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Formulation, Optimization and Evaluation of Meloxicam Loaded Transdermal Emulgel Using Design of Experiments

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Abstract: ***The present research paper summarizes the formulation, optimization and evaluation of a meloxicam-loaded transdermal emulgel intended to improve topical delivery of a poorly water-soluble non-steroidal anti-inflammatory drug. Meloxicam was characterized by organoleptic evaluation, melting point, solubility, UV spectrophotometry, Fourier transform infrared spectroscopy and differential scanning calorimetry. Oil-in-water emulgels were prepared with liquid paraffin, Tween 80, Carbopol 934, dimethyl sulfoxide, preservatives and triethanolamine. A Design of Experiments approach was used to study the effect of Carbopol 934, Tween 80 and DMSO on viscosity, spreadability and in-vitro drug release. The optimized formulation (F9) showed smooth white appearance, excellent homogeneity, skin-compatible pH of 6.5, spreadability value of 16, viscosity of 27,000 cP, drug content of 96% and 95% cumulative drug release at 8 h. Stability results after 3 months showed no change in appearance, minor pH change from 6.4 to 6.6, minimal viscosity reduction from 27,000 to 26,800 cP and drug content retention from 95.86% to 95.34%. The statistical model was significant for viscosity and spreadability, with Carbopol 934 being the dominant influencing factor. Overall, the developed meloxicam emulgel demonstrated acceptable physicochemical properties, sustained drug release and good short-term stability, indicating its potential as a topical/transdermal drug delivery system.***
Keywords: Meloxicam; emulgel; transdermal delivery; Carbopol 934; Tween 80; DMSO; Design of Experiments; in-vitro drug release.

I. INTRODUCTION

Topical and transdermal drug delivery systems are increasingly used to improve local and systemic therapy while reducing gastrointestinal exposure and first-pass metabolism. Conventional semisolid systems may provide ease of application but often show limited loading and inconsistent release for lipophilic drugs. Emulgels combine the solubilizing advantage of emulsions with the residence time and patient acceptability of gels. This biphasic system is especially useful for drugs with low aqueous solubility, because the oil phase can solubilize the drug while the gel network controls release and improves spreadability.

Meloxicam is a preferential COX-2 inhibitor with anti-inflammatory and analgesic activity. Its low aqueous solubility and lipophilic character support the development of an emulgel system for topical/transdermal delivery. The present study prepared and evaluated meloxicam emulgel formulations using Carbopol 934 as a gelling agent, Tween 80 as an emulsifier, liquid paraffin as the oil phase and DMSO as a penetration enhancer. The paper includes all main result observations from the thesis, including preformulation data, compatibility observations, formulation trials, DoE analysis, physicochemical evaluation, drug release and stability data.

II. MATERIALS AND METHODS

A. Materials and Instruments

The formulation of meloxicam emulgel was prepared using selected pharmaceutical and analytical grade ingredients, each having a specific functional role. Meloxicam, a pharmaceutical grade drug, was used as the active pharmaceutical ingredient responsible for therapeutic action. Carbopol, of herbal grade, served as the polymer to provide gel structure and consistency. Stearic acid was included as an emulsifying agent, while triethanolamine acted as a pH adjuster and co-emulsifier. Cetyl alcohol was used as a thickening agent to improve viscosity and texture. Liquid paraffin functioned as the oil phase and emollient, enhancing spreadability. Glycerin was incorporated as a humectant to retain moisture. Methyl paraben and propyl paraben were added as preservatives to prevent microbial growth and improve stability during storage of formulation.

B. Preformulation Studies

Meloxicam was evaluated for organoleptic properties, melting point, solubility and UV spectrophotometric behavior. For UV analysis, 10 mg of meloxicam was dissolved in methanol and diluted to prepare stock and working solutions. Absorbance was measured at the selected λmax, and a calibration curve was prepared using 2-10 µg/mL solutions.

C. Drug-Excipient Compatibility

FTIR spectra of pure meloxicam and meloxicam-excipient mixtures were compared over the 4000-400 cm^{-1} range. DSC thermograms of pure meloxicam and physical mixtures were recorded to assess thermal compatibility through shifts or changes in endothermic peaks.

D. Formulation Development

Carbopol 934 was dispersed in water and allowed to hydrate. Preservatives were dissolved in warm water and incorporated into the gel phase. The oil phase containing liquid paraffin and emulsifying components was heated to approximately 60-70°C. Tween 80 was dissolved in warm water and mixed with the oil phase to form the emulsion. Meloxicam was incorporated with DMSO/oleic phase as penetration-enhancing vehicle, and the emulsion was gradually mixed into the hydrated Carbopol gel base. Triethanolamine was added dropwise to neutralize Carbopol and obtain the desired emulgel consistency.

Table 1. Final formulation composition of meloxicam emulgel batches.

Ingredient (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F9 / Optimized
Meloxicam	10	10	10	10	10	10	10	10	10	10
Liquid paraffin	100	100	120	120	120	100	120	100	120	120
Tween 80	10	30	50	10	30	50	10	30	50	50
Carbopol 934	50	50	50	125	125	125	200	200	200	200
DMSO	50	100	150	50	100	150	50	100	150	150
Preservatives (MP+PP)	20	20	20	20	20	20	20	20	20	20
Triethanolamine	20	20	20	20	20	20	20	20	20	20
Distilled Water (qs)	500	500	500	500	500	500	500	500	500	500

E. Experimental Design and Evaluation Parameters

A factorial Design of Experiments was applied to study the influence of Carbopol 934 (A), Tween 80 (B) and DMSO (C) on viscosity (R1), spreadability (R2) and drug release (R3). Prepared batches were evaluated for physical appearance, pH, spreadability, viscosity, drug content, in-vitro drug release and stability.

Spreadability was calculated as $S = (M \times L) / T$, where M is the applied weight, L is the length moved by the slide and T is the time taken. Viscosity was measured using a Brookfield viscometer. Drug content and release samples were analyzed by UV-Visible spectrophotometry. In-vitro release was evaluated using a Franz diffusion cell with phosphate buffer pH 7.4 at 37 ± 0.5°C.

III. RESULTS AND OBSERVATIONS

A. Preformulation Results

Meloxicam was pale yellow, odorless to faintly characteristic, fine, smooth and solid. The observed melting point matched the reported value, supporting drug identity and purity. Solubility studies showed very low aqueous solubility and better solubility in organic/co-solvent systems, supporting selection of a biphasic emulgel formulation.

Table 4. Organoleptic characteristics of meloxicam.

Property	Observation
Color	Pale yellow
Odor	Odorless or very faint characteristic odor
Texture	Fine and smooth
State	Solid

Table 5. Melting point observation of meloxicam.

Test	Observed Result	Reported Value	Inference
Melting point	254–258°C	255–257°C	Confirms purity of drug

Table 6. Solubility observation of meloxicam.

Solvent	Solubility (mg/mL)
Distilled water	Very low
Methanol	High
Propylene glycol	Very high
Liquid paraffin	Moderate

UV spectroscopy showed maximum absorbance at 360 nm. Calibration data showed an increasing absorbance response over 2-10 µg/mL, indicating suitability for quantitative estimation of meloxicam in formulation samples.

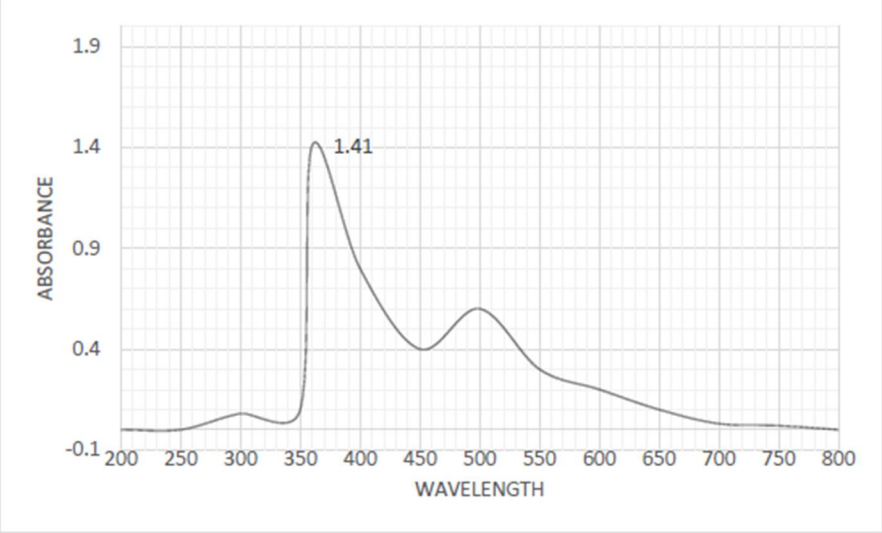

Figure 1. UV λmax spectrum of meloxicam.

Table 7. Calibration data of meloxicam.

Concentration (µg/mL)	Absorbance
2	0.115
4	0.221
6	0.305
8	0.445
10	0.556

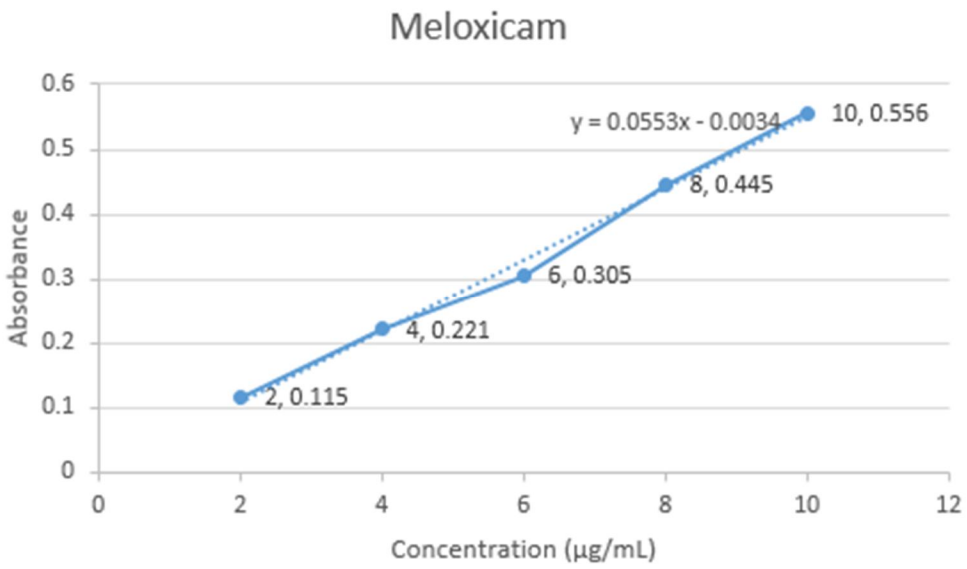

Figure 2. Calibration curve of meloxicam.

B. Compatibility Studies

FTIR spectra showed characteristic functional group peaks of meloxicam. The important peaks were retained in the drug-excipient mixture, suggesting absence of major chemical interaction. DSC showed a sharp endothermic peak for pure meloxicam at 249.69°C and a retained but slightly shifted broader peak at 242.68°C in the physical mixture, supporting compatibility between drug and excipients.

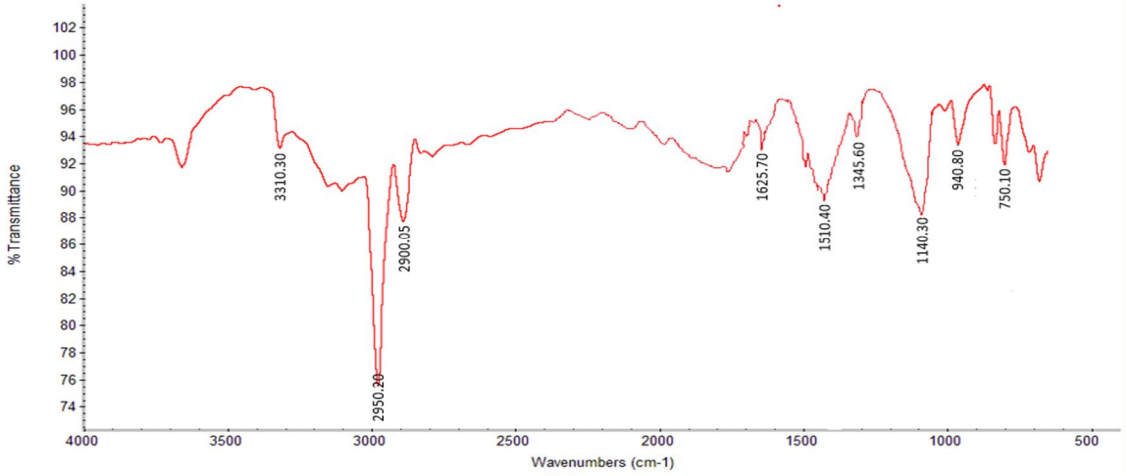

Figure 3. FTIR spectrum of pure meloxicam.

Table 8. FTIR observations of meloxicam.

Wavenumber (cm^{-1})	Intensity	Functional Group Assignment	Interpretation
3310	Medium	N–H stretching	Secondary amide
2950	Weak	Aliphatic C–H stretching	Alkyl groups
1625	Strong	C=O stretching	Amide carbonyl
1510	Medium	C=C stretching	Aromatic ring
1345	Strong	S=O stretching	Sulfonyl group
1140	Strong	S=O asymmetric stretch	Sulfone group

Wavenumber (cm^{-1})	Intensity	Functional Group Assignment	Interpretation
750	Medium	C–H bending	Aromatic substitution

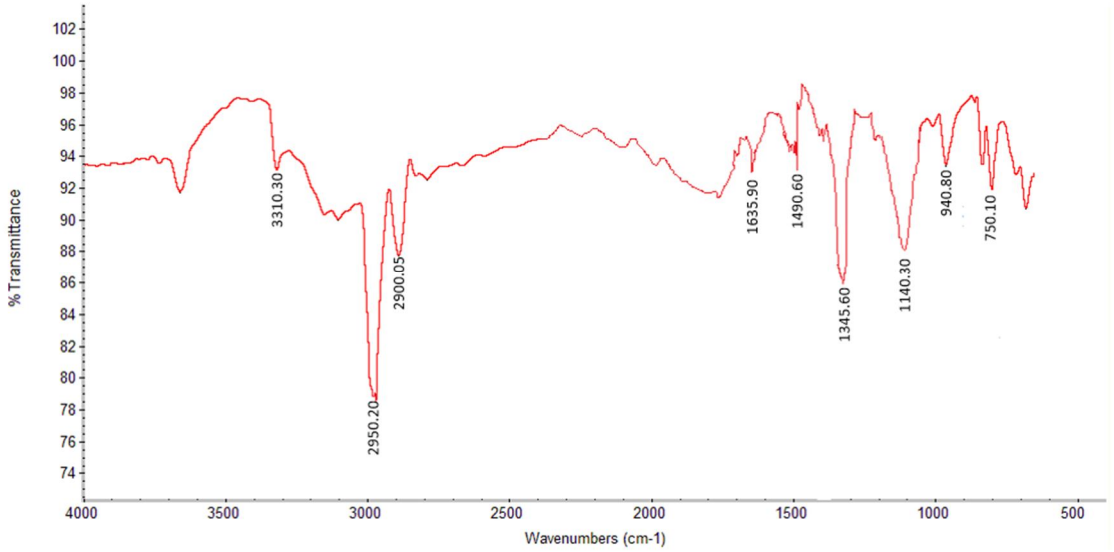

Figure 4. FTIR spectrum of meloxicam with excipients.

Table 9. DSC observations of meloxicam and physical mixture.

Sample	Peak Temperature (°C)	Nature of Peak	Enthalpy (ΔH)	Interpretation
Pure Meloxicam	249.69	Sharp endothermic	High	Corresponds to melting point; indicates crystalline nature and purity
Physical Mixture (All Excipients)	242.68	Broad peak	Reduced	Drug peak retained with slight shift; indicates compatibility

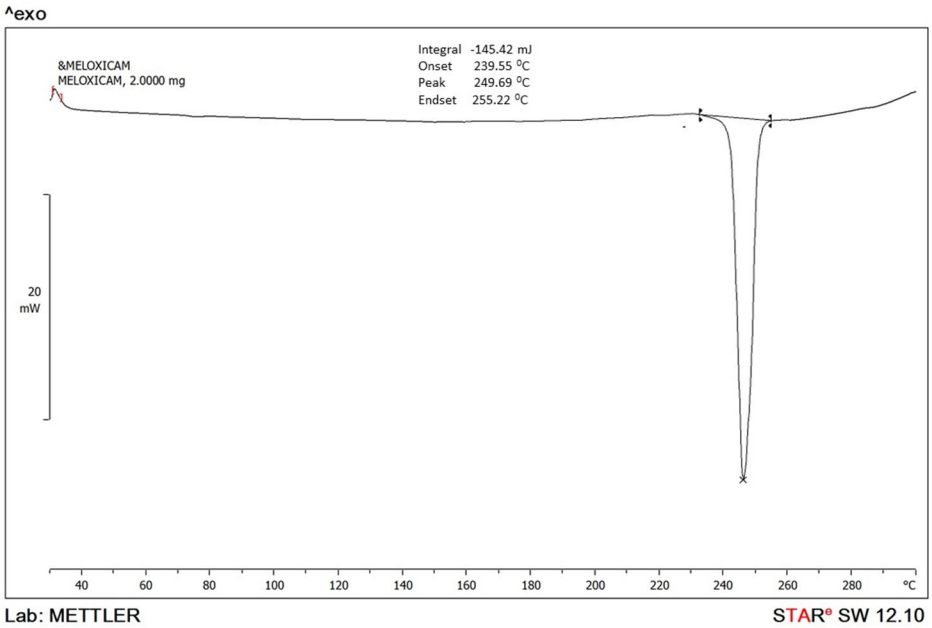

Figure 5. DSC thermogram of pure meloxicam.

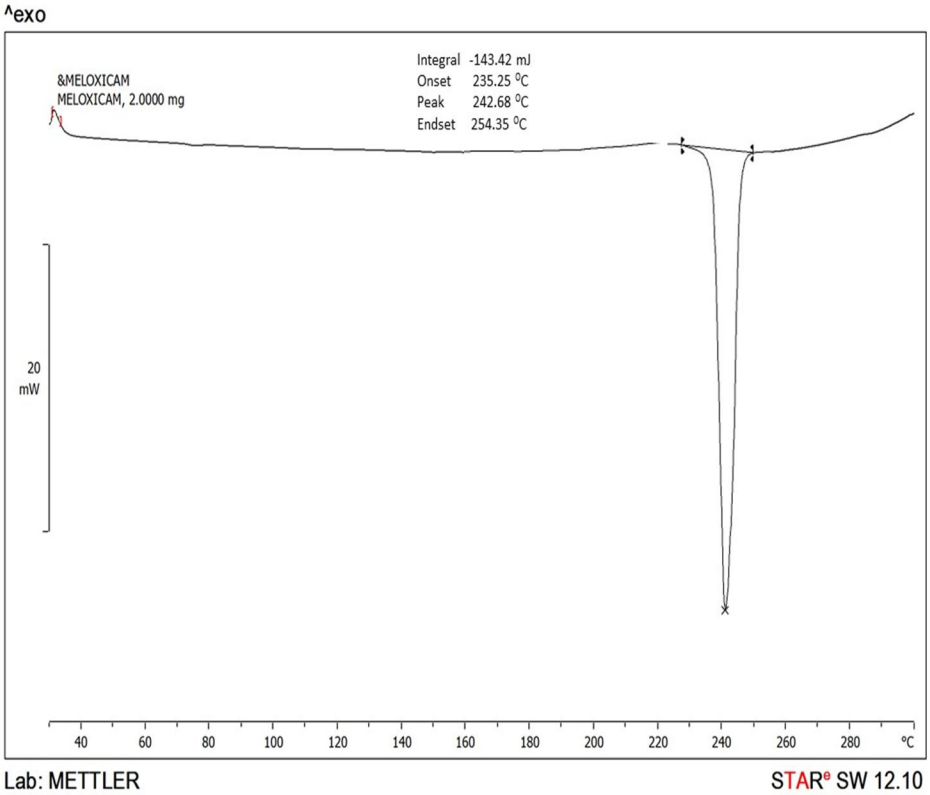

Figure 6. DSC thermogram of meloxicam with excipients.

C. Preliminary Trial Batches and DoE Results

Preliminary trials showed progressive improvement in viscosity, spreadability and release when formulation variables were increased. The data supported optimization through factorial design. In the final DoE batches, viscosity increased from 10,000 cP to 27,000 cP and spreadability increased from 6 to 16. F9 showed the highest 8 h release, drug content and rheological strength.

Table 20. Coefficients in terms of coded factors for quadratic model outputs.

	Intercept	A	B	AB	A^2	B^2
Viscosity	23562.5	-2.57472E-12	-583.333	-1125	3962.5	-1287.5
p-values		1.0000	0.3968	0.2009	0.0061	0.2281
Spreadability	18.0417	-0.166667	1.66667	0.25	-0.125	-4.625
p-values		0.0710	< 0.0001	0.0364	0.3153	< 0.0001
Drug Release	70.4671	7.79641	17.4491			
p-values		0.4264	0.1349			

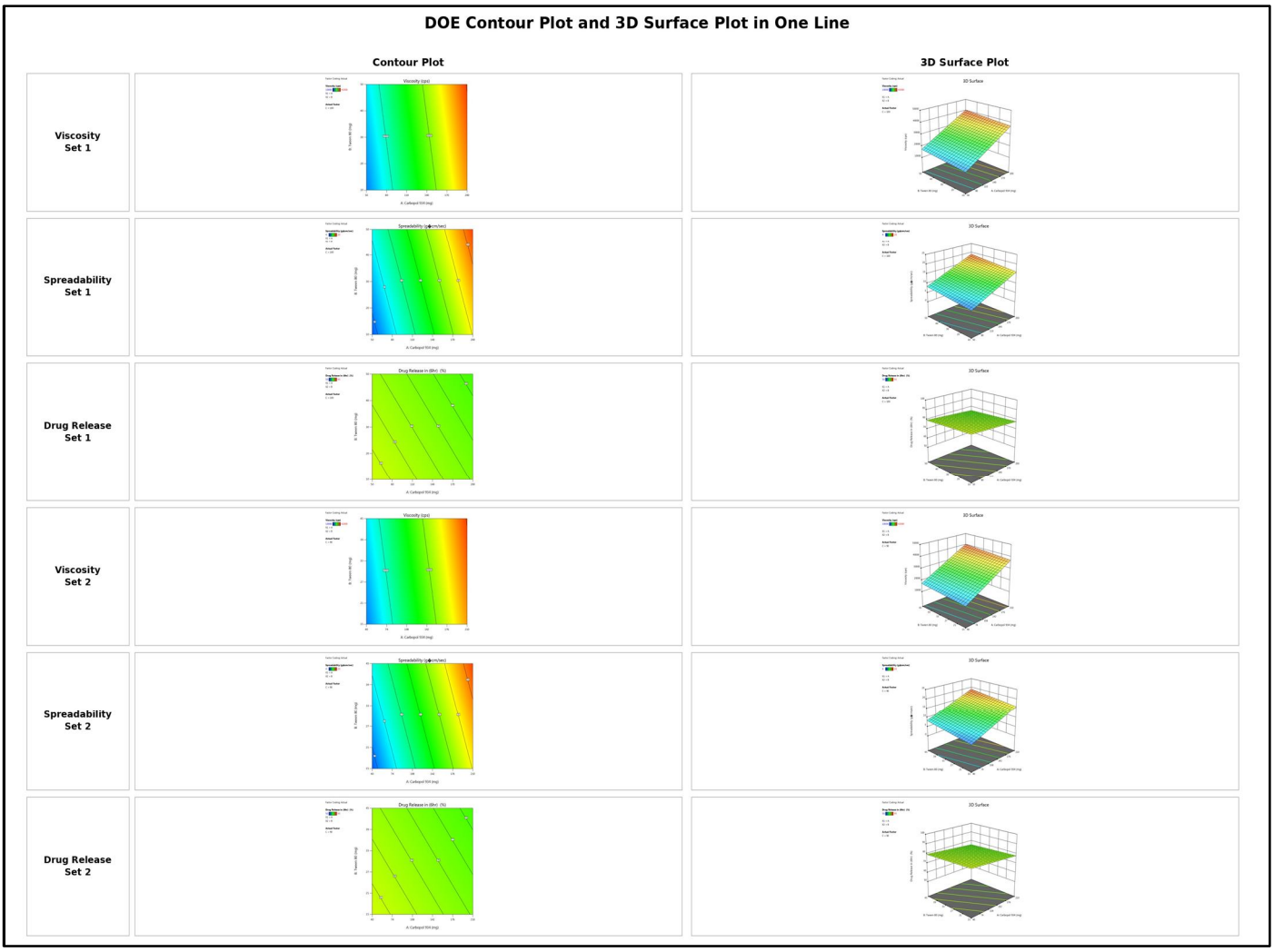

Figure 12. 3D surface plot for drug release response at 6 h.

D. Evaluation of Final Emulgel Formulations

All batches were white to off-white, smooth and homogeneous, with F9 showing excellent physical appearance and homogeneity. The pH values were within a skin-compatible range (6.0-6.7), with optimized F9 at pH 6.5. Spreadability and viscosity were highest in F9, indicating a strong gel matrix with acceptable application properties. Drug content ranged from 88% to 96%, with F9 showing the highest content.

The prepared meloxicam emulgel batches F1 to F9 were evaluated for important physicochemical parameters such as physical appearance, pH, spreadability, viscosity, and drug content. These evaluation parameters are essential for determining the suitability, stability, patient acceptability, and therapeutic performance of topical emulgel formulations. The physical appearance of all batches showed that the formulations were generally acceptable in terms of color, consistency, and homogeneity. Most of the batches were white in color, while F5 and F8 showed an off-white appearance. This slight change in color may be due to variation in excipient concentration, oil phase distribution, or increased viscosity of the formulation. The consistency of batches F1, F2, F3, F4, F6, F7, and F9 was smooth, indicating proper mixing of the emulsion phase with the gel base. F5 was slightly thick, whereas F8 was thick, which may be associated with higher polymer or thickening agent concentration. Homogeneity was found to be good in F1, F2, F5, F6, and F8, while F3, F4, F7, and F9 showed excellent homogeneity. Excellent homogeneity indicates uniform distribution of drug and excipients throughout the formulation, which is important for dose uniformity and consistent therapeutic action. Among all batches, F9 showed white color, smooth consistency, and excellent homogeneity, suggesting that it had the most desirable physical characteristics.

Table 21. Physical appearance of meloxicam emulgel batches.

Batch	Color	Consistency	Homogeneity
F1	White	Smooth	Good
F2	White	Smooth	Good
F3	White	Smooth	Excellent
F4	White	Smooth	Excellent
F5	Off-white	Slightly thick	Good
F6	White	Smooth	Good
F7	White	Smooth	Excellent
F8	Off-white	Thick	Good
F9 / Optimized	White	Smooth	Excellent

Table 22. pH observations of meloxicam emulgel batches.

Batch	pH
F1	6.4
F2	6.5
F3	6.7
F4	6.6
F5	6.3
F6	6.2
F7	6.3
F8	6.0
F9 / Optimized	6.5

The pH of topical formulations is an important parameter because it affects skin compatibility, drug stability, and patient comfort. The pH values of meloxicam emulgel batches ranged from 6.0 to 6.7. This range is considered suitable for topical application because it is close to the normal skin pH and is unlikely to cause irritation. F1 showed a pH of 6.4, F2 showed 6.5, F3 showed 6.7, F4 showed 6.6, F5 showed 6.3, F6 showed 6.2, F7 showed 6.3, F8 showed 6.0, and F9 showed 6.5. The slightly higher pH of F3 and F4 may be due to variation in triethanolamine concentration, which acts as a pH adjuster and neutralizing agent for Carbopol. The lowest pH was observed in F8, but it still remained within an acceptable range for skin application. The optimized batch F9 had a pH of 6.5, which indicates good skin compatibility and supports its suitability for topical use.

Table 23. Spreadability observations of meloxicam emulgel batches.

Batch	Spread ability
F1	6
F2	5
F3	7
F4	8
F5	9
F6	10
F7	11
F8	13
F9 / Optimized	16

Table 24. Viscosity observations of meloxicam emulgel batches.

Batch	Viscosity (cP)
F1	10000
F2	11000
F3	12000
F4	16000
F5	20000
F6	21000
F7	22000
F8	24000
F9 / Optimized	27000

Spreadability is a key factor for patient compliance because it determines how easily the emulgel can be applied over the skin surface. A formulation with good spreadability ensures uniform application, better contact with the skin, and improved drug absorption. The spreadability values increased gradually from F1 to F9. F1 showed the lowest spreadability value of 6, followed by F2 with 5, F3 with 7, F4 with 8, F5 with 9, F6 with 10, F7 with 11, F8 with 13, and F9 with the highest value of 16. The increase in spreadability may be due to optimized balance between gelling agent, oil phase, humectant, and emulsifying agents. Although F8 had relatively high spreadability, its thick consistency and only good homogeneity made it less preferable than F9. The optimized batch F9 showed the highest spreadability, indicating that it can be easily applied and distributed uniformly on the skin without excessive force.

Viscosity plays an important role in determining the stability, consistency, spreadability, and drug release behavior of emulgel formulations. The viscosity of the batches increased from 10,000 cP in F1 to 27,000 cP in F9. F1, F2, and F3 showed lower viscosity values of 10,000 cP, 11,000 cP, and 12,000 cP respectively, suggesting comparatively thinner formulations. F4 showed 16,000 cP, while F5 and F6 showed 20,000 cP and 21,000 cP respectively. F7 and F8 showed higher viscosity values of 22,000 cP and 24,000 cP, indicating increased thickness of the gel matrix. F9 showed the highest viscosity of 27,000 cP. An optimum viscosity is desirable because a very low viscosity formulation may flow away from the application site, while a very high viscosity formulation may be difficult to spread. The optimized batch F9 showed high viscosity along with smooth consistency and high spreadability, suggesting that the formulation had a well-balanced gel structure.

Table 25. Drug content observations of meloxicam emulgel batches.

Batch	Drug Content
F1	88
F2	91
F3	92
F4	90
F5	91
F6	93
F7	90
F8	93
F9 / Optimized	96

Drug content analysis is important to confirm uniform distribution of meloxicam in the emulgel formulation. The drug content of batches F1 to F8 ranged from 88% to 93%, whereas F9 showed the highest drug content of 96%. F1 showed the lowest drug content, which may indicate less uniform drug distribution or lower entrapment within the formulation base. F2, F3, F4, F5, F6, F7, and F8 showed improved drug content values, reflecting better incorporation of meloxicam. The optimized batch F9 showed maximum drug content, which confirms better drug loading and uniformity. Overall, the results indicate that F9 was the best formulation because it showed excellent homogeneity, suitable pH, highest spreadability, highest viscosity, and maximum drug content. Therefore, F9 can be considered the optimized meloxicam emulgel batch for further evaluation and topical application.

E. In-Vitro Drug Release

Cumulative drug release increased with time for all formulations. The optimized F9 batch released 9.2% at 0.5 h, 32% at 2 h, 58% at 4 h, 81% at 6 h and 95% at 8 h. This profile indicates controlled and prolonged release from the emulgel matrix. Compared with other batches, F9 produced the highest final release and therefore was selected as the optimized formulation.

Table 26. In-vitro cumulative drug release of meloxicam emulgel batches.

Time (hr)	F1	F2	F3	F4	F5	F6	F7	F8	F9 Optimized
0	0	0	0	0	0	0	0	0	0
0.5	9.2	7.2	8.3	8.4	8.4	7.2	7.2	9.4	9.2
1	18	14	17	16	16	14	15	18	18
2	30	24	29	28	28	25	27	31	32
3	40	34	41	39	39	35	38	43	45
4	42	43	53	50	50	44	48	55	58
5	50	58	69	61	60	57	62	68	75
6	52	61	70	68	72	62	68	76	81
7	60	66	71	72	74	68	73	83	87
8	65	70	72	85	80	72	91	89	95

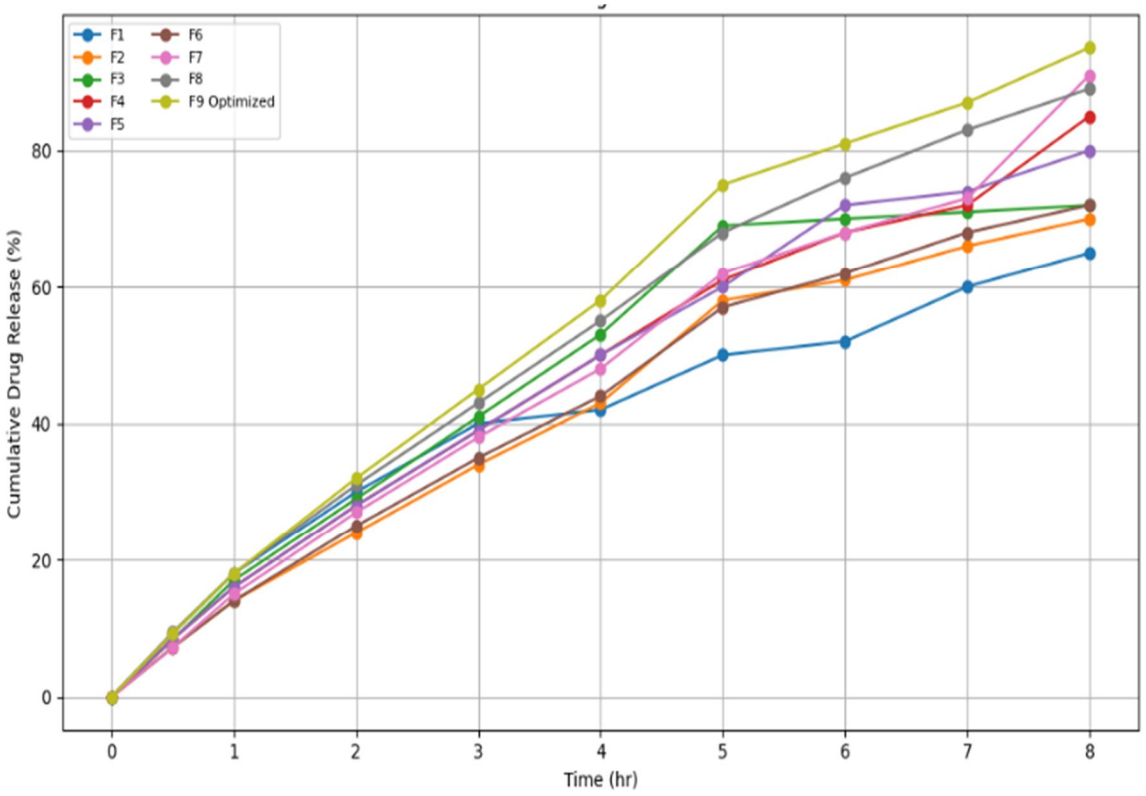

Figure 13. In-vitro drug release profile of meloxicam emulgel formulations.

F. Stability and Comparative Observation

The optimized formulation remained physically stable over 3 months. Appearance showed no change, pH remained within the acceptable range, viscosity decreased only slightly and drug content remained above 95%. Comparative stability observations showed no phase separation, retained homogeneity and better applicability compared with the marketed formulation. The original thesis table label was normalized from “Baclofen Cream” to “Meloxicam Emulgel” because the experimental work and formulation data are for meloxicam emulgel.

Table 27. Stability observations of optimized meloxicam emulgel.

Parameter	Initial (0 month)	After 3 months	Inference
Appearance	Smooth	No change	Stable
pH	6.4	6.6	Stable
Viscosity	27000 cP	26,800 cP	Stable
Drug content	95.86%	95.34%	Stable

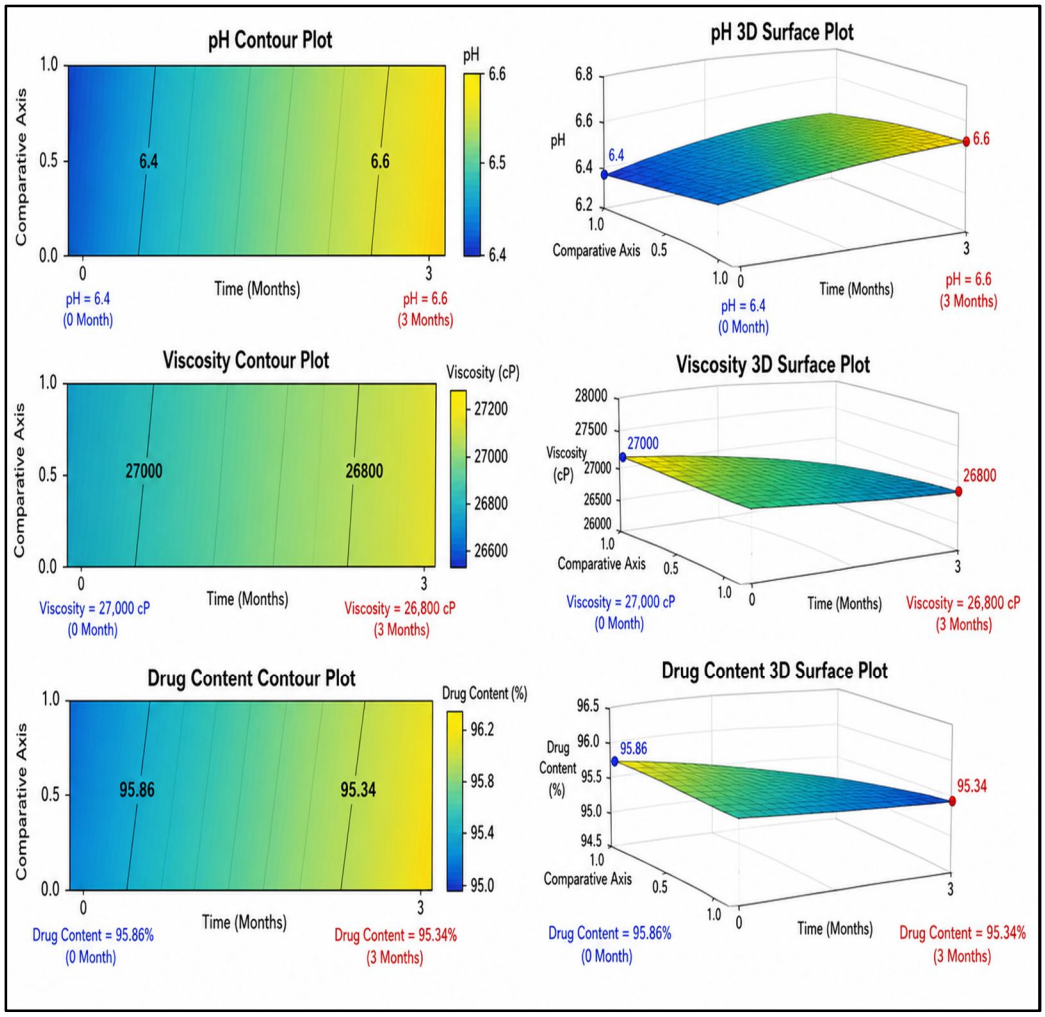

Fig: The comparative DOE contour and 3D surface plots

The comparative DOE contour and 3D surface plots explain the stability behavior of the developed meloxicam emulgel over a three-month period. The pH plots show a slight increase from 6.4 at 0 month to 6.6 after 3 months. This minor change indicates that the formulation remained within the skin-compatible range and is suitable for topical application. The viscosity plots show a small reduction from 27,000 cP to 26,800 cP, suggesting that the emulgel retained its gel structure and rheological stability during storage. The drug content plots show a slight decrease from 95.86% to 95.34%, confirming good drug retention and chemical stability. The contour plots provide a two-dimensional view of parameter variation with time, while the 3D surface plots visually represent the stability trend. Overall, the developed meloxicam emulgel showed minimal changes in pH, viscosity, and drug content, indicating good physical and chemical stability after three months.

Table 28. Comparative stability observation of developed meloxicam emulgel and marketed formulation.

Parameter	Developed Meloxicam Emulgel (0 Month)	Developed Meloxicam Emulgel (3 Months)	Marketed Formulation	Comparative Inference
Appearance	Smooth	No change	No visible change	Comparable physical stability
pH	6.4	6.6	Maintained within skin-compatible range	Good pH stability
Viscosity	27,000 cP	26,800 cP	Slight reduction during storage	Comparable rheological stability
Drug Content	95.86%	95.34%	Acceptable drug retention	Excellent chemical stability
Texture	Uniform and smooth	No phase separation	Stable	Good formulation consistency
Homogeneity	Homogeneous	Maintained	Stable	Comparable stability
Spreadability	Good	Maintained	Moderate to good	Improved patient applicability
Phase Separation	Absent	Absent	Absent	Physically stable formulation

The comparative stability study of the developed meloxicam emulgel showed that the formulation remained stable over a period of three months. At 0 month, the developed emulgel had a smooth appearance, uniform texture, homogeneous nature, and absence of phase separation. After three months of storage, no visible change was observed in appearance, and the formulation remained smooth without phase separation, indicating good physical stability comparable to the marketed formulation.

The pH of the developed emulgel changed slightly from 6.4 to 6.6 after three months. This minor variation remained within the skin-compatible range, suggesting that the formulation is unlikely to cause irritation during topical application. Viscosity showed a very small reduction from 27,000 cP to 26,800 cP, which indicates that the gel structure and rheological properties were well maintained during storage.

Drug content decreased only slightly from 95.86% to 95.34%, showing excellent chemical stability and good drug retention. The texture and homogeneity of the formulation were also maintained, confirming uniform distribution of drug and excipients. Spreadability remained good after storage and was better than the marketed formulation, which had moderate to good spreadability. Overall, the developed meloxicam emulgel demonstrated comparable or improved stability compared with the marketed formulation. The absence of phase separation, maintained pH, high drug content, uniform texture, and good spreadability confirm that the optimized emulgel is physically and chemically stable and suitable for topical use.

IV. CONCLUSION

The results demonstrate that the emulgel system is suitable for incorporation of meloxicam. Low aqueous solubility confirmed the need for a biphasic vehicle, while solubility in propylene glycol and moderate oil-phase solubility supported the formulation strategy. FTIR and DSC studies indicated compatibility between meloxicam and excipients, a prerequisite for stable semisolid formulation development.Carbopol 934 played the most important role in controlling the rheological profile. Increased Carbopol concentration produced higher viscosity and also influenced spreadability. Tween 80 and DMSO contributed to emulsion stabilization and drug release, but their statistical effects were less pronounced than Carbopol in the observed design. The optimized F9 formulation achieved the best combination of homogeneity, viscosity, spreadability, drug content and in-vitro drug release.

The in-vitro release profile of F9 reached 95% by 8 h, indicating sustained release from the gel matrix. Stability observations showed that the formulation remained smooth, homogeneous and chemically acceptable after 3 months, with minimal changes in pH, viscosity and assay. These data indicate the potential of meloxicam emulgel as a topical/transdermal dosage form with improved patient acceptability and controlled release characteristics.

A meloxicam-loaded transdermal emulgel was successfully formulated and optimized using a Design of Experiments approach. The optimized formulation F9 showed excellent homogeneity, suitable pH, high viscosity, good spreadability, 96% drug content and 95% drug release at 8 h.

Compatibility studies supported the absence of major drug-excipient interaction. Stability studies showed no physical instability and acceptable drug retention after 3 months. The study concludes that meloxicam emulgel is a promising topical/transdermal delivery system for sustained drug release and improved application properties.

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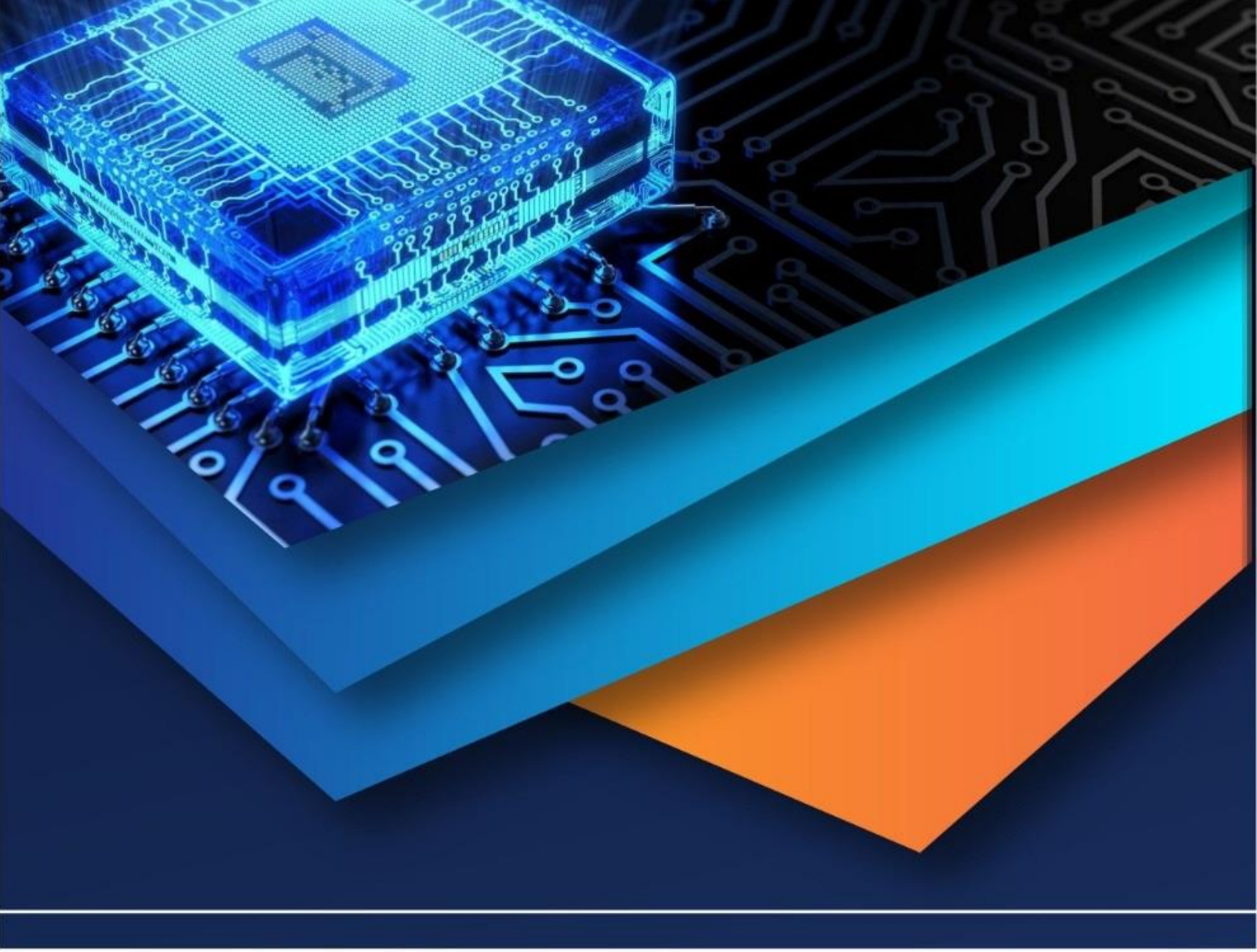

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