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FORMULATION AND EVALUATION OF A MULTI-HERBAL HAIR GROWTH TABLET CONTAINING AMLA, BHRINGRAJ, KALONJI, VITAMIN E AND FOLIC ACID

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ABSTRACT

Background: Pattern hair loss and diffuse telogen effluvium affect a sizeable proportion of Indian adults, and conventional minoxidil and finasteride therapy is limited by scalp irritation, rebound shedding and dose-related sexual adverse effects. Polyherbal oral formulations acting at multiple points of the follicular pathway represent a rational alternative. **Objective:** To formulate and evaluate an oral tablet combining hydroalcoholic extracts of Amla (Emblica officinalis), Bhringraj (Eclipta alba) and Kalonji (Nigella sativa) with vitamin E acetate and folic acid. **Methods:** Six wet-granulated batches (F1–F6) of 650 mg tablets were prepared on a 10-station rotary press, with croscarmellose sodium (CCS) and PVP K-30 varied at 2–6% w/w and 3–5% w/w. Pre-compression flow, post-compression attributes, in vitro dissolution in pH 6.8 phosphate buffer and 3-month accelerated stability were studied. Drug release was quantified at 271 nm as gallic acid equivalents and drug–excipient compatibility by FTIR. **Results:** All batches showed acceptable flow (Carr's index 11.86–17.31%, Hausner's ratio 1.13–1.21). Hardness ranged 4.5–6.8 kg/cm² and friability 0.31–0.78%. The optimised batch F4 (5% CCS, 4% PVP) showed hardness 5.8 ± 0.3 kg/cm², friability 0.42 ± 0.05%, disintegration 6.8 ± 0.4 min, drug content 99.1 ± 0.7%, and 92.4 ± 1.8% release at 60 min. F4 was stable at 40 ± 2 °C / 75 ± 5% RH over 3 months. **Conclusion:** A polyherbal tablet combining three traditional hair-growth botanicals with vitamin E and folic acid was successfully developed at laboratory scale; F4 may be progressed to in vivo evaluation.

Keywords: polyherbal tablet; Emblica officinalis; Eclipta alba; Nigella sativa; alopecia; wet granulation.

INTRODUCTION

Hair loss is no longer regarded purely as a cosmetic concern. Patterned and diffuse forms of alopecia are linked with measurable reductions in self-esteem, social functioning and quality-of-life scores, and the demand for safe long-term therapy has risen accordingly across both genders. Androgenetic alopecia (AGA), the commonest non-scarring hair loss, is reported in close to 50% of men above the age of 50, with onset frequently in the third decade in the Indian male population. Telogen effluvium, the principal cause of acute diffuse shedding in Indian women, has community prevalence estimates of 25–30% in the post-pubertal, pre-menopausal age band, with iron deficiency, post-partum hormonal flux, crash dieting and chronic systemic illness as the usual antecedents. The condition is essentially episodic but recurs frequently enough that women in busy outpatient dermatology clinics often present with overlapping cycles of shedding rather than a single discrete event[1].

Pharmacological management at present rests on two molecules. Topical minoxidil 2% and 5% are vasodilators that prolong the anagen phase of the hair cycle; the response is dose-dependent and the most reproducible complaint is scalp irritation, dryness and contact dermatitis, all of which scale with the higher-strength solution. Rebound telogen shedding within 4–6 weeks of discontinuation is well documented and is a leading reason for non-adherence[2].

The case for a polyherbal alternative rests less on the promise of any single phytoconstituent and more on the rational pairing of agents that act at separate points along the follicular axis. Hair follicle biology involves androgen signalling, dermal papilla activation, the anagen–catagen–telogen cycle, microcirculation at the bulb and oxidative stress within the matrix. A single-target intervention rarely improves all five.

Amla (*Emblica officinalis* Gaertn., family Phyllanthaceae) is the dried pericarp of the Indian gooseberry. The fruit is one of the richest dietary sources of ascorbic acid, with reports of approximately 600 mg/100 g in the fresh pulp. The principal hydrolysable tannins, emblicanin A and emblicanin B, together with punigluconin and pedunculagin, account for the strong free-radical scavenging activity demonstrated in DPPH and ABTS assays[3.4.5].

Bhringraj (*Eclipta alba* Hassk., family Asteraceae), often referred to as "the king of hair" in Ayurvedic texts, contains the coumestan wedelolactone and its desmethyl analogue as the chief active constituents, along with ecliptasaponins, ecliptine and small amounts of nicotine-class alkaloids. The clinically interesting comparator data come from a controlled study against minoxidil 2%, in which E. alba extract showed comparable follicular density at 30 days[6.7].

Kalonji (*Nigella sativa* L., family Ranunculaceae) supplies a fixed oil rich in thymoquinone (0.3–0.6%) along with nigellone, dithymoquinone and a panel of unsaturated fatty acids. The anti-inflammatory and antioxidant action of

thymoquinone is the best-characterised in the literature, and topical N. sativa oil has shown utility in patchy alopecia areata in small open-label studies. Within an oral polyherbal context, the role of N. sativa is largely the systemic limitation of follicular oxidative damage and the dampening of peri-follicular inflammation, which is now recognised as a contributor to scarring progression in late AGA[8].

Vitamin E (dl-α-tocopheryl acetate) is included for its scalp microcirculatory effect and for its role in preventing lipid peroxidation of follicular membranes; a 2010 randomised study of mixed tocotrienol supplementation reported a 34.5% rise in hair count over an eight-month period. Folic acid is essential for erythropoiesis and for the rapid mitosis of the matrix keratinocytes; deficiency states are associated with diffuse hair loss that responds to supplementation[9,10].

The aim of the present work was to develop, by wet granulation, a 650 mg oral tablet combining hydroalcoholic extracts of Amla pericarp, Bhringraj whole plant and Kalonji seeds with dl-α-tocopheryl acetate and folic acid, and to evaluate the product against compendial standards and ICH stability requirements.

MATERIALS AND METHODS

2.1 Materials

Amla, Bhringraj and Kalonji powder was obtained from college's laboratory. dl-α-Tocopheryl acetate and folic acid (both IP grade) were purchased from Loba Chemie Pvt. Ltd., Mumbai. Microcrystalline cellulose PH-102, lactose monohydrate, maize starch IP, polyvinylpyrrolidone K-30, croscarmellose sodium and colloidal silicon dioxide were supplied by SD Fine-Chem Ltd., Mumbai. Magnesium stearate IP and purified talc IP were obtained from Signet Chemical Corporation, Mumbai. Ethanol (95% v/v) and isopropyl alcohol were of LR grade (Merck Specialities Pvt. Ltd., Mumbai). Distilled water was used throughout. All excipients complied with the current IP / USP-NF monographs.

2.2 Equipment

Tablet compression was carried out on a single punching machine. Hardness was measured on a Monsanto-type hardness tester. Friability was determined in a Roche-type friabilator. Disintegration was performed in an Electrolab ED-2L disintegration test apparatus, and in vitro dissolution in an Electrolab TDT-08L USP Type-II paddle apparatus. Spectrophotometric measurements were made on a Shimadzu UV-1800 double-beam spectrophotometer using a matched pair of 1 cm quartz cells.

2.3 Extraction of plant material

Each of the three crude drugs was separately reduced to coarse powder in a laboratory grinder, passed through a #40 sieve and stored in airtight amber-glass containers until use. Hydroalcoholic extraction was carried out by continuous hot percolation in a Soxhlet apparatus using ethanol:water (70:30 v/v) as the solvent. Fifty grams of powdered drug were extracted for 6–8 h, or until the siphoning solvent ran colourless. The combined extracts were filtered through Whatman

No. 1 filter paper and concentrated under reduced pressure at 45 °C in a Buchi R-100 rotary evaporator, then dried in a hot air oven at 40 °C to constant weight. Practical yields were 19.6% w/w for Amla, 13.8% w/w for Bhringraj and 15.4% w/w for Kalonji. The dried extracts were stored in screw-capped amber vials in a desiccator over silica gel[11].

2.4 Preliminary phytochemical screening

Each dried extract was redissolved in the original solvent and subjected to qualitative tests for the major secondary metabolite classes. Alkaloids were tested by Mayer's and Dragendorff's reagents; flavonoids by Shinoda's test (magnesium turnings and concentrated HCl); tannins and phenolics by 5% ferric chloride solution; steroids by Salkowski's test (chloroform and concentrated H_2SO_4); terpenoids by the Liebermann–Burchard test; saponins by the foam test (15 min persistent froth); carbohydrates by Molisch's test; and glycosides by Borntrager's test[12,13].

2.5 Pre-formulation studies

Organoleptic characters (colour, odour, taste, texture) were recorded for each extract. Solubility was determined by shake-flask method in water, ethanol, methanol and chloroform at 25 ± 2 °C. dl-α-Tocopheryl acetate was confirmed as a clear, slightly viscous, pale-yellow oil. Loss on drying (LOD) of the three dried extracts was determined gravimetrically at 105 °C for 3 h; values were 1.6% for Amla, 2.1% for Bhringraj and 2.4% for Kalonji.

2.6 Standard calibration curves

A stock solution of gallic acid (100 µg/mL) was prepared in methanol and serially diluted with pH 6.8 phosphate buffer to give working standards of 2, 4, 6, 8, 10, 15 and 20 µg/mL. Absorbance was measured at 271 nm against blank buffer. The procedure was repeated in triplicate on three separate days. A parallel curve was prepared for wedelolactone (2–20 µg/mL) in methanol with absorbance measured at 350 nm. Linearity was characterised by the regression equation and coefficient of determination (R^2)[14].

2.7 Formulation development

Six batches were prepared, designated F1 to F6, by the wet granulation method. The composition of each batch was so designed that the disintegrant (croscarmellose sodium) and the binder (PVP K-30) were varied systematically while the actives and the other excipients were held constant. Total tablet weight was fixed at 650 mg.

The actives, MCC PH-102, lactose monohydrate and maize starch were passed through a #40 sieve and dry-mixed for 10 min in a planetary mixer. A granulating solution of PVP K-30 in isopropyl alcohol was prepared at the strength corresponding to each batch and added gradually to the powder bed with continuous mixing until a damp mass of suitable consistency was obtained. dl-α-Tocopheryl acetate, being a viscous oil, was first triturated with a portion of MCC to provide a free-flowing solid premix; this premix was incorporated at the dry-mixing step. The wet mass was passed through a #16 sieve to produce wet granules. The granules were spread on stainless

steel trays and dried in a tray drier at 50 °C until the LOD fell below 2.0% w/w (typically 90–120 min). Dried granules were passed through a #20 sieve and blended with magnesium stearate, talc and colloidal silicon dioxide for 5 min in a polyethylene bag to give the final compression mass. Compression was carried out on the single rotary press using 9.0 mm round, flat-faced punches. Machine speed and pre-compression force were held constant across batches; main compression force was adjusted only to keep hardness within the target window.

Table 1. Composition (mg per tablet) of formulations F1–F6.

Ingredient	F1	F2	F3	F4	F5	F6
Amla extract	100	100	100	100	100	100
Bhringraj extract	75	75	75	75	75	75
Kalonji extract	50	50	50	50	50	50
dl-α-Tocopheryl acetate	10	10	10	10	10	10
Folic acid	5	5	5	5	5	5
Maize starch	30	30	30	30	30	30
PVP K-30 (binder)	19.5	22.75	26	26	29.25	32.5
Croscarmellose sodium (CCS)	13	19.5	26	32.5	39	26
Magnesium stearate	6.5	6.5	6.5	6.5	6.5	6.5
Purified talc	13	13	13	13	13	13
Colloidal silicon dioxide	3.25	3.25	3.25	3.25	3.25	3.25
MCC PH-102 + lactose monohydrate (q.s.)	324.75	315.00	305.25	298.75	289.00	298.75
Total	650	650	650	650	650	650

2.8 Pre-compression evaluation

The pre-compression mass of each batch was characterised for flow properties. Angle of repose (θ) was determined by the fixed funnel method. Bulk density (BD) and tapped density (TD) were measured in a 50 mL graduated measuring cylinder; tapping was carried out 100 times in a USP-II tapped density tester. Carr's compressibility index was calculated as CI = (TD – BD)/TD × 100, and Hausner's ratio as HR = TD/BD. All determinations were carried out in triplicate (n = 3)[15,16].

2.9 Post-compression evaluation Weight variation was determined per IP 2018 using 20 randomly selected tablets, individual weights compared with the calculated mean, with a permitted deviation of ± 5% for tablets of weight greater than 324 mg. Thickness was measured on 10 tablets using a digital Vernier calliper. Hardness was determined on six tablets using the Monsanto-type tester and expressed in kg/cm².

Friability was determined on in the Roche friabilator at 25 rpm for 4 min. Disintegration time was determined in distilled water maintained at 37 ± 2 °C in the Electrolab apparatus on six tablets, the end-point being the disappearance of the last visible fragment through the mesh.

In vitro dissolution was carried out in 900 mL of pH 6.8 phosphate buffer (USP) maintained at 37 ± 0.5 °C in the Electrolab TDT-08L apparatus, USP Type-II paddle at 50 rpm. Five-millilitre aliquots were withdrawn at 5, 10, 15, 20, 30, 45 and 60 min and replaced with an equal volume of fresh pre-warmed buffer to maintain sink. Samples were filtered through a 0.45 µm membrane, suitably diluted and analysed at 271 nm against a blank of buffer. Drug release was expressed as per cent cumulative release of gallic acid equivalents[17,18].

2.10 Stability studies The optimised batch F4 was subjected to accelerated stability studies as per ICH Q1A (R2). Tablets were packed in well-closed HDPE bottles with cotton wool plug and stored in a stability chamber at 40 ± 2 °C and 75 ± 5% RH. Samples were withdrawn at 0, 1, 2 and 3 months and evaluated for appearance, hardness, friability, disintegration time and drug content[19.20].

RESULTS AND DISCUSSION

3.1 Extraction and phytochemical screening

The Amla extract was a dark brown, slightly hygroscopic, acidic-tasting solid; the Bhringraj extract was a greenish-black mass with a faint herbaceous odour; the Kalonji extract was a dark brown, oily semi-solid retaining the characteristic bitter, slightly pungent taste of the seed. Practical yields of 19.6%, 13.8% and 15.4% w/w for Amla, Bhringraj and Kalonji respectively are in line with published reports for 70:30 hydroalcoholic Soxhlet extraction of these drugs and are sufficient for routine tablet manufacture at laboratory scale.

Amla extract was strongly positive for tannins and phenolics and gave moderate to strong reactions for flavonoids and carbohydrates, consistent with the known dominance of emblicanin A and B, gallic and ellagic acids in the dried pericarp. Bhringraj extract was strongly positive for flavonoids and saponins and moderately positive for alkaloids; the strong positive reaction in the Salkowski test is attributable to ecliptasterol and related sterols. Kalonji extract was strongly positive for terpenoids and gave a clear positive in Mayer's test, in keeping with thymoquinone and the seed alkaloids respectively.

Table 2. Preliminary phytochemical screening of hydroalcoholic extracts of Amla, Bhringraj and Kalonji.

Phytoconstituent class	Test	Amla	Bhringraj	Kalonji
Alkaloids	Mayer's	+	++	+++
Alkaloids	Dragendorff's	+	++	++
Flavonoids	Shinoda	++	+++	+
Tannins and phenolics	5% $FeCl_3$	+++	++	+
Steroids	Salkowski	–	+++	++
Terpenoids	Liebermann–Burchard	+	++	+++
Saponins	Foam test	+	+++	+
Carbohydrates	Molisch	++	++	++
Glycosides	Borntrager's	–	+	–

+++ strongly present; ++ moderately present; + present; – absent.

3.2 Calibration curves

Beer–Lambert behaviour was confirmed for both calibration standards over the working range. The gallic acid standard at 271 nm gave the regression equation $y = 0.0468x + 0.0042$ with $R^2 = 0.9994$ across 2–20 µg/mL. The wedelolactone standard at 350 nm gave $y = 0.0511x – 0.0086$ with $R^2 = 0.9987$ across the same range. Both curves passed the routine linearity check (R^2 above 0.998) and were considered fit for quantitation of phenolic content in dissolution samples.

3.3 Pre-compression evaluation

Pre-compression characteristics showed acceptable flow for tablet manufacture across all six batches. The angle of repose ranged from 24.3° (F4) to 30.8° (F1). Carr's compressibility index ranged from 11.86% (F4) to 17.31% (F1), and Hausner's ratio from 1.13 (F4) to 1.21 (F1). Per the standard classification (Lachman and Lieberman), CI values below 15% correspond to good flow and 15–20% to fair flow. F4 thus showed the best flow and F1 the poorest, with the remaining batches falling into the "good to fair" band. The trend follows the binder content: as PVP K-30 increased from 3% to 4% the granule density and granule sphericity improved, with consequent improvement in flow. At 5% binder (F6) and at 6% CCS (F5), the powder bed became slightly more cohesive again, possibly because of the larger proportion of finer fines, with a small back-tick in CI.

Table 3. Pre-compression parameters of F1–F6 (mean ± SD, n = 3).

Batch	Angle of repose (°)	Bulk density (g/cm³)	Tapped density (g/cm³)	Carr's index (%)	Hausner's ratio
F1	30.8 ± 0.5	0.43 ± 0.02	0.52 ± 0.02	17.31 ± 0.8	1.21 ± 0.03
F2	28.9 ± 0.4	0.45 ± 0.01	0.53 ± 0.02	15.09 ± 0.7	1.18 ± 0.02
F3	26.5 ± 0.3	0.48 ± 0.02	0.56 ± 0.02	14.29 ± 0.6	1.17 ± 0.02
F4	24.3 ± 0.4	0.52 ± 0.01	0.59 ± 0.01	11.86 ± 0.5	1.13 ± 0.02
F5	25.7 ± 0.5	0.50 ± 0.02	0.58 ± 0.02	13.79 ± 0.6	1.16 ± 0.03
F6	27.2 ± 0.4	0.47 ± 0.02	0.55 ± 0.02	14.55 ± 0.7	1.17 ± 0.03

3.4 Post-compression evaluation

Post-compression evaluation showed all six batches to be within compendial limits. Weight variation in every batch was within the IP 2018 ± 5% limit for tablets above 324 mg, with no individual tablet falling outside the limit. Thickness lay between 4.24 and 4.58 mm and decreased monotonically as the binder content rose, which is consistent with the denser granules at higher PVP concentration leading to tighter packing under a fixed punch displacement. Hardness rose from 4.5 kg/cm² in F1 to 6.8 kg/cm² in F6, again tracking binder content; friability fell in the opposite direction, from 0.78% in F1 to 0.31% in F6. All friability values were below the 1.0% USP limit.

Disintegration time showed the most pronounced batch-to-batch variation. F1, with only 2% CCS, took 12.5 ± 0.7 min, whereas F5, with 6% CCS, disintegrated in 5.9 ± 0.3 min. F6, despite having 4% CCS, took 14.2 ± 0.6 min on account of its very high binder content; the dense, low-porosity matrix limited capillary uptake of water and offset much of the action of the disintegrant. Drug content lay within 97.8–99.6% of label claim across all batches.

Table 4. Post-compression parameters of F1–F6 (mean ± SD).

Batch	Weight (mg, n=20)	Thickness (mm, n=10)	Hardness (kg/cm², n=6)	Friability (%)	DT (min, n=6)
F1	648.3 ± 8.4	4.58 ± 0.04	4.5 ± 0.2	0.78 ± 0.06	12.5 ± 0.7
F2	649.7 ± 7.2	4.52 ± 0.05	4.9 ± 0.3	0.68 ± 0.04	10.2 ± 0.5
F3	651.2 ± 6.8	4.46 ± 0.03	5.4 ± 0.2	0.56 ± 0.05	8.4 ± 0.4
F4	650.5 ± 5.9	4.38 ± 0.04	5.8 ± 0.3	0.42 ± 0.05	6.8 ± 0.4
F5	649.9 ± 6.4	4.32 ± 0.03	6.3 ± 0.3	0.36 ± 0.04	5.9 ± 0.3
F6	651.6 ± 7.6	4.24 ± 0.05	6.8 ± 0.4	0.31 ± 0.03	14.2 ± 0.6

3.5 In vitro drug release The dissolution profile of the six batches showed a clear influence of both the disintegrant and the binder. At 60 min, cumulative release was lowest for F6 at 84.7% and highest for F4 at 92.4%. F5, despite having the highest CCS level, showed marginally lower release than F4 (90.5% versus 92.4%); the small decrement is consistent with the slightly higher binder concentration in F5 and indicates that beyond about 5% CCS the marginal gain in disintegration does not translate into a proportionate gain in dissolution.

The early-time release (5 and 10 min) closely tracked the disintegration time. F4 released 18.4% at 5 min versus 10.5% for F6, reflecting the slow early disintegration of the more strongly bound F6 matrix.

Table 5. Per cent cumulative drug release (mean ± SD, n = 3) of F1–F6 in pH 6.8 phosphate buffer.

Time (min)	F1	F2	F3	F4	F5	F6
5	12.4 ± 1.1	13.6 ± 1.2	15.2 ± 1.0	18.4 ± 1.3	17.2 ± 1.4	10.5 ± 0.9
10	22.8 ± 1.4	24.5 ± 1.3	27.1 ± 1.5	30.6 ± 1.6	29.4 ± 1.7	19.2 ± 1.2
15	32.1 ± 1.6	34.2 ± 1.5	36.5 ± 1.7	42.3 ± 1.8	40.8 ± 1.9	27.8 ± 1.5
20	41.6 ± 1.8	43.8 ± 1.7	46.2 ± 1.9	52.5 ± 2.0	50.6 ± 2.1	36.4 ± 1.6
30	56.3 ± 2.0	58.7 ± 1.9	60.9 ± 2.0	67.8 ± 2.1	65.4 ± 2.2	51.6 ± 1.8
45	72.5 ± 2.1	75.4 ± 2.0	78.6 ± 1.9	82.4 ± 1.8	80.7 ± 2.0	68.3 ± 1.9
60	86.8 ± 2.1	89.2 ± 1.9	90.6 ± 1.7	92.4 ± 1.8	90.5 ± 2.0	84.7 ± 2.3

3.6 Discussion of formulation behaviour

The threefold rise in CCS from F1 (2%) to F5 (6%) was accompanied by a halving of the disintegration time (12.5 to 5.9 min), in close agreement with previously reported behaviour of CCS in herbal extract tablets. Beyond about 5%, however, the disintegration curve flattened, suggesting that all available water-uptake sites had been saturated and further CCS contributed only as a non-functional bulking agent.

PVP K-30 is a hydrophilic film-former that on drying forms a brittle but cohesive bridge between primary particles. Up to about 4% it improved granule density and hardness without unduly retarding water ingress, and was associated with progressively better content uniformity and lower friability. Beyond 4%, however, the matrix became dense enough to limit medium penetration in the early phase of dissolution; F6 (5% PVP) thus showed both the longest disintegration time and the lowest 60-min release in spite of having a moderate (4%) CCS content.

F4, with 5% CCS and 4% PVP, struck the best compromise. Its hardness of 5.8 ± 0.3 kg/cm² is in the upper half of the acceptable window for film-coated and uncoated polyherbal tablets (typically 4–7 kg/cm²); friability at 0.42 ± 0.05% is comfortably below the USP 1.0% limit; disintegration at 6.8 ± 0.4 min satisfied the IP requirement for uncoated tablets (less than 15 min); and the cumulative drug release at 60 min was the highest in the series at 92.4 ± 1.8%, with the highest early-time release as well. F4 was therefore designated the optimised batch and taken forward into stability evaluation.

The phenolic and tannin fraction of Amla is expected to act locally and systemically at the level of the dermal papilla, both by reducing oxidative stress and by inhibiting 5α-reductase, the enzyme responsible for converting testosterone to the follicle-toxic dihydrotestosterone. Bhringraj contributes wedelolactone and ecliptasaponins that have been shown to prolong the anagen phase and stimulate dermal papilla cell mitosis. Kalonji, through thymoquinone, supplies a complementary anti-inflammatory and antioxidant effect, particularly relevant to peri-follicular oxidative stress. Vitamin E acts at the membrane level to limit lipid peroxidation and improves scalp

microcirculation; folic acid supports the rapid mitosis of follicular matrix cells.

3.7 Stability of the optimised batch

The tablets retained their appearance throughout; no darkening, mottling or capping was observed. Hardness fell only slightly, from 5.8 to 5.5 kg/cm², and friability rose marginally from 0.42% to 0.51%, both still well within accepted limits. Disintegration time lengthened from 6.8 to 7.5 min, an increase of about 10%, attributable to the slow loss of granule porosity under accelerated humidity. Drug content fell from 99.1% to 97.6%, a 1.5% loss over the three-month accelerated window, which extrapolates to acceptable real-time shelf-life behaviour. No batch fell outside the assay window of 96–101% at any time point.

Table 6. Stability data of the optimised batch F4 stored at 40 ± 2 °C / 75 ± 5% RH (mean ± SD, n = 3).

Parameter	0 month	1 month	2 months	3 months
Appearance	No change	No change	No change	No change
Hardness (kg/cm²)	5.8 ± 0.3	5.7 ± 0.3	5.6 ± 0.3	5.5 ± 0.4
Friability (%)	0.42 ± 0.05	0.45 ± 0.04	0.48 ± 0.05	0.51 ± 0.06
Disintegration (min)	6.8 ± 0.4	7.1 ± 0.4	7.3 ± 0.5	7.5 ± 0.5
Drug content (% LC)	99.1 ± 0.7	98.6 ± 0.8	98.2 ± 0.9	97.6 ± 1.0

CONCLUSION

A 650 mg polyherbal oral tablet combining hydroalcoholic extracts of Emblica officinalis, Eclipta alba and Nigella sativa with dl-α-tocopheryl acetate and folic acid was successfully developed by wet granulation. Systematic variation of croscarmellose sodium (2–6% w/w) and PVP K-30 (3–5% w/w) across six batches identified F4 (5% CCS, 4% PVP) as the optimised formulation, with hardness 5.8 ± 0.3 kg/cm², friability 0.42 ± 0.05%, disintegration time 6.8 ± 0.4 min, drug content 99.1 ± 0.7% and cumulative in vitro release of 92.4 ± 1.8% at 60 min. The batch passed compendial requirements and remained within specification under 3-month accelerated stability at 40 ± 2 °C / 75 ± 5% RH. FTIR supported the absence of significant chemical interaction.

Evaluation was confined to in vitro characterisation; no in vivo or clinical efficacy data are presented. The dissolution assay relies on gallic acid equivalents rather than constituent-specific HPLC, and long-term real-time stability was not undertaken.

The next steps are an in vivo evaluation of F4 in the testosterone-induced alopecia model in albino rats, with hair density, hair length and follicle counts as primary outcomes, followed by an open-label pilot study in adult volunteers with mild to moderate androgenetic alopecia.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

REFERENCES

1. Tomar KS, Kumar L, Verma A. FROM ROOTS TO RADIANCE: NUTRITIONAL SYNERGIES, INCLUDING VITAMIN E AND FOLIC ACID, FOR HEALTHY AND SHINY HAIR. Journal of Advanced Pharmaceutical Sciences and Natural Products. 2026 Jan 19;1(1).
2. Yokozawa T, Kim HY, Kim HJ, Okubo T, Chu DC, Juneja LR. Amla (Emblica officinalis Gaertn.) prevents dyslipidaemia and oxidative stress in the ageing process. Br J Nutr. 2007;97(6):1187–95.
3. Garg A. Herbs in cosmetics: An overview. Research Journal of Topical and Cosmetic Sciences. 2023;14(1):45-9.
4. Garg A. From Garden to Glamour Exploring Herbs in Hair Care. Research Journal of Science and Technology. 2025;17(3):211-9.
5. Krishnaveni M, Mirunalini S. Therapeutic potential of Phyllanthus emblica (amla): the ayurvedic wonder. J Basic Clin Physiol Pharmacol. 2010;21(1):93–105.
6. Yuandani, Jantan I, Husain K. 4,5,4′-Trihydroxychalcone, 8,8′-(ethene-1,2-diyl)-dinaphtalene-1,4,5-triol and rutin isolated from Phyllanthus emblica inhibit proliferative response of human lymphocytes. Phytother Res. 2017;31(7):1041–9.
7. Datta K, Singh AT, Mukherjee A, Bhat B, Ramesh B, Burman AC. Eclipta alba extract with potential for hair growth promoting activity. J Ethnopharmacol. 2009;124(3):450–6.
8. Roy RK, Thakur M, Dixit VK. Hair growth promoting activity of Eclipta alba in male albino rats. Arch Dermatol Res. 2008;300(7):357–64.
9. Ahmad A, Husain A, Mujeeb M, Khan SA, Najmi AK, Siddique NA, et al. A review on therapeutic potential of Nigella sativa: a miracle herb. Asian Pac J Trop Biomed. 2013;3(5):337–52.
10. Rossi A, Priolo L, Iorio A, Vescarelli E, Gerardi M, Campo D, et al. Evaluation of a therapeutic alternative for telogen effluvium: a pilot study. J Cosmet Dermatol Sci Appl. 2013;3(3A):9–15.
11. Beoy LA, Woei WJ, Hay YK. Effects of tocotrienol supplementation on hair growth in human volunteers. Trop Life Sci Res. 2010;21(2):91–9.
12. Trüeb RM. Oxidative stress in ageing of hair. Int J Trichology. 2009;1(1):6–14.
13. Patel BD, Patel HK. Formulation and evaluation of polyherbal tablet for the management of androgenetic alopecia. Int J Pharm Sci Res. 2019;10(8):3812–8.
14. Saraf S, Kaur CD. Phytoconstituents as photoprotective novel cosmetic formulations: a review. Pharmacognosy Rev. 2010;4(7):1–11.

15. Saraf S, Mishra K, Sahu N. Formulation and evaluation of polyherbal tablets containing Trigonella foenum-graecum and Emblica officinalis extracts. J Drug Deliv Ther. 2018;8(5):288–94.

16. Kumar A, Sharma N, Sharma PK. Design, development and in vitro evaluation of a polyherbal hair-restorative tablet. Int J Pharm Sci Res. 2021;12(4):2186–93.

17. Sharma S, Singh A, Kumar B. FORMULATION, OPTIMIZATION AND EVALUATION OF EXTENDED RELEASE TABLET OF CYANOCOBALAMIN BY USING POLYMER MATRIX SYSTEM. Journal of Advanced Pharmaceutical Sciences and Natural Products. 2026 Apr 26;1(2).

18. Reddy MS, Reddy NS, Bhanja S. Formulation and in vitro evaluation of fast disintegrating tablets containing Emblica officinalis dry extract. Int J Curr Pharm Res. 2017;9(6):75–80.

19. Shenoy P, Pai V, Bhat SS. Formulation and evaluation of orally disintegrating tablets containing a herbal extract using super-disintegrants. J Drug Deliv Ther. 2019;9(2-A):105–11.

20. Sharma NK, Kumar B. FORMULATION AND DEVELOPMENT OF SUSTAINED RELEASE TABLETS OF METHYLCOBALAMIN BY USING POLYMER MATRIX SYSTEM. Journal of Advanced Pharmaceutical Sciences and Natural Products. 2026 Mar 19;1(2).