

# A brief review on Nutraceuticals

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## I. NUTRACEUTICALS: A COMPREHENSIVE OVERVIEW

The term “Nutraceutical” is a combination of the words “nutrition” and “pharmaceutical.” It was coined in 1989 by Dr. Stephen DeFelice, the founder and chairman of the Foundation for Innovation in Medicine (FIM) in Cranford, New Jersey. A nutraceutical is defined as a food or part of a food that provides medical or health benefits, including the prevention and treatment of diseases. These products can range from isolated nutrients, dietary supplements, and herbal products to specially designed diets and processed foods such as cereals, soups, and beverages. Definition and Scope - Nutraceuticals include naturally occurring food components that provide therapeutic benefits beyond basic nutrition. These compounds may help prevent or treat diseases, improve physiological functions, and promote overall well-being. Essential nutrients, such as vitamins C and E, are considered nutraceuticals when they provide additional health benefits beyond their primary role in growth and maintenance. Nutraceuticals have gained prominence across various industries, including the food industry, herbal and dietary supplement market, pharmaceutical sector, and the emerging agribusiness-nutrition conglomerates.

Health Benefits of Nutraceuticals - Nutraceuticals offer a range of health benefits with minimal or no side effects, unlike synthetic drugs. These include:

- **Disease Prevention:** They help prevent chronic diseases such as cardiovascular disorders, diabetes, and cancer.
- **Nutritional Enhancement:** They supplement essential vitamins, minerals, and antioxidants, supporting overall well-being.
- **Detoxification:** Many nutraceuticals assist in removing toxins from the body, promoting cellular health.

- **Gut Health:** Certain compounds act as prebiotics and probiotics, encouraging the growth of beneficial bacteria in the intestine.
- **Improved Digestion:** They enhance the body’s ability to absorb nutrients and regulate enzymatic reactions.

Mechanism of Action - Nutraceuticals work through various biochemical pathways in the body, contributing to overall health in different ways:

1. **Acting as Substrates for Biochemical Reactions** – Providing essential compounds required for vital metabolic processes.
2. **Serving as Cofactors for Enzymatic Reactions** – Enhancing enzymatic functions that regulate digestion, metabolism, and immune response.
3. **Inhibiting Harmful Enzymatic Reactions** – Blocking enzymes that contribute to disease progression.
4. **Absorbing and Eliminating Toxins** – Acting as binders to remove harmful substances from the intestine.
5. **Enhancing Nutrient Absorption** – Increasing the bioavailability and stability of essential nutrients.
6. **Promoting Beneficial Gut Bacteria Growth** – Acting as a selective growth factor for probiotics while inhibiting harmful bacteria.
7. **Neutralizing Harmful Chemicals** – Functioning as antioxidants that scavenge free radicals and reduce oxidative stress.
8. **Modulating Cellular Activity** – Acting as ligands that interact with cell receptors to regulate immune function and inflammatory responses.

Properties of Nutraceuticals - Nutraceuticals exhibit a wide range of biological properties that contribute to their health benefits:

1. **Nutritional Properties:** They are rich in proteins, vitamins, and minerals. Many herbal spices, such as parsley and coriander, contain vitamins A, C,

and K, as well as essential minerals like calcium, iron, and phosphorus.

2. **Antioxidant Properties:** Antioxidants in nutraceuticals protect lipids and cellular components from oxidative damage. While synthetic antioxidants like BHA, BHT, PG, and TBHQ are commonly used in processed foods, natural antioxidants from herbs and spices are gaining popularity due to concerns over synthetic compounds' carcinogenic potential.
3. **Antimicrobial and Medicinal Properties:** Many nutraceuticals have antimicrobial effects, helping combat infections and support immune function.

**Dietary Supplements and Nutraceutical Therapy -** According to the Dietary Supplement Health and Education Act (DSHEA) of 1994, dietary supplements are products that supplement the diet and contain one or more dietary ingredients, such as vitamins, minerals, amino acids, botanicals, or other bioactive compounds. They can be consumed in various forms, including pills, capsules, tablets, and liquids. Unlike conventional food, dietary supplements are not meant to replace meals but rather to enhance nutritional intake.

Nutritional therapy is a holistic approach that utilizes nutraceuticals to support health by detoxifying the body, preventing vitamin and mineral deficiencies, and restoring gut health. Phytonutrients, or plant-based nutrients, play a crucial role in this therapy due to their ability to interact with various biological processes.

#### Economic and Pharmaceutical Significance

The growing demand for nutraceuticals has driven significant investment in research and development by the pharmaceutical and biotechnology industries. Consumers are increasingly turning to natural health solutions to avoid the potential side effects of synthetic drugs. This shift has led to the expansion of medical foods designed to manage conditions such as homocysteine Mia, pancreatic insufficiency, inflammatory diseases, and cancer cachexia. <sup>(1)</sup>

## II. HERBS AND THEIR USES

- **Alfaalfa**  
Alfaalfa is considered a rich source of vitamins, minerals, and antioxidants. It's traditionally used to support digestive health and boost energy levels.
- **Chicory**

Chicory root is used as a natural remedy for digestive issues, such as constipation and bloating. It's also rich in antioxidants and has anti-inflammatory properties.

- **Ginger**  
Ginger has been used for centuries in traditional medicine to aid digestion, reduce nausea, and alleviate pain. It's also known for its anti-inflammatory properties.
- **Fenugreek**  
Fenugreek seeds are traditionally used to support blood sugar control, digestion, and lactation in nursing mothers. They're also rich in antioxidants and have anti-inflammatory properties.
- **Garlic**  
Garlic is used in traditional medicine to support heart health, reduce blood pressure, and alleviate respiratory issues. It's also known for its antimicrobial properties.
- **Honey**  
Honey is traditionally used to soothe coughs, support wound healing, and aid digestion. It's also rich in antioxidants and has antimicrobial properties.
- **Amla**  
Amla, also known as Indian gooseberry, is traditionally used to support immune function, digestion, and skin health. It's rich in vitamin C and antioxidants.
- **Ginseng**  
Ginseng is used in traditional medicine to support energy levels, cognitive function, and immune function. It's also known for its anti-inflammatory properties.
- **Ashwagandha**  
Ashwagandha is traditionally used to support stress relief, anxiety, and sleep quality. It's also known for its anti-inflammatory and antioxidant properties.
- **Spirulina**  
Spirulina is a rich source of protein, vitamins, and minerals. It's traditionally used to support eye health, immune function, and energy levels. <sup>(2)</sup>

## III. CURRENT SCENARIO OF NUTRACEUTICALS

3.1 **Global Market and Growth Trends -** The global nutraceutical market has grown significantly over the

past decades due to rising consumer awareness about preventive healthcare. The increasing prevalence of lifestyle diseases such as diabetes, cardiovascular disorders, and obesity has driven demand for dietary supplements, functional foods, and beverages.

Market Size and Growth - According to a report by Market Research Future (2021) and Grand View Research (2022):

- The global nutraceutical market was valued at \$140.1 billion in 2010 and has been growing at a CAGR of 7.5%.
- By 2023, the global market is expected to reach \$722.5 billion.

Key Players in the Industry - Some of the largest multinational companies involved in nutraceuticals include:

- Pharmaceutical Companies: Novartis, Pfizer, Abbott, Cadila Healthcare
- FMCG Companies: Nestlé, Unilever, Danone, PepsiCo
- Specialized Nutraceutical Companies: Herbalife, Amway, GNC

Challenges and Regulatory Hurdles

- Europe has strict regulations under the European Food Safety Authority (EFSA), limiting product innovation.
- China is expected to become the second-largest market by 2025, due to increased awareness among the middle-class population (Euromonitor International, 2020).
- India and Southeast Asia are emerging as strong markets due to growing health consciousness.

3.2 United States Nutraceutical Market - The U.S. is the largest nutraceutical market globally, accounting for 36% of the total market. The industry is primarily governed by:

- The Dietary Supplement Health and Education Act (DSHEA), 1994
- U.S. Food and Drug Administration (FDA) Regulations

Market Trends

- The dietary supplement market in the U.S. was valued at \$32 billion in 2012 and was projected

to reach \$50 billion by 2025 (National Institutes of Health (NIH), 2015).

- About 150 million Americans use dietary supplements annually (Bailey et al., 2011, Journal of Nutrition).
- Multivitamins, protein supplements, and probiotics are the top-selling categories.

Challenges in the U.S. Market

- Lack of stringent quality control: Since dietary supplements are not considered “drugs,” they do not undergo rigorous FDA approval.
- Misinformation and false health claims made by supplement brands.

3.3 Indian Nutraceutical Market and Scope - The Indian nutraceutical market is one of the fastest-growing, with a CAGR of 18.46%. According to FICCI (2019) and IBEF (2022):

- The Indian market was valued at \$2 billion in 2012 and was projected to reach \$18 billion by 2025.
- Functional foods and beverages dominate 60% of the market, followed by dietary supplements (40%).

Market Segments in India

- Functional Foods and Beverages (60%) - Includes fortified foods, sports drinks, energy drinks, probiotics, and functional dairy products. Major players include Nestlé, Amul, and PepsiCo.
- Dietary Supplements (40%)
  - Vitamins, minerals, protein supplements, and traditional herbal products (Chyawanprash, Ashwagandha, etc.)
  - Pharma-led growth: Companies like Dabur, Himalaya, and Patanjali are focusing on herbal nutraceuticals.

Regulatory Challenges in India

- Lack of clarity on permitted additives and structure-function claims.
- FSSAI (Food Safety and Standards Authority of India) does not have well-defined regulations for nutraceuticals.

- Many nutraceuticals are classified as drugs under the Drugs and Cosmetics Act, 1940, leading to legal complexities.

### 3.4 Global Market Value of Nutraceutical Sector and Current Status

#### Market Distribution by Region (2010 Data)

Region	Market Value (US\$ Billion)	Market Share (%)
United States	\$50.4 billion	36%
Europe	\$35 billion	25%
Japan	\$27.7 billion	18%
China	\$15 billion	10%
India	\$2 billion	1.5%

#### Current Status (2023-2025 Forecasts)

- China is expected to surpass Japan as the second-largest market.
- India will grow at a CAGR of 18-20% and could be a top-5 global player by 2030.<sup>(3)</sup>

## IV. THE ROLE OF NUTRACEUTICALS IN DAILY LIFE AND GLOBAL USAGE TRENDS

Nutraceuticals have become an integral part of modern lifestyles, providing health benefits beyond basic nutrition. The global population increasingly relies on dietary supplements, functional foods, and herbal products to manage health conditions, prevent diseases, and enhance well-being. This article reviews the daily usage of nutraceuticals, their health benefits, global market trends, and regulatory challenges. Key insights from recent studies and industry reports highlight the growing demand for nutraceuticals in different regions.

### 4.1 Daily Usage of Nutraceuticals: A Global Perspective

Nutraceuticals, a combination of “nutrition” and “pharmaceuticals,” refer to food-derived products that offer health benefits beyond basic nutrition. They include functional foods, dietary supplements, herbal products, and medically beneficial beverages. Increasing global awareness of health and wellness, rising disposable incomes, and the growing prevalence of chronic diseases have led to a surge in the consumption of nutraceuticals.

### Nutraceutical Consumption Patterns by Region

- United States & Canada:
  - 70% of adults consume dietary supplements regularly.
  - Multivitamins, omega-3 fatty acids, and probiotics are among the most popular choices.
  - *(Source: National Institutes of Health, 2020)*
- Europe:
  - Functional foods like fortified dairy products and probiotic yogurt are widely consumed.
  - Stringent regulations by the European Food Safety Authority (EFSA) have slowed product innovation.
- Asia-Pacific (India, China, Japan):
  - Traditional herbal supplements like Ashwagandha, Ginseng, and Green Tea extracts are widely used.
  - The elderly population in Japan is a key consumer of functional foods and anti-aging supplements.
- Latin America & Africa:
  - Growing urbanization and western dietary influence have increased supplement usage.
  - Protein powders and vitamin supplements are gaining popularity.

### 4.2 Types of Nutraceuticals in Daily Life

#### I. Dietary Supplements

- Vitamins & Minerals: Essential for immune support, bone health, and metabolism (Vitamin C, D, Zinc).
- Botanicals & Herbal Extracts: Ashwagandha, Ginseng, Turmeric for stress relief and anti-inflammatory effects.

#### II. Functional Foods

- Fortified Cereals & Dairy: Enriched with calcium, Vitamin D, and probiotics (yogurt, milk).
- Omega-3 Rich Foods: Fish oils, flaxseeds, and nuts for cardiovascular health.

#### III. Sports Nutrition & Weight Management

- Protein Powders: Whey, casein, and plant-based proteins for muscle recovery.
- Energy & Electrolyte Drinks: For hydration and endurance.

### 4.3 Global Market Value and Trends

The global nutraceutical market was valued at \$140.1 billion in 2010 and is expected to surpass \$700 billion by 2025.

Market Share by Region (2023 Forecast)

Region	Market Value (US\$ Billion)	Market Share (%)
United States	\$110 billion	36%
Europe	\$85 billion	25%
Asia-Pacific	\$95 billion	27%
Latin America	\$30 billion	6%
Middle East & Africa	\$20 billion	4%

#### 4.4 Regulatory Challenges and Future Prospects

##### I. Regulations in Different Countries

- United States: FDA regulates dietary supplements under the Dietary Supplement Health and Education Act (DSHEA, 1994).
- Europe: EFSA enforces strict health claim approvals under EU Regulation 1924/2006.
- India: FSSAI is working to streamline approval processes for nutraceuticals under the Food Safety and Standards Act, 2006.

##### II. Future Growth Drivers

- Personalized nutrition and DNA-based supplement recommendations.
- Technological innovations in bioavailability and nano-nutraceuticals.

#### 4.5 Conclusion

The rising popularity of nutraceuticals reflects a shift toward preventive healthcare and self-care. As scientific research continues to validate their benefits, and regulatory frameworks evolve to ensure safety and efficacy, nutraceuticals are expected to become even more integrated into daily life across the globe. While challenges such as inconsistent regulations and misleading claims persist, the industry is poised for significant growth driven by technological advancements and increasing consumer awareness<sup>(4)</sup>

### V. MARKETED PRODUCTS

Nutraceuticals—derived from “nutrition” and “pharmaceuticals”—refer to products that offer both nutritional value and medicinal benefits, these products are formulated to promote health, support the prevention of chronic diseases, and improve overall well-being. Unlike conventional pharmaceuticals, nutraceuticals are typically sourced from food or

natural extracts and are used as dietary supplements, functional foods, or fortified products.

#### Key Characteristics:

- Bioactive Components: Nutraceutical products contain bioactive compounds such as vitamins, minerals, antioxidants, and herbal extracts. These components may help modulate physiological functions and contribute to health improvement.
- Safety and Natural Origin: With a focus on natural ingredients, nutraceuticals are generally considered safe when used appropriately. They often form part of a daily diet rather than acting as isolated medications.
- Preventive Healthcare: Kalia (2016, p. 132) emphasizes the role of nutraceuticals in preventive health care, noting that they offer a promising approach for managing conditions like cardiovascular disease, metabolic syndrome, and digestive disorders without the side effects sometimes associated with synthetic drugs.

In this introductory section, the reference lays the groundwork by discussing the scientific rationale behind nutraceuticals and outlining the regulatory and market challenges associated with their commercialization.

#### 5.1 Categories & Marketed Products

Building on the foundational definitions, Kalia (2016, p. 136–145) categorizes marketed nutraceutical products into three main groups:

1. Dietary Supplements: These include vitamins, minerals, and herbal extracts used to bridge nutritional gaps or target specific health needs.
  - Omega-3 Fatty Acids: Found in fish oil supplements, these compounds (EPA and DHA) are highly valued for supporting cardiovascular and brain health. Marketed under several brand names, they are among the most widely consumed dietary supplements.
  - Multivitamins: Widely available from brands like Centrum and One A Day, multivitamin supplements aim to ensure that the body receives a balanced intake of essential nutrients.
  - Probiotics: Products like Yakult and Align contain live microorganisms that help balance the gut microbiota, a key factor in digestive and immune health.

2. Functional Foods: Functional foods are everyday food items that have been enhanced to offer additional health benefits beyond their nutritional value.

- Fortified Cereals: For example, Kellogg's Special K is enriched with vitamins, minerals, and fibres that contribute to weight management and metabolic health.
- Probiotic Dairy Products: Yogurts such as Danone's Activia incorporate beneficial bacteria that improve gut health and support the immune system.
- Antioxidant-Rich Beverages: Green tea products, particularly those enriched with polyphenols and catechins (e.g., Lipton Green Tea), are marketed for their antioxidant properties and potential role in weight loss.

Reference: In his discussion, the author outlines how functional foods are positioned in the market as both everyday nutritional items and as products with targeted health benefits.

3. Herbal and Botanical Nutraceuticals: These products rely on traditional knowledge and modern extraction techniques to provide health benefits.

- Curcumin Supplements (Turmeric Extracts): With potent anti-inflammatory properties, these supplements (sold under brands such as Qunol and Nature Made) are frequently used to manage joint pain and inflammation.
- Ginseng-Based Products: Known for their energizing and immune-supporting qualities, ginseng extracts are marketed in various forms, including capsules and teas.
- Garlic Extracts: Used for cardiovascular support, garlic supplements have gained popularity in both tablet and liquid forms.

## 5.2 Market Trends, Challenges & Future Outlook

Market Trends: The nutraceutical market has witnessed exponential growth over recent years, driven by an increased focus on preventive healthcare and a rising consumer demand for natural products. According to, several trends have emerged:

- Consumer Awareness: Growing public interest in health and wellness has led to a surge in the use of nutraceuticals as part of daily diets.
- Innovation in Product Development: Manufacturers are continuously exploring new

sources and methods for extracting bioactive compounds, which leads to the development of novel products such as nano-emulsified supplements and time-release formulations.

- Global Expansion: While North America and Europe have traditionally dominated the market, Asia-Pacific is rapidly emerging as a key player due to both increased consumer spending on health products and supportive government policies.

Regulatory and Quality Challenges: Despite the growth, the nutraceutical industry faces several challenges:

- Regulatory Oversight: The classification of nutraceuticals as either food or medicine varies by country, creating a complex regulatory landscape. Kalia (2016, p. 155) notes that this often leads to inconsistent quality standards and marketing claims.
- Scientific Validation: While many nutraceutical products are backed by preliminary studies, there remains a need for more rigorous, large-scale clinical trials to validate their efficacy and safety fully.
- Consumer Trust: Maintaining high-quality production standards and clear labeling is crucial for sustaining consumer trust in an industry that bridges food and pharmaceutical sectors.

Future Outlook: concludes that as research continues to validate the health benefits of various nutraceutical compounds, the industry is likely to experience even greater growth. Future trends include personalized nutrition, where products are tailored to individual genetic and metabolic profiles, and further integration of nutraceuticals into mainstream healthcare practices. <sup>(5)</sup>

## VI.. NUTRACEUTICAL MARKET TURN OVER

6.1 Market Valuation and Growth:

- In 2016, the global nutraceutical market was valued at approximately USD 383 billion (EUR 311 billion).
- It was projected to reach around USD 561 billion by 2022 (EUR 456 billion).

#### 6.2 Factors Driving Market Expansion:

- **Aging Population:** An increasing number of elderly individuals seeking health-enhancing products.
- **Consumer Awareness:** Growing knowledge about the health benefits of nutraceuticals.
- **Lifestyle Changes:** Shifts towards healthier living and preventive healthcare.
- **Rising Healthcare Costs:** Consumers turning to nutraceuticals as cost-effective health solutions.
- **Marketing Channels:** Enhanced promotional strategies increasing product visibility.

#### 6.3 Regulatory and Safety Considerations:

- The absence of a universal definition and consistent regulatory framework for nutraceuticals across countries poses challenges.
- There is a noted lack of comprehensive evidence regarding the efficacy and safety of some nutraceutical products.

#### 6.4 Future Outlook:

- Prospective epidemiological studies are essential to better understand the health impacts of nutraceuticals.
- Establishing a consistent regulatory framework could facilitate further growth and segmentation within the industry.

These insights underscore the dynamic nature of the nutraceutical market and the importance of addressing regulatory and research challenges to sustain its growth trajectory. <sup>(6)</sup>

### VII. DURING THE COVID-19, THE USE OF NUTRACEUTICALS

During the COVID-19 pandemic, the use of nutraceuticals—products derived from food sources with health benefits—gained significant attention as potential adjuncts in preventing and managing SARS-CoV-2 infections. Various dietary supplements were explored for their roles in supporting immune function and mitigating disease severity. Below is an overview of key nutraceuticals investigated during this period:

#### 1. Vitamin D

- **Immune Modulation:** Vitamin D is known for its immunomodulatory and anti-inflammatory properties. It supports the immune system by inducing the production of antimicrobial peptides

like cathelicidin and defensins, which can reduce viral replication. Additionally, vitamin D may decrease the risk of cytokine storm syndrome, a severe immune reaction observed in some COVID-19 cases.

- **Clinical Observations:** Observational studies indicated an association between vitamin D deficiency and increased COVID-19 incidence and severity. However, clinical trials are ongoing to determine the efficacy of vitamin D supplementation in COVID-19 prevention and treatment.

#### 2. Vitamin C

- **Antioxidant Effects:** Vitamin C possesses antioxidant, anti-inflammatory, and antiviral properties. It can counteract pro-inflammatory cytokines, potentially reducing the severity of inflammatory responses in COVID-19 patients.
- **Therapeutic Use:** Some studies suggested that high-dose vitamin C supplementation might shorten the duration of hospital stays and improve pulmonary function in COVID-19 patients. However, results have been mixed, and further research is needed to confirm these findings.

#### 3. Zinc

- **Antiviral Properties:** Zinc plays a crucial role in immune function and exhibits antiviral properties. It has been shown to inhibit the replication of various viruses, including coronaviruses, and may suppress the entry of SARS-CoV-2 into host cells.
- **Supplementation Outcomes:** While zinc supplementation is generally considered safe and may support immune health, definitive evidence regarding its effectiveness specifically against COVID-19 remains limited. Clinical trials are underway to explore its potential benefits further.

#### 4. Omega-3 Fatty Acids (n-3 PUFA)

- **Anti-Inflammatory Effects:** Omega-3 fatty acids, such as EPA and DHA, are precursors to specialized pro-resolving mediators that help resolve inflammation. This property is particularly relevant in managing the hyperinflammatory responses seen in severe COVID-19 cases.
- **Potential Benefits:** Some studies have suggested that omega-3 supplementation could improve

respiratory and renal function parameters in critically ill COVID-19 patients. However, more robust clinical data are needed to substantiate these claims.

5. Probiotics

- **Gut-Immune Interaction:** Probiotics can modulate gut microbiota, which plays a significant role in immune function. They may enhance the host’s antiviral defenses and reduce the severity of gastrointestinal symptoms associated with COVID-19.
- **Clinical Insights:** While probiotics have shown promise in enhancing immune responses and potentially reducing the duration of respiratory infections, specific evidence regarding their efficacy against COVID-19 is still emerging.

6. Multivitamins

- **General Immune Support:** Multivitamins containing a combination of essential vitamins and minerals can support overall immune function. Antioxidant properties of certain vitamins may help reduce the risk of respiratory infections.
- **Usage Trends:** During the pandemic, there was a significant increase in the consumption of multivitamins as individuals sought to bolster their immune systems. However, clear evidence supporting their effectiveness specifically against COVID-19 is lacking.

The COVID-19 pandemic spurred considerable interest in the potential role of nutraceuticals as supportive measures in infection prevention and management. While some dietary supplements have demonstrated immunomodulatory and antiviral properties, the evidence regarding their efficacy specifically against COVID-19 varies, and further rigorous clinical trials are necessary to establish definitive benefits. Individuals considering nutraceutical supplementation should consult healthcare professionals to ensure safety and appropriateness based on their health status. <sup>(7)</sup>

IX.. THE FUTURE PROSPECTS OF NUTRACEUTICAL INDUSTRY

The world is becoming more sophisticated and interesting. Foods are becoming more attractive, appealing and fortified to meet the increasing demand of healthy nutrition. With the invention and recent advances in Living Modified Organisms (LMOs) and Genetically Modified Foods (GMFs), food for all agenda in the future will be attained or rather malnutrition would soon be history but new challenges may ensue. With the popping-in of tablets as nutrients to provide the body with complete Recommended Dietary Allowance (RDA) including fiber to ensure intestinal or bowel emptying, the prospects of nutraceuticals are limitless. The target of food and nutrition societies for a world rid of hunger in the future is possible with the potentials of nutraceuticals. At the core of the value-added market performance is the increasing responsiveness on the part of consumers as to how nutraceuticals <sup>(8)</sup>

VIII.CONCLUSION

Product	Group	Content	Company
Calcirol D-3®	Calcium supplement	Calcium and vitamins	Cadilla healthcare limited, India
Coral calcium	Calcium supplement	Calcium and trace minerals	Nature's answer, Hauppauge, NY, USA
Wellife®	Amino acid supplement	Granulated-L-glutamine	Daesang America Inc., Hackensach, NJ, USA
Proteinex®	Protein supplement	Predigested proteins, vitamins,	Pfizer Ltd., Mumbai, India
Daytime restore & nighttime repose	Restful sleep	Ginseng, Ginkgo biloba,	Xigo health
CogniSure	Amino acid supplement	Proline-rich polypeptide complex	Metagenics Inc
Omega woman	Immune supplement	Antioxidants, vitamins and phytochemicals	Wassen, Surrey, U.K

PNerplusTM	Neuropathic pain supplement	Vitamin and other natural supplement	NeuroHelp, San Antonio, Texas, USA
GRD	Nutritional supplement	Proteins, vitamins, minerals and carbohydrates	ZydusCadila Ltd. Ahmedabad, India
BiovincaTM	Neurotonic	Vinpocetine	Cyvex nutrition, Irvine,CA, USA

X.. IMMUNOMODULATORS: TYPES, MECHANISM, AND APPLICATIONS

Immunomodulators are agents that help regulate or modify the immune system. They play a crucial role in maintaining immune homeostasis by either stimulating or suppressing the immune response, depending on the body’s needs. These agents are widely used in autoimmune diseases, cancer therapy, organ transplantation, and infectious diseases.

The information provided in this section is based on the book “Immunopharmacology and Immunotoxicology” by Robert L. Eskay and Barbara M. O’Brien.

9.1 Definition of Immunomodulators

An immunomodulator is a substance that either enhances or suppresses the immune response to achieve a therapeutic effect. Unlike other immune agents, immunomodulators normalize immune function—they do not excessively increase or decrease the immune response but help maintain balance.

9.2 Types of Immunotherapies

**Activation Immunotherapy** - Activation immunotherapy aims to enhance or amplify the immune response. It is used in diseases where the immune system needs to be boosted, such as cancer, infections, and immunodeficiency disorders.

Examples:

- Checkpoint Inhibitors (e.g., Pembrolizumab, Nivolumab)
- Cytokine Therapy (e.g., Interferons, Interleukins)
- Cancer Vaccines (e.g., BCG vaccine for bladder cancer)

**Suppression Immunotherapy** - Suppression immunotherapy is designed to reduce or suppress the immune response. This type of therapy is crucial for treating autoimmune disorders, organ transplant rejection, and hypersensitivity reactions.

Examples:

- Corticosteroids (e.g., Prednisone, Dexamethasone)
- Calcineurin Inhibitors (e.g., Cyclosporine, Tacrolimus)
- Biologic Agents (e.g., TNF inhibitors like Infliximab)

9.3 Classification of Immunomodulators

**ImmunoAdjuvants** - ImmunoAdjuvants enhance the efficacy of vaccines and help induce a stronger immune response. They are considered specific immune stimulants because they are used alongside vaccines.

Examples:

- Alum (Aluminum Hydroxide and Phosphate)
- Monophosphoryl Lipid A (MPL)
- Squalene-based Adjuvants (AS03, MF59)

**Immunostimulants** - Immunostimulants (also known as immunostimulators) enhance the immune response by activating specific immune components. They are used in cases where the immune system needs boosting, such as in chronic infections, cancer therapy, and immunodeficiencies.

Examples:

- Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF)
- Interleukins (IL-2, IL-7)
- Beta-Glucans (Natural polysaccharides that enhance macrophage activity)

**Immunosuppressants** - Immunosuppressants are drugs that reduce the activity of the immune system. They are primarily used in:

- Organ Transplantation (to prevent rejection)
- Autoimmune Diseases (to reduce excessive immune response)
- Severe Allergic Reactions

Examples:

- Corticosteroids (Prednisone, Methylprednisolone)
- Calcineurin Inhibitors (Cyclosporine, Tacrolimus)
- Monoclonal Antibodies (Rituximab, Basiliximab)

9.4 Mode of Action of Immunomodulators - The exact mechanism of action of many immunomodulators remains a mystery, but they are believed to work in several ways:

- Regulating Cytokine Production (increasing or decreasing cytokines like IL-2, TNF- $\alpha$ )
- Modulating T-cell Activation (either stimulating or suppressing T-cell responses)
- Enhancing or Reducing Antigen Presentation (affecting how immune cells recognize pathogens)

9.5 Clinical Applications of Immunomodulators

Condition	Immunomodulator Used
Cancer (e.g., melanoma, lung cancer)	Checkpoint inhibitors (Pembrolizumab, Nivolumab)
Autoimmune diseases (e.g., rheumatoid arthritis, lupus)	TNF inhibitors (Infliximab, Etanercept)
Organ transplantation	Calcineurin inhibitors (Cyclosporine, Tacrolimus)
Chronic infections (e.g., HIV, hepatitis)	Interferons, Interleukins (IL-2, IL-7)

(9)

10. Phytochemical analysis is integral to the nutraceutical industry, ensuring the identification, quantification, and validation of bioactive compounds derived from plants. Techniques such as Ultraviolet (UV) Spectroscopy, Infrared (IR) Spectroscopy, High-Performance Liquid Chromatography (HPLC), and High-Performance Thin-Layer Chromatography (HPTLC) are pivotal in this analytical process.

1. Ultraviolet (UV) Spectroscopy - UV Spectroscopy is employed to detect conjugated systems in phytochemicals by measuring the absorption of UV light. This technique is particularly useful for identifying compounds like flavonoids and polyphenols. In Harborne’s book, the principles and applications of UV Spectroscopy in plant analysis are discussed extensively.

2. Infrared (IR) Spectroscopy - IR Spectroscopy is utilized to identify functional groups within phytochemicals by measuring molecular vibrations. This method provides insights into the structural components of bioactive compounds. Harborne elaborates on the use of IR Spectroscopy for plant analysis, detailing the interpretation of IR spectra.

3. High-Performance Liquid Chromatography (HPLC) - HPLC is a powerful technique for separating,

identifying, and quantifying individual components within complex plant extracts. It is widely used due to its high resolution and sensitivity. Harborne provides a comprehensive overview of HPLC methodologies, including the selection of mobile phases, detectors, and column types suitable for various phytochemicals.

4. High-Performance Thin-Layer Chromatography (HPTLC) - HPTLC offers a rapid and efficient means of analyzing multiple samples simultaneously. It is particularly advantageous for fingerprint analysis of plant extracts. Harborne discusses the preparation of samples, selection of suitable stationary phases, and detection techniques pertinent to HPTLC. <sup>(10)</sup>

XI. REGULATED GUIDELINES OF BRITISH PHARMACOPOEIA, EUROPEAN PHARMACOPOEIA, AND UNITED STATES PHARMACOPOEIA FOR NUTRACEUTICALS

Introduction - Nutraceuticals, a combination of “nutrition” and “pharmaceutical,” are food-derived products that provide health benefits beyond basic nutrition. These include vitamins, minerals, herbal extracts, probiotics, amino acids, and functional foods. Due to their increasing popularity, regulatory bodies and pharmacopoeias establish stringent guidelines to ensure their safety, efficacy, and quality. Among the most authoritative references are the British Pharmacopoeia (BP), European Pharmacopoeia (Ph. Eur.), and United States Pharmacopoeia (USP), which provide standardized methods for the evaluation and manufacturing of nutraceuticals.

These pharmacopoeias set standards for:

- Quality control (purity, potency, composition)
- Manufacturing standards (Good Manufacturing Practices - GMP)
- Analytical testing (identification, stability, contaminants)
- Labeling and claims (nutrient content, health benefits, dosage)

Each pharmacopoeia follows specific national and international regulatory frameworks to ensure compliance with health and safety requirements.

1. British Pharmacopoeia (BP) and Nutraceutical Guidelines - The British Pharmacopoeia (BP) is the official standard-setting body for medicinal substances and formulations in the United Kingdom. It is published annually by the

Medicines and Healthcare products Regulatory Agency (MHRA).

Role of BP in Nutraceuticals - BP provides official monographs and general guidelines for nutraceuticals, focusing on:

1. Quality Standards: Defines purity levels, active ingredient specifications, and contaminant limits.
2. Analytical Methods: Includes High-Performance Liquid Chromatography (HPLC), Gas Chromatography (GC), and Mass Spectrometry (MS) for identification and quantification of nutraceutical components.
3. Herbal and Botanical Extracts: Specifies herbal medicinal ingredients used in functional foods and dietary supplements.
4. Contaminant Limits: Sets permissible levels of heavy metals (lead, mercury, arsenic), pesticides, aflatoxins, and microbial contamination in nutraceutical products.
5. Labeling and Dosage Requirements: Provides standards for accurate labeling of active ingredients and recommended dosages.

Example of BP Monographs Related to Nutraceuticals

- Vitamin D – Specifies purity levels, analytical methods, and stability testing.
- Curcumin (from turmeric extract) – Defines limits for bioactive curcuminoids and permissible impurities.
- Omega-3 Fatty Acids (Fish Oil) – Establishes criteria for oxidation levels, purity, and concentration.

2. European Pharmacopoeia (Ph. Eur.) and Nutraceutical Guidelines - The European Pharmacopoeia (Ph. Eur.), established by the European Directorate for the Quality of Medicines & Healthcare (EDQM), provides harmonized pharmaceutical and nutraceutical standards across Europe.

Role of Ph. Eur. in Nutraceuticals

1. Monographs for Dietary Supplements: Covers vitamins, minerals, herbal extracts, amino acids, and probiotics.
2. Analytical Testing: Includes Thin Layer Chromatography (TLC), Nuclear Magnetic Resonance (NMR), and Liquid Chromatography (LC-MS) for quality assessment.

3. Toxicological Guidelines: Establishes maximum allowable levels of heavy metals, microbial load, and residual solvents in dietary supplements.
4. Probiotic Standards: Specifies acceptable strains, viability, and potency requirements for probiotics like *Lactobacillus* and *Bifidobacterium*.
5. Standardized Herbal Extracts: Provides methods for identifying active compounds in herbal supplements (e.g., Ginseng, Echinacea, Ginkgo Biloba).
6. Stability Testing: Guidelines on shelf life, degradation products, and stability under various storage conditions.

Example of Ph. Eur. Monographs Related to Nutraceuticals

- Coenzyme Q10 – Specifies purity, solvent residues, and testing methods.
- Probiotic Supplements (e.g., *Lactobacillus rhamnosus*) – Defines viable cell count and strain-specific standards.
- Green Tea Extracts – Establishes minimum catechin content and permissible contaminants.

3. United States Pharmacopoeia (USP) and Nutraceutical Guidelines - The United States Pharmacopoeia (USP), published by the United States Pharmacopoeial Convention (USPC), establishes scientific standards for pharmaceuticals, dietary supplements, and food ingredients in the United States.

Role of USP in Nutraceuticals

1. Dietary Supplement Monographs: USP contains monographs for vitamins, minerals, amino acids, botanical extracts, and dietary lipids.
2. USP-NF (National Formulary): Sets legally recognized quality standards for nutraceuticals.
3. USP Dietary Supplement Compendium (DSC): A dedicated resource for the quality, identity, purity, and strength of dietary supplements.
4. Analytical Testing: Standard methods for HPLC, Fourier Transform Infrared Spectroscopy (FTIR), and Titration.
5. Contaminant Control: Specifies limits for toxic elements, microbial contamination, and solvent residues.
6. Bioavailability and Dissolution Standards: Guidelines for absorption, solubility, and release profiles of nutraceuticals.

7. Labeling and Claims: Compliance with FDA's Dietary Supplement Health and Education Act (DSHEA, 1994) for truthful health claims. <sup>(9)</sup>

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