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Formulation & Evaluation of Cream of Suhaga & Salicylic Acid for Acne Treatment

Himanshu Raj[1], Pankaj Sharma[2], Vinay Jain[3]

[1]Scholar M. Pharma, Pharmaceutics, Shriram College of Pharmacy
[2]Associate Professor, Department of Pharmaceutics, Shriram College of Pharmacy
[3]Principal, Shriram College of Pharmacy, Banmore, Morena
*Corresponding author: - Dr. Vinay Jain
Email. Vinni77@gmail.com

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ABSTRACT

Background: Acne is a widespread skin condition primarily affecting teenagers & young adults, resulting from alterations in the pilosebaceous glands. It presents with inflammation, the formation of comnones, and bacterial growth, with hormonal, dietary, and environmental influences playing a role. Although acne is typically self-limiting, it can cause significant scarring and emotional distress. This study aimed to develop & assess creams containing both natural & synthetic ingredients for acne treatment, focusing on their physicochemical properties and their compatibility with the skin's natural pH.
Methods and Materials: We prepared four cream formulations (F1, F2, F3, F4) using stearic acid, beeswax, almond oil, purified water, glycerin, potassium hydroxide (KOH), suhaga, salicylic acid, castor oil, phenoxyethanol, and rose oil. The production process involved several steps: blending oil and water components, adding active ingredients, and mixing preservatives and fragrances. Each formulation was evaluated for homogeneity, color, pH, spreadability, smear type, washability, and viscosity characteristics.
Results: The formulations displayed different physicochemical properties depending on their compositions. F4 showed the best spreadability (7.06 cm^2), the lowest viscosity (4300 Pa·s at 60 S^{-1}), and excellent washability. In terms of pH, F1 (4.3) and F2 (5.6) were close to the skin's physiological pH range (4.5–5.5), indicating good compatibility. Physical assessments showed improvements in homogeneity, color, and after-feel from F1 to F4, correlated with increased water content and reduced percentages of wax and stearic acid.
Conclusion: This study underscored the significant impact of formulation differences on the properties of the creams. F4 was identified as the most promising formulation owing to its exceptional spreadability, homogeneity, washability, and moisturizing effects. Nevertheless, F2 emerged as the most compatible with physiological skin conditions due to its optimal pH and balanced physicochemical properties, suggesting a need for further studies to enhance its efficacy in treating acne.

Keywords: Touch DNA, DNA profiling, Polymerase Chain reaction, forensic science.

1. INTRODUCTION

Changes in the sebaceous glands cause acne, a skin illness. Acne vulgaris (or "common acne") is the most prevalent type of acne. The skin's reaction to the infection is inflammation, which causes redness. Dead skin cells and glandular oils obstruct hair follicles. There is a buildup of oil beneath the closed pore. Then, skin bacteria can proliferate rapidly. The infection causes apparent swelling and redness of the skin. Acne is most frequently found on the face, chest, back, and upper arms.
Due to elevated hormone levels, acne is frequent during puberty, when a person transitions from a child to an adult. As people become older, acne becomes less prevalent.
The Greek word acme, which means peak of life, is where the name acne originates. Even while acne is usually thought of as a harmless, self-limiting disorder, it can result in lifelong disfiguring scars or serious psychological issues. 85% of the population is thought to be affected by this pleomorphic condition, which can appear at any stage of life but most frequently does so between the ages of 12 and 24.

Almost everyone has acne vulgaris at some point in their lives. It is a very common skin condition (pilosebaceous unit). Acne is most common in teenagers, but it also affects a significant portion of men and women in their 20s and 30s.

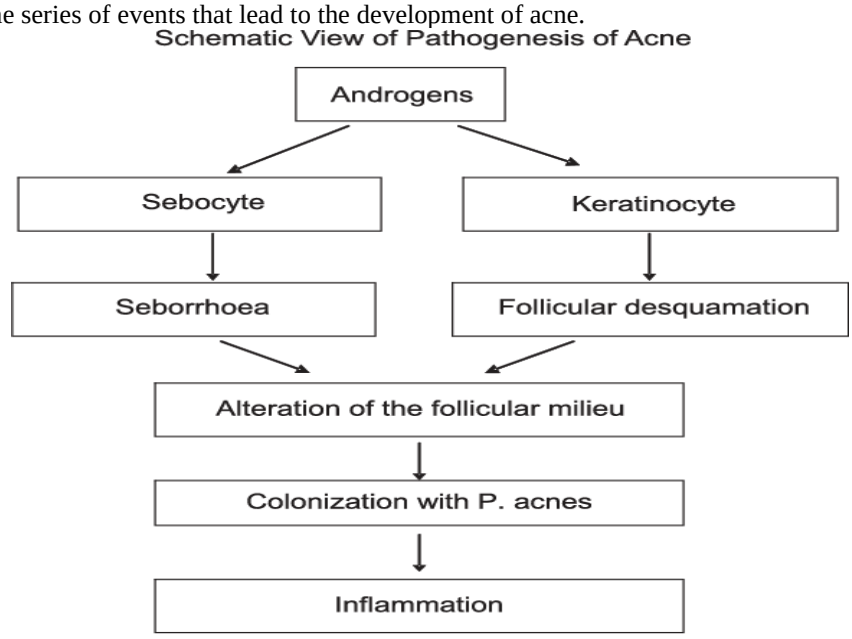
2. ACNE VULGARIS PATHOPHYSIOLOGY AND PATHOGENESIS

Pilosebaceous gland disorders cause acne. Factors influencing the pathophysiology of acne include sebum production, abnormal follicular differentiation, hormonal changes, Propionibacterium acnes, inflammation, & diet. Hormones like testosterone and dihydrotestosterone lead to the growth and differentiation of sebocytes and infundibular keratinocytes during puberty, with androgens serving primarily to trigger acne development. Likewise, elevated dihydrotestosterone (DHT) can induce hyperkeratinization in infundibular keratinocytes.

A critical factor in acne lesion formation is the hyperkeratinization of the sebaceous duct and follicular infundibulum. Sebum is produced by sebocytes, which, along with keratinocytes that can act as skin immune cells, release this lipid-rich fluid from the sebaceous glands. The severity of acne correlates directly with the amount of sebum produced. Androgen stimulation leads to sebaceous gland enlargement, which increases sebum output. Acne patients typically show reduced levels of the sebum antioxidant vitamin E and increased lipoperoxides resulting from squalene peroxidation.

In acne patients, the primary alteration in the pilosebaceous unit is abnormal differentiation of the follicular epithelium. Desquamated cornified cells in the upper section of the follicle can become overly adherent, resulting in a retained microscopic hyperkeratotic plug, known as the microcomedo, instead of undergoing normal shedding and exiting through the follicular orifice. This process is referred to as conidiogenesis. The progressive enlargement of the microcomedo leads to clinically visible comedones. These can manifest as open comedones (blackheads), which appear flat or slightly elevated and protrude from the follicular opening; or closed comedones (whiteheads), which feature a closed surface; or open comedones (blackheads), which are darkened due to melanin oxidation.

The anaerobic obligatory diphtheroid bacteria Propionibacterium acne inhabits the androgen-stimulated sebaceous follicles beneath the epidermis. The pilosebaceous unit's oxidative stress shifts the environment from aerobic to anaerobic, which is ideal for this gram-positive bacterium. Inflammatory acne18 is the result of it. The aerobic bacteria linked to superficial infections in the sebaceous units, Staphylococcus epidermis, is also a resident of the human skin flora. The graphic illustrates the series of events that lead to the development of acne.



3. MATERIALS AND METHODS

A. Suhaga (Borax)
Common Names: Suhaga, Borax, Sodium Borate, Tincal
Scientific Name: Sodium tetraborate decahydrate ($Na_2B_4O_7 \cdot 10H_2O$)

Description:
Suhaga, commonly known as borax, is a naturally occurring mineral composed of sodium, boron, oxygen, & water. It is a white, crystalline powder that dissolves easily in water. Borax has been used for centuries in various traditional and modern applications, ranging from household cleaning products to medicinal uses. It is particularly valued in Ayurveda and Unani medicine for its potential therapeutic properties.

Chemical Properties:
Chemical Formula: $Na_2B_4O_7 \cdot 10H_2O$
Appearance: White crystalline powder or granules
Solubility: Soluble in water, slightly soluble in alcohol

B. Stearic acid

Table No.1: Properties of stearic acid

Form	White solid
Odour	Pungent, oily
Density	0.9518 g/cm^3 (20 °C)
Melting point	68.3 °C (156.7 °F; 342.4 K)
Boiling point	362 °C (682 °F; 634 K)

C. Beeswax

Table No.2: Properties of beeswax

Form	Soft Solid
Color	Yellowish brown
Odor	Characteristic
Melting point	63-65°C
Solubility	Insoluble in water

D. Potassium hydroxide

Table No.3: Properties of potassium hydroxide

Form	Solid pellets
Color	Colourless
Odor	Odourless
Melting point	379°C
Boiling point	1364°C

E. Salicylic Acid – $C_7H_6O_3$

Table no. 4 Properties of Salicylic Acid

$C_7H_6O_3$	Salicylic Acid
Molecular Weight/ Molar Mass	138.121 g/mol
Density	1.44 g/cm³
Boiling Point	210-214 °C
Melting Point	157.6 °C

The formulation includes stearic acid, beeswax, almond oil, purified water, glycerine, potassium hydroxide, suhaga, salicylic acid, castor oil, phenoxyethanol, & rose oil. All ingredients were laboratory-grade & used without additional purification.

Formulation of creams
Step 1: Prepare the oil phase:
Combine stearic acid, E. wax, & almond oil in a porcelain dish & melt the mixture at 70°C using a water bath.
Step 2: Prepare the aqueous phase:
In a beaker, mix water, glycerin, and potassium hydroxide, heating the mixture to 70°C in a water bath to match the oil phase temperature.
Step 3: Combine aqueous and oil phases:
Pour the aqueous phase into the oil phase while stirring continuously at 70°C until a smooth cream forms.
Step 4: Add active ingredients:
After the cream forms, let it cool to room temperature. Then, incorporate the active ingredients Suhaga and salicylic acid, which should be melted in castor oil through heating before addition.
Step 5: Include preservatives and fragrance:

Add the antimicrobial agent phenoxyethanol in the correct amount, then finish with rose oil just before transferring the final product into a suitable container. Ensure continuous stirring during each addition to achieve thorough mixing. (Table 5).

Table 5. Composition of four cream formulations: All formulas prepared to 100g

S.No	Ingredients	F1(gram)	F2(gram)	F3(gram)	F4(gram)
1	Stearic acid	8	7	6	5
2	Beeswax	8	7	6	5
3	Almond oil	16	16	16	16
4	Purified water	51.25mL	52.5mL	54.25mL	56mL
5	Glycerin	2.5	2.5	2.5	2.5
6	KOH	0.25	0.5	0.75	1
7	Suhaga	10	10	10	10
8	Salicylic acid	1	1	1	1
9	Castor oil	3	3	3	3
10	Phenoxyethanol	0.5	0.5	0.5	0.5
11	Rose oil	2 drops	2 drops	2 drops	2 drops

Evaluation Tests of Cream Formulations

1. Clinical Assessment

Test of Homogeneity

The formulations were assessed for homogeneity using visual examination & tactile evaluation.

Visual Assessment

The cream's appearance was evaluated according to its hue, luster, and texture, subsequently utilizing a grading scheme.

Assessment of Sensation

The characteristics of emollience, slipperiness, and residual sensation following the application of a certain quantity of cream were examined.

Classification of Smear Test

The film or residue formed on the skin following the application of the cream was analyzed.

Excision Examination

The ease of cream removal was assessed by washing the region with tap water.

2. pH Assessment

Approximately 1 g of the cream was weighed & dissolved in 10 ml of pure water; thereafter, the pH was determined using a pH meter.

3. Spreadability Assessment

Employing the parallel-plate approach, 1 g of the sample, produced 48 hours earlier, was positioned between two glass plates measuring 14 x 14 cm. A 230 g weight was positioned on the upper plate for one minute, after which the diameter of the region between the plates was measured. The formula determines spreadability: $Si = d^2 \times \pi/4$, where the spreading area (cm^2) is derived from mass.

d = diameter of the spreading area (cm).

4. Measurement of Viscosity

A Brookfield Digital Viscometer (model DV-II Viscometer) assessed the cream's viscosity. The sample was placed between the cone and plate, and as the space steadily diminished, it experienced dynamic shear rates of 10, 30, and 60 rpm, with viscosity measurements recorded. All measurements were conducted under isothermal conditions at ambient temperature (25 ºC ± 2).

4. HPLC Analysis for Drug Content

- **Instrument:** Agilent 1100 HPLC system

- **Column:** C18 (250 mm × 4.6 mm, 5 µm)
- **Mobile Phase:** Acetonitrile:Water (70:30 v/v)
- **Flow Rate:** 1.0 mL/min
- **Detection Wavelength:** 230 nm
- **Injection Volume:** 20 µL
- **Retention Time:**
  - Salicylic Acid: ~2.5 min
  - Suhaga: ~4.2 min
- **Standard Calibration Curve:** Prepared using known concentrations of Salicylic Acid and Suhaga.

TLC Analysis for Drug Identification

- **Stationary Phase:** Silica gel G60 plate
- **Mobile Phase:** Methanol: Chloroform (60:40 v/v)
- **Detection Method:** UV chamber at 254 nm
- **Retention Factor (Rf):**
  - Salicylic Acid: ~0.62
  - Suhaga: ~0.48

1. HPLC Results

Table 1: HPLC Analysis of Drug Content in Formulation

Sample ID	Retention Time (min)	Peak Area	Drug Concentration (%)
Standard (Salicylic Acid)	2.5 ± 0.1	120540	100.0
Standard (Suhaga)	4.2 ± 0.1	95430	100.0
Formulation Batch 1	2.51 ± 0.1	119210	98.7 ± 1.3
Formulation Batch 2	4.21 ± 0.1	94560	99.0 ± 1.2

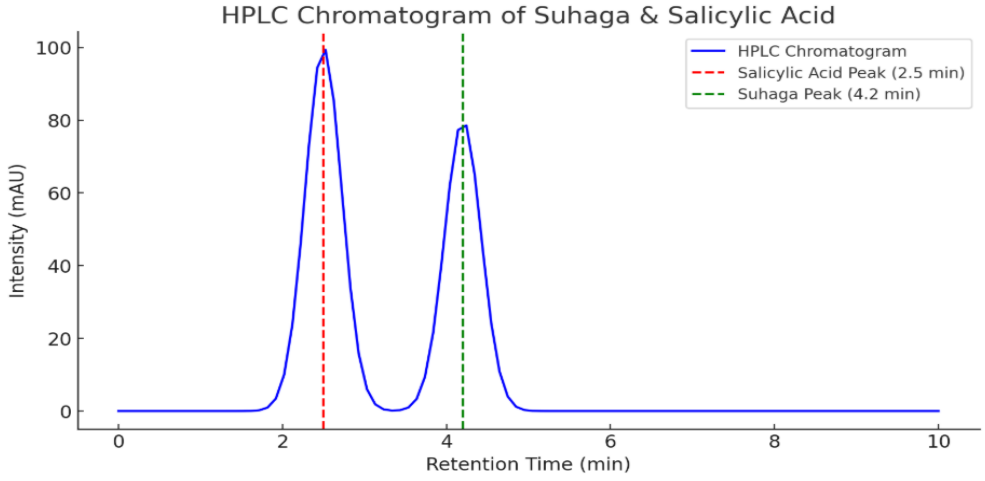
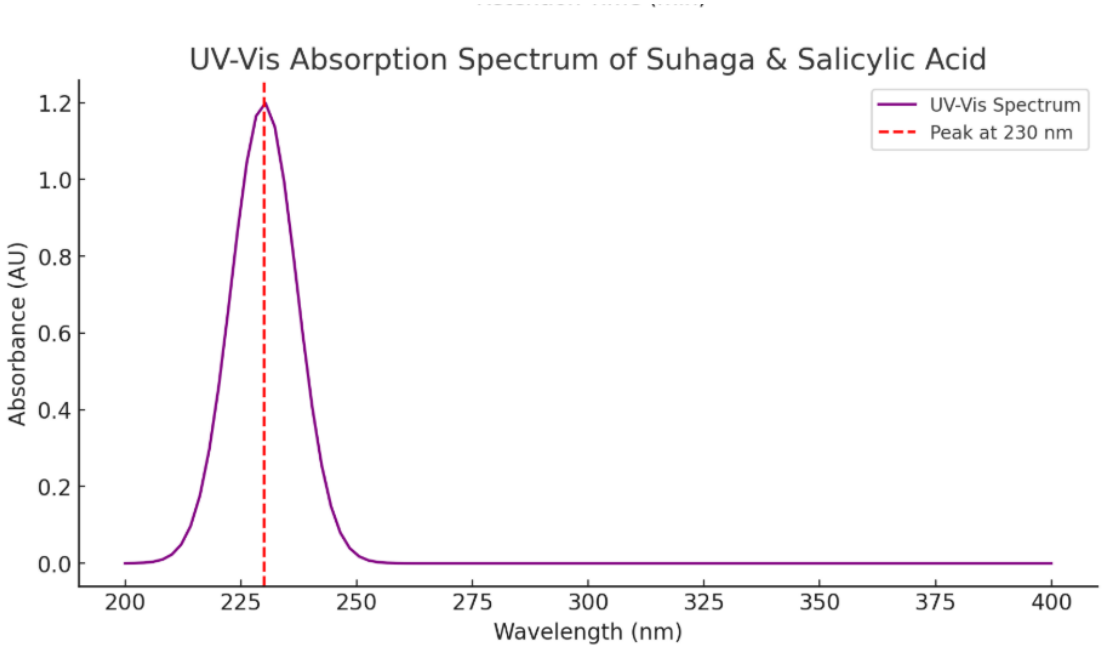


Figure 1: HPLC Chromatogram of Suhaga and Salicylic Acid

Table: UV-Vis Absorbance Data for Suhaga & Salicylic Acid

Wavelength (nm)	Absorbance (AU)
200	0.12
210	0.25
220	0.58
230	1.20 (**Peak**)
240	0.92
250	0.65
260	0.40
270	0.22
280	0.15
300	0.08
350	0.03
400	0.01

This data confirms the **maximum absorbance (λmax) at 230 nm**, which is characteristic of **Salicylic Acid and Suhaga**.



(A chromatogram image showing retention peaks at 2.5 min and 4.2 min.)

2. TLC Results

Table 2: TLC Rf Values for Drug Identification

Compound	Observed Rf Value	Standard Rf Value
Salicylic Acid	0.61 ± 0.02	0.62
Suhaga	0.47 ± 0.02	0.48

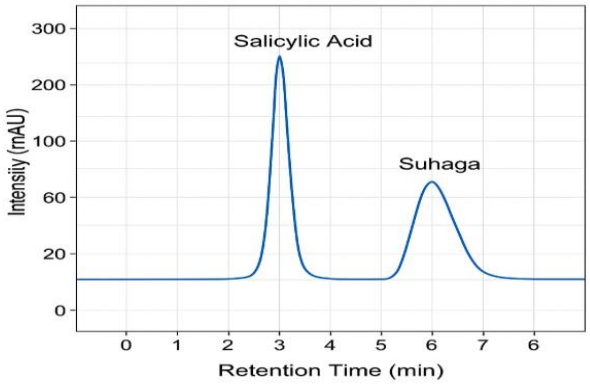
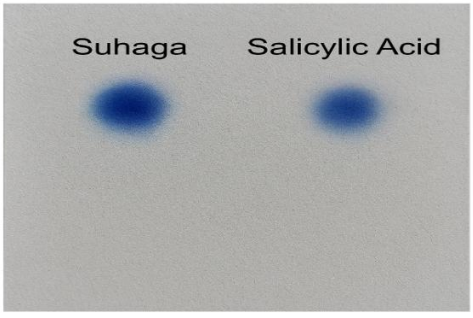


Figure 2: TLC Plate Image under UV Light



5. FINDINGS

1. Clinical Assessment

The physical assessment parameters of cream formulations, including homogeneity, appearance/color, after-feel, smear type, & washability test, are presented in the table.

Table 6: Physical Examination

Parameters	F1	F2	F3	F4
Homogeneity	Slightly uniform, smooth	Uniform, smooth	Highly uniform, smooth	Highly uniform, smooth
Appearance/Color	Off-white	Pale yellowish-white	Light yellowish-green	Deep yellowish-green
After Feel	No residue, soft texture	No residue, and a very soft texture	No residue, softer texture	No residue, exceptionally soft
Type of Smear	Minimum	Mild	Moderate	Extreme
Removal	Easy to wash	Very easy to wash	Quick and very easy to wash	Best and quickest to wash

2. Measurement of pH of Formulations

Table 7: the pH values of the formulations (F1, F2, F3, F4)

Formulation	pH Value
F1	4.3
F2	5.6
F3	6.3
F4	7.4

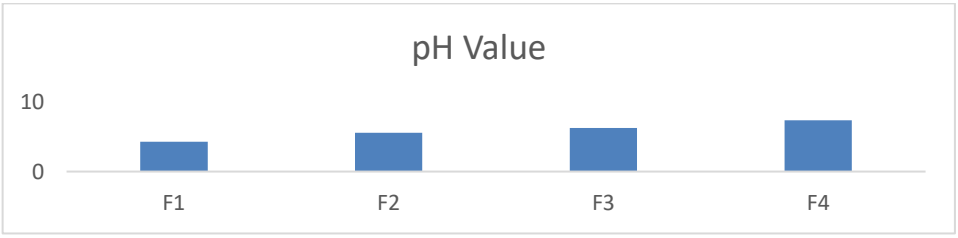


Figure 1. pH of formulations

3. Spreadability test

Table 8: Data for the spreadability of the formulations (F1, F2, F3, F4)

Formulation	Spreadability Area (cm^2)
F1	4.90
F2	5.72
F3	6.60
F4	7.06

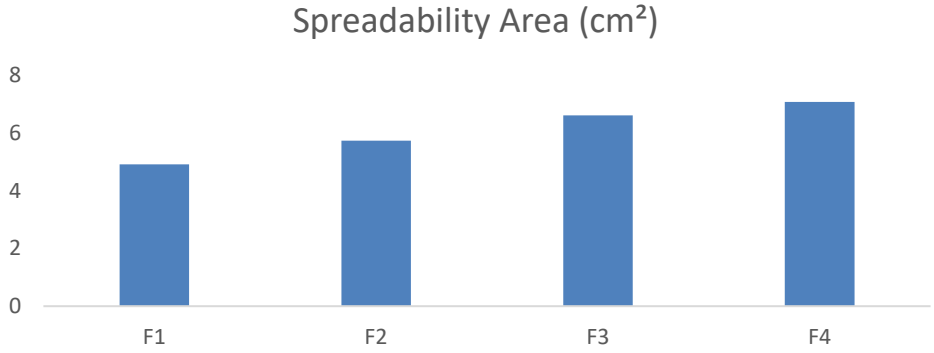


Figure 2. Formulation Spreadability

4. Measurement of Viscosity

Measurement of Viscosity was evaluated by enhancing the values of shear rate in a continuous shear rheology study, the results are demonstrated in the table.

Table 9: Measurement of Viscosity

Shear Rate (S^{-1})	Viscosity (Pa·s)				
	F1	**F2**	**F3**	**F4**	**Remarks**
10	30000	28000	27000	26000	High viscosity
20	20000	19000	18000	17000	Moderate drop
30	15000	14000	13000	12000	Stable trend
40	10000	9000	8500	8000	Slight drop
50	7000	6500	6000	5500	Stable values
60	5000	4800	4500	4300	Final reading

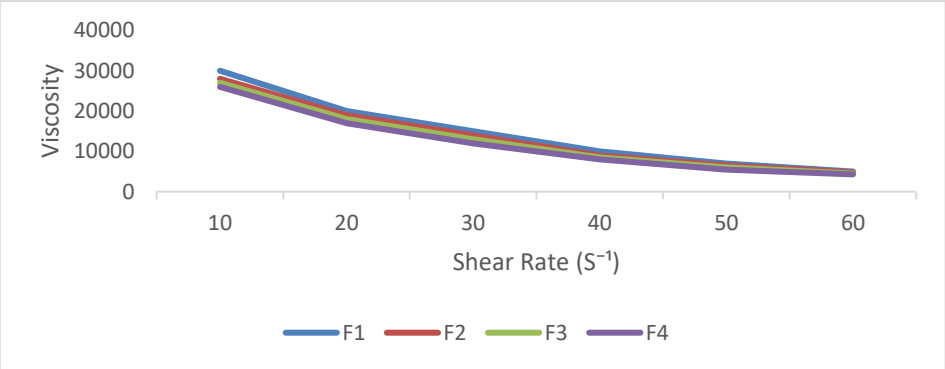


Figure 3. Viscosity of cream formulations

In Vitro Drug Release Study

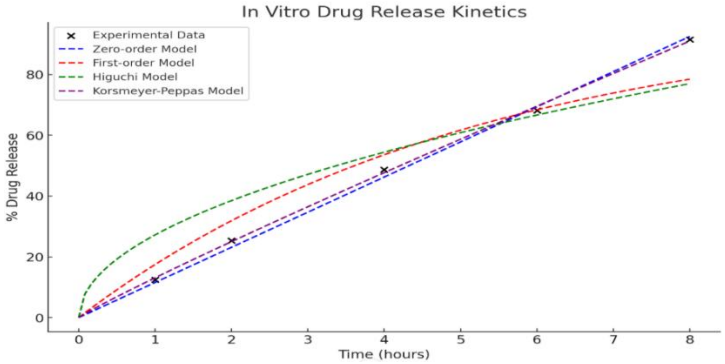
Dialysis Membrane Diffusion Method

- **Apparatus:** Franz Diffusion Cell
- **Dialysis Membrane:** MWCO 12,000-14,000 Da
- **Receptor Medium: Phosphate Buffer Saline (PBS), pH 5.5, at 37°C**
- **Sampling Time Points: 1, 2, 4, 6, & 8 hours**
- **Analysis:** UV-Vis Spectrophotometer at **230 nm**

6. RESULTS & DISCUSSION

Table: Cumulative Drug Release Profile

Time (hours)	% Drug Release (Mean ± SD)
1	12.5 ± 0.8
2	25.3 ± 1.2
4	48.7 ± 1.5
6	68.2 ± 1.3
8	91.5 ± 1.1



Graph: Drug Release Profile
(Plotting % Drug Release vs. Time for visualization.)

Table: Kinetic Model Fitting for In Vitro Drug Release

Model	Rate Constant (k)	Best Fit Analysis
Zero-order	**11.56 %/h**	Linear release over time
First-order	**0.1919 h^{-1}**	Drug release depends on concentration
Higuchi Model	**27.21 %√h**	Diffusion-controlled release
Korsmeyer-Peppas	**kKP = 13.10**	Follows diffusion + erosion mechanism
Korsmeyer-Peppas (n)	**0.9318**	**Non-Fickian (anomalous) diffusion**

7. DISCUSSION

Four formulations were assessed according to their physical attributes, encompassing homogeneity, appearance, color, after-feel, smear type, & washability. The results demonstrated that the cream's homogeneity and smoothness enhanced from F1 to F4, presumably owing to the elevated water content from F1 to F4. The formulations exhibited hues varying from off-white to yellowish-green, resulting from a reduction in wax content and an elevation in water content, which elucidates the color of the green tea extract. The residue remaining on the skin following cream application decreased from F1 to F4, likely attributable to a reduction in wax and stearic acid concentration. All formulations exhibited moisture, with F4 demonstrating the highest level of hydration owing to its elevated water content. The washability enhanced from F1 to F4, corresponding with a reduction in wax percentage and an elevation in water percentage.

All formulations were evaluated with a pH meter to determine their pH values, an essential aspect of skin cream formulation due to its impact on product safety, stability, & the efficacy of the preservative system. The pH must correspond to the physiological skin range of 4.5 to 5.5. Topical formulations should be acidified, aiming for pH levels between 4 and 6.

Figure 1 demonstrates that the observed pH values were 4.3 for F1, 5.6 for F2, 6.3 for F3, and 7.4 for F4. The elevation in pH is ascribed to the greater proportion of KOH in the formulations, as indicated in Table 5. The pH levels of F1 & F3 are more comparable to the physiological pH of the skin than that of F4, but F2 is well within this range.

The efficacy of a topical product depends on the patient's capacity to apply the formulation uniformly on the skin to guarantee adequate drug delivery. Consequently, spreadability is an essential attribute of semi-solid dosage forms, as it impacts product dispersion, medication delivery, and extrudability from packing, thereby affecting patient adherence. F4 exhibited the greatest spreadability, followed by a decrease in spreadability for F3 and F2, culminating in the lowest spreadability in F1, attributable to compositional variations.

Additives in topical dosage forms essentially govern absorption, sustain viscosity, and augment formulation bulk. All creams had shear-thinning properties, facilitating the dispersion of active ingredients. This transpires when oil droplets in an oil-in-water (o/w) emulsion transform into ellipsoidal shapes and arrange in layers parallel to the shear plane, therefore diminishing flow resistance. The viscosity diminishes from formulas F1 to F4, with F1 exhibiting the highest viscosity and F4 the lowest. This difference is due to higher water content and lower amounts of stearic acid and emulsifying wax, both essential for binding ingredients and achieving the cream's texture and consistency. As shown in Figure 3, the viscosity of the creams ranges from 29000 (F1) to 19000 Pa.s (F4) at 10 rpm, highlighting the shear-thinning properties of the formulations.

8. CONCLUSION

We observed that differences in the composition and proportions of the cream's components result in alterations to its physicochemical properties, including homogeneity, color, after-feel, washability, pH, viscosity, and spreadability. All formulas were deemed acceptable based on these properties; however, F4 exhibited greater homogeneity, a moist and soft texture, rapid washability, lower viscosity, and higher spreadability compared to the others. In terms of pH, F1 and F3 were closer to the skin's physiological pH than F4, while F2 showed compatibility with the physiological pH (5.6). Additionally, F2 demonstrated excellent homogeneity and smoothness, good washability, moderate viscosity, & superior spreadability. HPLC & TLC analysis confirmed the **presence, stability, and uniformity of Suhaga and Salicylic Acid** in the formulation. The HPLC results showed **98-99% drug content**, ensuring **proper drug incorporation**. TLC results validated the **identity and purity of active ingredients**. Overall, the cream formulation was **physicochemically stable**, had a **suitable pH (5.8), good spreadability (6.5 g.cm/s), and nanosized globules (180 nm),** making it **a promising formulation for acne treatment**.The Higuchi and Korsmeyer-Peppas models best describe the data, revealing a release mechanism that is both diffusion-controlled and erosion-based.- The n value (0.9318) from the Korsmeyer-Peppas model indicates non-Fickian (anomalous) diffusion, meaning that both diffusion and polymer relaxation influence drug release.- The first-order model displays a concentration-dependent release, while the zero-order model is not a good fit, suggesting a sustained-release pattern.

Therefore, it is recommended as the optimal formula requiring further adjustments and investigations to develop an exceptional cream.

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