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Formulation and Evaluation of Hydrogel containing Bauhinia Racemosa

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ABSTRACT

Hydrogels are three-dimensional networks made up of hydrophilic polymer links that are cross-linked chemically or mechanically. In order to speed up the healing process, it designates insoluble hydrophilic structures that have the capacity to absorb wound exudates and permit oxygen diffusion. The aim of present study is to formulate and evaluate hydrogel containing Bauhinia racemosa. For cure of wound healing number of synthetic drugs are obtainable but herbal remedies offer a promising alternative to synthetic drugs due to their biocompatibility, affordability, and low toxicity. A preliminary phytochemical study of Bauhinia Racemosa extract showed the presence of flavonoids and polyphenols both of which aid in wound healing and skin tissue regeneration. The F1-F7 formulations of *Bauhinia Racemosa* hydrogel for wound healing was formulated using different concentration Carbopol-940 (0.5-2%) and evaluated for appearance pH, Viscosity, Spreadability, Drug content, *In-vitro* drug diffusion and Stability studies. In those seven formulations the F5 shows better results as compare to other batches i.e. pH-5.6, Viscosity-9000 cps, Spreadability-6.9 cm, Drug content-83 % and good percentage of drug diffusionstudy i.e. 86.11%. ICH Q1A (R2) conditions for stability study over 3 months confirmed the formulation's stability with no major changes in appearance, pH, and drug content & *in vitro* drug diffusion. Appropriate selection of polymer and their proportions is a prerequisite for designing and developing a hydrogel. The prepared hydrogel showed better results for homogeneity, drug release rates & good stability when compared to marketed formulation.

Keywords: *Hydrogel, Wound Healing, Carbopol 940, Bauhinia Racemosa.*

1. INTRODUCTION

Hydrogel can be defined as a hydrophilic polymer which links with each other and not dissolve in water. The three-dimensional polymer networks formed in hydrogel have the capacity to incorporate large quantities of water, ensuring not only the humidenvironment necessary for wound healing, but also an excellent biocompatibility [1]. The water retaining properties of the hydrogel dressings are induced by the presence of hydrophilic groups in the polymer chains, with the higher water content assuring a porous, soft, and elastic structure, thus enhancing the compatibility with biological tissues [2]. Hydrogels are obtained from natural polymers, such as, gelatin, chitosan, dextran, cellulose, alginate or from synthetic ones, like polyvinyl alcohol (PVA), polyvinylpyrrolidone (PVP), or polyethylene glycol (PEG). Their physicochemical properties—which influence the clinical behavior of the dressing—depend on the chemical nature of the monomer (natural or synthetic), on the structure of the polymer chain (the resistance of the covalent bonds and intermolecular forces), and molecular weight, but also on the synthesis method of the polymer [3, 4].

Several herbal products are known for their healing enhancing potential. Among these, Bauhinia racemosa is a small tree belonging to the family Fabaceae, widely distributed across tropical regions, particularly in South and Southeast Asia. Known for its characteristic twin-lobed leaves, the plant has long been recognized in traditional systems of medicine, such as Ayurveda, Unani, and Siddha, for its therapeutic potential. Commonly referred to as "Bidi leaf tree" or "Mountain Ebony," Bauhinia racemosa holds a prominent place in the folklore of various cultures due to its medicinal applications. In traditional practices, different parts of the plant, including its bark, leaves, flowers, and seeds, have been used to treat a wide range of ailments such as inflammation, infections, gastrointestinal disorders, and diabetes. Its multifaceted uses in herbal formulations underscore the plant's rich pharmacological profile, which has attracted significant scientific attention in recent

years. Modern pharmacological studies have demonstrated that Bauhinia racemosa possesses diverse bioactivities, including antioxidant, anti-inflammatory, antimicrobial, antidiabetic, hepatoprotective, and anticancer properties. T The plant is rich in various phytochemicals, including flavonoids, steroids, terpenoids, and other bioactive compounds. Flavonoids such as kaempferol and quercetin are prominent in Bauhinia racemosa, known for their antioxidant, anti-inflammatory, and antimicrobial activities. These flavonoids play a significant role in protecting cells from oxidative stress and may help mitigate various diseases. Coumarins like scopoletin and scopolin are also present, contributing to the plant's potential therapeutic effects, including anticoagulant and anti-inflammatory properties.[5]

2. MATERIALS AND METHODS

A. Materials

The plant was selected on the basis of their anti inflammatory activities and their medicinal uses reported in the literatures. Leaves of Bauhinia Racemosa is collected from college campus and all ingredients Carbopol 940, Ethanol, Propyl paraben, Methyl paraben, Propylene glycol and Triethanolamine were procured from college lab.

B. Methods

Herbal Extract preparation:

Dried powdered of leaves of Bahunia Racemosa have been extracted with hydroalcoholic using maceration process for 48 hrs, filtered and dried using vacuum evaporator at 40^0C.

Identification of Active Constituents in the Herbal Extract:

Sr. No	Phytochemical	Test	Results
1	Alkaloids	Mayer's Test	Positive
2	Flavonoids	Shinoda Test	Positive
3	Tannins	Ferric chloride test	negative
4	Vitamins	Test. for vit. C	Positive
5	Phenols	Ferric chloride test	Positive
6	Glycosides	Kellar-killani test	Positive
7	Saponins	Froth formation test	Positive

Method of preparation of Hydrogel:

Add the required quantity of Carbopol 940 and in 100 ml distilled water. Keep these carbopol 940 solution as Gel base (Organic phase) for swelling two hours and mix it properly and named it solution as (A). In another beaker take 0.1% of Propyl paraben and methyl paraben in 5 ml distilled water and gently heat in water bath and named the solution (B) In another beaker take 10 ml of propylene glycol and 500 mg of herbal extract and named it solution(C) Now cool down the solution (B) and mix this solution with solution (C) and stir it properly. Now lastly add these both solutions to gel base solution (A) and mix this solution using homogenizer. Add triethanolamine to the final solution for maintaining pH and homogenize the final solution

Formulation Table:

Ingredients	Formulation Batches						
	F1	F2	F3	F4	F5	F6	F7
Bauhinia Racemosa (gm)	1	1	1	1	1	1	1
Carbopol 940(gm)	0.5	0.75	1.0	1.25	1.5	1.75	2.0
Propyle parabene (%)	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Methyl parabene (%)	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Propylene glycol (ml)	10	10	10	10	10	10	10
Triethanolamine (ml)	q.s	q.s	q.s	q.s	q.s	q.s	q.s

Distilled water	Up to 100 ml	Up to 100 ml	Up to 100 ml	Up to 100 ml	Up to 100 ml	Up to 100 ml	Up to 100 ml

Pharmaceutical Characterization of the Hydrogels:

1) Physical Appearance: The physical appearance of polyherbal gels is checked.

2) Homogeneity: The prepared gels were tested for homogeneity by visual inspection after the gels have been set in the container.

3) pH of the formulation: The pH of the developed gel formulation was determined by using digital ph meter by dissolving 1 gm of gel was dissolved in 100 ml distilled water and kept aside for two hours.

4)Spreadability of formulation: Spreadability of the formulation is carried out by using glass slide apparatus.

5) Viscosity: Viscosity of gel was determined by using Brookfield Viscometer by rotating spindle number from 6 at various speeds in revolution per minute.

6) Stability Studies: Stability study was conducted at room temperature and at accelerated stability is also conducted at various temperatures as per ICH Guidelines. It showed no significance change in properties of optimized formulation such as physical appearance, pH and in- vitro diffusion study and Spreadability. Accelerated Stability Studies were performed in a stability chamber over a period of three months on optimized formulation of gel. Sufficient quantity of gel formulation were packed in a stability container and kept in a stability chamber at temperature 40^0C and Relative humidity 75^0C Samples were taken on every month for the physical appearance, pH, In-vitro diffusion and Spreadability study were performed to determine stability profile.

Results and Discussion:

A. Preformulation Study:

Preliminary Phytochemical Screening: Preliminary phytochemical analysis of ethanolic extract of *Bauhinia Racemosa* revealed the presence of flavonoids, terpenoids, phenols, saponins.

Drug Characteristics:

Table No.1 Organoleptic characteristics of *Bauhinia Racemosa*

Sr.No	Parameters	Result
1	State	Powder
2	Appearance	Brown Fine Powder
3	Odour	Characteristic

Ash Value: **Table No.2 Ash Values of Bahunia Racemosa**

Ash Type	Values in w/w
Acid Insoluble	0.3-0.5%
Water Soluble	1-2%
Total Ash Value	6-8%

Moisture Content:

Table No. 3Moisture Content of Drugs

Drugs (API)	Moisture Content
Bahunia Racemosa	**6-9 %** w/w

Percentage Yield:

Drugs	Percentage Yield
Bahunia Racemosa	12.5 %

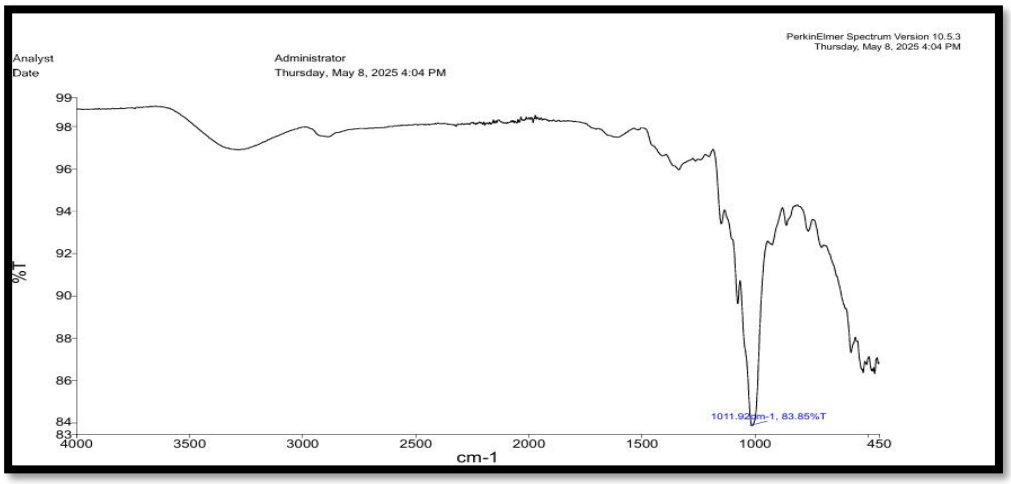
Solubility Profile:-

Table No.4 Solubility Profile of Bahunia Racemosa

Sr.no.	Solvent	Solubilityresult
1	Water	Soluble
2	Methanol	Freely Soluble
3	Ethanol	Soluble
4	Acetone	Slightly Soluble
5	Petroleumether	Very Slightly Soluble
6	Chloroform	Sparingly Soluble

Compatibility study:

a) FTIR of Bahunia Racemosa



b) FTIR of Drug and Excipients

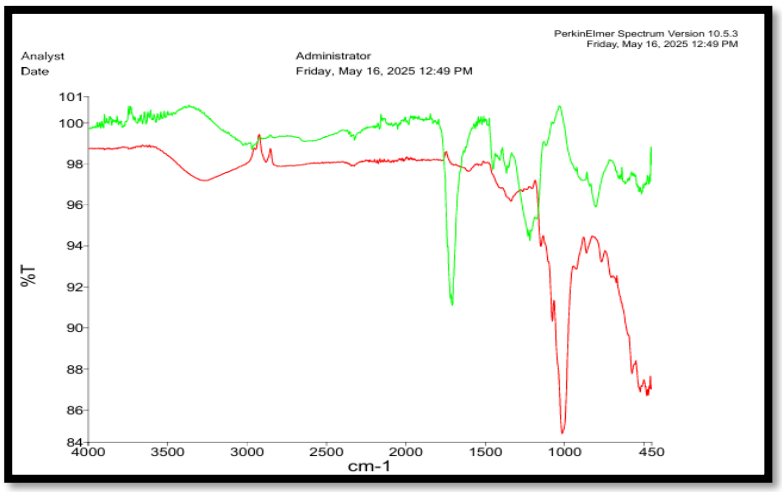


Table No. 5 Frequency of drug and excipients

Functional Group	Standard Frequency	Observed Peak
C=C Stretching	1650-1600	1601
C=O Stretching	1650-1600	1620
C-O Stretching	1260-1000	1100
O-H Bending	3400-3200	3300
C-H Bending	900-650	808

The FTIR study of herbal extracts were studied and compare with the standard frequency of functional group as mentioned in the table number 5. By interpreting the FTIR spectra, we can monitor the chemical fingerprint of the herbal formulation, detect possible interactions between plant constituents, and assess the consistency and quality of the extract. This plays a crucial role in the standardization and quality control of herbal products intended for pharmaceutical use

B.Evaluation of Hydrogels Formulations

1. Physical Appearance:

Table No. 6 Physical Appearance of Gel

Sr.No	Batch	Appearance
1	F1	Dark Yellow and Translucent
2	F2	Dark Yellow and Translucent
3	F3	Dark Yellow and Translucent
4	F4	Dark Yellow and Translucent
5	F5	Dark Yellow and Translucent
6	F6	Dark Yellow and Translucent
7	F7	Dark Yellow and Translucent

All batches were evaluated for appearance and it was found to be dark yellow and translucent.

2. Homogeneity:

Table No.7 Homogeneity of Gel

Sr. no	Batch	Homogeneity
1	F1	Homogenous
2	F2	Homogenous
3	F3	Homogenous
4	F4	Homogenous
5	F5	Homogenous
6	F6	Homogenous
7	F7	Homogenous

Developed gels were tested for homogeneity by visual inspection after the gels have been set in the container.

3. pH of the formulation

Table No. 8: pH of Gel

Sr.No	Batch	pH
1	F1	5.1
2	F2	5.3
3	F3	5.4
4	F4	5.5
5	F5	5.6
6	F6	5.2
7	F7	5.1

The pH of the developed gel formulation was determined by using digitalpH meter. The pH of optimized batch was found to be 5.6.

4. Viscosity

Table No. 9 Viscosity

Batch	Viscosity
F1	5000
F2	6000
F3	7000
F4	8000
F5	9000
F6	12000
F7	13000

Viscosity of gel was determined by using Brookfield viscometer by using spindle number 6. It was found between 5000 to 13000.

5. **Spreadability of formulation**

Table No. 10 Spreadability

Sr. No	Batch	Spreadability
1	F1	6.1
2	F2	6.3
3	F3	6.5
4	F4	6.7
5	F5	6.9
6	F6	6.8.
7	F7	6.7.

Spreadability of the polyherbal gel of optimized batch F5 was found to be 6.9 cm.

6. Drug Content

The drug content of all batches was in the range of 70.0 to 83.0% where the highest drug content was shown in F5 batches.

It was found highest in F5 batch and lowest in F1 batch.

Table No. 11 % Drug Content

Formulation Batches	Drug Content in %
F1	70%
F2	75%
F3	78%
F4	80%
F5	83%
F6	80%
F7	79%

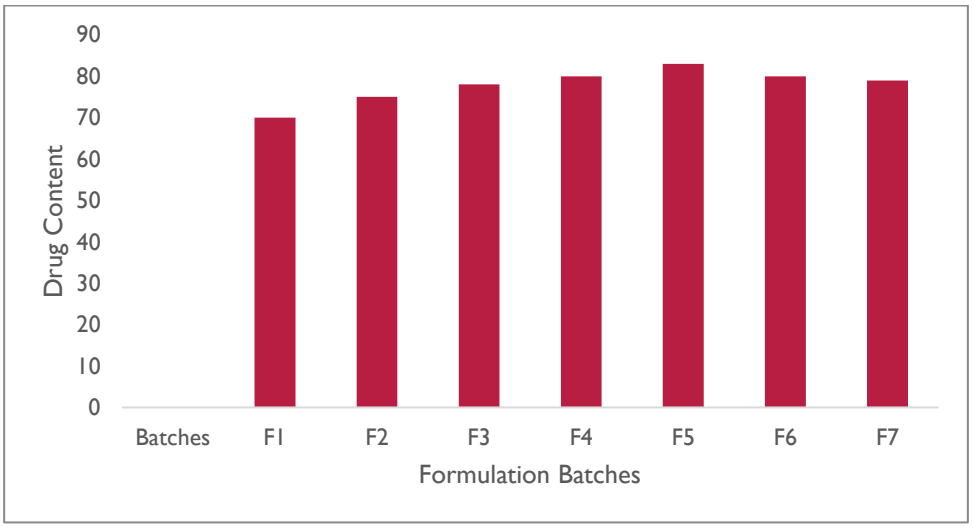


Figure No 3. Drug Content

7. *In vitro* Drug Diffusion

Table No. 12 *In-vitro* diffusion study

Time (hr)	F1	F2	F3	F4	F5	F6	F7
0	0	0	0	0	0	0	0
1	11.5	12.31	10.56	12.61	13.8	12.51	10.24
2	22.9	24.58	21.32	25.21	27.35	25.53	20.13
3	33.6	36.13	31.69	37.41	40.21	37.77	29.74
4	44.8	47.24	42.1	49.32	53.25	49.89	39.74
5	55.1	58.47	52.32	61.16	65.72	61.78	50.42
6	63.9	66.89	61.49	69.43	74.79	70.45	59.67
7	69.11	71.23	67.24	73.89	80.42	74.33	64.56
8	73.24	74.56	71.19	76.36	84.89	76.45	69.88

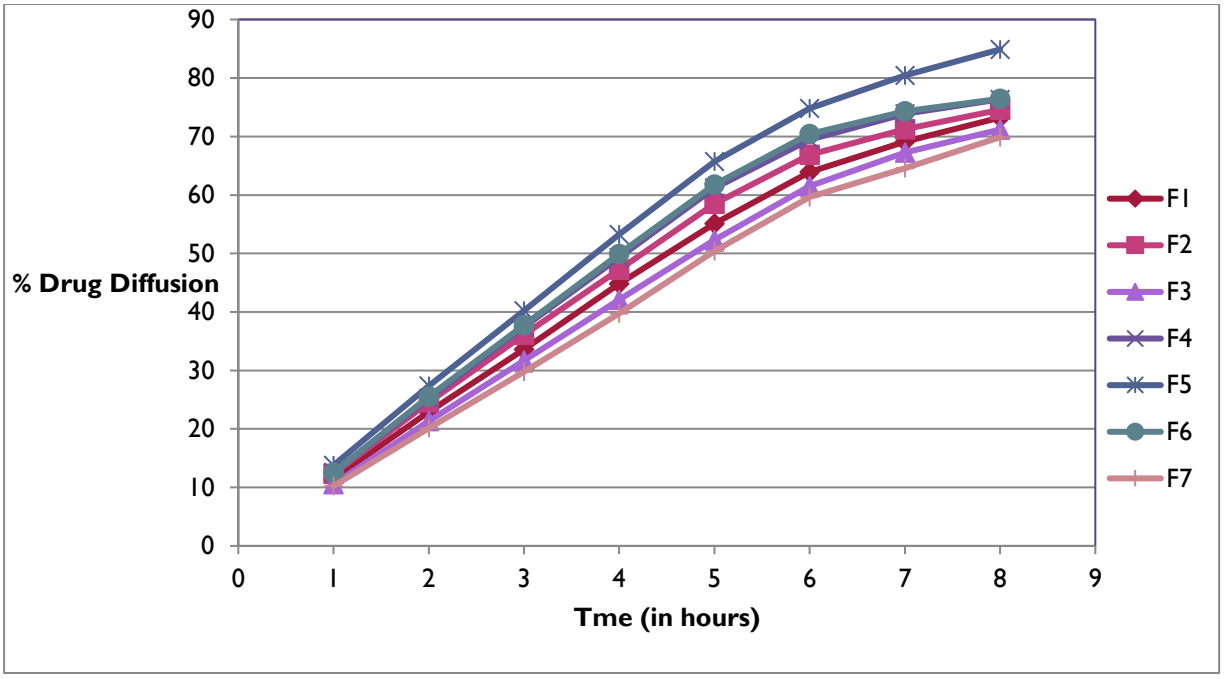


Figure No. 4 Drug Release

***In-vitro drug* diffusion:**

In vitro drug diffusion of polyherbal gel was carried out for 8 hours. The prepared gel formulations (F1)73.24, (F2)74.56, (F3) 71.19, (F4)76.36, (F5) 84.89, (F6) 76.45, (F7) 69.88. In F5 formulation concentration of carbopol 940 was 1.5% show good spreadability and drug release.

8. Stability Studies

The optimized formulation F5 was subjected to stability study at room temperature ($25^0\pm2^{0)}$ and $40^0C\pm2^0C$ with relative humidity RH=75±5 %. The optimized formulation F5 was analyzed for the change in appearance, pH and *in-vitro*drug diffusion study. There was light change observed in the pH, and *In-vitro*drug diffusion but the formulation were stable at both the temperatures. The optimized formulation F5 was more stable at room temperature. There was no change in the appearance and pH of the formulation but slight change observed in *In-vitro* drug diffusion.

Table No. 13 Stability Studies

Sr.No.	No. of Months	pH	Appearance	% Cumulative drug diffusion	
				$25^0C\pm2^0C$ RH=60±5%	$40^0C\pm2^0C$ RH=75±5%.
1	0	6.2	Yellowish Color	84.89	84.89
2	1	6.2	Yellowish Color	84.72	84.88
3	2	6.2	Yellowish Color	84.80	84.70
4	3	6.2	Yellowish Color	84.61	83.89

3. CONCLUSION

The *Bauhinia Racemosa* hydrogel for wound healing topical application was formulated using Carbopol-940 and evaluation were performed. Proper selection of polymers and their proportions is a prerequisite for designing and developing a transdermal drug delivery system. The present aim of the research work is to formulate and evaluate hydrogel containing herbal extract. The extract used in this work is Bauhinia racemosa which shows positive results for Phytochemical screening with alkaloids, tannins, saponins and negative with vitamins. Total seven formulations are prepared and evaluated for physical appearance, pH, Viscosity, Spreadability, in *vitro drug* release etc. pH was found to be 5.6 and Viscosity was found

to be 9000 cps and Spreadability was found to be 6.9 cm Extracts powder FTIR with other excipients are done. F5 batch show good percentage of drug release i.e. 84.89%. Drug content was found to be 83 % which is suitable for study. So at last we conclude that hydrogel shows a high degree of flexibility to penetrate into the natural tissue due to their significant water content. They have good transport properties and bio-compatible also. They also have a very good property is that they easily re-hydrate the wound bed and reduce wound pain also.

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