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An Updated Review on Cosmetic Science

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Abstract: *From hair care and lotions to makeup and perfume, consumers have a wide range of choices. It takes science to develop and test products to improve them, offer new benefits, and ensure safety.*

Keywords: Cosmetic Science, Hair cosmetic

I. INTRODUCTION

1. An Overview of Cosmetics Industry and its Market Size in India

The Indian cosmetics industry is majorly categorized into skin care, hair care, oral care, fragrances, and colour cosmetics segments. It currently has an overall market standing of USD 6.5 billion and is expected to grow to ~ USD 20bn by 2025 with a CAGR of 25%. In comparison, the global cosmetics market is growing steadily at 4.3% CAGR and will reach ~USD 450 billion 2025. This means that by 2025, India will constitute 5% of the total global cosmetics market and become one of the top 5 global markets by revenue.

With the improving purchasing power, demand for enhanced products and increasing image consciousness of the Indian clientele, many international brands started establishing footprints in India – among them are Mac Cosmetics, Avon, Estée Lauder, L'Oréal, and Willa professionals - across various retail formats. By 2020, a pool of luxury brands such as Labiocos, Bodyography, and Victoria Secret are expected to clamor for the Indian consumer wallet and mindshare. Social media &favourable demographics are playing an important role in spreading awareness about cosmetics products and developing fashion consciousness, not only in metros but also in tier-1 & 2 cities. This is a golden opportunity for many cosmetics companies to expand beyond the top-8 cities and generate handsome revenue from all across the country.[1]

Coupled with multiple other factors, herbal cosmetics products are driving growth due to increasing adoption, and the segment alone is expected to grow at 15%, as people become more aware of the possible perils in consistently using chemical formulations switch to 'safer' herbal and Ayurvedic products like Himalaya, Boutique, Dabur, Lotus, Patanjali, etc.. Many Indian & international brands have been trying to seize the established player position in this segment by launching multiple products across categories.[1]

Factors fuelling growth in cosmetics industry

The major factors that drive the cosmetics industry are:

- Cosmetics trial ups consumption
- Increasing channel penetration
- Adoption of natural products Changing retail landscape
- Rising disposable income
- Globalization impacting lifestyles[1]

II. OVERVIEW OF DRUG COSMETICS ACT 1940 AND 1945

The Drug and cosmetic Act, 1940 is an act to regulate import, manufacture, distribution & sale of drug and cosmetics. The Drug and Cosmetic rules, 1945 made under the act prescribe statuary requirements for grant of license to manufacture for sale and distribution of drug to ensure safety, efficacy and quality of drugs manufactured and sold in country.

In 1964, the act was amended to include Ayurveda and Unani drugs.

The primary objective of the Act is to ensure that the drugs and cosmetics sold in India are safe, effective and conform to prescribed quality standards. The Drugs Act was formulated in 1940 in pursuance of recommendations of Chopra Committee constituted in 1930 by Government of India. The Drugs Act, as enacted in1940, has since been amended several times and is now titled as "The Drugs and Cosmetics Act, 1940".[1]

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Drug includes Drug and Cosmetic Act, 1940:

Drug and Cosmetic Act is divided into five chapters and two schedules.

Chapter I: Introductory

Chapter II: The drugs technical advisory board, the central drugs laboratory and the drugs consultative committee

Chapter III: Import of drugs and cosmetics

Chapter IV: Manufacture, sale and distribution of drugs and cosmetics

Chapter IV a: Provisions relating to ayurvedic siddha and unani drugs

Chapter V: Miscellaneous The first schedule:

a. Ayurvedic and siddha systems
b. Unani system

The second schedule:

Standards to be complied with by imported drugs and by drugs manufactured for sale, sold, stocked or exhibited for sale or distributed

Drug and Cosmetic Rules, 1945:

Drug and Cosmetic rules contains following parts and schedules:

Parts:

Part I: Preliminary

Part II: The central drugs laboratory

Part III: Rules 9 to 20- omitted

Part IV: Import and registration

Part V: Government analysts, inspectors, licensing authorities and controlling authorities

Part VI: Sale of drugs other than homoeopathic medicines

Part VIA: Sale of homoeopathic medicines

Part VII: Manufacture for sale or for distribution of drugs other than homoeopathic medicines

Part VIIA: Manufacture for sale or for distribution of homoeopathic medicines[2].

III. IMPORT LICENSE OF DRUGS AND COSMETICS IN INDIA

Import, manufacturing, sale, and distribution of drug is regulated under Drugs and Cosmetics Act 1940 and Drugs and Cosmetic Rules 1945. Import license is provided for the import of drugs and cosmetics subject to those which are specified in Rule 10 and Rule 10A. In lieu to obtain Grant of Import License, an application for an import license is made in the form and manner prescribed in Rule24. The licensing authority on being satisfied will grant import license. When the conditions of the license will be fulfilled, the issue of an import license will be in Form 10 or Form 10-A. The Import license unless, it is suspended or canceled, must remain valid for a period of three years from the date of its issue[3].

IV. OFFENCES AND PENALTIES

Sr. No.	Offences	Penalties
1.	Non-compliance with conditions of the license and failure to pay duty	Imprisonment up to 6 months or fine upto 200 or both.
2.	Failure to supply information asked or Giving false in formation	Imprisonment upto 6 months or fine upto`200orboth.
3.	Attempting or committing or abetting Commission of any offence.	Imprisonment upto 6months or fine Upto `200 or both.
4.	The connivance of offences by owners or occupiers of land.	Imprisonment upto 6months or fine upto 500 or both.
5.	Vexatious search, seizure etc .by Excise Officer.	Fine upto 2000 for every offence.
6.	Failure of Excise Officer on duty.	Imprisonment upto 3 months or fine upto 3 months pay or both.

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7.	Improper maintenance of stocks or accounts.	Fine upto 100.
8.	Making false entries or tearing pages from Stock book.	Fine upto `2000 and goods liable to confiscation.
9.	Sale of dutiable goods otherwise than in prescribed containers bearing the labels.	Fine upto`1000 and goods liable to confiscation.
10.	Failure to furnish proof of export within specified period.	Fine upto`2000.

V. DOCUMENTATION

(A) Batch Formula Record

Also known sometimes as the Batch Production Record, this is an approved copy of the MFR for each batch of product being processed, in which data has been filled in during processing of the batch. It contains details of location where production is done, data entries, names of operators making the entries and their signatures with dates, supporting data records (such as cleaning records, equipment calibration details, in-process and final quality control test reports etc.).The BMR bears details of the unique batch number assigned to that particular batch. This information must be recorded in a log book along with date on which batch number is allotted, the identity of the product and the batch size.[6]

Contents of BMR

- Name of the product.
- Date and time of commencement and completion of important stages in the processing.
- Name of persons responsible for each critical stage, with initials of operators handling each operation and persons who checked these operations.
- Name and quantities of each raw material actually weighed with the batch number from which the material was drawn (including details of any re-processed materials added).
- Major equipment used in the processing.
- Results of readings for critical processing parameters.
- Details of samples drawn.
- In-process testing reports
- Actual yield obtained at critical phases.
- Any deviations from procedure, with signatures to authorize the deviations; their evaluation and investigation if conducted.
- Packaging material and label description, with representative material attached.
- Results and reports of QC testing of final product for approval of the batch.
- Statement about decision taken regarding approval or rejection of the batch along with the date, and name and signature of person making this decision.[6]

(B) Master Formula Record

Master Formula Record (MFR)

A Master Formula Record is defined as an approved master document, with instructions of how the entire manufacturing process must be performed for each batch size of each

product to be manufactured. This document ensures that there is uniformity across batches of the same product. The MFR must be prepared, signed and dated by one competent individual, and independently checked, signed and dated by another competent person in the quality department. All processing of a given batch must proceed as per its MFR.

Contents of MFR:

- Name of product, its strength and dosage form description.
- Name and measure/weight of each active ingredient per dosage unit or per unit weight or per measure of drug product.
- Statement of total weight or measure of a dosage unit.

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- List of component names and their weight or measure using same weight system.
- Statement of theoretical weight or measure where necessary in the processing phase.
- Statement of theoretical yield with minimum and maximum percentage of yield acceptable beyond which there must be an investigation of the process.
- Description of containers, closures and packaging materials to be used for the drug product packing. Specimen or copy of each label/labelling material with date and signature of authorized person who has approved the labelling.
- All manufacturing and control instructions in detail.
- Procedures for sampling and testing.
- Specifications for raw materials, intermediates and finished products.
- Instructions for storage of intermediates and finished products. Special notations and precautions to be observed.[7]

	Pharmaceutical Guidelines **Delhi, India** **Batch Manufacturing Record**		Page No. 1 of 16
Product	: Atorvastatin Tablets IP 40 mg	**B.M.R. No.**	XX/XXX/000
		B.M.R Revision No./ Date	00/ddmmyyyy
Batch Size	: 2,00,000 Tablets	**Ref. M.F.R. No**	XX/XXX/000
Batch No.	: XXXXX/XX	**M.F.R. Revision No. & Date**	00/ddmmyyyy

Batch Quantity	: 35.00 kg.	**COMPOSITION:** **Each Film Coated Tablet contains:** Atorvastatin Calcium IP Equivalent to Atorvastatin ------ 40 mg Color :Titanium Dioxide IP	
Reworking Added (If any)	:		
Theoretical Yield	:		
Mfg. Date:		Exp. Date:	
Document issued by: Date:		Document Received by: Date:	
This Document Supersedes	: None		
Reason for Change	: New		
Mfg. Licence No.	: XXXX/XX/XXXX	Material code No. - XXXXXXXX	
Shelf Life	: 36 Months or expiry of active ingredient whichever is less.		
Storage Condition	: Store in cool, dry & dark place.		
Marketed by	: XYZ Pharmaceuticals Ltd.		
Serial No.	:		

	Granulation	Compression	Coating
Date of Commencement:			
Date of Completion:			
Area Used:			
Previous Product Processed:			
Batch No:			
Checked by Pharmacist: Date:			

This batch has/has not been completed according to the instructions given in M.F.R. No. XX/XXX/00. Deviation sheet attached: Y/N	
Actual Yield:_____Tablets Reworking Generated:_____Kg. Total Yield: _____%	Date of Packing: Quantity:
Final BMR Checked By: Date:	Final BMR Checked By: Date:

Prepared By	**Checked By**	**Reviewed By**	**Approved By**
Quality Assurance	**Production**	**Production Head**	**QA & QC Head**
Date:	**Date:**	**Date:**	**Date:**

(C) Quality Audit

Audits serve to verify if the production and control systems are operating as intended. They help to uncover problem areas and thus, allow the timely correction of issues. Regular audits help to provide confidence that the organization is functioning under effective control. Audits performed in problem situations such as product recall or repeated market complaints is useful to identify non-compliance with cGMP and to drive initiatives to take the necessary corrective actions.[8]

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Audit Types:

Quality audits may be of three types - internal audits or self-inspections, external audits for contract manufacturing/testing and regulatory audits performed by regulatory bodies.

Internal audits are done by auditors within the company to assess cGMP compliance, identify problem areas and take corrective action, and to prepare for audits by regulatory bodies.

External audits are carried out by a company at the sites of its vendors or contract manufacturers or testing laboratories. This type of audit helps to assess if the outside party understands the contract-giver's requirements and adheres to the quality system to reduce failure risk.

Regulatory audits are performed by regulatory bodies to check for adherence to statutory requirements. These audits are a must to ensure data quality and integrity in respect of products that seek regulatory approva[9]

(D) DISTRIBUTION RECORDS

Batches are released for distribution by the QC department only after thorough testing and approval. The warehousing department must maintain records of batches released for distribution in a systematic manner. For every batch of product, it is important to maintain distribution records in sufficient detail to be able to trace to which places the product has been sent. This is critical in the event of a problem with the product batch that necessitates a product recall from the market. Some of the important details required include:

- Name of the product, its strength, and description of dosage form.
- Batch number/lot number of shipped product.[10]

(E) HANDLING RETURNED GOODS

Once a product recall has been initiated, the process must be monitored to ensure that the recall is completed within the stipulated timeframe. A check must be performed to evaluate the effectiveness of the recall. Following this, an investigation must be carried out to study the reason for the recall and remedial action must be worked out to ensure the defect does not recur.

When stock of recalled drugs is received, it must be placed under quarantine, in a segregated place, with no chance of being mixed up with other products. Entry to this area must be restricted to authorized personnel only. Samples must be drawn and testing performed to identify the root cause of the defects.

Once this has been established, corrective and preventive actions (CAPA) must be drawn up and implemented.

Based on the results of the investigation, the defective product may be re-processed or destroyed after due authorization. Generally, reprocessing is permitted only if it is sure to produce a product that will meet the same quality requirements after the re-working. Reprocessed batch details must be carefully monitored throughout their shelf life and the records must indicate the identity as a reprocessed batch.[11]

(F) WASTE DISPOSAL

Pharmaceutical industry generates a lot of waste during the manufacturing and testing of drugs. It is important to ensure that this waste is appropriately treated to prevent it from polluting the environment.

According to the provisions of cGMP under Schedule M of the Drugs & Cosmetics Act,

1. Sewage and effluents from a pharmaceutical manufacturing unit must conform with regulations of the Environment Pollution Control Board.
2. All bio-medical waste destruction should proceed in keeping with the provisions of. The Bio-Medical Waste (Management and Handling) Rules, 1996.
3. Rejected drugs must be stored and disposed with extra care to prevent them from getting mixed up with stock meant for distribution.
4. Waste disposal records shall be maintained.
5. Materials awaiting disposal must be stored in a safe way to avoid their misuse, and also to prevent any cross-contamination or mix-ups.[11]

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VI. COSMETIC INGREDIENT

1	**Allatonin**	**Skin Smoothening**	**Comfrey (Fm. Boraginaceae)**	**Soft cleansing emulsion**
2	**Aloe vera**	Softens skin	aloe vera (FM Asphodebceae)	Lotus herbal moisturizers
3	**Alpha. hydroxy acids(AHA)**	Exfoliates and improves circulation	Fruit acids (glycolic acid, lactic acid, citric acid, tartaric acid, pyruvic acid, maleic acid, etc.	Garnier anti wrinkle preparation
4	**Arnica**	Astringent & soothing	Arnica montane (Fm. Asteraceae)	Arnica herbal cream
5	**Arjunolic extract**	Antioxidant and antiinflammatory	Terminalia arjuna (Fm. Combretaceace)	Himalaya Arjuna
6	**Beta hydroxyl acids (BHA)**	Antibacterial	Salicylic acid (Salix alba)	Oxymed shampoo
7	**Beta-Carotene**	Minimizes lipid peroxidation and cellular antioxidant	Carrots and tomatoes (Fm Umberlliferae, Solanacea)	Environ body cream
8	**Boswellia**	Anti-inflammatory and anti aging	Boswellia serrata (Fm. Burseraceae)	Aroma silk boswelia antiwrinkle cream
9	**Calendula.**	Soothes, softens skin, and promotes cell formation.	Calendula officinalis (FM Asteraceae)	Weleda calendula paste
10	**Centella**	Skin conditioning agent increases collagen production, improves texture and integrity of skin, and reduces Appearance of stretch marks.	Centella asciatica (Fm. Mackinlayaceae)	Keratin complex
11	**Coleus forskoflii oil**	Antimicrobial aromatherapy/perfumer	Coleus sps.	Ayush neem plus
12	**Coriander seed oil**	Anti-inflarnmatory and anti-irritant, skin. lightening properties	Coriandrum sativa (Fm.Umbelliferae)	Tcc collagen complex
13	**Cucumber Cools res**	Refreshes, and tightens pores	Cucumis sativus (FM Cucurbiceae)	Eminence eye makeup remover
14	**Dry extract from yarrow**	Treatment of oily hair.	Achillea millefolium (Fm. Asteraceae)	Juniper yarrow moisturizer
15	**Essential fatty acids**	Smoothens,moisturizes and protects	Linolenic acids and arachidonic acid	Parachute hair oil

[13]

VII. GOOD MANUFACTURING PRACTICE (GMP) FOR COSMETICS

The Federal Food, Drug and Cosmetic Act prohibits the introduction or delivery for introduction into interstate commerce of cosmetics that are adulterated or misbranded (Sec. 301).

A cosmetic may be deemed adulterated (Sec. 601) for essentially four reasons, namely:

1. It may be injurious to users under conditions of customary use because it contains, or its container is composed of, a potentially harmful substance.

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2. It contains filth.
3. It contains a non-permitted, or in some instances non-certified, color additive.
4. It is manufactured or held under insanitary conditions whereby it may have become injurious to users or contaminated with filth.

A cosmetic may be deemed misbranded (Sec. 602) for reasons of:

1. False or misleading labelling.
2. Failure to state prominently and conspicuously any information required by or under authority of this act.
3. Misleading container presentation or fill.

To determine whether cosmetic firms manufacture, hold or deliver for introduction into interstate commerce cosmetics that are adulterated or misbranded, and to prevent these and other practices violating Sec. 301 of the FD&C Act, the law gives the agency the authority to enter the establishments of such firms and inspect their facilities as well as all pertinent equipment, finished and unfinished materials, containers and labeling therein. See Sec. 704(a) of the FD&C Act[14].

VIII. GUIDELINES

8.1 Building and Facilities.

a. Buildings used in the manufacture or storage of cosmetics are of suitable size, design and construction to permit unobstructed placement of equipment, orderly storage of materials, sanitary operation, and proper cleaning and maintenance.

b. Floors, walls and ceilings are constructed of smooth, easily cleanable surfaces and are kept clean and in good repair.

c. fixtures, ducts and pipes are installed in such a manner that drip or condensate does not contaminate cosmetic materials, utensils, cosmetic contact surfaces of equipment, or finished products in bulk.

d. lighting and ventilation are sufficient for the intended operation and comfort of personnel.[15]

8.2 Equipment

a. Equipment and utensils used in processing, holding, transferring and filling are of appropriate design, material and workmanship to prevent corrosion, build up of material, or adulteration with lubricants, dirt or sanitizing agent.

b. Utensils, transfer piping and cosmetic contact surfaces of equipment are well-maintained and clean and are sanitized at appropriate intervals.

c. Cleaned and sanitized portable equipment and utensils are stored and located, and cosmetic contact surfaces of equipment are covered, in a manner that protects them from splash, dust or other contamination.[15]

8.3 Personnel

a. The personnel supervising or performing the manufacture or control of cosmetics has the education, training and/or experience to perform the assigned functions.

b. Persons coming into direct contact with cosmetic materials, finished products in bulk or cosmetic contact surfaces, to the extent necessary to prevent adulteration of cosmetic products, wear appropriate outer garments, gloves, hair restraints etc., and maintain adequate personal cleanliness.[15]

8.4 Raw Materials

a. Raw materials and primary packaging materials are stored and handled in a manner which prevents their mix-up, contamination with microorganisms or other chemicals, or decomposition from exposure to excessive heat, cold, sunlight or moisture.

b. Containers of materials are closed, and bagged or boxed materials are stored off the floor.

c. Containers of materials are labeled with respect to identity, lot identification and control status.[15]

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8.5 Production

Check whether manufacturing and control have been established and written instructions, i.e., formulations, processing, transfer and filling instructions, in-process control methods etc., are being maintained. Determine whether such procedures require that:

- **a.** The equipment for processing, transfer and filling the utensils, and the containers for holding raw and bulk materials are clean, in good repair and in sanitary condition.
- **b.** Only approved materials are used.
- **c.** Samples are taken, as appropriate, during and/or after processing, transfer or filling for testing for adequacy of mixing or other forms of processing, absence of hazardous microorganisms or chemical contaminants, and compliance with any other acceptance specification.[11]

8.6 Laboratory Controls

- **a.** Raw materials, in-process samples and finished products are tested or examined to verify their identity and determine their compliance with specifications for physical and chemical properties, microbial contamination, and hazardous or other unwanted chemical contaminants.
- **b.** Reserve samples of approved lots or batches of raw materials and finished products are retained for the specified time period, are stored under conditions that protect them from contamination or deterioration, and are retested for continued compliance with established acceptance specifications.[15]

8.7 Records

Check whether control records are maintained of:

- **a.** Raw materials and primary packaging materials, documenting disposition of rejected materials.
- **b.** Manufacturing of batches, documenting the:
- **c.** Kinds, lots and quantities of material used.
- **d.** Processing, handling, transferring, holding and filling.
- **e.** Sampling, controlling, adjusting and reworking.
- **f.** Code marks of batches and finished products.
- **g.** Finished products, documenting sampling, individual laboratory controls, test results and control status.
- **h.** Distribution, documenting initial interstate shipment, code marks and consignees.[8]

A. ICH Guidelines for Stability

It provided at the time of applying to guidelines revision Q1A(R2) has been adopted registration process for the EU. This regions will not to the patients. The stability testing data must provide information about how the drug molecule changes over time under different storage conditions. This gives insight into how light, heat and humidity will influence the chemical nature of the product. Drugs which are unstable will need specific storage conditions if they have to remain effective. Therefore, it is vital to perform stress testing to study and document the conditions that lead to degradation of the drug molecule. This information is used to arrive at the shelf life of the drug and what conditions will be optimal for storage of the product.[8]

Types of Stability Testing

1. Real-time testing: This involves testing drug product for a longer duration to find out what is the maximum product degradation when stored as recommended.
2. Accelerated stability testing: Here, product is subjected to stress in the form of higher temperatures, moisture, agitation, light, pH, and packaging conditions to study its degradation profile.
3. Retained sample stability testing: This is testing of samples retained from each batch that has been sent into the market.
4. Cyclic temperature stress testing: Not routinely used. It involves subjecting the products to temperature stresses in a way to mimic likely market storage conditions.[16]

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Sr. No.	ICH Guideline Code	Title
1.	Q1A	Stability testing of new drug substances and products
2.	Q1B	Stability testing : Photostability testing of new drug substances and products
3.	Q1C	Stability testing of new dosage forms
4.	Q1D	Bracketing and matrixing design for stability testing of drug substances and products
5.	Q1E	Evaluation of stability data
6.	Q1F	Stability data package for registration applications in climatic zone III and IV
7.	Q5C	Stability testing of biotechnological/biological products

IX. HAIR COSMETIC

Hair is an integrated system with a peculiar chemical and physical behavior. It is a complex structure of several morphological components that act as a unit. The hair shaft of mammals is divided into three main regions: Cuticle, cortex and medulla. The medulla is present in corser hair like grey hair, thick hair and beard hair, and it is absent in fine hair of children.[16]

9.1 Hair Damage

The hydrophobicity of the hair is possible thanks to the 18-MEA lipid layer. Removal of this covalently linked fatty acid renders the fiber hydrophilic. When wet, virgin hair can be stretched by 30% of their original length without damage; however, irreversible changes occur when hair is stretched between 30% and 70%. Stretching to 80% causes fracture.[4] Hair is porous and damaged hair is intensely so. Water absorption causes the hair shaft swelling. Excessive or repeated chemical treatment, grooming habits, and environmental exposure produce changes in hair texture and if extreme can result in hair breakage.

9.2 Shampoos

Shampoos are not only scalp cleaners, but indubitably act as preventing the hair shaft damage. Many scalp diseases are also treated by active ingredients that are added to the shampoo's formulations. It is desirable that whatever may the disease or condition be (dermatitis, seborrhea, alopecia, psoriasis), the hair strands are kept aesthetically presentable, preserving its softness, combability and shine while treating the scalp.

Shampoos are typically composed of 10–30 ingredients although products with as few as four ingredients are available. The products are grouped into:

- Cleansing agents;
- Additives that contribute to the stability and comfort of the product;
- Conditioning agents, intended to impart softness and gloss, to reduce flyaway and to enhance disentangling facility, and
- Special care ingredients, designated to treat specific problems, such as dandruff and greasy hair.[16]

9.3 Surfactants

Surfactants are cleaning agents that substituted soap. They act through the weakening of the physicochemical adherence forces that bind impurities and residues to the hair. Surfactants dissolve these impurities, preventing them from binding to the shaft or the scalp. The cleansing ability of a shampoo depends on how well it removes grease as well as the type and amount of surfactants used.

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9.4 Silicones

Silicones are hybrid (inorganic-organic) inert, heat-resistant and rubber-like polymers derived from crystal quartz. Silica (silicon dioxide) common in sandstone, beach sand, and similar natural materials, is the initial material from which silicones are produced.

Dimethicone is the most widely used silicone in hair care industry, and entropy is important for its adsorption to the hair surface.

9.5 Other Substances: Mineral and Vegetable Oils

There are few articles published about the effect of mineral and vegetable oils on human hair. The main physical property of this class of ingredients is the hydrophobicity of the oil. Saturated and monosaturated oils diffuse into the hair much better than polyunsaturated oils. Oils play an important role in protecting hair from damage.

9.6 Diffusio into Keratin Fibers

There are two main ways for a substance to penetrate the hair fiber: Transcellular and intercellular diffusion, transcellular diffusion envolves epicuticle, A-layer, exocuticle, endocuticle and is much harder path way because of the high cross-linked regions.

9.7 Leave-On Conditioners

Creme rinses basically contain cationic surfactants, long-chain fatty alcohol or other lipid components. Cationic polymers are the also used, such as polyquaternarium-10. Some examples that we can find among the ingredients are ceremonious chloride and stearalkonium chloride. Examples of lipids are acetyl alcohol, steady alcohol or silicones such as dimethicone.[16]

9.8 African Hair and Curly Hair

Afro-ethnic hair presents variation of diameter at several points along the thread (the diameter at twisting points is smaller than at other areas), less water content, and most importantly, an ellipsoid shape. Hair fibers present torsions at many regions along the thread, while Caucasian hair has a cylindrical cross-section.

9.9 Hair Strength

Patients want their hair to be resistant to breakage with no split ends. Hair strength is a mix of hair body mass and resistance to breakage. A strong hair is a hair with its full capacity of growing healthy in both diameter and length and an intact cuticle and cortex.

9.10 Cosmetics for Thin Hair

Prescription medications are often focused on improving scalp hair density. Dermatologists are very used to prescribe monoxide and finasteride in order to stimulate the anagen hair phase. But it is not always possible to obtain terminal thick hair fiber.

9.11 Considerations about the Hair Washing and Grooming Procedures

Shampoo must aim the scalp more than a hair. The entire scalp has to be rubbed with the shampoo from the front to the back, and small amounts of shampoo have to be applied on each region of the head under the hair. Appling the shampoo on the top of the head will increase hair friction and cause hair tangling. After full rinse of the shampoo, the hair must be gently towel dried, and the conditioner should be applied on the hair length avoiding the scalp. The conditioner has to be completely rinsed out.

9.12 Hair Straighteners

Historically, the first hair straightener procedure was used for African hair and consisted on applying petrolatum based oils on the hair combined with hot irons or hot combs pressed to the hair so the device could slide easily and straighten the tresses.

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9.13 Damage by Heat

Thermal treatments produce decomposition of tryptophan residues to kynurenine type oxidation products. The consequences are yellowing of white hair and darkening of bleached hair. After the thermal treatment with the addition of lipid products, hair may seem to be easier to comb. However, after shampooing and removing the lipids, hair dries out exposing the damage caused by excess of heat.[16]

9.14 Hair Cosmetics Reaction

Reactions to cosmetic ingredients in decreasing order of frequency are: Fragrances, hair-colouring agents (p-phenylenediamine) preservatives: Formaldehyde, parabens, quaternium-15 (a formaldehyde donor); imidazolidinyl urea; DMDM hydantoin. Most of the cases are caused by leaving on products. Short contact cosmetics usually do not cause irritation or allergy. Van Lerberghe and Baeck described an acute oozing eczema of the scalp, forehead, and neck, and important edema of the eyelids The patient had performed a hair-smoothing treatment the day before, using a product (INOAR Moroccan Hair Treatment containing formaldehyde that had been bought in Morocco by her hairdresser. The patch test was positive to formaldehyde and nonformaldehyde ingredients (++).

9.15 Henna

Red henna is the dried and powdered leaf of Lawsonia inermis. Henna has been used as a dye for the skin, hair and nails.

9.16 Hair Dyes

There are many types of hair dyes classified according to the penetration of the dye to the surface or to deep parts of the hair shaft. In this chapter, we will approach the two most used types of hair dyes: Demi-permanent and permanent dyes.

9.17 Hair Straightening and Hair Dyes

Chemical hair straighteners are highly alkaline. For this reason, changing the color of a chemically straightened hair, either with hydroxides or with thioglycolate, is a delicate procedure that may cause hair damage and breakage.

Safety Of Hair Dyes

Epidemiologically and human monitoring studies have not detected any risk of carcinogenity of the ingredients used nowadays. Contact dermatitis is the main reaction.

X. HANDS ON INSTRUMENT

10. 1SOP for Texture Analyzer

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Standard Operating Procedures for Texture Analyzer TA-XTPlus

Turn on the instrument by flipping the switch located at the left rear corner.

1. Turn on the computer, click "User" to log on to the computer, then initiate the software "Exponent."
2. In the "Select a User Screen," choose "FNH 325", then click "OK".
3. A warning page will pop up, click "Yes" to continue.
4. The "Tip of the day" box will also pop up, click "OK" to continue.
5. Close the "Application Guide" screen, unless you are unsure what application to use for your products, in which case you should go through the guide.
6. To calibrate Force:
   - Install the appropriate probe of interest
   - Go to the "T.A." tab, click "Calibrate" then select "Calibrate Force."
   - Follow the instructions to place the appropriate calibration weight (2 kg) on the calibration platform, ensure that the calibration weight was also set to 2000 g, then click "next."
   - When the calibration is complete, click "finish" and remove the weight off the platform.
7. To calibrate Height
   - Go to the "T.A." tab, click "Calibrate" then select "Calibrate Height."
   - The probe will be lowered until it touches the plate and returns.
   - When the calibration is complete, click "ok."
8. To set the profile for texture analysis:
   - Go to the "T.A." tab, click "T.A. Settings."
   - Click on the "Library" button and choose a T.A. Sequence appropriate for your experiment.
   - For a simple compression test, select "1. Return to start" then click "OK."
9. To run a test:
   - Place your sample on the platform, go to the "T.A." tab and click "Run a Test."
   - If you have to move the probe up and down to fit your samples, toggle the up or down arrow button.
   - Name your file and choose an appropriate folder to Toanalyze a graph:
   - Go to the "Process Data" tab and select "Quick Calculation."
   - Check off any parameters of interest then click "OK."
   - The results will automatically[17]

XI. SOP BROOKFIELD FOR VISCOMETER

1. Install the proper spindle on the apparatus (#2 or #4).
2. Level the viscometer so the reading is zero (bubbles in circle should be centered)
3. Immerse the spindle into the samples. Note: Minimum level has to cover the dented.
4. To start, push the bar down and turn on the viscometer. As it starts to spin, let go of the bar.
5. The reading can be taken where the red line reads.
   Note: The hexagonal knob can be used to adjust the speed of the reading display.
6. After use, turn off.
7. Clean spindle properly, uninstall and place on the spindle rack.[18]

Brookfield Viscometer

XII. TABLET PUNCHING MACHINE

A tablet press is a mechanical device that compresses powder into tablets of uniform size and weight. A tablet press can be used to manufacture tablets of a wide variety of materials, including pharmaceuticals, nutraceuticals, cleaning products, industrial pellets and cosmetics. To form a tablet, the granulated powder material must be metered into a cavity formed by two punches and a die, and then the punches must be pressed together with great force to fuse the material together.

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Checks and Precautions – Compression Machine:

Ensure that die locking screws are not loose it may lead to accident.
Ensure that punches are freely moving in the dies and cam tracks.
Set the force feeder/ feed frame of the compression machine in such a manner to avoid friction with the turret.
Wear the secondary over gowning before starting the operation.
Do not clean the compression machine in the running condition.
Do not leave any granules in the hopper in case of a stoppage of the compression machine for the undue period and at the shift end.[19]

XIII. CAPSULE FILLING MACHINE

- Place the empty capsule loaded plate on base plate and lock the capsule body in the machine with the help of hand lever to separate the cap and body cap will remain on the loader plate.
- Push the handle at lower side to lift the capsule loading plate from base plate. Remove it and keep
- Release the capsule body by unlocking the lever and place the hopper on the base plate of the machine.
- Load the weighed quantity of blend and fill in the body with the help of scraper.
- If required, press the blend through pin plate and fill the remaining blend in body. Repeat this procedure till blend is evenly filled in the body of capsule.
- Remove the hopper and fix the capsule loading plate with cap.
- Bring the pressing plate on the capsule loading plate and lock it by the locking lever. Turn front knob in clockwise direction and press the handle to lock the capsules properly.
- Check that capsules are locked properly and evenly.

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- Unlock and lift the pressing plate. Turn front knob in anticlockwise direction and remove capsule loading plate by pressing the handle.
- Collect the filled capsules in drum with polythene bag.
- After completion of filling, dismantle the machine and clean as per cleaning SOP No.: PDN/CLN-032.[20]

Capsule filling machine are of two types;

- Automatic
- Semi-automatic

Semi automatic capsule filling machine

XIV. SPRAY DRYER

1. Mix feed solution in tank(s) located behind the spray dryer. Verify that the feed tank valves remain closed until you are ready to run.
2. Set (open) valves on feed tanks to feed stock solution to pump as desired.
3. Open pump petcock valve until feed stock flows out of valve, then close the valve.
4. If feedstock does not flow out of the pump valve, contact the lab manager.
5. Using a wrench or pliers, open the main gas pipe valve ½ turn so that the valve headpiece is in line with the pipe. The valve is located on the rear of the spray dryer.
6. Turn on the Omega HH509R thermometer located on the front of the spray dryer.
7. Open the main air supply valve located on the right side of the dryer ½-1 turn.
8. Set the air pressure regulation to 20 PSI. The air pressure regulator is located on the lower front panel. You may adjust the air pressure as required as you fine-tune your operating parameters. The airflow rate may be adjusted using the needle valve on the airflow rotometer. The units are SCFH
9. Open the liquid flow valve located on the base of the liquid flow rotometer on the front of the dryer.
10. Turn on the main power switch located on the upper left of the control panel.
11. Verify that the Baldor Drive Controller (VS1MD) displays 0.00.

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12. Verify that the FWR and STP/FLT indicator lights are on and that the PROG and RUN lights are off.
13. If the PROG light is on do not proceed, contact the lab manager.
14. Note that when adjusting the speed setting on the VS1MD, you must push firmly and hold the increment/ decrement arrow buttons in order for the setting to change.
15. Firmly press and hold the down arrow on the VS1MD, if the numbers on the display start to decrease hold the down arrow until the display reads 0.00. If the display reads 0.00 when the down arrow is held down, proceed to the next step.[21]

XV. HOMOGENIZER

Guidelines for Use

1. Different types of tissue require different speeds and times. Ensure the conditions for your sample are appropriate.
2. Maximum and minimum volumes for the unit should be followed at all times.
   Maximum _____
   Minimum _____
3. Consider the appropriate sample-to-solvent ratio. It is preferable to use the smallest sample volume and the smallest container
4. possible, which increases the sample exposure to the generator.
5. Samples should be approximately the same size as the generator diameter. Some initial fragmentation may be required to achieve this.
6. It may be preferable to run the motor in short bursts (~15 seconds) rather than for an extended time.[14]

Maintenance

1. Thorough cleaning is necessary after each use. Either run at low speed in water for a few minutes, or, with motor off, rinse with water.
2. If homogenization is done in organic solvents, rinse as above when finished.
3. Motor brushes should be checked after 100 hours of operation, or as recommended.

XVI. PREPARATION OF HERBAL SHAMPOO

Shampoos are most probably used as cosmetics. It is a hair care product that is used for cleaning scalp and hair in our daily life. Shampoos are most likely utilized as beautifying agents and are a viscous solution of detergents containing suitable additives preservatives and active ingredients. It is usually applied on wet hair, massaging into the hair, and cleansed by rinsing with water. The purpose of using shampoo is to remove dirt that is build up on the hair without stripping out much of the sebum. Many synthetic shampoos are present in the current market both medicated and non medicated; however, herbal shampoo popularized due to natural origin which is safer, increases consumer demand and free from side effect. In synthetic shampoos, surfactants (synthetic) are added mainly for their cleansing and foaming property, but the continuous use of these surfactants leads to serious effects such as eye irritation, scalp irritation, loss of hair, and dryness of hairs. Alternative to synthetic shampoo we can use shampoos containing natural herbals. However, formulating cosmetic products containing only natural substances are very difficult. There are a number of

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medicinal plants with potential effects on hair used traditionally over years around the world and are incorporated in shampoo formulation. These medicinal plants may be used in extracts form, their powdered form, crude form, or their derivatives. To develop a shampoo containing an only one natural substance which would be safer with milder effect, then the synthetic shampoo is difficult and also it should possess good foaming, detergency, and solid content as such synthetic shampoo. Hence, we considered in detailing an unadulterated natural cleanser utilizing conventional technique using regularly utilized plant material for hair washing.[22]

Methods

Preparation of extract

About 100 g of each powdered plant materials, namely H. rosa-sinensis, E. officinalis, A. concinna, S. indica, E. prostrate, A. Barbadensis, and C. auriculata, were homogenized.The powdered material was extracted with distilled water by boiling for 4 h. The extract of each plant material was separated and evaporated.[22]

Formulation of Herbal Shampoo

Formulation of the herbal shampoo was done as per the formula given. To the gelatin solution (10%), added the herbal extract and mixed by shaking continuously at the time interval of 20 min. 1 ml of lemon juice was also added with constant stirring. To improve aroma in the formulation, sufficient quantity of essential oil (rose oil) was added and made up the volume to 100 ml with gelatin.[21]

Materials required	Quantity to be weighed
Soap nut extract	0.5 g
Amla extract	0.5 g
Shikakai extract	0.5 g
Hibiscus	0.5 g
Bhringraj extract	0.5 g
Senna extract	0.5 g
Aloe vera	1 g
Gelatin	q.s
Lemon juice	q.s
Rose oil	q.s

Table 1: Ingredients of herbal shampoo

Evaluation of herbal shampoo

S. No.	Common name	Pictures	Botanical name	Parts used	Category
1	Hibiscus		*Hibiscus rosa-sinensis*	Flower	Conditioning agent
2	Amla		*Emblica officinalis*	Fruit	Anti-dandruff agent
3	Shikakai		*Acacia concinna*	Powder	Detergent
4	Soapnut		*Sapindus indica*	Fruit	Detergent
5	Cassia		*Cassia auriculata*	Leaves	Anti-dandruff agent
6	Bhringraj		*Eclipta prostrata*	Leaves, flower	Hair growth
7	*Aloe vera*		*Aloe barbadensis*	Leaf	Coolant

Table 2: Description of the ingredients of herbal shampoo

The prepared formulation was evaluated for product performance which includes organoleptic characters, pH, characterization, and for physicochemical solid content. To guarantee the nature of the items, particular tests were performed for surface tension, foam volume, foam stability, and wetting time using standard protocol.[22]

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Visual Assessment

The prepared formulation was assessed for color, clarity, odor, and froth content. pH determination The pH of the prepared herbal shampoo in distilled water (10% v/v) was evaluated by means of pH analyzer at room temperature [22]

Determination of Solid Content Percentage

The percentage of solid substance was determined by weighing about 4 g of shampoo in a dry, clean, and evaporating dish. To confirm result, the procedure was repeated again. The liquid portion of the shampoo was evaporated in a dish by placing on hot plate. The percentage and the weight of the solid contents present in the shampoo were calculated after drying completely .[22]

Surface Tension Measurement

The prepared shampoo in distilled water (10% w/v) was evaluated for surface tension using stalagmometer in room temperature.

Testing of Wetting

Wetting time was calculated by noting the time required by the canvas paper to sink completely. A canvas paper weighing 0.44 g was cut into a disc of diameter measuring 1-inch. Over the shampoo (1% v/v) surface, the canvas paper disc was kept and the time taken for the paper to sink was measured using the stopwatch.[21]

Foam Stability Test

The stability of the foam was determined using cylinder shake method. About 50 ml of formulated shampoo (1%) solution was taken in a graduated cylinder of 250 ml capacity and shaken for 10 times vigorously. Foam stability was measured by recording the foam volume of shake test after 1 min and 4 min, respectively. The total foam volume was measured after 1 min of shaking.

Dirt Dispersion Test

To 10 ml of refined water two drops of cleanser were included and taken in a wide-mouthed test tube. To the formulated shampoo, added one drop of Indian ink and shaken for 10 min after closing the test tube with a stopper. The volume of ink in the froth was measured and the result was graded in terms of none, slight, medium, or heavy .

Conditioning Performance Evaluation

An artificial hair tress of Indian women was received from a salon and divided into two swatches of length 10 cm approximately, weighing 5 g. The control swatch was the one without washing and the test swatch using the formulated shampoo was washed with. Each tress was added for 2 min to the combination of shampoo in water in the proportion 10:15 taken in a conical flask and washed using 50 ml of distilled water. Each tress was air dried at room temperature and the procedure was repeated for maximum of 10 times. The conditioning effect of the prepared shampoo in terms of softness and smoothness was determined using a blind touch test using volunteers of student 20 numbers selected randomly [17]. The conditioning performance of the shampoo was rated in terms of Score 1–4 (4 - excellent, 3 - good, 2 - satisfactory, and 1 - poor) by asking all the selected students to touch the tress washed with prepared shampoo.[22]

XVII. RESULTS

Herbal Shampoo Formulation

The shampoo was formulated by admixing the equal amount of the aqueous extracts of all the ingredients with soapnut (Table 1). The above plant extract contains phytoconstituents like saponins which is a natural surfactant having detergent property and foaming property. An ideal shampoo must have adequate viscosity and many natural substances possess good viscosity. The gelatine solution (10%) behaves as a pseudo plastic forming clear solutions. Lemon juice (1 ml) added to the shampoo serves as anti-dandruff agent, natural antioxidant, and chelating agent and maintains the acidic pH in the formulation.

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Evaluation of Formulated Shampoo

Physical Appearance

The prepared shampoo showed good characteristics in terms of foaming effect and appearance on the visual inspection of the formulation. The results are shown in Table

pH

The pH of the prepared solution of shampoo using distilled water (10%) was evaluated at 25°C temperature. For enhancing and improving the hair quality, pH of the shampoo is very important and also for stabilizing the scalp and minimizing irritation to the eyes [18]. For minimizing the damage of hair using shampoo, one of the ways in the present trend is to develop shampoos having lower pH value. Lowering of pH (mild acidity) promotes tightening of the scales and prevents swelling, thereby producing sheen. The results are presented in Table 2.

Solid Content

Shampoo with high solid content will be very difficult to rinse and hard to work with the hair. The prepared shampoo contains 23.25% of solid content. Thus, they considered easy to wash out when having less solid content during preparation of shampoos.

Surface Tension

The surface tension reduction in the prepared shampoo was found to be of about 35.18 dynes/cm. One of the mechanisms in the detergency property is the lowering of surface tension, and this will be the marker for a good detergency effect of the shampoo which could be done by reducing the surface tension of water from 72.8 dynes/cm to the surface tension of water 32–37 dynes/cm.

Wetting Time

To test the efficacy of the shampoo, wetting ability of a surfactant needs to be calculated which depends on the concentration of surfactant. For the evaluation of wetting ability of the shampoo, canvas disc method is used which is an efficient, quick, easy, and reliable method. The prepared shampoo shows the wetting time of the about 120 s. The maximum of wetting time shows that the shampoo contains lower amount of detergents.The mean score based on the opinion given by the volunteers from student population (n=20) on the conditioning effect of the shampoos on the selected tresses. Score 1 - poor, Score 2 - fair, Score 3 - good, and Score 4 – excellent[22]

Foaming Ability and Foaming Stability

From the consumer point of view, foam stability is one of the important needs of a shampoo. Important parameter that was considered in the shampoo evaluation was determination of foaming stability. The foam volume produced by the formulated shampoo is above 50 ml. The prepared shampoo generates uniform, small sized, compact, denser, and stable foam. The foam volume remains same throughout the period of about 5 min showing that the generated foam by the shampoo has good stability and the prepared shampoo exhibits higher foam property which may be due to the presence of both shikakai and soapnut.

Dirt Dispersion Test

In the dirt dispersion test using Indian ink, the volume of ink in the froth was measured and the result was graded as none, light, moderate, or heavy.[22]

Net Content

Before starting the experiment, outside of the bottle was marked at the surface level of liquid, and then at the end of the experiment, the volume of water required to fill it up to the mark was noted. If the formulated materials are paste or solid forms, then the materials were placed in an open can with the frozen material taking the weight of the container and the net content was noted.[22]

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Conditioning Performance

Based on the conditioning performance of the prepared shampoo, the average value reported by the student is given in Table 4. The score of conditioning performance of the control tress (without washing) was found to be 1.1 and for the tress that was washed with prepared shampoo; the score out of 4 was 3.0. The results revealed that the shampoo formulated is having good conditioning effect.[22]

Evaluation test	Formulated shampoo
Color	Brown
Transparency	Clear
Odor	Good
pH of 10% solution	7
Solid contents (%)	23.25
Foam volume (ml)	25
Foam type	dense, small
Surface tension (dynes/cm)	35.18
Wetting time (s)	120 s

Physiochemical study of herbal shampoo

XVIII. CONCLUSION

The present study was carried out with the aim of preparing the herbal shampoo that reduces hair loss during combing, safer than the chemical conditioning agents as well as to strengthen the hair growth. Herbal shampoo was formulated with the aqueous extract of medicinal plants that are commonly used for cleansing hair traditionally. Use of conditioning agents (synthetic) reduces the protein or hair loss. To provide the effective conditioning effects, the present study involves the use of shikakai, amla, and other plant extracts instead of synthetic cationic conditioners. The main purpose behind this investigation was to develop a stable and functionally effective shampoo by excluding all types of synthetic additives, which are normally incorporated in such formulations. To evaluate for good product performance of the prepared shampoo, many tests were performed. The results of the evaluation study of the developed shampoo revealed a comparable result for quality control test, but further scientific validation is needed for its overall quality.

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