation or instability was observed during the evaluation period. The anti-inflammatory potential of the formulation was assessed using the protein denaturation assay. The results demonstrated concentration-dependent inhibition of protein denaturation, indicating the therapeutic potential of the herbal gel. The observed activity may be attributed to the presence of phytoconstituents capable of modulating inflammatory responses and protecting proteins from denaturation.

Overall, the developed *Ficus racemosa* herbal gel showed satisfactory pharmaceutical characteristics and promising anti-inflammatory activity. The formulation offers a natural, economical, and patient-friendly approach for topical drug delivery and may serve as a potential alternative to conventional synthetic preparations. Further investigations involving advanced stability studies, safety assessment, and clinical evaluation are recommended to establish its long-term efficacy and therapeutic applicability.

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