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Overview of Cosmetics Science

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ABSTRACT

The cosmetics industry in India has undergone significant evolution, catering to diverse demographics with products ranging from makeup to personal care items. Governed by the Drug and Cosmetics Act of 1940, the regulatory framework emphasizes quality management through amendments such as the introduction of Schedule- H1 and standards for homoeopathic medicines. Prohibiting misbranded, adulterated, and spurious drugs, the Act outlines penalties for offenses, including imprisonment and fines. Obtaining a drug license entails a four-year practical experience requirement, with stringent regulations for manufacturing, storage, and sales. Import of drugs is allowed under specific conditions, involving licenses for specified classes of drugs. This comprehensive framework reflects the active phase of the Indian cosmetic industry, ensuring the safety, quality, and efficacy of products for an expanding consumer base across urban and rural areas, diverse socio-economic backgrounds, and age groups.

KEYWORDS: *Drug, Product, Skin, Cream, Quality, Hair, Cosmatic Product*

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INTRODUCTION

Introduction to the cosmetics industry, Overview of the Drug and Cosmetic Acts of 1940 and 1945, knowledge about the classes of cosmetics prohibited from import, manufacture, store, and sale in India, and related offences and penalties

Cosmetics have been around for thousands of years. When people hear the word "cosmetics," they tend to think of makeup and perfume designed for women. Cosmetics actually come in many forms, ranging from powders and body makeup to soap, shampoo, and toothpaste. We can trace the use of cosmetics back thousands of years, when people painted their bodies for religious ceremonies, war, and mating rituals. Cosmetics are used for beautifying purposes and cover a wide range of products, including cleaning body parts, enhancing features, and changing skin tones and colours, such as makeup, perfume, toothpaste, shampoo, and deodorant. In general, cosmetic companies have targeted the female audience based on the product itself. Prior to the 1990s, many people used to think that cosmetic products were only for adult women; the reality of today is slightly different [1].

The Indian cosmetic industry has witnessed rapid growth over the last couple of decades, when Indian competitors started manufacturing products in order to meet the increased needs of both the Indian and international markets. The Indian cosmetic industry caters to the increasing needs of cosmetic products in all spheres, from rural areas to cosmopolitan cities, from the poor to millionaires, and even from kids to the elderly. It could be observed that the Indian cosmetic industry is in an active phase in terms of product development and marketing.[2]

Rules under the drug and Cosmetics Act, 1940 (23 of 1940):

In exercise of the powers conferred by Sections 12, 33, and 33N of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government has made the following rules and necessary amendments thereto from time to time in the interest of the public for the total quality management of drugs.

Necessary schedules are also made to these rules.

The Drugs and Cosmetics Rules, 1945 (Amendments); 2) The Medical Devices Rules, 2017 (Amendments); and 3) The New Drugs and Clinical Trials Rules, 2019.

The Drugs and Cosmetics Rules, 1945 (Amendments):

Rules describe —short title, extend, and commencement." Similarly, definitions of homoeopathic medicines (dd), registered homoeopathic medical practitioner (ea), and registered medical practitioner are similar. Recent Amendments to the Drugs & Cosmetics Rules, 1945: Recently, vital amendments to these rules have been made in the public's interest. The introduction of Schedule-H1 to D&C Rules via Gazette Notification No. GSR 588(E) dated August 30, 2013 acts as a check on the multidrug-resistant T. b., rampant use of antibiotics prone to resistance, and habit-forming drugs. Sale of such drugs enlisted under Schedule-H1 are to be recorded in a separate register as per Rule 65(3)(h). 2. To improve the standard for the sale of homoeopathic

medicines, the educational qualification and period of experience for competent persons have been amended vide Gazette Notification No. GSR 1380(E) dated November 10, 2017[3].

Import of Drug and Cosmatic

Misbranded drugs

a) If it is so colored, coated, powdered, or polished that damage is concealed, or if it is made to appear to be of better or greater therapeutic value.

b) If it is not labelled in the prescribed manner.

c) If its label, container, or anything accompanying the drug bears any statement, design, device that makes any false claim for the drug or that is false or misleading in any particular.

Adulterated drugs.

a) If it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

b) If it has been prepared, packed, or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health.

c) If its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.

d) If it bears or contains, for purposes of colouring only, a colour other than one which is prescribed.

e) If it contains any harmful or toxic substance that may render it injurious to health.

f) If any substance has been mixed therewith so as to reduce its quality or strength.

Spurious drugs.

a) If it is imported under a name that belongs to another drug.

b) If it is a limitation of, or a substitute for, another drug, or resembles another drug in a manner likely to deceive, or bears upon it or upon its label or container the name of another drug, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug.

c) If the label or the container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist.

d) If it has been substituted wholly or partially by another drug or substance.

e) If it purports to be the product of a manufacturer, it is not truly a product.

Offences:

(I) Whoever, by himself or by any other person on his behalf, imports.

a) Any drug deemed to be adulterated under Section 9A or deemed to be a spurious drug under Section 9B, or any spurious cosmetic referred to in Section 9D, or any cosmetic of the nature referred to in Clause (ee) of Section 10, shall be punishable with imprisonment for a term which may extend to three years and a fine which may extend to five thousand rupees.

b) any drug or cosmetic other than a drug or cosmetic referred to in clause (a), the import of which is prohibited under section 10, or any rule made under this chapter, shall be punishable with imprisonment for a term which may extend to six months or with a fine which extends to five thousand rupees.

c) Any drug or cosmetic in contravention of the provision of any notification issued under Section 10A shall be punishable with imprisonment for a term which may extend to three years or with a fine which extends to five thousand rupees.

(II) Whoever has been convicted of an offence .

(a) under clause (b) of sub-section (1), is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may

extend to one year, or with a fine which may extend to one thousand rupees, or with both.

(III) The punishment provided by this section shall be in addition to any penalty to which the offender may be liable under the provision of Section 11.

Confiscation. —Where any offence punishable under Section 13 has been committed, the consignment of the drugs or cosmetics in respect of which the offence has been committed shall be liable to confiscation.

Jurisdiction.—No Court inferior to that of a

A [Metropolitan] Magistrate or a [Judicial] Magistrate of the First Class shall try an offence punishable under Section 13 [4]

Penalties:
Various punishments are involved for non-maintenance of documents, the manufacture of drugs other than those mentioned in the license, over and above the quantity mentioned in the license, etc., for which punishment includes life imprisonment for offenders involved in the manufacture, sale, and distribution of spurious and adulterated drugs likely to cause grievous harm. In certain cases, the minimum punishment includes the all penalties which may extend to life imprisonment, and a fine of Rs. 10 lakhs or three times the value of the confiscated goods, whichever is greater. The amendment also introduced provisions for providing compensation to the affected.

1. Conditions for obtaining licences for the import, manufacture, store, and sale of cosmeceuticals from various administrative authorities in India and abroad

The below-mentioned are the terms and conditions to obtain a drug licence under the Drugs and Cosmetic Act, 1940: an applicant to obtain a drug licence must have at least four years of practical experience in drug distribution. A drug licensee can only manufacture a drug under the supervision of an experienced pharmacist. It is forbidden by law to stock or sell any drug after its expiration. A drug retailer cannot provide any drug to a minor or a child below the age of 18 years. The drug retailers should make an entry in the register each time they sell any drug to maintain the record for future reference. Medications to cure animals must be labelled as ―not for human use, for treating animals only." [5]

Import of drugs under license:
The following classes of drugs can be imported under the licence or permit granted by the licencing authority:

1. Drugs specified in schedules C and C1, excluding those specified in schedule X.
2. Drugs specified in schedule X.
3. Minor quantities of drugs imported for the examination, test, or analysis.
4. Drugs for personal use covered by a prescription under RMP.
5. Any new drug.

Prohibition of the Manufacture and Sale of Certain Drugs:

The following drugs are prohibited to manufacture for sale under Section 18 of the Act:

1. Any drug or cosmetic which is not of standard quality or is misbranded, adulterated, or spurious.
2. Any patent or proprietary medicine whose formula and quantities are not disclosed on the label or container
3. Any cosmetic containing any ingredient that may render it unsafe or harmful for use.
4. any drug or cosmetic in contravention of this act or rules made thereunder

Manufacture of New Drugs:

As per Rule 122 E of the Drug and Cosmetic Rules 1945, a new drug can be:

1. A new substance of chemical, biological, or biotechnological origin, in bulk or in prepared dosage form, used for the prevention, diagnosis, or treatment of disease in man or animal, which except during local clinical trials has not been used in the country and which, except during local clinical trials, has not been recognised in the country as effective and safe.

2. A drug already approved by the licencing authority for the proposed claims, which is now proposed to be marketed with modified or new claims; or a fixed-dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio; or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, like:

(i) Indications.

(ii) Dosage form (including sustained release dosage form).

(iii) Route of Administration.

3. All vaccines shall be new drugs unless certified otherwise by the Licensing Authority.
4. A new drug shall continue to be considered a new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier .[6]

2. Documentation (Batch Formula Record, Master Formula Record, Quality Audit Report, Distribution Report, Handling Return Goods, Recalling, and Waste Disposal) and Vendor Evaluation Process

Batch Manufacturing Record (BMR):
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 the date on which the batch number is allotted, the identity of the product, and the batch size.

Contents of the 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
- The name and quantity of each raw material were actually weighed with the batch number from which the material was drawn (including details of any reprocessed 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 authorise the deviations; their evaluation and investigation, if conducted.
- Packaging material and label description, with representative material attached.
- Results and reports of QC testing of the final product for batch approval
- A statement about the decision taken regarding approval or rejection of the batch, along with the date and the name and signature of the person making this decision.

Master formula record:
A Master Formula Record is defined as an approved master document with instructions on 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 production

Contents of MFR:

- Name of product, its strength, and dosage form description
- Name and measure or weight of each active ingredient per dosage unit, per unit weight, or per measure of drug product.
- A statement of the total weight or measure of a dosage unit
- A list of component names and their weights or measurements using the same weight system• A statement of theoretical weight or measure where necessary in the processing phase; • A statement of theoretical yield with a 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 drug product packaging
- A specimen or copy of each label or labelling material, with the date and signature of the authorised 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 the storage of intermediates and finished products .

Quality audits:
A quality audit is an independent evaluation performed to determine if activities are performed in a manner to comply with set objectives defined in the company's quality system. In the pharmaceutical industry, audits are an effective means of verifying if the different departments comply with cGMP regulations.

Audit types:

a) internal audit-

are done by auditors within the company to assess cGMP compliance, identify problem areas and take

corrective action, and prepare for audits by regulatory bodies.

b)External audits-

The external audit are carried out by a company at the sites of its vendors, 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.

c) Regulatory audits-

The regulatory audit performed by regulatory bodies to check for adherence to statutory requirements. These audits are a must to ensure data quality and integrity with respect to products that seek regulatory approval.

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.

Distribution record details:

Some of the important details required include:

- the name of the product, its strength, and a description of the dosage form.
- Batch number or lot number of shipped product.
- Name and address of the consignee.
- Shipping date and quantity shipped
- Besides warehouse inventory records, distribution records also include invoices, receipts from customers, and bills of lading

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.

Drug Recalls:

A "drug recall" refers to the action of removing or withdrawing a batch of product from distribution or use to be returned to the manufacturer. This action is generally taken in cases where deficiencies are discovered in the safety, quality, or efficacy of drugs. It is important to note that product recalls do not include the normal removal of products that have passed their expiration date.

Waste Disposal:

The 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 to 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 of 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 mixtures [7].

Vendor evaluation process:

Vendor evaluation is a part of cGMP and is used to ensure the procured products are being produced consistently and reproducibly according to their quality standards. To avoid the procurement of substandard products from vendors, it is required to certify vendors or suppliers based on the cGMP guidelines. This can avoid adverse effects on the quality standards, regulatory requirements, and safety of the patients. The effective evaluation of the supplier or vendor is done by using the vendor evaluation questionnaire. The main objective of this review is to determine whether the company manufactured good-quality products that were delivered to customers and confirmed compliance with regulatory and statutory requirements.

3. Review of the list of ingredients on the labels of cosmetics, cosmeceuticals, baby care, and men's range products in the market and comparative study of the formulations

The following information must be listed on the label: Both of the primary container (the one that contains the product and is in contact with it) and of the secondary packaging (cardboard box, carton):

- The name or registered name and the address of the responsible person. If several addresses are indicated, the one where the responsible person makes the product information file readily available shall be highlighted.

- The country of origin shall be specified for imported cosmetic products.
- The nominal content.
- The date of minimum durability or "period after opening" (PAO, duration after first use)
- Take particular precautions during use (if necessary to ensure safe use).
- The batch number (to ensure the traceability of the product).
- The function of the cosmetic product, unless already clear from its presentation.

The list of ingredients (it may be indicated on the external packaging only) Package labelling is a vital aspect of marketing cosmetic products, as it is intended to help consumers find accurate details.about the product. Most countries have specific labelling and marking requirements for cosmetic products.

Concentration of active ingredient and labelling: The issue becomes more convoluted when the basis of the drug versus cosmetic differentiation centres on the concentration of the active ingredient. At the moment, sunscreen-containing products are classified as cosmetics, provided the sun protection factor (SPF) is below 4, while high-SPF sunscreens still have approval for sale over the counter (OTC). Interestingly, a recent proposal by the FDA entails classifying any sunscreen that specifies SPF as a drug. Similarly, while the FDA regards lactic acid at 12% as a drug, the same ingredient in lower concentrations is permitted in cosmetics. Regrettably, regulations appear to completely ignore the effects of vehicles, stabilizers, and other excipients.

Cosmeceutical Categories As Per Their Chief Indication Based On The Etiology Of The Target Condition:

1) Skin lightening or depigmenting
2) Sunscreens
3) Moisturizing agents
4) Anti-wrinkle/aging
5) Scar-reducing
6) Antioxidants
7) Hair strengthening
8) Specific disorder-related conditions, e.g., acne, rosacea, melasma
9) Miscellaneous

The following list enumerates a large number of commonly used and prescribed cosmeceuticals and nutraceuticals. The full list is too exhaustive and beyond the scope of this activity.

- Alpha-lipoic acid, oral
- Coenzyme Q10, oral
- Vitamin B-complex, oral
- Vitamin C, oral and topical
- Vitamin E, topical and oral
- Jojoba oil, topical
- Licorice topical
- Pune bark extract and topical
- Rose, topical
- Turmeric, topical and oral

5. Current Good Manufacturing Practices for Cosmetics as Per the Regulatory Authorities.

1. Scope

The purpose of this document is to provide guidance to manufacturers regarding the good manufacturing practise (GMP) of cosmetic products, in addition to that outlined in the I.S. EN

ISO 22716:2007 (hereinafter known as "the Standard"). The GMP requirements clearly outlined in the Standard are not repeated within this guidance document, as they are deemed to be self- explanatory and do not need additional clarification. This guide aims to explain in further detail the expectations of the Health Products Regulatory Authority (HPRA) with respect to the legal requirements of the standard.

2. Definition Of A Cosmetic Product

A "cosmetic product" means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, etc.) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, performing them, changing their appearance, protecting them, keeping them in good condition, or correcting body orders.

3. Quality Management

Cosmetic products must be manufactured in such a way as to ensure that they are fit for their intended use and do not place consumers at risk due to inadequate safety or quality.

3.1 Good Manufacturing Practice-Good manufacturing practise (GMP) is that part of quality management that ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use. GMP is concerned with both production and quality control. The basic requirements of GMP are that:

(i) All manufacturing processes are clearly defined, systematically reviewed in light of experience, and shown to be capable of consistently manufacturing cosmetic products of the required quality and complying with their specifications.

(ii) Critical steps of manufacturing processes and significant changes to the process are validated.

(iii) All necessary facilities for GMP are provided, including.

1. suitable equipment and services
2. correct materials, containers, and labels
3. approved procedures and instructions, in accordance with the quality system suitable storage and transport

(iv) Instructions and procedures are written in an instructional form in clear and unambiguous language, specifically applicable to the facilities provided.

(v) Procedures are carried out correctly, and operators are trained appropriately in these procedures.

(vi) Records are made, manually and/or by recording instruments, during manufacture that demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the product were as expected.

(vii) Any significant deviations are fully recorded, investigated with the objective of determining the root cause, and appropriate corrective and preventive action implemented.

(viii) Records of manufacture, including distribution, that enable the complete history of a batch to be traced are retained in a comprehensible and accessible form.

(ix) The distribution of the products minimises any risk to their quality.

x) A system is available to recall any batch of product from sale or supply.

(xi) Complaints about products are examined, the causes of quality defects investigated, and appropriate measures taken in respect of the defective products and to prevent reoccurrence.

3.1.2 Quality Control

Quality control is that part of GMP that is concerned with sampling, specifications, and testing, as well as with the organization, documentation, and release procedures that ensure that the necessary and relevant tests are actually carried out and that materials are not released for use or products released for sale or supply until their quality has been judged to be satisfactory.

3.1.3 Quality risk management

Quality risk management is a systematic process for the assessment, control, communication, and review of risks to the quality of the cosmetic product. It can be applied both proactively and retrospectively.

3.1 Personnel:

The responsibilities of key personnel, including representatives of the quality unit, should be documented in job descriptions.

3.2 Premises:

Manufacturers should consider the design, layout, and finish of manufacturing, filling, and packaging areas with the view to ensuring protection of the product, efficient cleaning and maintenance, and minimising the risk of mix-ups of products, raw materials, and packaging materials.

3.3 Equipment:

Instructions for the operation, calibration, maintenance, and cleaning of equipment should be documented in procedures under the company's QMS. Consideration should be given to all equipment used during manufacture (e.g., weighing scales, temperature recorders, mixers, etc.), and requirements for calibration should be assessed and documented.

3.4 Raw materials and packaging materials:

With respect to the evaluation of new suppliers, it is recommended that comparative analyses be conducted on different supplier lots of raw materials using the principles of QRM. Production

3.5 Finished Products:

Specifications for finished products should be documented including defined acceptance criteria relevant to the quality of finished products. Quality control laboratory

Testing of materials and the finished product should be conducted and documented as appropriate. Acceptable quality levels (AQLs) for critical, major, and minor defects for product inspections should be documented, and records of the results of inspections conducted should be maintained.

6. Study of ICH guidelines for stability studies

Pharmaceutical product stability is a complex process that requires considerable time, expense, use, and scientific expertise to develop pharmaceutical formulation effectiveness, quality, and safety [14].

Any alteration that occurs after its preparation in a pharmaceutical product that adversely affects a patient's fitness for use in the quality of the product is of interest in the stability screening of pharmaceutical researchers and regulators [15].

Importance of Stability Testing [11–16]:

1. Determining conditions of shelf life and processing for the development of new goods
2. Toxic products may be formed during the decomposition of active drugs.
3. ensuring that the brand is fit for use as long as it is on the market with all functionally acceptable attributes to protect the manufacturer's reputation.
4. To ensure that no modifications in the production or formulation method have been implemented that can negatively impact product stability.

Stability Testing Method:

Stability tests are a routine operation used in the various phases of product development for drug substances and products. Early stages use accelerated stability tests to measure the type of degraded products found following long-term storage. The main objectives of the pharmaceutical stability test are to ensure that products remain on the market for the duration of their acceptable fitness or quality and are fit for consumption until the last pharmaceutical unit is used.

Stability testing procedures are divided into bur groups.

1. Real-time stability testing .
2. Accelerated stability testing .
3. Retained sample stability testing.
4. Cyclic temperature stress testing .

Guidelines for stability testing:

In 1980, these guidelines were issued, and later the ICH was harmonised (made uniform) to solve the bottleneck for marketing and registration in other nations. In drug regulation, the regulatory authority in several nations has created regulations for the producers to submit stability information to ensure that molecules and products are generated with optimum stability, circulated, and provided to the patient. These guidelines aim to introduce consistency in testing from supplier to supplier and also involve fundamental problems linked to stability, stability information for application dossier requirements, and implementation steps. In June 1997, the United States Food and Drug Administration (USFDA) also issued guidance documents entitled "Expiration Dating of Solid Oral Dosage Forms Containing Iron." In 2004, WHO also issued guidelines for worldwide environmental stability research. These ICH guidelines for veterinary products were subsequently expanded. The Indian Drug Manufacturers Association also published a technical monograph on drug and production stabiity testing in India.

Q1A (R2): Stability testing of new drug substances and products Q1B: Photostability testing of new drug substances and products Q1C: Stability testing for new dosage forms

Q1D: Bracketing and matrixing design Q1E: Evaluation of Stability Data

Q1F: Stability data package for registration applications in climate zones III and IV Q5C: Stability testing of biotechnological and biological products.

Q7: Good manufacturing practise (GMP) guide for APIs

Stability testing for climatic zones:

Protocol for Stability Testing [16].

7. Knowledge about skin, oral cavity, hair, nails, and body cavity-related problems. Skin:

Skin has its own unique anatomy, which describes and determines its behaviour and explains how it functions the way it does. Understanding skin anatomy also helps to put in context and clarify the common skin disorders reviewed in later sections of this paper. It also helps to identify skin components that are dysfunctional and to plan for the right treatment. With the current interest of the authors, we will examine two of the three main layers of skin, namely the epidermis and dermis.

Common skin disorders:

This unwanted condition eventually affects the integrity of the skin. On an outward perspective, skin diseases can be categorised into three groups: dry skin (Eczema, Xerosis, Atopic Dermatitis, and Psoriasis), hyperpigmentation (Post-Inflammatory, Vitiligo, and Melasma), and acne. In a recent epidemiological study of skin diseases conducted in Himatnagar, Shah and Sheth (2019) found important statistics about skin diseases suffered among the patients they studied. Based on Figure 6, the top three skin diseases are eczema, xerosis, and acne, with specific percentages of 32%, 21%, and 16%, respectively. The three combined make up almost two-thirds (79%) of the total percentage. The next group is made up of atopic dermatitis (10%) and post-inflammatory fibrosis (9%). The third group, with 5% or less, consists of melasma (5%) and vitiligo (4%) and psoriasis (3%).

1. -Dry Skin
2. -Acne Skin
3. Hyperpigmented Skn
4. -Melasma[17]

Oral cavities:

Oral health plays an important role in overall health and is an indispensable part of general health. It is reported that there is a close relationship between oral diseases and other systemic diseases like diabetes, digestive disease, stroke, cardiovascular disease, metabolic syndrome, adverse pregnancy outcomes, obesity, et al. On the one hand, oral problems could result in a pro- inflammatory state where systemic diseases might develop. On the other hand, systemic disorders might be responsible for the development of oral problems. However, oral health care is always neglected, despite the importance of oral health in general health. Oral diseases are still one of the most prevalent problems that affect the overall health of humans. Periodontitis and dental caries, as two major oral problems, affect 60 and 36% of people worldwide, respectively. Surprisingly, according to the recently issued data acquired from the 4th national oral health epidemiology survey of China, the caries prevalence rates of children aged 5 and 12 were 70.1 and 34.5%, respectively, even higher than those reported by the 3rd national survey in 2005 [18].

Hair:

Hair is an important part of the human body. The problems associated with it include hair loss, unruly hair, lack of hair volume, conditioning, immature graying, dandruff, thinning of hair, dullness, etc. Hair can vary in shape, length, diameter, texture, and color. The cross section of the hair could also be circular, triangular, irregular, or flattened, influencing the curl of the hair. All mammals have hair. Its main purpose is to regulate body temperature. It also wants to decrease friction, guard against sunlight, and act as a way organ. Hair is the crowning glory of a person body cavities are the ventral cavity and the dorsal cavity. These two body cavities are subdivided into smaller body cavities. Both the dorsal and ventral cavities [21]

8. Cleansing and care needs for the face, eye lids, gums, dental cavities, hair, lips, hands, feet, nails, scalp, neck, body, and under-arm are necessary to maintain hygiene.

Skin Care Products:

1. Face Wash
2. Cleanser
3. Moisturizer Cream

Lip Care Products:

Lip Balms, Lip Gloss, Lip Liners, Lip Stains

Care Preparations For Eyelids:

1. Eye Shadow, Mascara, Eye Liner

Care For Hands:

1. Hand Moisturizer
2. Hand Sanitizer

Feet Care:

1. Washing
2. Keeping Them Dry
3. Moisturising
4. Removing Jagged Skin
5. Wearing socks
6. Wearing comfortable shoes
7. Apply antifungal foot creams.

Care for Neck:

1. moisturising cream
2. Cleansing cream
3. Face wash
4. Fairness cream

Care for Scalp:

1. Protect your scalp from the sun.
2. Shampoo Regularly.
3. Limit chemical treatment.
4. Massage.
5. Preserve moisture.

Care and Preparation for Nails:

1. Nail Lacqueres

Care for Under Arms:

1. Hair Removal
2. Shaving
3. Waxing
4. Deodrant [22].

9. Formulation consideration for ethnic needs of cosmeceuticals like moisturising cream, vanishing cream, cold cream, cleansing cream, shaving creams, shampoo, dentifrices, perfumes, prickly heat powder, aerosols, ointments, lotions, tablets, capsules, foot care products, nail and hair care products, perfumes, and other products.

Creams:

Creams are defined as a semisolid dosage form containing one or more drug substances dissolved or dispersed in a suitable base.

(I) Moisturizing Cream:

When water is lost from the stratum corneum more rapidly than it is received from the lower layers of skin, the skin becomes dehydrated.

The dehydrated skin loses its flexibility and appears rough.

-Creams that restore water or moisture and plasticize the stratum corneum, providing it with flexibility and making it soft. These types of creams are known as moisturising creams.

(Il) Vanishing Cream:

Creams that spread easily and seem to disappear rapidly when rubbed on the skin are termed

"vanishing creams‖. These creams are composed of emollient esters, which leave a thin apparent film on the skin. Traditional formulae of vanishing creams are based on stearic acid.

Stearic acid melts above body temperature and crystallises in a form so as to be invisible, providing a non-greasy film. It also imparts an attractive appearance to the cream.

(III) Cold Cream:

Cold cream is a water-in-oil type emulsion that, when applied to the skin, produces a cooling effect due to the slow evaporation of water present in the emulsion.

(IV) Shampoo:

A shampoo is a preparation of a surfactant in a suitable form (liquid, solid, or powder), which, when used under specialised conditions, will remove surface grease, dirt, and skin debris from the hair shaft and scalp without adversely affecting the user [23,24].

Preparation of SOPs for different equipment, instruments, and machineries as per the regulatory guidelines.

1. **Texture Analyzer**

Fig .TextureAnalyzer

.Procedure :-

-Unpack the instrument according to Section I.5.

Install base table in accordance with the instruction sheet that is enclosed with the base Table. Place the sample on the base table. Adjust the table height so that the surface of the Sample is within 5 mm of the probe.

Attach the selected probe. See Section IV.2 for more information.

Set the test mode to Normal. Please review Section III.6 for detailed explanation of operation Of Select/Scroll knob.

Set the trigger value as recommended below.

Set the test speed and distance. See Section IV.3 for more information.

--Press the START button. The weight of the probe will autozero and then the test will start.

2. Brookfield viscometer:

Fig:Brookfieldviscometer

Purpose:

The Brookfield Dial Viscometer measures fluid viscosity at given shear rates. Viscosity is a measure of a fluid's resistance to flow.

Procedure:

1. Turn on the viscometer and allow standing; it must be set to auto zero. After a few seconds, a screen appears that indicates 2 digits.
2. Now press the key. The screen displays to remove the spindle. After removing the spindle and pressing the key, the instrument begins; it is auto-zeroed.
3. After approximately 15 seconds, the screen displays the instruction to replace the spindle.
4. Attach the spindle to the viscometer by screwing it onto the lower shaft using left-hand thread.
5. Press the spindle key and the up and down arrow keys. When the desired code is displayed, release the arrow key.
6. To select a spindle, first press either the up or down key, which causes the area to show the current speed. Press the set speed key to adjust the speed.
7. Insert the centre of this spindle in the test material until the fluid level is at the immersion groove on the spindle shaft. Tilt the spindle slightly while immersing to avoid air entrapment.
8. To measure high viscosity, choose a small spindle and slow speed if the chosen spindle and speed result in torque above 10.0 percent, and then reduce the value.
9. Allow time for the individual reading to stabilize; record the value.
10. Press the motor on/off/escape key to turn off the motor.
11. The time mode allows the user to record the reading for a fixed period of time or until a set torque value is attained.
12. Then enter/auto turnkey allows determining the maximum calculated viscosity possible with the current spindle speed.
13. Pressing the up and down arrow keys will allow the viscometer data to be examined; pressing any other key (except the enter or press key) will bring back the normal display.
14. Turn off the mains after use.

3. Tablet Punching Machine

Fig:Tablet Punching machine

Purpose: The purpose of this SOP is to define the operating system.

Procedure:

1. Product changeover (Type A): Change the status of the area and equipment and ensure that a dully filled and signed status label is affixed to the equipment as per SOP for status labelling. Release the pressure before cleaning the machine. Switch off the electrical supply and remove all adhering powder from the machine with the help of a vacuum dust extraction pipe.

2. Use a compressed air gun to remove dust from the inner area. Remove the hopper, feed frame, tablet chutes, extraction points, and granule scraper studs and keep them in a SS trolley covered with a polybag and take it to the washing area. through an unclean equipment room.

3. Clean the machine parts thoroughly with sufficient potable water by using a nylon scrubber, and finally

rinse with purified water followed by drying with Remove the upper punches, lower punches, and dies carefully, clean them thoroughly with 70% IPA, and store them in the punches and dies cabinet as per SOP for Punches and Dies.

4. Remove the following parts from the machine and clean them with 70 percent IPA and dry with a lint-free cloth. Clean the upper cams with 70 percent IPA and dry with a lint-free cloth.

4. Operated Tablet Punching Machine:

Fig. operate Tablet Punching Machine

Purpose:

It is always used for filling the bulk of capsules. The capsule filling machine automatically ejects the capsule that is filled and locked in the machine.

Procedure:

1. Verify the cleanliness of the area and the equipment. Confirm that the "CLEANED" label is affixed to the equipment.
2. Enter the details in the "Equipment Usage Log."
3. Remove the "CLEANED" label and affix the "UNDER PROCESS" label.
4. Get a line clearance certificate from In Process Quality Assurance.

Knowing the different types of equipment and machinery required for the manufacturing and quality control of different cosmetic products

List of categories of cosmetics for the purpose of granting licences to manufacture and sell cosmetics in the country

Category:

(A) Powders

(B) Skin Powder for Infants

(C) Creams, lotions, emulsions, pastes, cleansing milks, shampoos, pomade, brilliantine, shaving creams, hair oils, etc.

(D) Nail polishes and nail lacquers

(E) Lipsticks and lipglosses

(F) Depilatories

(G) Preparations used for Eyes

Prepare and evaluation of herbal lotion. Introduction:

The concept of beauty and cosmetics dates back to ancient mankind and civilization. Generally herbal cosmetics are also referred to as natural cosmetics.(29, 30)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. The name itself suggests that herbal cosmetics are natural and free from all the harmful synthetic chemicals which otherwise may prove to be toxic to the skin.

e.g. aloe-vera gel and coconut oil. They also consist of natural nutrients like Vitamin E that keeps skin healthy, glowing and beautiful.

Skin irritation during cast immobilisation is a common complaint, especially for patients in humid tropical regions. It may lead to patient and caretaker stress, cast breakdown, and skin complications.1 Calamine lotion is a widely used topical agent to soothe skin irritation. Liquid dosage forms used in pharmacy are either monophasic or biphasic. Monophasic liquid dosage forms are classified into two groups:

(1). Liquids for internal application (31)

(2). Liquids for external application Ex; Lotions (32)

Aim and the scope of the present work:

The present work was designed on the basis of different approaches to guided study on herbal lotions. list of ingredients was made. Then the literature review was done. The materials were collected, the method of preparation was studied, and the identification tests for was performed on herbal lotion. The prepared formulations were evaluated for various properties, and the results were tabulated.

Materials and method:

Measuring cylinder., beaker, stirrer, heating mental, container, water bath.

Chemicals:

Aloevera gel, beeswax, tulsi extract, glycerin, methylparaben, vitamins E capsule.

Formulation ingredients:

Sr.no	Ingredients	Quantity given	Role
01	Calamine	15.0gm	Relieve itchiness
02	Zinc oxide	5.0gm	Bulking Agent
03	Bentonide	3.0gm	Lubricant
04	Sodium Citrate	0.5gm	Controls the pH
05	Liquified Phenol	0.5gm	Preservative
06	Glycerine	5.0ml	Moisturising Agent
07	Rose Water	10ml	Beauty products

Table no.3.1:formulation ingredients

Preparation before the formulation:-

Clean and sanitize your work area and all you packaging materials. It is suggested that you wear gloves, protective clothing and a hair net while preparing this recipe.

Procedure:

1) Depending in the formula quantity of preparation to be submitted the working formula is calculated.
2) Triturate Calamine, Zinc oxide and bentonite with a solution of sodium citrate.
3) Prepare by dissolving sodium citrate in about ¾th portion quantity of rose water.
4) Add liquefied phenol and glycerine to the above mixture and mix well.
5) Add sufficient rose water to produce the required volume
6) Shake the preparation to ensure an uniform distribution.
7) Transfer the preparation to a bottle.
8) Cap the bottle polish and submit.

Evaluation parameters:

1) Physical Test: physical parameters like colour, odour, texture, state, of lotion and evaluated. It is also include checking of pH using pH meter.
2) Irritancy test: Mark the area about 1 cm2 on left hand dorsal surface. Then the lotion is applied to area and time is noted, then it is check if irritancy after a hours.
3) Wash ability: Small amount of cream is applied on hand, then it is washed with tap water.(33)

Evaluation parameters Table:

Evaluation test	Observation	Inference
Physical evaluation	Colour: Pink Odour: Aromatic State: Liquid Texture: Smooth	The calamine lotion has been passed all the listed evaluation test.
Irritancy test	The lotion does not produces any irritancy.	The calamine lotion has been passed all the listed evaluation test.
Wash ability	Lotion was been washed with a tap water and it was washable	The calamine lotion has been passed all the listed evaluation test.

Table no.3.2: Evaluation parameters Result:

The present work on formulation and evaluation of herbal lotion was aimed at formulating a lotion using herbal ingredients with the hope of minimising the side effects produced by the available synthetic ones. Calamine lotion was prepared and submitted successfully.

Conclusion:

In this study, a formulation of herbal lotion was formed and evaluated in terms of their organoleptic properties [Appearance, Color and odor] and physiological parameters pH, Spreadability, easy of removal and irritancy test.The present work focus on the herbal extracts Provide nutrients necessary for the healthy skin. There are numerous herbs available naturally having different uses in cosmetic preparations for skincare as antioxidants. The Herbal Lotion we will avoid skin problems.

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