IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 11, May 2026
Impact Factor: 8.2

Formulation and Evaluation of Herbal Hair Spray

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Abstract: *Hair issues like too much hair loss, thinning hair, dandruff, and scalp infections are becoming more common. This is often due to different lifestyle habits, not eating well, pollution in the environment, and regularly using hair products that contain harsh chemicals. These problems frequently cause people to look for natural and safer options for taking care of their hair. Herbal remedies are widely accepted because they are effective, have few side effects, and have been used traditionally in different medical systems like Ayurveda. This study is focused on creating and testing a herbal hair spray that is made especially for refreshing and revitalizing hair. The formula has seven healing plants that are good for hair and scalp health: Coriandrum sativum (Coriander), Murraya koenigii (Aloe vera), rosa-sinensis (Hibiscus), Phyllanthus emblica (Amla), Azadirachta indica (Neem), Trigonella foenum-graecum (Fenugreek), and Murraya koenigii (Curry leaves). These herbs have been used for a long time to help make hair roots stronger, lessen hair loss, stop scalp infections, and enhance the overall feel and shine of the hair. Every ingredient is full of natural substances like antioxidants, vitamins (especially vitamin C and beta-carotene), flavonoids, and essential oils that help hair grow and keep the scalp safe from infections and damage caused by harmful substances. The process of making the product included preparing separate herbal extracts. These extracts were then mixed together in the best proportions and combined with natural preservatives and moisturizing ingredients. The last herbal spray was tested for important factors like how it looks, its pH level, how well it sprays, and how stable it is in various conditions. Also, we looked at how happy the users were by doing a small trial. The results showed that the spray was easy to use, stayed effective, and helped improve the quality of hair. In general, the created herbal hair spray looks very promising as a natural and complete way to help refresh hair and take care of the scalp.*

Keywords: Herbal hair spray, Hair rejuvenation, Scalp infection, Medicinal plant, etc.

I. INTRODUCTION

Hair is a thread-like protein that grows from tiny openings called follicles located in the skin, specifically in the layer known as the dermis. The hair follicle is a sensing, A reactive and multi-layered skin accessory serves various popular functions and usually needs a certain type. molecular surroundings to stay completely operational. In addition to giving a protective layer to the skin of. animals. It also helps with blending in for survival and is known to give sensory and touch information. about the environment. Hair follicles are created through the interaction between the outer layer of skin and the inner layer. appear during the first trimester in humans. Hair growth is a unique and complex process that involves a variety of factors. a constant process of growing, breaking down, testing, and starting over. Hair comes from the follicle, which is the root found beneath the skin. The hair gets its nourishment from blood vessels at the bottom, or the follicle, which helps it grow. This composition not only addresses functional scalp care but also encourages overall hair health, presenting a complete hair care solution for those looking for natural, long-lasting, and effective hair treatment. Our present formulation—a herbal hair spray—is a contemporary delivery system for timeless knowledge. It is formulated as a nonoily, leave-in spray infused with plant extracts and bioactive ingredients that address scalp health, follicle care, and microbiome balance . The active phytoconstituents are Neem, Amla, Fenugreek, Hibiscus, and oninon, cari leaves, coriander all of which are reported to have scalp-soothing, antimicrobial, antioxidant, and hair-

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strengthening properties . For better absorption and efficacy, chitosan nanoparticles are added, providing controlled release and penetration into deeper follicles. This composition not only addresses functional scalp care but also encourages overall hair health, presenting a complete hair care solution for those looking for natural, long-lasting, and effective hair treatment.

BASIC PHYSIOLOGY OF THE HAIR & SCALP[456]

The scalp and hair follicles work together to form a delicate and connected system that is important for growing and keeping hair healthy. The scalp is made up of different layers: the outer layer called the epidermis, the middle layer known as the dermis, and the deeper layer called subcutaneous tissue. Each of these layers helps to support the hair follicles found in the scalp.

Structure of Hair :

Hair is mostly made up of keratin, which is a tough protein created by special cells called keratinocytes in the hair growth area. Every hair comes from a hair follicle that is located deep in the skin. This follicle is surrounded by oil glands, tiny blood vessels, and nerve endings.

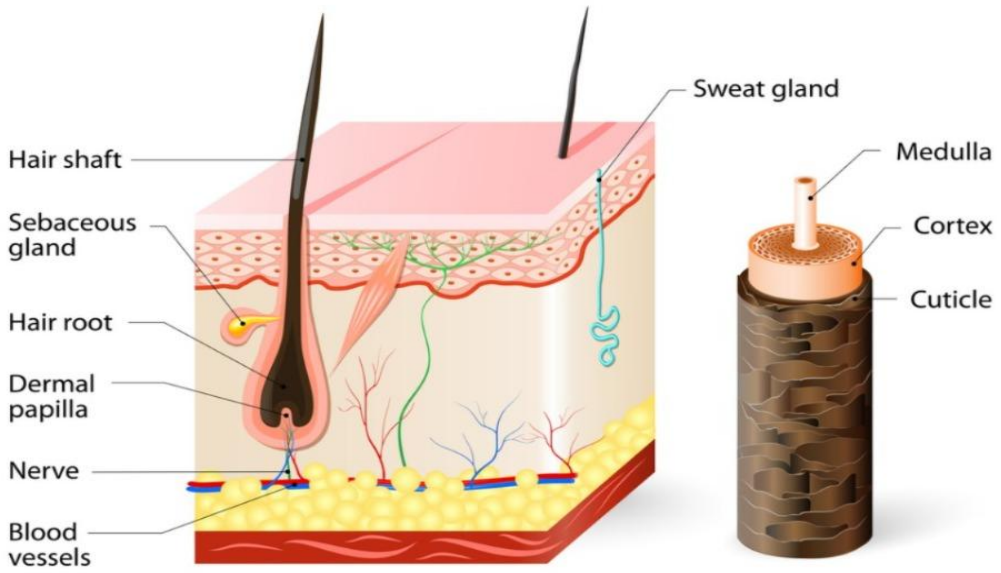

Fig:1 Structure of Hair

The hair follicle consists of the following components:

- Hair Shaft: The portion of hair that is seen above the scalp and constitutes the:
- Cuticle (outermost protective layer),
- Cortex (bulk of the hair, highly pigmented and structural protein rich),
- Medulla (innermost layer, found in thicker hair)

Hair Root: Projects into the dermis and has the hair bulb, dermal papilla, and matrix cells that produce hair growth.

Sebaceous Glands: Attached to the follicle, they release sebum, an oily secretion that keeps the scalp moist and helps in a natural defense barrier.

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Hair Growth Cycle:

Hair grows in cycles, which include:

1. Anagen (Growth phase) – This is when hair is actively growing, and it lasts between (2 to 6 years).
2. Catagen (Regression phase) – This is the stage of change that lasts for (2 to 3 weeks).
3. Telogen (Resting phase) – Hair is in the follicle but is not growing for about (2 to 4 months).
4. Exogen (Shedding phase) – Old hair falls out, and a new cycle begins

A healthy scalp is important for a longer growth phase and less hair shedding rhe resting phase. Inflammation, infections, not getting enough nutrients, and oxidative stress can disrupt this process, causing hair to become thinner or fall out.

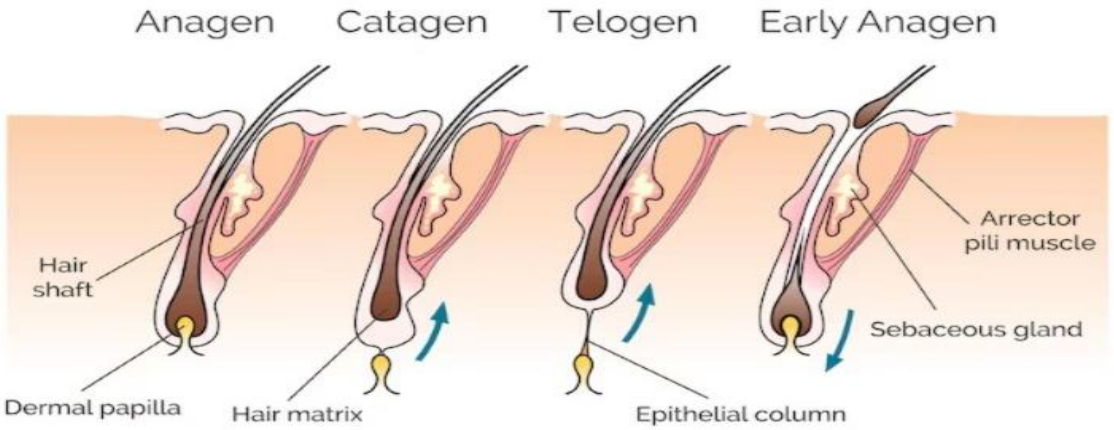

Fig: 2 Hair Growth Cycle

FUNCTIONS OF THE HERBAL HAIR SPRAY[7]

The multi-functional herbal hair spray is made to tackle various issues related to the scalp and hair. It combines natural ingredients, moisture-retaining substances, and essential oils in an easy-to-use, leave-in style. Key functional aspects include:

1. **Antimicrobial & Antifungal Action**: Neem extract off infections caused by microbes by breaking down the cell walls of fungi and bacteria. This action helps to get rid of dandruff and soothe scalp irritation.
2. **Follicular Nourishment:** Fenugreek and Amla are packed with phytonutrients and proteins that nourish hair follicles and promote the production of keratin, resulting in thicker and stronger hair.
3. **Antioxidant Protection:** Amla and Hibiscus are powerful antioxidants that help fight free radicals on the scalp, reducing oxidative stress, which is a significant cause of early hair loss and greying.
4. **Scalp Hydration & Soothing Effects :** Aloe Vera Gel and Glycerin balance moisture levels in the scalp, soften drynees, and promote epidermal barrier function.
5. **Enhanced Absorption & Targeted Delivery:** Chitosan Nanoparticles surround bioactive extracts, keeping them stable, increasing their availability, and allowing them to penetrate deeper into the follicles.
6. **Lightweight and Non-Greasy Use:** The water-based formula makes it easy to spray on without leaving any sticky or oily feeling, which makes it perfect for everyday use on all kinds of hair.

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II. REVIEW OF LITERATURE

1. LITERATURE REVIEW ON HERBAL HAIR NOURISHING FORMULATIONS

Pal R.S. et al., (2016) addressed the formulation and biological assessment of herbal hair nourishing formulations. The work had the aim to formulate hair care products employing alcoholic and aqueous extracts of selected herbs and their assessment for hair growth promotion in rabbits to ascertain the optimal formulation. The formulations were evaluated for their efficacy in promoting hair growth, with findings revealing encouraging effects. The research highlighted the increasing trend of herbal cosmetics because of their perceived safety and effectiveness in hair care.

2. LITERATURE REVIEW ON HERBAL HAIR GELS

Goswami A. et al., (2019) formulated and analyzed an herbal hair gel incorporating extracts of Piper nigrum, Hibiscus, and Ziziphus jujuba. The composition sought to consolidate the hair growth-supportive quality of the herbs into an easily usable gel form. Physicochemical testing provided encouraging outcomes, positing the potential application of the gel as a hair care product naturally. The work highlighted the efficacy of herbal resources in developing appropriate hair care preparations

3. LITERATURE REVIEW ON HERBAL HAIR SERUM FORMULATIONS

Singh V. et al., (2024) presented an overall review on the formulation and evaluation of an herbal hair serum. The review emphasized the need for healthy hair follicles and talked about different herbal ingredients which were reported to have positive effects on hair, including Citrus sinensis for the prevention of dandruff, Nigella sativa for strengthening hair texture, flaxseed for cleansing the scalp, and coconut oil for moisturizing. The research emphasized the usefulness of these herbal constituents in the development of effective hair serums that would stimulate hair growth and prevent hair loss.

4. LITERATURE REVIEW ON ANTI-FRIZZ HAIR PRODUCTS

Color Wow Dream Coat Supernatural Spray (2025) has been identified as a good anti-frizz hair product. The heat-activated spray forms a hydrophobic barrier on the hair, stopping frizz caused by moisture and leaving the hair silky and shiny. It is especially known for its long-lasting results, keeping frizz-free hair for days after application. The effectiveness of the product has earned it a top pick among hairstylists.

III. AIM & OBJECTIVE

Aim

The objective of creating and testing a new herbal hair spray is to create an efficient, natural product for enhancing scalp health, inhibiting dandruff, slowing down hair fall, and overall hair strength and growth. This composition combines highly active bioactive herbal extracts—Neem, Amla, Hibiscus, and Fenugreek—with moisturizing base ingredients like Aloe Vera, Sweet Almond Oil, and Glycerin, and is also supplemented with essential oils and chitosan nanoparticles for better scalp penetration and stability. The main aim is to provide a non-toxic, preservative-stable, and cosmetically acceptable herbal product that treats frequent hair and scalp disorders while providing user safety, product stability, and therapeutic effectiveness. The formulation will be assessed for parameters such as pH, viscosity, spreadability, homogeneity, microbial safety, and long-term stability with a view to possible clinical use and commercial viability.

Objective

Formulation and development: To make a reliable and visually pleasing herbal hair spray, we will use selected herbal extracts and essential oils combined with a suitable base. This will ensure it is easy to apply and absorbs well.

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Phytochemical Synergy: This study looks at how Neem, Amla, Hibiscus, Fenugreek, and other natural compounds work together to improve scalp health, promote hair growth, manage dandruff, and strengthen hair.

Safety and Toxicity Testing: This process is done to ensure the formula is safe for everyday use by checking for any possible side effects, such as scalp irritation or allergic reactions, and confirming that it meets safety standards for germs and heavy metals. Using tiny chitosan particles can help improve how well medicine is absorbed through the skin. This can lead to better treatment effects and make the products more stable.

Evaluating Physicochemical Properties and Performance: This involves checking important features of the formulation such as pH levels, thickness (viscosity), how easily it spreads, how long it takes to dry, how evenly mixed it is (homogeneity), and how well it stays stable during storage over time.

IV. PLAN OF WORK

- Review of literature
- Pharmacognostical study
- Physicochemical screening
- Formulation development
- Evaluation parameters
- Result and discussion
- Summaey and conclusion

Review of literature
Review of traditional and modern studies on hair care herbs, their phytochemistry, and market trends of herbal hair sprays.

Pharmacognostical Study
Macroscopic, microscopic, and organoleptic evaluation of the crude herbal materials used in the formulation.

Physicochemical Screening
pH, viscosity, spreadability, density, solubility, drying time, and other key formulation parameters will be evaluated.

Formulation development
Preparation of the final spray using an optimized concentration of each herbal extract, essential oils, stabilizers, and base.

Evaluation Parameters
Assessment of microbial load, heavy metal content, homogeneity, long-term stability, and performance upon application.

Result and discussion
Compilation of findings, comparative analysis, and interpretation of outcomes.

Summaey and conclusion
Overall conclusion drawn from formulation success, limitations encountered, and suggestions for future directions.

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V. PLANT PROFILE

Neem[8]

Synonyms : Indian lilac, Margosa tree, Nimba (Sanskrit), Nimtree

Biological Source: Neem consists of the leaves, bark, seeds, and oil obtained from Azadirachta indica A. Juss.

Family: Meliaceae

Chemical Constituents: Major constituents of neem include: Azadirachtin, Nimbin, Nimbidin, Nimbolide,Gedunin, Quercetin, Salannin, Fatty acids (in neem oil)

Uses:

- Antibacterial and antifungal agent
- Used in skin diseases and wound healing
- Insecticide and mosquito repellent
- Used in dental care products like toothpaste and mouthwas

Fig: 3 Neem

Amla[9]

Synonyms: Indian gooseberry**,** Amalaki**,** Emblic myrobalan

Biological Source: Amla consists of the fresh or dried fruits of Phyllanthus emblica Linn. (also known as Emblica officinalis).

Family: Phyllanthaceae (formerly placed under Euphorbiaceae)

Chemical Constituents: Major constituents include: Vitamin C (ascorbic acid), Tannins, Gallic acid, Ellagic acid, Emblicanin A and B, Pectin Flavonoids and polyphenols

Uses:

- Powerful antioxidant
- Used as an immunity booster
- Helps in digestion and gastric disorders
- Used in hair oils and tonics

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Fig: 4 Amla

Hibiscus[13]

Synonyms: China rose, Shoe flower, Jaswand

Biological Source: Hibiscus consists of the flowers and leaves of Hibiscus rosa-sinensis Linn.

Family: Malvaceae

Chemical Constituents: Major constituents include:,Anthocyanins, Flavonoids, Hibiscetin, Quercetin, Cyanidin derivatives, Mucilage, Organic acids

Uses:

- Used as a natural hair growth promoter
- Helps reduce dandruff and hair fall
- Used in herbal shampoos and hair oils
- Possesses antioxidant activit

Fig: 5 Hibiscus

Coriander[11]

Synonyms: Cilantro, Dhania, Chinese parsley

Biological Source: Coriander consists of the dried ripe fruits (seeds) of Coriandrum sativum Linn.

Family: Apiaceae (Umbelliferae)

Chemical Constituents: Major constituents include: Volatile oil (0.1–1%), Linalool (coriandrol), Geraniol, Borneol, Camphor, Flavonoids, Coumarins, Fatty oils and proteins

Uses:

- Powerful antioxidant
- Carminative and digestive aid
- Used in treating indigestion and flatulence
- Possesses antioxidant and antimicrobial properties

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Fig: 6 Coriander

Aloe vera[12]

Synonyms: Aloe, Ghritkumari, Barbados aloe

Biological Source: Aloe vera consists of the dried juice and gel obtained from the leaves of Aloe barbadensis Miller (commonly known as Aloe vera).

Family: Asphodelaceae (formerly placed under Liliaceae)

Chemical Constituents: Major constituents include: Aloin (barbaloin), Aloe-emodin, Anthraquinones, Polysaccharides (acemannan), Glycoproteins, Vitamins (A, C, E, B-complex), Enzymes and amino acids, Minerals such as calcium, magnesium, and zinc

Uses:

- Used for wound healing and burns
- Moisturizing and soothing agent for skin
- Used in cosmetics and skincare products
- Possesses anti-inflammatory and antimicrobial properties

Fig: 7 Aloe vera

Curry leaves[13]

Synonyms: Curry leaves, Sweet neem leaves, Kari patta, Meetha neem

Biological Source: Curry leaves consist of the fresh or dried leaves of Murraya koenigii (Linn.) Spreng.

Family: Rutaceae

Chemical Constituents: Major constituents include: Carbazole alkaloids (mahanimbine, koenimbine), Essential oils, Caryophyllene, Linalool, Flavonoids, Glycosides, Vitamins A, B, C, and E, Calcium, iron, and phosphorus

Uses

- Used as a flavoring agent in food
- Helps in digestion and appetite stimulation
- Possesses antioxidant and antimicrobial properties
- Used in diabetes management in traditional medicine

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Fig: 8 Curry leaves

Fenugreek Seeds[14]

Synonyms: Methi, Greek hay, Bird's foot, Fenigreek

Biological Source: Fenugreek consists of the dried ripe seeds of Trigonella foenum-graecum Linn.

Family: Fabaceae (Leguminosae)

Chemical Constituents: Major constituents include: Alkaloids (trigonelline, choline), Steroidal saponins (diosgenin), Mucilage, Flavonoids, Proteins and amino acids, Fixed oils, Fiber and vitamins

Uses:

- Used as a spice and flavoring agent
- Helps in diabetes management by lowering blood sugar
- Improves digestion and relieves constipation
- Used as a galactagogue to promote lactation

Fig: 9 Fenugreek Seeds

Onion

Synonyms: Pyaz, Common onion, Bulb onion

Biological Source: Onion consists of the underground bulbs of Allium cepa Linn.

Family: Amaryllidaceae (formerly placed under Liliaceae)

Chemical Constituents: Major constituents include:Volatile sulfur compounds, Allyl propyl disulfide, Quercetin, Flavonoids, Saponins, Vitamins C and B-complex, Minerals such as calcium, phosphorus, and potassium

Uses:

- Used as a flavoring and culinary agent
- Possesses antimicrobial and antioxidant properties
- Helps reduce blood cholesterol and blood sugar levels
- Used in cough and cold remedies

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Fig: 10 Onion

Almond Oil

Synonyms: Oleum Amygdalae, Sweet Almond Oil, Almond fixed oil

Biological Source: Almond oil is obtained from the seeds of Prunus amygdalus (also classified as *Prunus dulcis*)

Family: Rosaceae.

Chemical Constituents: Major constituents include: Fixed oil (about 40–55%), Olein (oleic acid glycerides), Linolein (linoleic acid glycerides), Palmitin, Proteins, Vitamins, Vitamin E (tocopherols), Minerals, Small amounts of sugars and mucilage, Bitter almonds additionally contain: Amygdalin (cyanogenic glycoside), Emulsin enzyme

Uses

- Used as an emollient and skin softener
- Used in cosmetics and massage preparations
- Mild laxative
- Used in hair oils and creams

Fig: 11 Almond Oil

VI. EXTRECTION METHODE

Fig: 12 Maceration of all the Herbs used

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Coriander (Coriandrum sativum) – Seed or Leaf[11]

Grind dried coriander seeds or leaves into a coarse powder. Soak 1 part of the powder in 5 parts of ethanol or a 50:50 ethanol-water mix. Let it sit for 24–48 hours in a covered jar, shaking occasionally. Strain through a fine cloth. This captures essential oils like linalool, as well as flavonoids and antioxidants that help reduce scalp inflammation and combat microbial growth. Coriander extracts are commonly used in hair care for their antifungal and refreshing properties.

Amla (Phyllanthus emblica) – Powder[9]

Dry amla pieces or use powder. Boil 1 part of dried amla in 5 parts of water for 15–20 minutes, then let it steep for an hour. Strain through cloth or sieve. This aqueous decoction preserves vitamin C, gallic acid, and tannins, all of which strengthen hair roots, prevent premature greying, and act as powerful antioxidants. Regular use of amla extract in hair products helps maintain a healthy scalp and shiny, strong hair.

Neem (Azadirachta indica) – Leaf[8]

Crush fresh or dried neem leaves. Simmer in water (1:5 ratio) for 15–20 minutes or soak overnight in cold water. Strain to use the antimicrobial-rich aqueous extract. For oil-soluble actives, soak leaves in warm sesame or coconut oil over low heat for 1 hour, then strain. Neem contains azadirachtin and nimbin, which are potent antifungal and antibacterial compounds. It helps treat scalp infections, dandruff, and lice while maintaining a clean, balanced scalp environment.

Fenugreek (Methi, Trigonella foenum-graecum) – Seed[14]

Soak fenugreek seeds in warm water overnight (1:5 ratio). In the morning, grind into a gel-like paste or strain the mucilaginous extract. This provides moisturizing mucilage and anti-inflammatory benefits. Fenugreek also contains nicotinic acid, proteins, and saponins, which nourish the scalp, reduce hair fall, and improve texture. The extract can be used as a natural conditioner or mixed into sprays and masks.

Curry Leaves (Murraya koenigii) – Leaf[13]

Grind fresh or dried curry leaves. Simmer in water or oil (coconut or sesame oil) for 20–30 minutes on low heat. Let cool and strain. The extract contains essential oils, alkaloids, and antioxidants that support hair pigmentation, strengthen follicles, and reduce hair loss. Curry leaves are traditionally known to prevent premature greying and promote stronger, shinier hair by nourishing the roots with iron, calcium, and amino acids

Hibiscus (Jaswand) – flowers[10]

Fresh or dried flowers and leaves. Simmer in water or oil (coconut or sesame oil)for 20–30 minutes on low heat. Let cool and strain. The extract contains flavonoids, anthocyanins, amino acids, mucilage, and antioxidants that help nourish the scalp, strengthen hair follicles, reduce hair fall, and improve hair texture. Hibiscus is traditionally used in hair-care preparations to promote hair growth, maintain natural hair pigmentation, reduce dandruff, and enhance softness and shine.

FORMULATION PROCESS[151617]

1. Weigh and Clean Herbs: o Accurately weigh all herbs using a digital scale. o Rinse fresh leaves like curry leaves under clean water; pat dry.
2. Pre-Process Seeds: o Lightly crush fenugreek, coriander, and black cumin seeds with a mortar and pestle to expose surface area for better extraction.
3. Decoction: o Combine all herbs and seeds in a stainless steel pot with 600 g of distilled water. o Bring to a gentle boil, then simmer on low heat for 20–25 minutes until the water reduces to approx. 500 ml (500 g).

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4. Cool and Strain: o Let it cool to room temperature. o Strain the liquid using muslin cloth or a fine strainer into a clean glass jar.
5. Essential Oil Addition (Optional): o Add 5–10 drops (0.25–0.5 g) of essential oil. o Stir well to incorporate.
6. Storage: o Store in the refrigerator. Use within 10–14 days.

Table Ingredients used and the it's quantity

Ingredient	Form	Weight (grams)
Amla	Dried / Powder	5g
Neem	Dried Leaves	5g
Curry Leaves	Fresh / Dried	5g
Fenugreek Seeds	Whole	5g
Coriander Seeds	Whole	5g
Hibiscus	Whole	5g
Aloe vere	Dried /Powder	5g
Distilled Water	Liquid Base	600 g (approx. 600 ml) – reduce to 500 ml
Optional: Almond Oil	Liquid	0.25–0.5 g (5–10 drops)

EVALUATION PARAMETERS[181920]

Physical Evaluation

Parameter	Result
Appearance	Clear to light brown liquid
Odor	Pleasant, herbal aromatic fragrance
Consistency	Low viscosity, easy to spray
pH	5.8 (suitable for scalp application
Sprayability	Smooth spray with fine mist
Drying time	3–4 minutes
Stickiness	Non-sticky after application

Stability Studies

Conducted under different storage conditions for 30 days:

Condition	Observation After 30 Days
Room Temperature	No phase separation, odor unchanged
Refrigeration (4°C)	No precipitation, stable
Elevated Temp (45°C)	Slight color darkening, no odor change

VII. RESULTS AND DISCUSSION

The formulated herbal hair spray demonstrated excellent physical stability over a period of 10–14 days under refrigerated storage. There was no visible phase separation, sedimentation, or microbial growth during the observation period, indicating the suitability of the water-based extract for short-term topical application. The spray was easy to apply, non-sticky, and dried quickly on the scalp, contributing to high user acceptability. The effectiveness of the spray can be attributed to the synergistic combination of medicinal herbs, each contributing unique therapeutic benefits. The presence of essential oils and antioxidants from coriander, curry leaves, and neem helped in maintaining scalp hygiene,

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reducing dandruff, and minimizing inflammation. These ingredients, known for their antimicrobial and antifungal properties, helped promote a clean and balanced scalp environment, which is essential for healthy hair growth.

Fig: Final Product Formulatrd – Herbal Hair Spray

VIII. CONCLUSION

The formulated herbal hair spray exhibits significant potential as a natural, safe, and effective hair care solution. Its multi-herbal composition—rich in antioxidants, essential oils, and bioactive phytochemicals scalp health, reduced dandruff, prevention o spray exhibits significant potential as a natural, safe, and effective hair care solution. Its rich in antioxidants, essential oils, and bioactive phytochemicals—contributes to improved scalp health, reduced dandruff, prevention of premature greying, and stimulation of hair growth. The synergistic action of ingredients such as amla, curry leaves, neem, hibiscus, fenugreek, coriander, and black cumin ensures both therapeutic and cosmetic benefits, making it a holistic alternative to chemical-based hair products.premature greying, and stimulation of hair growth. The synergistic action of ingredients such as amla, curry leaves, neem, hibiscus, fenugreek, coriander, and aloe vera ensures both of ingredients such as amla, curry leaves, neem, hibiscus, fenugreek, coriander, and aloe vera ensures both therapeutic and cosmetic benefits, making it a holistic alternative. The formulation also demonstrated good physical stability, user friendliness, and favorable sensory attributes, indicating its suitability for routine application. The formulation also demonstrated good physical stability, user friendliness, and favorable sensory attributes, indicating its suitability for routine application. However, while initial results and observations are promisin long-term clinical evaluations and stability testing under varied conditions are necessary to fully validate its efficacy, safety, and shelf life for commercial development. The formulation also demonstrated good physical stability, user friendliness, and favorable sensory attributes, indicating its suitability for routine application. However, while initial results and observations are promisin term clinical evaluations and stability testing under varied conditions are necessary to fully validate its efficacy, safety, and shelf life for commercial development

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