

EVALUATING HAIR GROWTH ACTIVITY OF HERBAL HAIR OIL

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ABSTRACT

Herbs & herbal drugs are clinically proved good for hair growth. Hair loss problem is of great concern to both males & females & the main problems associated with hair loss are hair fading, dandruff & falling of hair. Various synthetic medicines are available for hair loss which does not treat permanently & also shows severe side effects. The main objective of this work is to develop such an herbal hair oil formulation which can resolve the problem related to hair fall & other hair diseases. Herbs drugs like Aloe vera pulp, Tulsi, hibiscus, shikakai, onion, Fenugreek seeds (methi curb), coconut oil, Almond oil, Jasmine flowers were selected for the formulations of poly herbal hair oil. The hair oil was prepared.

INTRODUCTION

The concept of beauty and cosmetics dates back to an ancient mankind And civilization Generally herbal cosmetics are also referred to as Natural cosmetics. Herbal cosmetics are formulated using different Cosmetic ingredients to form the base in which one or more herbal Ingredients are used to cure various skin ailments. Plants are Highly Used for development of new drug products for cosmeceuticals and pharmaceutical applications.

Herbal Cosmetics are the products in which herbs are used in crude or extract form. Herbal Cosmetics, Referred as Products, are formulated, using Various permissible cosmetics ingredients to form the base in which One or more herbal ingredients are used to provide defined cosmetics Benefits only, shall be called as "Herbal Cosmetics". Herbs do not Produce instant cures. They offer a way to put the body in proper Tune with nature.

A huge number of cosmetic and toiletry Formulation have been designed and developed based upon Indian Herbs recently. Other than traditionally documented application, Some modern trials have also been using the utility of indian herbs in personal care products. The demand of herbs medicines is increasing Rapidly due to their skin friendliness and lack of side effects. The best thing of the herbal cosmetics is that it is purely made by the Herbs and Shrubs and thus is side- effects free. The natural content in the herbs does not have any side effects on the human body, instead Provide the body with nutrients and other useful minerals.

Cosmetics Are cosmetic-Pharmaceutical hybrids intended to enhance health and Beauty through ingredients that influence the skin's biological texture and function Cosmetics are commercially available products that are used to improve the appearance of the skin Even though the cosmetics field is closely to the pharmaceutical or food industry the expected of cosmetics product consumers and their needs are completely different.

They are more sophisticated and are looking for safe cosmetics products that actually do something beneficial to their skin.

Plants and plant derived ingredients are common and of major importance in the fields of pharmacy food and cosmetics some pharmaceutical companies have begun to develop cosmetic improvement lines.

Cosmetics

Cosmetics are constituted mixture of chemical compounds derived from either natural sources, or synthetically created ones. Cosmetics have various purposes. Those designed for personal care and skin care can be used to cleanse or protect the body or skin. It keeps the areas on which it is applied in good condition and also protect, cleans perfumes and changes their appearance without modifying them.

Cosmeceuticals – The name is a combination of two words "cosmetics" and "Pharmaceuticals".

'Cosmeceuticals' is fastest growing segment of the beauty industry. Cosmeceuticals are cosmetic –

pharmaceutical products intended to improve the health and beauty of the skin by providing a specific result, ranging from acne- control and anti- wrinkle effect, to sun protection.

The concept discovered by Dr. Albert Klingman states that 'The Cosmeceuticals are topical agents that are distributed across broad spectrum of materials, lying somewhere between pure cosmetics (lipsticks and rouge) and pure drug (antibiotics, corticosteroid).

Cosmeceuticals are products that have both cosmetic and therapeutic (medical or drug-like) effects, and are intended to have a beneficial effect on skin health and beauty. Like cosmetics, they are applied topically as creams or lotions but contain active ingredients that have an effect on skin cell function.

In a cosmeceutical product, the active principles are: dermis and act within the dermis.

Difference between Cosmetics and Cosmeceuticals.

Cosmetics	Cosmeceuticals
FD & C Act defines a cosmetic product by its intended use meaning, cleansing, beautifying, promote attractiveness or altering appearance.	Cosmeceuticals products on the other hand have pharmaceutical benefits to the skin.
Cosmetic products only deliver their ingredients at a very superficial level into the skin.	Cosmeceuticals products contain active ingredients that act on the skin cellular structure through topical application with either therapeutic, disease- fighting or healing properties.
Cosmetics do not delay your skin's aging process because they work at the uppermost layer of the epidermis which is the topmost layer of the skin.	Cosmeceuticals are more concentrated, pure and more effective giving pharmaceutical benefits.

Comparative study of marketed cosmetics and cosmeceutical product.

Marketed Cosmetics Baby Products- E.g. Himalaya's herbal baby powder Key Ingredients- Almond Oil, Khus Grass, Olive Oil, Natural Zinc	Marketed Cosmeceuticals baby Products- E.g. Baby hug Advanced talc free Dusting powder Key Ingredients :- Zinc oxide, chamomile extract, olive oil, maize starch, Rosehip oil, which
Marketed Cosmetic Men's Product- Eg. Parachute Lite Hair Oil Contains Key Ingredients – Mineral oil (79.7% v/v), coconut oil (20% v/v), fragrance with Jasmine extract, Benzophenone-3.	Marketed Cosmeceuticals Men's Product – Eg. Kama Ayurveda Extra Virgin Organic Coconut Oil Key Ingredients- Organic Honey, Natural Sugar, Apple Cider Vinegar, Wellness Juice & Powders.

Regulatory status of cosmetics or Cosmeceuticals Cosmeceuticals – Cosmetics or Drugs ?

The legal difference between a cosmetic and a drug is determined by a product's intended use. Under present concept, the boundary at which a cosmetic product becomes drug is not well- defined and different laws and regulations apply to each type of product.

The drugs and cosmetics Act 1940 defines a drug and cosmetic as :

Drug- "All Medicines for internal or external use of human beings or animals and all substances intended to be used for : or in The diagnosis, Treatment, mitigation or prevent of any disease or disorder in human or animals".

Cosmetic-"Any article intended to be rubbed, poured, sprinkled or sprayed on or introduction into or Applied

to any part of the human body for cleansing, beautifying. Promoting attractiveness or altering the appearance and includes any Article intended for use as a component of cosmetic".

Cosmetic and drug : Some product meet the definitions of both Cosmetics and drugs. This may happen when a product has more than One intended uses.

For example, a shampoo is a cosmetic because its Intended use is to clean the hair. An antidandruff shampoo is a drug Because its Intended use is to treat dandruff. Among the cosmetic / drug Combination are toothpastes that contain fluoride, deodorants that are Antiperspirants and moisturizers with sun – protection claims.

The Claims made about drug are subject to detailed analysis by the Food and Drug Administration (FDA)

review and approval process. But Cosmetics are not subject to mandatory FDA review.

Although there is No legal category called cosmetics, the term has found application to designed the products at the borderline between cosmetics and Pharmaceuticals.

Schedules that are applied for Cosmetics as per D & C Act, 1940

1. Schedule M (II) -

Requirement of premises, plant, equipment's for the manufacture of cosmetics.

2. Schedule Q –

List of coal tar colours permitted to be used in cosmetics and list of colours permitted to be used in soaps.

3. Schedule S –

Standard for cosmetics

5. Schedule T –

Requirements for factory premises and hygienic conditions for Manufacture of Ayurvedic (including Siddha) and Unani drugs.

6. Schedule U (II)-

Particulars to be shown in manufacturing records of cosmetics.

Provisions Relating to Cosmetics

(A) Import of Cosmetics- No Licence is required for import of cosmetics, But the imported should satisfy all other Necessary requirements as in the case of the drugs which are imported without licence.

Prohibition of import of certain cosmetics

The import of following classes of cosmetics is prohibited.

- Cosmetics which are not of standard quality.
- Misbranded cosmetics.
- Cosmetics containing Hexachlorophene.
- Cosmetics containing coal tar colour other than the one prescribed.
- Cosmetics containing prescribed colours which contain more than 2 p.p.m. of arsenic or 20 p.p.m. of lead or 100 p.p.m. of heavy metals other than lead.
- Cosmetics intended for use on the eye- brow or the eyelash, or around the eye containing any coal Tar dye colour, Coal tar base or Coal tar Dye intermediate.
- Cosmetic containing mercury compounds.
- Cosmetic containing any ingredient which may render them unsafe or harmful for use.
- Cosmetics coloured with arsenic or lead compounds.

(B) Manufacture of Cosmetics for Sale

For obtaining a licence one has to apply in the prescribed form 31 along with the necessary fees.

Conditions for obtaining license for

A. Manufacture of Cosmetic – A licence to manufacture cosmetics for sale against application in form 31, is granted in form 32, which remains valid up to 31st

December, of the year following the year in which it is granted.

1. The licensee shall provide and maintain staff, premises and equipment as specified in the respective rules.
2. The licensee shall comply with provisions of the Drugs and Cosmetics Act 1940 and rules made there under.
3. The licensee shall maintain the records (Schedule U₁) of necessary details of each batch of cosmetics manufactured and of raw materials used. The said records shall be retained for a period of three years.
4. The licensee shall test each batch of raw materials as well as final products and maintain record of register of the test performed. Such records shall be retained for a period of three years from the date of manufacture.
5. The licensee shall allow the Drug Inspector to enter with or without Notice for inspecting the manufacturing premises and to take samples of the manufactured cosmetics under a receipt.
6. The licensee shall allow an Inspector to inspect all the register and records maintained as per the provisions under the rules.
7. The licensee shall maintain an Inspection Book in form 35 so that an Inspector can record his views regarding inspection.

Conditions 3 and 4 mentioned above are not applicable for manufacture of soap. Procedure for testing of raw materials and the records to be maintained by a soap manufacturer shall be approved by the "Licensing Authority".

B) Sale of Cosmetic

Licence for sale of the cosmetics is not required. The dealers should sell only such cosmetics which do not contravene any of the provisions of Drugs and Cosmetics Act and the rules. If required, the dealer should disclose to the inspector the name, address and other particulars of person from whom he acquired the cosmetics.

C) Import of Cosmetic

Under the provisions of Drug and Cosmetics Act, 1940 and Rules made there under, the manufacture of cosmetics is regulated under a system of inspection and licensing by the State Licensing Authorities appointed by the respective State Governments, while the import of cosmetics is regulated under a system of registration by the Central Licensing Authority appointed by the Central Government.

The Drugs Controller (India) functions as the Central Licensing Authority who grants the Import Registration Certificate and regulates the import of cosmetics in to India vide Gazette Notification G.S.R. 763 (E) under the provisions of Drug and Cosmetics Act, 1940.

Current Good manufacturing Practice (cGMP) Regulation for Cosmetics

FDA ensures the quality of drug products by carefully monitoring drug manufactures, compliance with its Current Good manufacturing Practice (cGMP) regulations. The cGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing and packing of a drug product. The regulations make sure that a product is safe for use and that it has the ingredients and strength it claims to have.

FDA's portion of the CFR is in Title 21, which interprets the Federal Food, Drug and Cosmetic Act and related statutes, including the Public Health Service Act. The pharmaceutical or drug quality – related regulations appear in several parts of Title 21, including sections in parts 1-99, 200-299, 300-499, 600-799 and 800-1299.

The regulations enable a common understanding of the regulatory process by describing the requirements to be followed by drug manufactures, applicants and FDA.

21 CFR Part 314. For FDA approval to market a new drug.

21 CFR Part 210. Current Good manufacturing Practice in Manufacturing Processing, packing or Holding of Drugs.

21 CFR Part 211. Current Good Manufacturing Practice for Finished Pharmaceuticals.

21 CFR Part 212. Current Good manufacturing Practice for Positron Emission Tomography Drugs.

21 CFR Part 600. Biological Products : General.

ICH Guidelines for Stability Studies –

1. QIA (R2) – Stability Testing of New Drug Substances and Products.
2. QIB – Stability Testing : Photostability Testing of New Drug Substances and Products.
3. QIC – Stability Testing for New Disaggregates.
4. QID – Bracketing and Matrixing Designed for Stability Testing of New Drug substances and Products.
5. QIE – Evaluation of Stability Data.
6. QIF – Stability Data Package for Registration Application in Climatic Zones III and IV.

Information About Skin, Oral Cavity, Hair, nail Related Condition.

1. Skin related conditions

- Acne (Acne Vulgaris) Acne, the most common skin disorder.
- Atopic dermatitis (Eczema).
- Shingles (Herpes Zoster).
- Hives (Urticaria)
- Sunburn.
- Contact Dermatitis.
- Diaper Rash.
- Rosacea.

2. Oral Cavity related Condition

- Ulcers, Sores, Tender areas in the mouth that won't heal after a week or two.
- Bleeding or swollen gums after brushing or flossing.
- Chronic bad breath.
- Sudden sensitivity to hot and cold temperatures or beverages.
- Pain or toothache.

3. Hairs Related Condition

- Dandruff (Common scalp condition in which small pieces of dry skin flake off the scalp)
- Hair Loss.
- Dry Hair.
- Split Ends.
- Oily / Greasy Hair.
- Frizzy Hair.
- Dull hair.
- Heat Damaged Hair.

4. Nails Related Condition

- Brittle nails.
- Onycholysis (Onycholysis is the painless separation of the nail from the nail bed)
- Paronychia. (Paronychia is an infection of the tissue adjacent to a nail, most often a fingernail. It's Caused by injury or irritation, such as a hangnail, cuticle damage or continually wet hands.)
- Psoriasis (A condition in which skin cells build up and form scales and itchy, dry patches)
- Onychomycosis (A nail fungus causing thickened, brittle, crumbly or ragged nails.)

MATERIALS AND METHOD









Preparation & Evaluation of Herbal Hair Oil

The conception of beauty and cosmetics is as ancient as mankind and civilization. So, they use different beauty products that have herbs to look ravishing and young. Indian herbs and its intendment are popular worldwide.

Hair oils those embraces herbal drugs are called as hair tonics. These are contrived by herbal extracts in an oil base. Hair Oils are the hair care formulations applied for cure of hair disorder such as baldness, greying of hairs, hair falling and dryness of hairs. A plethora of herbs have been employed for hair treatments. A few of these herbs are amla, Henna, Neem, Methi, Lemon, Tulsi, Brahmi, Shikakai, Reetha, Liquorice root, Musk root, Mahabhringraj, Jantamasi, Chitraka, Marigold, Hibiscus, Nutmeg, Parsley, Rosemary, Thyme.

Herbal formulation always have tempted considerable attention because of their good bustle and comparatively lesser or nil side effects with synthetic drugs.

Table 1: Representing different herbs with figures used in the preparation of hair oil.

Sr.No.	Herbs	Figures
1.	Aloe Vera Pulp contain proteolytic enzymes which repairs dead skin cells on the scalp. It also feat as a great conditioner and leaves your hair all smooth and shiny. It bolster hair growth, prevents itching on the scalp, reduces dandruff and conditions your hair.	
2.	Tulsi is a cogent remedy for hair loss. It is Prepended an esential ingredient in herbal hair loss treatment. The herb works by strengthening the hair roots, thereby curbing hair fall, prevent bacterial and fungal infections.	
3.	Hisiscus Flowers are used to Clout premature graying of hairs, prevent hair loss and split ends.	
4.	Shikakai fights in contrast to dandruff and anticipate lice. Shikakai helps to remove dirty and excess oil from the scalp as well as promote hair growth. This is because of its kashaya (astringent) property.	
5.	Fengugreek seeds (Methi curb) stop hair fall and strengthens your hair from root to tip. Fenugreek seeds also have high protein and nicotinic acid content, which are known to be beneficial against hair fall and dandruff.	
6.	Coconut oil nourishes the scalp and proffer sine to the hairs.	
7.	Almond oil rich in vitamin E used in the treatment of hair loss and strengthen the hairs.	
8.	Jasmine flowers serves as anti-microbial agent, conditioning agent and also gives good odour to the oil.	
9.	Onion it has antiseptic and antibacterial properties. It also helps fight hair lice, dandruff and can be used as natural hair hourisher. Onion is the easiest product to use for smooth and shiny hair.	

Formulation of herbal hair Oil

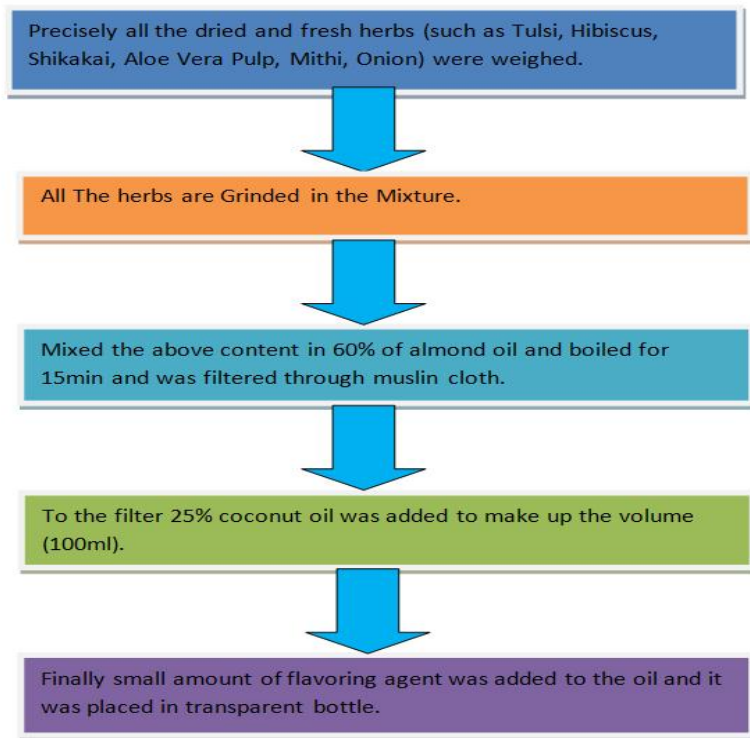


Fig. Steps Involved in Formulation.

Table 2: Ingredients used in formulation of herbal hair oil.

Ingredients	Quantity (%)
Aloe Vera pulp	4%
Tulsi	1%
Hibiscus	1%
Shikakai	2%
Coconut Oil	25%
Almond Oil	60%
Methi	4%
Jasmine	1%
Onion	2%

Evaluation of herbal hair oil

The formulate^{3d} herbal hair oil was levied to physical and biological evaluation.

1. Sensitivity test: The prepared herbal hair oil was applied on 1 cm skin of hand and exposed to sunlight for 4-5 min.
2. Acid value: i. Preparation of 0.1 Molar solution: weight 0.56g KOH pellets and dissolved in 100ml of distilled water and stirred continuously. The prepared 0.1 Molar KOH solution was filled in the burette. ii. Preparation of sample: 10ml oil was measured and dissolved in 50ml of 1:1 ethanol and ether mixture and shacked vigorously. 1ml of phenolphthalein solution was then added titrated with 0.1 Molar KOH solution.
3. Saponification value

- To accurately weight 1Ml of oil 250ml of conical flask, 10ml of ethanol, ether mixture (2:1) was added.
- To this 25ml of 0.5N alcoholic KOH was added and was kept undisturbed for 30min. and the flask was cooled.
- Then above solution was titrated against 0.5N HCL using phenolphthalein indicator. Similarly the blank titration was performed without taking oil (sample).
- Amount of KOH in mg used calculated using formula.

Saponification Value = 56.1 (B-S) N/W

Where,

B= Volume in ml of standard Hydrochloric acid required for the blank.

S= Volume in ml of standard Hydrochloric acid required for the sample

N= Normality of standard Hydrochloric acid.

W= weight of the oil taken in gram for the test.

1) **P^H**: The P^H of herbal hair oil was determine using P^H meter.

2) **Viscosity**: The viscosity was determine using Ostwald's viscometer.

3) **Specific Gravity**: Specific gravity bottle was rinsed with distilled water, dried in hot air oven for 15 minutes, cooled, capped, weighed and was noted as (a). Now the same specific gravity bottle was filled with the sample, capped and again weight (b). Weight of the sample per milliliter was determine by subtracting the weight (b-a)

RESULTS

Table 3: Role of herbs in herbal hair oil.

Ingredients	Importance
Coconut	Moisturizes dry hair.
Almond Oil	Treat hair loss and strengthens the hairs.
Tulsi	Anti bacterial
Hibiscus	Controls premature graying.
Shikakai	Anti dandruff.
Jasmine	Conditioning agent, Provides good odour.
Methi	Hair growth.
Aloe Vera	Boosting scalp health.
Onion	antiseptic and antibacterial, smooth and shiny hair.

Table 4: Evaluation of herbal hair oil.

Evaluation Parameter	Inference
Sensitivity test	Non sensitive
Irritation test	Non irritant
p ^H	6.4
Grittiness	Smooth
Specific gravity	0.94
Saponification value	197.04
Acid value	4.7
Color	Yellowish brown
Odour	Aromatic

DISCUSSION

In India, herbal cosmetics are used by more than 70% of the population for health care. Herbal cosmetics have been more popular in the personal care industry and there is a high demand for them in everyday life. Teeth that are in excellent shape, hair that shines and skin that glows are all important aspects of a person's appearance.

Herbal cosmetics are made using cosmetic components as a foundation, then one of more herbal substance are added to cure various skin diseases and beautify the skin. All of these cosmetic items, chemical formulation involve the inclusion of different natural ingredients such as leaves, among others. Cosmetics are substances that fall in between cosmetics (Lipstick, shampoo etc.) and pharmaceutical (antibiotics, antidandruff etc.).

Natural beauty preparation based on corrective formulation that provides cosmetic value or may be used as a safe addition to replace synthetic ingredients. More research and development is needed in the area of herbal cosmetics to show efficacy and create a safety profile for herbal cosmetics.

It is necessary to perform sufficient safety testing in accordance with current regulatory rules and requirements. Correct component knowledge, nature of body, personal requirements and consumer perception of product are all factors that influence the capacity to want the correct cosmetics for consumers.

The utilization of herbal cosmetics enhanced many folds in personal Hygiene and healthcare system. Hence there is a tremendous clamor for the herbal Cosmeceuticals individual Care or Personal health care industry, which is presently focusing and paying extra careful and persistent work or effort on the Development of herbal-based cosmetics.

Herbal oil provides numerous essential nutrients required to maintain normal function of sebaceous glands and promotes natural hair growth.

As nowadays, it is a fast developing segment with a huge Scope of manifold boost in coming years. Use of bioactive ingredients in cosmetic formulations have Valuable effect on body features and provide nutrients, which are essential for maintaining health and beautiful hair.

CONCLUSION

All the parameters showed that they are limits and since all the ingredients added have many advantages. At last it can be concluded that, this herbal hair oil formulation has significant quality with minimal side effects.

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