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A Review on the Cosmetics Rule 2020 and ISO 22716

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ABSTRACT

Cosmetics shall be defined as any article intended to be rubbed, poured, sprinkled, or sprayed into, or otherwise applied to, the human body or any part thereof for the purpose of cleaning, embellishing, promoting attractiveness or altering appearance, and shall include any article intended for use as a component of cosmetics. Good Manufacturing Practices for Cosmetics ISO 22716:2007 is the international standard for the Good Manufacturing Practices (GMP) for cosmetics. ISO 22716 provides guidance to documenting and regulating the production, control, storage, and shipment of cosmetic products. In this article, we discussed the new Cosmetic Rules 2020 which set out separate guidelines for the import and registration, manufacture, labeling and packaging of cosmetics in terms of sale or distribution, sampling procedures, approval of laboratories for testing and alternative tests for cosmetics.

Keywords: Cosmetics; GMP; ISO 22716; Cosmetic Rules

Introduction

Cosmetics shall be defined as any article intended to be rubbed, poured, sprinkled, or sprayed into, or otherwise applied to, the human body or any part thereof for the purpose of cleaning, embellishing, promoting attractiveness or altering appearance, and shall include any article intended for use as a component of cosmetics. To ensure the quality, safety, and efficacy of cosmetics. Strict regulations are being laid down and followed by regulatory authorities in all countries and regulations vary from country to country [1]. Cosmetics have been in use for ages and are a booming business now; they are an essential part of life and have increased demand over the last 3-4 decades. The first evidence of cosmetics was found in 4000 B.C. It was in ancient Egypt and Greece. The word cosmetics were derived from the Greek word "Cosmetics" which means "qualified in ordering and arranging"[1]. Cosmetics are used to enhance attractiveness, to alter appearance, to protect against UV rays to treat skin problems.

The cosmetics are classified as:

1. Skin Cosmetics: Cleansing preparation, skin moisturizers, skin tonic, shaving cream, face mask, vanishing cream, lotions, body butters, powders etc.
2. Hair Cosmetics: Hair dyes, hair oils, hair creams, hair gels, hair removing creams, shampoos etc.
3. Eye Cosmetics: Eye liners, eye gloves, kajal, Surma, contact lens, eyebrow pencil etc.
4. Nail Cosmetics: Cuticle creams, oils and removers, nail polish, nail stain removers etc.
5. Dental and Oral cavity Cosmetics: Toothpaste, tooth powders, mouth washes, teeth whitening, whitening etc.
6. Antiperspirant and Deodorants: Powder, liquid, creams and sticks etc.
7. Miscellaneous Cosmetics: Anti stress marks, black head removers, toilet soaps etc. [2] (Figure 1).

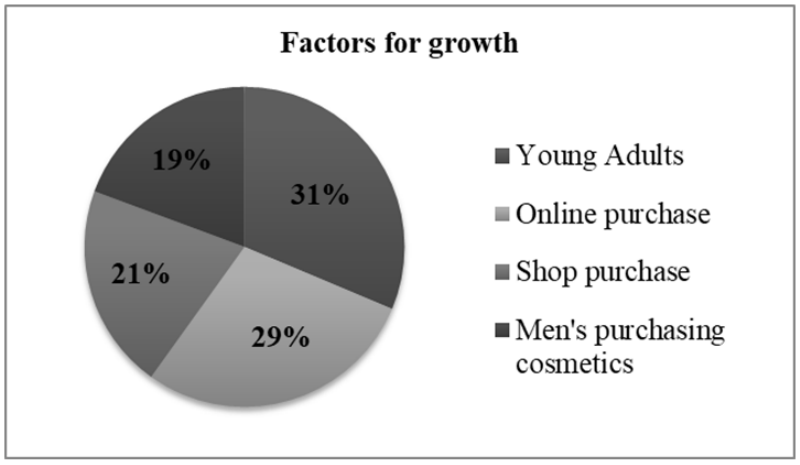

Figure 1: Factors for growth of cosmetics.

Regulatory Aspects of Cosmetics in India

In the exercise of the powers conferred by Sections 12 and 33 of the Drugs and Cosmetic Act 1940, the Central Government, after consulting the Technical Advisory Board on Drugs, made the rules for cosmetics 'Cosmetic Rules 2020'.The CDSCO referred to in Section 3 (aaa) defines cosmetics as 'any article intended to be rubbed, poured, sprinkled or sprayed onto, or otherwise applied to, the human body or any part thereof for cleaning, beautifying, promoting attractiveness or altering appearance, and includes any article intended for use as a component of cosmetics [3,4]. Schedule S of the Drugs and Cosmetics Act 1940 and the Ninth Schedule of the Cosmetics Rules 2020 laid down the final form standards that comply with the Indian Standard Specification laid down by the Bureau of Indian Standards (BIS) [5].

Cosmetic Rules, 2020

In order to codify and update the rules on cosmetics on a stand-alone basis, the central government published the Official Cosmetics Rules 2020 Gazette, which sets out separate guidelines for the import and registration, manufacture, labeling and packaging of cosmetics in terms of sale or distribution, sampling procedures, approval of laboratories for testing [6]. The Cosmetic Rules, 2020 consists of, 9 Chapters, 13 Schedules and Appendix (24 Forms) which is given in (Tables 1-3).

Table 1: Cosmetics Rules, 20 (chapters).

	Chapters
Chapter I	Preliminary
Chapter II	Authorities, officers, and laboratory
Chapter III	Import and Registration
Chapter IV	Manufacture of Cosmetics for Sale or Distribution
Chapter V	Permission for import or manufacture of new cosmetic
Chapter VI	Labelling, packaging and standards for sale or distribution of Cosmetics
Chapter VII	Procedure of sampling for test or analysis, seizure, and report
Chapter VIII	Approval of laboratory for carrying out tests on Cosmetics and their raw materials
Chapter IX	Miscellaneous

Table 2: Cosmetics Rules,2020 (Schedules).

Schedule		
First Schedule	Authorisation from manufactures (Authorisation to accompany an application for issuance of import registration certificate)	
Second Schedule	Part-I	Information and undertaking required to be furnished by the manufacturer or his authorised importer or distributor or agent of. the application form for import registration certificate.
	Part-II	Information and undertaking required to be furnished by the manufacturer with the application form for grant of manufacturing license or loan license
Third Schedule	Fee payable for license, permission, and registration certificate	
Fourth Schedule	List of categories of cosmetics for import	
Fifth. Schedule	Fee for test of analysis by the central cosmetics laboratories or by the state laboratories	
Sixth Schedule	Undertaking for the import of cosmetics to be submitted by the importer with application from import Registration Number	
Seventh Schedule	Good manufacturing practice md requirements: of premises, plants and equipment fur manufacture of cosmetics	
	I	General Requirements
	II	Requirements of plant and equipment
Eight Schedule	I - Particulars to be shown in the manufacturing. II - Records of raw materials	
Ninth Schedule	Standards for cosmetics	
Tenth Schedule	Part-I	List of Colorants allowed for use in cosmetics Products
	Part-II	List of Colours to be used in soaps
Eleventh Schedule	Good Laboratory Practices and requirements of premises and equipment	
Twelfth Schedule	Classes of cosmetics, Extend and Conditions of exemption	
Thirteenth Schedule	Rules, Sub, Parts, Schedules and Forms Omitted	

Table 3: Cosmetics Rules. 2020 (Forms).

Forms	
Form COS- 1	Application for issue of registration certificate for import of cosmetics into India
Form COS- 2	Import registration certificate to be issued for import of cosmetics into India
Form COS- 3	Permission to import or manufacture new cosmetics in India
Form COS- 4	Application for issue of Import Registration Number for import of already registered cosmetics
Form COS- 4A	Import registration number to be issued for import of already registered cosmetics into India
Form COS- 5	Application for grant of a licence to manufacture cosmetics for sale or for distribution
Form COS- 6	Application for grant of a loan license to manufacture cosmetics for sale or for distribution
Form COS- 7	Self-certification of compliance of good manufacturing Practice (GIP) for manufacture of cosmetics
Form COS- 8	Licence to manufacture cosmetics for sale or for distribution
Form COS- 9	Loan licence to manufacture cosmetics for sale or for distribution
Form COS- 10	Intimation to person from whom sample is taken
Form COS- 11	Form in which the inspection book shall be maintained
Fore OOS- 12	Application for grant of permission for new cosmetics for obtaining import registration certificate or manufacturing license
Fore COS- 13	Application from a purchaser for test analysis of a cosmetics under section 26 of the drug and Cosmetic Act, 1940

Fore COS- 14	Report of test or analysis by government analyst under section 26 of the Drugs and Cosmetic Act. 1940
Fore COS- 15	Report for stock of cosmetics for record. register, document, or material object analyst under section 22 (1)(c) or (cc)of the Drugs and Cosmetic Act. 1940
Fore COS- 16	Report for sample of cosmetics taken where fair price tendered the of under sub-section (1) of section 23 of label Drug md Cosmetics Act,1940 is refused
Fore COS- 17	Memorandum to government analyst
Fore COS- 1S	Order under section 22 (l)(c) of the Drugs and Cosmetics Act, 1940 requiring a person not to dispose of stock in his possession
Fore COS- 19	Report of tests or analysis of cosmetics by tbc government analyst
Fore COS- 20	Memorandum to the Director, Central cosmetics Laboratory
Fore COS- 21	Application for gram of approval for carrying out tests on cosmetics or raw materials used in the manufacture thereof on behalf of licenses for manufacture for sale of cosmetics
Form COS- 22	c for grant of approval for carrying out tests on cosmetics and raw materials used in the manufacture on behalf of licensees for manufacture for sale of cosmetics
Form COS- 23	Approval for carrying om Tests On cosmetics and raw materials used in their manufacture on behalf of forces for manufacture for sale of cosmetics
Form COS- 24	Report of test or analysis by approval institution

Registration Requirements for Cosmetics

The Seventh Schedule of the Cosmetics Rule 2020 sets out the Good Manufacturing Practice (GMP) and the requirements of premises, plants and equipment for the manufacture of cosmetics, which are divided into two parts, general requirements and plant and equipment requirements [7]. The General requirements include,

- Location and surroundings
- Buildings
- Personnel
- Water Supply
- Disposal of waste
- Health, clothing, and sanitary requirements of the staff
- Medical services
- Maintenance
- Testing and release of raw materials & finished cosmetic products.
- Washing facilities

Requirements of plant and equipment for powders, skin powders for infants, creams, lotions, emulsions, pastes, cleansing milks, shampoos, pomade, brilliantine, shaving creams and hair-oils, nail polishes and lacquers, lipsticks and lip gloss, depilatories, eyebrows, eyelashes, eyeliners, kajal and Surma, aerosols, alcoholic fragrance solutions, hair dyes, tooth powders, tooth paste and toilet soaps are explained and these are categories of cosmetics, for which the license will be granted for manufacture [8].The equipment and the area required for the manufacturing are given below in (Table 4). The manufacturing record should contain the following,

Table 4: Requirements of plants and equipment's.

Category	Equipment and area required
Powders: Face-powder, cake make-up, compacts, face-packs, masks, and rouges etc	Powder mixer, blender, sieves, Ball mill, Trays and scoops, Filling and sealing equipment, Weighing, and measuring devices, Storage tanks. Area: 15 square metres
Skin powder for Infants	Powder mixer, blender, sieves, Ball mill, Trays and scoops, Filling and sealing equipment, Weighing, and measuring devices, Storage tanks. Area: 15 square metres
Creams, lotions, emulsions, pastes, cleansing milks, shampoos, pomade, brilliantine, shaving-creams and hair-oils, etc.-	Mixing and storage tanks, Heating kettle, agitator, Colloidal mill, triple roller mill, Filling and sealing equipment, Weighing, and measuring devices. Area: 25 square metres
Nail Polishes and Nail Lacquers.	Mixer, Storage tanks, filling machine, Weighing, and measuring devices. Area: 15 square metres
Lipsticks and Lipgloss.	Vertical mixer, Jacketed kettle, mixing vessels, Triple roller mill/Ball mill, Moulds, Weighing and measuring devices Area: 15 square metres
Depilatories	Mixing tanks, Mixer, Triple roller mill, Filling and sealing equipment, Weighing, and measuring devices, Moulds. Area: 10 square metres

Eyebrows, Eyelashes, Eyeliners.	Mixing tanks, mixer, Homogeniser, Filling and sealing equipment, Weighing, and measuring devices Area: 10 square metres
Kajal and Surma	Base steriliser, Powder steriliser (dry heat oven), Stainless steel tanks, Mixer, Stainless steel sieves, Filling and sealing arrangements, Weighing, and measuring devices, Pestle, and Mortar. Area: 10 square metres
Aerosol	Air-compressor, Mixing tanks, Suitable propellant filling and crimping equipment's, Liquid filling unit, Leak testing equipment, Fire extinguisher, Suitable filtration equipment. Weighing and measuring devices. Area: 15 square metres
Alcoholic Fragrance solutions.	Mixing tanks with stirrer, Filtering equipment, Filling and sealing equipment, Weighing, and measuring devices. Area: 15 square metres
Hair Dyes	Stainless steel tanks, Mixer, filling unit, Weighing, and measuring devices, Masks, gloves and goggles. Area: 15 square metres
Toothpowders and toothpastes	Weighing and measuring devices, Dry mixer, Stainless steel sieves, Powder filling and sealing equipment's, Weighing, and measuring devices, Kettle, Planetary mixer with de-aerator system, Stainless steel tanks, Tube filling equipment, Crimping machine Area: 15 square metres
Toilet Soaps	Kettles or pans for saponification, Boiler, stirring arrangement, Storage tanks, Driers, Amalgamator, Mixer, Triple roller mill, Granulator, Plodder, Cutter, pressing stamping and embossing machine, Weighing and measuring devices Area: 100 square metres

Labelling and Packaging of Cosmetics

No person may manufacture, sell, or distribute cosmetics unless they are labelled and packaged in accordance with the Cosmetic Rules of 2020.

Manner of labelling

a. Name of the Cosmetics
b. Name of the manufacturer with complete address
c. Nam e of the country where it was actually manufactured.
d. Expiry (date and month)
e. Batch No. or Lot No.
f. Manufacturing License Nurnb er
g. Net Content and. weight
h. Name and quantities of the ingredients
i. Directions for safe use
j. Warning, cautions, or special directions required.
k. Import Registration Certificate Numberer (Reg. Cert. No)

- If a cosmetic package has only one label, the information present in both the inner and outer label should be present in the label.
- The alteration, obliteration or deface any inscription or mark made or recorded by the manufacturer or the container, label and wrapper shall not be done unless permission is obtained from the Central Licensing Authority.
- False and misleading claims are prohibited.
- If any ingredient is a product produces skin irritation or harm "caution" shall me mentioned
- The product should contain instructions in both English and local languages.
- Toothpastes containing fluorides should not be above 1000 ppm and the expiry date should be mentioned in both the tube and carton [9] (Table 5).

Table 5: Particulars of manufacturing record.

S. No	Particulars
1	Serial Number
2	Name of the product
3	Lot or batch size
4	Lot or batch number
5	Date of commencement of manufacture and date when manufacture was completed
6	Name of all ingredients, quantities required for the for the batch size, quantities used
7	Control reference numbers in respect of raw materials used information.
8	Reference to analytical report. numbers or unique code
9	Actual production and packing particulars indicating the size and quantity of finished packing's
10	Date of release of finished packing for distribution or sale
11	Signature of the expert staff responsible for the manufacture

Some of the Provisions Cosmetics as Per Cosmetics Rule, 2020

- Toothpastes containing fluorides shall not be more than 1000ppm, the fluoride content and the expiry date should be mentioned on tube and carton.
- Arsenic Trioxide- 2 parts per million of Arsenic
- 20 parts per million of lead
- 100 parts per million other that lead considered as the respective metals total.
- Soaps – Hexachlorophenes, should not exceed 1% w/w and should be mentioned "not to be used on babies."
- Cosmetics containing mercury should not exceed 0.007 per cent (for eyes) and for finished products not exceeding 1ppm.
- Lead and Arsenic for colouring cosmetics is prohibited.
- Animal study for cosmetics is prohibited.

Schedule ten of the Cosmetics Rule 2020 sets out colorants that may be used in cosmetic products as specified in the Cosmetics Rules 2020 are Phthalocyanine Blue, Citrus Red No.2, Aqueous Green Paste, Pigment Yellow 3, Irgalite Carmine F-P Powder or Pigments Red 5 and Monolite Red 4R HV Paste or Pigment Red 7 [10]. The Ninth Schedule sets out Indian standards for finished cosmetic products as amended by the Bureau of Indian Standards (Table 6).

Table 6: International Cosmetics Regulations.

Countries	Requirements
 India	❖ COSCO is the regulatory authority. ❖ The Drugs and Cosmetic Act 1940 and Rules 1945 (Cosmetics Rules,2020) regulates cosmetics in India. ❖ Chapter VI of the Cosmetic Rules, 2020 governs labelling, packaging and standards for sale or distribution of cosmetics and the labelling requirements should be as per the BIS standards. ❖ Pre-market approval is required form the state licensing authority. ❖ The Expiry of the product is indicated as "use before date." ❖ In India the post marketing reporting system is not applicable ❖ All the information should be mentioned on both the inner and outer cover. ❖ Labelling should be done in English. ❖ Manufacturer should maintain the safety record [11].
 United States of America	❖ USFDA *is* the regulatory authority. ❖ The Food, Drug and Cosmetic Act {FD&C and Fair Packaging and Labelling Act (FP&L) regulates cosmetics in USA. ❖ Labelling requirements: U.S. FDA CFR Title 21 701 and 740 and U.S. Federal Fair Packaging and Labelling Act (FPLA); U.S. FDA CFR Ti e 16 Section 500 ❖ U.S. FDA CFR Title 21 and Sections 73, 74, 81, 82, 250, 700-740 regulates the Cosmetic ingredients. ❖ With the exception of colour additives, no pre-market approval is needed for cosmetics. ❖ Safety warning on principle display panel ❖ The posit marketing reporting is done through the Voluntary Cosm1etic Registration Program [12].
 European Union	❖ EMA is the regulatory authority. ❖ Union Regulation (EC) No. 1123/2009 establishes requirements for cosmetics products that are placed within the European Union market. ❖ With the exception of colour additives, sunscreen active ingredients, and preservatives no pre-market approval is needed for cosmetics [13].

 Canada	❖ The Canadian government regulates the cosmetics industry through Health Canada's Cosmetics Program. Canadian regulations relating to Cosmetics (C.RC, c.869) form part of Canada's Food & Drugs Act. ❖ Manufacturers and importers must complete Cosmetic Notification Forms (CNF) to provide specific product information to Health Canada ❖ Claims on a label or in an ad for what a cosmetic can do must be accurate, so they do not mislead people. Claims are only allowed on drugs or natural health products, not on cosmetic products [l4].
 Australia	❖ The National Industrial Chemicals Notification .and Assessment Scheme (NICNAS) was the former entity responsible for controlling cosmetics and soaps. Since 1st July 2010, NICNAS was replaced by a new scheme Known as Australian Industrial Chemicals Introduction Scheme (AICIS). ❖ The product safety and cosmetic labelling standards are regulated by the Australian Competition .and Consumer Commission (ACCC). All cosmetic products must be labelled in accordance with the mandatory standard for labelling cosmetic products (Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulation 1991) [15].
 Japan	❖ In Japan, cosmetics are regulated by the Ministry of Health, Labour, and Welfare (MHLW) under the pharmaceutical and Medical Device Act ❖ The Act also classifies 1Cosmetics into two groups: Cosmetics and Medicated Cosmetics. Medicated Cosmetics is one category of Quasi Drugs. ❖ The pre-approval of cosmetics being brought to the market has not been needed if they meet the requirements of the negative list system and the full ingredients labelling system. ❖ The products manufactured in Japan and imported need to be fully notified before they are on the market [l6].

International Cosmetics Regulation

The Cosmetics have different standards and regulation globally and the comparison of the cosmetic regulation of India with other countries is given below [11].

ISO 22716 - Cosmetics - Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices

ISO 22716 has established guidelines for the production, control, storage, and delivery of cosmetic products, covering both the quality and safety aspects of cosmetics. Good Manufacturing Practices follow the principles of sound scientific assessment and risk assessment for the production of products with defined characteristics.

The key elements of ISO 22716 are,

- Quality management system and organization
- Premises and equipment
- Product realization and materials management
- Deviations, complaints and recalls.
- Continuous improvement

Quality Management System and Organization: The main focus of the GMP is on the establishment and maintenance of qualified personnel capable of producing a safe and effective product. The personnel in the cosmetics manufacturing company should have a strong knowledge and the tasks and responsibilities should be clearly described. In addition, the establishment of effective internal and external communication channels must be a top priority. In addition, the establishment of effective internal and external communication channels must be a top priority for management to ensure the participation and commitment of staff at all levels of the organization [12].

Premises and equipment: Proper design of manufacturing, storage, quality control and other areas is a key element and is well described in the standard. Areas should be adapted to their purpose in order to allow proper access and flow of materials. Clear separation of manufacturing and storage activities and proper cleaning and sanitization are important in order to avoid mix-ups and (cross-) contamination. Scheduled maintenance of premises and equipment and frequent calibration of monitoring equipment must be organized in the facility in order to perform tasks in accordance with defined and pre-defined parameters of manufacturing, packaging, and storage. Within all of these aspects, the quality unit of the organization must be strongly involved in the approval and assessment of any changes that occur and make it possible [13].

Product Realization and Materials Management: The organization working under ISO 22716 must set quality criteria at different stages of production, such as the specifications for raw materials, components and packaging materials purchased. In addition, criteria should be laid down for the testing and release parameters of starting

materials, intermediates (also referred to as cosmetic ingredients) and finished products. It is important that these characteristics are strictly followed by a clear indication of the quality status of these materials throughout the entire supply chain of operations. In this regard, it is important to note that contractors, such as third-party transporters and packaging units, must be included in the organization's quality efforts. Changes in the quality status of starting materials and (intermediate) products are solely the responsibility of the Quality Unit and, for this reason; this unit needs to be fully integrated into the operational activities of the organization [14].

Deviations, Complaints and Recalls: Each organization needs to have a system in place to deal with variations that occur anywhere in the supply chain of operations. These variations can have multiple origins and occur both internally and externally, e.g., during transport to a customer organization. These customer organizations need to be able to make complaints, if necessary, and the organization working under the ISO 22716 quality regime should investigate these complaints until a satisfactory solution has been found and communicated to the customer. In the event of serious quality deviations, which pose a serious threat to consumer health and safety, the organization needs to be able to coordinate an effective recall of the product or products [15,16].

Continuous Improvement: GMP is a quality system that makes use of state-of-the-art organizational aspects relevant to the cosmetics industry. For this reason, organizations need to be aware of current practices in their field and to aim for continuous improvement of quality in their operations and throughout their supply chain. The auditing process is the ultimate tool to do this. Internal audit is an inherent part of Cosmetics GMP in which non-compliance is documented, assessed, resolved, and prevented from recurring in the future. The optimal auditing system is the basis for efficient Corrective Action/ Preventive Action (CAPA) planning [17].

Merits of ISO 22716

1. Integrates the typical requirements for product and process quality Good Manufacturing Practices requirements with additional quality guidance, for example as laid down in the requirements of ISO 9001.
2. Easy implementation sizes and levels of complexity are allowed in all organizations.
3. Forms an internationally accepted basis for quality and safety compliance in the supply chain of cosmetic products.
4. Throughout the supply chain the cosmetic products hazards are controlled and help in the promotion of improvement continuously (Table 7) [18].

Table 7: Difference between Cosmetics Rules, 2020 (Seventh Schedule) and ISO 22716.

Criteria	Cosmetics Rules, 2020 (Seventh Schedule) (or) Schedule MII (Requirements of factory premises for manufacture of cosmetics)	ISO 22716 Cosmetics - Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices
Terms and Definition	The Good Manufacturing Practice does not contain any terms and definition for cosmetics.	The ISO 22716 has put forth the terms and definitions for acceptance criteria, audit, batch, batch numbers, bulk product, calibration, change control, cleaning, complaint, contamination, consumables, contract, acceptor, control, deviation, finished product, in-process control, internal audit, major equipment, maintenance, manufacturing operation, out-of-specification, packaging operation, maintenance, plant, premises, production, quality assurance, raw material, recall, reprocessing, return, sample, sampling, sanitization, shipment and waste.
Personnel	Adequate number of personnel, with experience and capability to do the work assigned. The personnel working should be free from contagious diseases and provided with uniforms, masks, gloves etc. The first-aid facilities are provided.	The personnel information is mentioned in subsections, which includes the organization chart, number of people, personnel and management responsibility, skills and training, training of newly recruited personnel, personal hygiene and health and untrained personnel.
Premises	The location, surrounding and buildings, water supply explains the requirements separately and the area required for different categories of cosmetics are also explained. The walls and floors should be free from dust; smooth, washable, covered and the test laboratories should be separate from the production area.	The premises includes the principle, types of area, space, flow, floors, walls, ceilings, windows, washing and toilet facility, lightening, ventilation, pipework, drains and ducts, cleaning and sanitation, maintenance, consumables pest control.
Equipment's	The maintenance of the equipment includes the calibration and records. The basic equipment's required for all categories of cosmetics are explained.	Equipment design, installation, calibration, cleaning and sanitation, maintenance, consumables, authorizations, and back-up systems.
Raw materials and Packaging materials	-----	The raw material and packaging material purchase, receipt, identification and status, release, storage, re-evaluation, quality of water used in production.

Production	------	The production includes manufacturing and production operation.
Finished Product	The storage condition of Nail polish, Nail Lacquers, kajal and Surma are only mentioned.	Contains the release, storage, shipment and return of the finished product.
Quality Control	The quality control involves sampling, inspecting, and testing of raw and packaging materials, in-process, intermediate bulk and finished product.	The quality control laboratory principle, test methods, acceptance criteria, results, Out-of-specification results, reagents, solutions, reference standard, culture media, sampling and retaining sample.
Out-of-specification product treatment	-----	Reporting and reprocessing information of finished and bulk products, raw materials, and packaging materials.
Waste disposal	The waste disposal must be in compliance with Environment Pollution control.	The principle, types of wastes, flow, containers, and disposal are mentioned.
Subcontracting	-----	The subcontracting agreement details about the giver and acceptor, with types of subcontracting.
Complaints & Recall and Deviations	-----	The principles of the product complaint, recall and deviations.
Change Control	-----	The change control affects the product quality, so it should be approved and performed by authorised personnel.
Internal Audit	-----	The principle, approach, and follow-up of the internal audit.
Documentation	-----	The documentation principles, types of documentation, writing, approval and distribution, revision, and archiving.

Conclusion

Cosmetics plays a very important role and has been increasingly demanding for decades. Regulations are being put forward globally for the production of high-quality and safe cosmetics. The Regulations for Drugs and Cosmetic Regulations was found that the Single Regulations for Drugs and Cosmetic did not provide strict provisions on drugs and cosmetics regulation; in order to codify all the regulation on cosmetics, the Government of India has published the Official Gazette, the new Cosmetics Regulation, 2020. All information on cosmetics is clearly presented in these new rules.

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