DEVELOPMENT AND EVALUATION OF EMULGEL FROM THE EXTRACT OF HIBISCUS ROSA-SINENSIS LINN

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ABSTRACT

The present study was performed to evaluate and develop the Emulgel from the extract of *Hibiscus Rosa-Sinensis*. The plant extract was isolated with the help of three different solvents. The formulation was prepared using different gelling agents such as Carbopol 934, Carbopol 940 and HPMC. Different parameters of the formulation were assessed and evaluated to identify whether the drug content incorporated into the gelling agent and release the drug. The parameters included PH, spreadability, viscosity, drug content, in vitro drug release. All the formulations examine it through these parameters. The result revealed that the formulation prepared by Carbopol 934 did have the significant drug release, spreadability, and viscosity. The formulations work well and are close to the Carbopol 934.

KEYWORDS *Hibiscus Rosa-Sinensis,* Herbal Emulgel, Anti-inflammatory Emulgel
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1. INTRODUCTION

Hibiscus Rosa-Sinensis is a species of hibiscus native to China. It is an evergreen shrub or small tree growing to 5 m tall. The leaves are deeply lobed with five or seven lobes, the flowers are large, up to 12 cm in diameter, and vary in color from white to pink to red. The fruit is a dry capsule containing numerous small seeds [1]. *Hibiscus Rosa-Sinensis* is widely cultivated in warm temperate and tropical regions for its showy flowers which bloom throughout the year.*Hibiscus Rosa-Sinensis* is not only ornamental but also has many uses. In traditional Chinese medicine, the flower buds are used as a tea to treat sore throat and upper respiratory infections while the flower petals are used to make a tonic that helps improve circulation. The leaves can be made into a poultice and applied externally to relieve pain from bruises and sprains while the fruit can be used as a laxative [2].

Hibiscus Rosa-Sinensis is a plant that has been used in Traditional Chinese Medicine for centuries. The pharmacological activity of *Hibiscus Rosa-Sinensis* has been studied extensively and it has been shown to have a wide range of medicinal properties [3]. Some of the most well-known and researched activities of *Hibiscus Rosa-Sinensis* include its ability to lower blood pressure, improve cardiovascular health, and boost immune system function. Additionally, *Hibiscus Rosa-Sinensis* has also been shown to possess anti-inflammatory, antibacterial, and antioxidant activity [4].

Hibiscus rosa-sinensis is a plant that has been used for centuries in traditional medicine for the treatment of various conditions. This review summarizes the available data on the use of hibiscus rosa-sinensis for the treatment of pain, inflammation, and fever [5]. Hibiscus rosa-sinensis has been shown to be effective in reducing pain and inflammation in animal studies. In human studies, hibiscus rosa-sinensis has been shown to be effective in treating fevers. The available data suggest that hibiscus rosa-sinensis may be a safe and effective option for the treatment of pain, inflammation, and fever [6].

Pain etiology can be divided broadly into two categories: nociceptive pain and neuropathic pain. Nociceptive pain results from activation of the body's normal pain-sensitive structures, such as skin, joints, or muscles [7]. Neuropathic pain is caused by damage to, or dysfunction of, the nervous system itself. This can include damage to nerve fibers (e.g., from trauma), the spinal cord (e.g., from compression), or higher brain centers (e.g., from stroke). Some types of pain fall into both categories; for example, post herpetic neuralgia—pain that persists after healing of a herpes zoster rash—involves both damage to nerve fibers and sensitization of nociceptors [8].

2. MATERIALS AND METHODS

2.1. Plant collection [9]

The plant was collected from the nursery which is located Delhi. The plant leaves were authenticated at ACME search solutions. The dried leaves were grinded and make them a fine powder which was again passed through the sieve. The dried powder was then subjected to the hot Soxhlet process along with the solvents. This process involves three different solvents. The extractive values was then calculated who are the various methods mentioned in the table-1.

2.2. Extraction and phytochemical analysis [10, 11]

The extraction process was involved the hot Soxhlet. Approximately 0.5 kg of the dry leaves powder was filled in the round bottom flask which was fitted to the Soxhlet assembly. The round bottom flask was then filled with the solvent and the extract was collected through the distillation process. The extract was then dried and stored in a closed container to avoid the air contact. This process was performed for other solvents also. The obtained extract was weighed and other extractive values were calculated. The phytochemical analysis was performed as per the procedure mentioned by Basak et al., 2018. The phytochemical results are mentioned the table-2.

2.3. Formulation of Emulgel [12]

Emulgel was prepared using a formula which is mentioned in Table-3. The formulation was prepared using two phases i.e. Emulsion and gel. Emulsion was prepared using the oil phase and aqueous phase. Both were mixed 60 degree Celsius temperatures at the ratio of 1:1. The oil phase was prepared by adding liquid paraffin into span 80 and the aqueous phase was prepared using tween 80 and water. The preservative was added in to propylene glycol and the drug was dissolved in water. Both the phases were mixed at the constant temperature. The gel phase was prepared using Carbopol 934, Carbopol 940 and HPMC. 0.5 % of each gelling agent was added into water and left it overnight for soaking. The pH of the gel was maintained using TME.To prepare the Emulgel emulsion and gel was added and stirred at 1000 RPM. The prepared formulation was stored in a closed container.

2.4. Evaluation Parameter

2.4.1. Physical Evaluation [13]

Physical evaluation of the formulation was performed visually by seeing the formulation in glass beaker. The formulation was inspected for colour, odour, grittiness, homogeneity. During visual inspection the formulation was found stable and particles were not observed against the light and dark. The odour of the formulation was slightly pungent and the colour of the formulation was light brown (table-4).

2.4.2. pH [14]

The pH of the formulation was examined using the digital pH meter. Approximately 1 gram of the gel was dissolved in 10 ml of the water and kept for 3 hours. After dissolving the Emulgel into the water the pH was taken in triplicates and recorded in table-5.

2.4.3. Viscosity [15, 16]

Viscosity was evaluated to identify the nature of the gelling agent and drug. Approximately 150 ml of the formulation was taken into the glass beaker and the spindle of the viscometer was dipped into the formulation. This test was performed at 50 RPM using spindle number 3. The reading was recorded when the digits of the viscometer stable. The test was performed three times for each formulation and recorded in table-6.

2.4.4. Spreadability [15]

This test was performed using two glass plates. Approximately 500 mg the formulation was weighed and placed over the glass plate. The glass plate was pre-marked at 15cm. Approximately 500 grams of weight was put over the glass plate and which allowed it to spread between the glass plates. The spread of the formulation was measured and recorded in table-7.

2.4.5. In vitro drug release [15-17]

This test was performed mimic the activity of the skin in in vitro. In vitro drug release study was performed using Franz diffusion cell apparatus. This apparatus contains six glass Chambers which are filled with the phosphate buffered saline and kept on the magnetic stirrer with hot plate. The glass containers which have an inlet and outlet and are fixed with the plastic tubes maintain the temperature inside the glass chambers. The formulation was placed over the dialysis membrane and allowed it to dip into the phosphate buffered saline which makes it transfer into the solution. The test was performed 8 hours, each hour 1 ml of sample taken and analyzed through the ultraviolet visible spectrophotometry 315nm.
Every time the glass chamber was replenished with 1 ml of the phosphate buffered saline. The percentage release of the drug was calculated according to the formula: (table-8)

$$C_n = C + (C_{n-1})\, V/V_t$$

- **Cn: Actual concentration in sample n**
- **C: Apparent concentration in sample n**
- **Cn-1: Actual concentration in sample n – 1**
- **Vt: Volume of receive phase**
- **V: Sample volume**

2.4.6. Extrudability [16]

Extrudability of the drug was examined using the aluminum tubes. The formulation was filled into the tubes and squeezed at the constant temperature and pressure. The extruded amount of the formulation was calculated and recorded. If the formulation extruded at the rate of 2 meter/second, the formulation is considered as the excellent. The results are mentioned at table-9.

- **90% extrudability: excellent,**
- **>80% extrudability: good,**
- **>70% extrudability: fair**

3. Results and Discussion

The study was performed to prepare herbal Emulgel of the leaf extract of Hibiscus Rosa-sinensis using three gelling agents'Carbopol 934, Carbopol 940, and HPMC. The leaves of the plant were collected in the month of June. The dried leaves were grinded up to the Powder and extracted using methanol, ethanol and water.

To phytoconstituents was extracted through the hot Soxhlet technique.

The extract of the plant was collected and dried using a rotatory evaporator. The percentage yield and other extractive values were calculated. All the extractive values and percentage yield was in limit.

Physical examination: physical examination was performed by inspecting the appearance of the formulated herbal formulated Emulgel.

The all the formulations were uniform, no particles were found, and the odour was slightly pungent.Formulation 1 appeared excellent in all respective areas as compared to formulation 2 and formulation 3. Physical appearance is mentioned in Table- 4.

pH: The pH was determined for all the formulations. The determination of PH was carried out by the digital pH meter to ensure whether the formulation pH is near to the skin pH. The results revealed that formulation 1 2 and 3 matched the skin pH. However, formulation number 1 was significant as compared to other formulations. Results are mentioned in table number 5.

Viscosity: The viscosity of the formulations was examined to determine whether the gel and drug content uniformly mixed. The other excipients did not interfere during the Incorporation of gel and drug. Viscosity was performed with the digital viscometer at 50 RPM using spindle number 3. All other formulations showed a better viscosity. However, formation number 1 was significant as compared to other formulations. Results are mentioned in table Number 6.

Spreadability: Spreadability was assessed to examine the smoothness of the formulation and to measure the spreading capability of the formulation to the skin. The spreadability was measured using the sandwich method; two glass plates were used to assess the spreadability. The formulation was pleased on the glass plate and covered with another glass plate. Both of the glass plates were applied pressure and then spreadability of the formulation was measured.This ensures the spreading capability of gel and other excipients during the Incorporation. Formulation number 1 was found excellent compared to other formulations. The results are mentioned in table number 7.

In vitro drug release: The drug release study was performed to evaluate the drug releasing capacity from the complex matrix of the gel and other excipients. The study was performed using Franz diffusion cell apparatus. The drug was applied on the dialysis membrane dipped to the phosphate buffered saline. The release drug was then analyzed through the ultraviolet visible spectrophotometry.The percentage drug release was calculated. Formulation number 1 showed excellent drug release with over 94%. Other formulations also performed well with 89 to 88%.

Extrudability: extrudability examined using the collapsible aluminum soft tubes. The formulation was filled into the tube and squeezed the optimum temperature and pressure. The results revealed that formulation number 1showed excellent extrudability.

4. Conclusion

The present study was performed to evaluate the Emulgel prepared using the leaves extract of the *Hibiscus Rosa-Sinensis***.** The herbal formulation was examined using parameters i.e. Viscosity, pH, spreadability, extrudability, and in vitro drug release. The formulation was prepared using three different gelling agents Carbopol 934, Carbopol 940 and HPMC. The results revealed that the formulation prepared using Carbopol 934 showed significant improvement as compared to the other formulation. Hence, the Emulgel of *Hibiscus Rosa-Sinensis*could be prepared using the Carbopol 934.

5. Tables

Table: 1- Extractive Values

Sn.	Extractive Values	Results
1	Water Soluble Extractive	6.41
2	Alcohol Soluble Extractive	5.19
3	Acid Soluble Extractive	1.14

Table: 2- Phytochemical Evaluations

Sn.	Test	Solvents		
		Methanol	Ethanol	Water
1	Alkaloids	+	+	++
2	Carbohydrates	-	+	-
3	Saponins	+	-	-
4	Glycosides	+	+	-
5	Steroids	+	+	-
6	Phenolic	-	+	++
7	Flavonoids	+	-	-

Table: 3- Formulae of Emulgel

Sn.	Ingredients	Formulations		
		F1	F2	F3
1	Extract	2	2	2
2	Carbopol 934	1	NA	NA
3	Carbopol 940	NA	1	NA
4	HPMC	NA	NA	1
5	Liquid paraffin	7.5	7.5	7.5
6	Propylene glycol	5	5	5
7	Methyl Parabene	0.03	0.03	0.03
8	Propyl Parabene	0.03	0.03	0.03
9	Span 20	1	1	1
10	Tween 20	0.5	0.5	0.5
11	Water	qs	qs	Qs

Table: 4- Physical Appearance

Sn.	Formulations	Odour	Color	Homogeneity	Grittiness
1	F1	Slight Pungent	Light Brown	Uniform	None
2		Slight Pungent	Light Brown	Uniform	None
3		Slight Pungent	Light Brown	Uniform	None
4	F2	Slight Pungent	Light Brown	Uniform	None
5		Slight Pungent	Light Brown	Uniform	None

6		Slight Pungent	Light Brown	Uniform	None
7	F3	Slight Pungent	Light Brown	Uniform	None
8		Slight Pungent	Light Brown	Uniform	None
9		Slight Pungent	Light Brown	Uniform	None

Table: 5 – pH Determination

Sn.	Formulations	Triplicates	pH
1	F1	1	6.37±0.15
2		2	
3		3	
4	F2	4	5.80±0.10
5		5	
6		6	
7	F3	7	6.03±0.12
8		8	
9		9	

Table: 6- Viscosity

Sn.	Formulations	Triplicates	Viscosity (cps)
			50
1	F1	1	5031.0±118.19
2		2	
3		3	
4	F2	4	4968.3±65.61
5		5	
6		6	
7	F3	7	4937.0±119.06
8		8	
9		9	

Table: 7-Spreadability

Sn.	Formulations	Triplicates	Spreadability(cm/sec)
1	F1	1	17.58±0.82
2		2	
3		3	
4	F2	4	15.83±0.73
5		5	
6		6	
7	F3	7	16.85±0.45

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8		8	
9		9	

Table: 8- in Vitro drug release

Sn.	Time	F1	F2	F3
1	0	0	0	0
2	1	10.30	9.54	11.53
3	2	27.50	29.40	26.54
4	3	34.31	38.54	29.57
5	4	50.56	59.11	49.42
6	5	59.17	60.63	60.18
7	6	61.7	72.27	67.61
8	7	78.25	84.54	77.61
9	8	89.29	94.95	88.98

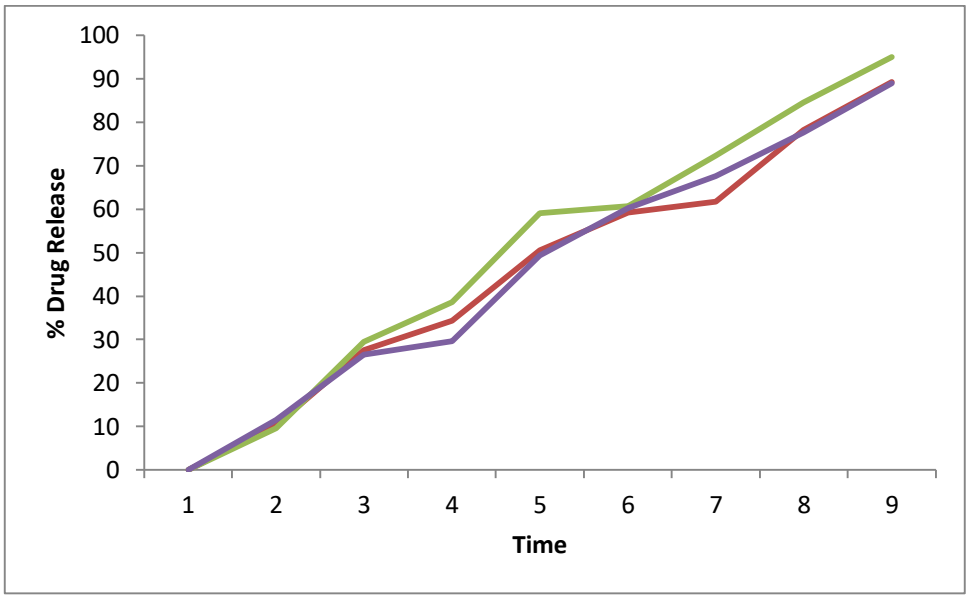

Fig:2- % Drug Release

Table: 9- Extrudability

Sn.	Formulations	Triplicates	Extrudability
1	F1	1	++
2		2	+++
3		3	++
4	F2	4	++
5		5	++
6		6	++
7	F3	7	++
8		8	++
9		9	++

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