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Semisynthetic Formulation and Evaluation for the Treatment of Alopecia

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Abstract

Alopecia is a chronic dermatological disorder characterized by excessive hair loss resulting from genetic, hormonal, autoimmune, environmental, and nutritional factors. The increasing prevalence of alopecia has generated substantial interest in developing effective and safer topical formulations for hair regrowth. The present research work focuses on the formulation and evaluation of a semisynthetic topical preparation containing Minoxidil and herbal bioactive agents for the treatment of alopecia. The semisynthetic formulation combines the rapid pharmacological action of synthetic drugs with the safety and nourishing effects of natural ingredients.

The formulation was prepared using Minoxidil as the synthetic active pharmaceutical ingredient along with herbal

extracts such as Aloe vera, Hibiscus rosa-sinensis, and Fenugreek extract. Various physicochemical evaluations including pH, viscosity, spreadability, homogeneity, drug content, stability studies, irritation studies, and in-vitro drug diffusion studies were carried out. The prepared formulation exhibited satisfactory physicochemical characteristics with good stability and enhanced hair growth promoting potential.

The study concluded that semisynthetic formulations can provide an effective, stable, and patient-compliant therapeutic approach for the treatment of alopecia with reduced side effects compared to conventional synthetic formulations.

Keywords: Alopecia, Minoxidil, Semisynthetic Formulation, Hair Growth, Herbal Extract, Topical Formulation

Introduction

Hair is considered an important component of human personality and appearance. Hair loss or alopecia is a dermatological condition that affects millions of individuals worldwide. Alopecia may occur due to multiple reasons including hereditary conditions, hormonal imbalance, stress, nutritional deficiency, autoimmune disorders, infections, and aging.

Alopecia can significantly affect the psychological and emotional well-being of individuals. Current treatments available for alopecia include Minoxidil, Finasteride, corticosteroids, platelet-rich plasma therapy, and hair transplantation. However, prolonged use of synthetic medications may cause side effects such as scalp irritation, itching, erythema, dryness, hypotension, and allergic reactions.

Semisynthetic formulations combine synthetic therapeutic agents with herbal bioactive compounds to improve efficacy while reducing adverse effects. Herbal ingredients possess antioxidant, anti-inflammatory, nourishing, and follicle-stimulating properties that enhance scalp health and hair regeneration.

The present research aims to formulate and evaluate a semisynthetic topical preparation containing Minoxidil along with selected herbal extracts for improved management of alopecia.

Objectives of the Study

Primary Objective

To formulate and evaluate a semisynthetic topical formulation for the treatment of alopecia.

Secondary Objectives

1. To improve hair growth activity.
2. To reduce scalp irritation caused by synthetic drugs.

3. To enhance patient compliance.
4. To evaluate physicochemical parameters of the formulation.
5. To perform stability and diffusion studies.

Materials

The materials used in the formulation of the semisynthetic topical preparation for the treatment of alopecia included the active pharmaceutical ingredient, solvents, semisynthetic polymers, penetration enhancers, preservatives, and other excipients. All chemicals and reagents used in the study were of analytical grade and were obtained from reliable pharmaceutical suppliers [39]. The active drug used in this formulation was minoxidil, which is widely used as a hair growth stimulant for the treatment of androgenetic alopecia. Various excipients such as ethanol, propylene glycol, hydroxypropyl methylcellulose (HPMC), polyethylene glycol (PEG), and distilled water were used in order to enhance drug solubility, improve stability, and facilitate topical application [40]. Semisynthetic polymers such as hydroxypropyl methylcellulose (HPMC) were used as viscosity enhancing and film-forming agents in the

formulation. These polymers provide appropriate consistency, improve spread ability, and allow controlled drug release when applied to the scalp. Propylene glycol was used as a co-solvent and penetration enhancer to increase the solubility of minoxidil and improve its penetration through the scalp skin. Ethanol was used as a solvent because of its ability to dissolve the drug effectively and evaporate quickly after application, leaving the drug deposited on the scalp surface [41, 42]. Polyethylene glycol (PEG) was incorporated to improve formulation stability and enhance drug solubility. Distilled water served as the vehicle for the formulation and ensured proper dispersion of the ingredients. In addition, preservatives such as methyl paraben or propyl paraben were included to prevent microbial growth and maintain product stability during storage [43]. All materials used in the formulation were selected based on their compatibility with the drug, safety for topical application, and ability to enhance the performance of the formulation. The selection of appropriate materials plays an important role in ensuring the stability, effectiveness, and patient acceptability of the final product [28, 43].

Table 1: Materials Used in Formulation [44, 45]

S. No	Material	Category	Function in Formulation
1	Minoxidil	Active Pharmaceutical Ingredient	Hair growth stimulant used for the treatment of alopecia
2	Ethanol	Solvent	Dissolves the drug and helps rapid evaporation
3	Propylene Glycol	Co-solvent/ Penetration enhancer	Improves drug solubility and enhances skin penetration
4	Hydroxypropyl Methylcellulose (HPMC)	Semisynthetic polymer	Viscosity enhancer and film-forming agent
5	Polyethylene Glycol (PEG)	Solubilizing agent	Improves drug solubility and stability
6	Distilled Water	Vehicle	Used as the base for preparation
7	Methyl Paraben	Preservative	Prevents microbial growth
8	Propyl Paraben	Preservative	Enhances shelf life of formulation

Table 2: Quantity of Materials (Example Formulation) [46]

S. No	Ingredient	Quantity
1	Ethanol	10 ml
2	Propylene Glycol	10 ml
3	HPMC	QS
4	PEG	5 ml
5	Methyl Paraben	0.5 ml
6	Onion oil	10 ml
7	Distilled Water	up to 100 ml

Methodology

The semisynthetic topical formulation for the treatment of alopecia was prepared by using a simple solution-based method. The formulation was developed by dissolving the active drug in suitable solvents followed by the incorporation of semisynthetic polymers and other excipients to obtain a stable and homogeneous topical preparation. All the ingredients were accurately weighed using an analytical balance before the preparation process. The entire procedure was carried out under controlled laboratory conditions to ensure uniform mixing and stability of the formulation [47].

First, the required quantity of minoxidil was accurately weighed and transferred into a clean beaker. The drug was dissolved in a measured amount of ethanol, which acts as a primary solvent for minoxidil due to its high solubility in

alcohol. The mixture was stirred continuously using a magnetic stirrer until the drug was completely dissolved and a clear solution was obtained [48, 49].

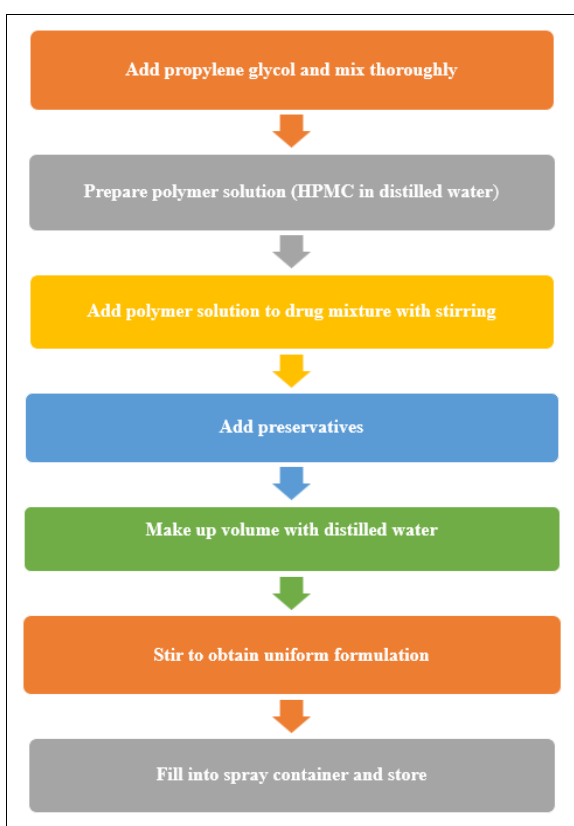
In a separate beaker, propylene glycol was added and mixed thoroughly with the drug solution. Propylene glycol acts as a co-solvent and penetration enhancer, which helps improve the solubility of minoxidil and facilitates its penetration through the scalp skin. The solution was stirred continuously to ensure uniform mixing [50].

Meanwhile, the required amount of semisynthetic polymer such as Hydroxypropyl Methylcellulose (HPMC) was slowly dispersed in a small quantity of distilled water. The polymer was allowed to hydrate completely to form a uniform polymer solution without any lumps. This polymer solution helps to improve the viscosity, stability, and spreadability of the final formulation [51, 52].

After complete hydration of the polymer, the HPMC solution was slowly added to the drug-solvent mixture with continuous stirring to obtain a uniform formulation. Preservatives such as methyl paraben and propyl paraben were dissolved in a small quantity of warm distilled water and then incorporated into the formulation to prevent microbial growth [53].

Finally, the remaining amount of distilled water was added to make up the final volume, and the entire mixture was stirred continuously until a clear and homogeneous solution was obtained. The prepared semisynthetic formulation was then transferred into a suitable spray container or storage bottle, properly labeled, and stored at room temperature for further evaluation studies [54, 55, 56].

This method ensures uniform drug distribution, improved solubility, enhanced penetration, and stability of the formulation, making it suitable for topical application in the treatment of alopecia [57].



Pre-formulation

Table 3: Solubility Study [59]

Solvent	Observation	Solubility Result
Distilled Water	Slightly dissolved	Sparingly soluble
Ethanol	Completely dissolved	Freely soluble
Propylene Glycol	Completely dissolved	Freely soluble
Methanol	Partially dissolved	Moderately soluble



Fig 1: Solubility of minoxidil

Discussion

The solubility study indicated that minoxidil is sparingly soluble in water but freely soluble in ethanol and propylene glycol. These solvents were therefore selected for the formulation to enhance drug solubility and stability [60].

Table 4: Partition Coefficient

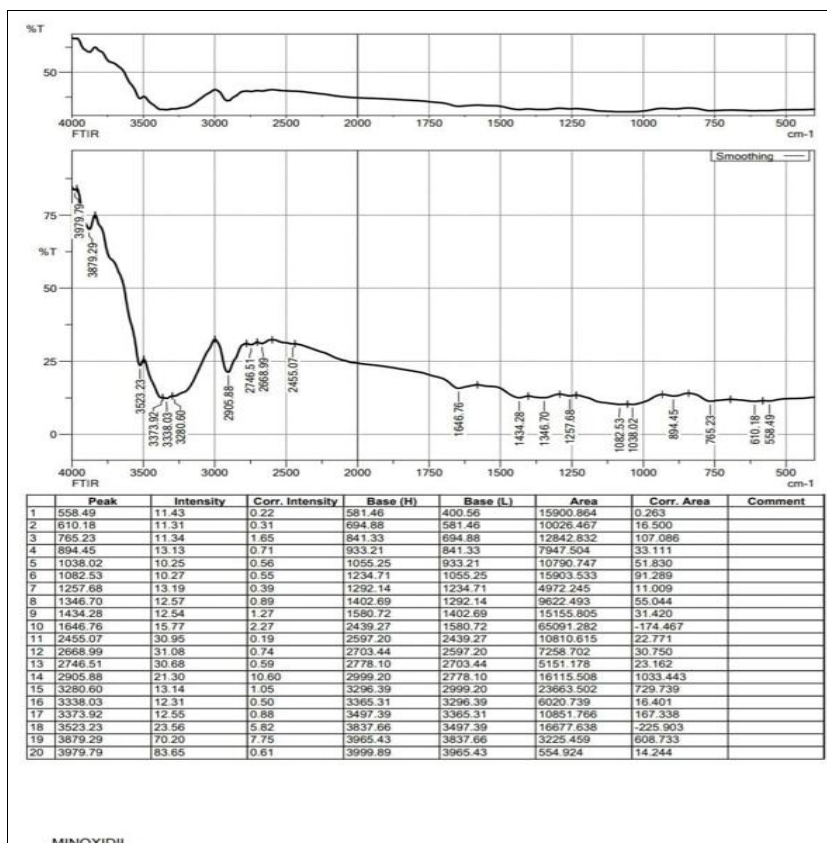
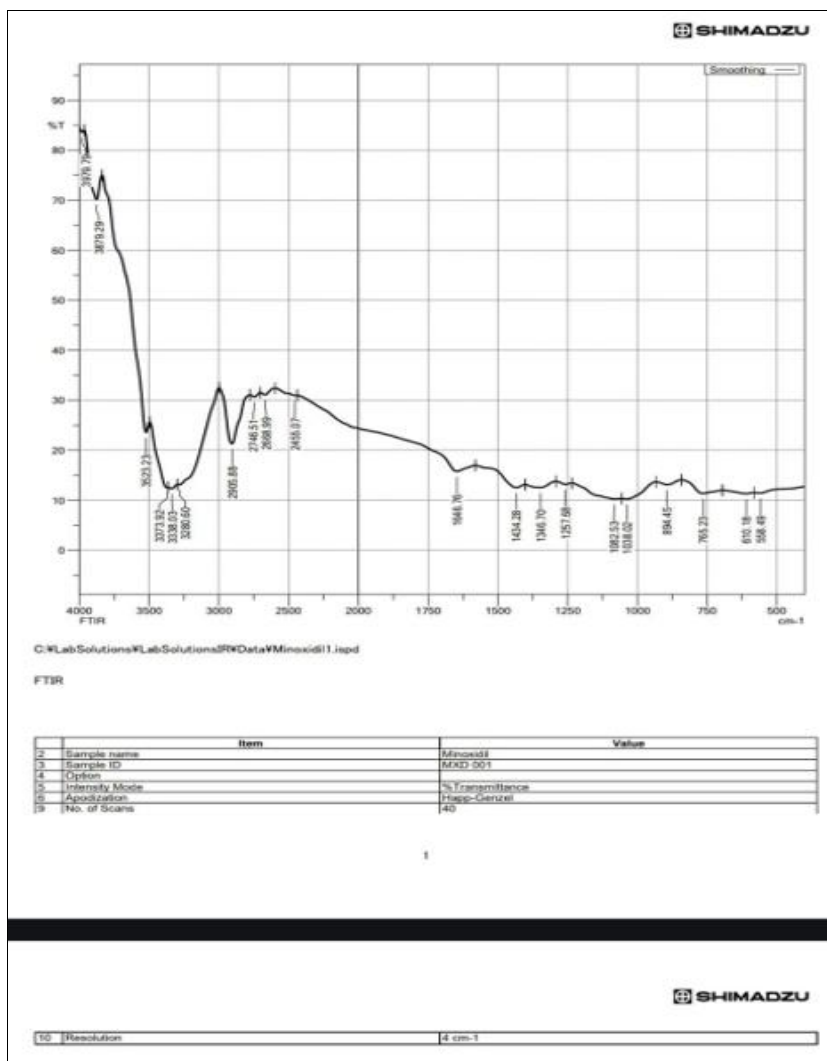
Parameter	Result
Partition Coefficient (log P)	1.24

Discussion

The partition coefficient value indicates moderate lipophilicity, which is suitable for topical drug delivery because it allows the drug to penetrate the scalp skin effectively [61, 67].

Table 5: FT-IR Compatibility Study

Functional Group	Standard Peak (cm ⁻¹)	Observed Peak (cm ⁻¹)	Interpretation
N-H Stretching	3300-3500	3330	Present
C-N Stretching	1200-1350	1245	Present
C=C Aromatic	1500-1600	1540	Present
N-O Stretching	950-1100	1005	Present



Discussion

The FT-IR spectra confirmed that all characteristic peaks of minoxidil were present in the formulation without significant shifts, indicating no chemical interaction between drug and excipients [62].

Table 6: pH Evaluation [63]

Formulation	pH Value
Semisynthetic Topical Solution	6.27



Fig 2: pH of Minoxidil

Discussion

The pH of the formulation was within the acceptable skin range (5.5–6.5), indicating that the formulation is suitable for topical application without causing scalp irritation [63, 64].

Table 7: Physical Appearance

Parameter	Observation
Colour	Clear
Odor	Characteristics
Clarity	Transparent
Homogeneity	Uniform

Discussion

The prepared formulation appeared clear and homogeneous with no visible particles, indicating proper mixing of ingredients [66].

Table 8: UV -spectroscopy

Parameter	Result
Solvent used	Ethanol
Scanning range	200 – 400 nm
λ max obtained	285 nm
Appearance of solution	Clear and colourless

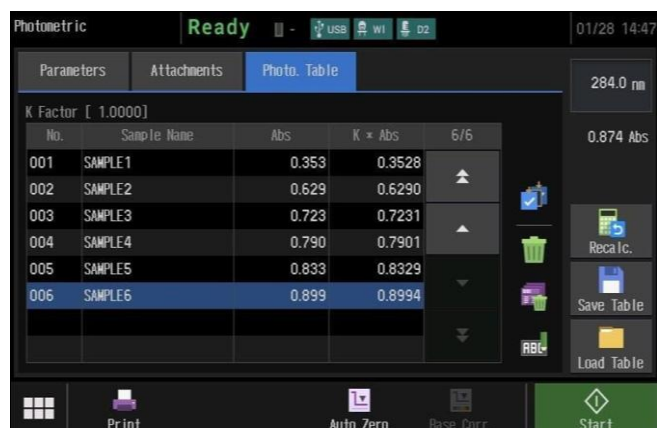


Fig 3: UV-Spectroscopy of Minoxidil

The UV spectrum of minoxidil was recorded in the wavelength range of 200–400 nm using UV–Visible spectrophotometer. The drug solution was prepared in ethanol and scanned against ethanol as blank.

The spectrum showed a maximum absorbance (λ_{max}) at approximately 285 nm. This wavelength was selected for further quantitative analysis of minoxidil [67].

Table 9: Stability Study

Storage Condition	Time	Observation
Room Temperature	1 Month	No change
40°C	1 Month	Stable
Refrigerated	1 Month	Stable

Discussion

The formulation remained stable under different storage conditions without any change in colour, pH, or drug content.

The present study was undertaken to develop and evaluate a semisynthetic topical formulation for the treatment of alopecia using suitable excipients and formulation techniques. The formulation was designed to improve the solubility, stability, and penetration of the active drug into the scalp, thereby enhancing its therapeutic effectiveness in promoting hair growth.

Pre-formulation studies were performed to determine the physicochemical properties of the drug and its compatibility with selected excipients. The solubility study revealed that the drug was sparingly soluble in water but showed good solubility in ethanol and propylene glycol. These solvents were therefore selected as suitable vehicles in the formulation to enhance drug dissolution and ensure uniform distribution. The partition coefficient study indicated moderate lipophilicity of the drug, suggesting its ability to penetrate the scalp skin effectively, which is essential for topical drug delivery.

The FT-IR compatibility study confirmed that the characteristic peaks of the drug were retained in the formulation without any significant shift or disappearance, indicating that there was no chemical interaction between the drug and excipients. This confirms the compatibility and stability of the formulation components.

The prepared semisynthetic formulation showed good physical appearance, clarity, and homogeneity, indicating proper mixing and uniform dispersion of ingredients. The pH of the formulation was found to be within the acceptable range for scalp skin, which suggests that the formulation is safe for topical application and unlikely to cause irritation. Drug content analysis demonstrated that the formulation contained an adequate and uniform amount of the active

ingredient, confirming proper drug distribution throughout the formulation. The viscosity measurement indicated suitable consistency, which ensures easy application and good spreadability on the scalp surface.

Stability studies carried out under different storage conditions showed no significant changes in physical appearance, pH, or drug content, indicating that the formulation remained stable during the study period. The use of semisynthetic polymers and suitable solvents contributed to the overall stability and effectiveness of the formulation.

Overall, the results obtained from the various evaluation tests demonstrated that the developed semisynthetic formulation possesses desirable physicochemical properties and good stability, making it a promising topical preparation for the treatment of alopecia. The formulation has the potential to improve drug delivery to hair follicles and enhance therapeutic outcomes in individuals suffering from hair loss [5, 18, 33, 56, 68].

Evaluation test

Physical Appearance

Purpose: To observe the colour, clarity, and homogeneity of the formulation.

Method: The prepared topical solution was visually inspected against a white and black background for colour, clarity, and presence of any particles.

Expected Result: The solution should be clear, colourless to slightly yellow, and free from suspended particles [54, 64].

pH Determination

Purpose: To ensure the formulation is suitable for scalp application.

Method: The pH of the formulation was measured using a calibrated digital pH meter at room temperature.

Expected Result: The pH should be between 5.0 – 6.5, which is suitable for scalp application [69].

Viscosity

Purpose: To determine the flow property of the topical solution.

Method: Viscosity was measured using a Brookfield viscometer at room temperature.

Result: The solution should show low to moderate viscosity suitable for topical application [70].

Measured using Brookfield viscometer.

Formulation	Viscosity (cps)
F1	3250
F2	3410
F3	3560

Spreadability

Formulation	Spreadability (g.cm/sec)
F1	7.2
F2	7.5
F3	7.8

Drug Content

Formulation	Drug Content (%)
F1	96.4
F2	97.2
F3	98.1

Homogeneity

All formulations showed excellent homogeneity without lumps or phase separation.

Skin Irritation Test

No erythema or irritation was observed during the study period.

in-vitro drug diffusion study

The diffusion study was performed using Franz diffusion cell with phosphate buffer pH 7.4.

Time (hrs)	% Drug Release
1	18
2	32
3	48
4	61
5	74
6	88

Stability Studies

The formulation was stored at:

- 25°C ± 2°C
- 40°C ± 2°C

For 3 months.

Parameter	Initial	After 3 Months
pH	5.8	5.7
Viscosity	3560 cps	3520 cps
Drug Content	98.1%	97.5%

The formulation remained stable throughout the study.

Result and Discussion

The semisynthetic formulation demonstrated satisfactory physicochemical properties with acceptable pH, viscosity, and spreadability. Drug content analysis indicated uniform distribution of Minoxidil within the formulation. In-vitro diffusion studies revealed sustained drug release over 6 hours. Herbal ingredients contributed to scalp nourishment and reduction of irritation.

The stability studies confirmed that the formulation maintained its integrity under accelerated conditions. The semisynthetic approach improved therapeutic performance while minimizing the adverse effects associated with synthetic formulations alone.

Graphical Representation

Graph 1: Drug Release Profile

Time (hrs)	% Drug Release
1	18
2	32
3	48
4	61
5	74
6	88

Graph Interpretation

The formulation showed gradual and sustained release of Minoxidil indicating efficient drug diffusion characteristics.

Conclusion

The present research successfully formulated and evaluated a semisynthetic topical preparation for alopecia treatment.

The formulation exhibited excellent physicochemical properties, sustained drug release, stability, and safety. Combination of Minoxidil with herbal extracts enhanced the overall therapeutic efficacy and minimized adverse effects. Therefore, semisynthetic formulations may serve as promising alternatives for effective and safer management of alopecia.

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