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Review Article

# A COMPREHENSIVE REVIEW ON REGULATORY AND MARKET STUDY OF COSMECEUTICAL PRODUCT IN INDIA

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*Abstract*
This As per the market analysis the cosmetic industry of India was prognosticate to reach a value of about 3 billion U.S dollar in 2012 to 20 billion U.S dollar in 2025. In this article the latest market value of cosmeceutical products in USD has been highlighted in a concise way. Cosmeceutical-grade products are a hybrid of pharmaceutical and cosmetic products but aren't FDA approved. From the Greek word "kosmetikos" the term "cosmetic" was created. Cosmetic which means any article intended to be rubbed, sprayed or applied to any part of the human body for cleansing and altering the appearance, also includes any article intended for use as a component of cosmetics. A cosmetic product can only be used on the skin's exterior layer; therefore, it cannot effectively treat a particular disease condition. The chemicals like BHA and BHT, Coal Tar Dyes, DEA (Cocamide DEA and Lauramide DEA), Di butyl Phthalate (DBP), parabens, perfume, siloxane etc; are the chemicals that are used while preparing cosmeceutical which possess many health issues. After observing the benefits and growth of cosmeceuticals, as well as the health hazard aspect of the cosmeceutical formulation, there is indeed a need for stringent regulation for control of harmful substances in cosmeceuticals i.e. the safety concern in the product. Not only has the incorporation of newer and modern formulation components in the cosmeceutical products also emphasized on the importance of how these products are regulated in the Indian market.

## *INTRODUCTION*

Dr. Albert Kligman, a dermatologist, created the term "cosmeceutical" in 1984; it is a hybrid of the words cosmetic and pharmaceutical [1]. Cosmeceuticals are products with therapeutic (drug-like or medical) as well as aesthetic benefits that are intended to enhance the health and appearance of the skin. They resemble cosmetics in that they are applied topically as creams or lotions, but they also include active compounds that alter the function of skin cells. Others can penetrate deeper layers of the skin and either enhances or inhibits normal skin functioning, while others, like exfoliants, just work on the skin's surface. Cosmeceuticals are products that are accessible "over-the-counter" (without the need of a prescription) and are frequently used in combination with a regular skin care routine to effectively improve lines and wrinkles, pigmentation, and skin texture and tone [2]. The first "cosmetologists" in the world are said to have originated in Egypt. Egyptians used chemistry because they were born chemists; they used vegetable oils and lotions to disguise the body, detoxify the skin, and remove odors; charcoal and charred wood was used as eyeliner to keep the eyes open, restore vision, and protect against infection while defending against demons. The use of art and hieroglyphics by the culture has also been discovered. The Greek term "*kosmetikos*" which means "balance and order," is the origin of the English word "cosmetics." Since porcelain skin was seen to be wealthy and attractive, powdered chalk and toxic white lead, also known as "fucus" was used as face paint. Honey, olive oil, and natural pigments and vegetable colors derived from herbs, flowers, fruits, and vegetables like beetroots comprised up the majority of the ingredients. Both men and women preferred the look of unibrows, which were created by joining the brows together with a dark powder. Anti-aging formulations for wrinkle creams first emerged in ancient Rome, where snail ashes were used to treat sun spots. The inspiration for them originated from empresses and gods like Venus, whose figures would adorn bath houses. In addition to boxes for storage, mirrors, spoons, and palettes for preparation gained popularity. Fashion and cosmetics interacted from 189 BC onward; attempts were made to prohibit the use of cosmetics that could be used to influence the public appearance of women under the "*Lex Oppia*" rule. Around 1000 AD, physician *Abulcasis* composed *Al-Tasreef* a medical handbook with a

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significant chapter on cosmetics. It was found that perfumed stocks were the ancestors of deodorant and lipstick. Beeswax, eggs, and gum Arabic were used to dye Chinese fingernails; rice powder and bird droppings were used by Japanese Geishas to lighten their skin; and the complex art of mehndi or henna was utilized to paint hands and feet. As in the 20th century, high-street companies, cutting-edge products like flavored lipsticks and glosses, innovative packaging, and costly advertising campaigns are used to promote scientific formulae and cutting-edge discoveries to the general public. The concern of the safety of cosmetics has been receiving a lot of attention, with demands for the replacement of current options with alternatives that don't use animals for testing and prefer environmentally friendly component choices. A cosmetic product can only be applied to the skin's outer layer; as a result, it cannot effectively treat a specific ailment. It cannot pass through the dermal-epidermal junction, an area between the epidermis and dermis. However, because cosmeceuticals are made with highly active principles, the active chemicals in them penetrate the epidermis and then work deeper inside the dermis [3] [4].

## INDIAN HISTORY OF COSMETICS

Approximately 2500 years before the arrival of Christ, temporary ancient wisdom Vedic and modern ancient Indian literature were used to create "Kohl" on the eyelashes, eyelids, and area beneath the eyebrows in the Indus Valley civilization. Earrings, bracelets, and nose studs made from gold, silver, and copper were worn as ornaments. An important thing for the decorating and applying of coiffures includes hairpins, combs, and mirrors. During sacrifices *cilyrium* was applied to the eyes, hands, and feet, and cosmetics including body paint, eye makeup, combs, and flowers were offered to the heavenly snake (*Sankhayana Grihya Sutra*). At Mohenjo-Daro various kinds of razors were used for depilatory purposes. Although the bride was washed in water that had been made fragrant by a variety of herbs and finest fruits along with fragrances on special occasions like marriage, rivers, tanks, and wells were used as bathing places (*Sankhayana Grihya Sutra*). According *to Satapatha Brahmana*, after bathing, the eyes and feet were anointed to protect off death. *Brahmacharin* was given a jeweled necklace, a wreath, two earrings, a pair of clothes, a turban, a parasol, a pair of shoes, and a staff as beautifying tools after he finished his studies in the *Asvalayana Grihya Sutra*. The seeds *of Karanja (Pongamiapinnata Pierre*) were used as powder, ointment, and eye salve for cosmetic purposes. The *Atharvaveda* frequently makes allusion to eye salve (*Anjana*). *Anjana* was said to give both eyes luster in the *Aitareya Brahmana*, where the name *Anjanakari* was mentioned for a female collyrium maker who likely made her livelihood by preparing it.

The origins of *Anjana* were mentioned in *Satapada* Brahman and *Atharvaveda [Yathanjanam Traikakudam Jatamhimavatspari]. Vritra* was killed by *Indra* and fled, to become the mountain *Trikakud* (which is modern *Trikota* in the north of Punjab and south of Kashmir). This *Trikakud* is considered as *Anjana's* starting place. The rigvedic ladies styled their hair in a variety of styles, including *Stukla, Kurira, Kumba, Opasa, and Kuparda.* Four *Kupardas* were worn in the young women's hair. *Kushtha* was applied as both a fragranced medicine having various indications and as a cosmetic. Different *Kushtha* characteristics and their significance were mentioned in the *Atharvaveda. Kushtha Yashtimadhu (Glycyrrhizaglabra Linn), Nalada (Vetiveriazizanioides (Linn) Nash),* and *Anjana (collyrium)* pastes were applied topically as cosmetics for a cooling effect. In his *Kamasutra, Vatsayana* provides us with thorough knowledge regarding the restroom and its accessories. *Anulepan* (ointment), *Siktha-Karnataka* (a basket of garlands), *Saugandhika Putika* (a perfume box), *Matulunga Twacha* (the skin of the citrus medica fruit), and betel leaf were included as toilet essentials. It was stated that a person should apply sandal or other fragrant pastes after attending to the call of nature, cleaning their teeth, bathing, etc; wear fragrant smoke fumigation attire, put on garlands and apply collyrium to their eyes and lac-dye to their lips. After looking in the mirror and being satisfied with their beatification, they were advised to chew a few betel leaves and continue with their daily tasks.

It was also recommended in this text to take a bath every day, get a massage and use shampoo (*Utsadana*) every other day, clean the body with a soap-like substance that generates lather (*Phenaka*) every third day, shave the chin every fourth day, and carry out the necessary thorough depilatory procedures every fifth and tenth day. Both men and women applied collyrium (*Kajjala*), red lead (*Sindhura*), saffron (*Kunkuma*), turmeric (*Haridra*), and saffron for beautification.

A housewife was advised by *Vatsayana* not to appear before her husband without any ornaments on. *Subhaga Karana* yoga was described by *Vatsayana* as enhancing the beauty of the body parts and providing protection for them. *Tagara* and *Kushtha* are combined to make the ointment. The preparations for *Subhagamkarana* are prepared from *Talisa Patra (Abieswebbiana Lindi). Subhagamkarana* is a term used to describe an internal treatment that combines the powders of *Padma (Nelumbonuciferagaertn), Utpala (Nymphaea*

*stellataWilld.),* and *Nagakesara (MesuaferreaLinn*) with honey or ghee. The 64 arts (*Kalas*) comprising the *Vatsayana Kamasutra* were*;*

1) "*Viseshaka Chodyam*" refers to applying *Tilaka* on one's face, chest, hair, and other body parts (a type of pain).
2) "*Dashana-vasanangaraga*" refers to elegantly decorated teeth and clothing.
3) The term "*Gandha-Yukti*" refers to a method of manufacturing scent.
4) "*Karna-patra-Bhanga*" is a method for ornamenting earlobes with ivory and conch shells [5].

Table1. Cosmeceuticals basically can be classified into following categories [6].

| CATEGORIES | SCOPE | PRODUCTS |
|---|---|---|
| Skin products | Skincare products | Face care products other than face mask; face mask, eye contour, lip care, hand care foot care and body care, external intimate care, chemical exfoliation, mechanical exfoliation, skin lightening products. |
| | Skin cleansing products | Soap, bath/shower, make up remover, external intimate hygiene and other cleansing products. |
| | Body hair removal products | Chemical depilatory, physical expiation; etc. |
| | Correction of body odor and perspiration | Product with antiperspirant activity. |
| | Shaving and pre- after shaving products | Shaving, pre-after shaving products. |
| | Makeup products | Foundation, concealer, mascara, eye shadow, eye pencil, eye liner, lipstick, lipstick sealer; etc. |
| Hair and scalp products | Hair, scalp care and cleansing products | Hair conditioner, anti-hair loss products, anti-dandruff products |
| | Hair coloring products | Oxidative hair color, hair bleaching and dye remover, and other hair coloring products. |
| | Hair styling products | Styling permanent wave products, hair relaxer products. |
| | Hair styling products | Hair sun protection products, other hair and scalp products. |
| Nail and cuticle products | Nail varnish and remover products | Nail glue remover products. |
| | Nail glue remover | Cuticle remover/ softener,<br>Nail sculpting products, other nail and cuticle products. |
| Oral hygiene products | Tooth care products | Mouth wash and breath spray |
| | Mouth wash | Breath spray |
| | Tooth whiteners | Tooth whiteners |

## Health hazards associated with chemicals used in formulation of cosmetics

Following are some of the most frequently used active ingredients in cosmeceutical formulations that are acknowledged to provide specific health hazards among the chemicals associated with the development of cosmeceuticals

- BHA and BHT

The synthetic substances BHA (butylated hydroxyl anisole) and BHT (butylated hydroxyl toluene), which are used as preservatives in moisturizers and lipsticks among other cosmetics, are closely related. The skin might respond allergically to BHA and BHT. The International Agency for Research on Cancer has identified BHA as a potential human carcinogen. Based on evidence that it affects hormone function, the European Commission on Endocrine Disruption has also listed BHA as a Category I priority substance. In some conditions, BHT may stimulate the growth of tumors. Little evidence indicates the possibility that excessive amounts of BHT may resemble estrogen; the main hormone involved in female sex, and inhibits the expression of male sex hormones, leading to harmful effects on reproduction.

- Coal Tar Dyes

Many elements made up of petroleum are found in coal tar. Most coal bitumen colours are used in cosmetics, and they are typically identifiable by a five-digit Color Index (CI) number. A typical coal tar dye found in many hair colours is p-phenylenediamine. Darker hair colours include more phenylenediamine than lighter ones do. Stinging sensations, an erythema rash, swelling, blisters and surface bleeding are some of the adverse affects of p-phenylenediamine. Several reports of acute allergic (and also anaphylactic) reactions to henna dyes have been found in the literature. In most cases, symptoms other than

skin reactions include sneezing, runny nose, coughing and shortness of breath. The greatest concern with specific coal tar colors (whether made from coal tar or artificially) are that they might be cancer-causing considering that coal tar may possibly be related to the disease. Some of these pigments are mixed with aluminum substrate and some of them may be found to be associated with trace amounts of heavy metals. Numerous heavy metals and aluminium compounds may have harmful effects on the brain. Even though some of the colours used to make these dyes are not permitted as food additives, they are however used in cosmetics like lipstick that can be taken. There is evidence that P-phenylenediamine causes cancer. It is known that women, who colour their hair especially for a long period of time, are more likely to develop non-lymphoma hodgkin's (Cancer of the lymph system). P-phenylenediamine has been classified as toxic (whether by contact, inhalation, or ingestion) and very harmful to aquatic organisms by the European Union due to the risk of long-term (chronic) effects on the aquatic environment.

- DEA (Cocamide DEA and Lauramide DEA)

Shampoos, soaps, and cleansers commonly contain chemicals that are associated to DEA (diethanolamine), which are used to make cosmetics creamy or as a pH adjuster to reduce the acidity of other components. Cosmetic containing nitrites and DEA combine to generate nitrosamines. Nitrites can occasionally be found in products as impurities or are added to them as anti-corrosive agents. When a product is exposed to air, some compounds used as preservatives in cosmetics might degrade and produce nitrites. High doses of DEA-related compounds have been proven to cause liver tumors during laboratory trials, as well as precancerous changes in the skin and thyroid. Additionally, these substances may cause minor to major skin and eye irritation. The acute toxicity of cocamide DEA to aquatic organisms and its potential for bioaccumulation make it hazardous for the environment. In June 2012, Cocamide-DEA was categorized as a carcinogenic toxicant. In soap, shampoo, hair dye, cosmetic and household cleaning formulations, the chemical essentially acts as a foaming agent. Cocamide DEA functions as a surfactant, which means it helps in the foaming and lathering of soaps and shampoos. A surfactant that is too powerful might dry out your skin by removing its natural oils from your body. If you don't have this built-in protection against microorganisms and other environmental aggressors, your skin may become dry and irritated. Also, the risk of skin infections increases. Sulfates, most commonly sodium laureth and sodium lauryl sulphate, and betaines are examples of heavy surfactants that can result in dry skin (usually cocamidopropyl betaine). Beyond simply drying out your skin, which is a severe, enough side effects. Cocamide DEA has been linked to much more serious and long-term health complications. Cocamide DEA and preservatives have the potential to combine to generate the extremely hazardous nitrosamines. NDELA, a compound that has been proven to give rats cancer, is one such example. NDELA is easily absorbed through the skin, particularly when applied to significant portions of the body. Though they are typically available in less expensive skin care products, nothing is more valuable than your health.

- Di butyl Phthalate (DBP)

DBP is mostly used in nail care products as a plasticizer to keep nail polish from drying up and hardening and as a dye solvent. It has been found to result in sperm count reduction, prostate and testicular abnormalities and developmental problems. Also, it has been discovered that it interferes with hormone function, acting as a possible endocrine disruptor that could harm an unborn child and worsen infertility. According to numerous studies, prolonged consumption of phthalate-containing products might cause serious health problems such liver and renal failure in young children. According to research, phthalates have a variety of adverse health impacts, such as a decrease in men's sperm counts and reproductive abnormalities in the growing male fetus (when the mother is exposed while pregnant).

- Parabens

Preservatives are utilized to protect cosmetics from microbiological contamination. Parabens are the preservative that is most commonly used in cosmetics. Parabens are included in about 75 and 90 percent of cosmetics (typically at very low levels). The epidermis is easily penetrated by parabens and they may interfere with hormone production (endocrine disruption). They replicate estrogens, the main hormone involved in female sex. Additionally, they could disrupt male reproductive functions. According to numerous studies, when methyl paraben is applied to the skin, it interacts with other chemicals and speeds up the ageing process and damages DNA. Parabens are also present in some foods, like barley, strawberries, carrots, onions, and vanilla. Foods contain parabens, which are metabolized when consumed and reduce some of their estrogenic potency. On the other hand, parabens in cosmetics avoid the metabolic process and reach the bloodstream and human organs unaltered when applied to the body and are absorbed by the body. Women are exposed to 50 mg of parabens from cosmetics each day, according to research.

They have adverse health effects including neurotoxicity and cancer.

- Perfume (Fragrance)

To provide a pleasant fragrance to the human body, animals, food, objects, and living places, perfume is a combination of essential oils or aromatic compounds, solvents, and other components. It is typically present in liquid form and applied to give the body of a person a pleasing aroma. Cosmetics also make use of fragrances. As perfumes, around 3,000 different compounds are used. In colognes, deodorants and perfumes, fragrance is a key component ingredient. Perfumes are present in almost all cosmetic products. These products may contain fragrance elements in the form of masking agents that inhibit the brain from detecting their odor, even though they are promoted as "fragrance-free" or "unscented". Many of the undeclared fragrance compounds are irritants that can increase allergies, migraines, and asthma symptoms. The use of perfume may make asthma conditions worse or possibly increase the development of asthma in youngsters. It is listed as the second most significant cause in patient allergies.

- Polyethylene Glycols (PEGs)

Petroleum-based substances known as polyethylene glycols (PEGs) are frequently used in creams as thickeners, solvents, softeners and moisture-carriers. PEGs could become contaminated with 1, 4-dioxane in detectable concentrations throughout the production processes. It has been determined that this 1, 4-dioxane causes cancer. It is difficult to decay and may remain in the environment for a long time after being flushed down the shower drain. PEGs can cause skin irritation and be hazardous to the body when applied to damaged skin. They also have some indications of genotoxicity.

- Petrolatum

In a variety of moisturizers, petroleum jelly creates a barrier to keep moisture in the skin. In order to make hair care products shimmer, it is utilized. It also goes by the name mineral oil jelly. In Petrolatum, polycyclic aromatic hydrocarbons (PAHs) could be found as a contaminant. Numerous researchers have found that long-term exposure to PAHs may be linked to cancer. Because of this, the European Union limits the use of petrolatum in cosmetics and classifies it as a carcinogen. Allergies and skin irritability may also be caused by petrolatum's PAHs.

- Siloxanes

To formulate various cosmetic products that are soft and smooth, siloxanes, that are silicone-based compounds, are used. They speed up the drying process for hair products and improve the flow ability of deodorant creams. The most widely for them are found in face treatments and moisturizers. Cyclotetra and cyclopenta siloxanes are two extensively used siloxanes that are toxic. Aquatic species may accumulate them through bioaccumulation. And is an endocrine disruptor, cyclotetra siloxane interferes with how human hormones work and as a potential reproductive toxin, may also reduce fertility in humans [7].

Health risks are also associated with use of some heavy metals in Cosmetics formulation and are highlighted below;

- Heavy metal

Most of the cosmetics that women use regularly contain heavy metals. The literature has analyzed the harmful impacts of heavy metals in a variety of cosmetic products, including facial makeup. Various health issues are known to be caused about by heavy metals that can accumulate in the body over time. Heavy metals in cosmetics are associated with a variety of health risks including cancer, disorders of the reproductive and developmental processes, neurological issues, problems with the cardiovascular, skeletal, blood, immune system, kidney and renal systems, headaches, vomiting, nausea, and diarrhea and lung damage, along with contact dermatitis, brittle hair and hair loss. While certain heavy metals are respiratory toxins, others can interfere with hormone function and ingestion or absorption through a break in the skin by two ways they might enter the body.

- Cadmium

In the environment, cadmium occurs naturally. Despite being present in almost all human tissues, cadmium from body and hair creams is absorbed into the body through dermal contact and is then deposited in the liver and kidney. According to the International Agency for Research on Cancer (IARC), it is "carcinogenic to humans and its compounds are classified as recognized human carcinogens by the United States Department of Health and Human Services. A prolonged exposure to lower levels can cause kidney damage, bone deformation and bone thinning that makes bones more brittle and prone to breaking. If consumed in large doses, it may cause severe stomach discomfort, vomiting and diarrhea.

- Lead

Lipsticks may contain lead as an impurity due to the use of contaminated raw materials or lead-containing pigments. Daily skin contact with lead has been discovered to result some lead to be absorbed via the skin. Blood-lead levels in children and women have been associated to the use of

leaded eye powders (such *Surma* and *Kohl*). Because it can easily cross the placenta and enter the fetus's brain, pregnant women and young children are more at concern. Additionally, it can be stored in bones and passed on to infants through lactating mothers' milk. It has been discovered that lead exposure causes miscarriages, hormonal changes, decreased fertility in both men and women, irregular menstruation and delays in the onset of puberty in girls. It has been determined that lead and its inorganic lead compounds may cause human cancer.

- Nickel

All of us are exposed to nickel in minute amounts through food, air, portable water, soil, household dust and skin contact with products that contain it, such as cosmetics. Nickel is abundant in nature. Depending on the route and the type of nickel exposed to, high exposure levels can have major health impacts. Metallic Nickel and its alloys have been identified as potentially carcinogenic to humans, despite the fact that some forms of nickel are regarded as "toxic" due to their ability to induce cancer. In addition to being allergenic, nickel can also induce severe contact dermatitis. Even though 1 ppm of nickel can cause an allergy to swell up in someone who already has one, eye makeup has been linked to the first instance of nickel allergy.

- Mercury

Skin-lightening soaps and lotions contain mercury as an ingredient. Other cosmetics, like mascara, hygiene products and eye makeup, also contain it. In some African and Asian nations, skin-lightening soaps and lotions are widely used. Mercury can be present in cosmetics in two different forms, namely inorganic and organic and it inhibits the production of melanin, making the skin lighter in tone. As skin-lightening ingredients in soaps and creams, inorganic mercury (such as ammoniated mercury) is used. In cosmetics including eye makeup, cleansing products and mascara, organic mercury compounds like ethyl mercury and phenyl mercuric salts are used as preservatives. Kidney damage is the primary side effect of inorganic mercury, which is present in skin-lightening soaps and lotions. Skin rashes, skin pigmentation and scarring, as well as a decrease in the skin's resistance and fungus infections, can all result from the use of mercury in skin-lightening treatments. Peripheral neuropathy, sadness, anxiety and psychosis are other adverse effects. The mercury is subsequently released into the environment, where it is methylated and forms highly poisonous methyl mercury, which is then consumed by fish. Methyl mercury is passed to the fetus when pregnant women consumes fish containing this substance, which may affect the children's neurodevelopment [8] [9].

It is definite that the majority of products are recalled from the market as a result of the harmful effects produced by untested excipients used in the preparation of cosmeceuticals. Other reasons for product recalls include adulteration by inferior ingredients; false advertising that is misleading and contamination that can occur as a result of completely inadequate quality control testing during the manufacturing process. Some of the recalled products are highlighted below in table no 2 [10].

Table No. 2: Recall products

| SNo. | Product name | Company name | Reason for recall | Recalled no |
|---|---|---|---|---|
| 1 | Lavender body cream | Nature's Truth LLC voluntarily recalled Nature's Truth | Product had very high concentration of yeast | F-0483-2021 |
| 2 | Scott foam Skin cleanser with moisturizers | The Kimberly-Clark corporation | Hand sanitizer was mistakenly listed on the bottle's front label. | F-0343-2021 |
| 3 | Lemon citrus foaming hand soap with essential oils | Scent Theory voluntarily | The product was contaminated with *Burkholderia Cepacia* | |
| 4 | Method Home | Method gel handwash, sea minerals | The product was contaminated with bacterium *Pseudomonas aeruginosa* | F-0111-2021 |
| 5 | Hydrator 125 mL Moisture Surge 72-Hour Auto-Replenishing by Clinique | Clinique Laboratories Inc. | There could be an unstated aroma in the unscented face moisturiser. | F-0066-2021. |
| 6 | Lysere advanced antioxidant mouthwash with Lingon berry mint | Norwex Usa Inc | Microbiological contamination exceeding the specified criteria | F-1546-2020 |

| SNo. | Product name | Company name | Reason for recall | Recalled no |
|---|---|---|---|---|
| 7 | Men grooming hair balm | Sene Gence International | Presence of mold (*Penicillium concentrium*) growth in some of the finished products | F-1353-2020 |
| 8 | Liberty hair and body shampoo | Montgomery County Chapter Nysarc , Inc | It was contaminated with *E.Coli* and *P.aeruginosa* | F -0643-2020 |
| 9 | Just shine you sparkle and Just shine stay magical make up kit | Tween Brands Inc | Unapproved colorants was used | F-0854-2020 |
| 10 | Monsepa Express peeling cream | T&A house ,LLC | FDA testing found high levels of mercury in the product | F-0785-2020 |
| 11 | Johnson's baby powder | Johnson & Johnson consumer Inc | Testing indicates that there are trace amounts of chrysotile asbestos present. | F-0136-2020 |
| 12 | 100-piece Simply Shine Lip & Eyeshadow Combination | Tween Brands Inc | Products could include unauthorized D&C Yellow #10 in eye makeup. | F-0116-2020 |
| 13 | Charcoal scented facial primer | Primark us corp | Products may contain *Burkholderia cepacian.* | F-1022-2020 |
| 14 | a. ENDURE Mild Moisturizing Foam Hand Soap<br>b. KEYSTONE FOAM HAND SOAP 750 ML<br>c. KEYSTONE FOAM HAND SOAP 1200 ML<br>d. Mild Foaming Hand Soap 25 US Fl oz (750 ml) | Ecolab Inc. | Products containing possible particulate matter | F-1151-2020 |
| 15 | Lysere Advanced Antioxidant Mouthwash with Nordic Lingonberry Mint 473 ML/16 Fl. Oz. | Norwex Usa Inc | potential microbiological contamination exceeding the specified | F-1546-2020. |

## Indian cosmeceutical market

Cosmeceuticals are classified into a variety of categories in India, including skin care, oral care, hair care, perfumes, and color cosmetics. Herbal cosmeceutical goods have become more popular globally due to the rising need for cosmeceutical products, which is not just limited to India. According to recent data, India's present cosmetics business is worth around 6.5 billion USD and is projected to grow to 20 billion USD by 2025, contributing for 5% of the whole world wide market, which is projected to be worth approx 450 billion USD by that time. India's estimated $50 million cosmetics business; the online market has indeed demonstrated a 2% contribution. The cosmeceutical market has grown exponentially over the years that are highlighted below in fig.no.1 [11]. It has also been predicted that Indian beauty and personal care market to grow at CAGR of 6.3, which is highlighted below in fig.no.2 [12]. India will rise to prominence as a major revenue market. Avon, L'Oreal, and other foreign brands like Mac cosmetics were developed in India as a result of the rising demand for cosmeceutical products. There are several causes for the significant rise in the cosmetics industry in India, but social media, a variety of fashion-related events and celebrity endorsements are the main ones. People who used chemical-based cosmetics over a long period of time experienced a variety of negative effects, which led to herbal cosmetics being more and more popular around the world and being seen as safer than chemical-based cosmetics. Many well-known Indian businesses, like Patanjali, Dabur, Himalayan and Boutique, are known for their herbal products. The global bank predicts that India's per capita income would grow from INR 93,231 (1403.5) in 2016 to INR 100,000 (USD 1,505.4) in FY 2017. Because of numerous goods like anti-ageing creams, blemish creams, exfoliators etc; the global skincare market has experienced rapid expansion in recent years. Men's personal care goods including pre and post shaving creams and bearer oils have also had a big part in

capturing the market. Many new products that treat the indications of weariness, stress and ageing were introduced in the market, which has significant impact. Due to India's expertise in extracting the best qualities from natural flowers, roots and oils among other things, their herbal products are in great demand all over the world. According to CHEMEXCIL, India is the world's second-largest exporter of herbal cosmetics after China (Basic chemicals cosmetics and Drugs Export Promotion Council). This falls under the Government of India's ministry of trade and industry. The most significant items with significant sales are colour cosmetics [13].

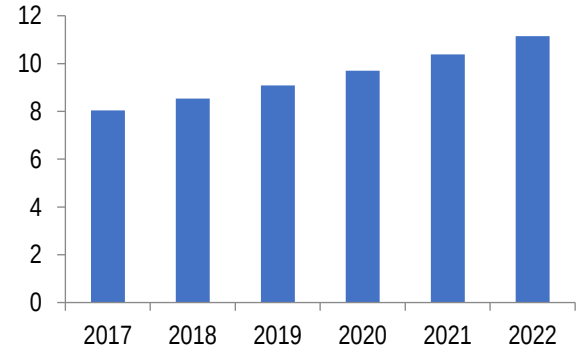


Fig.1. Cosmetics and Personal Care Market Size by Value 2017-2022 (Usd Billion)

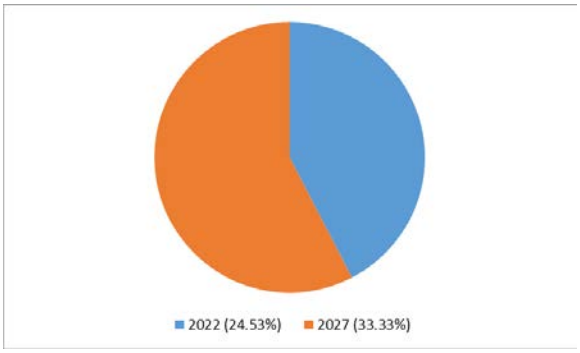


Fig 2. Indian Beauty and Personal Care Market (Market forecast to grow at a CAGR of 6.3%)

## Cosmetic regulation in India

According to the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder, the State Drug Control Department in India governs cosmetics manufacturing under a system of inspection and licensing, while the Central Drugs Standard Control Organization (CDSCO) which is the primary authority to govern activity related to cosmetics and implement and enforce corresponding regulations, regulates cosmetics importation under a system of registration. India restricts the import of cosmetics that have undergone testing on animals. Additionally, the manufacture and importation of cosmetics containing hexachlorophene, lead, arsenic and mercury compounds is prohibited [14]. The competent authority those governing the manufacturing and marketing of cosmeceuticals are listed in table 3.

Table 3: Competent authority for regulation of cosmetics;

| REGULATIONS | FUNCTIONS | STATUS |
|---|---|---|
| Drug and cosmetic act 1940 and rules 1945. | Rules and guidelines for the production, importation, distribution and sale of cosmetics. | In force |
| Instructions for registering the import of cosmetics. | Registration instructions for cosmetics imported for selling. | In force |
| Information on the importation and registration of cosmetics. | Explanation of information in guidelines that is not adhere to a standard | In force |

State and federal governments each have their own drug control authorities, but the Central Drugs Standard Control Organization (CDSCO) is primarily in charge of monitoring cosmetics-related practices and implementing appropriate legislation. As the executive sector, the CDSCO appoints the Drugs Controller General India (DCGI) to carry out activities such reviewing applications for registration or licensing [15].

### Exact functions of CDSCO include:

1. Registration of the import of cosmetic products under the 1945 Drugs and Cosmetic Rules.
2. Examining applications for registration of cosmetic items for import into the nation in accordance with the requirements of the Drugs and Cosmetics Act of 1940 and its implementing Rules, 1945.
3. Examining numerous requests for NOCs or clarifications on the import of cosmetics.
4. Preparation of tentative responses to RTI, VIP inquiries and a cosmetics-related Parliamentary question.
5. Responding to official correspondence and BIS as needed.
6. Managing public concerns and hearings about the procedure for registering cosmetic imports and providing advice.
7. Handling complaints and grievances regarding the standards of cosmetic items from the public, NGOs, and consumer forums.
8. Pre-screening of the applicant's submissions for registration of the importation of the cosmetic.
9. Modification of the pre-screening check list and creation of SOP in accordance with the current working practices on the assessment of requests for the import and registration of cosmetics.

### Manufacture licensing for cosmetic products

Licensing for manufacturing of cosmetics and retail establishments is regulated by the State Drug Control Department. Its main duty is to guarantee that residents of the State have access to high-quality drugs at a cost determined by the GOI (NPPA). The Bureau of Indian Standards (BIS) has also developed criteria for particular cosmetic goods as well as lists of ingredients that are permitted and prohibited from use in cosmetics. According to the 1940 Drugs and Cosmetics Act and Rules established thereunder, the drug control agency of each state administers an inspection and licensing system for the manufacture of cosmetics. The license application must be submitted to each Indian state's website. Every state has its own set of rules. For instance, the following are the documents needed in the Maharashtra States:

- Request in form 31 (for cosmetics).
- The payment challan for the MFW module.
- A specific authority of attorney naming the authorized signatory who will submit applications on the company's behalf.
- A lists of technical staff members, who are qualified, registered, experienced and have had prior FDA approvals, among other information.
- The letter of appointment or acceptance of the skilled technical personnel of the manufacturing department.
- The letter of appointment or acceptance of the testing sections qualified technical staff.
- A list of the equipment and machinery by section.
- The premises plan layout, as approved by the licensing authority.
- The Maharashtra State Pollution Control Board's approval for the establishment and operation.
- Department of Industrial Safety and Health for Noc.
- Process flow diagrams and specifics of the production process (for bulk drug).
- Installation and validation certification for AHU (wherever necessary).
- Certificate for the installation and validation of water systems (wherever necessary).

After the application is approved, the State Drug Control Department will check the applicant in person through conduction of exam, to see if they meet the requirements listed below:

1. A competent technical staff, consisting of at least one full-time employee who is certified in one or more of the following areas, shall direct and individually monitor the manufacture.

• holds a pharmacy diploma recognized by the Pharmacy Council of India in accordance with the Pharmacy Act of 1948 (8 of 1948), or

• has a Pharmacy Act of 1948 registration (8 of 1948), or

• has passed an exam approved by the licensing authority to be equivalent to the Intermediate Examination, which included Chemistry as one of the subjects.

2. The production units must adhere to the conditions and regulations listed in Schedule M-II of the Drugs and Cosmetics Rules, 1945.
3. The applicant must either:

• maintain sufficient personnel, facilities and laboratory equipment for evaluating the cosmetics produced and the raw materials used in their production; or

• arrange for such tests to be routinely performed in this regard by an institution that has been authorized by the Licensing Authority under Part XV (A) of these rules.

The license will be granted if they are satisfied with the exam results. The permit is valid for five years. If the request for renewal of an active license is made prior to its expiration or within six months of its expiration, after payment of an additional charge, the license will continue to be in effect until decisions are made on the application. The license is considered to have expired if the request is not made within six months of its expiration [16].

### Registration of importing Cosmetics for Sale

According to the Drug and Cosmetic Rules 1945, all cosmetics imported for sale in India must be authorized with the CDSCO [17].

### Rules and regulations for brand of cosmetic products

In India, during the registration of imported cosmetics, "brand" refers to the items in the "product" section of the classification. The word "brand" refers to all variations on a product, including its color, hues, pack sizes, etc. A product's trade name or the supplier themselves are not considered to be part of a "brand." A single application can cover any number of brands that a single company produces at one or more factories if the applicant desires to import the same brand from different countries. Manufacturers are required to submit significant applications and pay separate fees for every business. If the applicant wants to add any other brands of already registered categories from the above "product" list for the same manufacturer to a registration certificate that is already in effect, the importer must file a separate application. But there won't be a charge. In these cases, a provided registration certificate will add further product authorization to the already-approved category. Each appeal will be guided by a fee of USD 250 or its similar India rupees for each brand.

Who can register for authorizing of Importing Cosmetics in India?

1. Manufacturer who has registered office in India.

2. Manufacturer whose agent is certified.
3. The subordinate of the Manufacturer
4. Other importer.

An organization certified by the manufacturer in India is termed as an authorized Agent. The authorized agent will be taking charge of the manufacturer's functioning in India also make sure that the Drug and Cosmetic Act in all respects is followed. “Subsidiary" refers to a business that the manufacturer owns in India. "Any other importer" refers to any trade that, except the manufacturer, their authorized agents and its subsidiary, assert to import cosmetic products. Records required for authorization of cosmetic products are:

- Covering of Letter.
- Attorney power.
- Schedule (III) D
- Ingredients list.
- Labels of recommended products.
- Statement.
- Inserted Pack.
- Manufacturing License.
- Certificate of free sale.
- Declaration of non animal testing.
- Heavy Metal & Hexachlorophene present declaration.
- Other documents required (If any).
- Application Form-42.
- Fee: TR-6 Challan in Original.

### Labeling for registered imported cosmetic products

1. The label of cosmetics imported will support the registration certificate number of the brand and name and also the address of the registration certificate owner.
2. Characterization of labels containing the registration certificate number of the label, the name and address of the registration certificate owner may be allowed to import products at a suitable place approved by the Licensing Authority on an application made to the Licensing Authority of India.
3. The Label must carry the name and address of the manufacturer, name of the country where the product has been developed. If the product is not produced in a factory premises then the name, address of the proper manufacturer or the name of the country where it has been manufactured should be written on a product's labeling.

### Exemptions:

1. Cosmetic products that are imported into India as proportions for repackaging of 100% export to other countries do not require authorizing certificate. In such cases the importer has to procure mandatory permission from CDSCO. Importer must give on paper accountability that these products are not unconfined for domestic sale.
2. Registration certificates are not required for cosmetics imported for research and development reasons, such as consumer studies, shelf life studies and transport studies. In such cases the importer has to acquire compulsory authorization from head quarter of CDSCO. Importer must give on paper responsibility that these products are not declared for domestic sale.

### Time for issuance and validity of application form and documents:

- From the date of compliance of the application form and compliance of the mandatory credentials, the registration certificate will be issued within 6 months.
- For import of cosmetics the registration certificate is valid upto 3 years from the date of its issuance.

### General Label Requirements

According to the 1945 Drugs and Cosmetics Rules, a clear, distinct label is recommended for items, along with any variations (if any),this label should include the following;

- Name of the Cosmetic.
- Name and address of the supplier and name of the country where the product has been produced. If the product has not been manufactured in a factory owned by the producer, the name and address of the actual manufacturer or the name of the nation where it has been manufactured as “Made in (Name of the country)" should be present on the label.
- Further, for small size containers where the address of the manufacturer is not given, the name of the manufacturer and place of manufacture must be written along with pin code.
- Use Before.
- Direction for safe use.
- Batch no
- Manufacturing License no.
- Registration Certificate Number and name and address of R.C holders
- Details in accordance with Part XV of the Drugs and Cosmetics Rules1945.

### In addition, a cosmetic should carry:

1. on both the outer and inner label:

- Cosmetic name.
- The name of the manufacturer, address of the premises of the manufacturer where the cosmetic has been manufactured but if the cosmetic is present in a very small size container then the address of the manufacturer cannot be given, but the name of the

manufacturer and his principal place of manufacture must be present along with pin code.

On the outer label

- A statement of the net contents present in terms of weight for solids, fluid evaluated for liquids, weight for semi-solids, along with count if the content is sub-divided (provided that this statement need not required in case of a packaging of perfume, toilet water or the like the net content of which does not exceed 60 ml or any package of solid cosmetic the net content of which does not go beyond 30 grams).

1. on the inner label, where a hazard exists.

- Proper direction for safe use.
- Any caution, warnings essential to be observed by the consumer.
- A declaration of the names and quantities of the ingredients those are toxic.
- An individual batch number, the number by reference to which details of the particular batch from which the substance in the container is recorded and are available for examination, the batch number being preceded by the letter “b” (provided that this section shall not apply to any cosmetic containing 10 grams or less if the cosmetic is in solid or semi-solid form and 25 milliliter or less if the cosmetic is in a liquid state; in the case of soaps instead of the batch number, the month and year of manufacture must be given on the label).
- Manufacturing of license number, the number being denoted by the letter “m”.
- If a package of a cosmetic has only one label, such label must contain the information mandatory to be shown on both the inner and the outer labels.
- The list of products present in more than one percent should be scheduled in the descending order of weight or volume, followed by those in ratio of less than or equal to one percent and preceded by the words “ingredients”.
- Required labelling specified in the applicable Indian standard as given by the (Bureau of Indian Standards) for the cosmetics under (Schedule S) Standards for Cosmetics.

For hair dyes comprising dyes, colors and pigments, there is a special labelling need.

- Hair dyes which contains para-phenylenediamine other Dyes, Colors and Pigments must be labelled with the English and local languages and these should be written on both the inner and the outer labels.
- Warning this product may contain ingredients which may cause skin irritation and a prelude test according to the complementary way should be made first. This product must not be applied for the eye-lashes or eye-brows dyeing, it may cause blindness.
- Every package must contain instructions in English as well local languages on the following lines for carrying out the experiment.
- This preparation might cause serious irritation on the skin in some cases and so a preliminary test must always be carried out to find out whether special sensitivity exists or not. To make the test, first clean small area of skin behind the ear or upon the inner surface of the forearm, with soap and water or alcohol. Apply a small amount of the hair dye which is prepared for use to the specific area and let it dry. After twenty-four hours, the area should be washed gently with the help of soap and water. If no irritation or inflammation occurs, it can be assumed that it is safe to use because no irritation occurs due to dye used. The test must be carried out before each and every application.
- Fluoride present in tooth paste should not be more than 1000 ppm and the fluoride used in terms of ppm shall be mentioned on the tube and carton.
- Expiry date must be mentioned on carton and tube.

Prohibitions

1. No person can alter or deface any mark printed by the manufacturer on the container, label or cover of any cosmetic (provided that nothing in this rule must be applied to any alteration, mark made on the container, label or cover of any cosmetic, the direction or with the permission of the authority of licensing)

2. No cosmetic can claim to convey any idea which is copied or misleading to the intending customer.

Cosmetic Ingredients

1. Standards set for Cosmetics by BIS

- The Bureau of India Standards (BIS) issued classification of Cosmetics according to Raw Materials and Adjuncts used to specify necessities for ingredients used in cosmetics.
- In the classification it is claimed that with the view of the ill effect of specious cosmetics, in the absence of effective rules or regulations had broadly been classified into the ingredients that is used for cosmetics into two categories:

a) Generally recognized as safe (GRAS).

b) Generally not recognized as safe (GNRAS).

2. Restrictions Outlined

To align along the standards that are set by BIS, the "Drug and Cosmetic Act1940 & Rules1945" outlines several banned items in manufacturing and importing of cosmetics.

A) Prohibition of manufacturing or import cosmetics that contains dyes, colours and Pigments other than those approved by BIS.

No Cosmetic must contain dyes, colours and pigments other than those given by the Bureau of Indian Standards (IS: 4707 Part 1 as amended) and Schedule Q. The allowed Synthetic Organic and Natural Organic Colours used in the Cosmetic must not include more than;

- 2 parts per million of arsenic.
- 20 parts per million of lead.
- Lead-free heavy metals at a concentration of 100 parts per million.

B) Exclusion of manufacturing or import of cosmetic that contains Hexachlorophene, cosmetic containing hexachlorophene cannot be imported.

C) Prohibition of manufacturing or import of cosmetic that contains Lead or Arsenic compound, No cosmetic can be imported in which contains lead or arsenic compound that have been used for purposes of dyeing.

D) Regulation for import and manufacturing of cosmetics which contains mercury. Cosmetics that are imported into India or manufactured domestically must contain mercury in the given amount, namely in cosmetics which is intended for use only in the area of eye, the level of mercury must not exceed seventy parts per million (0.007 per cent), calculated as the metal and a preservative; in other refined cosmetic products, unintended mercury should not exceed one part per million.

E) Exclusion of importation of cosmetics tested on animals.

No cosmetic that has been experimented on animals after the origination of the Drugs and Cosmetics (Fifth Amendment) Rules, 2014 shall be imported into the country [18] [19].

## FDA Regulations for Cosmetic Products:

With the prominent exclusion of color additives, the FDA does not have a premarket authorization system for cosmetic products or chemicals. Drugs must, however, be given FDA authorization. Drugs shall naturally moreover acquire FDA premarket endorsement or adhere to final set of laws outlining the situation under which they are acknowledged to be safe, effective, as well not misbranded. At present, some over-the-counter (OTC) medications were advertised proceeding to the OTC medicine [20] [21].

## Conclusion

Demographic growth, improving socio-economic standards and large-scale development of digital and manufacturing sectors has resulted in a booming demand for cosmetic products in India, which is no longer restricted to metro and mini-metro urban centers, but also equally powerful in the rural areas. Those in the beauty business in India believe this boom can largely be attributed to the sudden influx of e-commerce retailers focused on the beauty segment. Leading businesses like Nykaa and Purplle have been particularly important in assisting smaller brands and startups to gain traction in the market, for instance; Earthyblend, a personal care firm based in Bengaluru that focuses on vegan, environment-friendly and safe products, introduced its brand True Frog in early 2020. Domestic demand in India is one of the fastest increasing in the world as a result of the 15-20 percent yearly growth in retail sales of cosmetics and other personal care items, and industry players like Atman believe that as brands continue to innovate and create education around trends such as clean beauty, skincare, and digital advertising, the market will continue to experience massive growth. Cosmetics contribute to wellbeing and healthy lifestyles. Beyond maintaining physical health, cosmetics can help us feel better, look better, and develop more self-esteem. They can also help to exhibit personal style and, as such, are an important means of social expression. Cosmeceuticals are cosmetic-pharmaceutical hybrids intended to enhance beauty including personal care items, face and body lotion, shampoo, soaps, hair styling products, deodorant, toothpaste, hair dyes, nail polish. The average adult uses about nine personal care products every day, and most consumers don't give their regimen a second thought they simply trust the cosmetic they're using, but the frequent exposure of chemicals like parabens, phthalates, formaldehyde, Sodium Laureth Sulfate, siloxane, lead, mercury, heavy metals etc. Used in the formulation of cosmetic products can lead to worrisome factors like eye infection and irritation, fire hazards of aerosol products in hair spray, skin allergies and may even cause cancer, and also linked to reproductive harm as well organ toxicity. That emphasizes on importance of selection of right ingredient during the formulation

Discovery of Nanotechnology, a scientific methodology conducted at nano-scale to let the tiny particles penetrate deep into the skin has allowed the researchers to create products which are more effective in fighting the skin-ageing fine lines. Importance of research and development cannot be subdued considering such innovative advancement in the cosmetics industry and for these reasons the rules and regulations for cosmeceuticals products in Indian market needs to be overlooked and if possible by harmonizing the laws and procedures for formulation of safe cosmeceutical products in the Indian market, further it'll be easy and efficient for manufacturer

and sale of products which creates long term and wider perspective of consumer.

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