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Development and Characterization of Minoxidil Loaded Nanosuspension Gel for the Treatment of Alopecia

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ABSTRACT

Background: Alopecia is a common hair-loss disorder in which topical minoxidil is commonly used. Conventional minoxidil preparations can have limitations related to solubility, skin penetration and irritation, particularly when alcohol-based formulations are used. This study was conducted to develop a minoxidil-loaded nanosuspension gel that can provide a better and more effective way to deliver the medicine for skin.

Methods: Minoxidil nanosuspensions were prepared using Poloxamer 188, polyvinyl alcohol, and Tween 80 as stabilizing agents. The prepared nanosuspensions were then incorporated into a gel containing Carbopol 940 and HPMC. Six different formulations (F1–F6) were developed and evaluated for various parameters, including particle size, zeta potential, drug content, pH, viscosity, spreadability, and in-vitro drug release. Preliminary studies were also performed to assess the physical appearance and solubility of minoxidil, along with its identification by UV spectroscopy and compatibility analysis using FTIR.

Results: The particle size decreased from 450 ± 12 nm in F1 to 185 ± 4 nm in the optimized F6 formulation. Zeta potential changed from -12.5 mV in F1 to -31.2 mV in F6, while drug content increased from 92.4% to 99.4%. The pH of the formulations remained in the range of 5.4-5.8. F6 showed a viscosity of 4900 cP and spreadability of 15. In the in-vitro release study, F6 showed the highest cumulative release at each measured time point and reached 96% at 8 h.

Conclusion: The study showed that minoxidil nanosuspension can be successfully incorporated into a topical gel while maintaining suitable physical properties. Among all the formulations tested, F6 showed the smallest particle size, highest drug content, and a more negative zeta potential. It also showed satisfactory pH, viscosity, and spreading ability. These findings suggest that F6 can be considered a promising formulation for further study and optimization of topical minoxidil delivery.

Keywords: Alopecia, Minoxidil, nanosuspension, topical gel, Carbopol 940, particle size, zeta potential.

I. INTRODUCTION

Alopecia, which is also commonly known as hair loss, can occur due to several factors, including genetics, hormonal changes, autoimmune conditions, nutritional deficiencies, and other causes. Among the different types of alopecia, androgenetic alopecia is one of the most common. It is characterized by the gradual shrinking or miniaturization of hair follicles. Minoxidil is a commonly used topical drug for promoting hair growth. It was initially introduced as an oral medicine for treating high blood pressure, but its unexpected hair-growth effect led to its use as a topical treatment for hair loss.

Minoxidil is commonly available in the form of topical solutions and foams. However, these conventional formulations may have some limitations, such as inadequate drug penetration into the skin, differences in treatment response, and skin irritation. Formulations containing alcohol may also cause dryness or discomfort in certain individuals. Because of these limitations, researchers have explored alternative drug delivery systems that may improve drug dissolution, increase the time the formulation remains on the skin, and enhance delivery to the hair follicles.

One such approach is nanosuspension-based drug delivery. Nanosuspensions contain very small drug particles that are maintained in a stable form with the help of polymers or surfactants. The reduction in particle size increases the surface area of the drug, which can enhance its dissolution. Incorporating a nanosuspension into a gel can further improve the formulation by combining the benefits of small drug particles with the better spreading, handling, and skin-retention properties of a topical gel.

The present study was undertaken to develop and evaluate a minoxidil-loaded nanosuspension gel. Six formulations were prepared

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by changing the concentrations of the stabilizers and surfactant while keeping the other main ingredients unchanged. The prepared formulations were evaluated and compared based on their physical, chemical, and performance characteristics. Based on the results obtained in this study, formulation F6 was selected as the optimized formulation for further consideration.

II. AIM AND OBJECTIVE

The aim of this study was to develop and evaluate a minoxidil-loaded nanosuspension gel for topical use in the treatment of alopecia.The study was carried out with the following objectives:

- To perform preformulations studies of minoxidil.
- To prepare minoxidil nanosuspensions using suitable stabilizing agents.
- To incorporate the prepared nanosuspension into a suitable gel base.
- To evaluate the developed formulations for their physical and nanoscale characteristics.
- To investigate the in-vitro release of minoxidil from the formulations.
- To study the short-term stability of the formulations under different storage conditions.

III. MATERIALS AND METHODS

Materials: Minoxidil was procured from an approved pharmaceutical supplier. Poloxamer 188, polyvinyl alcohol (PVA), and Tween 80 were selected as stabilizing agents and surfactants for the preparation of the nanosuspension. Carbopol 940 and HPMC were used to form the gel and adjust its viscosity. Other ingredients, including glycerin, propylene glycol, methylparaben, triethanolamine, and distilled water, were used in the formulation as required.

Preformulation Studies: The prepared drug sample was evaluated for its physical characteristics, including colour, odour, melting point, and partition coefficient. Its solubility was tested in different solvents, namely water, ethanol, and propylene glycol. UV-visible spectrophotometry was used to determine the maximum absorption wavelength of minoxidil. The compatibility between the drug and selected excipients was studied using Fourier Transform Infrared (FTIR) spectroscopy.

Preparation of Nanosuspension Gel: Minoxidil was first dispersed in an aqueous medium containing the required amounts of Poloxamer 188, PVA, and Tween 80. The mixture was processed using high-speed homogenization and then subjected to ultrasonication to produce the nanosuspension. In a separate step, Carbopol 940 was allowed to hydrate in distilled water, after which HPMC was added to obtain the desired viscosity. The prepared nanosuspension was then mixed into the gel base. Finally, triethanolamine was added to adjust the pH and obtain the final minoxidil nanosuspension gel.

Formulation Design: Six formulations were prepared. Each batch contained 5.0 g minoxidil, 1.0 g Carbopol 940, 1.0 g HPMC, 3.0 g glycerin, 7.0 g propylene glycol and 0.15 g methylparaben, with distilled water added up to 100 g. The concentrations of Poloxamer 188, PVA and Tween 80 were varied between batches.

Ingredient (g)	F1	F2	F3	F4	F5	F6
Minoxidil	5.0	5.0	5.0	5.0	5.0	5.0
Poloxamer 188	0.5	1.5	0.5	1.5	1.0	1.1
PVA	0.5	0.5	2.0	2.0	1.25	1.4
Tween 80	0.2	0.2	1.0	1.0	0.6	0.6
Carbopol 940	1.0	1.0	1.0	1.0	1.0	1.0
HPMC	1.0	1.0	1.0	1.0	1.0	1.0
Glycerin	3.0	3.0	3.0	3.0	3.0	3.0
Propylene glycol	7.0	7.0	7.0	7.0	7.0	7.0
Methylparaben	0.15	0.15	0.15	0.15	0.15	0.15
Triethanolamine	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Distilled water	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100

Evaluation of Formulations: The prepared formulations were visually examined for their colour, uniformity, and any signs of phase separation. The pH of each formulation was measured using a properly calibrated pH meter. Viscosity was determined using an appropriate viscometer, while spreading ability was evaluated using the standard slide method described in the

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study.Particle size and polydispersity were planned to be measured using dynamic light scattering (DLS). Zeta potential was determined to assess the physical stability of the nanosuspension. For drug content analysis, a known quantity of the formulation was taken and the drug was extracted. The extracted drug was then quantified using UV-Visible spectrophotometry.

In-vitro Drug Release: The in-vitro drug release study was carried out using a diffusion-cell setup. The prepared gel was placed in the donor compartment, while a suitable membrane was used to separate it from the receptor medium. At specific time intervals, samples were collected from the receptor medium and replaced with an equal volume of fresh medium. The cumulative amount of minoxidil released from formulations F1–F6 was monitored over a period of 8 hours.

Stability Study: Formulations were evaluated under refrigerated (4 ± 2°C), room-temperature (25 ± 2°C/60 ± 5% RH) and accelerated (40 ± 2°C/75 ± 5% RH) conditions. The listed evaluation parameters were appearance, pH, viscosity, spreadability and drug content.

IV. RESULTS AND DISCUSSION

Preformulation Results: The drug was reported as white and odourless, with a melting point of 274°C and a partition coefficient of 1.5. The observed solubility was 2.04 mg/mL in water, 23 mg/mL in ethanol and 72.38 mg/mL in propylene glycol. UV analysis identified a maximum absorbance around 286-288 nm. The calibration curve showed good linearity over 2-10 µg/mL, with the reported regression equation $A = 0.0602C + 0.0014$ and $R^2 = 0.9999$.

FTIR Findings: The reported FTIR spectrum of the minoxidil sample showed characteristic bands at 3451 cm^{-1} for N-H, 3282 cm^{-1} for hydrogen-bonded N-H, 2926 cm^{-1} for C-H stretching, 1723 cm^{-1} for C=N, 1543 cm^{-1} for aromatic C=C stretching and 1223 cm^{-1} associated with N-O stretching. The thesis uses these observations as evidence for identification of the drug.

Nanoscale and Chemical Properties: Particle size progressively decreased from F1 to F6, while the absolute zeta potential increased. Drug content also increased across the formulation series. F6 showed the smallest reported particle size (185 ± 4 nm), the most negative zeta potential (-31.2 mV) and the highest drug content (99.4%). These values indicate that the selected batch had a comparatively fine and more physically stable nanosuspension with efficient drug incorporation.

Formulation	Particle size (nm)	Zeta potential (mV)	Drug content (%)
F1	450 ± 12	-12.5	92.4
F2	380 ± 10	-15.2	94.1
F3	310 ± 08	-18.8	95.8
F4	240 ± 05	-22.1	97.2
F5	210 ± 06	-26.5	98.5
F6 (optimized)	185 ± 04	-31.2	99.4

Physicochemical properties: All six formulations had pH values between 5.4 and 5.8, which is within the range considered suitable for scalp application in the thesis. Viscosity varied from 4200 to 5000 cP. F4 and F6 showed the highest spreadability value of 15, suggesting that these formulations could be applied more easily than the other batches. F6 combined this spreadability with a viscosity of 4900 cP and pH 5.7.

Formulation	pH	Viscosity (cP)	Spreadability
F1	5.4	4200	12
F2	5.6	4500	14
F3	5.7	4800	13
F4	5.8	5000	15
F5	5.6	4700	14
F6 (optimized)	5.7	4900	15

In-vitro Drug Release: The release profile showed a clear difference among the six formulations. At 1 h, cumulative release was 12%, 15%, 10%, 14%, 16% and 18% for F1-F6, respectively. At 4 h, the corresponding values were 35%, 45%, 32%, 44%, 52% and 60%. By 8 h, F1-F6 reached 65%, 78%, 62%, 76%, 88% and 96%, respectively. F6 therefore showed the highest release throughout the reported study period.

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Time (h)	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
1	12	15	10	14	16	18
2	20	25	18	24	28	32
3	28	35	25	34	40	48
4	35	45	32	44	52	60
5	42	55	40	54	63	72
6	50	65	48	63	72	82
7	58	72	55	70	80	90
8	65	78	62	76	88	96

The greater drug release observed with F6 may be due to its smaller particle size and the combination of stabilizing agents used in the formulation. Smaller particles have a larger surface area, which can promote faster drug dissolution. In addition, the gel base may help the formulation remain in contact with the skin for a longer period. The results indicate that F6 showed better drug release characteristics than the other formulations tested. However, these findings do not confirm that the formulation is clinically more effective than commercially available minoxidil products.

Stability: Studies of formulations F1–F6 were carried out at 0, 1, 2, and 3 months. The available thesis data contain several observations represented by symbols rather than exact numerical values. F6 was considered to have comparatively better stability, with fewer expected changes in its physical and physicochemical characteristics during storage. However, since complete numerical stability data are not available, the results do not allow a precise or quantitative assessment of the stability of F6.

V. CONCLUSION

A minoxidil-loaded nanosuspension gel was successfully prepared using Poloxamer 188, PVA, and Tween 80 as stabilizing agents, along with Carbopol 940 and HPMC as the gel-forming polymers. Six different formulations were developed and evaluated for their physical properties, drug content, and performance. The results showed that changes in the formulation composition affected the particle size and drug content of the prepared formulations.

Based on the evaluation results, F6 was selected as the optimized formulation. It showed a particle size of 185 ± 4 nm, a zeta potential of −31.2 mV, and a drug content of 99.4%. The formulation also had a pH of 5.7, viscosity of 4900 cP, and spreading ability of 15. The in-vitro drug release from F6 reached approximately 96% after 8 hours.

Overall, the study indicates that a nanosuspension-based gel may be a useful approach for topical delivery of minoxidil. The findings provide a basis for further improvement of the formulation, extended stability studies, and additional in-vitro and in-vivo permeation studies.

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CONFLICT OF INTEREST

The author declares no conflict of interest.

ABBREVIATIONS

- FTIR: Fourier Transform Infrared Spectroscopy
- HPMC: Hydroxypropyl Methylcellulose
- PVA: Polyvinyl Alcohol
- PDI: Polydispersity Index
- UV: Ultraviolet
- RH: Relative Humidity
- cP: Centipoise
- nm: Nanometer
- mV: Millivolt

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