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Research Article

Formulation and Evaluation of Adapalene for Antiacne Topical Emulgel

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ABSTRACT

The present study aimed to develop and evaluate a topical emulgel formulation of Adapalene for effective treatment of acne. Nine different formulations (F1–F9) were prepared using varying concentrations of polymers and emulsifying agents. The formulations were assessed for various physicochemical parameters, including appearance, pH, spreadability, viscosity, drug content and in vitro drug release. Antibacterial activity was evaluated against Cutibacterium acnes using the agar well diffusion method. Among all, formulation F7 demonstrated optimal characteristics, showing a uniform white cream-like appearance, suitable pH (7.17), high spreadability, consistent drug content (102.4%), and favorable rheological behavior. The in vitro diffusion study confirmed sustained and efficient drug release from F7. Antibacterial testing revealed a progressive increase in the zone of inhibition across the formulations, with F7 exhibiting one of the highest activities, signifying effective microbial inhibition. Stability studies performed as per ICH guidelines confirmed that F7 remained stable in terms of appearance, pH, viscosity, and drug content over a 2-month period under accelerated conditions. These findings collectively highlight the potential of the optimized Adapalene emulgel (F7) as a promising topical treatment for acne vulgaris.

INTRODUCTION

Acne vulgaris is one of the most prevalent dermatological disorders, affecting nearly 80% of adolescents and young adults worldwide. It is characterized by the inflammation of the pilosebaceous unit, resulting in comedones, papules, pustules, nodules, and in severe cases, scarring [1]. The pathophysiology of acne involves excessive sebum production, abnormal follicular keratinization, proliferation of *Cutibacterium acnes* (formerly *Propionibacterium acnes*), and an inflammatory response [2]. Topical therapy remains the cornerstone of acne treatment, especially for mild to moderate cases, due to its ability to deliver therapeutic agents directly to the affected site with minimal systemic side effects.

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Adapalene, a third-generation synthetic retinoid, exhibits strong comedolytic, keratolytic, and anti-inflammatory properties, making it highly effective for acne management. It binds selectively to retinoic acid receptors in the epidermis, normalizing keratinocyte differentiation and reducing microcomedone formation. Compared to earlier retinoids like tretinoin, adapalene offers improved photostability and reduced skin irritation. However, its poor aqueous solubility and lipophilic nature present challenges in formulating stable, effective topical preparations [3,4].

To overcome these limitations, emulgel-based drug delivery systems have gained considerable attention. Emulgels combine the benefits of both emulsions and gels by incorporating emulsified drug droplets into a gel matrix. This hybrid system offers superior drug loading capacity for lipophilic drugs like adapalene, improved patient acceptability, controlled drug release, enhanced skin permeability, and better stability than conventional creams or ointments. The non-greasy texture, high spreadability and better cosmetic appeal of emulgels further contribute to enhanced patient compliance [5].

This research aims to formulate a topical adapalene emulgel using suitable gelling agents and emulsifying systems, and to evaluate its physicochemical properties, drug release profile, skin permeation characteristics, and overall stability. The successful development of such a formulation is expected to enhance the therapeutic efficacy of adapalene while minimizing local irritation and maximizing user satisfaction.

MATERIALS AND METHODS

MATERIALS

Adapalene was procured from Aarati Pharmaceuticals, Mumbai. Carbopol 934, HPMC, Span 20, Tween 20, Triethanolamine, Methyl Paraben, and Liquid Paraben were obtained from Research Lab Fine Chem., Mumbai. Propylene Glycol was sourced from Modern Industries, Nashik. All chemicals used were of analytical grade and utilized as received without further purification.

Preformulation Studies

Preformulation testing is the first step in rational development of dosage forms of a drug substance Preformulation study is the process of optimizing the delivery of drug through determination of physicochemical properties of the new compound that could affect drug performance and development of an efficacious, stable and safe dosage form It gives the information needed to define the nature of the drug substance and provide a framework for Preformulation studies were performed for the obtained sample of the drug for identification and compatibility studies.

Organoleptic Properties: Appearance and color were determined by visual inspection [6].

Melting Point Determination

Thiele's Tube method was used to establish Adapalene melting point. The glass capillary was sealed from one end and drug was filled into it from another end. Then the capillary tube was tied to the thermometer and placed in the Thiele's tube containing liquid paraffin. The tube was heated and melting point of the drug was determined by observing the temperature on the thermometer when the particles have just started to melt and when all the drug particles were melted [7].

Solubility

Determination of drug solubility in various solvent

The solubility of adapalene was checked in different solvents like distilled water, methanol, ethanol, polyethylene glycol, ether, chlo, acetone, propylene glycol and phosphate buffer pH 6.5 [7,8].

Determination of drug solubility in various oils

The solubility of adapalene in various oils was determined by adding an excess amount of drug to 3 ml of selected oils separately in capped glass tubes. The tubes were equilibrated at 37° C for 48 hrs. The equilibrated samples were centrifuged at 3000 rpm for 15 min. and the supernatant was filtered through 0.45 µm membrane filter. The filtrate was diluted with appropriate solvent (acetone) and adapalene solubility was subsequently quantified by UV-visible spectrophotometer [9].

Ultraviolet-Visible Spectroscopy

Determination of λ Max in Acetone

The UV spectrum of adapalene was obtained by using UV-visible spectrophotometer (UV 3000). Accurately weighed 10 mg of the drug was dissolved in sufficient quantity of acetone and volume was made up to 100 ml. The stock solution was obtained in a concentration of 100 µg/ml. 1 ml of aliquots was withdrawn and volume was made up to 10 ml using acetone to obtain the concentration of 10 µg/ml. The resultant solution was scanned from 400 to 200 nm and the spectrum was recorded to obtain the value of maximum wavelength in respective solvents.

Preparation of Calibration Curve in Acetone

Stock solution of drug 100 mg /ml was prepared in solvent acetone. The stock solution of 100µg/ml was used to prepare different dilutions in the range of 2-10µg/ml in respective solvents. The absorbances of resulting solutions were measured at 231 nm using respective blank solvents by UV-visible spectrophotometry [10].

Infra-Red Spectrum

The infrared absorption spectrum of adapalene was recorded with a KBr disc over the wave number 4000 to 400 cm^{-1} using Fourier Transform Infrared Spectrophotometer (Agilent Technologies Cary 630, USA).

Drug excipients compatibility study

Drug excipient compatibility was performed by liquid Fourier Transform Infrared (Agilent Technologies Cary 630, USA). It was performed by mixing drug with excipients in equal proportion and then IR spectrum was noted for mixture using NaCl cell. Small amount of the mixture was placed on the sample cell, the cell was then fitted in sample holder, spectra were scanned over a frequency range 4000-400 cm^{-1} recorded with FTIR instrument and the spectral analysis were done [11].

Differential Scanning Calorimetry (DSC) Study

DSC was performed to study the thermal behaviour and compatibility of adapalene with the polymers and excipients used in the formulation. Thermal analysis of pure drug, polymer (Carbopol 934 and HPMC), their physical mixture and the optimized emulgel formulation was carried out using a DSC instrument. Approximately 5–10 mg of each sample was sealed in an aluminum pan and heated in the range of 30°C to 320°C at a heating rate of 10°C/min under a nitrogen atmosphere to prevent oxidative degradation. The thermograms were analysed for any shift, appearance or disappearance of melting endotherms, which could indicate physical or chemical interactions between drug and excipients [11,12].

Optimization by 3^2 factorial design:

The three level designs are written as a 3k factorial design. It means that k factor is considered each at 3 levels. These are usually referred to as low, intermediate and high levels. These levels are numerically expressed as 0, 1 and 2 or -1, 0 and +1. A study in which there are two factors with 3 levels is called a 3^a factorial design. A 3^2 randomized full factorial design (FFD) was constructed where the amounts of Carbopol 934 and HPMC were selected as the independent factors. The three levels and two factors were selected on the basis of the preliminary studies carried out before implementing [13].

Experimental design

All other formulation and processing variables were kept invariant throughout the study. The % cumulative drug release and viscosity was selected as dependent variables.

-1	0.75	0.75
0	1	1
+1	1.5	1.5

Table 2: Experimental Design as Per 3^2 Factorial Design

Formulation Code	Coded Values			
	X1	(%)	X2	(%)
F1	-1	0.75	-1	0.75
F2	0	1	-1	0.75
F3	+1	1.5	-1	0.75
F4	-1	0.75	0	1
F5	0	1	0	1
F6	+1	1.5	0	1
F7	-1	0.75	+1	1.5
F8	0	1	+1	1.5
F9	+1	1.5	+1	1.5

Selection of Oils, Surfactants for Formulation Study

Oil and excipients were selected on the basis of higher solubility of drug in them; tween 20 and Span 20 as emulsifiers, Carbopol as gelling agent, liquid paraffin as oil base, propylene glycol which showed higher solubility capacity for the drug was selected for further formulation study [14].

Table 1: Coded and Actual Values

Coded Values	Actual Values	
	X1 (%)	X2 (%)

Emulgel Formulation

Table 3: Composition of Emulgel

No.	Ingredients (% w/w)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Adapalene	1	1	1	1	1	1	1	1	1
2	Carbopol 934	0.75	1	1.5	0.75	1	1.5	0.75	1	1.5
3	HPMC	0.75	0.75	0.75	1	1	1	1.5	1.5	1.5
4	Liquid Paraffin	5	5	5	5	5	5	5	5	5
5	Span 20	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
6	Tween 20	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
7	Propylene Glycol	5	5	5	5	5	5	5	5	5
8	Methyl Paraben	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03
9	Triethanolamine	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
10	Distilled Water (Up to ml)	100	100	100	100	100	100	100	100	100

Preparation of Adapalene Antiacne Emulgel

The Adapalene anti-acne emulgel was prepared using a stepwise procedure. Initially, a gel base was formed by dispersing Carbopol 934 in distilled water and allowing it to swell, while HPMC was separately dissolved and hydrated. Both were combined and mixed to obtain a

homogenous gel base. For the oil phase, Adapalene was dissolved in liquid paraffin with gentle heating (60°C), and Span 20 was added as a lipophilic surfactant. Simultaneously, the aqueous phase was prepared by dissolving Tween 20, propylene glycol, and methyl paraben in distilled water, maintaining the same temperature. The aqueous phase was then added to the oil phase under continuous stirring to form a stable emulsion. This emulsion was slowly incorporated into the gel base with gentle stirring to form the emulgel. The pH was adjusted to 5.5–6.5 using triethanolamine, and the final volume was made up with distilled water. The formulation was stored in airtight containers at room temperature for further evaluation [15].

Evaluation of Adapalene Antiacne Emulgel

Physical Appearance

The prepared emulgel formulations were visually inspected for their color, homogeneity and consistency. All formulations exhibited a smooth and uniform texture without phase separation or grittiness [16].

pH Measurement

The pH of each emulgel formulation was measured by dispersing 1 g of the sample in 100 mL of distilled water and allowing it to equilibrate. The pH was then recorded using a digital pH meter calibrated prior to use. All formulations showed a pH within the acceptable range for topical application (approximately 5.5–6.8) [17].

Viscosity

The viscosity of the formulations was determined using a Brookfield Digital Viscometer (Model DV-E) at 25 ± 2°C. Spindles number 61 or 64 were used depending on the consistency of the sample, and readings were taken at three rotational speeds: 20, 60, and 100 rpm. The viscosity was expressed in centipoise (cP), and all formulations displayed pseudoplastic flow behavior [16].

Drug Content Determination

One gram of each formulation was accurately weighed and dissolved in 100 mL of acetone. The solution was sonicated for 15 minutes, filtered, and suitably diluted. The absorbance was measured at 231 nm using a UV-visible spectrophotometer, and drug content was calculated using a previously prepared calibration curve. All batches showed drug content within the range of 95–102% [18].

Spreadability

The spreadability of each formulation was evaluated using the slip and drag method. A fixed amount of emulgel was placed between two glass slides. A weight of 80 g was allowed to rest on the upper slide, and the time taken for the slide to slip over a distance of 7.5 cm was recorded [19]. The spreadability was then calculated using the formula:

$$S = M \times L / T$$

Where

M = weight tied to upper slide (g),

L = distance moved (cm), and

T = time taken (sec).

The results indicated good spreadability for all batches.

Antibacterial Activity

The antibacterial activity was assessed using the agar well diffusion method against *Cutibacterium acnes*. The bacterial culture was inoculated on nutrient agar plates, and wells (5 mm diameter) were punched. A volume of 100 µL of each emulgel formulation was added to the wells. Plates were incubated anaerobically at 37°C for 48–72 hours. Zones of inhibition were measured in

millimeters, and higher activity was observed in formulations containing optimal Adapalene concentration [20].

In Vitro Drug Release

In vitro release studies were carried out using Franz diffusion cells. A weighed amount of the emulgel was placed on the donor compartment over a cellophane membrane. The receptor compartment contained phosphate buffer (pH 7.4), maintained at 37 ± 0.5°C with continuous stirring. At predefined time intervals (30, 60, 120, and 240 minutes), 5 mL of the sample was withdrawn and replaced with fresh buffer. The samples were analyzed at 330 nm using a UV spectrophotometer to calculate cumulative drug release [19].

Stability Studies

The stability of the optimized formulations was tested under accelerated conditions (40 ± 2°C and 75 ± 5% RH) for two months. Formulations were stored in aluminum tubes and evaluated at monthly intervals for physical appearance, pH, viscosity and drug content. No significant changes were observed, indicating good stability [21].

RESULTS AND DISCUSSION

Preformulation Studies

Organoleptic Properties

Adapalene was visually examined for its organoleptic characteristics. It was found to be crystalline in nature, white in color and odorless, confirming its typical physical appearance and absence of volatile impurities.

Melting Point

The melting point of Adapalene was determined and found to be 314°C. This result was consistent with the standard melting range of 312–318°C, indicating the drug sample was pure and free from contaminants.

Solubility Profile

Solubility studies were performed in various solvents and oils to aid in the selection of suitable formulation excipients. Adapalene was found to be practically insoluble in distilled water, sparingly soluble in tetrahydrofuran, and slightly soluble in ethanol. However, it was soluble in chloroform, acetone, polyethylene glycol, and propylene glycol, while poorly soluble in liquid paraffin. Among the tested oils, maximum solubility was observed in propylene glycol (85.34 mg/mL), followed by liquid paraffin (79.32 mg/mL), and castor oil (48.33 mg/mL). Based on these results, liquid paraffin was selected as the oil phase in the emulsion system and propylene glycol was utilized as a co-solvent to enhance the solubility of Adapalene in the final emulgel formulation.

Ultraviolet Visible (UV-Vis) Spectrophotometry

a) Spectrometric Scanning and Determination of λ-Max of Adapalene in Acetone

Spectrometric scanning of Adapalene in acetone was carried out to determine its maximum wavelength of absorbance (λ-max). The scan revealed a sharp peak at 231 nm, which was identified as the λ-max of Adapalene. This wavelength was selected for further spectrophotometric analysis. Acetone was used as the solvent throughout the study due to its good solubilizing capacity for Adapalene.

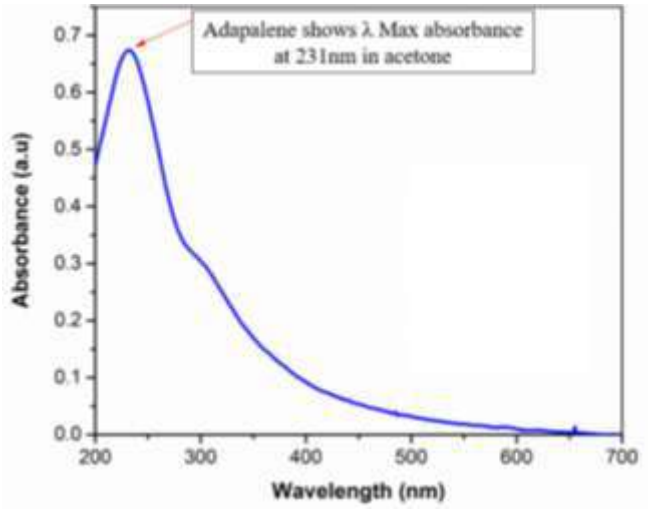


Figure 1: UV-Vis spectra of Adapalene in Acetone

b) Calibration Curve of Adapalene in Acetone

A calibration curve was prepared using Adapalene solutions at concentrations ranging from **2 ppm to 10 ppm** in acetone. The absorbance of each solution was measured at 231 nm. The results showed a strong linear relationship between concentration and absorbance, with a correlation coefficient (R^2) of **0.9996**, indicating excellent linearity. The linear regression equation was found to be:

y = 0.0991x - 0.0048,

where **x** represents the concentration (ppm) and **y** the absorbance.

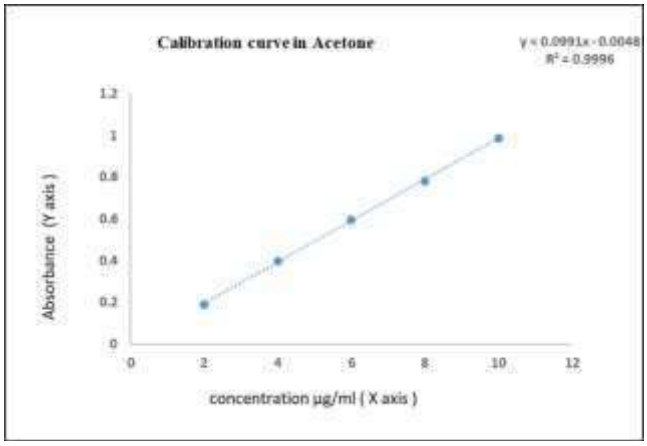
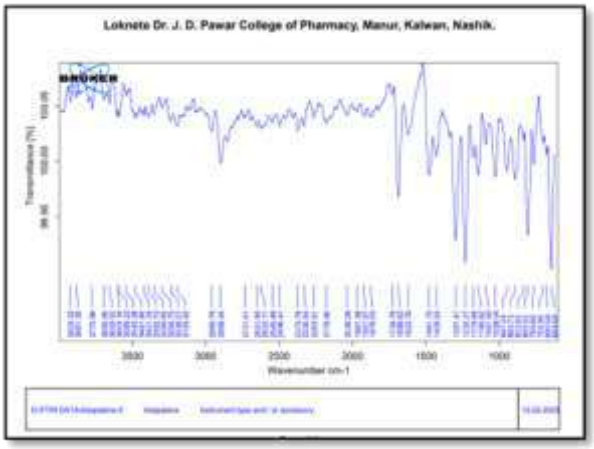


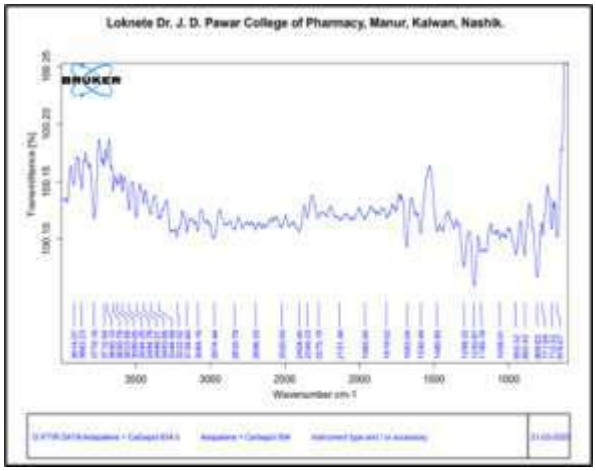
Figure 2: Calibration Curve of Adapalene in Acetone

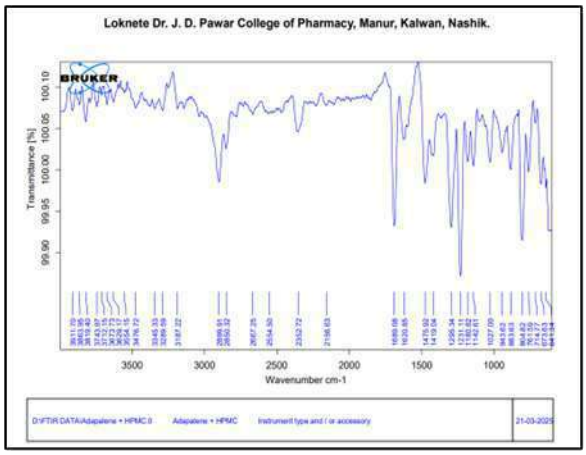
FTIR Spectroscopy of Drug

FTIR spectral analysis was performed to evaluate the possible interactions between Adapalene and formulation excipients such as Carbopol 934, HPMC, and the final formulation (FB1). The FTIR spectrum of pure Adapalene (Figure 3) showed distinct peaks at 3062 cm^{-1} (aromatic C–H stretching), 1716 cm^{-1} (C=O stretching of carboxylic acid), 1601 and 1502 cm^{-1} (aromatic C=C stretching), and 782 cm^{-1} (C–Cl stretching), which confirm the structural identity of the drug. The spectrum of Adapalene with Carbopol 934 (Figure 3) retained all the major characteristic peaks of Adapalene with slight shifts, particularly in the regions around 1700 cm^{-1} and 1500 cm^{-1}. This suggests minor physical interaction but no chemical bond formation, indicating

compatibility. Similarly, the FTIR spectrum of Adapalene with HPMC (Figure 3) also retained all essential Adapalene peaks without significant changes in position or intensity, affirming compatibility between the drug and HPMC. The FTIR spectrum of the final formulation FB1 (Figure 3) also displayed key functional peaks of Adapalene, including peaks at ~1658 cm^{-1} (C=O stretching), ~1600 cm^{-1} (C=C aromatic), and around ~750–800 cm^{-1} (C–Cl bending). No new peaks were observed, and no existing peaks were significantly shifted or disappeared, confirming the absence of chemical interaction between Adapalene and excipients during the formulation process. Overall, FTIR analysis confirmed that Adapalene is chemically stable and compatible with Carbopol 934, HPMC, and other excipients used in the final formulation, supporting the integrity and stability of the emulgel system.







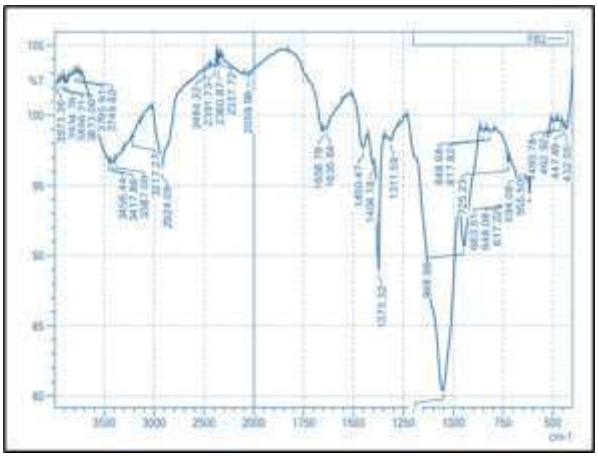
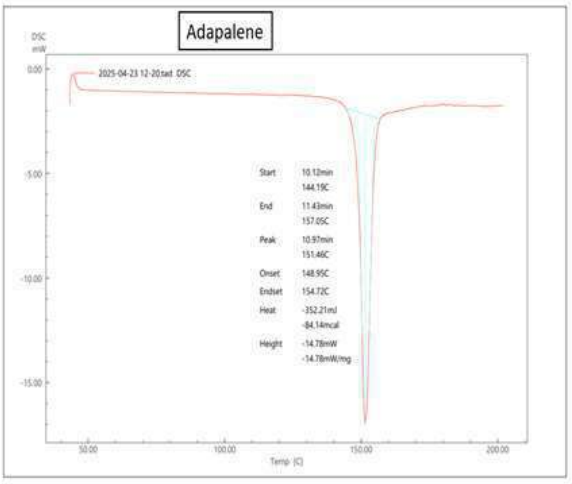


Figure 3: FTIR Spectrum Peaks of Drug + All Excipients

Differential Scanning Calorimetry (DSC)

The thermal behavior of pure Adapalene and its physical mixture with excipients was assessed using Differential Scanning Calorimetry (DSC) to determine its crystallinity, purity, and compatibility prior to formulation development. The DSC thermogram of pure Adapalene exhibited a sharp endothermic peak at 151.46°C, with an onset at 148.95°C and endset at 154.72°C, indicating a narrow melting range. This sharp, well-defined melting point and high peak height (−14.78 mW) are indicative of a pure, crystalline, and thermally stable drug substance with no evidence of polymorphic transitions or degradation. The enthalpy of fusion (ΔH) was recorded as −352.21 mJ (−84.14 cal), further confirming the crystalline nature of the drug. In

contrast, the DSC thermogram of the physical mixture of Adapalene with formulation excipients demonstrated significant thermal changes. The melting peak shifted to 113.13°C, with an onset at 108.88°C and endset at 123.42°C. A notable reduction in enthalpy (−348.27 mJ) and peak height (−3.17 mW) was observed, suggesting a decrease in crystallinity and potential partial amorphization of Adapalene within the excipient matrix. The absence of the original melting point of pure Adapalene around 151°C in the mixture further supports the possibility of drug–excipient interaction or molecular dispersion in the polymeric network. Importantly, no additional endothermic or exothermic peaks were observed in the mixture, indicating that no chemical degradation or incompatibility occurred during blending. These findings suggest that Adapalene is compatible with the selected hydrogel-forming excipients and that the formulation process may lead to improved drug dispersion, potentially enhancing solubility and bioavailability in the final product.



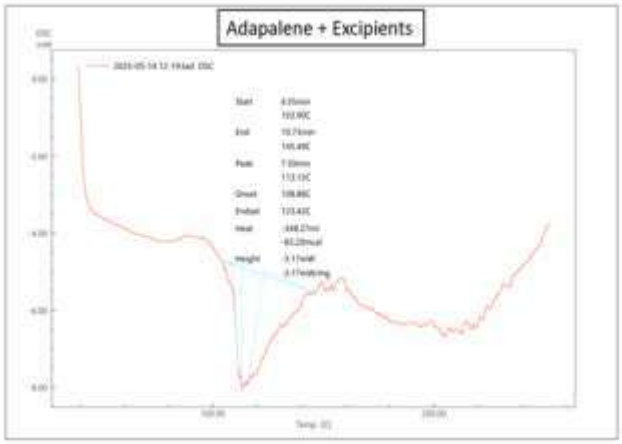


Figure 4: DSC Analysis of Adapalene and Adapalene–Excipient Mixture

Optimization by 3² Factorial Design

To optimize the formulation of the topical gel, a 3^2 full factorial design was employed. This design facilitated the evaluation of two independent variables Carbopol 934 (X_1) and Hydroxypropyl methylcellulose (HPMC) (X_2) each at three levels. The dependent variables selected for evaluation were viscosity and percentage cumulative drug release. The experimental data were analyzed using Design Expert® software and the significance of model terms was assessed through Analysis of Variance (ANOVA).

Figure 5: Formulation of Emulgel

Y1=viscosity **Y2=%CDR**

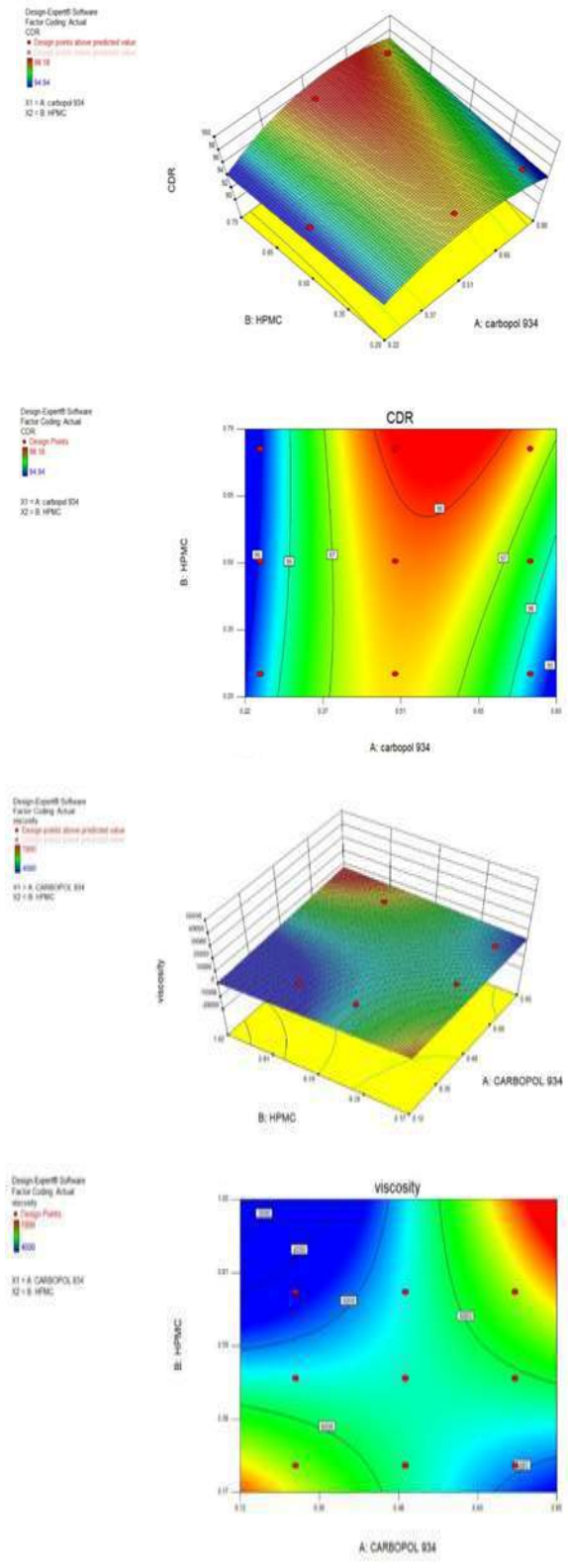


Figure 6: Optimization by Factorial Design

Evaluation of Adapalene Antiacne Emulgel

Physical Appearance

The physical appearance of all prepared emulgel formulations (F1 to F9) was evaluated visually. Each formulation exhibited a white, cream-like texture that was homogenous in nature. No grittiness or phase separation was observed, confirming uniform dispersion of the drug and excipients in the formulation.

Measurement of pH

The pH of all formulated batches (F1 to F9) was measured using a calibrated digital pH meter at room temperature. The pH values ranged from **6.72 to 7.17**, which falls within the acceptable range for topical formulations, indicating suitability for skin application. Minimal standard deviation (±SD) across the batches demonstrates uniformity and reproducibility of the formulation process.

Rheological studies (Viscosity)

The viscosity of all emulgel batches (F1–F9) was measured at different spindle speeds (20 rpm, 60 rpm, and 100 rpm) to assess their rheological behavior and stability. The results are as presented in Table 4 and indicate a clear shear-thinning (pseudo-plastic) behavior, which is characteristic of well-formulated topical emulgels. This behavior is desirable, as it allows the gel to spread easily upon application (reduced viscosity at higher shear rates) while maintaining adequate consistency at rest (higher viscosity at lower shear rates). Among the tested formulations, viscosity increased progressively from F1 to F7, suggesting a correlation with the concentration or type of polymeric gelling agents used (e.g., Carbopol 940, HPMC). Batch F7 exhibited the highest viscosity across all spindle speeds (5920 ± 22 cps at 20 rpm, 5530 ± 16 cps at 60 rpm, and 5000 ± 12 cps at 100 rpm), indicating the presence of optimal polymeric content, likely contributing to better structural integrity and stability of the formulation.

Conversely, F1 displayed the lowest viscosity values at all measured speeds (5120 ± 15 cps at 20 rpm, 4760 ± 12 cps at 60 rpm, and 4390 ± 10 cps at 100 rpm), reflecting a comparatively thinner consistency, which might affect retention on the skin and sustained drug release. Batches F8 and F9 showed a slight decrease in viscosity compared to F6 and F7, suggesting either a reduction in polymer concentration or the influence of excipient interaction that disrupted the gel matrix. Overall, the decrease in viscosity with increasing shear rate confirmed the non-Newtonian, pseudo-plastic nature of the emulgels, which is highly favorable for topical applications. The optimized formulation (F7) with balanced viscosity values is likely to provide ideal application characteristics, adequate drug release, and enhanced patient compliance. These viscosity findings play a crucial role in predicting the emulgel's performance, including ease of application, spreadability and potential drug diffusion.

Table 4: Viscosity of Emulgel Batches F1–F9

Batch Code	20 rpm (cps)	60 rpm (cps)	100 rpm (cps)
F1	5120 ± 15	4760 ± 12	4390 ± 10
F2	5240 ± 18	4875 ± 14	4435 ± 12
F3	5380 ± 20	4990 ± 15	4560 ± 13
F4	5500 ± 19	5120 ± 13	4680 ± 14
F5	5625 ± 17	5245 ± 12	4775 ± 11
F6	5790 ± 21	5390 ± 14	4895 ± 13
F7	5920 ± 22	5530 ± 16	5000 ± 12
F8	5480 ± 16	5105 ± 12	4660 ± 10
F9	5330 ± 19	4980 ± 15	4520 ± 13

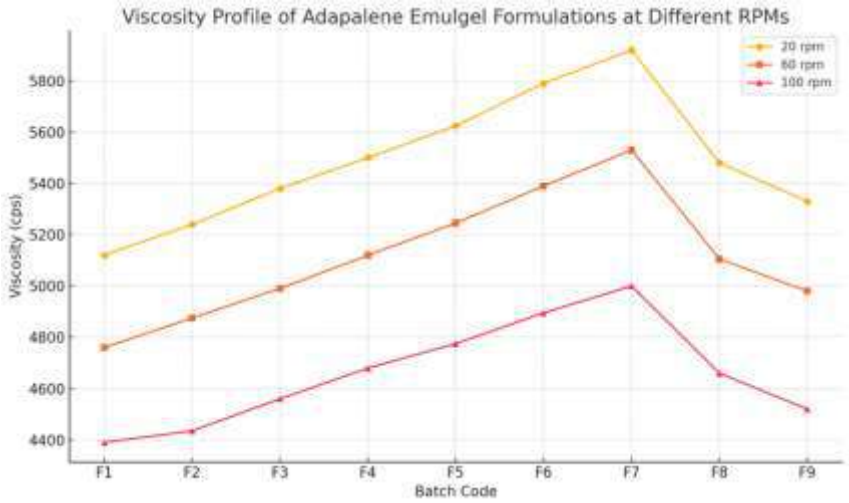


Figure 7: Viscosity of Emulgel Batches (F1–F9) at Different rpm

Drug Content Determination

The drug content analysis was conducted to evaluate the uniformity and efficiency of drug incorporation within each formulation. The drug content ranged from 98.0% ± 0.32 (F1) to 102.4% ± 0.20 (F7), demonstrating excellent homogeneity across all batches. Batch F7 exhibited the highest drug content at 102.4% ± 0.20, reflecting superior drug entrapment and uniform distribution within the emulgel matrix. This result indicates optimized formulation parameters, including ideal mixing time, emulsification, and gelling conditions, which contributed to maximum drug loading without significant degradation or loss. Other batches such as F1 and F2 showed slightly lower drug content (98.0% and 98.5%, respectively), possibly due to suboptimal dispersion of the active ingredient or minimal loss during the manufacturing process. However, all formulations remained within the acceptable limit of ±5% deviation as per pharmacopoeial standards, confirming their content uniformity and dosage accuracy.

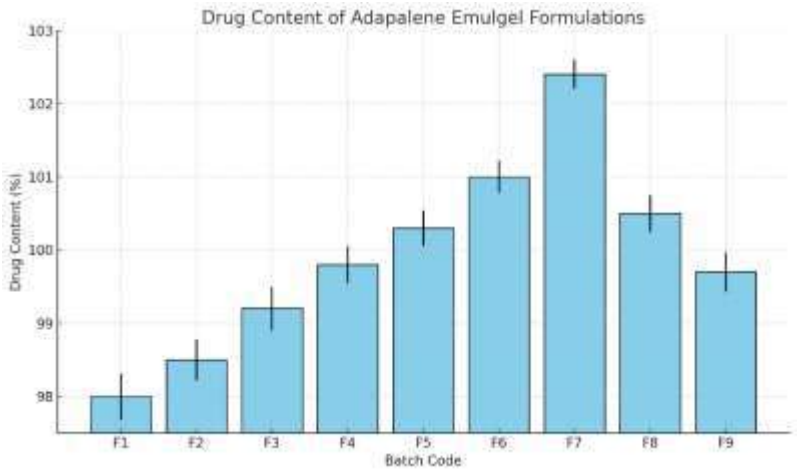


Figure 8: Drug Content of Emulgel Formulation (F1–F9)

Spreadability Determination

Spreadability is an essential parameter in evaluating the performance of topical formulations, as it directly influences the ease of application, patient acceptability, and uniform distribution of the drug over the skin surface. The spreadability of the prepared emulgel formulations (F1 to F9) was measured and the results are presented in Table 5.

The spreadability values ranged from 95.78 ± 0.32 g·cm/sec (F1) to 99.71 ± 0.22 g·cm/sec (F7). A progressive increase in spreadability was observed from batch F1 through F7, indicating that the formulation parameters were optimized to enhance the application characteristics. Batch F7 exhibited the highest spreadability value of 99.71 ± 0.22 g·cm/sec, suggesting excellent spreadability, which would facilitate smooth application with minimal shear force and good coverage over the affected area. The high spreadability observed in Batch F7 may be attributed to the optimal ratio of gelling agents and emulsifiers, which resulted in a semi-solid consistency that balances viscosity with mobility. Formulations with low viscosity, such as F1 and F2, also showed relatively lower spreadability, possibly due to poor structural consistency, which can reduce film-forming ability and coverage. Although Batches F8 and F9 also showed high spreadability values (99.45 ± 0.23 and 99.10 ± 0.24, respectively), they were marginally lower than that of F7, which further supports the conclusion that Batch F7 is the most optimized formulation in terms of physical performance, including ease of application. In conclusion, the spreadability study confirms that Batch F7 provides an ideal balance between consistency and spreadability, ensuring better patient compliance and effective topical delivery of the drug. Its superior spreadability, when considered alongside its optimal viscosity and highest drug content, establishes it as the most promising formulation among all batches.

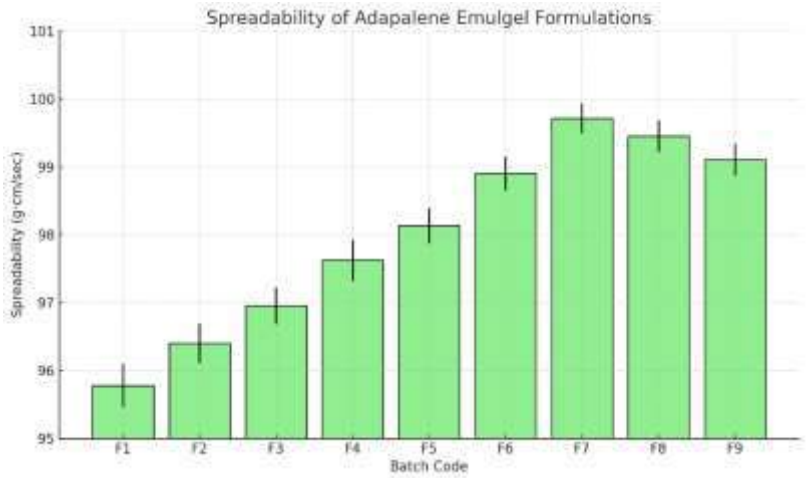


Figure 9: Spreadability of Emulgel formulations F1–F9

Antibacterial Activity Evaluation Using Agar Well Diffusion Method (for Antiacne Study)

The antiacne activity of the Adapalene Emulgel formulations (F1–F9) was evaluated using the agar well diffusion method against *Cutibacterium acnes* and the zone of inhibition was measured in millimeters to assess the effectiveness of each formulation in inhibiting microbial growth. The results revealed a progressive increase in the zone of inhibition from F1 to F7, indicating improved drug release and bioavailability with formulation optimization. Among all batches, Batch F7 exhibited the largest zone of inhibition, measuring **19.6 ± 0.2 mm**, which confirms its superior antimicrobial efficacy. This enhanced activity can be attributed to its optimal viscosity, uniform drug distribution, and excellent spreadability, which collectively facilitated better contact and diffusion of the drug to the target site. Other formulations such as F6 (**17.5 ± 0.3 mm**) and F4 (**16.4 ± 0.3 mm**) also demonstrated appreciable antimicrobial effects, although they were slightly lower compared to F7. On the other hand, lower zones of inhibition observed in F1 (**13.2 ± 0.3 mm**) and F3 (**14.0 ± 0.5 mm**) suggest limited drug release or suboptimal formulation characteristics. Overall, the findings from the zone of inhibition study strongly support that **Batch F7 is the most effective formulation**, offering potent antimicrobial action in addition to excellent physical and pharmaceutical properties, making it the most suitable candidate for further development and therapeutic application.

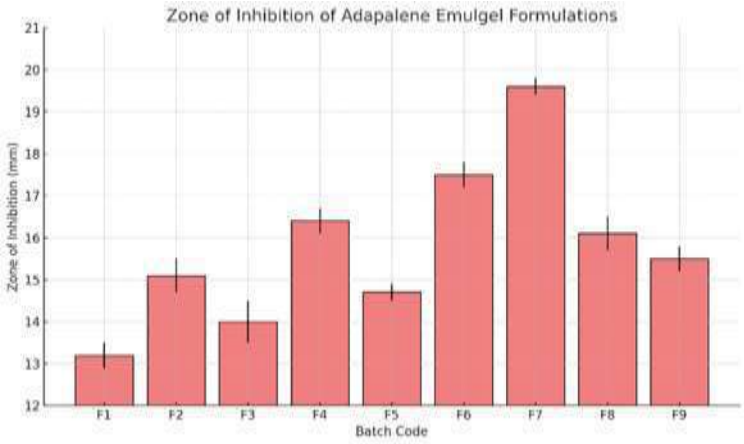


Figure 10: Zone of Inhibition for Adapalene Emulgel Formulation (F1–F9)

Table 5: Evaluation of Emulgel Formulations for Different Parameters

Batch Code	Spreadability (g·cm/sec) ± SD	Drug Content (%)	Zone of Inhibition (mm) ± SD
F1	95.78 ± 0.32	98.0 ± 0.32	13.2 ± 0.3
F2	96.40 ± 0.29	98.5 ± 0.28	15.1 ± 0.4
F3	96.95 ± 0.27	99.2 ± 0.30	14.0 ± 0.5
F4	97.62 ± 0.30	99.8 ± 0.26	16.4 ± 0.3
F5	98.13 ± 0.26	100.3 ± 0.24	14.7 ± 0.2
F6	98.90 ± 0.25	101.0 ± 0.22	17.5 ± 0.3
F7	99.71 ± 0.22	102.4 ± 0.20	19.6 ± 0.2
F8	99.45 ± 0.23	100.5 ± 0.25	16.1 ± 0.4
F9	99.10 ± 0.24	99.7 ± 0.27	15.5 ± 0.3

In-Vitro Release Study

The in-vitro drug release study was conducted to evaluate the release behavior of the drug from all emulgel formulations (F1 to F9) over a period of 240 minutes. The results, as shown in Table 6, revealed variation in the release profiles across different batches, which can be attributed to differences in polymer concentration, viscosity, and overall matrix composition. Among all batches, Batch F1 showed the highest cumulative drug release of 88.0 ± 2.5% at 240 minutes, closely followed by Batch F7 with 86.3 ± 2.3%, and Batch F4 with 85.1 ± 2.2%. These results indicate that these formulations provided efficient drug release over the study period, with F7 demonstrating a release pattern nearly identical to that of F1, but with better viscosity, spreadability, and antimicrobial activity, making it more pharmaceutically suitable overall. Batch F7 showed a steady and controlled release with 17.9 ± 0.8% at 30 minutes, 34.0 ± 1.2% at 60 minutes, 57.4 ± 1.9% at 120 minutes, and 86.3 ± 2.3% at 240 minutes, confirming its sustained release capability. The consistent release profile of F7 can be attributed to its optimal polymer composition and rheological properties, which allow gradual diffusion of the drug from the emulgel matrix into the receptor medium. On the other hand, formulations such as F5 and F9 exhibited comparatively lower cumulative drug release values (70.1 ± 1.7% and 74.3 ± 1.8%, respectively), likely due to higher viscosity or denser gel matrix formation that may have hindered drug diffusion. Overall, the in-vitro drug release results demonstrated that while F1 had the highest release, Batch F7 maintained a strong balance between efficient drug release and favorable physicochemical characteristics, including optimal viscosity, spreadability, drug content, and antimicrobial activity. Hence, Batch F7 was confirmed as the most optimized formulation, capable of delivering the drug effectively in a sustained manner while maintaining high-quality pharmaceutical attributes ideal for topical delivery.

Table 6: *In-Vitro* Drug Release Profile of Emulgel Formulations (F1–F9)

Formulation	30 min	60 min	120 min	240 min
F1	18.2 ± 0.9	34.9 ± 1.3	58.6 ± 2.0	88.0 ± 2.5
F2	16.5 ± 0.8	32.4 ± 1.2	53.1 ± 1.9	83.2 ± 2.1
F3	14.7 ± 0.6	29.6 ± 1.1	47.2 ± 1.6	78.0 ± 2.0
F4	17.6 ± 0.7	33.7 ± 1.3	56.9 ± 1.8	85.1 ± 2.2
F5	12.4 ± 0.5	24.5 ± 0.9	39.3 ± 1.5	70.1 ± 1.7
F6	15.2 ± 0.6	30.3 ± 1.0	49.8 ± 1.7	80.4 ± 1.9
F7	17.9 ± 0.8	34.0 ± 1.2	57.4 ± 1.9	86.3 ± 2.3

F8	16.0 ± 0.7	31.2 ± 1.1	51.5 ± 1.8	82.1 ± 2.0
F9	13.8 ± 0.5	27.0 ± 0.8	43.5 ± 1.4	74.3 ± 1.8

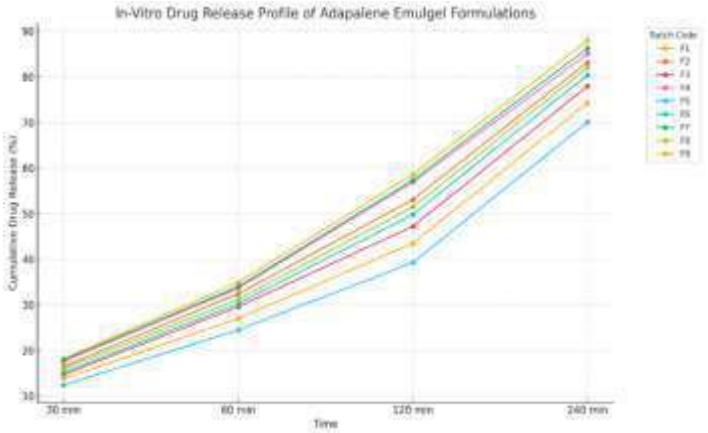


Figure 11: *In-Vitro* Drug Release Profile of Emulgel Formulations (F1–F9)

Stability Study

In compliance with ICH guidelines, stability tests of F9 formulations examined the effects of aging on the physio-chemical properties of the emulgel formulations. Appearance, pH, drug content and viscocity were measured at one-month intervals. The evaluation criteria for the original and retained emulgel formulations did not differ substantially, according to the results. When kept at 40 ± 2°C and 75 ± 5% relative humidity, the F7 emulgel formulations did not change.

Table 7: Stability Study of F7

Sr. No.	Parameters	Time Span		
		0 Months	1 Month	2 Month
1	Appearance	White cream like	White cream like	White cream like
2	pH	7.05	7.05	7.05
3	Drug content (%)	102.4	102.4	102.4
4	Viscosity (CP)			
	At 20 rpm	5920	5918	5918
	At 60 rpm	5530	5523	5523
	At 100 rpm	5000	4996	4996

CONCLUSION

The developed Adapalene emulgel formulations were successfully optimized through a series of physicochemical, microbiological, and stability evaluations. The formulation F7 emerged as the most promising candidate, demonstrating excellent physical characteristics, stable pH, consistent drug content, efficient spreadability, and sustained drug release. The antibacterial evaluation against *Cutibacterium acnes* confirmed significant inhibitory activity, indicating its therapeutic relevance in acne management. Furthermore, the formulation retained its integrity and performance under accelerated stability conditions, validating its shelf-life and formulation robustness. Thus, the Adapalene emulgel F7 can be considered a safe, stable and effective formulation for the topical treatment of acne.

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