

## **CURRENT TRENDS AND FUTURE PROSPECTIVE OF NUTRACEUTICALS IN HEALTH PROMOTION**

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**Abstract-** Plants play an important role in the daily life, which are essential not only for food, shelter and clothing but also for recreation world is colorful because of diversified flora of dye yielding plants. Plants are one of the most important resources of human foods and medicines. Rapidly increasing knowledge on nutrition, medicine, and plant biotechnology has dramatically changed the concepts about food, health and agriculture, and brought in a revolution on them. Nutritional therapy and phytotherapy have emerged as new concepts and healing systems have quickly and widely spread in recent years. Strong recommendations for consumption of nutraceuticals, natural plant foods, and the use of nutritional therapy and phytotherapy have become progressively popular to improve health, and to prevent and treat diseases. With these trends, improving the dietary nutritional values of fruits, vegetables and other crops or even bioactive components in folk herbals has become targets of the blooming plant biotechnology industry. This review attempts to display and remark on these aspects. It summarizes the progress made on nutraceuticals, nutritional therapy, phytonutrients, phytotherapy, and their related epidemiological investigations and clinical studies. It also covers markets of these health-promoting products and disease-preventing or healing systems, as well as regulations behind them that direct the development of biotechnology study and application. Finally, related patents are listed and briefly analyzed, regarding of plant biotechnological research and progress on transgenic crops to improve nutritional value, phytotherapy efficiency, or to produce pharmaceutically important secondary metabolites or high-valued protein medicines such as vaccines and antibodies. In the case of plant foods, phenolics and polyphenolics constitute a main group of compounds that render beneficial effects, in part, due to their antioxidant potential, among other mechanisms of action.

**Keywords:** Nutraceuticals, clinical trial, metabolic engineering, phytonutrients, plant biotechnology

### **Introduction**

Neuraceutical is regarded as the bio active substance and the constituents are either of known therapeutic activity or are chemically defined substance generally accepted to contribute substantially to the therapeutic activity of the drug. Phytochemical screening involves botanical identification, extraction with suitable solvents, purification and characterization of the bioactive constituents of pharmaceutical importance<sup>1</sup>. Quality control for the officiality and safety of herbal product is essential. The quality control of phytochemical may be defined as the status of a drug which is determined either by identity, purity, constant and other chemical physical biological properties or by manufacturing process. Compound with synthetic drug<sup>2</sup>. The critical and approach for herbal drug are much more complex<sup>6</sup>. Phytopharmaceutical are always mixtures of many constituents and are therefore vary variable and difficult to characterize. The active principles in Phytopharmaceutical are not always known<sup>3</sup>. The quality criteria for herbal drugs are based on a clear scientific definition of the raw material. Depending on the type of preparation, sensory properties, physical constants, moisture, ash content, solvent residues and adulterations have to be checked to prove identity and purity. Microbiological contamination, foreign materials,

heavy metals, pesticide residues, all toxins and radio activity also need to be tested<sup>12</sup>. To prove the constant composition of herbal preparations, appropriate analytical methods have to be applied and different concepts have to be used in order to establish relevant criteria for uniformity<sup>10</sup>. Health drinks contain Ashwagandha, Tulsi, Ginger, Mulethi, Awala, Shatavari, Gokhru, Arjuna, Giloy, Safed musli, Lemon, Sugarcane Kalimirchi, Haldi, Jaiphal have been reported as nervine tonic, immunomodulatory agents, antioxidants, tonics for heart and liver, blood purifier. *Withania somnifera* (Ashwagandha) is a tonic, abortifacient, astringent, deobstruent, nervine, aphrodisiac and sedative. It has been used in diseases such as rheumatism, leprosy and arthritis. It is used to treat general debility, arthritis, depression, chronic fatigue, insomnia, anxiety, depressed immunity, infertility and memory loss<sup>4,5,6</sup>. It increases the iron content. *Myristica fragrans* is aromatic, carminative, digestive, anti-inflammatory, diuretic, lactagogue, aphrodisiac, hypnotic, hallucinogenic, antispasmodic and stimulant agent. *Piper nigrum* (Kalimirchi) stimulates appetite, encourages peristalsis, tones the colon muscles and is a general digestive tonic. Sometimes it is used in gonorrhoea. On account of its

stimulant action it aids digestion and is especially useful in a tonic dyspepsia and turbid condition of the stomach. *Tinospora cardifolia* is antiperiodic, antipyretic, alterative, diuretic, antiinflammatory<sup>8,9</sup>. It is a constituent of several compound preparations. It clears out brain toxin that hinders mental activity. *Curcuma longa* (Haldi) is also used as an anti-inflammatory agent, and remedy for gastrointestinal discomfort associated with irritable bowel syndrome, and other digestive disorders. The present article reviews the general concept, categories, and research developments, areas of concern and regulatory aspects of nutraceuticals. The term 'nutraceutical' was coined in 1979 by Stephen DeFelice, founder and chairman of the Foundation for Innovation in Medicine located in Cranford, New Jersey. It was defined as 'a food or part of food, that provides medical or health benefits, including the prevention and treatment of disease'<sup>2</sup>. Nutraceuticals may range from isolated nutrients, herbal products, dietary supplements and diets to genetically engineered "designer" foods and processed products such as cereals, soups and beverages. Doubtlessly, many of these products possess pertinent physiological functions and valuable biological activities<sup>11,15</sup>. With the passage of the Dietary Supplement Health and Education Act of 1994, the definition of nutraceuticals has been expanded to include vitamins, minerals, herbs and other botanicals, amino acids and any dietary substance for use by humans to supplement the diet by increasing total dietary intake and subsequently increased the use of nutraceuticals dramatically. However, functional food concept is different from nutraceuticals and can be defined as food products to be taken as part of the usual diet in order to have beneficial effects that go beyond what are known as traditional nutritional effects<sup>18, 17</sup>. The goal of achieving an optimal or maximal state of nutrition and health is becoming an increasing challenge with the introduction of many nutraceuticals. The ascribed health benefits of nutraceuticals are legion. Various products are claimed not only to reduce the risk of cancer and heart disease but also to prevent or treat hypertension, high cholesterol, excessive weight, osteoporosis, diabetes, arthritis, macular degeneration (leading to irreversible blindness), cataracts, menopausal symptoms, insomnia, diminished memory and concentration, digestive upsets and constipation and not to mention headaches. Nutraceuticals are marketed in concentrated forms as pills, capsules, powders and tinctures either as a single substance or as combination preparations.

### Categories of nutraceuticals

Nutraceuticals are non-specific biological therapies used to promote wellness, prevent malignant processes and control symptoms. These can be grouped into the following three broad categories<sup>12</sup>:

1. Substances with established nutritional functions, such as vitamins, minerals, amino acids and fatty acids - *Nutrients*

2. herbs or botanical products as concentrates and extracts - *Herbals*

3. reagents derived from other sources (e.g. pyruvate, chondroitin sulphate, steroid hormone precursors) serving specific functions, such as sports nutrition, weight-loss supplements and meal replacements - *Dietary supplements*.

### Nutrients

The most commonly known nutrients are antioxidant, water and fat-soluble vitamins. Many potential benefits have been attributed to antioxidant use in the form of dietary intake or supplementation. Antioxidants, in general, may be useful in the prevention of cancer and cerebrovascular disease. High dietary intake of vitamin E may prevent Parkinson's disease. Agus *et al.*, determined that the oxidized form of vitamin C, dehydroascorbic acid, readily crosses the blood brain barrier<sup>4</sup>. These findings have implications for increasing the uptake of antioxidants in the central nervous system; thus, some feel that this has the potential for improving the treatment of Alzheimer's disease. Jialal and Fuller found that the combination of vitamin E, C and beta carotene has been useful in reducing low density lipoprotein oxidation and subsequent atherosclerosis. Vitamin supplement is associated with increased antibody titre response to both hepatitis B and tetanus vaccines as a result of macrophage and T cell stimulation<sup>9</sup>. Those genetically predisposed to pancreatic cancer have low serum levels of selenium; thus, it is assumed that supplementation with selenium may help to prevent this condition. Those suffering from asthma and skin cancer have also been evaluated with selenium for its potential use, although results have been inconclusive. Zinc is an essential component of more than hundred enzymes involving digestion, metabolism and wound healing. L-arginine is a semi-essential amino acid that is a substrate for nitric oxide production. Ceremuzynski *et al.*, demonstrated that supplementation of L-arginine improved exercise capacity in patients, who had angina. A list of common nutrients with their health benefits is given in Table 2 and formulations in Table 1..

### Herbals

Herbals are as old as human civilization and they have provided a complete storehouse of remedies to cure acute and chronic diseases. The knowledge of herbals has accumulated over thousands of years so that today we possess many effective means of ensuring health care<sup>21,22, 23, 24</sup>. Numerous nutraceuticals are present in medicinal herbs as key components<sup>25, 26</sup>. A list of commonly known herbal and phytochemical products with their therapeutic activity is shown in Table 2. Herbal extracts, including *b*-sitosterols (found in Saw Palmetto berry), cernilton (pollen extract), and *pygeum africanum* (African plum) have been clinically evaluated for use in the treatment of benign prostatic hyperplasia. It has been found that common herbal treatment is in the use of *Echinacea* for the prevention and treatment of colds and flu<sup>17</sup>. A series of five placebo controlled studies

evaluating the use of Echinacea produced mixed results, which the authors attribute to either the use of healthy volunteers, rather than patients, or the use of extracts that were not standardized or chemically defined monopreparations. Ernst suggested that St John's wort is efficacious for mild to moderate depression, but serious concern exists about its interactions with several conventional drugs. Echinacea may be helpful in the treatment or prevention of upper respiratory tract infections, but trial data are not fully convincing. Saw Palmetto has been shown in short term trials to be efficacious in reducing the symptoms of benign prostate hyperplasia. Kava is an efficacious short term treatment for anxiety. None of these herbal medicines is free of adverse effects. St. John's wort, for instance, interacts with prescription drugs leading to potentially serious consequences. It is a mild monoaminoxidase inhibitor and cannot be used with high tyramine foods and antidepressants. A case describes a kidney transplant patient whose cyclosporin level dropped dramatically and dangerously after self-medicating St. John's wort extract at only one-third of the recommended dose. It was suggested that ginkgo is of questionable use for memory loss and tinnitus but has some effect on dementia and intermittent claudication.

#### **Dietary supplements**

Dietary supplements have also been developed to manage a variety of diseases. For instance, prepackaged, nutritionally balanced meals that meet the recommendations of national health organizations influenced multiple risk factors for patients with cardiovascular disease and increased patient compliance with dietary restrictions<sup>24</sup>. Ketogenic diets, comprised of foods high in fat and low in protein and carbohydrate content, have been reported to improve seizure control. However, these diets are widely acknowledged to be unpalatable, making sustained compliance with dietary restrictions difficult. Cereals and grains is an area of nutraceuticals in which calcium fortification is very strong. Kellogg's is a leader with calcium fortified All-Bran plus and Nutrigrain bars. Researchers have found that minimally refined grains may reduce the incidence of diabetes and may be beneficial in the prevention of gastrointestinal cancers. Bugeon is bread containing soya flour and linseeds, which provide phytoestrogens, natural substances that mimic the structure of hormone oestrogen. Phytoestrogens have been documented to enhance oestrogens levels when hormonal levels are low or to weaken the effects of oestrogen when levels are high. This action may prevent against both hot flushes and breast cancer. Other common foods that may have potential therapeutic value include edible mushrooms. Nutraceuticals are becoming more widely accepted as an adjunct to conventional therapies for enhancing general well being. As a result of extensive research on these nutraceuticals various products are available in National and International market and some of these are shown in Table 4.

#### **Dietary Nucleotides**

Nucleotides are essential dietary supplements during certain conditions of body to meet its physiological requirements such conditions mainly include rapid growth, during limited food supply and metabolic stress<sup>13</sup>. Nucleotides have been demonstrated to affect a number of immune functions, including reversing malnutrition, starvation induced immunosuppressing, enhancing T-cell maturation and function, enhancing natural killer cell activity, improving delayed cutaneous hypersensitivity, aiding in resistance to infection agents and modulation T-cell response. Recently dietary nucleotides have been shown to serve as a modulatory nutrient for hemopoiesis<sup>14</sup>. Further many drugs used in the therapy or prevention of AIDS with nucleoside analogue reverse transcriptase inhibitors (NRTIs) and Cancer can theoretically affect every organs system through mitochondrial toxicity. One of the most debilitating side effects of long-term highly active antiretroviral therapy (HAART) is the physical alteration of body composition, also known as lipodystrophy. Mitochondrial toxicity may manifest as lipotrophy, polyneuropathy, steatosis, steatohepatitis or acute liver failure [However earlier studies indicate that the nucleotide, particularly Uridine or uridine derivatives completely prevent and treat the mitochondrial toxicity of NRTIs by abrogating mitochondrial DNA depletion<sup>20, 13</sup>.

#### **Global Nutraceutical Market**

Japan gave birth to functional foods in the 1980's. Europe in 1995 launched new taste effects from unrelated flavours, creating products with high interest in fortification and a well balanced taste sensation, probiotic cultures. The estimated global market size for functional foods is US \$100 billion. Today, 55% of food, 36% of pharmaceutical and 90% of biotech firms are actively researching nutraceutical products.

#### **Areas of concern**

The lack of quality control is a major area of concern for nutraceuticals. The quality of plant material and manufacturing processes used for nutraceuticals are regulated by food laws, which lack the specificity required for botanical drugs. This can have serious consequences. Contamination, for instance, with toxins after fungal infection of raw plant material or with other ingredients has been repeatedly reported and can have potential fatal consequences. Adulterations and numerous other types of impurity of nutraceuticals conceivably remain undetected simply because there is an almost total absence of specific quality control. Absence of quality control not only increases the risk to the consumer, it also results in a total lack of impetus to conduct adequate research that demonstrates the potential benefits of nutraceuticals or ensures their safety. New clinical applications of nutraceuticals are increasingly being reported, but there are fundamental differences between formulation, production and the evidence supporting clinical use. Nutraceuticals generally fall within the novel foods and ingredients

regulations but their purity, dosage requirements and clinical consequences exceed those of most 'healthfoods'. Replacement of one nutrient or antioxidant is unlikely to correct the cascade of interconnected metabolic abnormalities associated with many diseases. Cost is another factor that receives scant attention. These products sell for substantial amounts more than mainstream products, in as much as botanicals are costly to produce.

### Regulatory aspects

In USA, watershed legislation was passed in 1994 to regulate the manufacture and marketing of nutraceuticals. This law, known as the Dietary Supplement Health and Education Act, reversed 45 years of increasing FDA regulation of health related products. The FDA may establish good manufacturing practices for nutraceuticals as long as these regulations are molded after the less stringent regulations for foods as opposed to those for drugs. A draft law reminiscent of the Dietary Supplement Health and Education Act is in development in India to regulate manufacturing, importing and marketing of health foods/dietary supplements and other nutraceuticals. Also the country's central drug control department has put some structures in place for dietary supplements, but it is taking a long time for states to cooperate and some states have rejected the structures when their own rules and regulations conflict. Also a new independent association has been formed in India to address some of these issues. The Indian Health and Dietary Supplement Association was created to represent pharmaceutical, nutraceutical, herbal, direct selling and other service oriented industry companies and plans to affiliate with the International Alliance of Dietary Supplement Associations in the near future. The association is planning a scientific conference to bring the industry and government together to share information, experience and perspectives on the use and regulation of dietary supplements.

### Conclusion

Nutraceuticals are destined to play an important role in future therapeutic developments but their success will be governed by control of purity, safety and efficacy without inhibiting innovation. Nutraceuticals will continue to appeal because they are convenient for today's lifestyle. Some are also genuinely researched and offer novel ingredients that can bring about health benefits quicker than would normally be the case through eating conventionally healthy foods alone. The present accumulated knowledge about nutraceuticals represents undoubtedly a great challenge for nutritionists, physicians, food technologists and food chemists. Public health authorities consider prevention and treatment with nutraceuticals as a powerful instrument in maintaining health and to act against nutritionally induced acute and chronic diseases, thereby promoting optimal health, longevity and quality of life. A place for nutraceuticals in

clinical practice is emerging, but important pharmaceutical and clinical issues need to be addressed by further research.

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Table 1-Herbal Health Drink Formulation

Plant Neutraceutical Concentrate	Quantity per litre
Ashwagandha concentrate	400 mg
Brahmi concentrate	400 mg
Tulsi concentrate	200 mg
Ginger concentrate	200 mg
Awala concentrate	400 mg
Shatavari concentrate	100 mg
Gokharu concentrate	100 mg
Arjuna concentrates	100 mg
Giloy concentrate	100 mg
Safed musli concentrate	100 mg
Aloe vera concentrate	100 mg
Haldi concentrate	50 mg
Sugarcane	100ml

Table 2- Common herbal and Phytochemical products

Plant	Therapeutic activity
Aloe vera gel (Aloe vera L. N.L. Burm.)	Dilates capillaries, anti-inflammatory, emollient, wound healing properties
Garlic (Allium sativum L.)	Antibacterial, antifungal, antithrombotic, hypotensive, fibrinolytic, antihyperlipidemic, Anti-inflammatory
Ginger (Zingiber officinale Rosc.)	Carminative, antiemetic, cholagogue, positive inotropic, treatment of dizziness
Tinospora cardifolia	antiperiodic, hepatoprotective, antipyretic, alterative, diuretic, antiinflammatory. It is a constituent of several compound preparations.
Piper nigrum (Kalimirchi)	Stimulates appetite, encourages peristalsis, tones the colon muscles and is a general digestive tonic
Withania somnifera (Ashwagandha)	Nerve tonic, abortifacient, astringent, deobstruent, nervine, aphrodisiac and sedative.

Table 3- Common nutrients and their associated health benefits

<b>Plant Nutraceutical Components</b>	<b>Health benefits</b>
<b>Fat Soluble Vitamins</b> Vitamin A Vitamin D Vitamin E Vitamin K	<ul style="list-style-type: none"> <li>• Antioxidant, essential, for growth and development, maintains healthy vision, skin and mucous membranes, may aid in the prevention and treatment of certain cancers and in the treatment of certain skin disorders.</li> <li>• Essential for formation of bones and teeth, helps the body absorb and use calcium</li> <li>• Antioxidant, helps form blood cells, muscles, lung and nerve tissue, boosts the immune system</li> <li>• Essential for blood clotting</li> </ul>
<b>Water Soluble Vitamins</b> Vitamin C Vitamin B1 Vitamin B2 Vitamin B3 Vitamin B6 Vitamin B12 Folic acid Pantothenic acid	<ul style="list-style-type: none"> <li>• Antioxidant, necessary for healthy bones, gums, teeth and skin, helps in wound healing, may prevent common cold and attenuate its symptoms</li> <li>• Helps to convert food in to energy, essential in neurologic functions</li> <li>• Helps in energy production and other chemical processes in the body, helps maintain healthy eyes, skin and nerve function</li> <li>• Helps to convert food in to energy and maintain proper brain function</li> <li>• Helps to produce essential proteins and convert protein in to energy</li> <li>• Helps to produce the genetic material of cells, helps with formation of red blood cells, maintenance of central nervous system and synthesize amino acids and is involved in metabolism of fats, protein and carbohydrates</li> <li>• Necessary to produce the genetic materials of cells, essential in first three months of pregnancy for preventing birth defects, helps in red blood cell formation, protects against heart disease</li> <li>• Aids in synthesis of cholesterol, steroids and fatty acids, crucial for intraneuronal synthesis of acetylcholine.</li> </ul>
<b>Dietary Nucleotides</b>	<ul style="list-style-type: none"> <li>• Nucleotides have been demonstrated to affect a number of immune functions and health rejuvenation</li> </ul>
<b>Minerals</b> Calcium Iron Magnesium Phosphorous	<ul style="list-style-type: none"> <li>• Essential for building bones and teeth and maintaining bone strength, important in nerve, muscle and glandular functions</li> <li>• Helps in energy production, helps to carry and transfer oxygen to tissues</li> <li>• Essential for healthy nerve and muscle function and bone formation, may help prevent premenstrual syndrome (PMS)</li> <li>• Essential for building strong bones and teeth, helps in formation of genetic material, energy production and storage</li> </ul>
<b>Trace elements</b> Chromium Cobalt Copper Iodine Selenium Zinc	<ul style="list-style-type: none"> <li>• With insulin helps to convert carbohydrates and fats into energy</li> <li>• Essential component of vitamin B , but ingested cobalt is metabolized in vivo to form the B12, coenzymes</li> <li>• Essential for hemoglobin and collagen production, healthy functioning of the heart, energy production, absorption of iron from digestive tract</li> <li>• Essential for proper functioning of the thyroid</li> <li>• Antioxidant, essential for healthy functioning of the heart muscle</li> <li>• Essential for cell reproduction, normal growth and development in children, wound healing, production of sperm and testosterone</li> </ul>
<b>Vitamin like compounds</b> Biotin L- Carnitine Choline Vitamin F Inositol Taurine	<ul style="list-style-type: none"> <li>• Required for various metabolic functions</li> <li>• Oxidation of fatty acids, promotion of certain organic acid excretion and enhancement of the rate of oxidative phosphorylation</li> <li>• Lipotropic agent used to treat fatty liver and disturbed fat metabolism</li> <li>• Involved in proper development of various membranes and synthesis of prostaglandins, leukotrienes and various hydroxy fatty acids</li> <li>• Lipotropic agent necessary for amino acid transport and movement of potassium and sodium</li> <li>• Aids in retinal photoreceptor activity, bile acid conjugation, white blood cell antioxidant activity,</li> <li>• CNS neuromodulation, platelet aggregation, cardiac contractility, sperm motility, growth and insulin activity</li> </ul>

Table 4- List of Marketed Nutraceutical Products

<b>Product</b>	<b>Category</b>	<b>Manufactures</b>
Coral calcium <sup>TM</sup>	Calcium supplement	Nature's answer, Hauppauge, NY, USA
Weight smart	Nutritional supplement	Bayer corporation, Morristown, NJ, USA
Omega woman <sup>TM</sup>	Immune supplement	Wassen, Surrey, U.K.
Appetite Intercept <sup>TM</sup>	Appetite suppressant	Natrol, Chatsworth, CA, USA
Chaser <sup>®</sup>	Hangover supplement	Living essentials, Walled lake, MI, USA
Rox	Energy drink	Rox America, Spartanburg, SA, USA
Mushroom optimize <sup>TM</sup>	Immune supplement	Jarrow formulas, Los Angeles, CA, USA
Biovinca <sup>®</sup>	Neurotonic	Cyvex nutrition, Irvine, CA, USA
Proplus <sup>TM</sup>	Nutritional supplement	Campbell soup company, Camden, NJ, USA
Snapple-a-day <sup>®</sup>	Meal replacement bevera	Snapple beverage group, White Plains, NY, USA
Welife <sup>TM</sup>	Amino acid supplement	Daesang America Inc., Hackensack, NJ, USA
PNer plus <sup>TM</sup>	Neuropathic pain supplement	NeuroHelp, San Antonio, Texas, USA
Olivenol <sup>®</sup>	Dietary supplement	Cre Agri, Hayward, CA, USA
Threptin Diskettes <sup>®</sup>	Protein supplements	Raptakos, Brett & Co. Ltd., Mumbai, India
GRD <sup>®</sup>	Nutritional supplement	Zydus Cadila Ltd. Ahmedabad, India
Proteinex <sup>®</sup>	Protein supplement	Pfizer Ltd., Mumbai, India
Calcirol D-3	Calcium supplement	Cadilla healthcare limited, Ahmedabad, India.