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Nutraceuticals: Recent Advances, Therapeutic Potential, and Future Directions – A Comprehensive Review

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For health management, nutraceuticals are chosen based on the risk of toxicity and adverse effects of pharmaceuticals.Nutraceuticals avoid side effects and are natural dietary supplements. As a result, nutraceuticals hold certain advantages over conventional medicines. These products are broadly classified into three categories—nutrients, herbal formulations, and dietary supplements—based on their natural origin and chemical composition. To ensure the safety of dietary supplements as food items, they are regulated by the FDA. In India, the government introduced the Food Safety and Standards Act in 2006 to oversee the regulation of the nutraceutical industry. Herbal nutraceuticals serve as effective tools for promoting optimal health, enhancing longevity, and improving overall quality of life.They play a crucial role in combating both acute and chronic diseases that arise from nutritional deficiencies. This review highlights various recent developments and emerging perspectives on nutraceuticals, particularly focusing on their potential to influence disease progression based on specific medical indications.

Keywords: Dietary Supplements; FOSHU; FSSAI; Nutraceutical Supplements; Regulatory Authorities

Foods or parts of foods called nutraceuticals provide health or medical benefits, including prevention or treatment of disease. In 1989 the term nutraceutical was coined by Dr. Stephan De Felice. The blend of nutraceutical characteristics and pharmaceutical resulted in the name nutraceuticals.[1] A nutraceutical is a substance that is not traditionally recognized as a nutrient but has beneficial physiological effects on the human body. Food and drug laws are not easily applied to nutraceuticals.

Numerous diseases linked to oxidative stress—such as allergies, Alzheimer's, cardiovascular conditions, cancer, diabetes, eye disorders, immune dysfunction, inflammation, Parkinson's disease, and obesity—are often associated with nutraceutical deficiencies.[2]These beneficial products can vary widely, including essential nutrients, dietary supplements, genetically modified designer foods, and herbal preparations. In Canada, the health minister has broadened the definition of nutraceuticals to include food-derived substances—typically sold in medicinal form—that have been shown to offer physiological benefits.[3] Research also supports the role of nutraceuticals in managing chronic illnesses.Nutraceuticals are sometimes referred to as functional foods, emphasizing their ability to help prevent and/or treat various diseases and disorders beyond just anemia.

A dietary supplement, on the other hand, is intended to supply nutrients that may be lacking or insufficient in a person's regular diet. Common types of dietary supplements include vitamins, minerals, herbal remedies, amino acids, proteins, and essential fatty acids.[4,5]

Some commonly used Nutraceuticals in market

• Lutein and Zeaxanthin: These are carotenoids responsible for controlling vision.[6]

• Lycopene: It is widely exploited nutraceutical derived from tomatoes. It is a proven antioxidant that neutralizes free radicles which may damage body cells.[7]

• Rutin and Quercetin: These are bioflavonoids that have anti-inflammatory and anti-oxidant effect.[8]

• Chondroitin Sulphate: It is used for chondro-degenerative symptoms in osteoarthritis.[9]

• Glucosamine Sulphate: It stimulates the biosynthesis of glucosamine-glycan such as chondroitin sulphate.

• Polycosanol:This is a long-chain alcohol derived from plant waxes. It is commonly used as a dietary supplement to help reduce LDL cholesterol, boost HDL cholesterol levels, and support cardiovascular health by aiding in the prevention of atherosclerosis.[10]

• Alfacalcidol: It is a 1-hydroxycholecalciferol analog of Vitamin D, known for its longer half-life, making it a more effective option for Vitamin D supplementation. This compound also demonstrates notable effects on the immune system, particularly in relation to regulatory T cells.[11]

• Methyl Sulphonyl Methane: It is a natural source of biologically active sulfur. This is a naturally occurring organosulfur compound found in various plants and present in small quantities in numerous foods and beverages. It is often used in conjunction with glucosamine and/or chondroitin to help prevent or manage osteoarthritis.[12]

• Fructo-oligosaccharide: It is used as alternative sweetener. These are oligosaccharides fructans that serves as a substrate for microflora in the large intestine and increases overall GI health and hence used as prebiotic.[13]

• Chromium Picolinate/Chromium Polynicotinate: It is a coordination compound derived fromchromium and picolinic acid. It is used to treat nutritional deficiency of chromium. It is essential for glucose utilization by insulin in hospital patients on long term defined diets.[14]

• Calcium Microcrystalline Hydroxyapatite: It is a bone building supplement with superior absorption when compared to elemental calcium.[15]

• Carbonyl Iron: It is highly purest form of iron prepared by chemical decomposition of purified iron pentacarbonyl composed of spherical microparticles. It can be used as a substrate for ferrous sulphate.[16]

• DecosaHexanoic Acid (DHA): It is a primary structural component of human brain, cerebral cortex, skin etc. It is an omega 3 fatty acid.[17,18]

• Gamma Linolenic Acid (GLA): This is a fatty acid predominantly found in plant-based oils and is commonly used as a dietary supplement.

• Coenzyme Q10 (Ubiquinone or Ubidecarenone): It is a component of the electron transport chain that generates energy in the form of ATP. It is an oil soluble vitamin like substance. It is produced in large quantities by microbial fermentation. It can be used as an antioxidant in various formulations. It is indicated in cardiovascular diseases like congestive heart failure. It helps to correct the reduced blood levels of Co Q10 in the body that resulted from the use of HMG Co-A reductase inhibitor drugs. It is used in treatment of elevated cholesterol levels.[19]

• Chitosan: It is derived from processed exoskeletons like shrimps. It has great affinity towards fats forming a non-absorbable polymer. It is a natural aminopolysaccharide.

• L Selenomethionine: It is a selenoamino acid where selenium replaces the sulphur of methionine molecule. When it is given particularly in selenium based diet deficiency, it is readily absorbed from GI tract.[20]

• Tetrahydrocurcumin: It is derived from curcumin and is an anti-oxidant substance.

• Boswellic acid: It is indicated in apoptosis of cancer cells in particular brain tumors, leukaemia and colon cancer. By inhibiting leukotriene synthesis, Acetyl boswellic acid has indicated anti-inflammatory behavior.

• Fenufiber: It is derived from fenugreek. It has fiber rich fraction.[21]

• Forskollin (Coleand): It is a labdanediterpene. It is produced by Indian coleus plant, *Coleus forskohli*. Forskohlin activates enzyme adenylcyclase and it increases intracellular levels of c-AMP which is an important second messenger.[22]

• Probiotics as Nutraceuticals: Lactic acid bacteria and Bifidobacteria are among the most

beneficial microorganisms used in maintaining a healthy gut microbiota. These live cultures act as non-digestible food components that promote the growth of favorable bacteria in the digestive system. Probiotics also help enhance the population of beneficial bacteria, supporting overall gastrointestinal health.

Nutraceutical Health Drinks

Health drinks and functional beverages are gaining increasing popularity in today's health-conscious society. These beverages serve as effective carriers for various dietary supplements, including vitamins, coenzymes, antioxidants, and essential minerals.Some health drinks are useful to provide glyconutrients that are essential for proper cell to cell communication. They are so vital for proper functioning of every human cell and its role is critical for proper immune function. Different plants contain different glyconutrients that can overcome the deficiency of modern diet. Nutraceutical supplement provides a critical wellness initiative. Since they are non toxic in nature it can be supplemented to people of any age. Few examples of popular health drinks in the market are,

• Green tea and *Aloe vera* juice: It is useful for its glyconutrient supplement from the inner leaf juice of *Aloe vera* and also useful for its antioxidant activity from polyphenols of green tea. [23]

• Aloe vera and Noni juice: Noni fruit (*Morinda citrifolia*) consists of number of phytochemicals such as flavonoids, lignans, oligosaccharides, polysaccharides, fatty acids and scopoletin.

• Fortified Soy Milk: This serves as an excellent alternative source of calcium and vitamin D. It also provides high-quality protein and contains all essential micronutrients, making it a nutritionally balanced option.

Caloric beverages include fruit juice, vegetable juice, whole milk, sports drink and vitamin enhanced water with some nutrients. 100% of fruit juice contains most of nutrients of fruit itself. But it usually provides more energy. Fruit smoothies are not recommended as healthy beverages because of its high calories level. Vegetable juice is recommended as an alternative to fresh juice due to its low calories level but it may contain more sodium.[24]Sports beverages are given to athletes to provide carbohydrates, electrolytes and fluids during high intensity workouts. These sports drinks contain fewer calories compared to soft drinks and supply small quantities of essential electrolytes such as sodium (Na), potassium (K), and chloride (Cl).Sweetenedbeverages usually include carbonated and non-carbonated soft drink which givesmany calories to the body and virtually no other nutrients. Due to these sweetened beverages, weight gain and type II diabetes are most common issues. Sugar levels in energy drinks are almost same as in soft drinks and also have enough caffeine to raise blood pressure. Additives in these drinks with long term health effects are unknown. Hence non-calorically sweetened beverages are the best choice compared to sugar sweetened beverages. In calorie free beverages, calorie free artificial sweeteners such as aspartame, saccharine or sucralose are used. Stevia is a natural calorie free sweetener which can be used to replace artificial sweeteners.

Nutraceuticals from wastes

• To prepare chitin, chitosan usually shrimp and crab shells are used.

• Chitin is a fat binder which is used in weight management.

• Astaxanthin is a chromophore present in shrimp cells which is used as an antioxidant with efficacy 500 times compared to vitamin E.

• Grape pomace which is obtained from vineyard wastes that contain pectins, tartaric acid, citric acid and polyphenols.

Safety of nutraceuticals

• Grape fruit juice is a potent inhibitor of cytochrome p450 enzyme and CYP 3A4 enzyme. Naringin is a flavonoid present in it which is converted to naringenin. Breast cancer is a risk associated with this.

• Bergamot orange contains bergapten (bergamot oil). It shows concentration dependant phototoxic effect upon application to skin.

• Genotoxic carcinogen is present in *Foeniculum vulgare*.

• Liver toxicity is observed with green tea (*Camellia sinensis*).

Various Regulatory Authorities in Nutraceuticals

• DSHEA (Dietary Supplement Health and Education Act):

Enacted in 1994 by the United States, this legislation serves as an amendment to the Federal Food, Drug, and Cosmetic Act. It was introduced to set standards and regulations specifically for dietary

supplements.It is helpful to provide guidelines for safety of dietary supplements claims, statement of nutritional support, dietary supplement, ingredient labelling and nutritional information labeling (misbranded supplements), percentage level claims, good manufacturing practices and it also defines a new dietary ingredient.

FOSHU (Food for Specified Health Use)

Introduced in 1991 by Japan's Ministry of Health and Welfare, this regulatory framework sets guidelines for foods with specific health benefits. It includes provisions for verifying health effects, ensuring the safe and appropriate use of ingredients, preventing excessive intake, and guaranteeing compatibility with general food regulations.Further it is divided into three sections: Qualified FOSHU, Standardized FOSHU and Reduction of disease risk-FOSHU.

FNFC (Food with Nutrient Function Claims)

It is referred to all food that is labeled with nutrient function claims specified in Japan. It established Standards and Specifications for 17 ingredients (12 Vitamins and 5 minerals).

CFDA (China Food and Drug Administration)

Established in 2013 by the Chinese government, it was formed based on the previous State Food and Drug Administration (SFDA), serving as its successor to oversee food and drug safety regulations.It defines food borne illness and contaminants information about ingredients, additives and contact substances, GRAS and allergens along with general guidance. It is helpful to reduce the risk of malicious criminal or terrorist actions on the food supply. It also addresses the research areas of biotechnology.

FSSAI (Food Safety and Standards Authority of India)

It has been established in the year 2006 under the Food Safety and Standards Act. In 2011 Food Safety Standards Regulation Amendments provides regulations for licensing and registration, food additives, contaminants and toxins and residues regulation, laboratory and sampling analysis regulations. Lab Manuals are provided for process of analysis of foods.

Challenges with Nutraceuticals

Compared to pharmaceutical drugs, the phytochemicals found in nutraceuticals generally exhibit lower potency as bioactive agents. However, their long-term physiological effects can be significant due to regular consumption and intake in larger quantities as part of the daily diet. These products are typically well tolerated and considered safe for general use. Nevertheless, interpreting research findings remains challenging due to inconsistencies across studies and limitations in study design.

Nutraceuticals are associated with fewer side effects compared to conventional medications and are often used in managing specific health conditions. Despite this, they tend to be more expensive and may lack the rigorous manufacturing standards seen in the pharmaceutical industry. In some cases, they may also fail to produce the desired results.The composition and concentration of active compounds in plant-based sources can vary widely depending on environmental factors such as season, temperature, humidity, and soil conditions. Therefore, it is essential to implement standardized procedures for sourcing, verifying, preserving, and quantifying these critical variables.Innutraceutical research, the development and application of advanced analytical methods are crucial. This includes discovering new nutraceuticals, determining their chemical structures and biological activities, quantifying them in natural sources, developing dosage forms, and ensuring consistent quality control. Due to the complexity of natural matrices, sophisticated techniques such as mass spectrometry (MS), nuclear magnetic resonance (NMR), high-performance liquid chromatography (HPLC), capillary electrophoresis (CE), HPLC-MS, GC-MS, CE-MS, and quadrupole time-of-flight (QTOF) mass analyzers have proven invaluable. These allow for the analysis of complex mixtures—such as four fatty acids and nine polar lipids—without requiring extensive sample preparation or derivatization. For example, squalene in rice can be effectively analyzed using gas chromatography coupled with flame ionization detection (GC-FID) and mass spectrometry (GC-MS). Chiral chromatography enables differentiation between dietary and non-dietary isomers, while reversed-phase HPLC allows for the simultaneous quantification of water-soluble vitamins in nutraceutical formulations.[25]

One major challenge lies in analyzing multiple components from different chemical classes within a single matrix. The choice of analytical method depends heavily on the target

compounds, the nature of the matrix, and the physicochemical properties—such as polarity, molecular size, and volatility—which influence sample preparation, separation mechanisms, and detector selection.To better understand the health benefits of nutraceuticals and assess how the body absorbs and utilizes these compounds after ingestion, advanced analytical tools are essential. Bioavailability studies should be integrated into the early stages of product development. Unlike standard drugs, which require extensive testing to confirm efficacy, regulatory requirements for nutraceuticals in many countries are less stringent under current legislation. [26]

Role of R and D in Nutraceuticals

• Either by combining existing ingredients or identifying new ingredients that can be used in nutraceutical products is essential to develop new products.

• The development of more effective and efficient ways to produce nutraceutical ingredients.

• To test the safety, potency and purity of nutraceuticals.

• Testing procedures should be developed to ensure the consistency of dosages of ingredients in nutraceuticals.

Nutraceuticals comprises of large group of preventive and curative healthcare ingredients that are primarily obtained from plants, especially those with a well established use as foodstuff. In the official pharmacopoeial compendiums a number ofnutraceuticals are now included for their curative value. Also a large number of nutraceuticals had a place in European Herbal/botanical compendium as botanical remedies,

1. Guggul is used for lowering cholesterol which is included in Indian Pharmacopoeia.
2. L Selenomethionine is a source of essential selenium which is included in US Pharmacopoeia
3. Glucosamine is now included in US Pharmacopoeia for arthritic pain.

Due to the availability of natural products, good quality fruits and vegetables India is an ideal location for manufacturing products. India is considered as home for almost all kind of plants ranging from tropical, subtropical and temperate zone plants. The benefit of knowledge-based remedies gives India a tremendous development in finding newer applications. Well established Ayurvedic system of India has a chance or opportunity because of existing Indian exports are not even 5-7% of exports in value terms.[27]

Concerns in Nutraceuticals

While manufacturing a nutraceutical product, following points should be considered:

• The levels of key bioactive components—such as amino acids, lipids, polysaccharides, volatile oils, polyphenols, alkaloids, lignins, and terpenes—should be clearly identified and standardized.

• It is also essential to screen for potential contaminants, including heavy metals, mycotoxins, pesticide residues, and polycyclic aromatic hydrocarbons (PAHs), to ensure product safety and quality.

• The shelf-life time for stability of ingredients used in food supplements should be properly demonstrated.

• Any information regarding possible degradation should be demonstrated.

• Food exposure should be well defined. Adequate strategies regarding assessment of exposure should be developed. Eg. Intake of synephrine from *Citrus aurantium*.

• The matrix effect and interactions with other compounds can influence the kinetics and toxicity expression of naturally occurring substances. The impact of the surrounding matrix may either enhance or reduce their inherent toxicity, and such changes should be carefully evaluated and reported.

• Adulteration issues which are not naturally occurring should be checked and onlyknown ingredients should be listed in specifications. Information regarding the process of manufacture such as process through which raw material is converted into preparation, extraction; plant extract ratio etc. should be well defined.

Nowadays there is a high demand and interest for nutraceutical plants in industries, academia and health sciences. A major percentage of world's population relies on medicinal plants for their preventive properties. As nutraceuticals are natural doesn't mean that they are safe always and that are subjected to regulation. Methods of detection of pharmacological activity should be specific and increasingly reliable and avoiding the use of laboratory animals. Nutraceuticals can be specifically targeted. The risk of hepatotoxicity should be assessed and dosage guidelines should be developed. Proper regulations are essential to establish efficacy for each ingredient for each plant.

Thereforeindustries have a need to work on these points for better prevention measures.

CONCLUSION

Nutraceuticals have a long way to go as apart from dietary supplementary food additives for being pharmaceutical grade standardized nutrients. This is because of complicated nature of phytoconstituents present in them. Nutraceuticals have gained significant attention in recent years due to their nutritional value, safety profile, and potential therapeutic benefits. Emerging research on these compounds has shown promising outcomes in addressing a variety of health conditions. With proven positive effects on well-being, nutraceuticals can help prevent diseases and support the maintenance of overall good health when incorporated into one's diet.

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Author contributions

Dr.P.V.Kamala Kumari gathered details of manuscript and contributed to writing the manuscript regarding this work; Ms P Sindhura Devi contributed for the collection of information from various books.

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