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Formulation, Optimization and Evaluation of Baclofen-Loaded Transdermal Cream for Enhanced Skin Permeation

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Abstract: ***The present research paper summarizes the formulation, optimization and evaluation of a baclofen-loaded transdermal cream developed to enhance topical and transdermal delivery. Baclofen, a GABA-B receptor agonist used for muscle spasticity and neuropathic pain, has limitations when administered orally, including systemic adverse effects and fluctuating plasma concentrations. Therefore, an oil-in-water cream system was developed using stearic acid, cetyl alcohol, liquid paraffin, glycerin, triethanolamine, methyl paraben, propyl paraben and propylene glycol. A factorial Design of Experiment (DoE) approach was applied to study the influence of formulation variables on critical quality attributes such as viscosity, spreadability and drug release. Preformulation studies confirmed acceptable organoleptic properties, suitable solubility behavior, UV absorbance at 220 nm and compatibility of baclofen with excipients through FTIR and DSC. Evaluation of the prepared batches indicated acceptable near-neutral pH, absence of phase separation, satisfactory consistency, controlled viscosity and uniform drug content. The optimized cream showed sustained in-vitro release with 96.87% cumulative drug release over 6 h and good stability under storage conditions. Comparative assessment suggested better residence time, non-greasy texture and patient acceptability than marketed gel formulations. Overall, the developed baclofen cream provides a promising patient-friendly platform for localized muscle relaxation, neuropathic pain relief and enhanced transdermal drug delivery.***

Keywords: Baclofen; transdermal cream; Design of Experiment; viscosity; spreadability; in-vitro release; topical drug delivery.

I. INTRODUCTION

Transdermal drug delivery systems offer controlled drug permeation through the skin for systemic or localized therapeutic effects. This route is attractive because the skin provides a large and accessible surface area, allows non-invasive application and can reduce the limitations of oral therapy, including gastrointestinal degradation and hepatic first-pass metabolism. The stratum corneum is the principal barrier to permeation, but suitable formulation strategies such as cream bases, penetration enhancers, polymers and nanocarriers can improve drug partitioning and diffusion through skin layers [1-6].

Baclofen is a skeletal muscle relaxant and GABA-B receptor agonist used in the management of muscle spasticity, neuropathic pain, muscle stiffness and musculoskeletal disorders. Oral baclofen therapy may produce sedation, dizziness, weakness, nausea and systemic exposure-related adverse effects. A topical cream formulation can deliver baclofen locally to affected tissues, improve patient compliance and reduce the requirement for frequent oral dosing. In the present work, baclofen was formulated as a transdermal cream and optimized using a Design of Experiment approach to obtain balanced viscosity, spreadability, stability and controlled release.

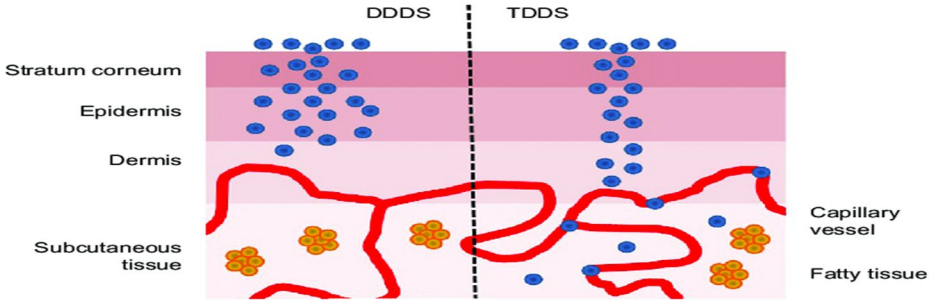

Figure 1. Schematic representation of transdermal drug delivery through skin layers.

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II. MATERIALS AND METHODS

A. *Materials*

Baclofen was used as the active pharmaceutical ingredient. Stearic acid and cetyl alcohol were used for emulsifying, thickening and cream consistency. Liquid paraffin functioned as an oil phase and emollient, glycerin as a humectant, triethanolamine as pH adjuster/emulsifier and methyl paraben and propyl paraben as preservatives. The details of materials used are presented below.

B. *Instruments*

Analytical and formulation instruments included UV-visible spectrophotometer, FTIR spectrophotometer, differential scanning calorimeter, Brookfield viscometer, digital pH meter, mechanical stirrer, Franz diffusion cell and Expert Design software for DoE analysis.

C. *Preformulation and compatibility studies*

Preformulation studies included organoleptic evaluation, solubility studies, melting point determination and UV spectrophotometric analysis. Baclofen was examined for appearance, odor, physical nature and impurities. Solubility was studied in water, phosphate buffers and organic solvents. A calibration curve was prepared using the UV method at the selected wavelength. Compatibility of baclofen with excipients was evaluated by FTIR and DSC to identify possible interactions.

D. *Formulation design and optimization*

A factorial DoE strategy was used to evaluate the influence of formulation variables on responses. Stearic acid, cetyl alcohol and propylene glycol were selected as independent variables, whereas viscosity, spreadability and drug release/permeation were selected as response variables. Nine baclofen cream batches were prepared by varying the concentrations of formulation components. The oil and aqueous phases were separately heated, mixed under stirring and cooled with continuous trituration to obtain uniform cream.

Table 2.1 . Composition of baclofen cream formulations (F1-F9).

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Baclofen (g)	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Stearic acid (g)	14	10	14	10	10	6	10	6	10
Cetyl alcohol (g)	2	0.1	1.05	1.05	1.05	1.05	1.05	0.1	2
Liquid paraffin (g)	8	8	8	8	8	8	8	8	8
Glycerin (g)	5	5	5	5	5	5	5	5	5
Propylene glycol (g)	4	8	8	4	12	8	8	12	8
Methyl paraben (g)	0.18	0.18	0.18	0.18	0.18	0.18	0.18	0.18	0.18
Propyl paraben (g)	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
Triethanolamine (mL)	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3
Purified water (q.s. to 100g)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

E. *Evaluation parameters*

The prepared creams were evaluated for physical appearance, pH, spreadability, viscosity, drug content uniformity, in-vitro drug release and stability. Appearance was assessed by observing color, consistency, homogeneity and phase separation. pH was measured with a digital pH meter. Spreadability was determined using the slip-drag method. Viscosity was measured by Brookfield viscometer. Drug content was analyzed by UV spectrophotometry after suitable dilution. In-vitro release was performed in diffusion medium using a membrane-based diffusion system, and stability samples were monitored for physical and chemical changes during storage.

III. RESULTS AND DISCUSSION

A. *Preformulation results*

Baclofen was found to be white to off-white, odorless and crystalline in nature without visible impurities. Solubility studies showed that baclofen was freely soluble in distilled water and phosphate buffer, moderately soluble in ethanol and slightly soluble in propylene glycol. These observations supported its incorporation into the cream base and use of phosphate buffer pH 7.4 as a release medium.

Table 3.1. Organoleptic evaluation of baclofen.

Parameter	Observation
Color	White to off-white
Odor	Odorless
Physical nature	Crystalline powder
Impurities	Not observed

Table 3.2. Solubility observations of baclofen.

Solvent	**Solubility**
Distilled water	Freely soluble
Phosphate buffer pH 6.8	Freely soluble
Ethanol	Moderately soluble
Propylene glycol	Slightly soluble

The UV spectrophotometric method showed linear absorbance behavior across the studied concentration range. The calibration equation reported in the thesis was y = 0.0526x + 0.0349, which was used for drug content and release calculations.

Table 3.3. UV calibration data for baclofen.

Concentration (µg/mL)	**Absorbance**
2	0.134
4	0.245
6	0.374
8	0.432
10	0.566

B. *3.2 Drug-excipient compatibility*

FTIR spectra confirmed the presence of characteristic functional groups of baclofen without major disappearance or shifting of significant peaks. The important assignments included N-H stretching, O-H stretching, aromatic C=C stretching and C-Cl stretching. DSC results showed a minor shift in peak temperature between pure drug and drug-excipient mixture, but no major change was observed, indicating absence of significant incompatibility.

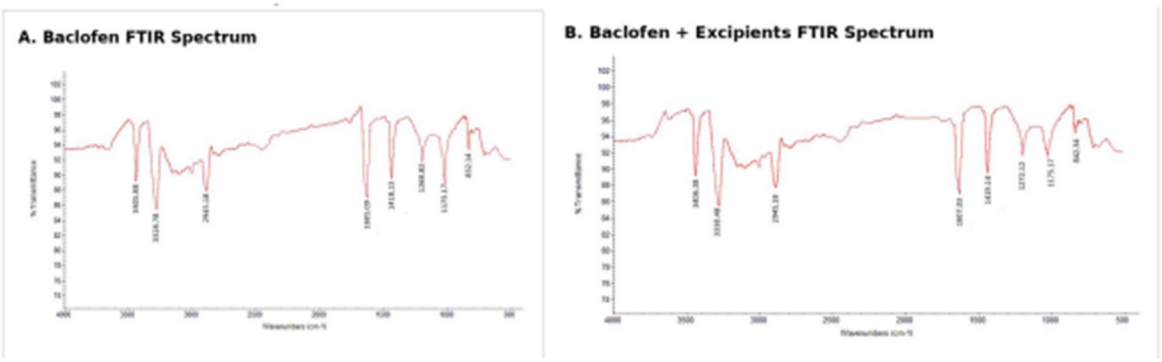

Fig 3.1: Baclofen FTIR spectra

Table 3.4. FTIR spectral assignments of baclofen.

Wavenumber (cm^{-1})	Assignment	Functional Group	Intensity
3405	N-H stretching	Primary amine (-NH_2)	Medium
3328	O-H stretching (broad)	Carboxylic acid (-COOH)	Broad, Strong
2945	C-H stretching	Aliphatic (CH_2)	Medium
1605	C=C stretching	Aromatic ring	Strong
1418	O-H bending	Carboxylic acid	Medium
1268	C-N stretching	Amine	Medium
1175	C-O stretching	Carboxylic acid	Strong
832	C-H bending (out-of-plane)	Aromatic ring	Weak

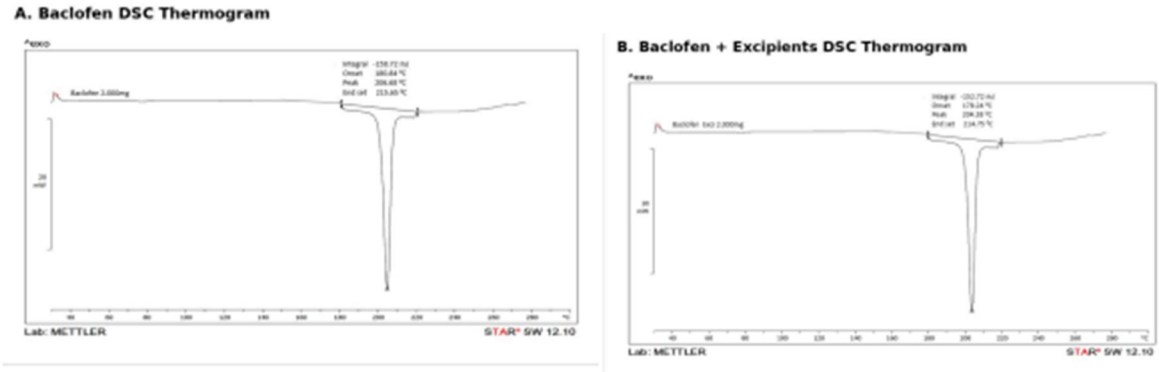

Fig 3.2: Baclofen DSC

Table 3.5. DSC compatibility observations.

Parameter	Pure Drug	Drug + Excipients	Interpretation
Onset Temperature	180.8	178.2	Minor shift
Peak Temperature	206.6	204.3	Slight decrease
Endset Temperature	215.6	214.7	No major change
Enthalpy (ΔH)	158 mJ	152 mJ	Slight decrease

C. 3.3 DoE analysis and formulation optimization

The factorial design generated nine experimental runs. The viscosity of the batches ranged from 2440 to 30000 cP, spreadability ranged from 9 to 16 g.cm/s and drug release ranged from 85% to 94% in the DoE experimental matrix. The results showed that polymeric and fatty components affected cream consistency, skin applicability and drug release. Higher thickening or structuring components increased viscosity but could reduce spreadability, while optimized concentrations provided a balanced performance.

Table 3.6. DoE experimental runs and observed responses.

Run	A:Concentration of Steric Acid	B:Concentration of Cetyl Alcohol	C:Concentration of Propylene glycol	R1 Viscosity cps	R2 Spreadability gm/cm	R3 Drug Release %
1	14	2	4	3150	16	85
2	10	0.1	8	2400	9	86
3	14	1.05	8	30000	10	90
4	10	1.05	4	2450	10	91
5	10	1.05	12	2450	10	89
6	6	1.05	8	18000	10	85
7	10	1.05	8	24000	10	91
8	6	0.1	12	18000	9	92
9	10	2	8	2440	15	94

Table 3.7. Response summary from DoE study.

Response	Name	Units	Minimum	Maximum	Mean	Std. Dev.	Ratio
R1	Viscosity	cP	2440	30000	16800	18.08	1.46
R2	Spreadibility	gm/cm	9	16	12.5	4.02	1.14
R3	Drug Release	%	85	94	89	11.23	1.02

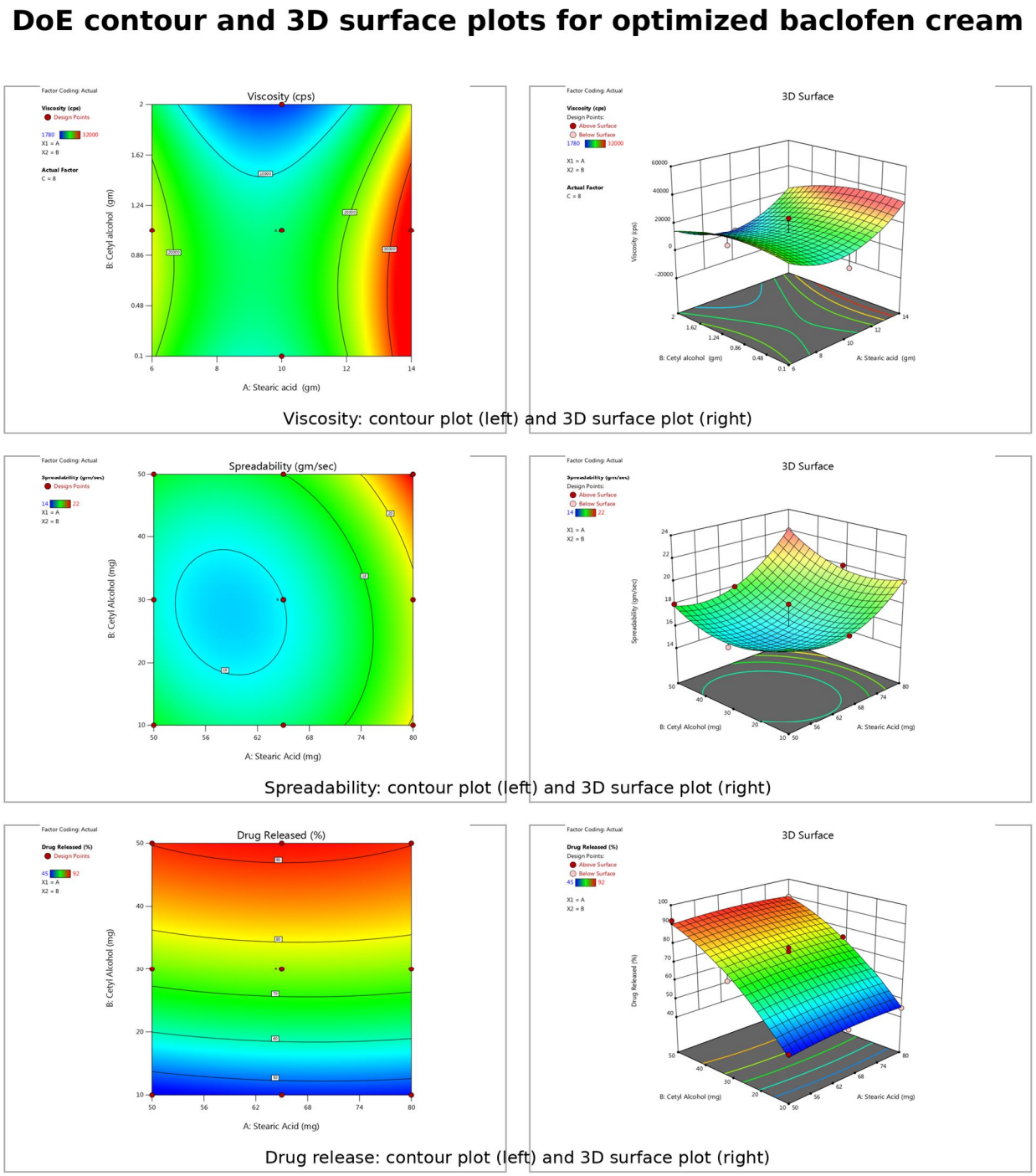

Figure 3.3. Contour and 3D surface plots demonstrating the influence of formulation variables on viscosity, spreadability and drug release.

D. Evaluation of baclofen cream formulations

1) Physical Appearance

All batches were off-white to white and free from phase separation. Most batches showed smooth consistency, while F5 and F9 were slightly thick. Homogeneity was good to excellent, confirming acceptable physical quality of the cream base. The optimized batch F9 was off-white, slightly thick, showed good homogeneity and remained free from phase separation.

Table 3.4.1. Physical appearance of baclofen cream batches.

Batch	Color	Consistency	Homogeneity	Phase separation
F1	Off-white	Smooth	Good	Absent
F2	Off-white	Smooth	Good	Absent
F3	Off-white	Smooth	Excellent	Absent
F4	Off-white	Smooth	Excellent	Absent
F5	White	Slightly thick	Good	Absent
F6	Off-white	Smooth	Good	Absent
F7	White	Smooth	Good	Absent
F8	Off-white	Smooth	Excellent	Absent
F9	Off-white	Slightly thick	Good	Absent

2) pH

The pH of prepared batches ranged from 6.0 to 7.2. Most formulations were near-neutral and suitable for topical application. The optimized batch F9 showed pH 7.2, indicating a slightly alkaline but acceptable pH that should be monitored during further skin-irritation testing.

Table 3.4.2. pH observations of baclofen cream batches.

Batch	pH
F1	6.0
F2	6.1
F3	6.2
F4	6.3
F5	6.0
F6	6.4
F7	6.8
F8	6.9
F9	7.2

3) Spreadability

Spreadability values ranged from 11.00 to 16.3 g.cm/s. Higher spreadability indicates easier application and better distribution on the skin surface, while lower values reflect greater consistency and retention. F5 showed the highest spreadability, whereas the optimized batch F9 showed 11.00 g.cm/s, suggesting a thicker cream with adequate retention on the application site.

Table 3.4.3. Spreadability observations of baclofen cream batches.

Batch	Spreadability (g·cm/s)
F1	13.8
F2	14.5
F3	15.2
F4	16.2
F5	16.3
F6	16.0
F7	16.2
F8	14.9
F9	11.00

4) Viscosity

The viscosity of baclofen cream batches ranged from 22,700 to 40,500 cP. The range indicates that the formulations possessed adequate consistency for topical retention. The optimized batch had a viscosity of 32,500 cP, showing a suitable balance between structural strength and spreadability.

Table 3.4.4. Viscosity observations of baclofen cream batches.

Batch	Viscosity (cps)
F1	35,200
F2	37,800
F3	40,500
F4	28,100
F5	27,000
F6	29,900
F7	22,700
F8	26,200
F9	32,500

5) Drug Content Uniformity

Drug content was determined in triplicate by UV spectrophotometric analysis. The observed drug content values were 91.20% to 98.25%. The low variation among trials confirmed uniform distribution of baclofen in the cream base and satisfactory content uniformity.

Table 3.4.5. Drug content uniformity of optimized baclofen cream.

Batch	Drug Content Uniformity (%)
F1	91.20
F2	92.45
F3	93.80
F4	94.65
F5	95.30
F6	95.85
F7	96.40
F8	96.95
F9	98.25

6) In-vitro drug release

The optimized formulation demonstrated controlled and sustained release of baclofen. The cumulative release increased from 89 % to 96.8% at 8 h. The gradual release pattern indicates diffusion-controlled drug release from the cream matrix and prolonged drug availability at the application site.

Table 3.4.6.1. In-vitro drug release profile of optimized baclofen cream.

Time (hr)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
0.5	20	22	30	31	33	34	35	36	40
1	45	48	52	55	58	60	63	66	70
2	58	60	64	66	69	72	74	76	80
3	66	68	71	73	76	78	80	82	85
4	72	74	76	78	81	83	85	87	90
5	77	79	81	83	85	87	89	91	91
6	82	83	85	87	89	90	92	93	93
7	86	87	89	90	91	92	93	94	95
8	89	90	91	92	94	95	94	95	96.8

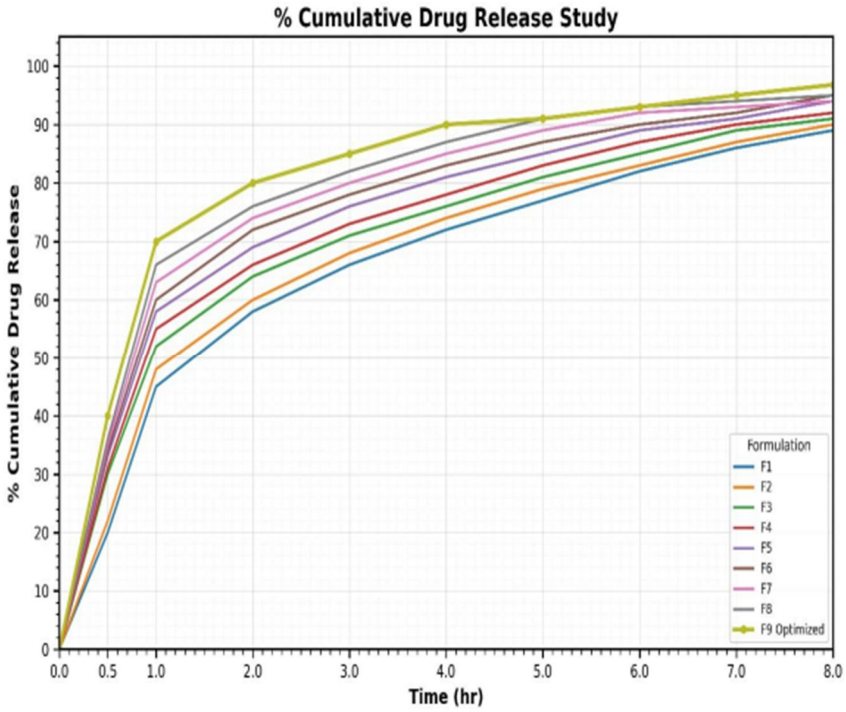

Figure 3.4.6.1 Cumulative in-vitro release profile of baclofen from optimized cream.

E. Stability and comparative study

Stability studies under long-term and accelerated conditions showed no significant changes in physical appearance, pH, viscosity or drug content. No phase separation or degradation was observed, and drug content remained within acceptable limits. These results indicate that the optimized baclofen cream was physically and chemically stable during the stability period.

A comparative study with a marketed baclofen-containing gel showed that the developed cream had non-greasy texture, excellent spreadability, optimized viscosity, sustained release, higher residence time on the skin and minimal irritation potential. The marketed formulation had faster release and moderate residence time. The developed formulation therefore showed better topical retention and patient acceptability while maintaining easy washability.

Table 3.5.1. Comparative evaluation of developed baclofen cream and marketed formulation.

Parameter	Developed Baclofen Cream	Marketed Formulation
Dosage Form	Cream	Gel
Active Ingredient	Baclofen	Baclofen + Gabapentin + Lidocaine
Drug Concentration	2% w/w	Baclofen 2% w/w
Appearance	Smooth white cream	Transparent/semi-transparent gel
Texture	Non-greasy, soft	Slightly sticky
Spreadability	Excellent	Moderate
Viscosity	Optimized for prolonged retention	Lower than cream
Skin Feel	Moisturizing and soothing	Cooling effect
Drug Release	Sustained release	Faster release
Residence Time on Skin	Higher	Moderate
Permeation Enhancer	Propylene glycol/Ethanol	Lidocaine and solvent system
Irritation Potential	Minimal	Mild irritation possible
Stability	Good physical stability	Good
Patient Compliance	High	High
Therapeutic Purpose	Muscle relaxation and enhanced transdermal delivery	Neuropathic pain relief
Washability	Easy	Easy
Occlusiveness	Moderate	Low

IV. CONCLUSION

The present research successfully formulated and optimized a baclofen-loaded transdermal cream using a systematic DoE approach. Preformulation studies confirmed the suitability of baclofen for topical formulation, while FTIR and DSC indicated compatibility with excipients. The developed cream batches showed acceptable appearance, pH, homogeneity, spreadability, viscosity and drug content. The optimized formulation demonstrated sustained in-vitro drug release of 96.87% over 6 h, absence of phase separation and satisfactory stability. DoE contour and 3D surface plots confirmed the interaction of formulation variables and helped identify a balanced optimized region. Comparative evaluation indicated improved skin retention, non-greasy texture and patient applicability compared with marketed gel formulation. Overall, the optimized baclofen cream is a promising topical/transdermal delivery system for localized muscle relaxation, neuropathic pain and musculoskeletal disorders, with potential to reduce systemic side effects associated with oral therapy.

V. FUTURE SCOPE

Future work may focus on incorporation of nanoemulsions, liposomes, niosomes, transfersomes or solid lipid nanoparticles to improve skin permeation and controlled drug release. Additional studies using different penetration enhancers, natural polymers and bioadhesive materials may further improve transdermal flux, safety and skin retention. In vivo pharmacokinetic and pharmacodynamic studies, large-scale manufacturing trials, long-term stability studies and comparative clinical evaluations are recommended to establish commercial feasibility and therapeutic effectiveness. Quality by Design and artificial intelligence-based optimization may also improve future formulation development and manufacturing consistency.

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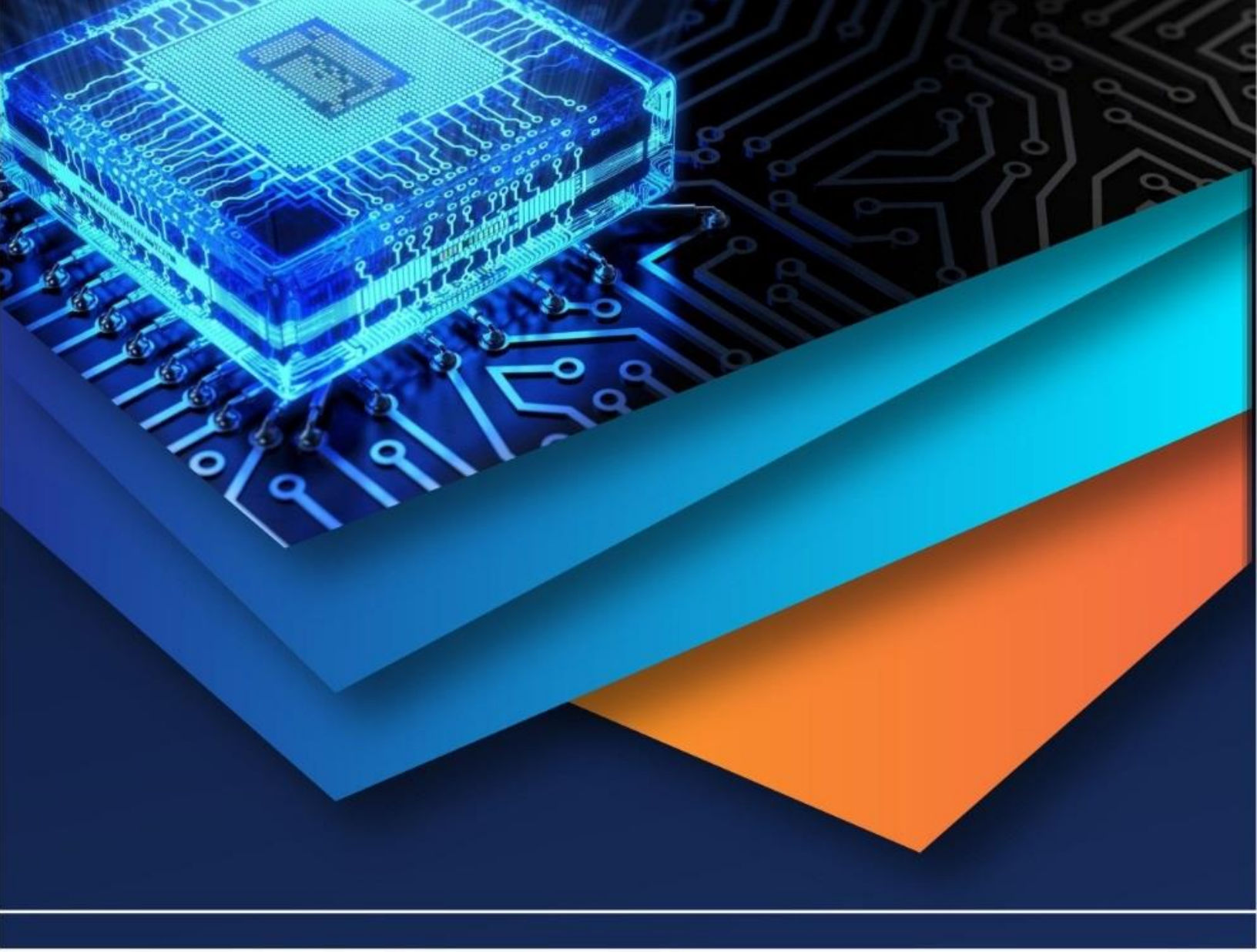

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