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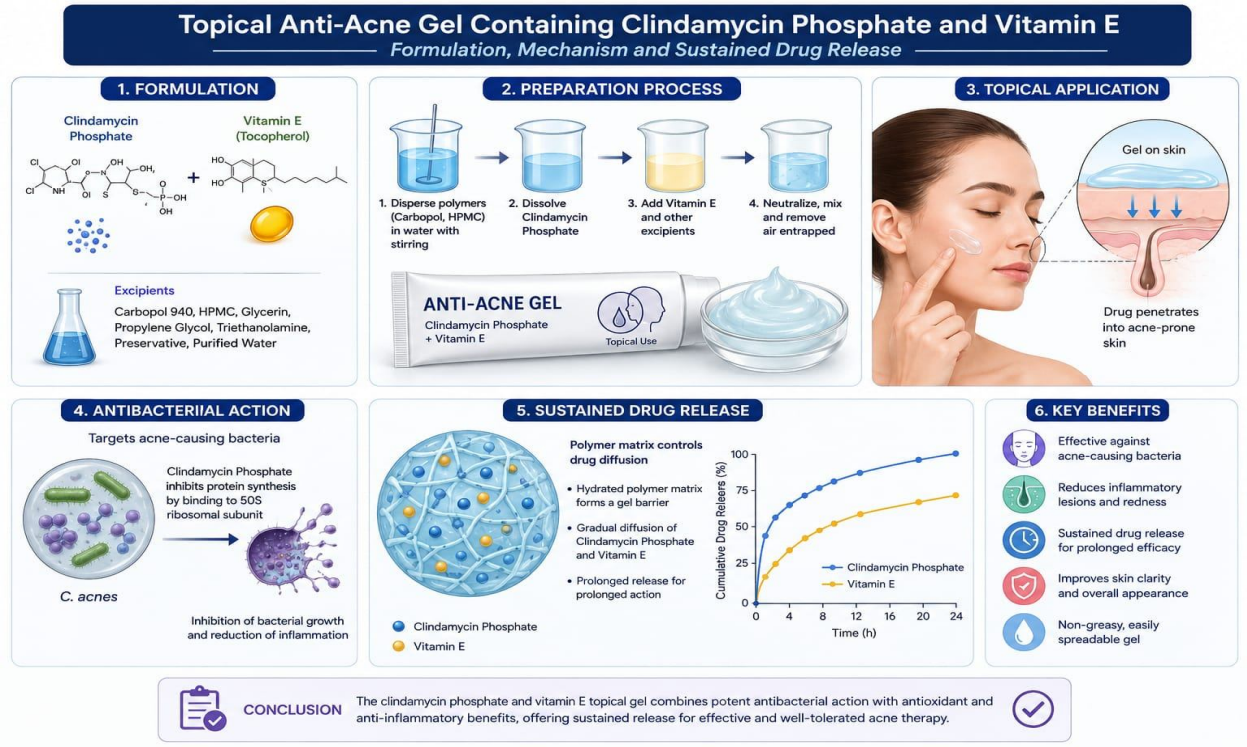
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Formulation and Evaluation of Topical Gel Containing Clindamycin Phosphate and Vitamin E for Acne Treatment

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Graphical Abstract



Overview of formulation and evaluation of Clindamycin Phosphate and Vitamin E Topical gel for Acne Treatment

Abstract: ***Background: Clindamycin phosphate is widely used in topical anti-acne preparations because of its antibacterial activity against Cutibacterium acnes. Vitamin E possesses antioxidant and skin-protective properties that may improve skin tolerability and formulation stability.***
Objective: The objective of the present investigation was to formulate and evaluate a stable topical gel containing clindamycin phosphate and vitamin E for enhanced anti-acne activity and improved patient compliance.
Methods: Four gel formulations (F1–F4) were prepared using Carbopol 940 at varying concentrations. Prepared gels were evaluated for physical appearance, pH, viscosity, spreadability, extrudability, drug content, in vitro diffusion, antimicrobial activity, skin irritation, and accelerated stability studies.
Results: The optimized formulation F3 showed satisfactory homogeneity, pH (6.2 ± 0.1), viscosity (5810 ± 32 cPs), spreadability (7.4 ± 0.2 g·cm/sec), and drug content (98.7 ± 0.4%). In vitro drug diffusion studies demonstrated sustained drug release of 94.2 ± 0.5% within 8 h.
Conclusion: The developed topical gel exhibited acceptable pharmaceutical characteristics and may serve as a promising topical delivery system for acne management.
Keywords: Acne vulgaris, topical gel, clindamycin phosphate, vitamin E, Carbopol 940, antimicrobial activity.

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I. INTRODUCTION

Acne vulgaris is one of the most prevalent dermatological disorders affecting adolescents and young adults worldwide. The condition involves multifactorial pathogenesis including increased sebaceous gland activity, abnormal keratinization, microbial colonization, and inflammatory responses. Topical drug delivery systems are widely preferred in acne therapy because they provide localized action with minimal systemic side effects. Clindamycin phosphate is a semi-synthetic lincosamide antibiotic effective against anaerobic bacteria and commonly employed in topical acne therapy. Vitamin E is a potent antioxidant that protects skin lipids from oxidative damage and improves skin hydration. Incorporation of vitamin E in topical gels may reduce irritation and improve formulation stability. Topical gels are transparent, non-greasy, easily spreadable, and cosmetically elegant dosage forms. Carbopol-based gels exhibit excellent rheological behavior and controlled drug release properties.

II. MATERIALS AND METHODS

Table 1 Material

S.NO	Ingredients List	Functions
1	Clindamycin Phosphate	Active Drug
2	Vitamin E Acetate	Antioxidant
3	Carbopol-940	Gelling Agent
4	Propylene Glycol	Humectant
5	Methyl Paraben	Preservative
6	Propyl Paraben	Preservative
7	Triethanolamine	Ph Adjuster
8	Purified water	Vehicle

A. Formulation Table

Table 2: Composition of Topical Gel Formulations (% w/w):

Ingredients	F1	F2	F3	F4
Clindamycin phosphate	1	1	1	1
Vitamin E acetate	0.5	0.5	0.5	0.5
Carbopol 940	0.5	1.0	1.5	2.0
Propylene glycol	5	7	10	10
Methyl paraben	0.2	0.2	0.2	0.2
Propyl paraben	0.02	0.02	0.02	0.02
Triethanolamine	q.s.	q.s.	q.s.	q.s.
Purified water	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100

B. Method of Preparation

1) First, Carbopol 940 was slowly added into purified water with continuous stirring.
2) The mixture was kept for 24 hours so that the Carbopol could swell and form a gel base properly.
3) Preservatives (methyl Paraben and Propyl Paraben) were dissolved in Propylene glycol.
4) Clindamycin phosphate was dissolved separately in purified water.
5) Vitamin E acetate was mixed into the propylene glycol solution.
6) Both prepared solutions were added slowly into the hydrated Carbopol gel with continuous stirring.
7) Triethanolamine was added drop by drop until the required gel consistency and pH were obtained.
8) Finally, the prepared gel was filled into laminated tubes and stored at room temperature.

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Figure 1 Optimized topical gel formulation (F3) containing clindamycin phosphate and vitamin E

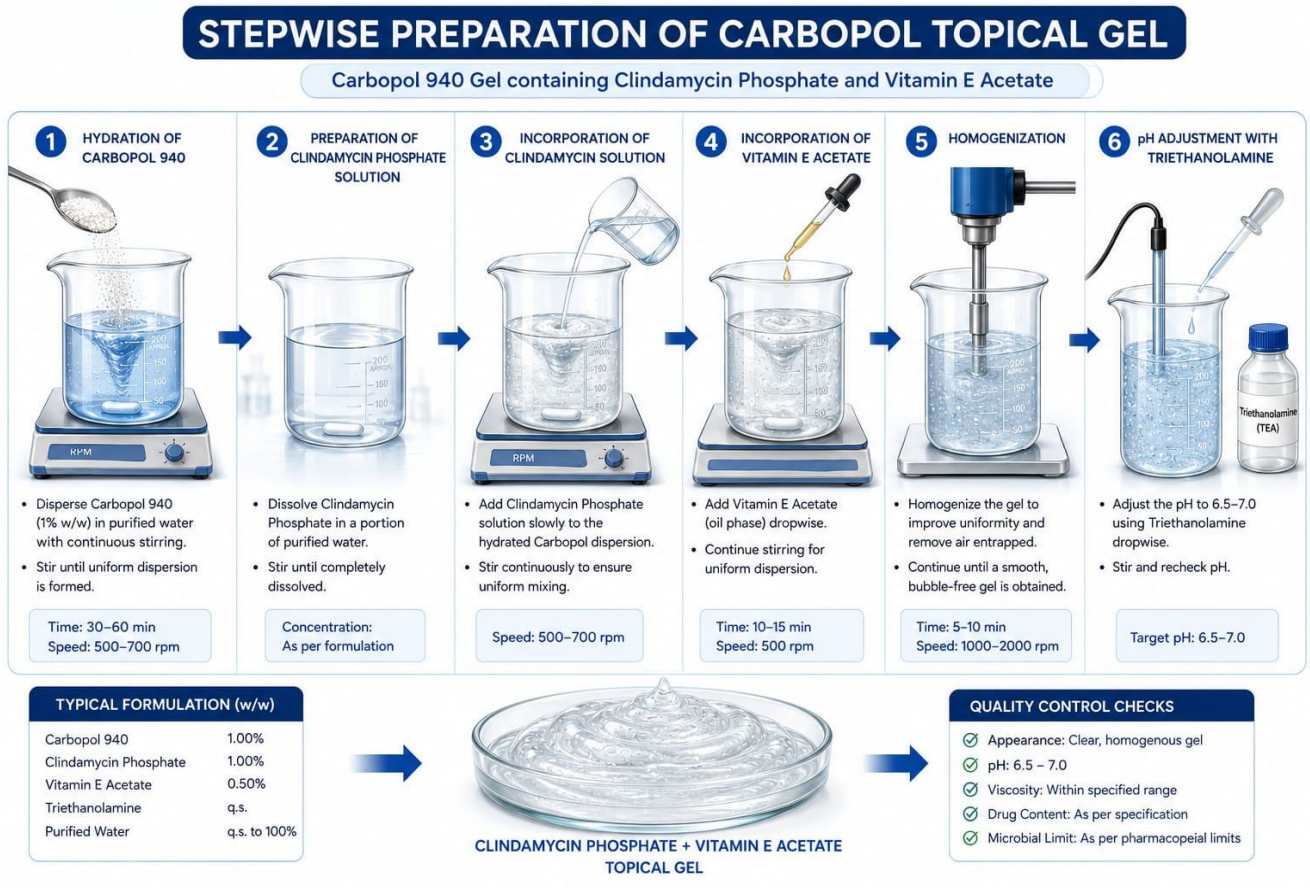


Figure 2 Schematic representation of preparation method for topical gel formulation

III. EVALUATION PARAMETERS

Table 3 Physical Appearance

Formulation	Color	Appearance	Homogeneity	Phase Separation
F1	Transparent	Smooth	Good	Absent
F2	Transparent	Smooth	Good	Absent
F3	Translucent	Excellent	Excellent	Absent
F4	Slightly opaque	Thick	Good	Absent

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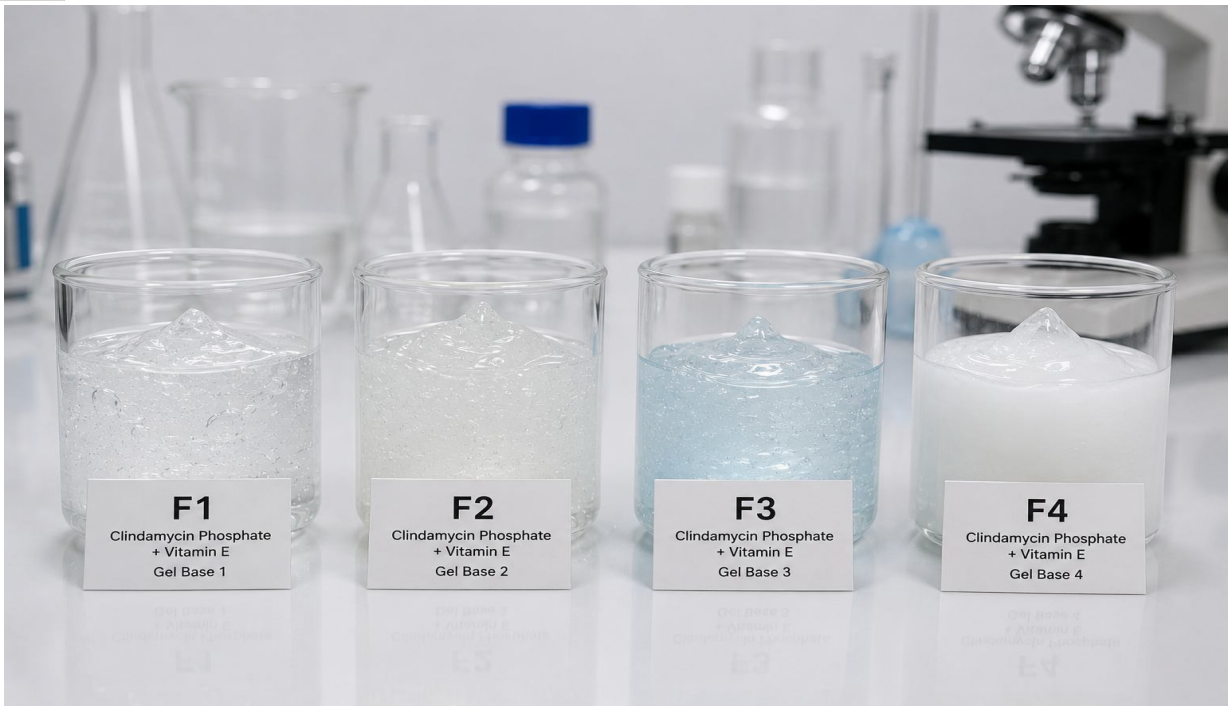


Figure 3 Physical appearance comparison of topical gel formulations F1–F4

A. pH Determination

Table 4 pH Determination:

Formulation	PH
F1	5.7 ± 0.1
F2	6.0 ± 0.2
F3	6.2 ± 0.1
F4	6.4 ± 0.2

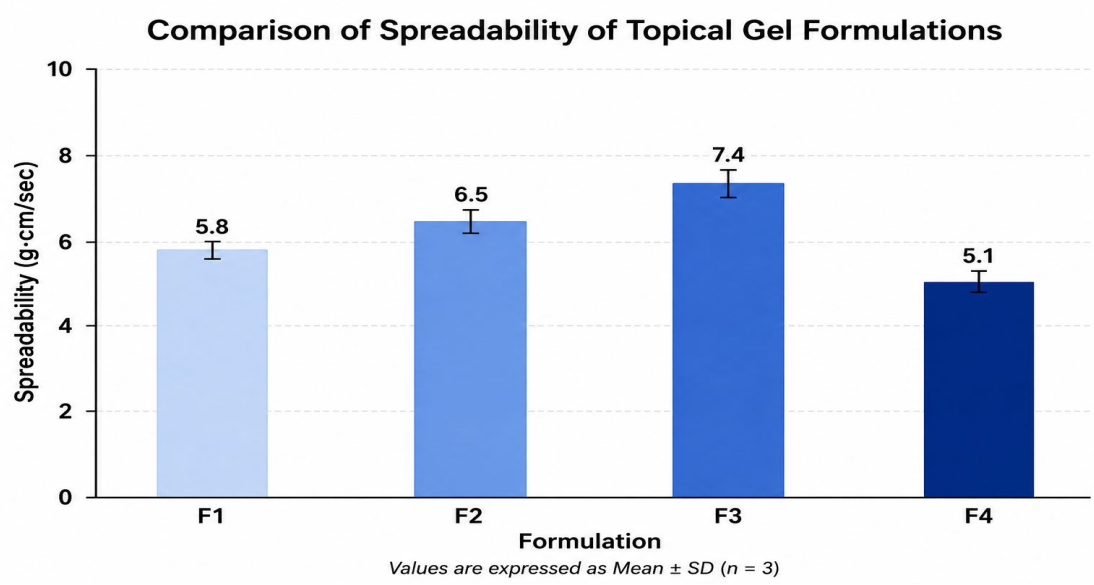


Figure 4 Comparative pH profile of topical gel formulations



Figure 5 Measurement of pH of optimized topical gel formulation using digital pH meter

B. Viscosity

Table 4 Viscosity

RPM	Viscosity
10	6200
20	5810
50	5400
100	4920

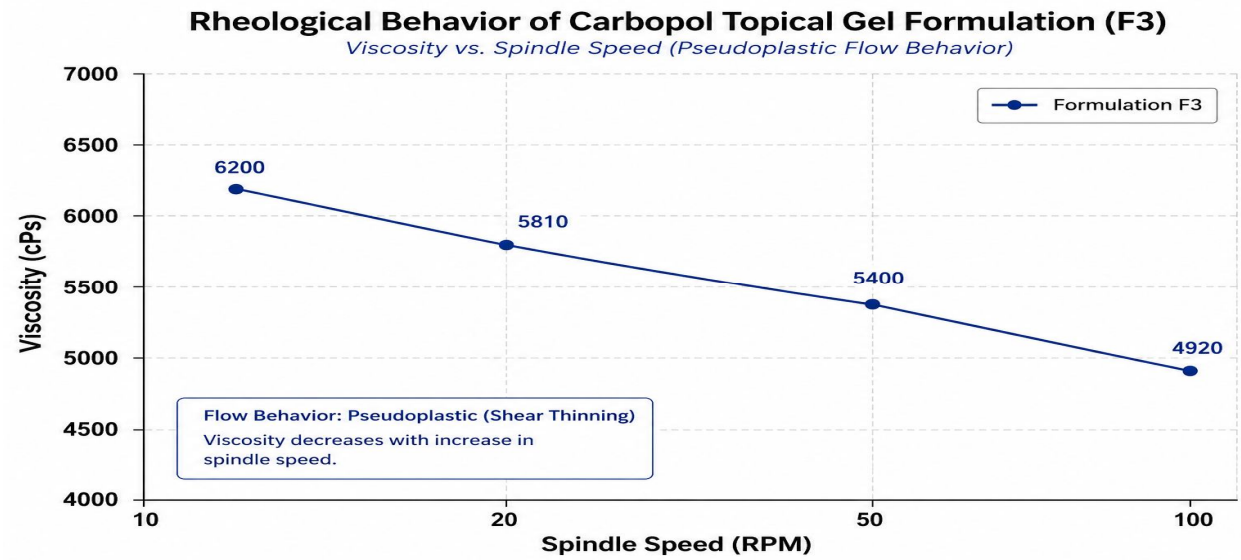


Figure 6 Rheological behavior of optimized gel formulation F3 indicating pseudoplastic flow

C. Spreadability

$S = M \times L / T$

Table 5 Spreadability

Formulation	Spreadability (g·cm/sec)
F1	5.8
F2	6.5
F3	7.4
F4	5.1

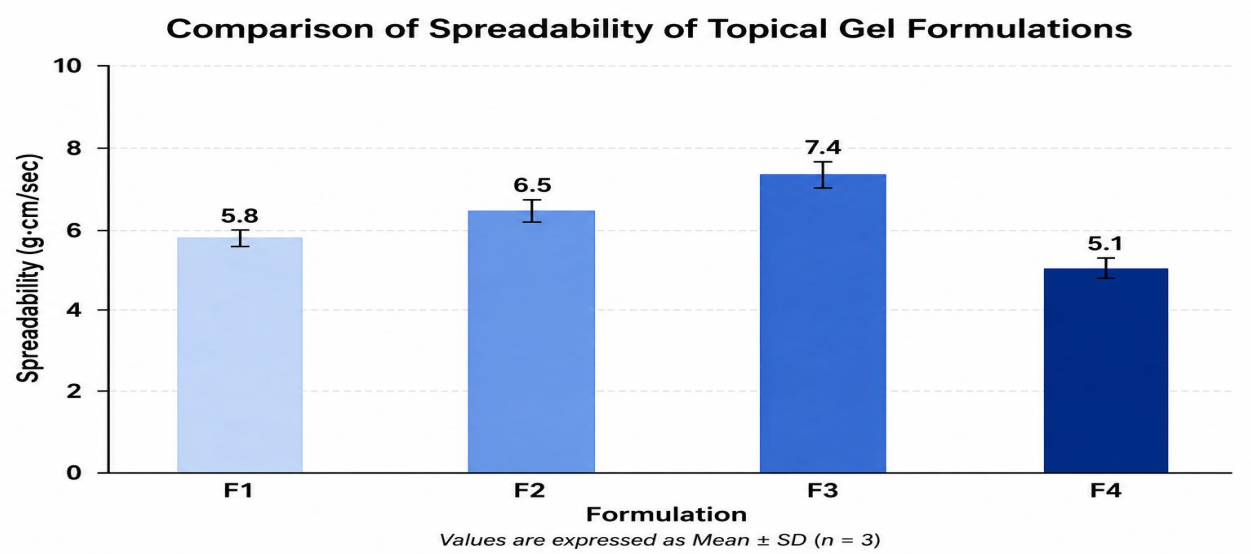


Figure 7 Comparative spreadability profile of different gel formulations

D. Drug Content Determination

Gel equivalent to 10mg drug as dissolved in phosphate buffer ph 6.8 and analyzed spectrophotometrically at 210 nm.

Table 6 Drug Content Determination:

Concentration (µg/ml)	Absorbance
2	0.112
4	0.222
6	0.334
8	0.448
10	0.556

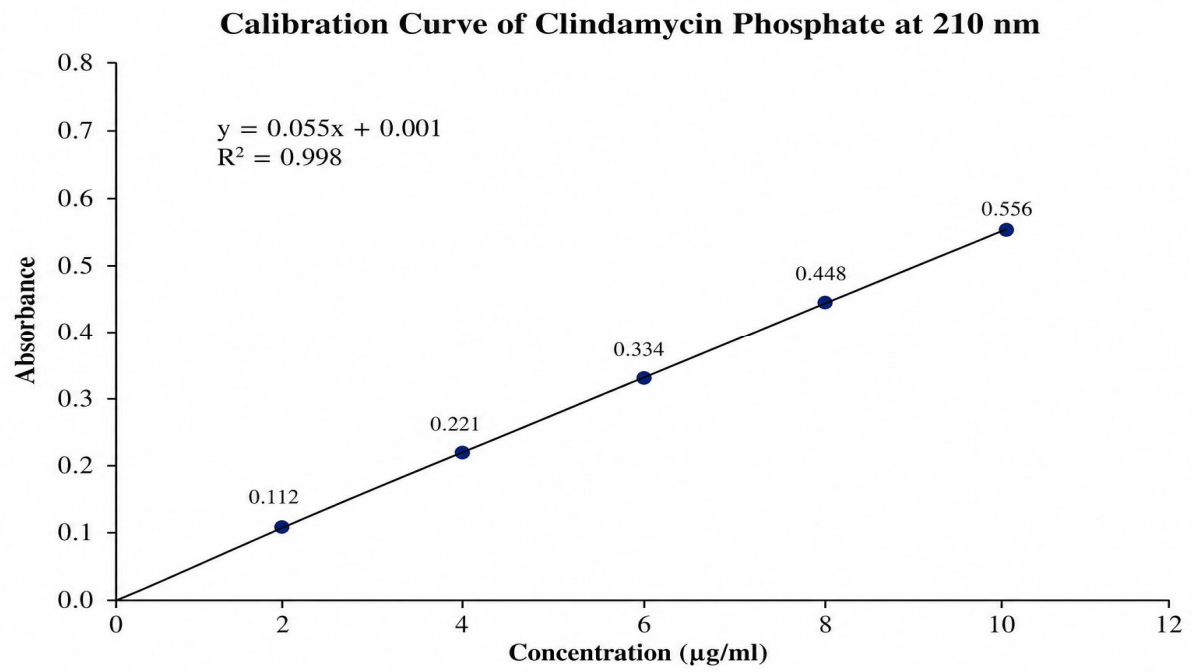


Figure 8 Calibration curve of clindamycin phosphate at 210 nm showing linearity between concentration and absorbance

E. In Vitro Drug Diffusion Study

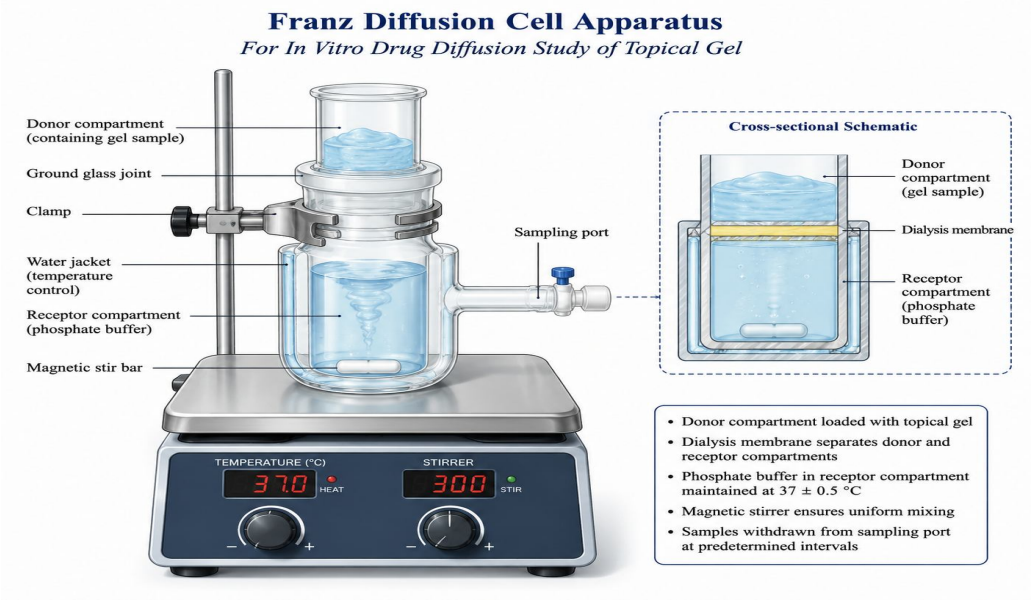


Figure 9 Franz diffusion cell assembly used for in vitro drug release study

IV. RESULTS AND DISCUSSION

Table 7 pH, Viscosity and Spreadability:

Formulation	PH	Viscosity (cPs)	Spreadability
F1	5.7 ± 0.1	4210 ± 25	5.8 ± 0.2
F2	6.0 ± 0.2	5120 ± 30	6.5 ± 0.1
F3	6.2 ± 0.1	5810 ± 32	7.4 ± 0.2
F4	6.4 ± 0.2	6930 ± 28	5.1 ± 0.3

F3 showed optimum viscosity and excellent spreadability suitable for topical application.

Table 8 Drug Content

Formulation	Drug Content(%)
F1	96.2 ± 0.3
F2	97.4 ± 0.4
F3	98.7 ± 0.4
F4	97.9 ± 0.5

A. In Vitro Drug Release

Table 9: Drug Release Profile of Optimized Formulation (F3)

Time(h)	% drug release
1	18.4 ± 0.2
2	33.1 ± 0.3
4	59.2 ± 0.4
6	79.4 ± 0.5
8	94.2 ± 0.5

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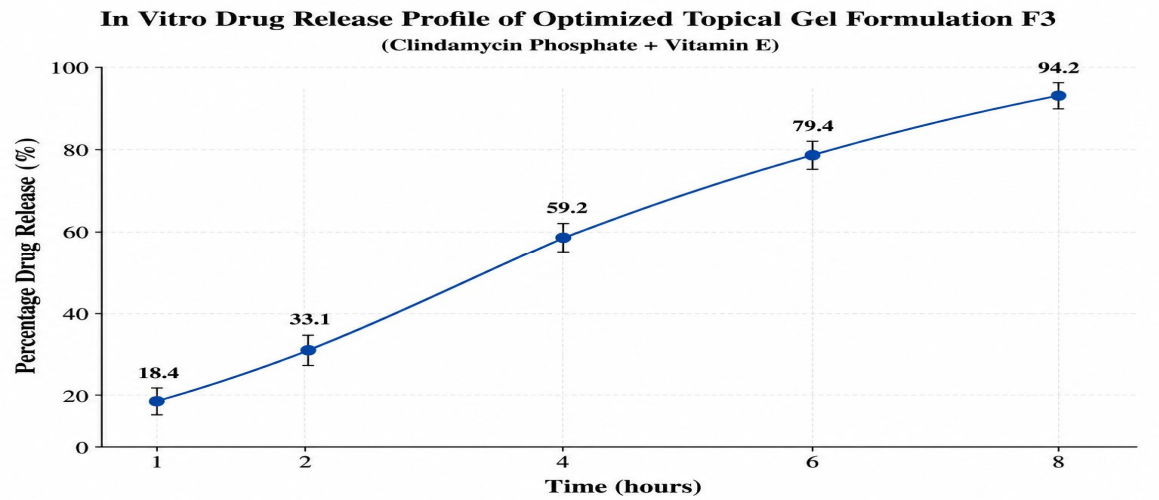


Figure 10 In vitro drug release profile of optimized formulation F3 over 8 h

B. Antimicrobial Activity

Table 10 Antimicrobial Activity

Formulation	Zone of Inhibition(mm)
F1	18
F2	20
F3	24
F4	21

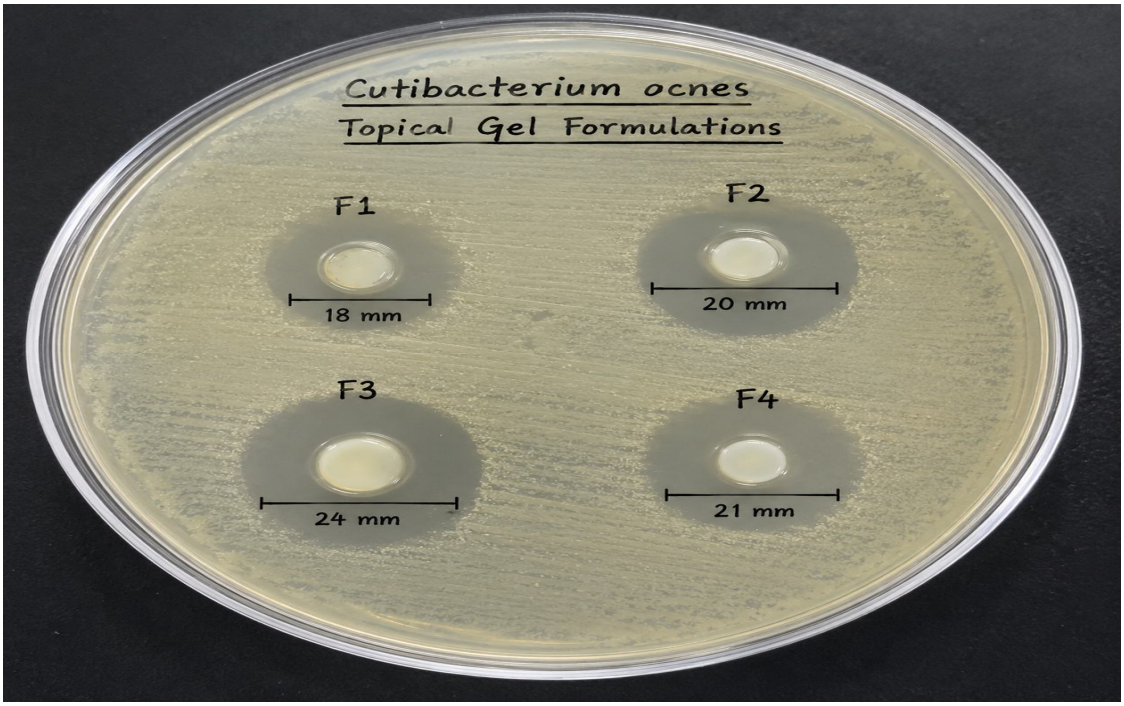


Figure 11 Antimicrobial activity of topical gel formulations against Cutibacterium acnes.

C. Stability Study

Table 11 Stability Study

Month	Drug Content(%)
0	98.7
1	98.3
2	97.9
3	98.5

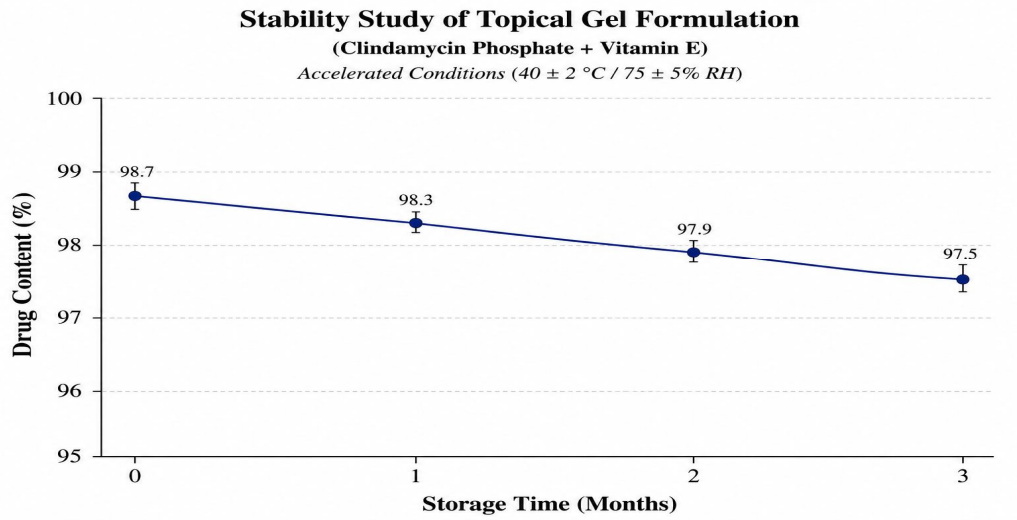


Figure 12 Stability profile of optimized formulation during accelerated stability testing.

D. FTIR Compatibility Study

Table 12 FTIR Peak Data:

Functional Group	Peak (cm^{-1})
O–H stretching	3412
C=O stretching	1724
C–N stretching	1250
N–H bending	1542

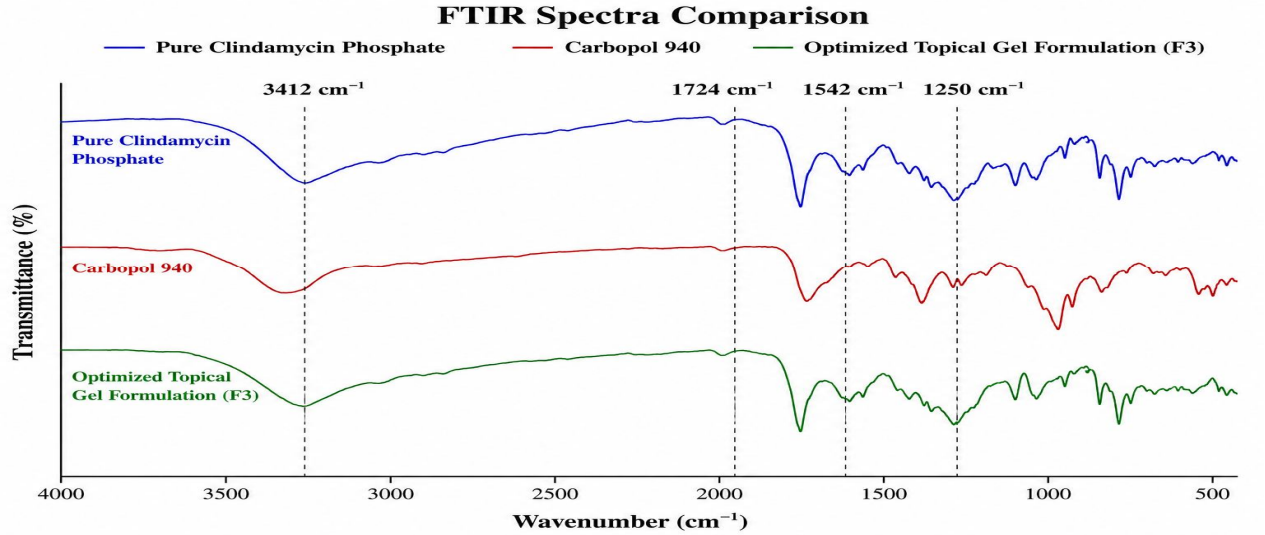


Figure 13 FTIR spectra showing compatibility between clindamycin phosphate and formulation excipients.

E. Extrudability Study

Table 13 Extrudability Study:

Formulation	Extrudability
F1	Good
F2	Very Good
F3	Excellent
F4	Moderate

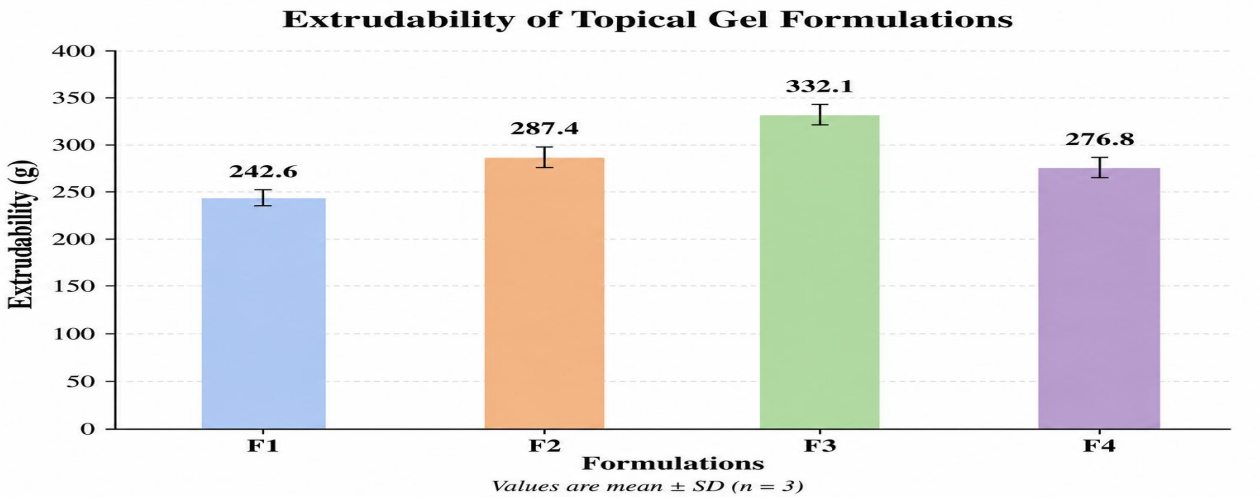


Figure 14 Comparative extrudability profile of topical gel formulations.

F. Skin Irritation Study

Table 14 Skin Irritation Study:

Formulation	Erythema	Edema
F1	None	None
F2	None	None
F3	None	None
F4	Slight	None

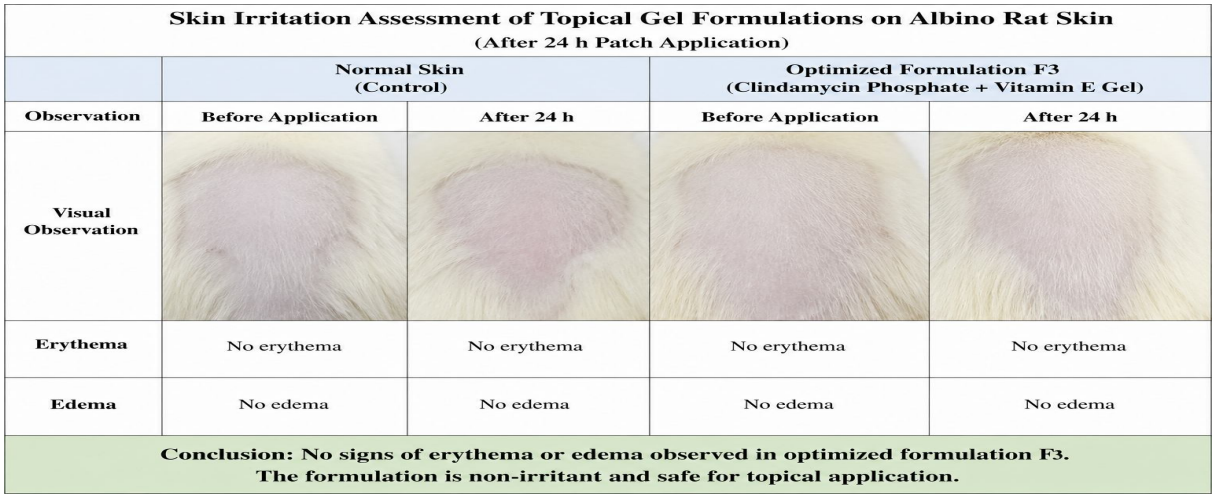


Figure 15 Skin irritation evaluation of optimized topical gel formulation.

G. Drug Release Kinetics

Table 15: Release Kinetics Parameters

Model	R^2 Value
Zero order	0.942
First order	0.958
Higuchi	0.991
Korsmeyer–Peppas	0.972

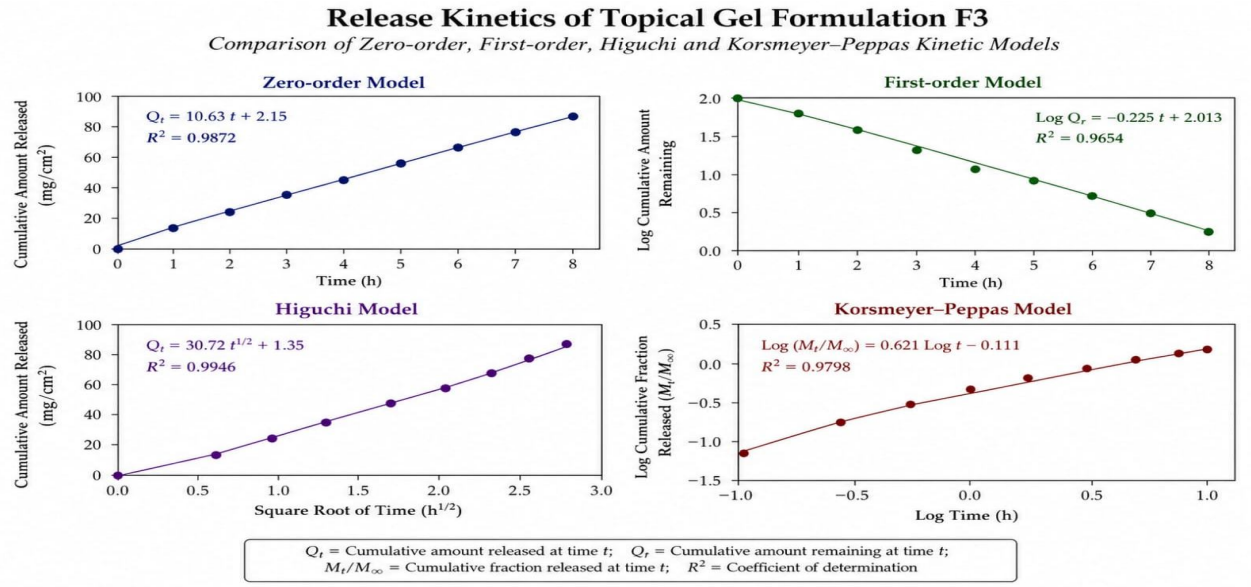


Figure 16 Drug release kinetic modeling of optimized gel formulation.

H. Statistical Analysis

All experimental studies were performed in triplicate (n = 3) and results were expressed as mean ± standard deviation. Statistical analysis was performed using one-way ANOVA followed by Tukey's post hoc test. Differences were considered statistically significant at $p < 0.05$.

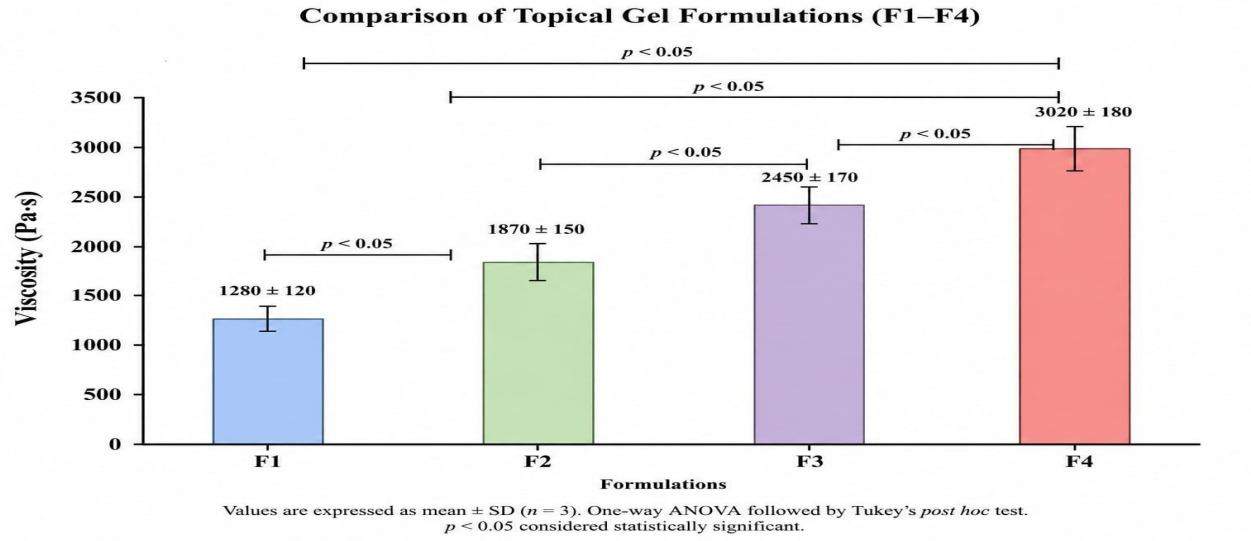


Figure 17 Statistical comparison of formulation evaluation parameters.

V. NOVELTY OF THE STUDY

The novelty of the present study lies in the incorporation of vitamin E into clindamycin phosphate topical gel to improve antioxidant protection, enhance patient tolerability, and provide sustained antibacterial activity using a Carbopol-based delivery system.

VI. LIMITATIONS OF THE STUDY

The present investigation was limited to in vitro and preliminary skin irritation studies. Long-term clinical evaluation and large-scale stability studies are required to establish therapeutic efficacy and commercial feasibility.

VII. FUTURE SCOPE

Future studies may focus on clinical evaluation in acne patients, advanced permeation studies, and development of nano-enabled topical delivery systems for enhanced therapeutic efficacy.

VIII. ETHICAL APPROVAL STATEMENT

Animal handling and experimental procedures were performed according to institutional ethical committee guidelines for laboratory animal care and use.

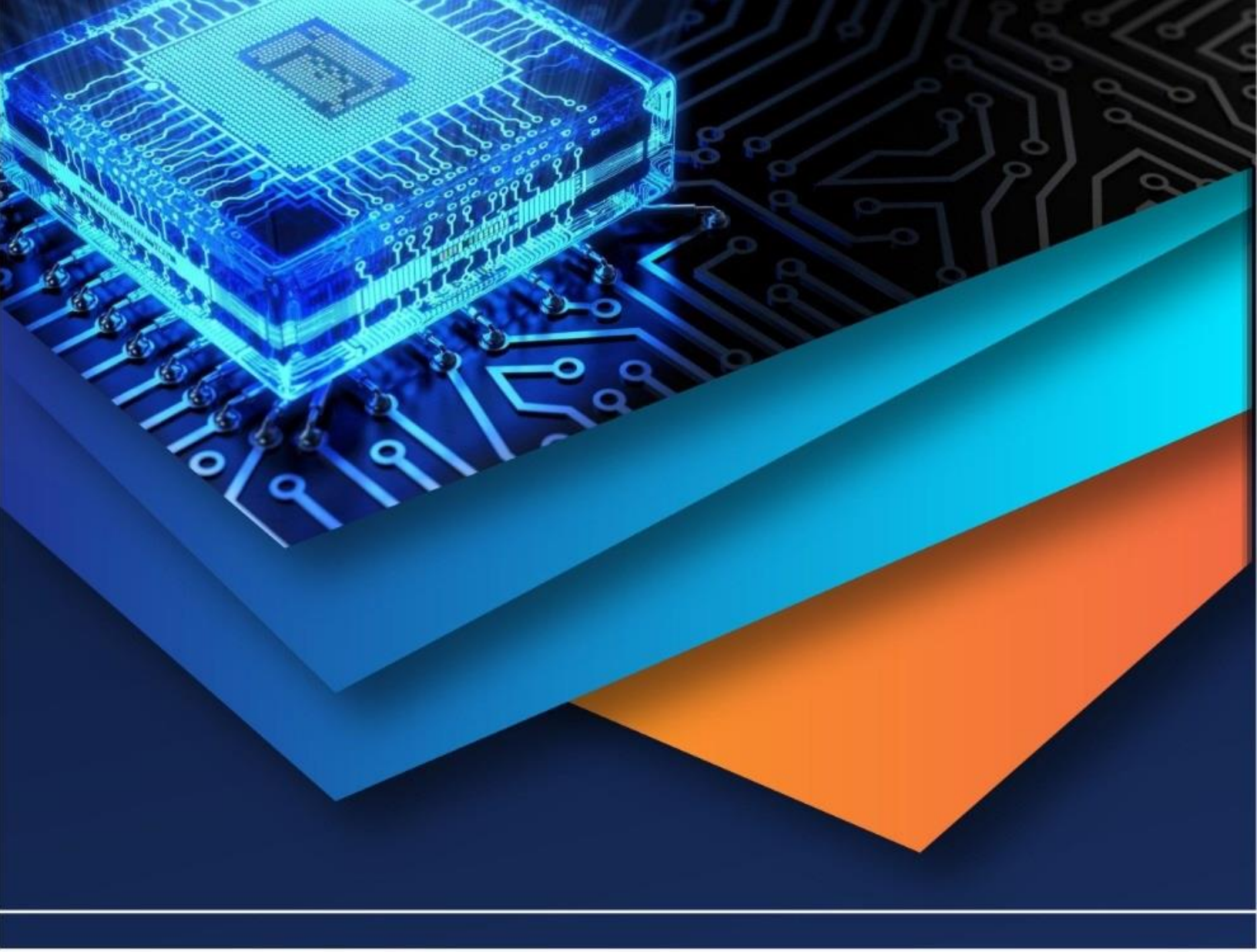
IX. CONCLUSION

The present investigation successfully developed and evaluated a topical gel containing clindamycin phosphate and vitamin E using Carbopol 940 as a gelling agent. Among all formulations, F3 demonstrated optimum physicochemical properties, satisfactory drug content, controlled drug release, and excellent antimicrobial activity. Incorporation of vitamin E improved skin compatibility and formulation stability. Therefore, the developed gel may serve as an effective topical therapy for acne vulgaris.

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