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Research Article

Herbal Shampoo Formulation and Evaluation: Herbal Ingredients, Quality Control, Stability Studies, and Future Perspectives

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ABSTRACT

Herbal shampoos contain plant extracts as well as cleansing and conditioning agents. But, as with any product, the presence of plant-derived ingredients does not necessarily mean they are safer or more effective. This review paper summarises the common botanicals, formulation techniques, physicochemical evaluation, quality control, stability assessment and the relevant Indian cosmetic legislation. The reported components include Amla (Phyllanthus emblica), soap nut/Reetha (Sapindus mukorossi), Shikakai (Senegalia rugata), hibiscus (Hibiscus rosa-sinensis), neem (Azadirachta indica), and aloe vera. Each of them has different phytochemical profiles and potential cosmetic applications [1–6]. Although the test procedures and results vary with the formulations, published research on shampoos generally covers pH, viscosity, foaming, wetting, filth dispersion, solid content and cleansing efficacy [2,7–10]. Therefore, the numerical values given for a single formulation should not be considered as universal acceptability crite-ria. Quality assurance should include botanical identification and raw material controls, appropriate preservation and microbiological testing, product-specific stability studies and compliance with relevant regulations in the Cosmetics Rules, 2020 and the Drugs and Cosmetics Act, 1940 [11–16]. Important evidence gaps include: limited comparative clinical data, variability of plant extracts and the need to distinguish between proven benefits of completed rinse-off products, and traditional use or in-vitro activities.

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INTRODUCTION

1.1 Herbal shampoo introduction

Shampoos are rinse-off treatments that cleanse the hair and scalp of residues, sweat, dirt and sebum. The efficiency of cleaning is influenced by the surfactant system, pH of the formulation, contact time, water conditions and other chemicals [1–2,17–18]. 'Herbal shampoo' does not mean that the shampoo has no synthetic ingredients, but is a washing medium which usually contains one or more plant extracts. Claims of intrinsic safety, sustainability, mildness, or effectiveness of botanical products over traditional shampoos require evidence from the specific formulation and use conditions [1–2,17–18]. Good repeatable goods need standardised tests of identity, quality, preservation and performance. Traditional constituents like Amla, Reetha and Shikakai are still of importance in formulation research [1-3].

1.2 Importance and advantages of herbal shampoo

Plant-derived compounds are selected based on their known constituents and potential uses, such as conditioning, cleansing, antioxidant properties or for the benefit of scalp hygiene. Hibiscus and amla contain polyphenolic components, whereas soapnut and shikakai contain saponin-rich fractions [1,3–4]. Laboratory antioxidant or antibacterial activity may not always be a therapeutically relevant effect when an ingredient is incorporated into a rinse-off shampoo, but these qualities are worth formulation research. Just because something is natural does not mean it is better or safer. Product quality is determined by botanical authentication, extract composition, formulation compatibility, preservative effectiveness and finished product safety and performance testing [1–2,13–14,19–21].

1.3 Herbal and Conventional Shampoos

Such overlapping formulation technologies include anionic, amphoteric and non-ionic surfactants, conditioning ingredients, rheology modifiers and preservatives which are used in both conventional and herbal-labelled shampoos. Herbal products may also contain conventional surfactants or preservatives; the choice of ingredients should be evaluated by the formulation and label, not only by the product category [1-2,17-18]. And it's the entire formula and exposure conditions that dictate variations in cleanliness, irritation potential, flow behaviour and stability. Comparisons should be made with specified procedures and appropriate controls [1–2,17] rather than making assumptions based on whether chemicals are described as natural or synthetic.

1.4 The aim and objectives of the review

The present narrative review summarises the literature on botanical ingredients, formulation design, evaluation techniques, quality control, stability, safety and Indian regulatory considerations of herbal shampoos.

It aims to:

- Botanical profiling: describe the components and proposed cosmetic applications for popular botanicals, distinguishing between preliminary data and established effects in finished products [1, 3–6].
- Chemistry of formulation: discuss excipients, surfactant systems, extraction techniques and factors in formulation development [1–2,7–10].
- Physicochemical evaluation: review of commonly published tests for solid content, pH, viscosity, foam, wetting, filth dispersion and cleaning efficiency [2,7–10]. Quality and stability: discuss preservative efficacy evaluation, cosmetic microbiological standards, botanical quality controls and product-specific stability testing [13–16,19–22].
- Safety and regulation: list relevant guidelines of ISO 22716, Indian laws and regulations, safety aspects of cosmetics [11–12,15–17].

Verify the range and the method. Official regulatory documents, accepted standards, review articles, and some original investigations are reviewed in the present article concerning the development and evaluation of herbal shampoos. A replicable systematic search strategy and screening flow was not provided in the source material. Thus, this paper is a narrative review with no claims of PRISMA compliance or systematic review completeness. If required by the chosen publication, the author shall include the databases and search dates actually used prior to submission.

2. Herbal Ingredients Used in Shampoo

Identification, extract composition, vehicle compatibility and desired cosmetic function of the botanicals used in shampoo formulations are considered. The following components are reported in the relevant literature; their quantities and effects may vary depending on the plant part, origin, extraction technique and analytical method [1, 3–6]. **2.1 Phyllanthus emblica or Amla**

The fruit of Amla (Phyllanthus emblica) is reported to contain hydrolysable tannins and polyphenols including components related to gallic and ellagic acids [4]. In the laboratory, several substances have been studied for their antioxidant properties. The study of Wongrakpanich et al. on Amla extract in transfer some carriers for follicular delivery should not be cited as evidence that a traditional rinse-off Amla shampoo promotes hair growth [23]. Amla extract can be explored as a botanical additive in shampoo formulations but its effect should be shown in the final product [1,4,23].

2.2 Reetha or Sapindus mukorossi

Sapindus mukorossi (Reetha or soapnut) contains triterpenoid saponins which may improve surface activity and foaming [1,3]. A single percentage range should not be presented as universal, as the quantity and profile of saponins are dependent on the plant source, plant portion, extraction and analytical technique. Crude extracts vary in colour, odour and performance and it is important to validate raw materials and standardise extracts [1,3].

2.3 Senegalia rugata or Shikakai

Senegalia rugata (sometimes under the synonym Acacia concinna) is a traditional preparation for cleaning hair, which consists of substances related to saponins [1,3]. The extract and the whole composition determine the pH of the mixture and its cleaning power. It is not enough to extrapolate claims of hair regrowth or follicle rejuvenation based on traditional use alone, but adequate evidence is needed for the final product [3,17].

2.4 Hibiscus rosa sinensis

The published research [1, 3] reported the presence of phenolic constituents and mucilage/polysaccharides in the flowers and leaves of Hibiscus rosa-sinensis. These materials could be considered as conditioning or rheology-modifying additives [1,3,24]. Claims of increased combability, less friction or antioxidant protection should be confirmed in the intended formulation rather than inferred from the presence of the constituents alone.

2.5 Azadirachta indica (Neem)

The antibacterial activity of neem products has been investigated. Azadirachta indica (neem) contains a number of limonoids and other secondary metabolites [5]. These results do not endorse the efficacy of all neem extracts or finished shampoos in the treatment of seborrhoeic dermatitis or dandruff. Any therapeutic or anti-dandruff claim must be evaluated in accordance with the applicable regulatory framework and supported by adequate product-specific data [5,11–12,17]. Neem extracts may also have an impact on odour, colour and formulation compatibility.

2.6 Aloe barbadensis or Aloe vera

One of the [3,6] is acemannan, a polysaccharide in the gel of the aloe vera leaf (which is mostly water). Some personal care products contain chemicals from aloe, but whether those effects (like moisturising or calming) work depends on the quality of the compounds, their concentration, how they're processed, and the product in its entirety. Unstable botanical material can present challenges in terms of quality and microbiological control, therefore requiring proper ingredient specifications and preservation [1,6,21].

2.7 Role of phytochemicals for hair health

Different phytochemical classes are claimed to have different capabilities. Polysaccharides may affect hydration or rheology; polyphenols may demonstrate antioxidant activity in laboratory testing and saponins may be important in surface activity. This information encourages research into botanical compounds, but does not constitute evidence of therapeutic hair-growth, anti-dandruff or protective properties until the relevant finished-product data is available [1,3-6].

Table 1: Selected Botanical Ingredients, Reported Phytoconstituents, and Potential Relevance to Herbal Shampoo Formulation

Botanical ingredient	Plant part used	Representative reported constituents	Potential relevance to shampoo formulation
Phyllanthus emblica (Amla)	Fruit (including pericarp)	Hydrolysable tannins, gallic- and ellagic-acid-related compounds, and flavonoids.	Polyphenolic constituents have been investigated for antioxidant activity. Any benefit in a finished rinse-off shampoo requires product-specific evidence. [1,4,23]
Sapindus mukorossi (Reetha / soapnut)	Fruit pericarp	Triterpenoid saponins; the composition varies with plant source and extraction.	Saponin-containing extracts may contribute to interfacial activity and foam. Cleansing performance depends on extract quality and the complete formulation. [1,3,25]
Senegalia rugata (Shikakai; also reported as Acacia concinna)	Fruit pods	Saponin-related constituents, including reported glycosides.	Traditionally used in hair-cleansing preparations. Cleansing performance, pH, and compatibility should be evaluated in the finished formula. [1,3,26–27]
Hibiscus rosa-sinensis (Hibiscus / Jaswand)	Flowers and leaves	Mucilage/polysaccharides and reported phenolic constituents, including flavonoids and anthocyanins.	May be explored as a conditioning or rheology-modifying botanical additive; the intended effect should be tested in the finished product. [1,3]
Azadirachta indica (Neem)	Leaves and/or seed-derived material, as specified by the extract	Limonoids and other secondary metabolites; the profile depends on the plant part and extraction method.	Neem preparations have been investigated for antimicrobial activity. This does not establish anti-dandruff efficacy of a finished shampoo. [3,5]
Aloe vera (Aloe barbadensis)	Inner leaf gel	Polysaccharides, including acemannan.	Used in personal-care formulations. Moisturizing or conditioning effects depend on ingredient quality, processing, concentration, and the complete formula. [3,6]

3. Formulation of Herbal Shampoo

3.1 The parts and their functioning

The plant extract is formulated in an herbal shampoo base with a suitable carrier and excipients selected for compatibility, cleansing, stability, sensory aspects and preservation. Published formulae are examples and not general standards and the ingredients and quantities must be chosen for the specific extract and product [1–2, 7–10].

3.2 Other excipients, surfactants

Surfactants reduce interfacial tension and help disperse oily soil during washing. The selection of a formulation should take into account water quality, preservation, compatibility with botanical extracts, irritation potential and washing performance [1,6-7,17-18]. Primary and secondary surfactants: conventional anionic, amphoteric or non-ionic surfactants can be used to give the required cleaning and foaming properties, and plant derived saponins may provide some surfactant activity. The ultimate decision should be based on data on product performance and safety.

Rheology modifiers and suspending agents are gums, cellulose derivatives or other polymers that can be used to modify viscosity and suspend dispersed constituents, but their compatibility should be checked throughout the whole formulation.

pH Adjustment: Lactic acid, citric acid or any other suitable pH adjusters may be used. Set a target and an acceptable range based on product, constituents and safety/performance evaluation. There is no pH number that will assure compatibility with the scalp universally. Chelating agents: should be considered compatibility and regulatory restrictions. A suitable

chelator can help control metal ions that impact colour, stability, or preservative efficacy./1Preservatives: Water containing botanical preparations requires good preservation. Low pH alone does not confirm adequate preservation; the concentration and choice of the preservative must be in conformity with the applicable requirements and validated by preservative efficacy testing on the finished product [14].

3.3 Methods of herb extraction

Extraction technique, solvent, temperature and solid-to-liquid ratio affect the composition and yield of the extract. The choice of the best technique depends on the plant portion and constituents to be obtained, but the most common methods are maceration, infusion, decoction, Soxhlet extraction, and hydroalcoholic extraction [1,9]. Residual solvents or other pertinent impurities should be controlled, as appropriate, and the extraction procedure and the conditions for the removal of the solvent should be documented.

1. **Maceration**: Cold extraction of solids by liquid .Suitable for heat sensitive polyphenols and polysaccharides. Slow and moderate yield.
2. **Decoction**: Water soluble saponins are extracted by boiling the thick pericarp and pod tissues such as Reetha and Shikakai in aqueous solvent for a long time.
3. **Infusion**: Short dipping in hot water of fine plant tissues (e.g. hibiscus petals) to prevent long term thermal degradation.
4. **Soxhlet Extraction**: The method is an automated continuous reflux extraction with polar or semi-polar solvents to get maximum extraction of lipophilic compounds including neem limonoids.
5. **Hydroalcoholic Extraction:** Polar glycosides and semi-polar aglycones are extracted by breakdown of the cell walls with mixtures of ethanol and water (typically 50:50 to 70:30 v/v), which leave no harmful residues after removal of the solvent.

3.4 Herbal shampoo preparation methods

Typical examples of a liquid-shampoo manufacturing sequence are botanical raw-material authentication and preparation, extract preparation and clarification, vehicle preparation, controlled incorporation of surfactants and other excipients, addition of heat sensitive ingredients at an appropriate temperature, pH/viscosity adjustment, deaeration, filling and packaging [7,9]. They are not generic parameters for operation but require establishment and validation of the precise order, temperature, mixing speed and equipment for the specific formula.

1. **Processing of Raw Materials:** Botanical materials are dried, cleaned from foreign matter and ground to a uniform size of particles (mesh #40–60) after authentication.
2. **Preparation of extracts:** Extraction and concentration Extracts are prepared by controlled solvent extraction and cleared by microfiltration (0.45 μm) and concentrated by rotary evaporation under low pressure.
3. **Vehicle Preparation:** Purified, deionised water is charged into the processing vessel and rheology modifiers are hydrated under high-shear mixing until they are fully dispersed.
4. **Incorporation of surfactant:** Primary and secondary surfactants are mixed at 40-45 °C by gentle planetary motion to avoid over aeration.
5. **Blending extraction:** The base is cooled down to below 35° C in an effort to protect heat sensitive ingredients and then standardised plant extracts and humectants such as aloe vera gel are added.
6. **Preservative and pH Adjustment:** Add chelating agents, preservative, and essential oil. Reduce bulk pH to 5.2-5.6 with diluted citric acid under inline monitoring.
7. **Deaeration and Packaging:** The final bulk shampoo is deaerated to remove air bubbles and checked for the desired viscosity before being packaged in high-density polyethylene (HDPE) containers.

3.5 Development and optimization of formulation

When optimising formulation, cleaning efficiency, foam, viscosity, stability, sensory properties, preservation and safety are considered. Design-of-experiments approaches may be used to evaluate interactions between different ingredients but the response criteria and study design must be appropriate to the specific project.

Published formulations present different methods, not showing one generally ideal composition [1–2,7–10].

Table 2: Example Ingredient Categories and Formulation Considerations for Herbal Shampoo (Not a Validated Formula)

Ingredient / Constituent	Source / Classification	Concentration approach	Technological / Formulation Function	Quality / Processing Control Notes
Sapindus mukorossi Extract	Botanical (Fruit)	No universal range; determine experimentally for the specific extract and product	Primary natural foaming agent and biosurfactant	Specify extract identity and marker/quality criteria where justified; do not assume a universal saponin minimum
Senegalia rugata Extract	Botanical (Pods)	No universal range; determine experimentally for the specific extract and product	Secondary plant surfactant; natural acidic cleanser	Verify identity, extraction conditions, and compatibility
Phyllanthus emblica Extract	Botanical (Pericarp)	No universal range; determine experimentally for the specific extract and product	Antioxidant; cuticular protection; acidifier	Use a justified marker/ fingerprint if appropriate; no universal marker threshold
Hibiscus rosa-sinensis Extract	Botanical (Flower)	No universal range; determine experimentally for the specific extract and product	Natural conditioning agent and gloss enhancer	Characterize the extract and assess compatibility in the finished product
Aloe barbadensis Leaf Juice	Botanical (Inner Gel)	No universal range; determine experimentally for the specific extract and product	Scalp humectant and anti-irritant agent	Specify the grade, processing, and microbial quality of the ingredient
Decyl Glucoside / CAPB	Non-ionic / Amphoteric	No universal range; determine experimentally for the specific extract and product	Foam booster, co-surfactant, irritation mitigator	Select based on compatibility, preservation, and sensory testing
Xanthan Gum / HPMC	Natural Polysaccharide	No universal range; determine experimentally for the specific extract and product	Viscosity builder and physical suspending polymer	Hydration and compatibility should be established experimentally
Sodium Benzoate / K-Sorbate	Organic Salt System	No universal range; determine experimentally for the specific extract and product	Antimicrobial preservative system	Confirm permitted use levels and preservative efficacy in the finished product
Citric Acid / DI Water	Acidifier / Vehicle	No universal range; determine experimentally for the specific extract and product	pH buffering agent and continuous liquid vehicle	Adjust to a justified target pH; vehicle quality should meet the applicable specification

4. Evaluation of Herbal Shampoo

Shampoo studies often report evaluation tests such as appearance, pH, viscosity, foam behaviour, wetting time, dirt dispersion, solid content and cleansing performance [2,7–10]. Methods, sample preparation, equipment and conditions must all be clearly reported to permit comparison of results. Acceptance criteria should be defined and justified for the product under development, rather than copied from unrelated formulations with universal values.

4.1 Organoleptic evaluation:

Organoleptic evaluation is for documentation of homogeneity, colour, Odor, appearance and any detectable phase separation or precipitation. Changes that occur during storage can be helpful indicators of instability, but other measurements and product-specific criteria should be used to support their interpretation [2,10,16].

4.2 pH determination:

Use a well calibrated pH meter with a temperature and sample preparation procedure described in detail. The text should state whether the test is performed on the neat product or a dilution as the values may vary according to the procedure. In the manufacture of shampoo, a slightly acidic pH is usually considered, but there is no single pH range that guaranties compatibility for all scalps, ingredient systems or products; support the target and analyse the final mixture [2,6,17].

4.3 Viscosity measuring:

Apparent viscosity depends on instrument geometry, spindle, speed, temperature, sample history, and the formulation's flow behaviour. Report all relevant conditions and use the same procedure for comparisons. A general viscosity range should not be claimed for all herbal shampoos; the objective should reflect dispensing, sensory, and stability needs for the particular product [2,8,10].

4.4 Foam volume and foam stability:

Foam volume and persistence may be measured using a prescribed cylinder-shaking approach or another acceptable method. Record dilution, water quality, agitation, temperature, and measurement times. Foam is a consumer-relevant feature but is not, by itself, a reliable measure of cleansing performance [2,10]. Mathematical Expression: Foam Retention (%) = [Vt / V₀] × 100 The foaming behaviour of botanical saponins depends on extract composition and the total surfactant system. Co-surfactants may be examined when needed, but any claimed improvement should be proved empirically in the finished formulation [1–2,10].

4.5 Wetting time:

Wetting time can be measured using a specific canvas-disc or other equivalent means. Sample concentration, disk material and dimensions, water quality, and endpoint should be recorded; a shorter time might mean a faster wetting under the test conditions chosen, but does not necessarily translate into better cleaning [2]. 4.6 Dust dispersion test the ink-dispersion method is a test of dirt-dispersion and can be used to test the ability of a formulation to disperse particulates between the liquid and foam. Note the ink volume, mixing method, sample concentration and assessment criteria. It is not a validated universal predictor of dirt redeposition on hair but a comparative screening test [2,10].

4.7 Determination of solid matter:

Solid content can also be determined gravimetrically by weighing a known sample before and after drying to constant weight under specified conditions [2,10]. The sample mass, the drying temperature, time and the calculation should be reported. Solid content is dependent on the formulation and should not be assigned a universally acceptable range without product-specific justification.

Gravimetric formula: Solid Content (%) = [(Weight of Dry Residue) / (Weight of Wet Specimen)] x 100

Reported solid content levels in shampoo formulations and test methodologies vary. Instead of believing that a greater or lower value is intrinsically superior, interpret the result in respect to the entire formula, ease of rinsing, dispensing, and comparable goods [2,10].

4.8 Cleaning efficiency:

Cleaning performance can be compared using a determined hair-tress or suitable substrate model with a repeatable soil load. Describe the substrate, soil composition, conditioning, washing and rinsing conditions,

number of replicates, weighing method and computation. These laboratory techniques provide data for comparison, but do not determine clinical performance on their own [2,8].

Cleaning Formula Cleaning Efficiency (%) = [(W_s - W_w) / (W_s - W_unsoiled)] × 100

Al Badi and Khan [2] and Bakr et al. [10] have provided assessments of specific shampoo formulations using functional and physicochemical testing. They do not create a universal detergency acceptance range or demonstrate that all polyherbal shampoos function similarly to commercial products, thus their individual results should only be quoted after verifying the original data and methodologies.

Table 3: Common Evaluation Tests and Product-Specific Acceptance Criteria

Evaluation Parameter	Analytical Methodology / Apparatus	Scientific Significance / Purpose	Suggested acceptance approach
Visual & Sensory Profiling	Visual and olfactory organoleptic inspection	Confirms optical homogeneity, lack of phase separation, odor stability	Define product-specific appearance and homogeneity criteria
Potentiometric pH	Calibrated digital glass electrode (10% w/v solution)	Guarantees compatibility with scalp acid mantle; prevents cuticular frizz	Set a justified target range for the particular formula; report sample dilution and temperature
Apparent Viscosity	Brookfield rotational viscometer (Spindle 3/4, 20 rpm)	Determines non-Newtonian flow, pouring, spreading, and suspension	Set based on dispensing, sensory, and stability requirements; report spindle, speed, and temperature
Foam Volume & Stability	Cylinder inversion / Ross-Mile's method (10% v/v)	Assesses initial lather capacity and 5-min foam persistence	Compare using a defined method; no universal foam threshold
Wetting Efficiency	Canvas disc wetting test (1% w/v aqueous dilution)	Quantifies interfacial tension reduction across fibrous surfaces	Compare using a defined method and fixed test conditions
Dirt Dispersion Index	India ink partitioning test (10% v/v shampoo)	Verifies soil retention in water phase to prevent rinse redeposition	Use a defined scoring system; interpret as a comparative screen
Total Solid Content	Gravimetric thermal desiccation (105°C to constant mass)	Quantifies non-volatile surfactants, extract solids, and gums	Report the measured value; set product-specific criteria
Quantitative Detergency	Artificial sebum tress washing model (gravimetric loss)	Measures functional sebum removal and soil clearance	Use a justified comparator and reproducible test method; no universal efficacy threshold

5. Quality Control and Stability Studies

5.1 Quality control of herbal ingredients

Botanical raw materials may be substituted, adulterated, contaminated with pesticides, mycotoxins, microbiological contaminants and elemental contaminants. The identity tests and quality standards should be chosen depending on the plant material, source, intended application and relevant requirements [19–21]. The WHO quality-control procedures include methods for testing herbal products [21]. However, ash, moisture, and contaminant limits should be derived from the specific monograph or regulation and not be assumed as universal values for all botanicals.

5.2 Standardisation of herbal extracts

The aim of standardisation is to increase the uniformity of the botanical constituents between batches. If science supports it, suitable methods may be quantitative testing for specific markers, chromatographic fingerprinting and botanical authenticity [19–20,28].

- HPTLC can provide a comparative fingerprint or semi-quantitative marker assessment, when appropriate reference materials and well-established circumstances are available.
- If a suitable validated method and reference standard are available, specific constituents can be quantified by HPLC/UHPLC or LC-MS. Fixed standards of gallic acid or azadirachtin should not be used unless they are appropriate to the product and the raw material.
- GC-MS: may be useful for the characterisation of volatile components. Chromatographic fingerprinting is not enough to infer residual solvent testing, instead an appropriate validated approach is needed.

5.3 Tests for microbial quality

Many herbal shampoos are water-containing cosmetic products and need microbiological quality control. ISO 17516 describes cosmetic microbiological limits and specific microorganisms, and the category and acceptance criteria depend on the product's intended application. Do not list a universal yeast/Mold limit [13,29–31] unless mandated by the relevant specification or law. ISO lists a replacement for ISO 17516:2014 as being under publication at the time of this review (October 13, 2026); check the relevant edition immediately prior to submission [13].

- Total aerobic microbial count: record the test procedure, sample units and the limit for the relevant ISO 17516 product category [13, 30].
- Yeast and mould: do not have a single limit as required by ISO 17516 universally [13,31]; to be tested when required by the product specification or risk assessment, using an appropriate method.
- Specific microorganisms: Determine the presence/absence of the microorganisms in accordance with the local regulations and the relevant standard or category. Specify the exact standard edition and the way [13, 30–31].

The effectiveness of preservatives should be evaluated using an appropriate method such as ISO 11930 and interpreted according to the method criteria and the risk assessment of the product [14]. The technique, organism, time point and acceptance criterion should be defined prior to boiling down the standard to a single log-reduction rule. The preservative effectiveness of the final formulation must be demonstrated, not just selected based on pH or constituents. **5.4 Studies on chemical and physical stability**

Cosmetic stability programs should be designed for the specific formula, packaging, expected storage conditions and distribution environment. ISO/TR 18811 provides recommendations [16] rather than a single mandatory test schedule for each cosmetic. Methods of screening or stability could include real-time and accelerated storage, temperature cycling and centrifugation, where applicable; however, exact temperatures, durations, cycle numbers and acceptance criteria need to be defined in the study protocol and not as general ISO standards [16,22].

- **Real time stability:** Select appropriate storage conditions and duration for the packaging, target market and proposed shelf life. Document the justification.
- **Accelerated stability:** Select higher temperatures or other stress conditions based on the product characteristics. Accelerated findings are not a substitute for real time data.
- **Temperature cycling:** As appropriate to the study protocol, define cycle temperatures, hold times and number of cycles; these are product-specific screening conditions.
- **Centrifugation:** this can be used as a first physical-stability screen but should not be provided as an ISO-mandated test; the speed, duration, rotor radius, and interpretation should be provided.

5.5 Storage conditions and shelf life

Stability data should support proposed shelf life and packaging selection. Look at relevant characteristics such as appearance, odour, pH, viscosity, packaging

compatibility, marker content where appropriate and microbiological quality. Do not estimate shelf-life based on accelerated data [16, 22, 32] without a scientifically validated model and supporting real-time information.

Table 4: Examples of Stability Parameters to Consider for Botanical Shampoos

Testing Parameter	Test Condition & Interval	Failure Criterion / Physical Defect	Corrective Formulation Action
Visual & Phase Integrity	Defined real-time and/or stress-storage conditions appropriate to the formula and pack; inspect at justified intervals	Use predefined, product-specific criteria for appearance, phase separation, and precipitation	Adjust rheology modifier; incorporate co-surfactants
Bulk Formulation pH	Measure at defined intervals using the same sample-preparation method and calibrated instrument	Define acceptable pH change based on formula and safety/performance data	Reinforce buffer capacity (citric acid / sodium citrate)
Viscosity & Rheology	Measure using the same instrument settings and sample history at specified intervals	Define acceptable change using a consistent validated method	Optimize polymer hydration; balance ionic strength
Active Marker Content	Quantify only where a suitable marker and validated method are available	Set marker-retention criteria only where a marker and validated assay are justified	Add natural chelators (phytic acid); improve light barrier
Microbial Integrity	Use a justified sampling plan and the applicable microbiological specification	Apply the relevant microbiological specification and suitable preservative-efficacy evidence	Reformulate preservative; investigate water purity

6. Safety and Regulatory Aspects

6.1 Safety of the herbal components

In the safety evaluation, the identity, purity, concentration, impurities, known sensitisation potential, route of exposure and intended use of each botanical ingredient and of the final product should be evaluated [6,17,19,21]. In-vitro testing and other relevant safety data can help in the evaluation, but no single assay can prove a shampoo is entirely safe. **6.2 Considerations for inflammation of the skin and scalp**

Skin/scalp compatibility should be assessed by methods suitable to the product and in the light of ethical and legal requirements. Validated in-vitro techniques may be employed where applicable; human patch testing requires adequate supervision and consent. Not all shampoos require ocular testing, but the testing approach should be based on exposure, formulation and the relevant safety evaluation [6,17,32].

6.3 Good Manufacturing Practices (GMP)

ISO 22716:2007 [15] gives guidance on good manufacturing practices for cosmetics. The reference to Schedule M-II as a current national cosmetic GMP requirement has been removed and current Cosmetics Rules and other official notifications [11] may be checked for the applicable Indian requirements. The written quality system appropriate to the manufacturing operation shall address equipment, water quality, sanitation, recordkeeping and traceability.

6.4 Indian cosmetic and labelling regulations

In India, the governing rules for cosmetics are India's Cosmetics Rules, 2020 and Drugs and Cosmetics Act, 1940. The formal regulations and announcements can be found on the CDSCO website [11–12]. Specific requirements differ depending on whether the product is manufactured in the United States or imported, and the specific regulations and license/registration process.

- Check the relevant State Licensing Authority and associated licence/loan-licence pathway and forms for domestic manufacturing with the current Cosmetics Rules; do not use a form number as a substitute for checking the current regulations and product conditions [11].
- Imports: Please confirm current procedure and documents with CDSCO before submission or commercial activity. Cosmetics imported into

India are required to be registered as per the Cosmetics Rules, 2020 [11].

- Product claims must be truthful, based on evidence and consistent with the legal classification of the product. Claims that imply treatment or prevention of a disease or other therapeutic benefits may cause regulatory issues. Classification is dependent on the claim, ingredients and applicable law and should not be generalised into a rule [11–12].
- Labelling: satisfy the Legal Metrology requirements and Cosmetics Rules provisions for the product and packaging. Instead of a generic checklist, validate all statements demanded by the current official regulations [11,33].

Table 5: Summary of Regulatory and Quality Considerations for Herbal Shampoos in India

Regulatory Domain	Statutory Provision / Standard	Specific Legal & Technical Requirement
Primary Legislation	The Drugs and Cosmetics Act, 1940	Establishes legal framework prohibiting spurious, misbranded, or adulterated cosmetics
Administrative Code	Cosmetics Rules, 2020	Governs domestic manufacturing licenses (Form COS-8) and import registration (Form COS-2)
Manufacturing Standards	ISO 22716:2007; applicable Indian Cosmetics Rules	ISO 22716 provides cosmetic GMP guidance; confirm current national requirements from official rules and notifications. Do not cite Schedule M-II as a current cosmetic GMP requirement.
Microbiological Limits	ISO 17516:2014 and applicable product category	Apply the microbiological limits and specified-organism criteria for the appropriate product category; do not combine a universal yeast/mould limit with ISO 17516 unless separately justified.
Product Labeling	Applicable labelling provisions in Cosmetics Rules, 2020	Verify required declarations against the current official rule text and product type.
Consumer Packaging	Legal Metrology (Packaged Commodities) Rules, 2011	Ensures compliance with standardized package declarations, net quantity, and MRP display

7. Challenges and Future Perspectives

7.1 Differences in raw ingredients of herbs

Botanical composition can be affected by plant parts, cultivation, harvesting, processing, storing and extraction. This variation may affect colour, odour, extract yield and formulation performance [19,21,28]. Authentication, supplier certification, appropriate standards and marker-based standardisation when appropriate can improve batch consistency. Do not state a single universal saponin percentage for all Sapindus material.

7.2 Problems of Formulation and Preservation

Aqueous formulations containing botanical extracts require microbiological control and appropriate preservation mechanism. The choice of preservative depends on the pH of the formulation, solubility, ingredient compatibility, packaging and any limitations that may apply. The effectiveness of potassium sorbate and sodium benzoate is pH dependent but aiming for a pH level alone will not ensure sufficient preservation. Validate the final product using a suitable preservative-efficacy method [13–14].

7.3 The need for scientific evidence and standardisation

Traditional use, antioxidant assays or in-vitro antimicrobial outcomes should not be taken as supporting marketing claims of such hair regrowth, follicle regeneration or reversal of greying. Product claims must comply with applicable law, and provide evidence relevant to the final formulation [11-12]. Good comparative research can help determine if a botanical shampoo has benefits over and above its carrier or comparator.

7.4 Future advances in herbal shampoo

Further potential areas include improved botanical identification, improved repeatability of extraction and standardisation, improved compatibility of conservation and packaging, ecologically assessed surfactant systems and more robust comparative studies of final goods [1,14,16,19]. Instead of proven solutions for rinse-off shampoos, research opportunities should be encouraged to develop new delivery methods or advanced analytical technologies.

- Delivery systems: For some constituents vesicular or polymer-based carriers may be considered but for the intended rinse-off product better follicular delivery or consumer advantage has to be demonstrated [23].
- Extraction: Scope for investigation of microwave-, ultrasonic- or other aided extraction techniques where they enhance yield or selectivity. Claims of efficiency, sustainability or solvent residues need comparative data and proof specific to the process.
- Biosurfactants: formulation studies on microbial surfactants. Instead of making assumptions based on the origin of the material, one should consider the biodegradability, safety, supply consistency, performance, and environmental impact of the specific material.
- Digital quality control: DNA-based authentication and high-resolution analytical techniques may assist some quality control tasks but their applicability, validation, cost and function in final product testing should be assessed on a case-by-case basis.

Table 6: Summary of Core Technical Challenges and Emerging Technological Solutions in Herbal Shampoo Engineering

Technical Bottleneck	Industrial & Scientific Manifestation	Emerging Technological / Methodological Horizon
Batch Phytochemical Drift	Fluctuating detergency, color shifts, and unstable lather	Contract GACP farming; HPLC marker standardization; normalized extract dosing
Microbial Spoilage Vulnerability	Rapid spoilage of extract-rich water vehicles	Hurdle technology; synergistic organic acid combinations; validated ISO 11930 PET
Colloidal Destabilization	Phase syneresis, precipitation of tannins with polymers	Advanced hydrocolloid complexes; micro fluidization; pH-buffered vehicle design
Unsubstantiated Hair Claims	Regulatory vulnerability under Drugs & Cosmetics Acts	Double-blind, trichoscopy-backed clinical trials with objective instrumental end-points
Poor Follicular Deposition	Rapid washout of bioactive during water rinsing	Lipid-core transferosomes, phytosomes, and cationic natural polymer deposition matrices

CONCLUSION

The formulation systems of herbal shampoo need to blend the botanical extracts with the appropriate cleansing agents, excipients, preservation, and packaging. Published work supports tests such as pH, viscosity, foam behaviour, wetting, dirt dispersion, solid content and comparative cleansing assessments, but methodologies and findings differ between investigations [1–2,7–10]. Therefore, formulation concentrations and acceptable ranges must be justified for each product and not treated as general standards. Quality assurance should cover botanical identity and variability, suitable analytical controls, microbiological quality and preservative efficacy, product-specific stability, safety and adherence to the relevant Indian cosmetic regulations [11,13–16,19–21]. A finished rinse-off shampoo cannot be considered therapeutically effective on the basis of results obtained from isolated constituents or laboratory assays. Future research should focus on transparent procedures, repeatable formulations, comparative testing, and reliable product claim substantiation.

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