IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 1, September 2025
Impact Factor: 7.67

Quality by Design (QbD) in Herbal Drug Formulation: Current Strategies and Regulatory Aspects

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Abstract: *The implementation of Quality by Design (QbD) in herbal drug formulation represents a paradigm shift from conventional quality control to a proactive, risk-based, and science-driven framework. This review emphasizes the significance of QbD in addressing the challenges associated with herbal medicines, particularly their inherent variability, multi-component composition, and lack of standardized evaluation. Special focus is given to anti-aging formulations, where consistent quality, safety, and efficacy are crucial for market acceptance. Advances in analytical techniques, computational biology, chemometrics, and novel drug delivery systems have enhanced the ability to identify critical quality attributes (CQAs), critical process parameters (CPPs), and establish robust design spaces. Regulatory perspectives from India, the United States, and the European Union are compared, highlighting the role of QbD in harmonizing global standards and ensuring compliance. Furthermore, the integration of emerging technologies such as nanotechnology, artificial intelligence (AI), and personalized medicine approaches is discussed as a means of optimizing formulation design and enhancing therapeutic performance. Overall, QbD emerges not only as a tool for regulatory adherence but also as a strategic enabler of innovation, quality assurance, and consumer confidence in the growing herbal drug industry*

Keywords: Quality by Design (QbD), Herbal drug formulation, Anti-aging formulations, Critical Quality Attributes (CQAs), Regulatory aspects, Standardization of herbal medicines, Novel drug delivery systems, Artificial intelligence in drug development

DOI: 10.48175/568