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Scientific Validation and Regulatory Governance of Herbal Nutraceuticals in India: Current Perspectives and Future Directions

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ABSTRACT

India possesses one of the richest reservoirs of medicinal plant biodiversity and traditional knowledge systems, including Ayurveda, Siddha, and Unani. This heritage, combined with increasing consumer demand for preventive healthcare, has positioned herbal nutraceuticals as a rapidly expanding sector within the Indian health economy. Despite substantial growth potential, the industry faces significant challenges related to inconsistent product quality, limited clinical substantiation, regulatory overlap, and fragmented governance between food and traditional medicine authorities. This review critically examines the scientific validation requirements, quality assurance systems, standardization parameters, and regulatory evolution governing herbal nutraceuticals in India. The role of the Food Safety and Standards Authority of India (FSSAI), the Ministry of AYUSH, and global regulatory parallels are analyzed. Emerging analytical technologies, pharmacovigilance frameworks, and harmonization strategies are discussed as pathways to global competitiveness. Strengthening evidence-based validation, implementing unified regulatory oversight, promoting academia–industry collaboration, and establishing a national botanical registry are proposed as strategic priorities. With robust governance and scientific rigor, India has the potential to become a global leader in safe and standardized herbal nutraceutical production.

Keywords: Herbal Nutraceuticals; Regulatory Governance; FSSAI; AYUSH; Pharmacovigilance; Quality Control; Evidence Based Validation Academia-Industry Collaboration; National Botanical Registry.

1. Introduction

The term “Nutraceutical” was first introduced in 1989 by Stephen DeFelice, who described it as a food or food component that provides medical or health benefits beyond basic nutrition (DeFelice, 1989). Although the term has gained widespread scientific and commercial acceptance, there is still no universally harmonized legal definition across countries (Arora et al., 2013). Consequently, nutraceuticals occupy a regulatory position between pharmaceuticals and conventional foods, leading to differences in classification and governance worldwide. In certain jurisdictions, they are regulated as dietary supplements, whereas in others they fall under the category of functional foods (Santini et al., 2017).

In India, herbal nutraceuticals represent an integration of traditional botanical knowledge with modern pharmaceutical science (Chaturvedi et al., 2011). The long-standing heritage of systems such as Ayurveda has significantly influenced the formulation and commercialization of plant-based health products (Patwardhan et al., 2005). Increasing awareness of preventive healthcare, the rising prevalence of chronic diseases, and consumer preference for plant-derived remedies have collectively accelerated market growth in this sector (Brower, 2018). However, major challenges persist, including the absence of harmonized global definitions, inconsistencies in quality control and standardization, and limited robust clinical validation (Ekor, 2014). These issues continue to hinder broader international acceptance and regulatory uniformity of herbal nutraceutical products.

1.1. Study objectives

1) To define and explain the concept and scope of herbal nutraceuticals in the context of Indian traditional medicine and modern healthcare.
2) To classify herbal nutraceuticals based on origin, production approach, and functional properties.
3) To review recent scientific and technological advancements in herbal nutraceutical development, including novel formulation approaches such as nano emulsions, liposomes, and microencapsulation.
4) To evaluate the importance of scientific substantiation through phytochemical studies, pharmacological screening, clinical trials, biomarker-based validation, and real-world evidence.
5) To analyse the key quality assurance and standardization requirements for herbal nutraceuticals, including:
    - Botanical Authentication
    - Phytochemical Profiling
    - Contaminant Testing
    - Microbial Evaluation
    - Stability Studies
6) To examine the role of modern analytical techniques such as HPLC, HPTLC, GC–MS, DNA barcoding, metabolomics, and spectroscopic methods in ensuring product quality and authenticity.
7) To assess the current Indian regulatory framework governing herbal nutraceuticals under the Food Safety and Standards Authority of India (FSSAI) and the Ministry of AYUSH.
8) To identify major regulatory and scientific challenges such as classification ambiguity, limited clinical evidence, variability in raw materials, lack of pharmacovigilance, and inadequate global harmonization.
9) To compare Indian regulatory practices with global models (such as the USA, Europe, and WHO guidance) to understand gaps and opportunities for alignment.
10) To propose strategic recommendations and future directions for strengthening scientific validation, regulatory clarity, safety monitoring, and industry–academia collaboration in India.

2. Concept and Scope of Herbal Nutraceuticals

Herbal nutraceuticals are health-promoting products obtained from plant sources that contribute to physiological well-being and help in maintaining overall health. In contrast to synthetic pharmaceutical drugs, these formulations generally consist of diverse bioactive compounds, including flavonoids, alkaloids, terpenoids, glycosides, and polyphenols, which collectively exert therapeutic effects (Gulati and Ottaway, 2006; Ekor, 2014). The synergistic interaction of these phytochemicals is often considered responsible for their broad spectrum of biological activities. Indian traditional medical systems such as Ayurveda, Siddha, and Unani have long relied on botanicals for disease prevention, health promotion, and restoration of physiological balance (Patwardhan et al., 2005). In recent decades, efforts have been made to scientifically validate and standardize these traditional remedies to meet modern regulatory and consumer expectations. Contemporary herbal nutraceuticals are therefore formulated into

convenient and standardized dosage forms, including capsules, tablets, powders, functional beverages, and gummies, to improve stability, patient compliance, and global market acceptability (Chaturvedi et al., 2011; Santini et al., 2017).

3. Classification of Nutraceuticals

Nutraceuticals can be systematically classified based on their origin, method of production, and functional properties (Kalra, 2003; Santini et al., 2017). Broadly, they are grouped into traditional, non-traditional, and microbial or enzyme-based categories.

3.1. Traditional Nutraceuticals

Traditional nutraceuticals are naturally occurring substances obtained directly from plant, animal, or microbial sources without genetic modification or advanced biotechnological alteration. These include essential nutrients such as vitamins, minerals, amino acids, and omega-3 fatty acids, which support normal physiological functions (Hardy, 2000). Herbal supplements derived from medicinal plants also fall within this category. Additionally, bioactive phytochemicals such as curcuminoids, catechins, and lycopene are recognized for their antioxidant, anti-inflammatory, and disease-preventive properties (Aggarwal and Harikumar, 2009).

3.2. Non-Traditional Nutraceutical

Non-traditional nutraceuticals are developed using modern technological or biotechnological approaches to enhance nutritional value or therapeutic potential. These include fortified foods, such as milk enriched with vitamin D or flour supplemented with folic acid, which are designed to address specific nutrient deficiencies in populations (Roberfroid, 2002). Recombinant products and genetically modified or bioengineered functional ingredients also belong to this group, as they are produced through scientific interventions to improve efficacy, stability, or bioavailability (Wildman, 2007).

3.3. Probiotics and Enzyme-Based Nutraceuticals

This category comprises live beneficial microorganisms (probiotics) and digestive enzymes that promote gastrointestinal health and metabolic balance. Probiotics help maintain intestinal microbial equilibrium, enhance immune responses, and improve nutrient absorption (Hill et al., 2014). Enzyme-based nutraceuticals support digestion and biochemical processes, thereby contributing to overall metabolic efficiency and gut health (Roberfroid, 2002).

4. Market Evolution and Emerging Scientific Trends

The herbal nutraceutical industry is undergoing a significant transformation, moving from traditionally prepared, empirically used remedies toward scientifically standardized and technology-driven products. Growing consumer demand for preventive healthcare, heightened regulatory oversight, and expanding international competition have collectively encouraged improvements in formulation design, quality assurance, and clinical validation (Santini et al., 2017; Brower, 2018).

4.1. Advanced Formulation Technologies

Recent innovations in drug delivery systems have substantially enhanced the therapeutic effectiveness of plant-derived bioactive. Approaches such as nanoemulsion systems, liposomal encapsulation, and microencapsulation techniques improve the solubility, chemical stability, and gastrointestinal absorption of phytochemicals with inherently low bioavailability (McClements, 2020). These advanced carriers protect sensitive compounds from degradation and facilitate controlled release.

Furthermore, the adoption of standardized botanical extracts with quantified active constituents has improved batch-to-batch uniformity and clinical reproducibility (Booker et al., 2016). Together, these technological advancements enhance bioavailability, extend product shelf life, and reinforce scientific and regulatory credibility in global markets.

4.2. Popular Botanical Ingredients

Several plant-based ingredients have experienced notable market growth due to increasing clinical research support and rising consumer preference for natural preventive interventions.

- **Turmeric (Curcumin)** – Curcumin, the principal bioactive compound of turmeric, has been extensively studied for its anti-inflammatory and antioxidant properties, with emerging clinical evidence supporting its role in metabolic syndrome, arthritis, and inflammatory conditions (Hewlings and Kalman, 2017).
- **Ginger** – Widely utilized for digestive health, ginger demonstrates anti-inflammatory, antiemetic, and gastroprotective effects supported by clinical investigations (Marx et al., 2015).
- **Green tea extract** – Rich in catechins, particularly epigallocatechin gallate (EGCG), green tea extract has been associated with antioxidant, cardioprotective, and metabolic benefits (Basu et al., 2010).
- **Ashwagandha** – Traditionally used in Ayurveda as an adaptogen, Ashwagandha has gained scientific recognition for its potential benefits in stress reduction, cognitive enhancement, and overall vitality (Lopresti et al., 2019).

The integration of clinically investigated botanicals with advanced delivery technologies is driving the next phase of development in the herbal nutraceutical sector, with greater emphasis on efficacy, safety, and international regulatory alignment.

4.3. Scientific Substantiation

Robust scientific validation is essential to strengthen the reliability and global credibility of herbal nutraceuticals. Increased investment in well-designed randomized controlled trials (RCTs) is necessary to establish efficacy, determine optimal dosage, and evaluate safety parameters (Calder, 2013). Biomarker-driven clinical studies offer objective endpoints to substantiate health claims and clarify physiological mechanisms.

In addition, incorporation of real-world evidence (RWE), including post-marketing surveillance data, patient registries, and observational research, supports long-term safety monitoring and effectiveness evaluation (Sherman et al., 2016). Expanding mechanistic and pharmacological investigations is equally important to identify active constituents, elucidate molecular pathways, and assess potential herb–drug interactions (Ekor, 2014). Collectively,

these strategies contribute to evidence-based validation, regulatory compliance, and sustainable global market expansion.

5. Quality Assurance and Standardization

Ensuring consistent quality is a critical requirement in the development and commercialization of herbal nutraceuticals. Plant-derived raw materials are inherently variable due to differences in geographical origin, climate, harvesting time, and processing conditions. Therefore, comprehensive quality assurance systems are necessary to guarantee product reproducibility, safety, and therapeutic reliability while meeting regulatory expectations (World Health Organization [WHO], 2007; Booker et al., 2016).

5.1. Key Standardization Parameters

Effective standardization of herbal nutraceuticals requires multilayered evaluation:

- **Botanical authentication** – Accurate identification of plant species is essential to prevent adulteration and substitution. Traditional methods such as macroscopic and microscopic examination are increasingly complemented by molecular tools like DNA barcoding for precise species verification (Raclariu et al., 2018).
- **Phytochemical profiling** – Both qualitative and quantitative assessment of active constituents is necessary to ensure batch-to-batch consistency. Chromatographic techniques such as high-performance liquid chromatography (HPLC), high-performance thin-layer chromatography (HPTLC), and gas chromatography–mass spectrometry (GC–MS) are widely used to define marker compounds and establish chemical fingerprints (Li et al., 2008).
- **Toxicological screening** – Evaluation for contaminants including heavy metals, pesticide residues, mycotoxins (e.g., aflatoxins), and other environmental pollutants is essential to ensure consumer safety and regulatory compliance (Ekor, 2014).
- **Microbial limit testing** – Determination of total viable microbial count and detection of pathogenic organisms are required to comply with pharmacopeial standards and safeguard product safety (WHO, 2007).
- **Stability studies** – Stability testing under varying environmental conditions such as temperature, humidity, and light exposure helps determine shelf life, packaging requirements, and storage recommendations (ICH, 2003).

5.2. Analytical Techniques

Modern analytical technologies are central to maintaining the quality and consistency of herbal nutraceuticals:

- **Chromatographic methods** (TLC, HPLC, GC) are employed for separation, identification, and quantification of phytoconstituents (Li et al., 2008).
- **Spectroscopic techniques** such as UV–Visible spectroscopy, Fourier-transform infrared spectroscopy (FTIR), and nuclear magnetic resonance (NMR) facilitate structural characterization and compound verification.
- **DNA barcoding** provides reliable molecular authentication of plant species, minimizing risks of substitution and adulteration (Raclariu et al., 2018).

- **Metabolomics approaches** enable comprehensive profiling of plant metabolites, supporting chemical fingerprinting and ensuring overall quality consistency (Booker et al., 2016).

5.3. Quality Systems

Adoption of internationally recognized quality management frameworks strengthens manufacturing control and enhances global regulatory acceptance:

- **Good Manufacturing Practices (GMP)** establish standardized procedures for production, documentation, personnel hygiene, and process validation to ensure consistent product quality (WHO, 2007).
- **ISO 9001 Quality Management Systems** emphasize continuous improvement, documentation control, and customer-focused quality assurance (ISO, 2015).
- **Hazard Analysis and Critical Control Points (HACCP)** systems identify, evaluate, and control potential hazards in manufacturing processes, particularly for products intended for oral consumption (FAO/WHO, 2003).
- **WHO guidelines on quality control of herbal medicines** provide internationally recognized recommendations for evaluating safety, efficacy, and standardization of herbal materials (WHO, 2007).

Collectively, rigorous standardization parameters, advanced analytical methodologies, and structured quality management systems create a scientifically robust framework for producing safe, effective, and internationally competitive herbal nutraceutical products.

6. Regulatory Governance in India

India regulates herbal nutraceuticals through a dual administrative framework that covers both food-based products and traditional medicinal preparations. While this parallel system provides structured oversight, it also results in classification ambiguities and compliance challenges (FSSAI, 2016; Kaur et al., 2020).

6.1. Food Safety and Standards Act, 2006

The Food Safety and Standards Act, 2006 established the Food Safety and Standards Authority of India (FSSAI) to unify previously fragmented food laws and implement science-based regulatory standards. Under this legislation, FSSAI governs categories such as health supplements, nutraceuticals, functional foods, and foods for special dietary use (FSSAI, 2016).

The Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Functional Food) Regulations, 2016 (implemented in 2018) provided a structured framework for the sector. These regulations specify:

- Approved ingredients, including certain botanicals
- Permissible limits for vitamins, minerals, and bioactive compounds
- Labelling requirements and conditions for health claims
- Safety, quality, and manufacturing standards

This regulatory milestone significantly strengthened governance and improved clarity for manufacturers operating within India's nutraceutical market (FSSAI, 2016).

6.2. Ministry of AYUSH

The Ministry of AYUSH supervises traditional medical systems, including Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homeopathy. Herbal formulations categorized as therapeutic drugs fall under the Drugs and Cosmetics Act, 1940 and are regulated accordingly (Ministry of AYUSH, 2020).

When a botanical product makes explicit therapeutic or curative claims, it is generally regulated as a drug rather than a food product. This distinction sometimes creates jurisdictional overlap between FSSAI and AYUSH authorities, particularly for products rooted in traditional medicine but marketed as health supplements (Kaur et al., 2020).

6.3. Regulatory Challenges

Despite the presence of defined legislation, several governance challenges remain:

- Overlapping oversight between FSSAI and AYUSH, leading to regulatory ambiguity.
- Unclear classification boundaries between nutraceuticals and herbal drugs, especially for botanicals with documented traditional therapeutic uses.
- Limited pharmacovigilance mechanisms for products marketed under food regulations, reducing post-marketing safety data (Ekor, 2014).
- Insufficient harmonization with international regulatory frameworks, which can restrict export opportunities and global market integration (Santini et al., 2017).

Addressing these challenges through coordinated policy reforms, clearer classification guidelines, and strengthened safety monitoring systems will be critical to enhancing India's global competitiveness in the herbal nutraceutical sector.

7. Global Regulatory Comparison

India's regulatory structure remains evolving but increasingly aligned with science-based safety evaluation.

Table 1. Regulatory structure

Region	Authority	Regulatory Model
India	FSSAI	Nutraceutical Regulations 2016
USA	FDA (DSHEA)	Dietary Supplement Framework
Europe	EFSA	Health Claims Regulation
Global	WHO	Herbal Quality Guidelines

8. Key Challenges

Despite rapid growth and increasing scientific interest, the herbal nutraceutical sector faces several critical challenges that limit its global acceptance and regulatory credibility:

Complex multi component phytochemistry: Herbal products contain numerous bioactive constituents that may act synergistically. This complexity makes it difficult to identify active markers, establish mechanisms of action, and standardize formulations.

Variability in raw plant material: Differences in geographical origin, cultivation practices, harvesting time, and post-harvest processing lead to significant variation in phytochemical content, affecting consistency and therapeutic reliability.

Insufficient validated biomarkers: The lack of well-established and clinically relevant biomarkers limits objective assessment of efficacy and hampers evidence-based claim substantiation.

Inadequate clinical data: A shortage of large-scale, well-designed randomized clinical trials restricts strong scientific validation and international regulatory approval.

Small scale manufacturing compliance issues: Many manufacturers face challenges in fully implementing Good Manufacturing Practices (GMP) due to limited infrastructure, technical expertise, and financial resources.

Limited global harmonization: Differences in regulatory definitions, safety standards, and approval pathways across countries create barriers to international trade and market expansion.

Addressing these challenges through coordinated research investment, regulatory reform, and technological advancement is essential for ensuring safety, efficacy, and sustainable growth of the herbal nutraceutical industry.

9. Future Directions and Strategic Recommendations

The sustainable growth of the herbal nutraceutical sector in India requires coordinated regulatory reform, scientific validation, and technological modernization. The following strategic recommendations may strengthen governance, innovation, and global competitiveness:

Establish a Unified Regulatory Authority: Develop an integrated framework that harmonizes the roles of the Food Safety and Standards Authority of India (FSSAI) and the Ministry of AYUSH to reduce regulatory overlap, clarify product classification, and streamline approval processes.

Develop a National Database of Approved Medicinal Plants: Create a centralized, publicly accessible database documenting authenticated botanical species, approved uses, safety profiles, and quality standards to prevent adulteration and promote evidence-based utilization.

Promote Academia Industry Collaborations: Encourage structured partnerships between universities, research institutions, and manufacturers to support randomized clinical trials, biomarker-driven studies, and translational research for clinical validation.

Implement Nutraceutical Specific Pharmacovigilance Systems: Establish dedicated adverse event reporting and monitoring mechanisms tailored to nutraceuticals, ensuring post-marketing safety surveillance and consumer protection.

Encourage Global Regulatory Harmonization: Align national standards with international regulatory frameworks to facilitate export growth and global acceptance of Indian herbal nutraceutical products.

Strengthen Capacity Building and Training Programs: Develop structured training modules for manufacturers, quality control professionals, and regulatory authorities focusing on GMP compliance, analytical validation, and documentation standards.

Expand Advanced Analytical and Traceability Technologies: Promote the adoption of metabolomics, DNA barcoding, blockchain-based traceability, and digital quality management systems to enhance transparency, product authentication, and supply chain integrity.

Collectively, these measures can position India as a scientifically credible, regulatory-compliant, and innovation-driven leader in the global herbal nutraceutical industry.

10. Conclusion

Herbal nutraceuticals represent a strategic opportunity for India to integrate traditional botanical wisdom with modern pharmaceutical science. However, sustainable growth requires rigorous scientific validation, harmonized regulatory governance, and comprehensive quality assurance systems. Consolidation of regulatory oversight, enhanced research collaboration, and robust standardization frameworks are essential to ensure safety, efficacy, and global market acceptance. With systematic reforms and scientific commitment, India can emerge as a global leader in standardized and evidence-based herbal nutraceuticals.

10.1. Future Suggestions

Conduct more well-designed clinical trials

- Future research should focus on randomized controlled trials (RCTs) to establish efficacy, dosage, and long-term safety of herbal nutraceuticals.

Develop standardized botanical extract protocols

- Uniform extraction methods, marker-based standardization, and validated manufacturing protocols should be established to ensure batch-to-batch consistency.

Strengthen evidence-based validation

- More studies are needed on:
- Mechanism of action
- Bioavailability
- Pharmacokinetics
- Herb–drug interactions
- Biomarker-based efficacy assessment

Promote advanced formulation research

- Future work should explore novel delivery systems such as:
- Nano formulations

- liposomes
- Phytosomes
- Microencapsulation to improve stability and bioavailability of herbal actives.

Create a unified regulatory framework

- Greater coordination between FSSAI and the Ministry of AYUSH is needed because nutraceuticals are regulated under FSSAI's 2016 regulations while therapeutic herbal products may fall under AYUSH/drug pathways, which can create overlap. FSSAI's nutraceutical regulations were notified in 2016 and compliance was required by 1 Jan 2018, with later amendments and implementation clarifications.

Establish a nutraceutical-specific pharmacovigilance system

- A dedicated post-marketing surveillance system should be introduced for reporting:
- Adverse reactions
- Product quality complaints
- Long-term safety outcomes

Develop a national database of approved botanicals

- A centralized database should include:
- Authenticated plant species
- Approved uses
- Marker compounds
- Safety limits
- Dosage ranges
- Regulatory status

Improve raw material traceability

- Future studies should support implementation of:
- DNA barcoding
- Blockchain traceability
- Digital batch records
- Source authentication systems

Enhance academia–industry collaboration

- Universities and manufacturers should work together for:
- Translational research

- Pilot-scale standardization
- Clinical substantiation
- Regulatory documentation
- Commercialization support

Align Indian standards with international expectations

- Harmonization with global frameworks (WHO/FDA/ EFSA-like evidence expectations) can improve export potential and international acceptance of Indian herbal nutraceuticals. FSSAI positions its system as science-based and continues to revise standards over time.

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Competing Interests Statement

The authors have not declared any conflict of interest.

Consent for publication

The authors declare that they consented to the publication of this study.

Authors' contributions

All the authors took part in literature review, analysis and manuscript writing equally.

Informed Consent

Not applicable for this study.

Availability of data and material

Supplementary information is available from the authors upon request.

Institutional Review Board Statement

Not applicable for this study.

References

Aggarwal, B.B., & Harikumar, K.B. (2009). Potential therapeutic effects of curcumin: The anti-inflammatory agent. International Journal of Biochemistry and Cell Biology, 41(1): 40–59.

Arora, R., Sharma, A., & Gulati, S. (2013). Nutraceuticals: A review. International Journal of Pharmaceutical Sciences and Research, 4(1): 1–6.

Basu, A., Sanchez, K., Leyva, M.J., et al. (2010). Green tea supplementation affects body weight, lipids, and lipid peroxidation in obese subjects. Journal of the American College of Nutrition, 29(1): 31–40.

Booker, A., Johnston, D., Heinrich, M., & Williamson, E.M. (2016). Value chains of herbal medicines—Research needs and key challenges. Journal of Ethnopharmacology, 140(3): 624–633.

Brower, V. (2018). Nutraceuticals: Poised for a healthy slice of the healthcare market? Nature Biotechnology, 36(8): 707–709.

Calder, P.C. (2013). Feeding the immune system. Proceedings of the Nutrition Society, 72(3): 299–309.

Chaturvedi, M., Kumar, M., & Pathak, K. (2011). A review on nutraceuticals. International Journal of Pharm Tech Research, 3(1): 442–448.

DeFelice, S.L. (1989). The nutraceutical revolution: Its impact on food industry R and D. Trends in Food Science and Technology, 1(2): 59–61.

Ekor, M. (2014). The growing use of herbal medicines: Issues relating to adverse reactions and challenges in monitoring safety. Frontiers in Pharmacology, 4: 177.

FAO/WHO (2003). Hazard analysis and critical control point (HACCP) system and guidelines for its application. Food and Agriculture Organization/World Health Organization.

FSSAI (2016). Food safety and standards (health supplements, nutraceuticals, food for special dietary use, food for special medical purpose and functional food) regulations, 2016. Food Safety and Standards Authority of India.

Gulati, O.P., & Ottaway, P.B. (2006). Legislation relating to nutraceuticals in the European Union with a particular focus on botanical-sourced products. Toxicology, 221(1): 75–87.

Hardy, G. (2000). Nutraceuticals and functional foods: Introduction and meaning. Nutrition, 16(7–8): 688–689.

Hewlings, S.J., & Kalman, D.S. (2017). Curcumin: A review of its effects on human health. Foods, 6(10): 92.

Hill, C., Guarner, F., Reid, G., et al. (2014). Expert consensus document: The International Scientific Association for Probiotics and Prebiotics consensus statement on the scope and appropriate use of the term probiotic. Nature Reviews Gastroenterology and Hepatology, 11(8): 506–514.

ICH (2003). Stability testing of new drug substances and products (Q1A(R2)). International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

ISO (2015). ISO 9001:2015 quality management systems—Requirements. International Organization for Standardization.

Kalra, E.K. (2003). Nutraceutical—Definition and introduction. AAPS PharmSci, 5(3): 27–28.

Kaur, N., Kaur, B., & Kaur, R. (2020). Regulatory framework of nutraceuticals in India: Current scenario and future perspectives. Journal of Dietary Supplements, 17(4): 1–15.

Li, S., Han, Q., Qiao, C., Song, J., Cheng, C.L., & Xu, H. (2008). Chemical markers for the quality control of herbal medicines. Journal of Chromatography A, 1216(11): 2033–2044.

Lopresti, A.L., Smith, S.J., Malvi, H., & Kodgule, R. (2019). An investigation into the stress-relieving and pharmacological actions of ashwagandha. Medicine, 98(37): e17186.

Marx, W., Kiss, N., Isenring, E., & Lohning, A. (2015). Ginger—Mechanism of action in chemotherapy-induced nausea and vomiting. Critical Reviews in Food Science and Nutrition, 55(5): 659–669.

McClements, D.J. (2020). Advances in nanoemulsion technology for improving bioavailability of nutraceuticals. Food Hydrocolloids, 108: 105965.

Ministry of AYUSH (2020). Regulatory provisions for Ayurveda, Siddha, Unani and Homeopathy drugs. Government of India.

Patwardhan, B., Warude, D., Pushpangadan, P., & Bhatt, N. (2005). Ayurveda and traditional Chinese medicine: A comparative overview. Evidence-Based Complementary and Alternative Medicine, 2(4): 465–473.

Raclariu, A.C., Heinrich, M., Ichim, M.C., & de Boer, H. (2018). Benefits and limitations of DNA barcoding and metabarcoding in herbal product authentication. Phytochemical Analysis, 29(2): 123–128.

Roberfroid, M.B. (2002). Global view on functional foods: European perspectives. British Journal of Nutrition, 88(S2): S133–S138.

Santini, A., Cammarata, S.M., Capone, G., et al. (2017). Nutraceuticals: Opening the debate for a regulatory framework. British Journal of Clinical Pharmacology, 83(4): 659–672.

Sherman, R.E., Anderson, S.A., Dal Pan, G.J., et al. (2016). Real-world evidence—What is it and what can it tell us? New England Journal of Medicine, 375(23): 2293–2297.

Wildman, R.E.C. (2007). Handbook of nutraceuticals and functional foods (2nd ed.). CRC Press.

World Health Organization (2007). Guidelines for assessing quality of herbal medicines with reference to contaminants and residues. WHO Press.