SJIF Impact Factor (2025): 8.688| ISI I.F. Value: 1.241| Journal DOI: 10.36713/epra2016 ISSN: 2455-7838(Online)
EPRA International Journal of Research and Development (IJRD)
Volume: 10 | Issue: 11 | November 2025 - Peer Reviewed Journal

SAFETY, REGULATION AND QUALITY CONTROL OF COSMECEUTICALS

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ABSTRACT
Cosmeceuticals represent a rapidly expanding segment of the global cosmetic industry, offering aesthetic improvement along with therapeutic activity due to the presence of biologically active ingredients[1]. However, the lack of a universal regulatory definition and inconsistent global standards creates major concerns regarding product safety, quality, and efficacy[2]. This review discusses safety evaluation parameters, international regulatory frameworks, and essential quality control techniques necessary for ensuring reliable cosmeceutical products[3].

KEYWORDS- *Cosmeceuticals; Safety evaluation; Regulation; Quality control; FDA; BIS; EU Regulation*

INTRODUCTION
Cosmeceuticals combine cosmetic benefits with pharmaceutical activity, containing active compounds such as vitamins, antioxidants, peptides, botanical extracts, and enzymes[4]. Their popularity has increased significantly due to consumer interest in anti-aging, skin-brightening, and dermatological wellness solutions[5]. However, regulatory ambiguity and safety issues remain major challenges[6]. Since these products are applied frequently and directly onto the skin, ensuring safety through dermatological, toxicological, microbial, and stability assessments is essential[7].

Regulatory authorities across India, the USA, and the EU follow different standards, creating global variability in monitoring and compliance[8]. Quality control further ensures product consistency, microbial safety, stability, and accurate active ingredient content[9].



CONCEPT OF COSMECEUTICALS
Cosmeceuticals are products that lie between cosmetics and pharmaceuticals, offering both appearance-enhancing and therapeutic effects[10]. These contain active ingredients capable of influencing biological skin functions[11]. They differ from:
* Cosmetics – only beautify
* Drugs – diagnose, treat, cure
* Cosmeceuticals – appearance + biological activity[12]

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Common active ingredients include vitamins A, C, E, alpha-hydroxy acids, peptides, herbal extracts, flavonoids, coenzyme Q10, and sunscreens[13].

SAFETY OF COSMECEUTICALS

Safety Concerns

Cosmeceuticals may cause several safety issues such as:
* Skin irritation and dermatitis[14]
* Allergic reactions from parabens, dyes, lanolin[15]
* Phototoxicity from essential oils and herbal extracts[16]
* Heavy metal contamination in low-quality products[17]
* Microbial contamination due to poor preservation[18]

Safety Evaluation Tests

Major safety evaluation tests include:
* Patch test[19]
* Dermatological evaluation[20]
* Stability testing under various environmental conditions[21]
* Microbial limit test[22]
* Preservative efficacy (challenge) test[23]
* Ocular irritation test for eye-area products[24]

REGULATION OF COSMECEUTICALS

India-

Regulated under:
* Drugs and Cosmetics Act, 1940
* *BIS standards (IS 4707)*[25]
Mandatory elements:
* Labeling rules
* Ingredient safety
* CDSCO import registration[26]

United States (FDA)

FDA does not legally recognize “cosmeceutical.”
It classifies products either as:**
* Cosmetic — only beautifying
* Drug — if therapeutic claims are made[27]
Drug-level approval is required for biological/therapeutic claims[28].

European Union (EU)

Regulated under EC Regulation 1223/2009[29]. Requirements include:
* *CPSR (Cosmetic Product Safety Report)*[30]
* *PIF (Product Information File)*[31]
* CPNP notification[32]
* *GMP compliance (ISO 22716)*[33]

QUALITY CONTROL OF COSMECEUTICALS

Physicochemical Tests

* pH measurement[34]
* Viscosity and spreadability[35]
* Appearance, odour, colour
* Accelerated stability testing[36]

Microbial Quality Control

* Total viable count[37]

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* Yeast and mold count[38]
* Pathogen detection — Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans[39]
* Preservative efficacy test[40]

Active Ingredient Testing
* Vitamin assay
* Antioxidant activity
* SPF determination (ISO 24444)[41]
* HPLC analysis of herbal actives[42]

Packaging Quality Control
* Compatibility evaluation
* Leaching test
* Migration study[43]

DISCUSSION

Cosmeceuticals represent a dynamic and rapidly emerging segment of skin-care technology. Despite their commercial success, inconsistent regulatory frameworks and misleading marketing claims pose major risks to consumer safety[44]. Stronger guidelines and harmonized global standards are needed to ensure scientific safety validation and reliability of products[45].

FUTURE PROSPECTS

Future advancements in cosmeceuticals may include:
* Nanotechnology-based delivery systems
* Standardized herbal formulations
* Green and sustainable cosmetic chemistry
* Personalized and AI-based skincare solutions[46]

CONCLUSION

Cosmeceuticals occupy a unique space between cosmetics and pharmaceuticals. Ensuring their safety, regulatory compliance, and scientific quality control is essential to protect consumers and enhance efficacy[16]. The development of stronger, harmonized global guidelines will promote high-quality, reliable, and safe cosmeceutical products[47].

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