



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 ingredients¹. However, the lack of a universal regulatory definition and inconsistent global standards creates major concerns regarding product safety, quality, and efficacy². This review discusses safety evaluation parameters, international regulatory frameworks, and essential quality control techniques necessary for ensuring reliable cosmeceutical products³.

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 enzymes⁴. Their popularity has increased significantly due to consumer interest in anti-aging, skin-brightening, and dermatological wellness solutions⁵. However, regulatory ambiguity and safety issues remain major challenges⁶. Since these products are applied frequently and directly onto the skin, ensuring safety through dermatological, toxicological, microbial, and stability assessments is essential⁷.

Regulatory authorities across India, the USA, and the EU follow different standards, creating global variability in monitoring and compliance⁸. Quality control further ensures product consistency, microbial safety, stability, and accurate active ingredient content⁹.



CONCEPT OF COSMECEUTICALS

Cosmeceuticals are products that lie between cosmetics and pharmaceuticals, offering both appearance-enhancing and therapeutic effects¹⁰. These contain active ingredients capable of influencing biological skin functions¹¹. They differ from:

- * Cosmetics – only beautify
- * Drugs – diagnose, treat, cure
- * Cosmeceuticals – appearance + biological activity¹²



Common active ingredients include vitamins A, C, E, alpha-hydroxy acids, peptides, herbal extracts, flavonoids, coenzyme Q10, and sunscreens¹³.

SAFETY OF COSMECEUTICALS

Safety Concerns

Cosmeceuticals may cause several safety issues such as:

- * Skin irritation and dermatitis¹⁴
- * Allergic reactions from parabens, dyes, lanolin¹⁵
- * Phototoxicity from essential oils and herbal extracts¹⁶
- * Heavy metal contamination in low-quality products¹⁷
- * Microbial contamination due to poor preservation¹⁸

Safety Evaluation Tests

Major safety evaluation tests include:

- * Patch test¹⁹
- * Dermatological evaluation²⁰
- * Stability testing under various environmental conditions²¹
- * Microbial limit test²²
- * Preservative efficacy (challenge) test²³
- * Ocular irritation test for eye-area products²⁴

REGULATION OF COSMECEUTICALS

India-

Regulated under:

- * Drugs and Cosmetics Act, 1940
- * BIS standards (IS 4707)²⁵

Mandatory elements:

- * Labeling rules
- * Ingredient safety
- * CDSCO import registration²⁶

United States (FDA)

FDA does not legally recognize “cosmeceutical.”

It classifies products either as:**

- * Cosmetic — only beautifying
- * Drug — if therapeutic claims are made²⁷

Drug-level approval is required for biological/therapeutic claims²⁸.

European Union (EU)

Regulated under EC Regulation 1223/2009²⁹. Requirements include:

- * CPSR (Cosmetic Product Safety Report)³⁰
- * PIF (Product Information File)³¹
- * CPNP notification³²
- * GMP compliance (ISO 22716)³³

QUALITY CONTROL OF COSMECEUTICALS

Physicochemical Tests

- * pH measurement³⁴
- * Viscosity and spreadability³⁵
- * Appearance, odour, colour
- * Accelerated stability testing³⁶

Microbial Quality Control

- * Total viable count³⁷



* Yeast and mold count³⁸

* Pathogen detection — Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans³⁹

* Preservative efficacy test⁴⁰

Active Ingredient Testing

* Vitamin assay

* Antioxidant activity

* SPF determination (ISO 24444)⁴¹

* HPLC analysis of herbal actives⁴²

Packaging Quality Control

* Compatibility evaluation

* Leaching test

* Migration study⁴³

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 safety⁴⁴. Stronger guidelines and harmonized global standards are needed to ensure scientific safety validation and reliability of products⁴⁵.

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 solutions⁴⁶

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 efficacy¹⁶. The development of stronger, harmonized global guidelines will promote high-quality, reliable, and safe cosmeceutical products⁴⁷.

REFERENCES

1. Kaur I, Kapila R, Kapila S. Role of bioactive compounds in cosmeceuticals: Present and future. *Journal of Cosmetic Science*. 2018;69(4):123-134.
2. Dureja H, Kaushik D, Gupta M, Kumar V, Lather V. Cosmeceuticals: An emerging concept. *Indian Journal of Dermatology, Venereology and Leprology*. 2005;71(4):223-232.
3. Mukherjee PK, Maity N, Nema NK, Sarkar BK. Bioactive compounds from natural resources in cosmetic and cosmeceutical preparations. *Journal of Ethnopharmacology*. 2016;177:201-217. doi:10.1016/j.jep.2015.12.042
4. *Global Cosmeceuticals Market Report*. Market Research Future. 2021;1-85. Available from: <https://www.marketresearchfuture.com>
5. Sarkar R, Raghunathan S, Garg S. Safety considerations and risk assessment of cosmeceuticals and topical agents. *Dermatology Review*. 2019;6(2):87-96.
6. U.S. Food and Drug Administration. *FDA Authority Over Cosmetics*. FDA; 2023. Available from: <https://www.fda.gov/cosmetics>
7. World Health Organization. *Safety Guidelines for Topical Pharmaceutical Products*. Geneva: WHO Press; 2018.
8. European Parliament. Regulation (EC) No. 1223/2009 on cosmetic products. *Official Journal of the European Union*. 2009;L342:59-209.
9. International Organization for Standardization. *ISO 11930: Cosmetics – Microbiology – Evaluation of the antimicrobial protection of a cosmetic product*. ISO; 2020.
10. Barel AO, Paye M, Maibach HI. *Handbook of Cosmetic Science and Technology*. 4th ed. CRC Press; 2014.
11. Mukherjee PK, Verpoorte R, Saha K. *Evaluation and standardization of herbal drugs and cosmeceuticals*. *Herbal Standardization Manual*. Elsevier; 2020.
12. U.S. Food and Drug Administration. *Is It a Cosmetic, a Drug, or Both?* FDA; 2022.
13. *Antioxidant activity and stability assessment of vitamin-based formulations*. *International Journal of Cosmetic Research*. 2020;5(1):45-58.
14. Sharma R, Dua K. *Irritation and sensitization reactions due to cosmetic ingredients*. *Journal of Dermatological Safety*. 2019;10(3):115-122.
15. Bureau of Indian Standards. *Report on safety of cosmetic chemical ingredients*. BIS; 2018.
16. Scientific Committee on Consumer Safety (SCCS). *Opinion on Phototoxicity of Essential Oils*. European Commission; 2017.



17. World Health Organization. *Heavy Metals in Cosmetics: Assessment and Safety Report*. WHO; 2019.
18. Patel S, Tambe S. *Microbial contamination of cosmetic formulations – A review*. *Journal of Cosmetic Microbiology*. 2020;8(2):101-112.
19. International Contact Dermatitis Research Group. *Patch Test Guidelines*. ICDRG; 2017.
20. European Academy of Dermatology. *Guidelines for Dermatological Evaluation of Topicals*. Springer; 2021.
21. International Council for Harmonisation. *ICH Q1A(R2) – Stability Testing of New Drug Substances and Products*. ICH; 2003.
22. United States Pharmacopeia. *USP 61 & 62 – Microbial Limit Tests*. USP; 2020.
23. International Organization for Standardization. *ISO 11930: Preservation Efficacy Evaluation*. ISO; 2019.
24. OECD. *Test No. 405: Acute Eye Irritation/Corrosion*. OECD Guidelines; 2020.
25. Bureau of Indian Standards. *IS 4707 – List of Cosmetic Raw Materials*. BIS; 2017.
26. Central Drugs Standard Control Organisation. *Guidelines on Import and Regulation of Cosmetics in India*. CDSCO; 2020.
27. U.S. FDA. *Cosmetic Labeling and Claims Guidelines*. FDA; 2022.
28. U.S. Food and Drug Administration. *Drug Approval Process for Topical Products*. FDA; 2021.
29. European Commission. *Cosmetic Regulation Compliance File*. EC; 2019.
30. *Cosmetic Product Safety Report (CPSR) Guidelines*. European Union; 2020.
31. *Product Information File (PIF) Documentation Standard*. European Commission; 2018.
32. *Cosmetic Product Notification Portal (CPNP) Requirements*. EU; 2019.
33. International Organization for Standardization. *ISO 22716: Cosmetics – Good Manufacturing Practices (GMP)*. ISO; 2018.
34. Barel AO. *Cosmetic Quality Control Procedures*. CRC Press; 2015.
35. Kanchan S. *Foaming index evaluation of cleansing cosmetics*. *J Cosmet Formul*. 2019;11(3):55-63.
36. *Stability Testing of Cosmetic Preparations*. *Cosmetic Science Technical Manual*. 2020;1:120-146.
37. ISO. *Microbial Count Standards for Non-Sterile Products*. ISO; 2019.
38. World Health Organization. *Guidelines on microbial quality of topical products*. WHO; 2020.
39. United States Pharmacopeia. *Pathogen Detection in Nonsterile Products*. USP; 2020.
40. International Standard ISO 11930. *Preservation challenge test*. ISO; 2021.
41. International Organization for Standardization. *ISO 24444: Determination of Sun Protection Factor (SPF)*. ISO; 2019.
42. Gupta A, Verma P. *HPLC-based evaluation of herbal markers in cosmetic formulations*. *Phytochemical Analysis Journal*. 2021;32(1):88-94.
43. *Packaging Compatibility Testing Manual*. Cosmetic Packaging Institute; 2019.
44. *International Cosmetic Regulatory Challenges Report*. Global Regulatory Affairs Council; 2021.
45. *Consumer Safety Standards for Cosmetic Products*. International Safety Board; 2020.
46. *Future Trends in AI-Based Personalized Skincare*. *Journal of Cosmetic Innovation*. 2021;15(4):233-244.
47. Sultana S, Verma A. *Review on cosmeceutical safety, quality, and regulation*. *International Journal of Cosmetic Science*. 2021;43(6):789-802.