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Research Article

Formulation and Evaluation of Finasteride Loaded Nanoparticles Based Topical Gel for the Management of drogenetic Alopecia

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Abstract

The present study aimed to develop and evaluate Finasteride-loaded nanostructured lipid carriers (NLCs) for topical delivery in the management of androgenetic alopecia. Finasteride, a 5α-reductase inhibitor, is widely used for treatment but is associated with systemic side effects when administered orally. To overcome this limitation, NLCs were prepared using Compritol 888 ATO and oleic acid by hot emulsification followed by ultrasonication technique. The optimized formulation exhibited a mean particle size of 248.2 nm and entrapment efficiency of 84.37%. The in vitro drug release study demonstrated a biphasic release pattern with sustained drug release up to 6 h. The optimized NLCs were further incorporated into Carbopol 940 gel for topical application. The gel showed satisfactory pH (6.8), spread ability, viscosity, and drug content (97.45%). The results suggest that Finasteride-loaded NLC gel may serve as a promising topical delivery system with improved localization, sustained release, and potential reduction in systemic side effects.

Keywords: Finasteride; Androgenetic alopecia; Nanostructured lipid carriers; Topical gel; 5α-reductase inhibitor; Controlled release

INTRODUCTION

Androgenetic alopecia (AGA) is one of the most prevalent forms of progressive hair loss and is characterized by gradual miniaturization of hair follicles, resulting in reduced hair density and thinning of scalp hair. The condition is primarily associated with genetic predisposition and androgenic activity, particularly the action of dihydrotestosterone (DHT), which is produced from testosterone by the enzyme 5α-reductase. Elevated levels of DHT contribute to follicular regression, shortening of the anagen phase, and progressive hair loss in susceptible individuals.[1,2]

Finasteride is a selective inhibitor of type II 5α-reductase and is widely employed in the management of androgenetic alopecia. By suppressing the conversion of testosterone to DHT, Finasteride reduces androgen-induced follicular damage and promotes maintenance of hair growth.[3,4]Although oral Finasteride has demonstrated significant therapeutic efficacy, prolonged systemic administration may be associated with undesirable adverse effects. Consequently, topical delivery systems have gained increasing attention as an alternative strategy to achieve localized drug action at the scalp while minimizing systemic exposure and related side effects.

Nanostructured lipid carriers (NLCs) represent an advanced lipid-based drug delivery system designed to overcome limitations associated with conventional formulations. NLCs consist of a blend of solid and liquid lipids that form a partially disordered lipid matrix capable of accommodating higher drug loads and improving formulation stability.[5] Owing to their nanoscale size, NLCs provide increased surface contact with the skin, enhanced follicular targeting, improved drug retention, and controlled drug release characteristics, making them particularly suitable for topical applications.[6,]

In the present study, Finasteride-loaded nanostructured lipid carriers were formulated using Compritol 888 ATO as the solid lipid and oleic acid as the liquid lipid. Tween 80, Span 80, and Poloxamer 188 were employed as surfactants and stabilizers to obtain a stable nanoparticulate system. Various formulations were prepared by varying lipid compositions to identify an optimized carrier system. The optimized NLC formulation was subsequently incorporated into a Carbopol 940 gel base to develop a topical delivery

system for androgenetic alopecia. The developed NLC-based gel was expected to enhance follicular localization of Finasteride, provide sustained drug release, improve therapeutic efficacy, and reduce systemic adverse effects associated with conventional oral therapy.[7]

Therefore, the present study was aimed at developing and evaluating Finasteride-loaded nanostructured lipid carriers (NLCs) for topical delivery in the management of androgenetic alopecia. The prepared NLCs were optimized on the basis of physicochemical characteristics, entrapment efficiency, and drug release behaviour. Furthermore, the optimized NLC formulation was incorporated into a Carbopol 940 gel base and evaluated for its suitability as a topical drug delivery system.[8]

MATERIALS AND METHODS

Materials

Finasteride was procured from Dham Tek Pharma and Consultants. Compritol 888 ATO, oleic acid, Tween 80, Span 80, Poloxamer 188, Carbopol 940, glycerine, triethanolamine, methanol, and other analytical grade reagents were used throughout the study. Distilled water was used in the preparation of all formulations.[9]

Preparation of Finasteride Loaded Nanostructured Lipid Carriers (NLCs)

Finasteride-loaded nanostructured lipid carriers were prepared using the hot nano emulsification technique.[10] Briefly, Compritol 888 ATO and oleic acid were accurately weighed and melted at 65 ± 2°C. Finasteride was dispersed in the molten lipid phase followed by the addition of Tween 80, Span 80, and Poloxamer 188. The aqueous phase was heated separately to the same temperature and gradually added to the lipid phase under continuous stirring to obtain a homogeneous nano emulsion.

The resultant nano emulsion was stirred continuously for 30 minutes and subsequently cooled rapidly using an ice bath to facilitate lipid recrystallization and formation of nanostructured lipid carriers. The prepared NLC dispersion was collected and stored at 4°C until further evaluation. [10,11]

Table 1: Composition of NLCs for Final Batches with Varying Drug and Lipid Ratios in (%)

Batches	Finasteride	Compritol 888 ATO	Oleic Acid	Tween 80	Span 80	Polaxomar 188	Lipid %	Ratio (Compritol: oleic acid)
G1	5	28	12	30	5	20	40	70:30
G2	5	24	16	30	5	20	40	60:40
G3	5	32	8	30	5	20	40	80:20
G4	5	31.5	13.5	28.6	4.7	18.9	45	70:30
G5	5	27	18	28.6	4.7	18.9	45	60:40
G6	5	36	9	28.6	4.7	18.8	45	80:20
G7	5	35	15	27.25	4.35	18	50	70:30
G8	5	30	20	27.25	4.35	18	50	60:40
G9	5	40	10	27.25	4.35	18	50	80:20

Preparation of Finasteride Loaded NLC Gel

The optimized NLC formulation was incorporated into a Carbopol 940 gel base. Carbopol 940 was dispersed in distilled water and allowed to hydrate completely. The optimized NLC dispersion was added slowly with continuous stirring to ensure uniform distribution of nanoparticles throughout the gel matrix. Glycerine was incorporated as a humectant, and triethanolamine was added dropwise to adjust pH and obtain the desired gel consistency. The prepared gel was stored in a closed container for further evaluation.[12]

Table 2: Composition of NLCs based gel for optimized Batches

Sr.no.	Excipients	Quantity(%)
1	Carbopol940	1
2	Glycerine	1.5
3	Triethanolamine	Q.S
4	Water (Q.S)	Up to 20 ml

Characterization and Evaluation of Finasteride Loaded Nanostructured Lipid Carriers (NLCs)

1) Appearance

All prepared formulations were visually examined to assess their physical appearance, homogeneity, and presence of any visible aggregates or phase separation.

2) Fourier Transform Infrared (FTIR) Spectroscopy of Pure Drug

FTIR spectroscopy was performed to confirm the identity of pure Finasteride. The infrared spectrum was recorded over the range of **4000–400 cm^{-1}**using an FTIR spectrophotometer. The obtained spectrum was evaluated for the presence of characteristic functional group peaks and compared with reported literature values.[13]

3) Differential Scanning Calorimetry (DSC) of Pure Drug

Differential Scanning Calorimetry (DSC) was carried out to investigate the thermal behaviour and crystallinity of pure Finasteride. Approximately 5 mg of drug sample was sealed in an aluminium pan and subjected to thermal scanning under a nitrogen atmosphere at a controlled heating rate. The thermogram was analysed for the characteristic melting endothermic peak of the drug.[14]

4) Particle Size Analysis

The mean particle size and particle size distribution of the prepared NLC formulations were determined using a Malvern Zetasizer. Samples were suitably diluted with distilled water prior to analysis. The average particle size was recorded and expressed in nanometres (nm).[15]

5) Zeta Potential Measurement

The zeta potential of the NLC formulations was determined using a Malvern Zetasizer. Samples were appropriately diluted with distilled water and analysed at room temperature. The average zeta potential value was recorded to evaluate the surface charge and physical stability of the formulations.

6) Entrapment Efficiency

Entrapment efficiency of the NLC formulations was determined by separating the unentrapped drug through ultracentrifugation at 7000 rpm for 1 h. Following centrifugation, the supernatant containing free drug was collected and analysed spectrophotometrically at 252 nm.[16] The percentage entrapment efficiency was calculated using the following equation:

Entrapment Efficiency (%) = [(Total Drug − Free Drug) / Total Drug] × 100

7) Drug Content

Drug content of the NLC formulation was estimated by appropriate dilution with methanolic phosphate buffer. One millilitre of formulation was diluted to 10 mL, followed by sonication for 5 min to ensure uniform dispersion. The solution was filtered and further diluted as required. Absorbance was measured at 252 nm using a UV–Visible spectrophotometer.[17]

Drug Content (%) = (Practical Drug Concentration / Theoretical Drug Concentration) × 100

8) In Vitro Drug Release Study

The in vitro release of Finasteride-loaded NLC was carried out using the dialysis bag diffusion method. Simulated intestinal fluid (SIF, pH 6.8) was used as the dissolution medium. The study was performed at 37 ± 0.5°C under continuous magnetic stirring at 100 rpm. An amount of formulation equivalent to 5 mg of Finasteride was placed into a dialysis membrane having a molecular weight cut-off of 12–14 kDa. To maintain sink conditions, the dissolution medium was supplemented with 0.5% w/v Tween 80 and 5% v/v ethanol. Samples were withdrawn at predetermined intervals and analysed at 252 nm using a UV–Visible spectrophotometer.[18,19]

Evaluation of Finasteride Loaded NLC Gel

1) Organoleptic Characteristics

The prepared Finasteride-loaded NLC gel formulations were visually evaluated for color, appearance, homogeneity, consistency, grittiness, and phase separation.

2) pH Determination

The pH of the gel formulation was determined by dispersing 1 g of gel in 20 mL of distilled water. The pH was measured using a calibrated digital pH meter at room temperature. All measurements were performed in triplicate and the mean value was recorded.[20]

3) Spreadability

Spread ability of the gel was determined using the glass slide method. Approximately 1 g of gel was placed between two glass slides, and a weight of 500 g was applied for 5 min.(21) The diameter of the spread gel was recorded, and spread ability was calculated using the following equation:

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

Where:

S = Spread ability

M = Applied weight (g)

L = Length moved by the glass slide (cm)

T = Time taken for separation (s)

4) Viscosity

The viscosity of the gel formulation was measured using a Brookfield viscometer at room temperature. Measurements were recorded at spindle speeds of 10, 20, 50, and 100 rpm to evaluate the rheological behavior of the formulation.[22]

5) Drug Content

Drug content of the gel formulation was determined by dissolving 1 g of gel in phosphate buffer (pH 7.4). The

resulting solution was filtered through Whatman filter paper, suitably diluted, and analysed spectrophotometrically at 252 nm using a UV–Visible spectrophotometer.[23]

Drug Content (%) = (Practical Drug Content / Theoretical Drug Content) × 100

6) Washability

Washability of the gel was evaluated by applying approximately 0.5 g of formulation onto a glass surface and spreading it uniformly. After allowing the gel to remain for 1–2 min, it was washed with a gentle stream of water.[24] Ease of removal and the presence of any residual film were visually assessed.

7) Extrudability

Extrudability was determined by filling the gel into a collapsible aluminium tube and applying uniform manual pressure. The ease of gel extrusion and formation of a continuous ribbon were observed and recorded.[25]

8) In Vitro Drug Diffusion Study

The in vitro drug diffusion study was performed using the dialysis membrane diffusion technique. One gram of gel formulation was placed into a pre-soaked dialysis membrane and immersed in phosphate buffer saline (PBS, pH 7.4) maintained at 37 ± 1°C under continuous stirring at 100 rpm. Samples were withdrawn at predetermined time intervals and replaced with an equal volume of fresh medium. The withdrawn samples were analysed at 252 nm using a UV–Visible spectrophotometer, and cumulative percentage drug release was calculated.[26]

9) Release Kinetics Study

The in vitro drug release data obtained from the optimized gel formulation were fitted into zero-order, first-order, Higuchi, and Korsmeyer–Peppas kinetic models. The release mechanism was determined based on the correlation coefficient (R^2) values obtained from each model.

10) Stability Study

The stability study of the optimized Finasteride-loaded NLC gel was carried out under refrigerated (2–8°C), room temperature, and accelerated (40 ± 2°C) storage conditions for 25 days. Samples were periodically evaluated for physical appearance, pH, viscosity, drug content, and in vitro drug release behaviour.[27]

RESULTS AND DISCUSSION

1)Physical Appearance of NLCs

All prepared NLC formulations were visually examined for colour, homogeneity, and physical stability. The formulations appeared homogeneous and free from visible aggregation or phase separation. The optimized formulation (G4) exhibited a light-yellow appearance with uniform consistency, indicating successful formation of a stable nanostructured lipid carrier system.

Figure 1: Physical Appearance of NLCs

2) FTIR Spectroscopy of Pure Finasteride

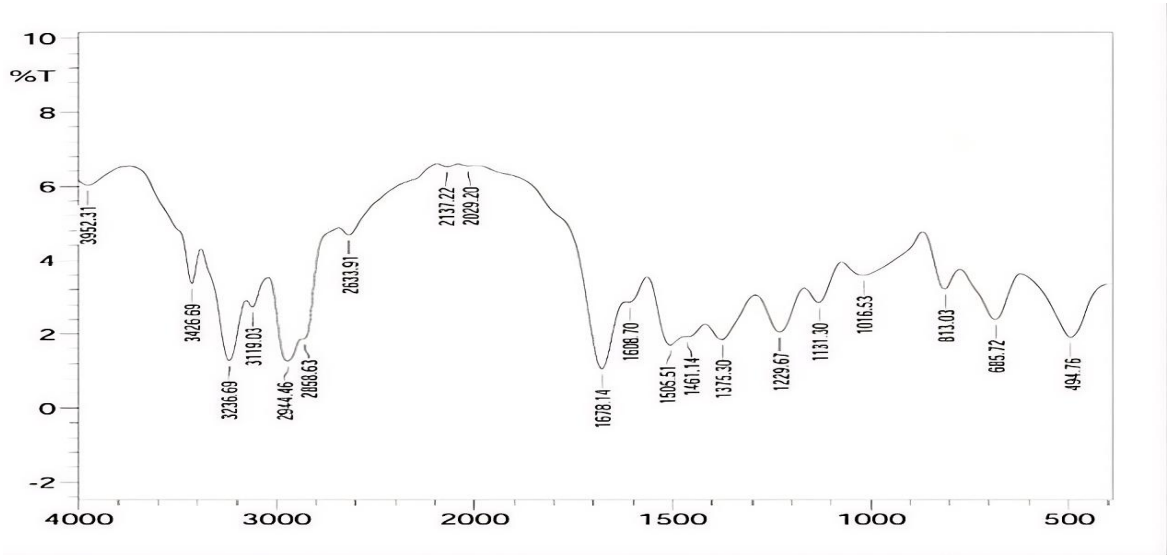

Figure 2: FTIR Spectrum of Pure Finasteride

The FTIR spectrum of pure Finasteride showed characteristic absorption bands corresponding to N–H stretching, C=O stretching, C–N stretching, and aromatic C=C vibrations. The observed peaks were consistent with reported literature values, confirming the identity and purity of the drug. No additional peaks indicating the presence of impurities were observed.

3) Differential Scanning Calorimetry (DSC)

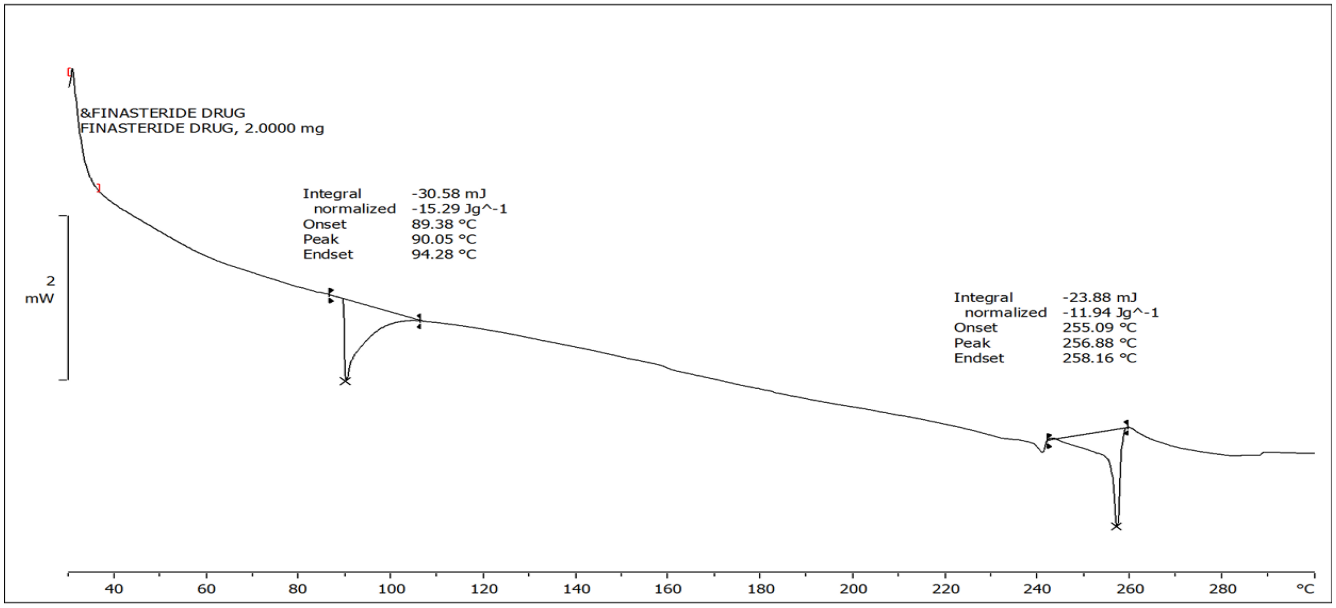

Figure 3: DSC Thermogram of Pure Finasteride

The DSC thermogram of pure Finasteride exhibited a sharp endothermic peak at 256.88°C corresponding to its melting point. The sharp and well-defined peak confirmed the crystalline nature and purity of the drug. No evidence of thermal degradation or polymorphic transition was observed during the analysis.

4) Particle Size and Zeta Potential

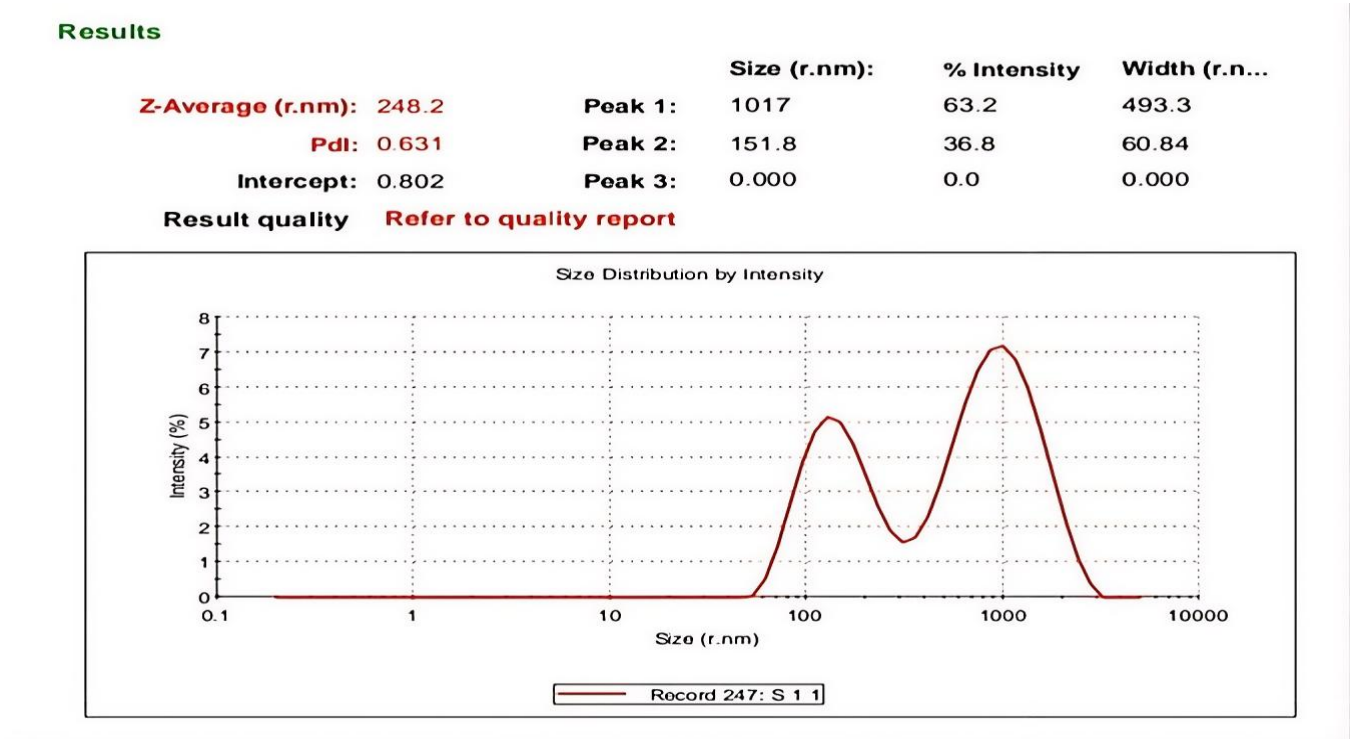

Figure 4: Particle Size of Optimized Batch

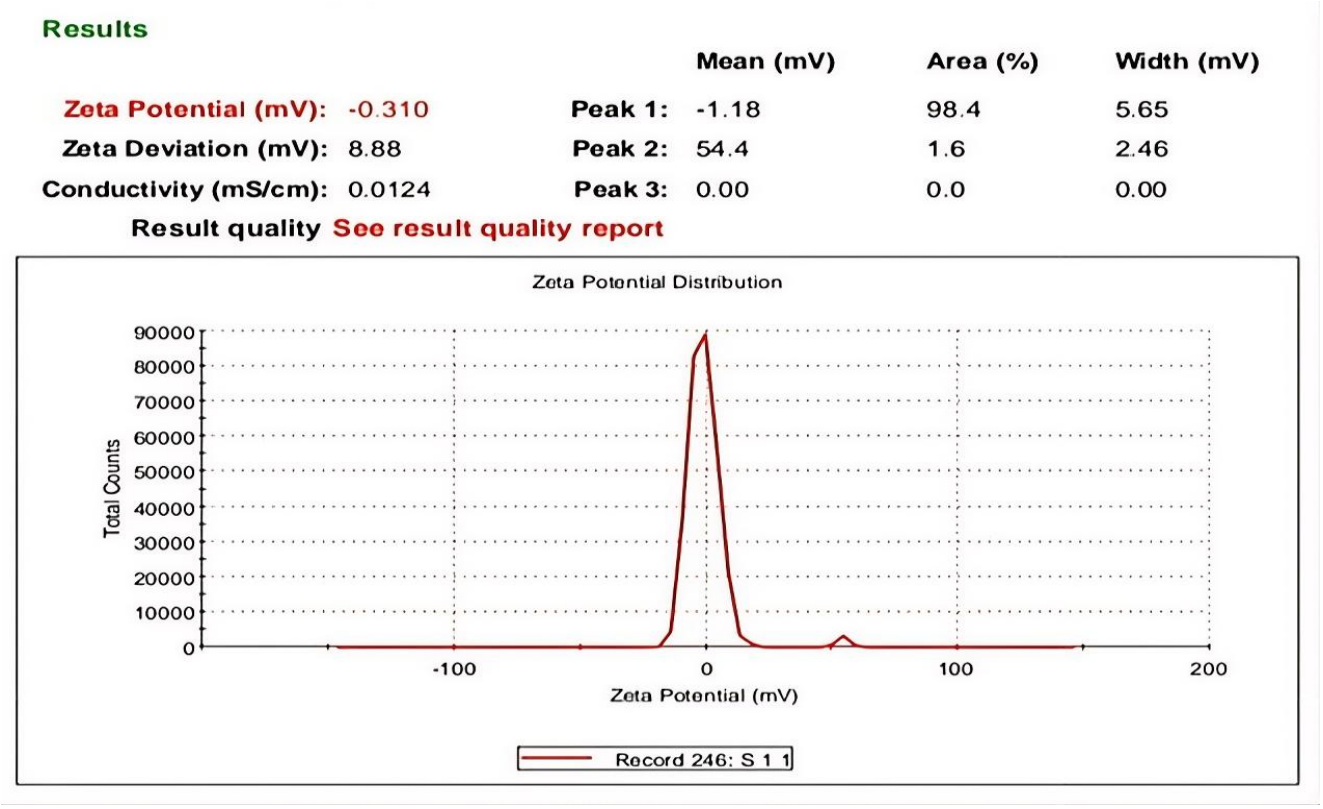

Figure 5: Zeta Potential of Optimized Batch

Result :

Particle Size (nm)	248.2
Zeta Potential (mV)	-0.310

The optimized NLC formulation exhibited a mean particle size of 248.2 nm and a zeta potential of −0.310 mV. The particle size obtained was within the nanometric range and considered suitable for follicular targeting and topical drug delivery. Although the zeta potential value was relatively low, the formulation remained physically stable, which may be attributed to steric stabilization provided by the non-ionic surfactants present in the formulation.

5) Entrapment Efficiency and Drug Content

Table 3: Entrapment Efficiency and Drug Content of NLC Formulations

Sr. No	Batch Name	% EE	Drug content (%)
1	G1	80.37	88.4%
2	G2	80.18	91.7%
3	G3	80.5	94.5%
4	**G4**	**84.37**	**97.2%**
5	G5	79.05	95.8%
6	G6	79.44	96.3%
7	G7	80.12	92.7%
8	G8	80.61	95.2%
9	G9	82.27	96.7%

The entrapment efficiency and drug content values of all formulations are presented in Table 3. The entrapment efficiency ranged from 79.05% to 84.37%, while drug content ranged from 88.4% to 97.2%. Among all formulations, G4 exhibited the highest entrapment efficiency (84.37%) and drug content (97.2%). This may be attributed to the optimized ratio of Compritol 888 ATO and oleic acid, which facilitated efficient incorporation of Finasteride within the lipid matrix.

6) In Vitro Drug Release Study

Table 4: In Vitro Drug Release Profile of Finasteride Loaded NLCs

Time	G1	G2	G3	**G4**	G5	G6	G7	G8	G9
30 min	0.08	2.02	2.24	**3.58**	3.55	1.89	0.2	2.21	2.8
1 hr	2.87	7.80	8.22	**10.99**	7.23	3.46	1.23	10.03	6.55
2 hr	10.01	19.67	15.55	**18.4**	18.66	5.88	3.02	18.35	10.26
3 hr	18.66	36.88	23.44	**25.98**	29.55	8.55	7.95	27.25	14.29
4 hr	24.55	45.68	31.55	**34.67**	35.22	12.5	16.22	34.14	18.76

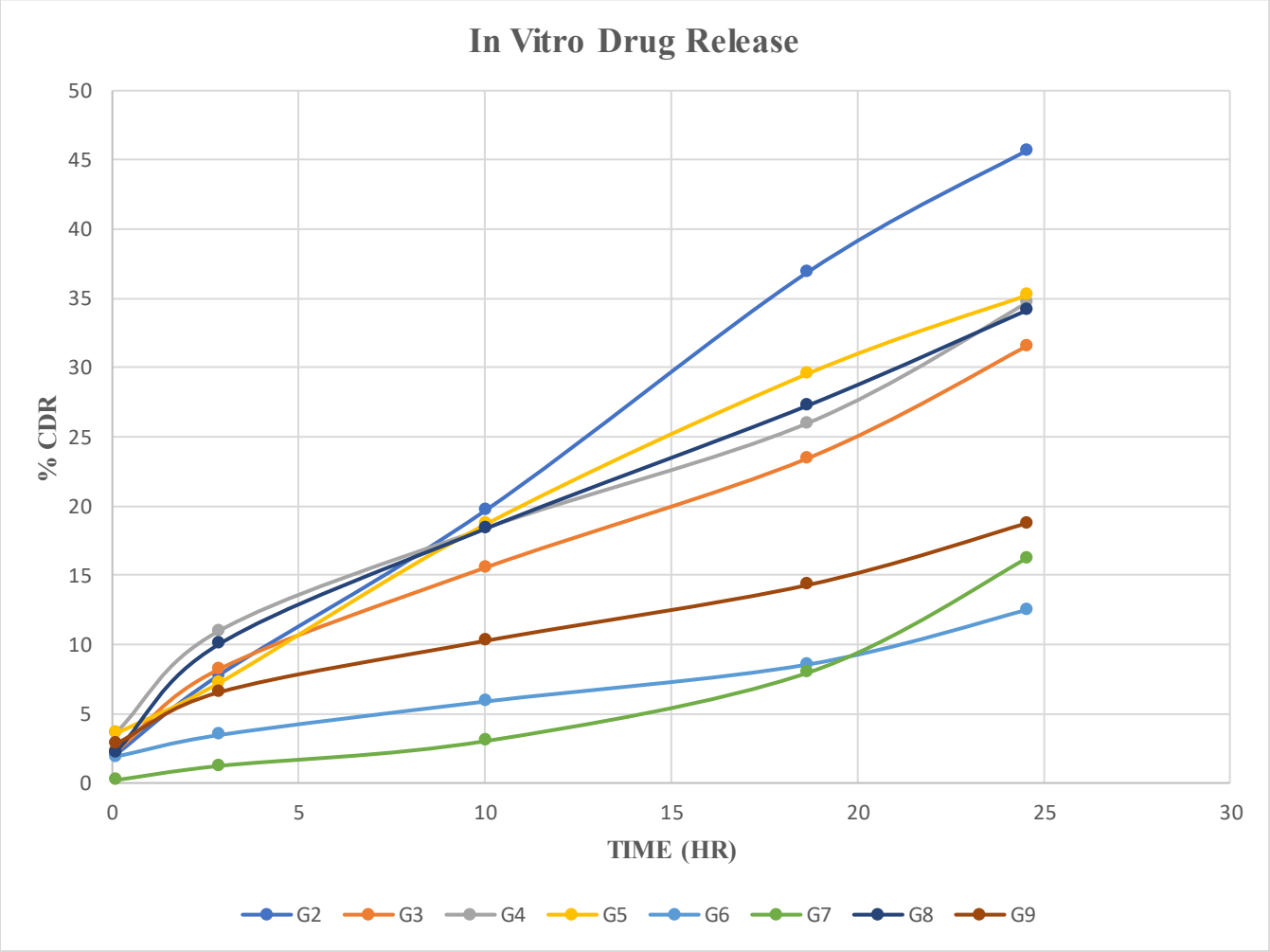

Figure 6: Comparative Drug Release Profile of NLC Formulations

The cumulative drug release profiles of all formulations are shown in Figure 6. All formulations exhibited biphasic drug release characterized by an initial burst release followed by sustained release. The initial release may be attributed to the drug present near the particle surface, whereas the subsequent sustained release was associated with diffusion of the drug through the lipid matrix. Based on the release profile, formulation G4 demonstrated the most desirable release characteristics and was therefore selected as the optimized formulation.

7) Selection of Optimized Formulation

Based on particle size, entrapment efficiency, drug content, and in vitro drug release profile, formulation G4 was selected as the optimized batch for further incorporation into the Carbopol gel base.

Evaluation of Finasteride Loaded NLC Gel

1) Organoleptic Characteristics

The optimized Finasteride-loaded NLC gel was smooth, homogeneous, and milky white in appearance. No evidence of grittiness, lump formation, or phase separation was observed, indicating uniform distribution of the nanostructured lipid carriers throughout the gel matrix.

2) pH, Spread ability and Viscosity

Table 5: Physicochemical Evaluation of Optimized NLC Gel

Parameter	Result
pH	6.8
Spread ability (g·cm/s)	8.36
Viscosity (cP)	2081.9

The pH of the optimized gel was found to be 6.8, indicating compatibility with the physiological pH of the skin. The gel exhibited a spread ability value of 8.36 g·cm/s, suggesting ease of application. The viscosity was found to be 2081.9 cP, indicating suitable rheological characteristics for topical administration and prolonged retention at the site of application.

3) Drug Content

The drug content of the optimized gel formulation was found to be 97.45%, demonstrating uniform distribution of Finasteride throughout the gel matrix and minimal drug loss during formulation.

4) Washability and Extrudability

The gel exhibited satisfactory washability and could be easily removed from the applied surface using water. The formulation also demonstrated good extrudability from the collapsible tube, producing a smooth and continuous ribbon of gel upon application of slight pressure.

5) In Vitro Drug Diffusion Study

Table 6: In Vitro Drug Diffusion Profile of Optimized NLC Gel

Sr. No.	Time	%CDR
1	1 hr	6.13
2	2hr	12.34
3	3hr	21.61
4	4hr	33.96
5	5hr	37.19
6	6hr	40.32

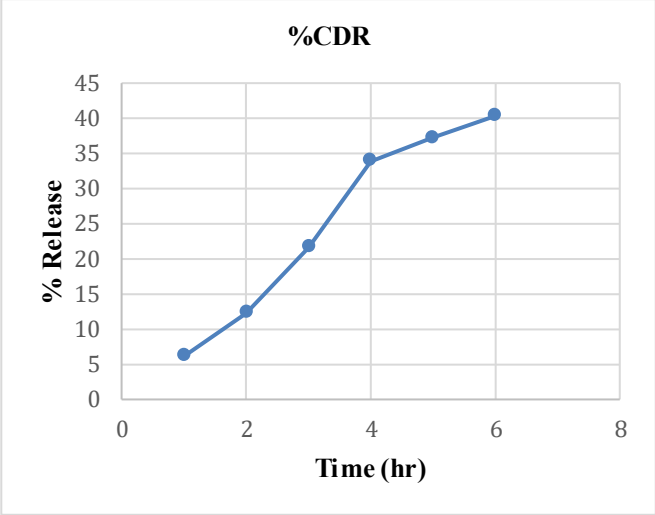

Figure 7: In Vitro Drug Diffusion Profile of Optimized NLC Gel

The optimized gel formulation exhibited sustained drug diffusion throughout the study period. The comparatively slower release observed from the gel formulation, when compared with the NLC dispersion, may be attributed to the additional diffusion barrier provided by the Carbopol gel network.

6) Release Kinetics Study

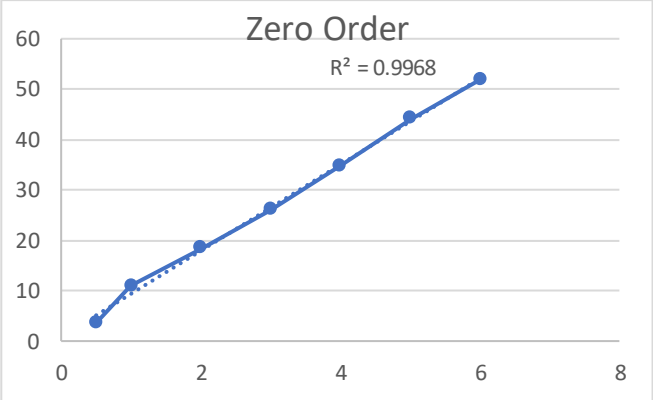

Figure 8: Drug release kinetics for zero order

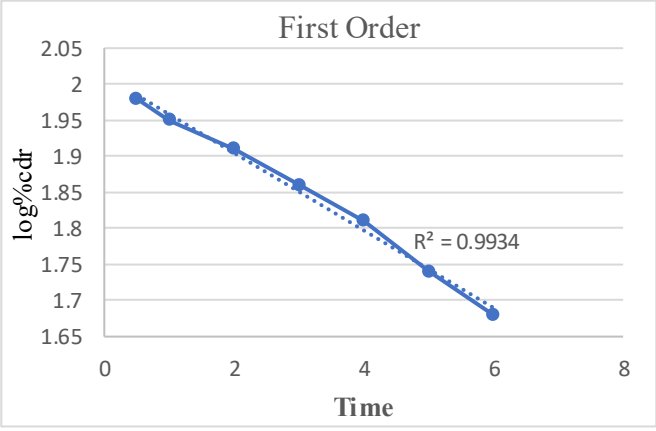

Figure 9: Drug release kinetics for first order

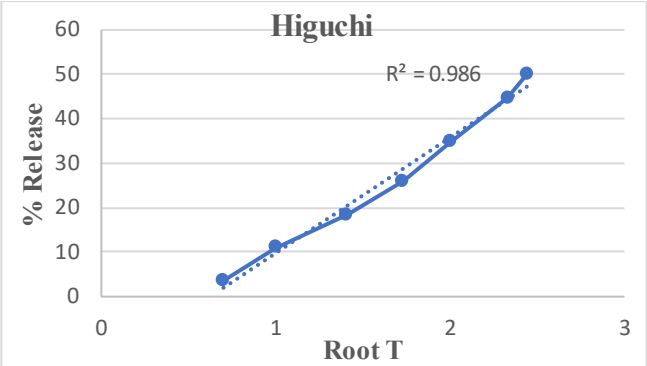

Figure 10: Drug release kinetics for Higuchi model

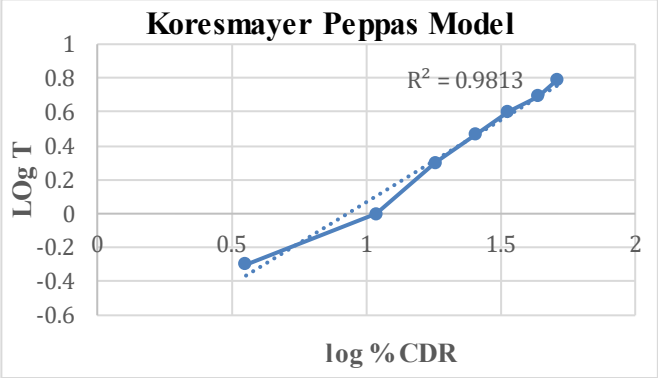

Figure 11: Drug release kinetics for peppas model

Table 7: Release Kinetic Parameters of Optimized NLC Gel

Model	R^2 Value
Zero Order	0.9912
First Order	0.9965
Higuchi	0.9891
Korsmeyer-Peppas	0.9905

The release profile of the optimized gel formulation was analyzed using various kinetic models. The release data best fitted the First-order kinetic model (R^2 = 0.9965), indicating concentration-dependent drug release. The Korsmeyer–Peppas release exponent (n = 0.72) suggested a non-Fickian diffusion mechanism involving both drug diffusion and polymer relaxation.

7) Stability Study

Table 8: Stability Study of Nanostructured Lipid Carrier

Sr.No.	Days	Drug Entrapment Efficiency (%)		
		2-8⁰ c	Room Temp	40±2⁰c
1	0	84.37	84.37	84.37
2	5	84.10	83.60	82.80
3	10	83.80	82.90	81.50
4	15	83.40	82.10	79.90
5	30	83.00	81.20	77.80

Table 9: Stability Study of Nanostructured Lipid carrier

Sr.No.	Days	Physical Appearance		
		2-8⁰ c	Room Temp	40±2⁰c
1	**0**	light yellow	light yellow	light yellow
2	**5**	light yellow	light yellow	light yellow
3	**10**	light yellow	light yellow	light yellow
4	**15**	light yellow	light yellow	light yellow
5	**30**	light yellow	light yellow	light yellow With Turbidity

The optimized NLC gel formulation remained physically stable under refrigerated conditions (2–8°C) throughout the study period. No significant changes in appearance, homogeneity, or drug content were observed. A slight reduction in stability was noted under accelerated storage conditions (40°C), possibly due to lipid matrix rearrangement and partial drug leakage. Therefore, refrigerated storage was

considered suitable for maintaining the long-term stability of the formulation.

Overall, the developed Finasteride-loaded NLC gel system demonstrated promising characteristics for topical delivery in androgenetic alopecia with sustained release and good stability.

CONCLUSION

The present study successfully developed Finasteride-loaded nanostructured lipid carriers (NLCs) incorporated into a Carbopol gel base for effective topical delivery. The formulated system exhibited desirable physicochemical properties including nanosized particle distribution, high entrapment efficiency, and uniform drug content.

The in vitro drug release and diffusion studies demonstrated a sustained release profile, which may help in maintaining prolonged drug availability at the site of application. The release kinetics suggested a controlled release mechanism suitable for topical therapy. The gel formulation also showed appropriate pH, viscosity, spreadability, and washability, indicating good patient compliance and suitability for dermal application.

Stability studies confirmed that the formulation remained stable under refrigerated conditions with minimal changes in physicochemical properties, suggesting good formulation integrity over time.

Overall, the developed Finasteride-loaded NLC gel system can be considered a promising approach for the management of androgenetic alopecia by improving topical delivery, enhancing drug retention, and potentially reducing systemic side effects. However, further in vivo studies are recommended to confirm its clinical efficacy and safety.

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Author Contribution:

Atharv S. Jawanjal: Conceptualization, formulation development, experimental work, data analysis and manuscript writing.

Dr. Sandeep C. Atram: Supervision and review of the manuscript.

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Conflict of Interest: The authors declare that there are no conflicts of interest regarding the publication of this manuscript.o

Ethical Approval: The study did not involve human participants or animals; therefore, ethical approval was not required.

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