

# Cosmetics Science

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**Abstract:** *Cosmetics are substances that want to reinforce the appearance or odour of the human body. The word cosmetics derives from the Greek word which suggests the technique of dress & ornament Women need to colour their cheeks in colour by first coating their face, neck, and other spare a white powder without knowing that white powder contained lead that destroys their complexion after a certain period. Modern cosmetics include skin-care preparations; foundation, powder, and rouge (blusher); eye makeup; lipstick; shampoo; hair curling and straightening preparation; colours dyes, and bleaches; and nail enamel. Related products include antiperspirants, mouthwashes, depilatories, astringents, bath crystals, and much of other types of products.*

**Keywords:** Cosmetics, Drug, and cosmetic act 1940, Cosmeceuticals, cGmp gudlines, Instruments

## I. INTRODUCTION

Cosmetic industry includes colour cosmetics, like foundation and mascara, skincare like moisturizers and cleansers, haircare like shampoos, conditioners, and hair colours, and toiletries like bubble baths and soap. The manufacturing industry is dominated by a little number of multinational corporations that originated in the early 20th century, but the distribution and sale of cosmetic areas spread among a good range of different businesses.[1]

**The Drugs and Cosmetics Act, of 1940** is an act of the Parliament of India which regulates the import, manufacture, and distribution of medicine in India. the first objective of the act is to ensure that the drugs and cosmetics sold in India are safe, effective, and conform to state quality standards.[1] The related Drugs and Cosmetics Rules, 1945 contains provisions for the classification of medicine under given schedules and there are guidelines for the storage, sale, display, and prescription of every schedule.[2]

This act was originally mentioned because of the Drug Act and was passed in 1940. the primary activity was prepared by the recommendations of the Chopra Committee formed in 1930. The related Drugs Rule was as passed in 1945. Since 1940, the act has undergone several amendments and is now mentioned because of the Drugs and Cosmetics Act of, 1940.[3]

The term "drug" as defined within the act includes a good variety of substances, diagnostic and medical devices [4]

Section 16 of the act defines the standards of quality for The Section 17 defines "misbranding". A drug is considered misbranded if it claims to be of more therapeutic value than it is. The manufacturer of such a drug could even be asked to suspend the manufacture of the drug under Section 18. Section 27 deals with fake and adulterated drugs. [5]

**The Drugs and Cosmetic Act Restricts the Import of Drugs or cosmetics of substandard quality.**

1. Any misbranded or spurious cosmetic.
2. Any adulterated or spurious cosmetic.
3. Any patent or proprietary medicine which has no description of truth formula or list of active ingredients included in it, along with the quantities thereof.
4. Any drug which purports or claims to cure or mitigate any such disease or ailment within the shape form of a statement, design, or device accompanying it.
5. Any cosmetic which includes an ingredient that can render it unsafe or harmful for consumption. [6]

Drugs or cosmetics which are prohibited for import under these provisions. Drugs or cosmetics which are prohibited for import under these provision sare valued more than it is. The manufacturer of such a drug could also be asked to the pend manufacture of the drug under Section 18. Section 27 deals with fake and adulterated drugs. The act requires more that the ingredients of the drugs should be printed on the label. [7]

## II. MANUFACTURING OF MEDICINES AND COSMETICS

Drugs and cosmetics fall on the list of drugs that must be delicately handled. While it is often a life-saving remedy, it also can be a bane with inappropriate usage. This prompts the necessity for a regulation, which in India is often found in the Drugs and Cosmetics Act of 1940. This text explores the norms about the manufacture, sale, and distribution of medicine and cosmetics as laid out in this Act.[8]

### 2.1 Manufacturing Restrictions

As per the directions of the Drugs and Cosmetics Act, the following drugs are prohibited from being manufactured for sale, distribution, exhibition, or being offered for sale:

1. Drugs and cosmetics of sub-standard quality
2. Misbranded drugs or cosmetics
3. Adulterated drugs
4. Spurious drugs or cosmetics
5. Patent or proprietary medicine (if it does not depict the exact formula or list of active ingredients and their quantities on its label or container)
6. Any drug which purports or claims to prevent, cure, or mitigate any disease or ailment
7. Cosmetics that consist of any ingredient which can render it unsafe or harmful for use.
8. Any drug or cosmetic which is manufactured in contravention of the conditions specified.
9. Trading of any drug or cosmetic by not complying with the provisions of this Act.[9] Top of Form Bottom of Form

### 2.2 Prohibition of the Manufacture and Sale of Certain Drugs and Cosmetics

From such date as can be fixed by the State Government by notification in the Official Gazette on this behalf, no person shall himself or by any other person on his behalf- Any drug which is not of a standard quality, or is misbranded, adulterated, or spurious;

1. Any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities, thereof
2. Any drug which by means of any statement design or device accompanying it or by the other means, purports, or claims [(Note: Subs. by Act 11 of 1955, sec.9, for "to cure or mitigate") to stop, cure or mitigate] any such disease or ailment, or to possess any such other effect as can be prescribed;
3. Any cosmetic containing any ingredient, which can render it unsafe or harmful for use under the directions, indicated or recommended;
4. Any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made there under;
5. Sell or stock or exhibit or offer purchasable or distribute any drug which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made there under,

[(Note: Subs. by Act 68 of 1982, sec.14, surely words manufacture for sale or distribution, or sell, or stock or exhibit or offer purchasable,] or distribute any drug [(Note: Ins. by Act 21 of 1962, sec.14 (w.e.f. 27-7-1964)) or cosmetic], except under, and in accordance with the conditions of, a license issued for such purpose. Provided that nothing during this section shall apply to the manufacture, subject to prescribed conditions, of small quantities of any drug for the aim of examination, test, or analysis.[10]

### 2.3 Disclosure of the Name of the Manufacturer

All not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall, if so required, open to Inspector the name, address, and other information of the person from whom he acquired the drug or cosmetic.[11]

### 2.4 Maintenance of Records and Furnishing of Information

All holding a license under clause (c) of section 18 shall keep and maintain such records, registers, and other documents as even be prescribed and shall furnish to any officer discharging any function under this Act such information as is required by a such officer for completing the purposes of this Act.[12]

### 2.5 Pleas

Save as here in after provided during this it shall be no defines in a during prosecution under this act to prove merely that the accused was ignorant of the nature, substance, or quality of the drug [(Note: Ins. by Act 21 of 1962, sec.15) or cosmetic] in respect of which the offense has been committed or of the circumstances of its manufacture or import, or that a purchaser, having bought just for the purpose of test or analysis.

For the needs of section 18 a drug shall not be deemed to be misbranded or adulterated or spurious] or to be below standard quality nor shall a cosmetic be deemed to be misbranded or to be below standard quality] only by reason of the very fact that –

1. There has been added thereto some innocuous substance or ingredient because the same is required for the manufacture or preparation of the drug [(Note: Ins. by Act 21 of 1962, sec.15 or cosmetic] as an article of commerce in a state fit for carriage or consumption, and to not increase the bulk, weight, or measure of the drug [(Note: Ins. by Act 21 of 1962, sec.15) or cosmetic] or to hide its inferior quality or other
2. In the process of manufacture, preparation, or conveyance some extraneous substance has unavoidably become intermixed with it if provided that this clause shall not apply in relation to any sale or distribution of the drug [(Note: Ins. by Act 21 of 1962, sec.15 (w.e.f. 27-7-1964)) or cosmetic] occurring after the seller or distributor became aware of such intermixture.
3. A person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall not be responsible for a contravention of section 18 if he proves –
4. That he acquired the drug or cosmetic from a duly licensed manufacturer, distributor, or dealer thereof;
5. That he did not know and could not, with reasonable diligence, have ascertained that the drug or cosmetic in any way contravened the provisions of the section; and
6. That the drug or cosmetic, while in his possession was probably stored and remained within the in the same state as when he acquired it.[13]

### 2.6 Government Analysts

The Government can, by notification within the Official Gazette, appoint such persons because it thinks fit, having the prescribed qualifications, to be Government Analysts for such areas in the State and with respect to such drugs or classes of cosmetics or classes of cosmetics] as can be specified in the notifications. The Central Government can also, by notification within the Official Gazette, appoint such persons because it thinks fit, having the prescribed qualifications, to be Government Analysts in respect of such drugs classes of drugs or such cosmetics or classes of cosmetics] as can be specified in the notification.[14]

### 2.7 Offenses

Whomever himself or by another person on his behalf imports

1. Any drug deemed to be adulterated under section 9A or deemed to be a spurious drug mentioned in section 9B or any spurious cosmetic referred to in section 9D or any cosmetic of the nature referred to in clause of section 10 shall be punishable with imprisonment for a term which can extend to three years and a fine which can extend to five thousand rupees;
2. Any drug or cosmetic apart from 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 can extend to six months, or with fine which can extend to five hundred rupees, or with both.[15]

### 2.8 Whoever Having Been Convicted of An Offense

(a) under clause (b) of sub-section is again convicted of an offense there under that clause, shall be punishable with imprisonment for a term which can extend to five years, or which can extend to ten thousand rupees, or with both. The punishment provided by this section shall be in addition to any penalty to which the offender is often liable under the provisions of the section. [16]

### 2.9 Penalty

Penalty for manufacture, sale, etc., of medicines in contravention –

Whoever, himself or by the opposite's person on his behalf, manufactures, for distribution, or stocks or exhibits or offers purchasable for sale or distributes,

1. any drug deemed to be adulterated under section 17A or spurious under section 6 when employed by a person for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder.
2. Is probably visiting to cause his death or is likely to cause such harm on his body as would amount to previous the hurt within the meaning of section.
3. Because the case is often, [punishable with imprisonment for a term which shall not be but ten years but which can extend to imprisonment for life.
4. If provided that the fine imposed on and released from, the person convicted under this clause shall be paid, by way of compensation,
5. Provided further that where the utilization of the adulterated or, spurious drugs mentioned during this clause has caused the died because of a person who used such drugs, the fine imposed on and realized from, the person convicted under this clause, shall be paid to the relative one that of had died because of the use of the adulterated drug

### 2.10 Explanation

For the wants of the second proviso, the expression “relative” means— (I) spouse of the deceased person; or (ii) a minor legitimate son, and unmarried legitimate daughter and a widowed mother; or (iii) parent of the minor victim; (iv) if wholly enthusiastic into the earnings of the deceased person at the time of died person, a son or a daughter who has attained the age of eighteen years; or (v) a person if wholly or in partially enthusiastic into the earnings of the deceased person at the time of death

1. Without a legitimate license as needed under clause (c) of section 18, shall be punishable with imprisonment for a term.
2. Provided that the Court can, for any adequate and special reasons to be recorded within the judgment, impose a sentence of imprisonment for a term. any drug deemed to be spurious under section 17B, but not being a drug mentioned in clause (a) shall be punishable with imprisonment for a term which shall not but less than seven years but which can extend to imprisonment for life and with a fine which shall not be three lakh rupees or three times the value of the drugs confiscated, whichever is more.[17]

### 2.11 Cosmetic License

Every manufacturer of Cosmetics or must obtain this license. The nonsupervisory authority for Cosmetic Registration in India is the Central Drug Standard Control Organization.[18]

### 2.12 Manufacturing Drug License

1. This license shall be obtained by the manufacturing units which manufacture drugs analogy as Allopathic, Ayurvedic, Cosmetics products or any other drugs.
2. There must be competent technical staff consisting at least of one person who is a whole-time employee and who is a graduate of Pharmacy or Pharmaceutical Chemistry.
3. Adequate space, plant, and outfit for the manufacturing operations to have complied with Schedule M.
4. There shall be separate arrangements for carrying out tests for the strength, quality, and chastity of the drugs at a testing unit and the repacking unit
5. Travelling agents of licensed manufacturers and importers of drugs involved in the distribution of samples of medicines among members of the medical profession, hospitals, dispensaries, and medical institutions or disruption institutions are not required to obtain a License.[19]

### 2.13 Import Drug License

1. This license shall be attained by the persons who are using in the distribution of imported drugs

2. The demesnes to be equipped with proper storage accommodation for conserving the properties of the drugs, where the imported substances will have gazed.
3. Patent or particularly medicines to be imported in holders intended for retail trade
4. All instruments of drugs to be imported to be accompanied by a tab or other statement containing the name and address of the manufacturer and the name and quantities of the drugs as well
5. The importer must submit a declaration to the Drugs Controller before importing any kind of drugs that are not covered under mandatory licensing. The declaration should be signed by the manufacturer or importer.[20]

#### **2.14 Sale Drug License**

This license shall be obtained by the wholesalers and retailers who are engaging in the distribution of Drugs. There are three classes of drug licenses:

1. Wholesale drug license
2. Retail drug license
3. Restricted license for general store [21]

#### **2.15 Documents Required for Drug and Cosmetics**

The list of documents required for the Wholesale /Retail or sale drug and cosmetic License are following: KYC documents of each Director/Partner/ or Proprietor

1. Proof of premises such as rent agreement, electricity bill, property tax receipt, etc
2. Site plan.
3. KYC details of the Technical Person.
4. List of Cosmetics with Product sheets in specified proforma for approval of products along with their composition formula.
5. Ownership details of the brand of cosmetic whether it is registered or under trademark if any. [22]

#### **2.16 Batch Manufacturing Record**

This is a written record that documents the entire manufacturing process and the history of a product batch. A batch is a specific quantity of a chemical, food, drug, or other material that, according to the FDA, "has a uniform character and quality, within specific limits.[23]

#### **2.17 Master Formulation Record**

Master Formulation Record is used to validate the specific information for each batch and is an important element of nonsupervisory compliance and effective process control. This detailed record of procedures describes how the medical product is to be prepared. According to USP< 795> and< 797>, a Master Formulation Record must be created for each unique expression of a compounded nonsterile medication (CSNP) compounded sterile medications (CSP) for further than 1 case CSP from nonsterile component(s)[24]

#### **2.18 Quality Audit Report**

The report should also give sufficient information for the association being checked (auditee) to correct any problems linked. [25]

#### **2.19 The Payroll Distribution Report**

The Payroll Distribution report provides detail of payroll deals to help with the conciliation of department and design statements. The" Payroll Distribution Report within Dept RIT" feathers by the department and provides payroll detail by hand for each pay period included in the requested date range. The" Payroll Distribution Report within Project RIT" provides the same information but feathers by design which makes it easier to use for coordinating entitlement and other design statements. [26]

### **2.20 Returned Goods**

The material which has been returned in case they do not meet their acceptance criteria or has been returned based on breakage/ damaged packaging, marketable or executive aspects, or based on client complaint disquisition and action.

### **2.21 Recalling Drugs**

To stop the distribution and trade of the affected product. Effectively notify operation, guests, and nonsupervisory authority. Efficiently remove the affected product from the requested place, storehouse, or distribution areas. Dispose and conduct a root cause analysis and report the effectiveness and outgrowth of the recall. apply a corrective action plan to help another recall.[27]

### **2.22 Reasons For Drug Recall**

Potentially dangerous or serious product quality issues have come to light through complaints. obligatory regulations have been violated and come to the notice of a nonsupervisory agency. Labelling crimes and incorrect external quilting. Lack of assurance of sterility and medicine. types of waste hazardous:

1. Non-hazardous chemo
2. Waste Bio hazardous
3. Inert Waste Radio hazardous

seller assessment is an evaluation and blessing process that businesses can use to determine if prospective merchandisers and suppliers can meet their organizational norms and scores formerly under contract. The end thing is to secure a low-threat, stylish-in-class seller, and supplier portfolio.[28]

### **2.23 Waste Disposal**

Waste includes all particulars that people no longer have any use for, which they either intend to get relieved of or have formerly discarded. Pharmaceutical waste potentially generated includes- Expired medicines, Cases discarded specifics, defiled garments, absorbents, Hypes, vials, iv bags, tubing's, and Waste accoutrements containing chemotherapy medicine remainders. Open holders of medicines that cannot be used. [29]

### **2.24 Vendor**

Dealer assessment is an evaluation and blessing process that businesses can use to determine if prospective merchandisers and suppliers can meet their organizational morals and scores formerly under contract. The end thing is to secure a low-trouble, swish-in-class dealer, and supplier portfolio.[30]

### **2.25 Cosmetic Labelling**

The cosmetics distributed in the United States must act to the labelling regulations published by the FDA under the authority of the FD&C Act and the FP&L Act. Labelling means all markers and other written, published, or graphic matter on or accompanying a product. The marker statements demanded under the authority of the FD&C Act must appear on the inside as well as any outside vessel or wrapper. FP&L Act conditions., element labelling, and statement of the net volume of contents on the top display panel, only apply to the marker of the external vessel. The labelling conditions are codified at 21 CFR 701 and 740. Cosmetics bearing false or deceiving marker statements or else not labelled in agreement with these conditions can be considered misbranded and can be subject to nonsupervisory action.

The top display panel, i.e., the part of the marker most likely displayed or examined under customary conditions of display for trade (21 CFR701.10), must state the name of the product, identify by descriptive name or illustration the nature or use of the product, and bear an accurate statement of the net volume of contents. The protestation must be distinct, placed in the lowermost area of the panel in a line generally analogous to the base on which the package rests, and in a type size commensurable with the size of the vessel as specified by regulation. The net volume of contents statement of a solid, tenacious, or thick dress must be in terms of the avoirdupois pound and ounce, and a statement of liquid measure must be in Timotheus. A gallon of 231 boxy elevation and the quart, pint, and fluid services the of. However, it must be expressed in ounces, followed in the gap by a protestation of the largest whole units (a, If the net

volume of contents is one pound or one into morale., pounds and ounces or quarts and pints and ounces). The net volume of contents can also be stated in terms of the metric system of weights or measures.

The name and place of business of the establishment dealing with the product must be stated on an information panel of the marker (21 CFR701.12). The address must state the road address, megacity, state, and zip code. However, the road address can be neglected, if an establishment is listed in a current mega city or telephone directory. However, this fact must be stated on the marker by the qualifying expression" Manufactured for, If the distributor is not the manufacturer or p 4. The Tariff Act of 1930 requires that all imported papers state on the marker the English name of the country of origin. The Tariff Act of 1930 requires that all imported papers state on the marker the English name of the country of origin.[31]

### 2.26 Cosmeceuticals

The term "cosmeceutical" was introduced by dermatologist Rd. Albert Kligman in 1984 is derived from a combination of the words cosmetic and pharmaceutical. Cosmeceuticals are products that have both cosmetic and remedial (medical or drug- suchlike) goods and are intended to have a salutary effect on skin health and beauty. Like cosmetics, they are applied topically as creams or plasters but contain active ingredients that influence skin cell function. In some cases, their action is limited to the skin face (analogous to exfoliants), while others can pierce deeper situations, either enhancing or limiting normal skin functions. Cosmeceuticals are available "untoward" (without tradition) and are generally used as part of a regular skin care governance to help meliorate skin tone and texture, achromatism, and fine lines.[32]

### 2.27 Baby Care

Baby watches the skin of a child differs from grown-ups as it is less hairy, thinner, and lower cornified therefore proper care is to be taken. therefore, to avoid any type of vexation or infection baby care products are used. Johnson's Baby is an American brand of baby cosmetics held by Johnson & Johnson. Baby plasters, oils, Maquillages, and Creams are products that are intended to be used to moisturize and soften the skin of babies and children under the age of three. These products are specially formulated to be mild and on-prickly. multitudinous Baby plasters, Creams, and oils contain mineral oil painting oil.[33]

### 2.28 Men's Used Products

1. Future Market perceptivity prognosticates a comparison and reviews analysis of the dynamics of the men's skincare products request, which is vanquished to an array of sedulity factors along with numerous definite influences concerning shoes that support sedulity invention.
2. Some new advances that have taken place in the request include changing men's station towards skincare products and their benefits have led manufacturers to develop new products, specifically for men. According to FMI analysis, the variation between the BPS values observed in the men's skincare products request in H1, 2022- Outlook over H1, 2022 Projected reflects the growth of 120 units. still, compared to H1, 2021, the request is anticipated to spike by 132 BPS in H1- 2022.
3. Pivotal reasons for this change in growth rate are attributed to the request growth during the first half of the cast period, owing to the adding awareness about skincare, tone-grooming, and healthy-looking among men. In August 2021, Mai Johns the Mai Johnson &Co. offers a quotidian head cleanser, colour, anti-aging skin serum, moisturizer, anti-aging night cream, eye cream, water colour masks, and body cream.

### 2.29 Skincare

Skincare As per the analysis, in terms of the source, organic skincare products are anticipated to rise at an emotional CAGR in the cast time. People are now apprehensive of the side goods of synthetic chemicals in ornamental products, so maturity of males is moving towards natural and organic skincare products. Natural constituents like UV pollutants, vitamins, antioxidants, and botanical excerpts do not beget any dangerous effects and indeed these constituents cover skin from blue light, UV radiations, and pollution. thus, the demand for natural and organic products is and this propels the growth of the men's skincare products request. [34]

### 2.30 cGMP Guidelines

The purpose of stability testing is to give substantiation on how the quality of a medicine substance or medicine product varies with time under the influence of a variety of environmental factors similar as temperature, moisture, and light, and to establish a test period for the medicine substance or shelf life for the medicine product and recommended storehouse conditions.

- 1. Building and Installations:** Check whether structures used in the manufacturer store house of cosmetics are of suitable size, design, and construction to permit unstopped placement of outfits, the orderly storehouse of accoutrements, aseptic operation, and proper cleaning and conservation. bottoms, walls, and ceilings are constructed of smooth, fluently cleanable shells and are kept clean and in good form. Institutions, tubes, and pipes are installed in such a manner that drip or condensate does not pollute ornamental accoutrements, implements, ornamental contact shells of outfits, or finished products in bulk. Lighting and ventilation are sufficient for the willed operation and comfort of the labour force. Water force, washing and restroom installations, bottom drainage, and sewage system are acceptable for aseptic operation and cleaning of installations, outfits, and implements, as well as to satisfy hand requirements and grease particular cleanliness.
- 2. Equipment.** Check whether: 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. Utensils, transfer piping, and cosmetic contact surfaces of equipment are well-maintained and clean and are sanitized at appropriate intervals. 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.
- 3. Personnel.** Check whether: The labour force supervising or performing the manufacture or control of cosmetics has the education, training, and/ or experience to perform the assigned functions. Persons coming into direct contact with ornamental accoutrements, finished products in bulk, or ornamental contact shells, to the extent necessary to help contamination of ornamental products, wear applicable external garments, gloves, hair conditions, etc., and maintain acceptable cleanliness. Consumption of food or drink or use of tobacco is confined to meetly designated areas.
- 4. Raw Materials.** Check whether: Raw accoutrements and primary packaging accoutrements are stored and handled in a manner that prevents their blend-up, impurity with microorganisms or other chemicals, or corruption from exposure to inordinate heat, cold waves, sun, or humidity. Containers of accoutrements are closed, and bagged or boxed accoutrements are stored off the bottom. Containers of accoutrements are labelled with respect to identity, lot identification, and control status. Accoutrements are tried and tested or examined in conformance with procedures assuring the absence of impurity with smut, microorganisms, or other extraneous substances to the extent necessary to help the contamination of finished products. Pay particular attention to accoutrements of beast or vegetable origin and those used in the manufacture of cosmetics by cold processing styles with respect to impurity with smut or microorganisms. Accoutrements not meeting acceptance specifications are duly linked and controlled to help their use in cosmetics.
- 5. Production:** Check whether manufacturing and control have been established and written instructions, i.e., phrasings, processing, transfer and filling instructions, in-process control styles, etc., are being maintained. Determine whether similar procedures bear that absence of hazardous microorganisms or chemical contaminants, and compliance with any other acceptance specification. Weighing and measuring of raw materials is checked by a second person, and containers holding the materials are properly identified. importing and measuring of raw paraphernalia is checked by an alternate person, and holders holding the paraphernalia are properly linked. Major outfits, transfer lines, holders, and tanks are used for processing, filling, or holding cosmetics and are linked to indicate contents, batch designation, control status, and other material information. Labels are examined for identity before labelling operations to avoid mix-ups. The outfit for processing, holding, transferring, and filling of batches is labelled regarding identity, batch identification, and control status. Packages of finished products bear endless law marks. Returned cosmetics are examined for deterioration or contamination.



6. **Laboratory Controls.** Check whether: Raw accoutrements , in- process samples and finished products are tested or examined to corroborate their identity and determine their compliance with specifications for physical and chemical parcels, microbial impurity, and dangerous or other unwanted chemical pollutants. Reserve samples of approved lots or batches of raw accoutrements and finished products are retained for the specified time period, are stored under conditions that cover them from impurity or deterioration, and are checked for continued compliance with established acceptance specifications. The water force, particularly the water used as an ornamental component, is tested regularly for conformance with chemical-logical and microbiological specifications. Fresh as well as retained samples of finished products are tested for acceptability of preservation against microbial impurity which can do stoner nicely foreseeable condition of the storehouse and consumer use.
7. **Records.** Raw Paraphernalia and primary packaging paraphernalia, establishing disposition of rejected paraphernalia.
  - a. Manufacturing of batches, establishing the Processing, handling, transferring, holding, and filling.
  - b. Testing, controlling, conforming, and revamping.
  - c. Law marks of batches and finished products.
  - d. Finished products, establishing slice, individual laboratory controls, test results, and control status. Distribution, establishing original interstate cargo, law marks, and consignees.
8. **Labelling.** Check whether the markers of the immediate and external vessel bear On the top display panel The statement" Warning-- The safety of this product has not been determined" if the safety of the separate product has not adequately been substantiated. Determine whether and what toxicological and/ or other testing the establishment conducted to substantiate the safety of its products. See 21 CFR740.10. On the information panel. the list of constituents (only on the external vessel) if intended for trade or customarily ended to consumers for consumption at home.
  - a. The warning statement(s) needed at 21 CFR740.11,740.12 and740.17.
  - b. Any other advising statement necessary or applicable to help a health hazard. Determine the health hazard or their base for a warning statement.
  - c. Any direction for safe use of the product.
  - d. In the case of a hair colour product, the caution statement of Sec. 601(a) of the Act and applicable directions for primary patch testing. This warning only applies to coal- navigator hair colourings which, if so labelled, are also exempted from the contamination provision of the Act.
10. **Complaints:** Check whether the establishment maintains a consumer complaint train and determine
  - a. The kind and inflexibility of each reported injury and the body part involved.
  - b. The product associated with each injury, including the manufacturer and law number.
  - c. The medical treatment involved, if any, including the name of the attending croaker
  - d. The name(s) and position(s) of any bane control centre, government agency, croaker's group etc., to whom formula information and/ or toxin data are handed.[35]

### 2.31 ICH Guidelines

Sr No	ICH Guidelines 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 drug substances.
4	Q1D	Bracketing and matrixing design for stability of drug substances and products
5	Q1E	Evaluation of substance data
6	Q5F	Stability data package for registration application in climatic zone 3 and zone 4.
7	Q5C	Stability testing of biotechnological products.

This Guideline provides recommendations on stability testing protocols including temperature, moisture, and trial duration for Climatic Zone I and II. likewise, the revised document considers the conditions for stability testing in Climatic Zones III and IV in order to minimize the different storehouse conditions for submission of a global dossier. substantially explains the stability studies of medicines. The main purpose of stability testing is to insure the efficacy, safety and quality of active medicine substance and lozenge forms and to establish shelf life or expiration period and to support marker claims.[36]

## 2.32 Knowledge About Following Point

### A. Oral Cavity Problems

**Oral health refers to the health of the teeth, epoxies, and the entire oral-facial system that allows us to smile, speak and chew.** Some of the most common conditions that impact our oral health include depression (tooth decay), goo(periodontal) complaints, and oral cancer. further, then 40 of grown-up's report having felt pain in their mouth within the last time, and further than 80 of people will have had at least one depression by age 34. The nation spends further than\$ 124 billion on costs related to dental care each time. On average, over 34 million academy hours and further than\$ 45 billion in productivity are lost each time as a result of dental extremities taking unplanned care.[37]

### B. Skincare

A recent study has revealed that the skin can absorb up to 60 percent of the chemicals in products it comes in contact with." Beauty products cannot conduct the projected results. On the negative, unacceptable quality, grade, and dangerous compositions can affect disinclinations, discoloration, texture revision, or endless damage to the skin or hair. Increased operation and limited product have led to steep rise in side goods suffered by the consumers. I have seen the number of cases twice, especially in the youngish to middle aged cases."[38]

### C. Skin Problems

1. Congested Pores
2. Early Aging
3. Sot or unctuous Skin
4. Breakout
5. Antipathetic response
6. Colour Changes
7. Eye Infections
8. Cancer

### D. Hair Problems

Hair problems are an important tool that helps to increase cases of alopecia and crown treatments.

1. Soaps, conditioners, hair straightening products, hair colourings, and henna; regarding their tradition and guards
2. The dermatologist's knowledge of hair care products, their use, and their possible side goods can extend to an understanding of ornamental coffers and help dermatologists to more treat hair and crown conditions according to the diversity of hair types and race. Epidemiologically and mortal monitoring studies have not detected any threat of carcinogenetic of the constituents used currently.
3. Communicate dermatitis is the main response. Turabi etal. Meta-analysis definitively barred any perceptible redundant threat of bladder cancer among hair colour druggies. Although paraphenylenediamine is a common allergen, resorcinol, and m- aminophenol was set up more constantly in the work of Hamann etal.[39]

### E. Nail Problems

Nail problems Onycholysis to artificial nails and methacrylate cement.

- Hand dermatitis due to artificial nails and methacrylate cement.
- Paronychia as a response to nail enamel.

- Eyelid dermatitis due to nail enamel mislike.
- Facial dermatitis due to nail enamel mislike.
- Casket dermatitis due to nail enamel mislike.[40]

### 2.33 Cleansing and Care Needs For

#### A. Face

Cleansing of face Sanctification of face Cleanliness of the face is a veritably important task of the diurnal base, as it is a sensitive part and essential part to looking seductive and fresh. Sanctification of the face is essential because it faces numerous disciplines and microbial exertion

1. Face wash
2. Face cleansers
3. Face moisturizer
4. Face masks:

#### B. Eyelids

Eyes are a veritably sensitive part and point-seeking part of the body. care should be taken to maintain eyes. Not only care is essential but also sanctification and timber-up are also essential.

1. After washing your hands, bedew a washcloth with a mild cleaning result.
2. Precisely wipe your eyelashes and eyelids.
3. Rinse using warm water.

#### C. Gums

Then are many ways you can help keep your epoxies healthy.

1. Floss. Floss at least formerly a day.
2. Get regular dental cleanings. Your dentist can descry early goo complaint symptoms if you see them on a regular base.
3. Quit smoking.
4. Encounter twice a day.
5. Use fluoride toothpaste.
6. Use a remedial mouthwash.

#### D. Dental Cavities

Dental depressions Healthy teeth are clean and have no depressions. Healthy epoxies are pink and firm and do not bleed. To maintain healthy teeth and epoxies, follow this way

- Floss at least formerly per day. It is stylish to floss after brushing. Flossing removes the shrine that is left before after brushing from between the teeth and on the epoxies.
- Encounter your teeth doubly a day with a soft-bristled toothbrush. Encounter for at least 2 twinkles each time. Use fluoride toothpaste. The fluoride helps strengthen tooth enamel and helps help tooth decay.
- Replace your toothbrush every 3 to 4 months or sooner if demanded. A worn-out toothbrush will not clean your teeth as well. However, change heads every 3 to 4 months as well, if you use an electric toothbrush.
- Eat a healthy diet. You are less likely to get good complaints if you eat healthy foods.
- Avoid sweets and candied drinks. Eating and drinking a lot of sweets increases your threat of cavities. However, brush your teeth soon after, if you do eat or drink sweets.
- Don't bomb. Smokers have further teeth and goo problems than non-smokers.
- Keep dentures, retainers, and other appliances clean. This includes brushing them regularly. You can also need to soak them in a sanctification result. Schedule regular check-ups with your dentist. numerous dentists recommend having the teeth professionally gutted every 6 months for optimal oral health. Seeing the dentist every 3 to 4 months can be demanded if your epoxies come unhealthy.

### **E. Hair**

The purpose of a hair cleaner and soap is the same i.e., drawing your hair to remove dirt, smut, and product makeup. still, hair cleaners are important and milder in nature and they tend to make your hair soft. Hair cleaners are sulphate-free and hence are gentle to use on your hair. Wash Your Hair Regularly. Washing your hair regularly ensures that your crown and hair are free of dirt and redundant oil painting.

1. Use Chemical Free Shampoos.
2. Condition rightly.
3. Dry Your Hair Naturally.
4. Oil painting Your Hair duly.
5. Use A Wide- toothed Comb.
6. Style Your Hair Naturally.
7. Trim Your Hair Regularly.

### **F. Lips**

It is a watch need for lips

1. Do not touch or master your lip
2. Follow a healthy diet
3. Stay doused by drinking a lot of water
4. Keep your lips doused late
5. Blarney your lips
6. Drop your lips
7. Always carry a lip attar

### **G. Hands**

1. Apply hand cream regularly
2. Use vitamin E oil painting to moisturize your nails.
3. Treat cracks on your hands with an ointment.
4. Treat your hands with a mask daily

#### **Keeping Your Hands Clean**

1. Wash with a moisturizing hand cleaner.
2. Clean under your nails with a nail encounter.
3. Slip your hands weekly your nails trim and well- shaped guarding Your Hands

#### **Protecting Your Hands**

1. Use sunscreen on your hands
2. Wear gloves when doing chores.
3. Apply a retinol treatment to dark spots.

### **H. Feet**

Bases You should at least formerly in a month wax and bleach your bases; it removes the tan. In the shower, take a pumice gemstone or PEDI scrubber and clean the bottom of your bottom smoothly. Almond oil painting is veritably good for your skin. Applying it regularly to your bases after the bath will get you a smooth result. Soak bases for 10 twinkles in warm water to which a swab has been added. Remove and drop dry, especially between the toes. This is the easiest way to relax tired bases. In the case of a sprain, add Epsom swab to the water for stylish results. To get relieve of dry skin from bases, put cleaner on sponger and irk on bases and marshland. Keep heels smooth by rubbing them sometimes with fresh lime juice or massage with a nutritional cream. However, blend 10 drops of lavender oil painting in water and soak bases in it for 15 twinkles, if your bases sweat too important. Pat dry and apply talcum greasepaint.

### **I. Nail**

Keep your nails short. Unevenly trimmed, short nails are less likely to collect bacteria and dirt. Get cleaner and water under your nails when you wash. Soak your hands completely. Moisturize.

## **2.34 Formulation Consideration for Ethnic Needs of Cosmeceuticals**

### **A. Cleansing Cream**

Sanctification cream in foremost times, sanctification was done by using a piece of bone or gravestone to scrape the skin. Latterly societies used accoutrements of factory origin along with water for sanctification. Numerous different societies can be given credit for discovering cleaner. The first ornamental sanctification cream to be manufactured on an artificial scale was cold cream, a conflation made with mineral or almond oil painting along with beeswax, borax, and water. Cleaners of this type were designed to melt or run when applied to the skin- they were thixotropic which is why they were appertained to as liquefying sanctification creams.

### **B. Cold Cream**

The invention of cold cream is credited to Galen, a croaker in the alternate century from Greece. This cold wave cream is thick and softens when it touches the skin. It is perfect for dry skin on the elbows, bases, and knees and perfect for natural ways of removing makeup and avoiding eczema in the dry corridor of your body. The conflation is of a "water in oil painting" type unlike the "oil painting in water" type conflation of evaporating cream, so-called because it seems to vanish when applied to the skin.

### **C. Moisturizing Cream**

The appearance and function of the skin are maintained by an important balance between the water content of the stratum corneum and skin face lipids. The skin represents the most superficial subcaste of the body, and so it is constantly exposed to different environmental stimulants. Exposure to external factors as well as endogenous factors can disrupt this balance. In addition, frequent use of detergents, cleansers, and topical annoyances like alcohol and hot water can remove the skins and face's lipids. Dislocation of the skin hedge led to the colourful type of skin problems most common condition is a loss of water content which leads to the blankness of skin like roughness, scaling, cracks, greenish Ness, and an uncomfortable feeling of miserliness, occasionally with itching and surcharging. Treatment with moisturizer aims at maintaining skin integrity and well-being by furnishing a healthy appearance of the existent. Figures of moisturizers are available under the marker of natural, safe, organic, and herbal while the introductory parcels of a sleepover, exclusivity and emollience are harmonious across all moisturizers. Utmost of the available moisturizers uses synthetic bonds, emulsifiers, incensing agents, colours, surfactants, and thickeners to form the base. There is an expansive need to replace poisonous synthetic agents from the base using natural agents.

### **D. Shaving Creams**

Shaving cream is a product put on the skin (primarily face and legs) to give lubrication which helps help razor burn and discomfort during paring. It comes in a wide variety of formats including creams, gels, and utmost general lathers. While paring creams can take numerous forms from liquids to poultices, gels, and creams, they all contain constituents that help soften the hair and slick the skin. The primary constituents include surfactants, detergents, humectants, conditioning agents, lubricants, and aesthetic constituents.

### **E. Shampoo**

Soaps are ornamental products generally in result form designed for a particular reason, cleaning hair. Surfactants are the main component of soap. They can compass the oil painting notes so that they can be irrigated off latterly with water. The simplest form of an expression is the result. Thus, if you are just starting care products, soaps are the easiest to start with as you just need to mix all the constituents

### III. PREPARATION OF SOPS OF DIFFERENT EQUIPMENT AND INSTRUMENTS

Preparation of bribes of different outfits and instruments A Standard Operating Procedure(bribe) is a set of written instructions that validate a routine or repetitious exertion followed by an association. The development and use of bribes are an integral part of a successful quality system as it provides individuals with the information to perform a job duly, and facilitate thickness in the quality and integrity of a product or result. The term “bribe” cannot always be applicable and terms like protocols, instructions, worksheets, and laboratory operating procedures can also be used.

#### 3.1 SOP Preparation

The association should have a procedure in place for determining what procedures or processes need to be proved. Those bribes should also be written by individuals knowledgeable about the exertion and the association's internal structure. These individuals are subject-matter experts who perform the work or use the process. A platoon approach can be followed, especially formulate-tasks processes where the guests of several individualities are critical, which also promotes “buy- in” from implicit druggies of the bribe. bribes should be written with sufficient detail so that someone with limited experience with or knowledge of the procedure, but with an introductory understanding, can successfully reproduce the procedure when unsupervised. The experience demand for performing an exertion should be noted in the section on labour force qualifications. For illustration, if an introductory chemistry or natural course experience or fresh training is needed that demand should be indicated.

#### 3.2 Hands on Instrument

##### A. Texture Analyser

Depending upon the chosen inquiry/ institution, the Texture Analyser can perform contraction, extension, cutting, banishing, bending, and shearing tests – and in doing so, can measure parcels similar as fractur capability, chewiness, stickiness, thickness, suck force and springiness. a tensile cadence equipped with special examinations (in the form of acrylic cylinder and pristine- sword sphere), which can access the measured sample of a product recording the force, distance, and time. The instrument simulates the action of a mortal cutlet touching the face and probing the parcels of an object. The set-up has been preliminarily shown to quantify the rheological/ textural parcels of ornamental and pharmaceutical products similar as creams, embrocation, and gels as well as rheological gets of mortal skin. The results include the analysis of water, glycerine, and mineral oil painting as well as waterless results of thickeners like Acrylates/ C10- 30 Alkyl Acrylate Cross polymer (Ultras- 20 attained from Noveon), and Carbomer. results of common surfactants and complex surfactant phrasings like soaps have also been delved into. The results, in the form of plots of force as a function of time or distance, performed from slow-directional inquiry movement (submergence and-submergence) in the anatomized fluid, were interpreted by considering buoyancy, drag, and thick drag force given by Stokes equation. The data can be used to relate to tactile evaluations of products by trained panel evaluations. This composition is defended by the brand. All rights reserved. [Figure 1]



Figure 1: Texture Analyser

##### B. Brookfield Viscosity

Generally, refers to a density dimension performed with a Brookfield Viscometer, occasionally appertained to as a Brookfield viscosimeter. The Brookfield viscometer is a rotational viscometer. To measure the density, a measuring



body(spindle) is immersed in the oil painting and rotated at a defined speed. The force needed to keep this speed constant is a dimension for the dynamic density. [Figure 2]



Figure 2: Brookfield Viscosity

C. Tablet Punching Machine

A tablet press is a mechanical device that compresses grease paint into tablets of invariant size and weight. A tablet press can be used to manufacture tablets of a wide variety of accoutrements, including Medicinals, nutraceuticals, drawing products, artificial bullets, and cosmetics. To form a tablet, the granulated greasepaint material must be metered into a depression formed by two punches and a bone, and the punches must be pressed together with great force to fuse the material. [Figure 3]

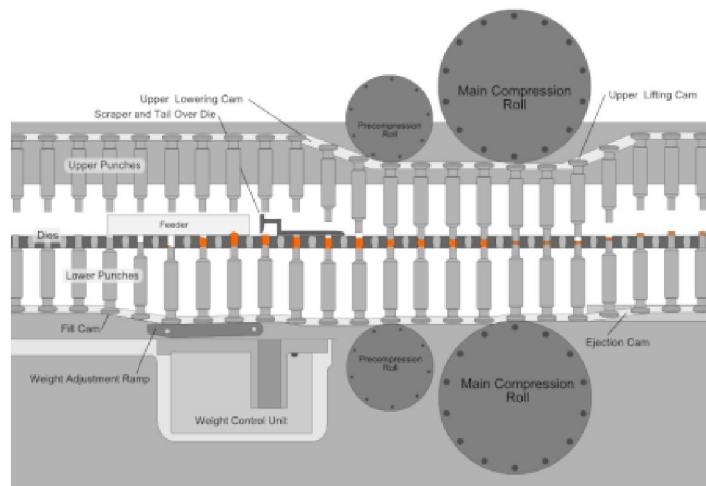
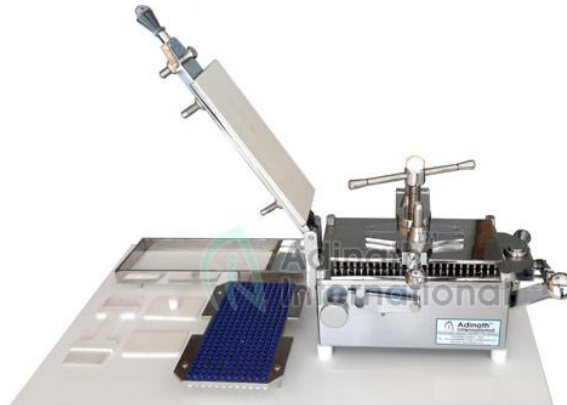


Figure 3: Tablet Punching Machine

D. Capsule Filling Machine

Tamping leg capsule filling machine uses a tamping punch to make greasepaint compacted. The dosing slice will turn for formerly after reining to transfer the greasepaint to next tamping punch and greasepaint over the dosing slice will automatically fill the dosing slice holes. And after tamping, the greasepaint will be filled into the capsule body. Hand Operated Capsule Filling Machine is table top machine suitable for airman & product batch conditions. Machine is having 300 holes with 25 x 12 combinations made in Stainless Steel constructions meeting GMP conditions. Machine can fill size 00 to size 5 capsules with help of different machines and exchangeable corridor. Assembly has been done in such a way that it can be fluently strike for drawing operations. Though all the operations are homemade, the machine calls for perfection crafted factors and assembled with largely professed labour force. Machine having wide operation in R&D laboratories, Research Institutions, Herbal & Nutraceutical medications, Unani & Ayurvedic drugs. [figure No: 4]



**Figure 4:** Capsule Filling Machine

### E. Spray Dryer

Takes a liquid slurry and separates the solute or suspension as a solid and the detergent into a vapor. The solid is generally collected in a barrel or cyclone. The liquid input slurry is scattered through a nozzle into a hot vapor slurry and cracked. Solids form as humidity rapidly leaves the drop. Product of dry flavouring is achieved fluently with spray drying. The Spray Drying process involves a waterless feed material which includes water, carrier, and the flavour is comminuted into a slurry of hot air. The atomized particles tend to dry fleetly. The unpredictable flavour ingredients are trapped inside the droplets. The greasepaint is occasionally recovered via cyclone collectors. Since spray drying fashion is inversely good in running of both water answerable and oil painting-answerable flavour systems, it continues to be the preferred encapsulation process. It is also fairly brought effective and can be fluently gauged from airman factory to the marketable product. [figure 5]



**Figure 5:** Spray Dryer

### F. Freeze Dryer

Freeze drying processes due to the preservation of the rates of the constituents used in their natural and raw form. This point of freeze drying allows ornamental brands to capture the constituents of their products in their stylish and most active form, without the need to add fresh preservatives. It is a freeze-drying machine specially used in the field of cosmetics and cosmetics, like the freeze-dried mask, mesh red freeze-dried grease paint, and so on. Because it is dry at low temperatures, it can retain the original natural exertion of the cosmetics well and is suitable for long-term storehouse and stable efficacy. Freeze-drying works in three phases.

1. Indurating
2. Primary Drying (Sublimation)
3. Secondary Drying (Adsorption) [Figure No 6]





**Figure 6:** Freeze Dryer

### G. Homogenizer

Beauty and soft skin and fragrance aside, homogenizers are used for an array of purposes. They reduce particle size by forcing liquid through a narrow tube at high pressure; the resulting product can be used to create anything from tasty beverages to cancer treatments homogenizer machines are pieces of equipment used for the homogenization of various types of material. High-pressure homogenization in the pharmaceutical industry has proven its ability to make more stable products, with better API dispersion. The homogenizer principle of operation is a rather simple one: spread the laser energy, typically concentrated at the center of the beam, by scattering the beam so that it overlaps itself multiple times, creating a beam with a larger divergence angle than the original beam [ Figure No 7]



**Figure 7:** Homogenizer

### H Ultrasonic

The principle of the ultrasonic cleaning machine is to convert the sound energy of the ultrasonic frequency source into mechanical vibration through the transducer. The vibration generated by the ultrasonic surge is transmitted to the drawing liquid through the cleaning tank wall, so that the micro-bubbles in the liquid in the tank can keep wobbling under the action of the sound surge, destroying and separating the dirty adsorption on the face of the object. When low pressure is applied to the liquid, high-intensity ultrasonic swells are produced, creating small vacuum bubbles in the liquid. As the bubbles reach their achromatism position, they collapse and this happens in the high-pressure cycle. In the ultra-sonication process, cavitation leads to dissipation, homogenization, decomposition, mixes, birth, and so no chemical goods of the liquids. High-power ultrasound is introduced to the liquid which creates regions of high pressure (known as contraction) and low pressure (known as refraction) [Figure No 8]



**Figure 8:** Ultrasonic

### I. Colony Counting

The purpose of colony counting is ultimately to estimate the number of cells present based on their given ability to continue to grow and expand under certain conditions. The colony counters can use fluorescent labels or contrast between light. [Figure No 9]



**Figure 9:** Colony Counting

## IV. PREPARATION AND EVALUATION OF LIP BALM

### 4.1 Preparation

1. Give 3 or 4 red roses.
2. Wash roses and clean their petals.
3. Separate their petals. [ use always fresh flowers]
4. Take a cotton cloth and dry all petals. make Shure you wipe it carefully. it should not contain any moisture.
5. Take mortal and postal and crushes all leaves
6. Add a few amounts of coconut oil. coconut oil is very good for lips, they make them soft and brighter.
7. Mix leaves with oil, and crush leaves with oil so that the colour mix with the oil.
8. Now take out the pest in a beaker.
9. Add 2 tbsp of coconut oil again, and mix them well.
10. Now pest takes in a water bath for heating for 10 mins, stirring occasionally.
11. This process makes the leaves give away their colour, it will combine with oil.
12. Strain this paste. then it should be dry.
13. Give an empty balm bottle, and store it.
14. Store in a cool place for 2 hours.
15. Tiny leaves settle at the bottom, now mix them up
16. Take in the microwave for 5 sec then get a clear upper layer
17. Now refrigerate for 1 hour.
18. Ready a pink lip balm.

#### 4.2 Evaluation of Lip Balm

The quality of a lip attar product can be assessed by the product's performance. thus, the significance of the evaluation parameters of any product is abundant. It helps to maintain stability along with the chastity and uniformity of the product. The main evaluation parameters of lip attar products are described in this section. The appearance of cosmetics products plays a consummate part from the consumer's perspective. This includes colour, odour, and texture of the product. By imaging in 10x exaggeration under a microscope colour and appearance can be characterized, while odour can be The spread capability of lip attar can be tested by applying the formulated lip attar on a glass slide at room temperature to observe uniformity in the expression of the defensive subcaste and whether the stick fragmental is misshaped or broken during operation for applicable results of the different expression. The melting temperature and pH of lip attar are also generally estimated by capillary system and pH cadence independently. Ex-vivo and in vivo tests should be performed for skin vexation test. The product needs to study for the face anomalies similar as conformation chargers on shells or impurity by moulds, fungi etc. There should not be signoff any face blights.

#### 4.3 Report

Cosmetics are substances that want to reinforce the appearance or odour of the human body. The word cosmetics derives from the Greek word which suggests the technique of dress & ornament Women need to colour their cheeks in colour by first coating their face, neck, and other spare a white powder without knowing that white powder contained lead that destroys their complexion after a certain period. There are many cosmetics products used in daily life. examples: lipstick, mascara, creams, lotion. they are made from herbal or synthetic drugs. they give many side effects. Cosmetics are helpful in men's and women's life.

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