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ANALYTICAL EVALUATION, LABEL CLAIM VERIFICATION, AND REGULATORY COMPLIANCE OF SELECTED NUTRACEUTICALS IN INDIA: A REVIEW

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ABSTRACT

Concerns about product quality, label accuracy, and regulatory compliance have been raised by the nutraceutical market's explosive growth in India. Nutraceuticals with probiotics, calcium, omega-3 fatty acids, vitamins (A, B-complex, C, and D), and other nutrients are frequently taken for both therapeutic and preventive purposes. However, in both Indian and foreign markets, disparities between label claims and actual content have been widely documented. The regulatory frameworks governing nutraceutical regulations in India, specifically those under the Food Safety and Standards Authority of India (FSSAI), are critically assessed in this review and compared to international norms. HPLC, spectrophotometry, titrimetry, ICP-MS, gas chromatography, and microbiological enumeration are among the analytical techniques used for active ingredient quantification and verification. Probiotic viability evaluation and omega-3 oxidative stability, two important quality factors frequently linked to product non-compliance, are given particular attention. The review identifies gaps in post- marketing surveillance, analytical standardization, and enforcement in

India and suggests ways to improve laboratory validation and regulatory harmonization. Maintaining industry credibility and safeguarding consumer health depend on accurate label declarations and adherence to FSSAI limits.

KEYWORDS: Regulatory compliance, label claim, nutraceutical regulation, FSSAI, Analytical methodologies.

1. INTRODUCTION

Vitamins, minerals, probiotics, fatty acids, and herbal extracts that are meant to provide health advantages beyond basic nutrition are included in the hybrid category of nutraceuticals, which lies between food and pharmaceuticals.[1,2] Due to rising consumer demand for dietary supplements for immunity, bone health, cardiovascular protection, and gut health, India has become one of the world's fastest-growing nutraceutical markets.[3, 4]

The Food Safety and Standards Act (2006) and later rules like the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Functional Foods) Regulations.[5–7] govern nutraceuticals in India. However, there have been reports of inconsistent quality, false label claims, and variations in microbial viability, particularly in probiotic formulations.[8–11]

International investigations have also reported significant discrepancies between labeled and measured vitamin content, omega-3 concentration, and probiotic counts.[12–15] Such inconsistencies underscore the importance of robust analytical validation and regulatory enforcement.

This review focuses on.

- Regulatory oversight of nutraceuticals (Indian and global)
- Analytical methodologies for vitamin, mineral, omega-3, and probiotic testing
- Label claim verification
- Challenges and future regulatory directions

2. Regulatory Framework Governing Nutraceuticals

2.1 Indian Regulatory Structure

In India, nutraceuticals are regulated by **(FSSAI)** under the Food Safety and Standards Act, 2006.[5]

Specific provisions include.

- Permissible limits of vitamins and minerals
- Recommended Dietary Allowance (RDA)-based upper limits
- Labeling requirements
- Restrictions on disease claims.[6–8]

FSSAI mandates that nutrient content should fall within declared label claims and not exceed prescribed upper safe limits.[6]

Table 1: Comparison of parameters globally.

Parameter	India (FSSAI)	USA (DSHEA)	EU (EFSA)
Pre-market approval	Limited	No	Yes (for novel ingredients)
Upper limits	RDA-based	Manufacturer responsibility	Scientifically evaluated
Label verification	Post-market	Post-market	Pre-market assessment

The severity of pre-market evaluations varies greatly throughout global regulatory systems.[9–12] The European Food Safety Authority mandates scientific support for health claims, while the United States regulates supplements under DSHEA (1994).[13,14]

3. Analytical Evaluation of Selected Nutraceuticals

3.1 Vitamin Analysis: Water-soluble Vitamins

Vitamin B- complex

- Method: HPLC with fluorescence detection
- Challenges: Multiple vitamers, instability.[15-17]

Flowchart – Vitamin B-complex Analysis

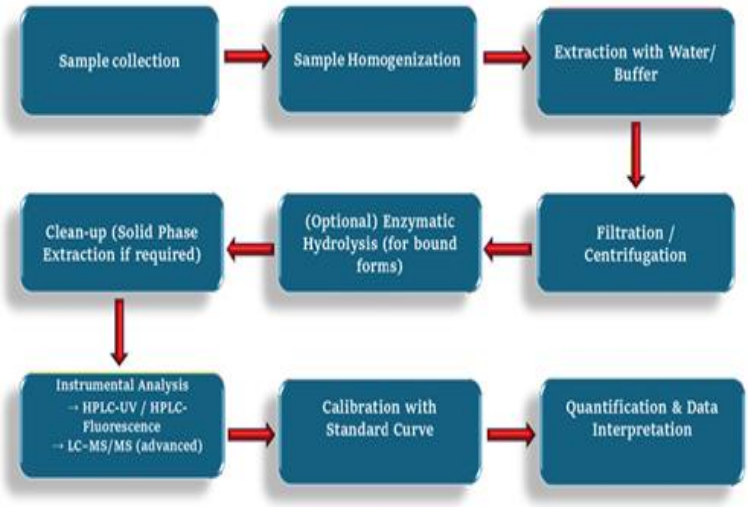

Fig. (1)- B-complex Analysis.

Vitamin C

- Method: Iodometric titration / HPLC
- Stability concern: Oxidation sensitivity
- Reported deviation cases: ±20% from label claims.[15–18]

Flowchart – Vitamin C Analysis

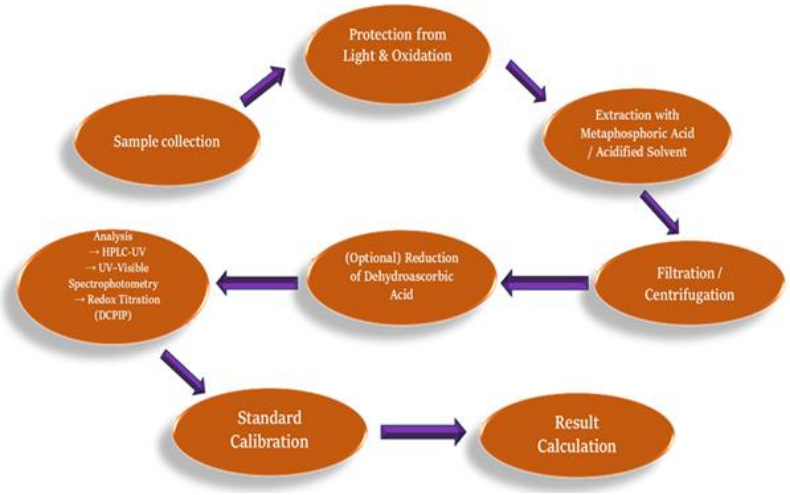

Fig. 2:- Vitamin C Analysis.

Fat-Soluble Vitamins

Vitamin A

- Method: HPLC with UV detection
- Extraction: Organic solvent phase separation
- Issues: Photodegradation, matrix interference.[19–22]

Flowchart – Vitamin A Analysis

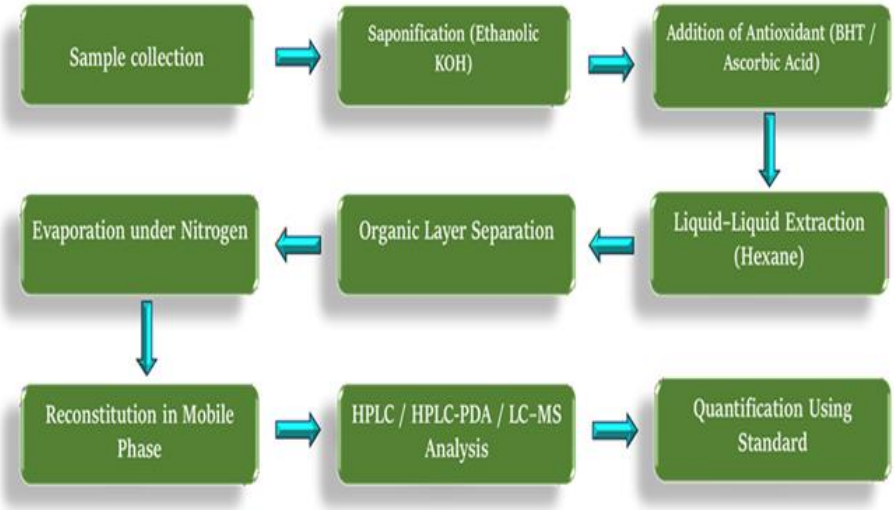

Fig. 3- Vitamin A Analysis.

Vitamin D

- Method: HPLC, UV detection, LC-MS, colorimetry
- Issues: Loss during extraction, sensitivity to heat and light.[23-25]

Flowchart – Vitamin D Analysis

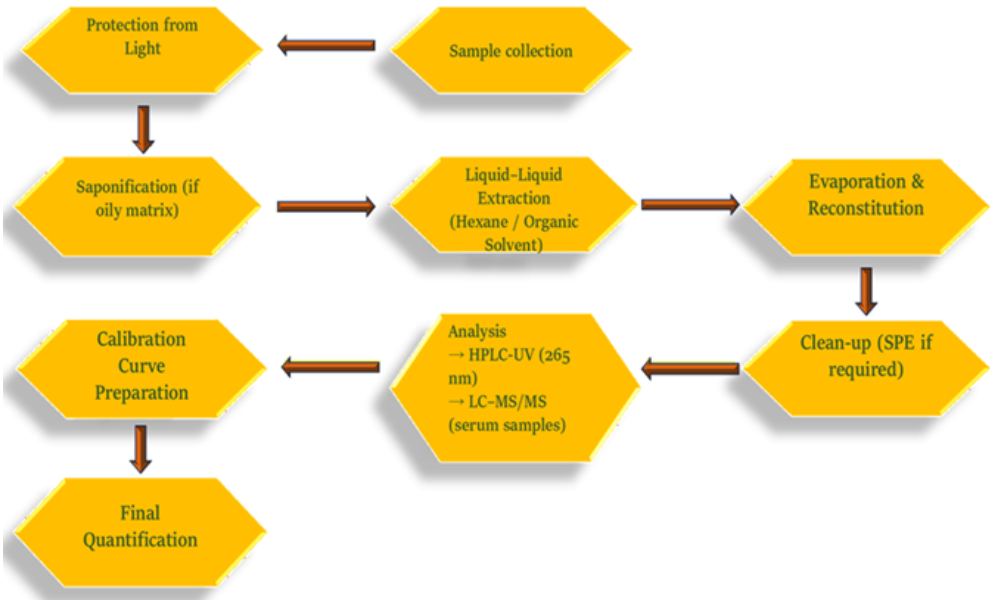

Fig. 4: Vitamin D Analysis.

Vitamin E

- Method: HPLC, UV- Vis Spectrophotometry
- Issues: Sensitive to light and oxygen

Flowchart – Vitamin E Analysis

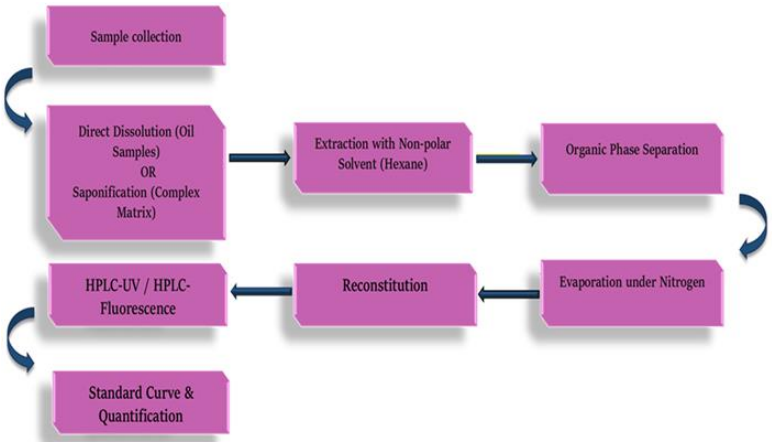

Fig. (5)- Vitamin E Analysis.

Vitamin K

- Method: HPLC, UV- detection, HPTLC
- Issues: Photodegradation, oxidation instability

Flowchart – Vitamin K Analysis

Fig. 5: Vitamin K Analysis.

3.2 Omega-3 Fatty Acids.

- Method: Gas Chromatography (GC-FID)
- Oxidative stability tests: Peroxide value, anisidine value
- Frequent finding: Lower EPA/DHA content than label claim.[26–28]

Flowchart – Omega-3 Analysis

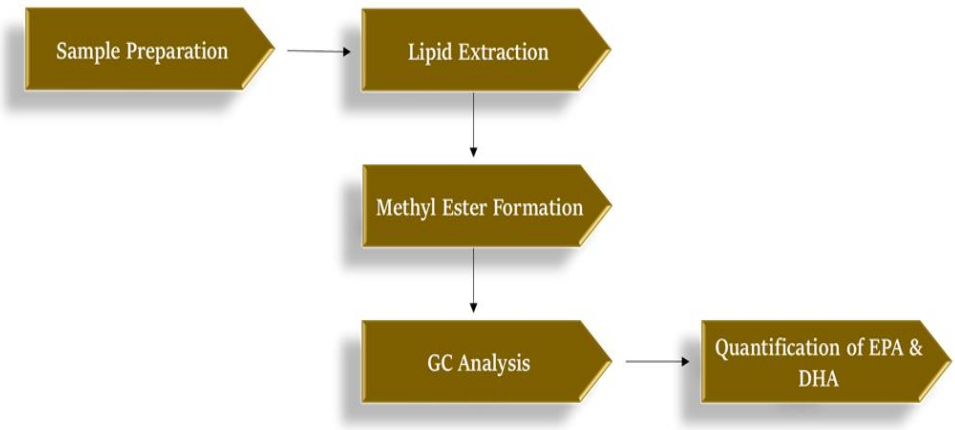

Fig. (7)- Omega -3 Analysis.

3.3 Probiotic Analysis

Probiotic efficacy depends on viable cell count at end of shelf life.

Methods

- Plate count (CFU/g)
- Flow cytometry
- qPCR for strain identification.[29–32]

Common issue: Decline in CFU below declared levels before expiry.[33–36]

3.4 Calcium Quantification

Methods:

- EDTA complexometric titration
- Atomic Absorption Spectroscopy (AAS)
- ICP-MS[37–39]

Variability in bioavailability and elemental content has been reported.[40]

4. Label Claim Verification Studies

Disparities between declared and real vitamin and probiotic content have been found in numerous national and international surveys.[41–45] Studies conducted in India have shown that different brands and dose forms have different compliance rates.[46–48] Mislabeling of probiotics, including misidentification of strains, has been documented worldwide.[49,50]

Table 2: Comparison: Analytical vs Regulatory Challenges.

Analytical Challenge	Regulatory Gap
Vitamin instability	Lack of mandatory stability reporting
Probiotic viability decline	No strict end-of-shelf-life CFU enforcement
Omega-3 oxidation	Limited oxidative parameter labeling
Mineral bioavailability variation	No bioavailability disclosure requirement

5. Advantages and Limitations

Advantages

- Growing regulatory oversight in India.[6]
- Improved analytical instrumentation availability.[18]
- Increasing consumer awareness.[3]

Limitations

- Limited post-marketing surveillance.[8]
- Inconsistent laboratory standardization.[9]
- Stability degradation during storage.[22]
- Viability loss in probiotics.[33]

CONCLUSION

Stronger synergy between analytical validation and regulatory enforcement is required due to India's growing nutraceutical industry. Although standardized nutrient limits and labeling standards are provided by FSSAI laws, post-market quality monitoring needs to be strengthened even more.

The accuracy of content verification is improved by sophisticated analytical techniques like HPLC, GC, ICP-MS, and molecular probiotic identification tools. Nonetheless, there is still variation in compliance.

Consumer safety and industry transparency might be greatly enhanced by harmonization with international standards, enhanced laboratory accreditation, and required stability studies.

Conflict of interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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