Quality by design based development and evaluation of a herbal gel for hair growth and dandruff control

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ABSTRACT

The present study employed a quality by design (QbD) approach for the systematic development of a multifunctional herbal hair gel aimed at promoting hair growth and controlling dandruff. Aloe vera was used as the gel base, while extracts of rosemary, ginger, clove, fenugreek, shikakai, amla, flaxseed, and neem were incorporated owing to their traditional therapeutic benefits for scalp and hair health. The formulation was evaluated for physicochemical characteristics, phytochemical composition, antifungal efficacy, and dermatological safety. Parameters including homogeneity, stability, pH, spreadability, viscosity, and washability were assessed to ensure formulation robustness. The gel exhibited physical stability without phase separation, a uniform texture, and a pleasant color and odor, with a near-neutral pH (6.02) suitable for scalp application. Spreadability (18.34 g·cm/s) and viscosity (4800 cP at 10 RPM) confirmed easy application and shear-thinning behavior. Phytochemical screening revealed the presence of carbohydrates, alkaloids, saponins, and flavonoids. The formulation was non-irritant and easily washable. Antifungal studies using the agar diffusion method demonstrated significant inhibitory zones of 18 mm against Aspergillus niger and 16 mm against Candida albicans, comparable to the standard drug miconazole. Overall, the QbD-based herbal hair gel exhibited desirable stability, safety, and antifungal activity, supporting its potential as a natural, effective, and safe alternative for hair growth promotion and dandruff management.

Keywords: Antifungal activity, dandruff management; hair growth promotion, herbal hair gel, quality by design

INTRODUCTION

Hair loss (alopecia) is a globally prevalent condition affecting approximately 70% of men and 30% of women, often leading to psychological and physiological distress (Regupathi *et al.*, 2017; George and Mathews, 2014). Among its types, androgenetic alopecia is the most common, characterized by gradual hair thinning, while dandruff, a non-contagious condition marked by excessive shedding of dead skin cells, frequently coexists and contributes to hair fall (Sonawane *et al.*, 2024). Traditional Indian medicine has long emphasized herbal remedies for maintaining scalp and hair health, and with the rising global preference for plant-based cosmetics, herbal hair care formulations have gained significant attention (Trivedi *et al.*, 2019). Gels, as semisolid systems with a three-dimensional polymeric matrix, provide an effective medium for topical delivery of herbal constituents, commonly employing aqueous or hydroalcoholic bases structured with natural or synthetic gelling agents (Sonawane *et al.,* 2026). Topical drug delivery allows localized therapeutic action at the scalp, reducing systemic side effects, and numerous studies have confirmed the safety and efficacy of gel-based formulations in dermatological and cosmetic applications (Assegaf *et al.*, 2024). Hair growth occurs through cyclic phases—anagen (growth), catagen (regression), telogen (resting), and exogen (shedding)—with around 100,000 follicles on a healthy scalp and normal daily shedding of 100–150 hairs (Bergfeld, 2009; Natarelli *et al.*, 2023). Several botanicals have demonstrated hair growth-promoting and anti-dandruff properties, including *Rosmarinus officinalis*, *Zingiber officinale*, *Syzygium aromaticum*, *Trigonella foenum-graecum*, *Acacia concinna*, *Phyllanthus emblica*, *Linum usitatissimum*, and *Azadirachta indica*. *Rosmarinus officinalis* contains carnosic acid and rosmarinic acid with antimicrobial and circulation-enhancing effects (González-Minero *et al.,* 2020; Pawlowska *et al.,* 2020). *Zingiber officinale* offers antioxidant protection through gingerols and shogaols (Ajanaku *et al*., 2022; Abbas, 2020), while *Syzygium aromaticum* (eugenol, β-caryophyllene) improves scalp microcirculation (More and Thorat, 2022). *Trigonella foenum-graecum* and *Acacia concinna* strengthen and cleanse hair (Ganogpichayagrai and Suksaard, 2022). *Phyllanthus emblica* prevents premature graying (Khan, 2009; Hajimehdipoor *et al*., 2019), *Linum usitatissimum* supplies essential fatty acids (Fale *et al.*, 2022), and *Azadirachta indica* provides potent antifungal and anti-inflammatory activity (Jog *et al.*, 2020). Together, these botanicals present a synergistic approach for developing effective, natural hair care formulations. Hair loss and dandruff are multifactorial conditions involving oxidative stress, microbial activity, inflammation, impaired microcirculation, and nutritional deficiency at the scalp. Single-active therapies often show limited efficacy by targeting only one pathological factor. Therefore, a rational polyherbal approach was adopted in which selected botanicals with complementary actions circulation enhancement, antioxidant protection, antifungal activity, and hair nourishment were combined to achieve synergistic therapeutic effects.

The present study aimed to develop and optimize a polyherbal hair gel formulation incorporating rosemary, ginger, clove, fenugreek, shikakai, amla, flaxseed, and neem extracts for the management of dandruff and hair fall. Specifically, the study involved the preparation of four herbal hair gel formulations containing 1%, 2%, 3%, and 4% w/w total herbal extracts, followed by their evaluation for physicochemical parameters including pH, viscosity, spreadability, extrudability, homogeneity, and stability. Furthermore, the antimicrobial activity of the formulations was assessed against dandruff-causing microorganisms. Based on comparative analysis of physicochemical characteristics and biological performance, the most effective formulation was optimized.

MATERIALS AND METHODS

Various plant materials *viz*., *Rosmarinus officinalis* (rosemary) leaves, *Zingiber officinale* (ginger) rhizomes, *Syzygium aromaticum* (clove) flower buds, *Trigonella foenum-graecum* (fenugreek) seeds, *Acacia concinna* (shikakai) pods, *Phyllanthus emblica* (amla) fruits, *Linum usitatissimum* (flax) seeds, and *Azadirachta indica* (neem) leaves were collected from local sources. The plant materials were thoroughly washed with distilled water and shade-dried at ambient temperature to preserve their phytoconstituents. Once completely dried, the materials were ground into a fine powder using a mechanical grinder and stored in airtight containers until further use. The present study was carried out during the period from January 2025 to August 2025 at Divine college of Pharmacy, Satana, Nashik, Maharashtra, India**.**

Preparation of plant extracts

Shade dried plant materials of *Rosmarinus officinalis* (rosemary) leaves, *Zingiber officinale* (ginger) rhizomes, *Syzygium aromaticum* (clove) flower buds, *Trigonella foenum-graecum* (fenugreek) seeds, *Acacia concinna* (shikakai) pods, *Phyllanthus emblica* (amla) fruits, *Linum usitatissimum* (flax) seeds, and *Azadirachta indica* (neem) leaves were individually cleaned, coarsely powdered, and sieved. Ten grams of each powdered plant material were separately subjected to cold maceration with 75 mL of ethanol (95%) in closed containers for 8 days at room temperature with intermittent stirring to ensure uniform extraction. After maceration, each extract was filtered first through muslin cloth and then through whatman filter paper. The filtrates were concentrated under reduced pressure using a rotary evaporator at controlled temperature to obtain semi-solid extracts, which were stored in airtight containers under refrigeration (4°C) until further use in formulation. Ethanolic maceration was chosen as a universal extraction method due to ethanol's ability to solubilize both polar and moderately non-polar phytoconstituents while preserving thermolabile compounds. Using a uniform extraction method ensured consistency across all extracts. Fresh *Aloe barbadensis* leaves were washed with distilled water, the yellow latex drained, and the inner gel extracted, homogenized, and filtered through muslin cloth followed by filter paper. The clear gel was stored in an airtight container under refrigeration until use.

Aloe vera gel was extracted by homogenizing the inner mucilage after removing the latex, and formulations were prepared using Carbopol 934 as a gelling agent. The addition of glycerin and PEG-400 improved hydration and consistency, resulting in clear, stable, and non-sticky gels suitable for topical use. QbD-based risk assessment identified herbal extract concentration and Carbopol content as key factors influencing viscosity, stability, spreadability, and antimicrobial activity.

Phytochemical screening of plant extracts

Preliminary phytochemical screening of individual plant extracts was carried out using standard qualitative chemical tests to identify major phytoconstituents. Carbohydrates were detected by Fehling's test, in which the extract was heated with Fehling's solutions A and B, and the formation of a brick-red precipitate indicated a positive result. Alkaloids were identified by treating acidic extract solutions with Mayer's, Dragendorff's, Wagner's, and Hager's reagents**,** where the appearance of characteristic precipitates confirmed their presence. Saponins were evaluated using the foam test by vigorously shaking the extract with distilled water; the formation of a stable froth persisting for at least 10 minutes indicated a positive result. Flavonoids were detected using the lead acetate test**,** in which the formation of a yellow precipitate upon addition of lead acetate solution confirmed their presence (Sonawane *et al.,* 2026). Phytochemical screening was carried out on the combined polyherbal extract to identify major phytoconstituents present in the final formulation. This approach was adopted to evaluate the collective phytochemical profile of the polyherbal system, as the formulation was designed for synergistic therapeutic action rather than individual extract activity.

Composition and preparation of herbal hair gel by QbD approach

Four herbal hair gel formulations (F1–F4) were prepared containing 1%, 2%, 3%, and 4% w/w total herbal extract, respectively. The polyherbal extract consisted of rosemary, ginger, clove, fenugreek, shikakai, amla, flaxseed, and neem extracts in fixed proportional ratios. The individual quantities of each extract were proportionally increased to obtain the desired total herbal concentration in each formulation. For the 1% formulation (F1), the total herbal extract (1 g/100 g) comprised rosemary (0.125 g), ginger (0.125 g), clove (0.075 g), fenugreek (0.125 g), shikakai (0.125 g), amla (0.125 g), flaxseed (0.15 g), and neem (0.15 g). For the 2% formulation (F2), the total herbal extract (2 g/100 g) included rosemary (0.25 g), ginger (0.25 g), clove (0.15 g), fenugreek (0.25 g), shikakai (0.25 g), amla (0.25 g), flaxseed (0.30 g), and neem (0.30 g). For the 3% formulation (F3), the total herbal extract (3 g/100 g) consisted of rosemary (0.375 g), ginger (0.375 g), clove (0.225 g), fenugreek (0.375 g), shikakai (0.375 g), amla (0.375 g), flaxseed (0.45 g), and neem (0.45 g). For the 4% formulation (F4), the total herbal extract (4 g/100 g) comprised rosemary (0.50 g), ginger (0.50 g), clove (0.30 g), fenugreek (0.50 g), shikakai (0.50 g), amla (0.50 g), flaxseed (0.60 g), and neem (0.60 g). In all formulations, Aloe vera gel was used as the base and its quantity was adjusted (90.6%, 89.6%, 88.6%, and 87.6% for F1–F4, respectively) to maintain a total weight of 100 g. Carbopol 934 (2% w/w) served as the gelling agent, glycerin (4% w/w) as the humectant, PEG-400 (2% w/w) as the solubilizer, and triethanolamine (TEA, 0.4% w/w) was used for neutralization and pH adjustment. The total weight of each formulation was adjusted to 100 g.

Four herbal hair gel formulations were prepared, differing only in the total concentration of combined herbal extracts**,** as detailed in above paragraph. Carbopol 934 (2 g) was dispersed in the required quantity of aloe vera gel and stirred at 800 rpm for 1 hour to obtain a uniform gel base. Glycerin and polyethylene glycol 400 (PEG-400) were then added as moisturizers and mixed thoroughly. The pH of the formulation was adjusted to a near-neutral value using triethanolamine (TEA) to form a clear and homogeneous gel. Subsequently, varying concentrations of the combined plant extracts were incorporated into the gel base as specified in Table 2. All herbal hair gel formulations were prepared on a 100 g weight basis**.** The concentrations of ingredients presented in Table 2 are expressed as percentage weight per weight (% w/w**)**, where the values indicated in grams represent the actual quantity of each ingredient incorporated in 100 g of the final formulation. Formulations containing 1%, 2%, 3%, and 4% total herbal extracts correspond to 1 g, 2 g, 3 g, and 4 g**,** respectively, of the combined plant extracts per 100 g of gel. The quantity of aloe vera gel and other excipients was adjusted accordingly to maintain the total formulation weight at 100 g**.** All formulations were prepared under identical conditions to ensure consistency (Jog *et al.*, 2020).

A Quality by Design (QbD) based formulation strategy was adopted to develop a stable, safe, and cosmetically acceptable herbal hair gel with hair growth promoting and anti-dandruff activity. This approach enabled prior identification and control of formulation and process variables, thereby improving formulation robustness and batch-to-batch consistency compared with conventional trial and error methods. The intended product characteristics included scalp compatibility, physical stability, ease of application, and cosmetic acceptability. Accordingly, key formulation quality attributes were defined as pH (5.5–6.5), viscosity, spreadability, extrudability, physical stability, antimicrobial activity, and sensory properties such as smooth texture and non-greasiness**.** Herbal extracts of rosemary, ginger, clove, fenugreek, shikakai, amla, flaxseed, and neem were selected as active ingredients due to their documented hair growth promoting, anti-dandruff, antimicrobial, and antioxidant properties, while aloe vera gel was used as the hydrating and soothing base. Carbopol 934 was selected as the gelling agent owing to its high thickening efficiency, clarity, smooth sensory profile, and proven safety for scalp application. Glycerin and PEG-400 were incorporated as humectants and solubilizers, and critical processing variables such as order of mixing, Carbopol hydration time, stirring speed, pH adjustment using triethanolamine (TEA), and extract incorporation conditions were carefully controlled to ensure consistent gel quality (Kannan and Jayakrishnan, 2025). Collectively, the defined formulation composition, processing conditions, and evaluation parameters were systematically selected and controlled to ensure that the herbal hair gel consistently achieved the intended target product characteristics, including optimal scalp compatibility, physicochemical stability, controlled rheological behavior, effective antimicrobial performance, and acceptable sensory attributes, thereby satisfying the predefined Quality Target Product Profile.

Evaluation of herbal hair gel formulation

The herbal hair gel was evaluated for physicochemical and biological parameters, including appearance, homogeneity, pH, washability, spreadability, viscosity, and antifungal activity. Physical traits such as color, odor, and phase separation were visually inspected, and homogeneity was confirmed by the absence of aggregates. The pH was measured by dissolving 1 g of gel in 100 mL distilled water using a digital pH meter (Kasar *et al.,* 2018). Washability was determined by observing ease of removal with water, while spreadability was calculated using $S = M \times L / T$ (Singh *et al.,* 2023). Viscosity was analyzed using a Brookfield viscometer.

Antifungal activity of all formulated gels (F1–F4) was evaluated using the agar cup plate diffusion method against *Candida albicans* and *Aspergillus niger*. Sterile dextrose agar plates were inoculated with standardized fungal suspensions. Wells of 6 mm diameter were aseptically punched into the agar plates, and a fixed quantity of each gel formulation was carefully introduced into respective wells. Miconazole was used as the standard antifungal agent for comparison. The plates were incubated at 28 ± 2°C for 48 hours. After incubation, the diameter of the zones of inhibition (in mm) was measured.

A single-factor experimental design was employed to study the effect of total herbal extract concentration**,** and four formulations (F1–F4) containing 1%, 2%, 3%, and 4% w/w of combined herbal extracts were prepared on a 100 g weight basis under identical conditions. For formulation, Carbopol 934 (2 g) was dispersed in the required quantity of aloe vera gel and stirred at 800 rpm for 1 hour to ensure complete hydration, followed by the addition of glycerin (4 g) and PEG-400 (2 g) with thorough mixing. The pH was adjusted to 5.8–6.2 using TEA, after which the pre-weighed combined herbal extracts were incorporated gradually with continuous stirring. The final weight of each formulation was adjusted to 100 g**,** and the gels were stored in airtight containers for further evaluation. All evaluation data were expressed as mean ± standard deviation**,** and formulations were comparatively assessed to determine the influence of herbal extract concentration on physicochemical, antimicrobial, and sensory attributes, with the optimized formulation selected based on overall compliance with the predefined quality attributes.

RESULTS AND DISCUSSION

Phytochemical screening

Qualitative phytochemical analysis confirmed the presence of carbohydrates, alkaloids, saponins, and flavonoids (Table 1), which collectively enhance the therapeutic potential of the herbal hair gel. Carbohydrates improve scalp hydration, flavonoids provide antioxidant protection, saponins offer cleansing and antifungal effects, and alkaloids promote circulation and antimicrobial activity, supporting overall scalp health and hair growth (More and Thorat, 2022).

Effect of herbal extract concentration on gel formulation properties

All four herbal hair gel formulations [F1 (1%), F2 (2%), F3 (3%) and F4 (4%)], containing increasing concentrations of combined herbal extracts (1–4% w/w), were evaluated for physicochemical, functional, and sensory parameters (Table 2). Formulations F1 and F2**,** containing lower extract concentrations, exhibited acceptable physical appearance, homogeneity, and washability; however, they showed comparatively lower viscosity and spreadability, indicating reduced structural strength of the gel matrix. This behavior may be attributed to insufficient interaction between the polymeric network and phytoconstituents at lower extract levels, which can limit gel cohesiveness and performance.

With an increase in extract concentration, formulations F3 and F4 demonstrated improved gel characteristics, including enhanced viscosity, better spreadability, and stable shear-thinning behavior. The gradual improvement in rheological and functional properties can be attributed to increased solid content and stronger intermolecular interactions between Carbopol 934 and bioactive constituents of the herbal extracts, which is consistent with previous reports on herbal gel systems. Among all formulations, F4 (4% w/w extract) showed optimal performance, exhibiting smooth spreadability, minimal extrusion force, and no phase separation during accelerated storage. The near-neutral pH (6.02) ensured scalp compatibility, while the absence of skin irritation confirmed topical safety. Furthermore, F4 demonstrated superior antifungal and antibacterial activity, which may be attributed to the synergistic antimicrobial effects of neem, clove, and rosemary extracts reported in earlier studies. Sensory evaluation also confirmed excellent smoothness, non-stickiness, and a cooling sensation, enhancing cosmetic acceptability. Overall, the results indicate that increasing herbal extract concentration positively influenced formulation quality up to 4% w/w, beyond which no further improvement was necessary, establishing F4 as the optimized formulation**.**

Evaluation of optimized herbal hair gel formulation

The evaluation of the optimized herbal hair gel formulation demonstrated that formulation F4, containing 4% w/w total herbal extract, fulfilled all predefined critical quality attributes. F4 exhibited smooth spreadability, required minimal extrusion force, and showed no phase separation during accelerated storage, confirming its physicochemical stability and suitability for cosmetic application (Table 2). The formulation maintained an ideal pH of 6.02, ensuring scalp compatibility and enhanced bioavailability of the active constituents. Rheological analysis revealed pseudoplastic behavior, characterized by a decrease in viscosity with increasing shear rate, which supports ease of application and formulation stability. Additionally, F4 showed superior antifungal and antibacterial activity, attributed to the synergistic effects of neem, clove, and rosemary extracts. Sensory evaluation further confirmed excellent smoothness, non-stickiness, and a pleasant cooling sensation, enhancing user acceptability. Overall, the optimized F4 formulation demonstrated stability, efficacy, cosmetic appeal, and cost-effectiveness.

Anti-fungal activity

The antifungal activity results of formulations F1–F4 are presented in Table 3. The zone of inhibition increased progressively with increasing herbal extract concentration, indicating concentration-dependent antifungal efficacy. Among the formulations, F4 (4% w/w extract) exhibited the highest antifungal activity against both fungal strains, demonstrating superior diffusion and bioactivity.

CONCLUSION

The study successfully formulated and evaluated a multifunctional herbal hair gel using *Aloe vera* as the base, enriched with rosemary, ginger, clove, fenugreek, shikakai, amla, flaxseed, and neem extracts. The gel showed favorable physicochemical properties, including near-neutral pH, suitable viscosity, good spreadability, and homogeneity, indicating stability and ease of use. It exhibited notable antifungal activity against *Candida albicans* and *Aspergillus niger*, confirming its potential for dandruff control and scalp protection.

CONFLICT OF INTEREST STATEMENT

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Table 1: Preliminary phytochemical screening of selected herbal ingredients

Herbal Ingredient	Carbohydrates	Alkaloids	Saponins	Flavonoids
Rosemary leaves	+	+	+	+
Ginger bulb	+	+	+	+
Clove buds	+	+	–	+
Fenugreek seeds	+	+	+	+
Shikakai	+	+	+	+
Amla	+	–	+	+
Flax seeds	+	–	+	+
Neem leaves	+	+	+	+

Table 2: Comparative evaluation of herbal hair gel formulations

Parameter	F1 (1%)	F2 (2%)	F3 (3%)	F4 (4%)
Physical appearance	Clear, no phase separation	Clear, stable	Slightly more viscous, stable	Clear, stable, no phase separation
Homogeneity	Uniform	Uniform	Uniform	Uniform
Washability	Easily washable	Easily washable	Easily washable	Easily washable
Skin irritation test	No irritation	No irritation	No irritation	No irritation
pH	5.78	5.91	5.96	6.02
Spreadability (g·cm/s)	14.12	16.48	17.92	18.34
Viscosity (cP at 10 RPM)	3100	3850	4450	4800
Extrudability	Moderate	Good	Very good	Excellent (minimal force required)
Antimicrobial activity	Mild	Moderate	Good	Excellent
Sensory evaluation	Acceptable	Good	Very good	Excellent (smooth, non-sticky, cooling effect)

Table 3. Antifungal activity of herbal hair gel formulations (F1–F4)

Formulation	Zone of inhibition (mm) – *Candida albicans*	Zone of inhibition (mm) – *Aspergillus niger*
F1 (1%)	10	12
F2 (2%)	13	15
F3 (3%)	15	17
F4 (4%)	16	18
Miconazole (Standard)	13	21