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Formulation Development and Evaluation of Halcinonide Topical Gel

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Abstract: ***Halcinonide is a potent topical corticosteroid widely used for the treatment of inflammatory skin disorders such as psoriasis, eczema, dermatitis, and allergic skin conditions. The present study was undertaken to formulate, optimize, and evaluate a topical gel of Halcinonide with improved physicochemical characteristics, patient acceptability, and drug release properties. Preformulation studies, including melting point determination, Fourier Transform Infrared (FTIR) spectroscopy, Differential Scanning Calorimetry (DSC), and solubility studies, confirmed the purity of the drug and its compatibility with selected excipients. Carbopol 934 was employed as the gelling polymer, while propylene glycol, glycerin, and triethanolamine were incorporated to obtain a stable and homogeneous gel formulation. A Design of Experiments (DOE) approach was utilized to optimize the formulation variables affecting viscosity and in-vitro drug release. Nine formulation batches (F1–F9) were prepared and evaluated for appearance, pH, homogeneity, spreadability, viscosity, drug content, and in-vitro diffusion. Among all formulations, batch F7 exhibited the most desirable characteristics, including good homogeneity, smooth texture, acceptable viscosity, pH (6.7 ± 0.25), spreadability (4.3 ± 0.15 cm), drug content (97.32 ± 0.54%), and maximum cumulative drug diffusion of 93.14% within 3 hours. Stability studies demonstrated that the optimized formulation remained physically stable without significant changes in appearance, pH, viscosity, or drug content.The results indicate that the optimized Halcinonide topical gel provides excellent physicochemical properties and efficient drug release, making it a promising topical dosage form for the effective management of inflammatory skin disorders. Further clinical evaluation is recommended to establish its therapeutic efficacy and safety in human subjects.***

Keywords: Halcinonide, Topical Gel, Carbopol 934, Design of Experiments (DOE), In-vitro Drug Release, FTIR, DSC, Stability Studies.

I. INTRODUCTION

Topical dosage form are the dosage form which can be applied to body surfaces such as skin or mucous membrane such as the vagina , anus , throat , eyes and ears. The word Topical is derived from the Ancient Greek topos (plural: topoi), meaning "place" or "location". Many topical medications are epicutaneous, meaning that they are applied directly to the skin.[1] Topical medication may also be inhalational such as the asthma medication or applied to the surface of the tissues other than the skin such as eye drops applied to conjunctiva or ear drops placed in the ear or medication applied to surface of the tooth. Topical effect in pharmacodynamics sense, may refer to local, rather than systemic, target for medication. However many topically administered medication have systemic effect rather than local. Variety of therapeutic agents has been formulated as topical dosage forms for varies reasons like therapeutic agents having short biological half-lives, to increase the bioavailability of the mediation, to avoid the gastric irritation associated with the oral use of some therapeutic agents etc.[2]

The administration of drugs and other biological materials to the bloodstream via a transdermal route or to the localized site of the action has received much attention in recent years (Surver and Davis, 2002).Topical delivery includes two basic types of product. For the most part topical preparations are used for the localized effects at the site of their application by virtue of drug penetration into the underlying layers of skin or mucous membranes. Although some unintended drug absorption may occur it is sub therapeutics quantities and generally of minor concern[3]

A. Topical delivery includes two basic types of product[4]

- External topical that are spread, sprayed, or otherwise dispersed on to cutaneous tissues to cover the affected area.
- Internal topical that are applied to the mucous membrane orally, vaginally or on an rectal tissues for local activity

1) Advantages of topical drug delivery systems[5]

- Avoidance of the first pass metabolism.
- Convenient and easy to apply.
- Avoidance of risks and inconveniences of the intravenous therapy and of diverse conditions of absorption like PH changes, presence of enzymes, gastric emptying time.
- Deliver drug more selectively to a specific site.
- Avoidance of the gastro-intestinal incompatibility.
- Providing utilization of drugs with short biological half-life, narrow therapeutic window.

2) Disadvantages of Topical Drug Delivery Systems[6]

- Poor permeability of some drugs through skin.
- Drugs with larger particle size can't be easily absorbed through the skin.
- Risk of allergenic reactions.
- Can be used only for the drugs which need very small plasma concentration for action

II. MATERIAL AND METHOD

Halcinonide was obtained from Tokyo Chemical industry Co,Ltd, Hyderabad India as a. Propylene glycol . Glycerine, Carbopol 934p and triethanolamine were purchased from Research-Lab Fine Chem. Industry –Mumbai. All other chemical and solvent were of Pharmaceutical Grade.

A. Formulation Of Halcinonide Topical Gel

Formula for 25 g of 0.1% halcinonide topical gel

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Halcinonide (mg)	25	25	25	25	25	25	25	25	25
Concentration of Carbapol 934 (gm)	0.30	0.30	0.20	0.25	0.30	0.30	0.20	0.20	0.20
Concentration of Propylene Glycol (ml)	11.5	9.5	9.5	10.5	11.5	9.5	11.5	11.5	9.5
Concentration of Glycerine (ml)	2	2	4	3	4	4	2	4	2
Triethanolamine (ml)	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Methanol (ml)	2	2	2	2	2	2	2	2	2
Water (ml)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

III. RESULTS AND DISCUSSION

A. Preformulation Study

Confirmation of Drug

Confirmation test of drug was carried out by Melting Point determination method, UV Spectrophotometer, Infrared spectroscopy (IR) and DSC.[8]

1) Melting point

Melting point of Halcinonide was found by glass capillary method and DSC. The observed melting point of Halcinonide was confirmed with the standard melting point of Halcinonide. As Shown in table 1.2

Method	Reported Melting Point	Observed Melting Point
Glass capillary method	271-276°c	272-274°c

Table 1.2: Capillary Melting Point of Pure Drug

2) Differential Scanning Calorimetric

Melting point of Halcinonide was measured; and found to be in the range 271-278^{0}C. It was confirmed with the reported melting point of Halcinonide. It was also confirmed by Differential scanning Calorimetry at scanning rate of 10^{0}C/min exhibits a sharp melting endothermic peak at temperature of 276.32^{0}C as shown in Figure 1.3

PARAMETER	VALUES OBTAINED (˚c)
Onset Point	277.32
Peak Point	279.43
End set Point	282.07
Glass Transition Temperature	Onset 226.41
	Midpoint 227.21

Table 1.3: DSC of Pure Drug

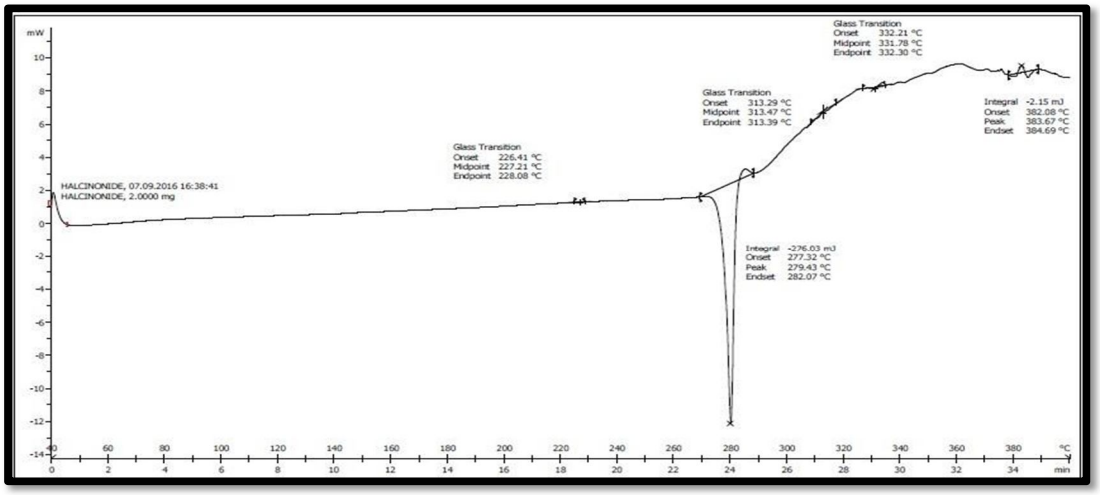

Figure .: DSC Thermo gram of Pure Halcinonide

3) Infrared Spectrum

The IR spectrum was measured in the solid state as potassium bromide dispersion. The IR spectrum of Halcinonide is shown in Figure 8.2. Observed peaks are shown in Table 8.3, these peaks are similar to reported peaks of Halcinonide.

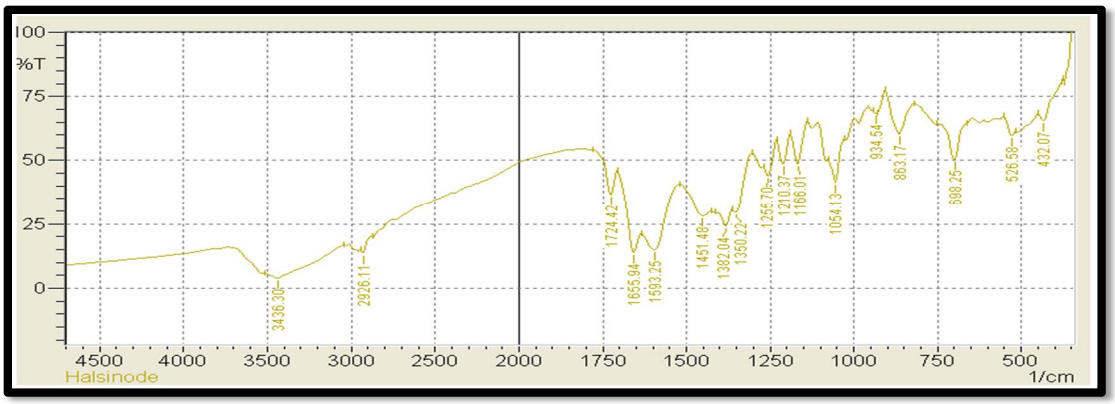

Figure : IR Spectrum of Halcinonide

4) Solubility determination

The solubility of Halcinonide in distilled water, Methanol and phosphate buffer pH 6.8 at 37 ± 0.5^{0}C was found by UV-spectrometrically at ƛ max 239nm as follows:

SOLVENTS	OBSERVED SOLUBILITY (mg/ml)
Distilled water	Insoluble
Methanol	0.59mg/ml
Phosphate buffer pH 5.5	0.027mg/ml

Table : Solubility Determination of halcinonide

5) UV Spectroscopy

The UV spectrum of Halcinonide in Methanol at 400 nm to 200nm. The maximum absorbance was determined using UV-Visible Spectrometer (UV 1700, Shimadzu, Japan) to confirm the λ max of the drug 239, Shows in figure 8.4

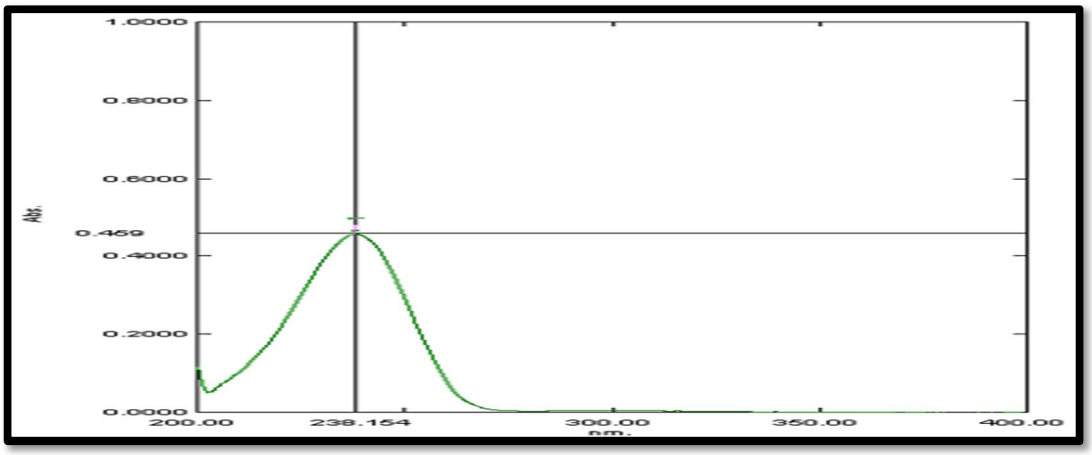

Figure : UV spectrum of Halcinonide

SOLVENTS	ƛ max (nm)
Methanol	239

Table : UV Spectrometric Determination of Halcinonide Standard calibration curve of Halcinonide in Methanol buffer

Graph of absorbance Vs concentration was plotted and found to be linear over the range of 3 to 21 µg/ml for Methanol and for PBS pH-5.5 the range was found to be 10 to 70 µg/ml indicating its compliance with Beer's and Lambert's law. Results are shown in Figure 8.5.

Sr. No.	Concentration.(µg/ml)	Absorbance
1	0	0
2	3	0.156
3	6	0.321
4	9	0.425
5	12	0.589
6	15	0.721
7	18	0.856
8	21	0.986

Table Calibration Curve of Halcinonide In Methanol

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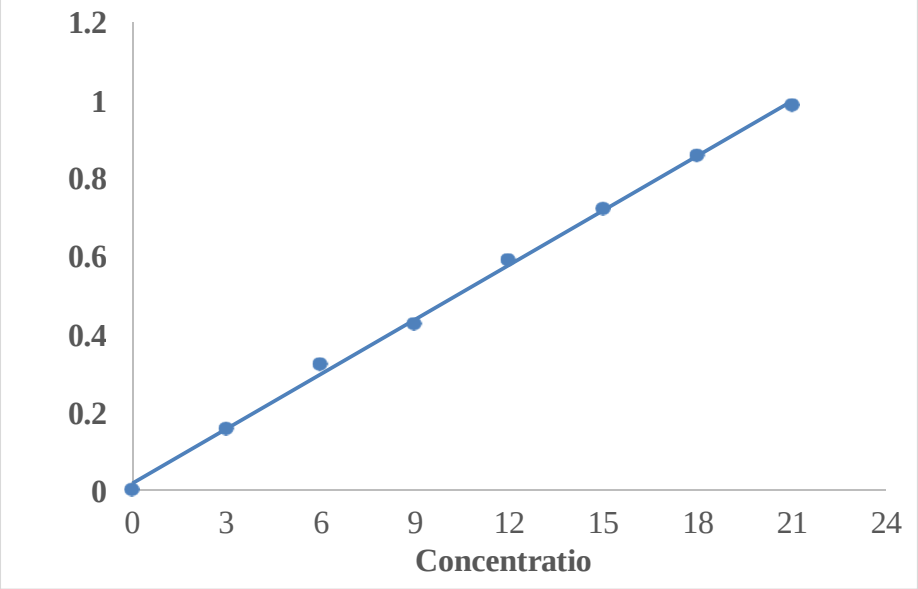

Figure : Standard Calibration Curve of Halcinonide in Methanol

B. Experimental Design (Full factorial design)

Full factorial design is a statistical optimization method used in pharmaceutical formulation to study the effect of formulation variables on the quality of the gel. In your Halcinonide topical gel, a 3^2 full factorial design is commonly used because after selecting suitable concentration from trail batches then apply 3^2 full factorial design there are 3 independent variables and 2 levels for each variable, giving 9 formulation batches (F1–F9). This design helps optimize the gel with minimum trials and identifies the best formulation The study utilised a 2-level factorial design with a 3FI (three-factor interaction) model to evaluate the influence of independent formulation variables on the selected responses, namely viscosity and percent drug release.

Selection of Independent Variables (Factors)

Based on preliminary trials and literature, select the most influential formulation variables:

Factor (Independent Variable)	Symbol	Levels
Carbapol 934 (Gm)	X_1	Low, High
Propylene Glycol (ml)	X_2	Low, High
Glycerine (ml)	X_3	Low, High

IV. ANALYSIS OF DATA

A. Effect of Concentration and Propylene Glycol and Concentration of Carbapol 934 on Viscosity

The 3D response surface plot illustrates the combined effect of Carbopol 934 concentration (Factor A) and propylene glycol concentration (Factor B) on the viscosity of the halcinonide topical gel, while keeping glycerine concentration constant at 2 ml. The graph demonstrates that viscosity increased markedly with increasing concentration of Carbopol 934, thus confirming its dominant role as the primary viscosity-enhancing polymer in the gel system. A gradual rise in viscosity was also observed with increasing propylene glycol concentration, although its influence was comparatively less pronounced than that of Carbopol 934. The upward slope and colour transition from blue to red indicate progressive enhancement in viscosity values from lower to higher factor levels. At lower concentrations of Carbopol 934 (0.20 gm), the gel exhibited minimum viscosity values of around 5000 cP, whereas higher polymer concentrations (0.30 gm) produced viscosity values exceeding 8500 cP.

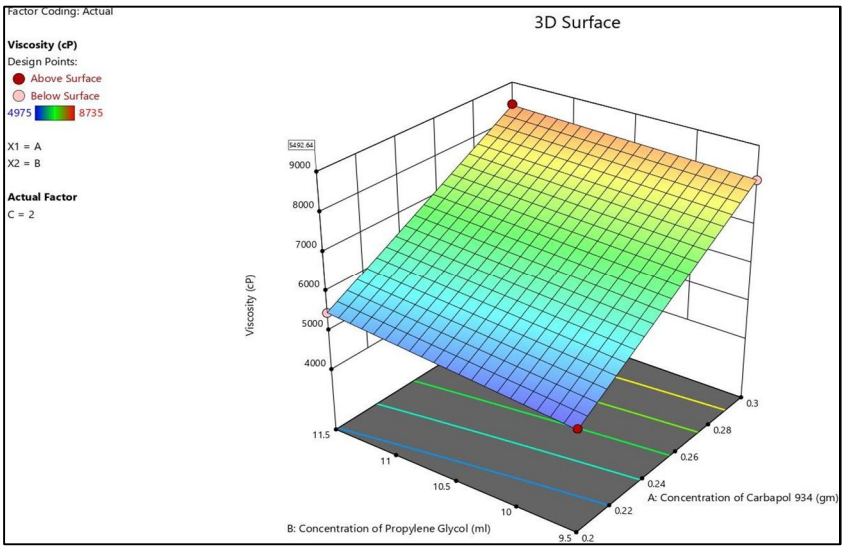

Figure : 3D surface graph showed effect of factor A & B on Viscosity

The relatively smooth and linear surface suggests favourable interaction behaviour between the formulation variables and confirms the adequacy of the developed statistical model. The response surface analysis demonstrates that the viscosity of the Halcinonide topical gel was predominantly controlled by Carbopol concentration, with propylene glycol contributing a moderate supportive effect on the rheological properties of the formulation.

B. Effect of concentration and glycerine and Concentration of Carbapol 934 on Viscosity

The 3D response surface plot illustrates the combined influence of Carbopol 934 concentration (Factor A) and glycerine concentration (Factor C) on the viscosity of the Halcinonide topical gel, while maintaining propylene glycol concentration constant at 11.5 ml. The graph clearly demonstrates that viscosity increased significantly with increasing concentration of Carbopol 934, confirming its major role in controlling the rheological properties of the gel formulation. A slight increase in viscosity was also observed with increasing glycerine concentration, although its effect was comparatively smaller than that of Carbopol 934. The gradual colour transition from blue to red and the upward inclination of the surface indicate progressive enhancement of viscosity. values as the concentrations of both variables increased. At lower concentrations of Carbopol 934 and glycerine, the gel exhibited minimum viscosity values of around 5000 cP, whereas higher levels of these variables produced viscosity values approaching 8700 cP. The smooth and nearly linear response surface suggests a predictable relationship between the formulation variables and viscosity response, thus confirming the adequacy of the developed statistical model.

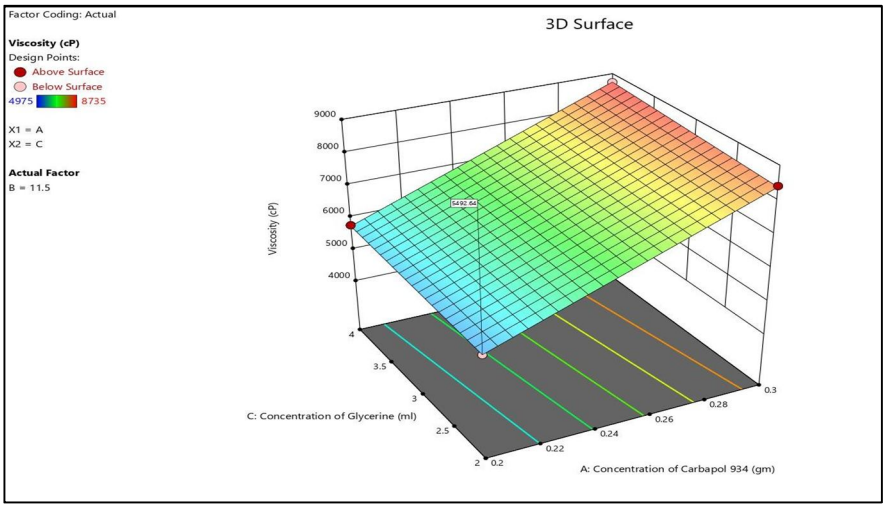

Figure : 3D surface graph showed effect of factor A & C on Viscosity

The overall analysis of the plot indicates that Carbopol 934 was the predominant factor affecting viscosity, while glycerine contributed a moderate supportive effect on gel consistency and structure.

C. Colter counter graph of effect of Propylene glycol and Concentration of Carbapol 934 on Viscosity

The contour plot illustrates the combined influence of Carbopol 934 concentration (Factor A) and propylene glycol concentration (Factor B) on the viscosity of the halcinonide topical gel, while keeping glycerine concentration constant at 2 ml. The gradual colour transition from blue to red is indicative of an increase in viscosity values from lower to higher levels across the formulation space. The contour lines indicate a significant increase in viscosity with increasing Carbopol 934 concentration, while changes in propylene glycol concentration produced only a comparatively minor effect on the response. At lower Carbopol concentrations (0.20 gm), the formulations exhibited minimum viscosity values close to 5000 cP, while higher Carbopol, vertical orientation of the contour lines suggests that Carbopol 934 was the dominant factor controlling the rheological behaviour of the gel, whereas propylene glycol exerted only a moderate supportive influence.

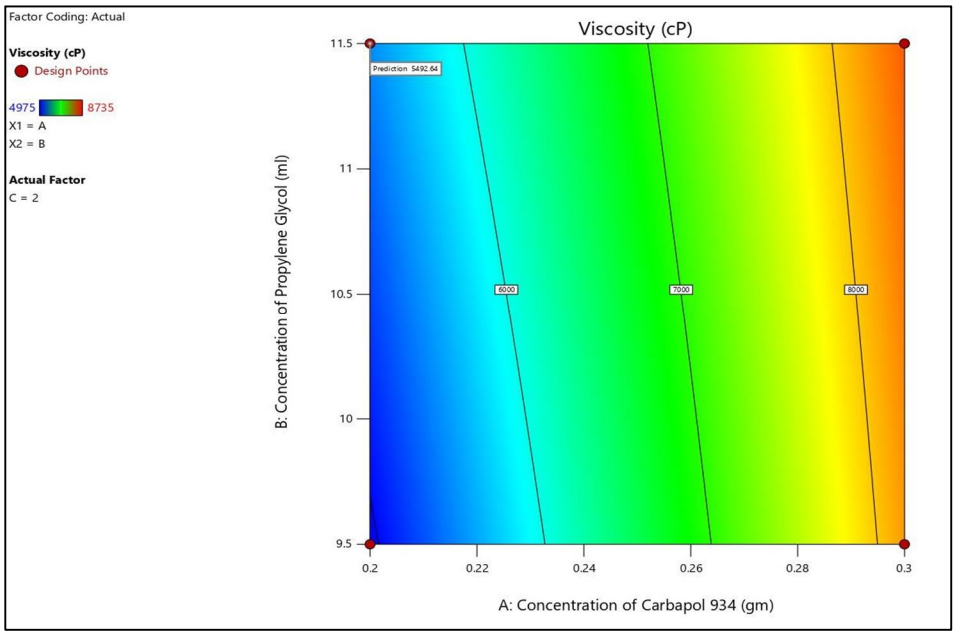

Figure : Colter counter graph showed effect of factor A & B on Viscosity

The uniformity of the contour pattern serves to validate the statistical model, thereby demonstrating a predictable relationship between the formulation variables and viscosity response within the selected design space.

D. Colter counter graph of effect of glycerine and Concentration of Carbapol 934 on Viscosity

The contour plot illustrates the combined effect of Carbopol 934 concentration (Factor A) and glycerine concentration (Factor C) on the viscosity of the Halcinonide topical gel, while maintaining propylene glycol concentration constant at 11.5 ml. The gradual colour transition from blue to red indicates an increase in viscosity values across the formulation region. The contour lines demonstrate that viscosity increased significantly with increasing concentration of Carbopol 934, whereas glycerine concentration produced only a comparatively minor effect on the response. At lower Carbopol concentrations (0.20 gm), the formulations exhibited lower viscosity values of approximately 5000 cP, while increasing the polymer concentration to 0.30 gm resulted in viscosity values approaching 8500 cP.

The nearly vertical contour pattern indicates that Carbopol 934 was the principal factor governing the rheological behaviour of the gel system. As demonstrated in Figure, an increase in glycerine concentration led to a modest enhancement in viscosity, attributable to the humectant and viscosity-supporting properties of the compound. However, the influence of glycerine was found to be significantly less pronounced in comparison to that of the polymer concentration.

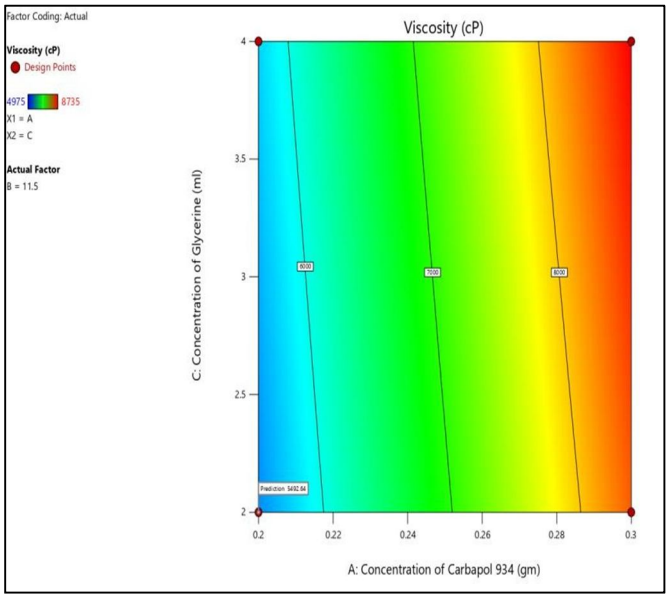

Figure : Colter counter graph showed effect of factor A & C on Viscosity

The uniform and consistent contour distribution further suggests that the model is adequate and demonstrates a predictable relationship between the formulation variables and viscosity response within the experimental design space.

V. EVALUATION OF FORMULATION

A. Physical Characterization

All the prepared batches (F1–F9) and the optimized batch (F7) were visually inspected for physical appearance, homogeneity, and phase separation. All batches were observed to be clear and colorless, indicating complete dissolution and uniform dispersion of the drug and polymers in the aqueous medium. No turbidity, cloudiness, or discoloration was noted, reflecting good compatibility between Halcinonide, Carbopol 934P. The gels were homogeneous, with uniform consistency and no lumps, confirming effective polymer hydration and thorough mixing, which ensures even drug distribution throughout the formulation.

B. Measurement of pH

The ph of formulation shown below table.

Batch	PH (Mean ± S.D)
F1	6.9 ± 0.1
F2	7.2± 0.15
F3	6.9 ± 0.12
F4	6.8 ± 0.15
F5	7.1 ± 0.1
F6	7.1 ± 0.2
F7	6.7 ± 0.25
F8	7.0 ± 0.18
F9	6.8 ± 0.14

Table : Result of PH

VI. DRUG CONTENT

The drug content analysis of all nine Halcinonide gel formulations (F1–F9) demonstrated uniform distribution of the drug throughout the gel matrix, with values ranging from 93.33 ± 0.17% to 97.32 ± 0.54%. All formulations exhibited drug content within the acceptable pharmaceutical limits (90–110%), indicating the accuracy of the formulation process and efficient incorporation of Halcinonide into the gel base. Among the prepared formulations, F7 showed the highest drug content (97.32 ± 0.54%), followed by F8 (97.05 ± 0.26%), suggesting superior drug loading and excellent content uniformity. The slight variations observed among the batches were minimal and may be attributed to normal experimental variations during formulation. Overall, the results confirm that the developed topical gel formulations possess satisfactory drug content uniformity, with F7 identified as the optimized formulation based on its highest drug content and consistent performance.

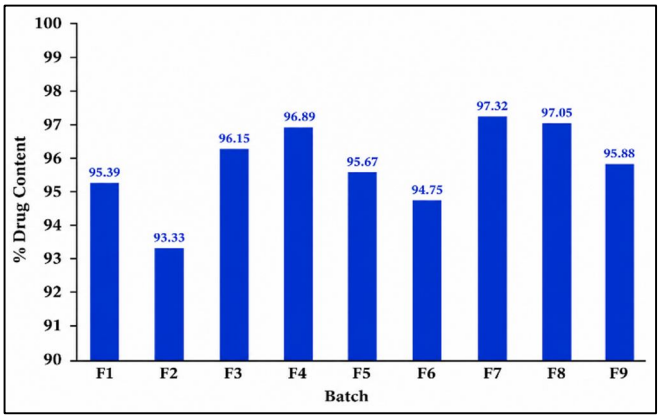

Fig: Drug Content

A. Spredability

Spreadability is an important parameter that indicates the ease with which a gel can be applied and spread on the skin. The formulated gels showed spreadability values ranging from 2.9 ± 0.28 cm to 4.3 ± 0.15 cm, demonstrating satisfactory spreading characteristics for topical application. Among all formulations, F7 exhibited the highest spreadability (4.3 ± 0.15 cm), while F2 showed the lowest (2.9 ± 0.28 cm). Overall, all batches possessed acceptable spreadability, with F7 demonstrating the best spreading performance.

B. In vitro Diffusion studies

In vitro release studies of formulations were performed using the diffusion cell apparatus with dialysis membrane. PBS pH 5.5 was used as diffusion media. The initial rate of drug release was found to be rapid due to incomplete gel formation, but as the time progresses the release rate decreases due to the complete formation of Gel. F1 batch result found to be 78.52, F2-72.84, F3-88.36, F4-81.47, F5-75.26, F6-69.72,F7-93.14, F8-85.26, F9-85.26. F2 and F6 batch less drug released than other seven batches. Shown in table 8.30. The results showed that the developed Gels had the ability to release the drug for the duration of about 180 minutes. In vitro release study indicated that the release of drug varied according to the type and concentration of polymers. F7 Batch released drug 93.14% in time 3 h.

Time	% Drug release								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
30	18.42	15.28	22.84	20.16	17.36	14.52	26.35	23.18	21.42
60	33.58	29.46	40.15	35.82	31.45	27.68	46.26	38.16	38.16
90	49.16	42.75	56.12	50.78	45.68	40.84	64.62	53.48	53.48
120	61.35	55.84	70.36	64.42	58.24	52.74	79.98	66.72	66.78
150	70.24	64.16	80.18	73.65	67.18	61.38	91.24	76.84	76.84
180	78.52	72.84	88.36	81.47	75.26	69.72	93.14	85.26	85.26

Table : In-Vitro Drug Release

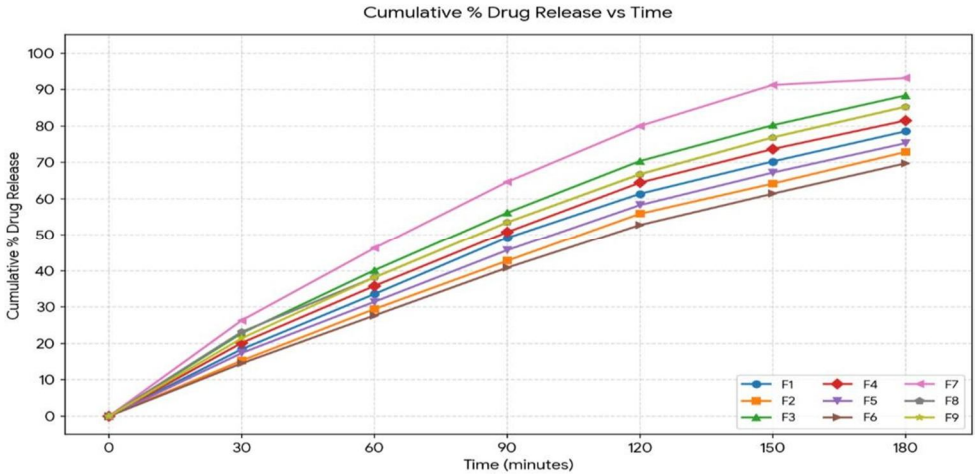

Figure: In-Vitro Drug Release

C. Viscosity Study

Viscosity is a critical parameter that influences the consistency, stability, spreadability, and ease of application of topical gel formulations. The viscosity of the prepared batches ranged from 4975 cP to 8735 cP, indicating suitable consistency for topical use. Among the formulations, F5 exhibited the highest viscosity (8735 cP), followed by F6 (8540 cP) and F1 (8420 cP), suggesting a thicker gel consistency. In contrast, F9 showed the lowest viscosity (4975 cP), followed by F3 (5210 cP) and F7 (5485 cP), indicating comparatively lower consistency. Overall, all formulations exhibited acceptable viscosity suitable for topical application, providing a balance between ease of spreading and formulation stability.

Batch	Viscosity (cP)
F1	8420
F2	8155
F3	5210
F4	6825
F5	8735
F6	8540
F7	5485
F8	5790
F9	4975

Table : Result of Viscosity

D. Stability Studies

The stability study demonstrated that the optimized gel formulation remained physically and chemically stable throughout the 3-month storage period. No changes were observed in appearance or homogeneity, indicating good physical stability. The pH showed only a slight decrease from 6.7 ± 0.25 to 6.65 ± 0.24, remaining within the acceptable range for topical application. Similarly, drug content decreased marginally from 97.32 ± 0.54% to 96.51 ± 0.86%, confirming good chemical stability. A slight reduction in spreadability (4.30 ± 0.15 to 4.22 ± 0.14 cm), viscosity (5485 to 5400 cP), and drug release at 180 min (93.14% to 92.08%) was observed; however, these changes were minimal and did not significantly affect the formulation's performance. Overall, the results indicate that the optimized gel formulation remained stable, maintaining its physicochemical properties and drug release characteristics during the storage period.

Parameter	Initial	1 Month	2 Months	3 Months
Appearance	Clear,colorless	No change	No change	No change
PH	6.7 ± 0.25	6.69 ± 0.22	6.68 ± 0.21	6.65 ± 0.24
Drug Content (%)	97.32 ± 0.54	97.05 ± 0.48	96.82 ± 0.42	96.51 ± 0.86
Spreadability (cm)	4.3 ± 0.15	4.28 ± 0.13	4.25 ± 0.14	4.22 ± 0.14
viscosity (cP)	5485	5460	5435	5400
% Drug release at 180 min	93.14	92.85	92.42	92.08
Homogeneity	Very Good	Very Good	Very Good	Very Good

Table: Stability Studies

VII. CONCLUSION

The present study successfully formulated and optimized a Halcinonide topical gel using Carbopol 934 as the gelling agent. Preformulation studies confirmed the compatibility of the drug with the selected excipients. The prepared formulations exhibited satisfactory physicochemical properties, including acceptable pH, good homogeneity, suitable viscosity, excellent spreadability, and uniform drug content. Using the Design of Experiments (DOE) approach, batch F7 was identified as the optimized formulation, exhibiting 97.32 ± 0.54% drug content, pH 6.7 ± 0.25, spreadability of 4.3 ± 0.15 cm, viscosity of 5485 cP, and 93.14% cumulative drug release within 180 minutes. Stability studies confirmed that the optimized formulation remained stable over 3 months without significant changes in its physicochemical properties or drug release. Overall, the developed Halcinonide gel demonstrated satisfactory quality, stability, and in-vitro performance, indicating its potential as an effective topical formulation for the treatment of inflammatory skin disorders. Further **in-vivo** and **clinical studies** are required to confirm its therapeutic efficacy and safety

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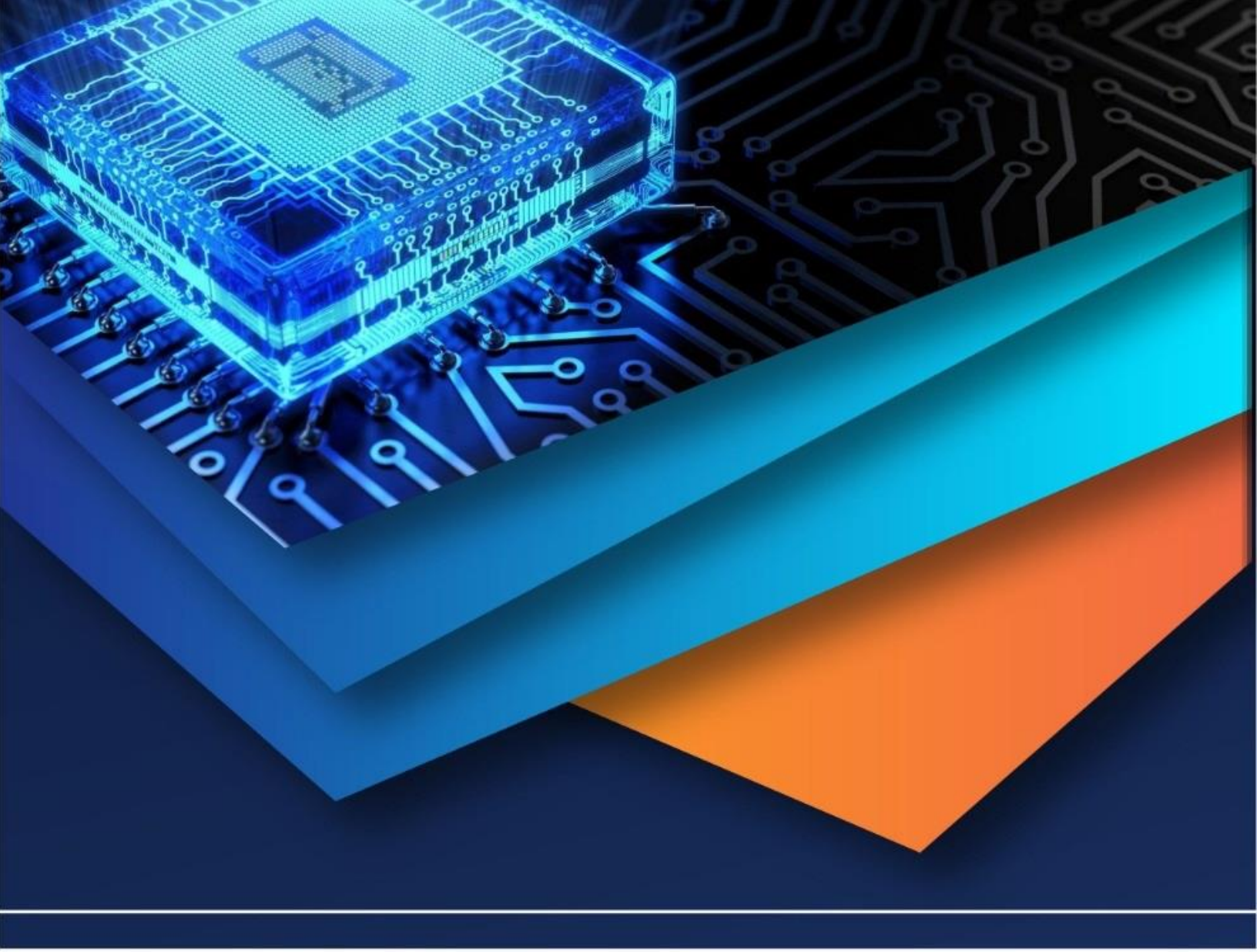

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