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## **NEED FOR REGULATORY ASPECTS OF COSMECEUTICALS**

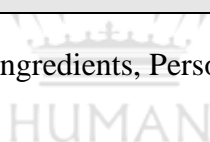
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### **ABSTRACT**

Nowadays a new hot topic in the cosmetic industry is 'Cosmeceuticals', which is the fastest growing segment of the natural personal care industry. Cosmeceuticals are the future generation of skincare. Cosmeceuticals have become the fastest-growing segment of the personal care industry. Cosmeceuticals are cosmetic products with biologically active ingredients purporting to have medical or drug like benefits. This paper will give information regarding current and future trends of cosmeceuticals.

**Keywords:** - Cosmeceuticals, Active ingredients, Personal Care, Skin Care.



## 1. INTRODUCTION

### 1.1 Definition of Cosmeceuticals:

“Cosmeceuticals are topical cosmetic- pharmaceutical hybrids intended to enhance health and beauty of skin”. Some cosmeceuticals are naturally derived and others are synthetic but all contain functional ingredients with either therapeutic, disease-fighting, or healing properties.

### 1.2 History of Cosmeceuticals:

The Ebers Medical Papyrus wrote in 1600 BC, made frequent reference to several cosmeceutical type products. Their favorite formulation was honey and milk which helped to cure skin diseases. The founder of U.S. society of Cosmetic Chemist, Rayman Reed created a concept of cosmeceuticals in 1961. This word was then popularized by American Dermatologist Dr. Albert Kligman in 1970.

**Table No. 1: Difference between Cosmetic and Cosmeceuticals:**

Cosmetic	Cosmeceuticals
According to Food, Drug and Cosmetics (FD&C ) Act cosmetic product is defined as a preparation applied to the body, to improve its appearance.	Cosmeceuticals are the products which lie between the borderline of cosmetics and pharmaceuticals.
These products only deliver their ingredient at a very superficial level into the skin.	Cosmeceuticals contain active ingredients that act on the skin cellular structure through topical application with either therapeutic, disease-fighting or healing properties.
Cosmetics do not delay your skins aging process because they work at the uppermost layer of the epidermis which is topmost layer of the skin.	Cosmeceuticals are more concentrated, pure and more effective giving pharmaceutical benefits.
E.g. Perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations etc.	E.g. Anti-ageing creams, Hair colorants and Dyes, Shampoos, Growth Stimulators and Conditioners etc.

## **2. Ayurvedic cosmeceuticals <sup>[3]</sup>**

Ayurvedic cosmeceuticals are referred as products, are formulated, using various permissible cosmetic ingredients to form the base in which one or more ayurvedic ingredients are used to provide benefits and various ailments.

### **2.1 Advantages of Ayurvedic Cosmeceuticals: <sup>[3]</sup>**

#### **Natural Product:**

The name itself suggests these products are natural and free from all the harmful synthetic chemicals which may prove to be toxic to the skin. There are a rising number of consumers who demand more natural products with natural ingredients, free from harmful chemicals.

#### **Safe to use:**

Compared to other beauty products, Ayurvedic cosmeceuticals are safe to use. Since they are made of natural ingredients, people don't have to worry about the adverse effects.

Example- BHA (Butylated Hydroxyanisole) and BHT (Butylated Hydroxytoluene) are synthetic antioxidants and are used as preservatives in lipsticks and moisturizers. BHA and BHT can induce allergic reactions in the skin.

#### **Compatible with all skin types:**

Ayurvedic cosmeceuticals are mostly suitable for all skin types. No matter if you are dark or fair, you will find natural cosmetics like foundation, eye shadow, and lipstick which are appropriate irrespective of your skin tone. Women with oily or sensitive skin can also use them and never have to worry about degrading their skin condition.

Example- Coal tar-derived colors are used extensively in cosmetics, Coal tar is recognized as a human carcinogen and the main concern with individual coal tar a color (whether produced from coal tar or synthetically) is they can cause cancer. But natural colors that are obtained from herbs are safer.

### **Fits your budget:**

Ayurvedic cosmetics are not expensive. In fact, some of these products are more affordable than synthetic products. They can be offered at discounted prices and are sold for a cheap price during sales. An estimate of WHO demonstrates about 80% of world population depends on natural products for their health care, because of side effects inflicted and rising cost of modern medicine. World Health Organization currently recommends and encourages traditional herbal cures in natural health care programs as these drugs are easily available at low cost and are comparatively safe.

### **Less or no side effects:**

The synthetic beauty products can irritate your skin, and cause pimples. They might block your pores and make your skin dry or oily. With natural cosmetics, one need not worry about these. The natural ingredients used assure no side effects; one can apply them anytime, anywhere. For example herbal cosmetics are free from parabens that are the most widely used preservative in cosmetics and can penetrate the skin.

### **3. Regulatory Aspects of Cosmeceuticals:**

There is no specific regulatory category for cosmeceuticals. In fact, the FDA does not even recognize the word as an official product type. But there is regulation of cosmetics under the Federal FD and C Act. The claims made about pharmaceuticals are subject to high scrutiny by the Food and Drug Administration (FDA) review and approval process, but cosmetics are not subject to mandatory FDA review. Although, much confusion exists regarding the status of 'cosmeceuticals.' Cosmeceuticals has found application and recognition to designate the products at the borderline between cosmetics and pharmaceuticals. There is no legal class called Cosmeceuticals. Cosmeceuticals are not subject to FDA review and the Federal Food, Drug and Cosmetic Act do not recognize the term itself. It is difficult for consumers to determine whether 'claims' about the actions or efficacies of cosmeceuticals are in fact valid unless the product has been approved by the FDA or equivalent agency.<sup>[1-2]</sup>

Some countries have the classes of products that fall between the two categories of cosmetics and drugs: for example, Japan has 'Quasi-drugs'; Thailand has 'controlled cosmetics' and

Hong Kong has 'cosmetic-type drugs.' The regulations of cosmeceuticals have not been harmonized between the USA, European, Asian and other countries. .<sup>[1-2]</sup>

The Drugs and Cosmetics Act, 1940 governs the provisions relating to manufacture, sale, storage, distribution and import of Drugs as well as cosmetics in India. Whereas it clearly defines the terms "Drug" and "Cosmetics" but there is no term as "Cosmeceutical" in the Act. Therefore nobody has a legal or statutory right to use the term for drawing benefits of any sort. For all intents and purposes either "drug" or "cosmetic" terms have to be used or usage of any other term to replace or substitute either of these two terms is simply illegal.<sup>[1]</sup>

#### **4. Future of Cosmeceuticals:**

Cosmeceuticals play an important role in future therapeutic developments but their success will be governed by control of purity, safety and efficacy without hindering innovation.

1. **Genomics:** - The role of genomics is not only limited to pharmaceutical industry. Research is ongoing to find the key genes in biological processes. This technology will find application in skin pigmentation, hydration and in wrinkles.<sup>[4]</sup>

**Example:** - Research in controlling aging of skin through a method called gene expression profiling.<sup>[4]</sup>

2. **Nanotechnology:** - This is new technology used in personal care industry. It uses extremely tiny (Nano) particles to penetrate through the skin. It also includes Nanoemulsions, Nanocapsules. Research is ongoing on hair care products.<sup>[4]</sup>

**Example:** - Use of nanotechnology in cosmeceutical preparation to make fragrance last longer, sunscreen anti ageing cream more effective.<sup>[4]</sup>

3. **Nutricosmetics:** - This is the combination of Nutraceuticals and Cosmeceuticals. They incorporate ingredients in topical delivery system. These products are formulated to beautify the skin through anti-aging or anti-wrinkle and also to beautify the hair or prevent hair loss. It generally focuses on the area: - skin, hair & beauty. They are taken orally either as pills or liquids.<sup>[4]</sup>

## **CONCLUSION**

Currently, the cosmeceutical market is considered to be a potential market for the cosmetic and pharmaceutical industries. Proper regulation of cosmeceuticals and standardization will lead to tremendous and significant growth in cosmeceuticals. The regulatory framework should include the term cosmeceutical and also there should be existence of Cosmetovigilance system and Cosmeceutical Consultative Committee (CCC) for the safety and efficacy of cosmeceuticals.

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