Available online at www.nutraceuticalsjournal.com

DOI: http://dx.doi.org/10.18782/2583-4606.104

ISSN (E): 2583 – 4606

Emrg. Trnd. Nutr. (2022) *1*(1), 24-36

Review Article

Emerging Trends in Nutraceuticals

Peer-Reviewed, Refereed, Open Access Journal

Nutraceuticals: A Critical Review

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Received: 18.01.2022 | Revised: 20.02.2022 | Accepted: 4.03.2022

ABSTRACT

Nutraceutical is a combination of "nutrition" and "pharmaceutical." In general, nutraceuticals are foods or parts of foods that play a substantial role in changing and sustaining proper physiological functions in humans. The present demographic and health trends are the primary drivers of the nutraceutical market's global expansion. Dietary fibre, prebiotics, probiotics, polyunsaturated fatty acids, antioxidants, and other herbal/natural foods are examples of food products utilised as nutraceuticals. These nutraceuticals aid in the treatment of some of the century's most pressing health issues, including obesity, cardiovascular disease, cancer, osteoporosis, arthritis, diabetes, and cholesterol. Overall, the term "nutraceutical" has ushered in a new era of medicine and health, in which the food sector has evolved into a research laboratory. The challenges and opportunities, and regulations of nutraceuticals were discussed. This article also focused on some scope and use of the nutraceuticals and their health benefits, like probiotics and prebiotics, proteins and peptides, oils and fatty acids, carbohydrates and fibers, catching and lycopene.

Keywords: *Nutraceuticals, Functional food, Health Benefits, Nutrients.*

INTRODUCTION

The saying "Let food be medicine, and medicine be food," coined by Hippocrates over 2500 years ago, is gaining popularity today as food scientists and consumers recognise the numerous health advantages of various foods. These foods have elements that boost our health and well-being by assisting specific body functions.

Cite this article: Chaudhary, K., Sharma, D., & Parihar, S. (2022). Nutraceuticals: A Critical Review, *Emrg. Trnd. Nutr. 1*(1), 24-36. doi: http://dx.doi.org/10.18782/2583-4606.104

For the past century, "essential nutrients," or those required to avoid specific diseases, have been a prominent focus of human nutrition study. During the 1980s, Japan began to create a sophisticated nutraceuticals and functional foods sector (S.A.E., 2012). Beyond their fundamental nutritional capabilities, functional foods are foods that are enhanced with functional components to provide medicinal and physiological advantages or to minimise the risk of chronic diseases. Nutraceuticals are bioactive compounds that have been separated or purified from foods and are intended to be used medicinally.

Because of the widespread usage of numerous chemicals, heavy metals, electromagnetic waves, and other potentially harmful man-made products, industrialization has resulted in air and water pollution, as well as soil and food contamination. Diabetes, obesity, malignancies, vascular diseases, physiological issues, and other degenerative diseases leading to severe immune dysfunction have all increased as a result of these issues. Consumers are worried about how their health care is managed, delivered, and priced. They are dissatisfied with modern medicine's pricey, high-tech approach to disease treatment and management; the customer is looking for supplementary or alternative helpful items, and the red tape of managed care makes nutraceuticals particularly enticing (Zhao, 2007). Getting enough nutrients from a variety of foods is critical for maintaining proper human body function. As a result of recent advances in medical and nutrition sciences, natural goods and health-promoting foods have gotten a lot of attention from both health professionals and the general population. Nutraceuticals, nutritional therapy, phytonutrients, and phytotherapy are some of the new concepts that have emerged as a result of this development.

In 1979, Stephen DeFelice coined the term "nutraceutical." According to the definition, "a food or portions of food that provide medicinal or health benefits, including illness prevention and treatment." Nutraceuticals include isolated nutrients, herbal products, nutritional supplements, and diets, as well as genetically modified "designer" foods and processed foods, including cereals, soups, and beverages. The term "food extract supplement" refers to any non-toxic food extract supplement with scientifically documented health benefits for both the treatment and prevention of disease (Prabu et al., 2012).

Concepts of Nutraceuticals

In the pharmaceutical development process, clinical test results from animal testing and research are necessary for effect verification. In the past, however, there was no verification mechanism for foods used in illness prevention. In recent years, food composition has been scientifically proven to cause lifestyle-related diseases, and as a result, it has become a social issue. (Gupta & Chauhan, 2010).

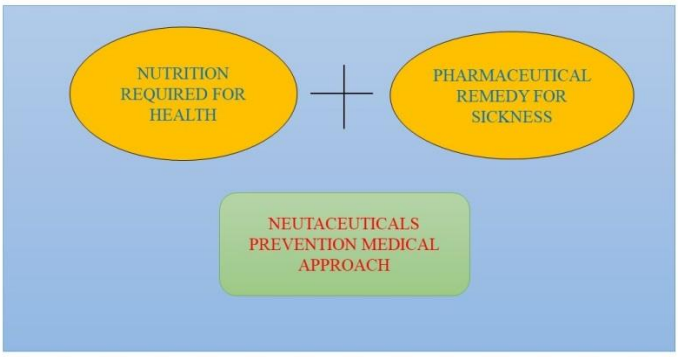

Figure 1: Concept of Nutraceuticals

How Nutraceuticals differ from Functional food?

Functional foods are not the same as nutraceuticals. When a product is cooked or prepared with "scientific intelligence," with or without comprehension of how or why it is utilised, it is referred to as functional food. As a result, functional food delivers the vitamins, lipids, proteins, carbohydrates, and other nutrients that the body needs to stay healthy. Other than anaemia, a nutraceutical is a functional food that aids in the prevention and/or treatment of disease(s) and/or disorder(s). (Because most functional foods are antianemic in some form, the exception to anaemia is considered in order to distinguish between the two concepts, functional food and nutraceutical.) Fortified dairy products (such as milk) and citrus fruits are examples of nutraceuticals (e.g. orange juice) (Takayuki et al., 2008).

Classification of Nutraceuticals(Chanda & Tiwari, 2019**)**

Nutraceuticals and functional foods are categorised according to their natural origins, pharmacological conditions, or chemical constitution.

1. On the basis of natural source, it can be classified as the products obtained from plants, animals, minerals, or microbial sources.
2. Nutraceuticals as per the chemical groupings

(i) Chemical constituents

(a) Nutrients

(b) Herbals

(c) Phytochemicals

(ii) Probiotic microorganisms

(iii) Nutraceutical enzymes

(1) Chemical Constituents

(a) Nutrients

Amino acids, vitamins, and fatty acids were primary metabolites with well-defined roles in distinct metabolic pathways. Plant and animal products, as well as vitamins, provide several health benefits and can aid in the treatment of disorders of the heart, kidneys, and lungs, among others.

Natural products derived from plants are useful in the treatment of a variety of ailments, including brittle bones and low haemoglobin counts, and they strengthen bones and muscles, aid neuron transmission, and keep heart muscles in rhythm.

Common nutrients and their associated health benefits shown in below Table (Allen, 1997).

S.No	Nutrients	Health Benefits
1	Vitamin A	Antioxidant that is necessary for growth and development as well as the treatment of several skin conditions.
2	Vitamin K	Essential for blood clotting.
3	Vitamin C	Antioxidant for healthy bones, gums, teeth, and skin, wound healing, and preventing and alleviating the symptoms of the common cold.
4	Vitamin B1	Aids in the conversion of food into energy, which is necessary for brain processes.
5	Vitamin B2	Aids in the creation of energy and other chemical reactions in the body, as well as the maintenance of healthy eyes, skin, and nerve function.
6	Folic Acid	Produces cell genetic materials in pregnancy to prevent birth abnormalities, RBC creation, and heart disease protection.
7	Iodine	Essential for proper functioning of the thyroid.
8	Calcium	Bones and teeth, as well as preserving bone strength, are essential for nerve, muscular, and glandular function.

(b) Herbals

Nutraceuticals, when combined with herbs, were found to have a substantial impact on the prevention of a number of chronic diseases, hence enhancing quality of life. Salicin, an anti-inflammatory, analgesic, antipyretic, astringent, and antiarthritic chemical found in willow bark (Salix nigra), has been clinically demonstrated. Psoralen is a diuretic, carminative, and antipyretic flavonoid found in parsley (Petroselinum crispum).

(c) Phytochemicals

The majority of the time, phytochemicals are employed to classify them. Carotenoids (isoprenoids) are found in vegetables and aid in the immune system's function, particularly killer cells, which aid in the anticancer response. Noncarotenoids are present in legumes (chickpeas and

soybeans), grains, and palm oil, and they lower cholesterol and are anticarcinogenic.

Flavonoids, a class of secondary metabolites found in most plants and with over 4000 variants, have been shown in clinical trials to help prevent diseases like cancer, diabetes, heart disease, and kidney disease by virtue of their antioxidant qualities and bioactive components (Ehrlich, 2009).

Phenolic acids are the most common type of secondary metabolite, and they're mostly found in citrus fruits and red wine. They're antioxidants that scavenge free radicals created by numerous metabolic pathways like protein, glucose, and fat. They have anticancer and antitumor properties as well.

Cynodondactylon plays a key role in ethnomedicinal practises and traditional medicinal systems. It can help with a wide range of symptoms and illnesses. Because the species is a weedy grass that does not require cultivation, it can be easily researched in its natural habitat for human purposes. (Pariharm & Sharma, 2021) When all nine herbal plants are combined in a garden, it provides excellent health, prosperity, and money. These Navagraha plants have the ability to treat a wide range of ailments (Pariharm & Sharma, 2021) Horse grain has a wide range of applications and is now used as a phytotherapeutic agent. It is mostly grown in India and belongs to the Fabaceae family. In India, it's used as an anti-obesity natural food supplement. (Chirania & Sharma, 2021) Saffron, as well as other natural compounds derived from plants, herbs, and spices, may be useful in the prevention and treatment of a range of ailments, including diabetes and cancer (Sharma & Gupta, 2018).

Because of its wide range of pharmacological actions, extracts of the plant Ribes fasciculatum (R. fasciculatum) have been employed in a variety of dietary health supplements. (Gupta et al., 2018) Medicinal plant extracts can be used to treat a range of ailments. The annual grass C. dactylon (L.) Pers. has a wide range of therapeutic effects. It's cultivated all over the world. For therapeutic purposes, the entire plant is used. With numerous nutrients, it has a lot of undiscovered medicinal, decorative, and other potential. Extracts of Green tea leaves it is supplied in the dietary supplements which will maintain the health (Sharma et al., 2018).

(2) Probiotic Microorganisms

The word "probiotic" was invented by Metchnikoff. Its use in modern medicine has been bolstered by its capacity to make the intestine more favourable for activities like absorption and metabolism. Probiotics are highly vital for making life easier by removing toxic bacteria from the intestine and maintaining a pleasant environment, such as Bacillus bulgaricus intake (Holzapfel, 2001).

3) Nutraceutical Enzymes

Enzymes are biocatalysts with a proteinous structure that are created by the cell. It speeds up the living process by lowering the metabolic rate. GERD (gastroesophageal reflux disease), constipation, diarrhoea, and ulcerative colitis are among medical conditions that can be addressed with enzyme supplements. For diabetic patients, the enzyme could be a superior option.

Non-traditional nutraceuticals are artificial foods prepared with the help of biotechnology. Food samples contain bioactive components which are engineered to produce products for human- wellness. They are arranged into

a) Fortified nutraceuticals

b) Recombinant nutraceuticals

a) Fortified nutraceuticals

It consists of food that has been fortified with increased nutrients and/or additives as a result of agricultural breeding. For example, calcium-fortified orange juice, vitamin- and mineral-fortified cereals, and folic acid-fortified flour. Milk supplemented with cholecalciferol, for example, is used

to treat vitamin D insufficiency (Casey et al., 2010).

b) Recombinant nutraceuticals

Biotechnology is used to make energy-giving foods including bread, wine, fermented starch, yoghurt, cheese, vinegar, and others.

Classification Based on Mechanism of Action

Specific therapeutic qualities, such as antibacterial, anti-inflammatory, and antioxidant capabilities, have been assigned to nutraceuticals. As a result, physicians are now prescribing a variety of nutraceuticals products to treat these lethal disorders. In the table below, several of these nutraceuticals with considerable pharmacological activity are listed. (Gosslau & Chen, 2004).

Table: Nutraceuticals with their pharmacological activity

Antioxidants	Anti-inflammatory	Anti-cancer	Anti-influenza
Ascorbic acid	Capsaicin	α-tocopherol	β-glucan
Chlorogenic acid	Curcumin	Capsaicin	β-sitosterol
Ellagic acid	Gamma-linolenic acid (GLA)	Carnosol	Guar
Hydroxytyrosol	Quercetin	Diallyl sulfide	Pectin
Lutein	Docosahexenoic acid (DHA)	Glycyrrhizin	Tannins
Polyphenolics	Eicosapentaenoic acid (EPA)	Lactobacillus acidophilus	Saponins
β-carotene	Linoleic acid	Equol	Monosaturated fatty acids

Aside from the categories described above, nutraceuticals are also classified as beverages, dietary supplements, and functional foods (Shahidi, 2009). Beverages are liquids that are produced through the fermentation process and are beneficial to a variety of health conditions. Energy drinks, sports drinks, and fortified juices are just a few examples of beverages. Traditional food products with significant physiological benefits are defined as functional food. Omega-3 fatty acids and various probiotics fall within this group of nutraceuticals. Because of the presence of carotenoids, phenolic/polyphenolic chemicals, phytates, vitamin minerals, and uric acid, they are widely employed as antioxidants. Plant sterols, also known as phytosterols, have been shown to be effective in the treatment of a variety of chronic conditions. Dietary supplements, on the other hand, must contain one or more dietary ingredients such as amino acids, vitamins, minerals, herbs, and so on. These are often approved/certified antibiotics and other biological products that are intended for consumption in capsules, liquid forms, pills, and tablets. Dietary supplements consist of examples like use of ginkgo Biloba for arthritis, chondroitin, glucosamine and memory loss etc.

Classification Based on Chemical Nature

Isoprenoid derivatives, phenolic substances, fatty acids, carbohydrates, and amino acid-based substances are among the primary and secondary metabolite sources used to classify these categories.

Nutraceuticals can be classified in a variety of ways, including food sources, method of action, chemical composition, and so on. All of the food sources used as nutraceuticals are natural and fall into the following categories:

1. Dietary Fiber
2. Probiotics
3. Prebiotics
4. Polyunsaturated fatty acids
5. Antioxidant vitamins
6. Polyphenols
7. Spices (Kalia, 2005)

Nutraceutical can be broadly classified into the following 2 groups:

(i)Potential nutraceuticals.

(ii)Established nutraceuticals.

Health Benefits of Nutraceuticals:

- Avoid the side effect.
- May increase the health beneficial effect.

- May have naturally dietary supplement, so do not have unpleasant side effects.
- May increase the health value, our diet and improve medical condition of human.
- May easily be available and economically affordable.

Nutritional therapy is a supplementary therapy that uses food therapies or nutraceuticals. This therapy is based on the idea that meals can provide medicinal benefits in addition to providing nutrition and energy.

It accomplishes this purpose, according to nutraceutical and nutritional therapy theory, by utilising the efficiency of such nutraceuticals in detoxifying the body, avoiding vitamin and mineral shortages, and restoring good digestion and eating habits. Plant nutrients with specific biological actions in support of human health are known as phytonutrients (Zhao, 2007).

SCOPE OF NUTRACEUTICALS

Nutraceuticals are critical for human health since they help to change and sustain normal physiological function. Nutraceuticals include foods such as dietary fibre, prebiotics, probiotics, polyunsaturated fatty acids, antioxidants, and other herbal natural foods. Nutraceuticals are used to treat obesity, cardiovascular disease, cancer, osteoporosis, arthritis, diabetes, cholesterol, and other diseases. Overall, the term "nutraceutical" has ushered in a new era of medicine and health, transforming the food sector into a research-driven industry.

1. CVS DISEASE: Dietary fibres, antioxidants, Omega-3 polyunsaturated fatty acids, vitamins, and minerals for CVS disease prevention and treatment (Verma et al., 2006) Polyphenols (found in grapes) help to prevent and manage vascular disorders. Flavonoids (found in onions, vegetables, grapes, red wine, apples, and cherries) inhibit ACE and help to strengthen the tiny capillaries that transport oxygen and nutrients to all cells. Rice bran improves cardiovascular health by lowering serum cholesterol levels, lowering the level of (LDL) and increasing the level of (HDL).

The essential fatty acids, omega-3, omega-6, omega-9 and folic acid in rice bran are also promoting eye health. It is reported that a low intake of fruits and vegetables is associated with a high mortality in CVS disease.

2. DIABETES: In diabetic patients, ethyl esters of n-3 fatty acids (Anwar, 2007) may be advantageous. Docosahexaenoic acid is important for neurovisual development as well as insulin resistance. Antioxidant lipoic acid is used to treat diabetic neuropathy. Psyllium dietary fibres have been used to manage blood sugar in diabetic individuals and to lower lipid levels in hyperlipidemia patients.

Various nutraceuticals are used to treat Diabetes are as follow:

- Antioxidant
- Vitamin C
- Calcium/Vitamin D
- Carbohydrate
- Fats
- Fibers
- Protein

3. CANCER: Nutraceuticals are substances that are used to cure and improve human health. Estrogen-induced malignancies are reduced by flavonoids, which suppress estrogen-producing enzymes. A wide spectrum of phytopharmaceuticals with purported hormonal activity, known as "phytoestrogens," is prescribed to prevent prostate/breast cancer. Isoflavones from soyfoods, curcumin from curry, and soy isoflavones all have cancer-preventive qualities. Lycopene is found in high concentrations in the skin, testes, adrenals, and prostate, where it helps to prevent cancer.

4. HEART FAILURE AND LUNG CANCER: Corn contributes to heart health not only because of its fibre, but also because of the high levels of folate it contains. Corn maintains homocysteine, an intermediate product in the methylation

cycle, a key metabolic activity. Homocysteine causes blood vessel damage such as heart attack, stroke, and peripheral vascular disease. It has been calculated that consuming 100 percent of the daily value (DV) of folate will reduce the number of heart attacks by 10% on its own. Cryptoxanthin, a natural carotenoid pigment, is also found in corn.It has been found that cryptoxanthin can reduce the risk of lung cancer by 27% on daily consumption.

5. GASTROINTESTINAL DISEASE:

Eating patterns, as well as food production and consumption trends, have health, environmental, and social effects. Gut health is influenced by diet. An imbalance of intestinal microbial flora causes ulcerative colitis, Crohn's disease, irritable bowel syndrome, and gluten therapy-resistant celiac disease, which are all linked to one's diet. The state of one's stomach determines one's overall health (Avrelija et al., 2010). The following nutraceuticals are used to treat GI disease:

- Dietary fibers
- Curcumin
- Antioxidant
- Aloe Vera
- The Bael
- Garlic
- Honey
- Probiotics
- Minerals
- Carbohydrate diets
- Omega-3-fatty acids

CURRENT STATUS:

Herbal/botanical raw materials are used to make nutraceutical foods or dietary components that aid in the treatment and prevention of diseases. This is a fast-growing business (7-12 percent per year), with millions of individuals using natural products around the world. By 2015, the worldwide nutraceutical market is expected to exceed $ 450 billion. According to a recent Euro monitor study, global sales of health and wellness products are on course to hit a new high of almost $1 trillion by 2017, fuelled by functional/fortified products that provide specific health benefits (Ajit, 2012).

Nutraceuticals with their therapeutic benefits (Sarin et al., 2012).

Name of Nutraceutical	Therapeutic Benefits
Natural Lycopene	Reducing risk of prostate and cervical cancers. Supporting cardiovascular health.
Natural Purified Lutein Esters	Dietary supplement Functional foods Antioxidants.
Garlic	Cholesterol-lowering Cardiac diseases Diabetic support
Green Tea	Cancer prevention Weight management Lowering cholesterol
Gymnema, Momordica	Diabetic control
Glucosamine	Arthritis treatment
Ginkgo Biloba	Allergy relief
Digestive Enzymes	Digestive support
Ginseng	Immunomodulator
Phycocyanin Powder	Antioxidant

Traditional nutraceutical ingredients are little understood by Indian consumers, and nutraceutical makers must take up the cause and educate the Indian audience about their products. In the last decade, the global nutraceutical market has risen at its fastest rate. Drinks and functional foods are expected to grow at a far quicker rate than dietary supplements in India during the next five years (Rajasekaran et al., 2008).

In Asia Pacific, Japan is the most active user of nutraceutical products, followed by China. The functional food market in India is predicted to grow slowly in 2017, with functional foods and drinks accounting for over 71% of the dietary supplement market. Between 2007 and 2011, dietary supplements were the fastest-growing market segment in the nutraceutical market in the Middle East and Africa, with annual growth of around 31%.

In 2011, non-herbals were the fastest expanding market segment, while proteins and peptides were the most profitable. The rise of the nutraceutical goods market in Eastern Europe is being propelled by the expansion of the dietary supplement and functional food markets. Russia is the region's major user of nutraceuticals (Ajit, 2012). In 2017, Hungary and Russia are expected to have little more than 20% and slightly less than 24.5 percent of the nutraceutical market, respectively. Modern nutraceuticals are accessible as forms of food, contained in meals, or as whole foods themselves, such as probiotic drink and yoghurt, while traditional nutraceuticals came in the form of capsules, tablets, or powder in a predetermined quantity. Current issues include a lack of funding and focus on research and development, as well as an imbalance in the food provided to the undernourished through government initiatives.

Challenges and opportunities:

The subject of nutraceuticals and functional foods is new, and there are numerous information gaps. For example, it is widely accepted that the health-promoting characteristics of meals are attributable to a few or several active substances, rather than a single component. The pharmaceutical model, which is predicated on the efficacy of single drugs, undergoes a fundamental paradigm change as a result of this. Many of the bioactive phytochemicals under investigation have been overlooked for a long time, therefore there are few ways for handling and measuring them. On their product labels, manufacturers want to make precise claims about health advantages. All parties, however, share the objective to enhance personal and public health through dietary changes, as well as the social and economic benefits that would follow. Although there is some overlap between the two domains, they are very different. Food and nonfood plants can benefit from genetic modification techniques to increase phytochemical content. There are various obstacles to overcome when introducing a new food product to the market (Siddiqui et al., 2020). People are becoming more aware of the substantial link between diet, quality food consumption, and good health, and these people are the best targets. Furthermore, people prefer name-brand products because they know they will be of higher quality, even if the price is a little higher. Identification of the genuine source of raw materials, purity of the molecule, presence of other active compounds, quality, lack of scientific evidence, deceptive advertising, heavy metal contamination, and interactions between supplements and medications are all issues. For example, California ginseng, wild ginseng, prickly ginseng, Pacific ginseng, Malaysian ginseng, Indian ginseng, Peruvian ginseng, Southern ginseng, Brazilian ginseng, and wild-red ginseng are all variants of the common herb "ginseng."

CHALLENGES IN FORMULATION OF NUTRACEUTICAL DOSAGE FORM

Analytical challenges

- Because nutraceuticals are a collection of chemical entities, identifying and quantifying all of the chemicals in the products is difficult.
- Characterising and recognising contaminants, as well as guaranteeing that they are not detrimental to the customer (Chaudhari et al., 2017).

Formulation challenges

Tablet Dosage form. – Botanicals are complex, containing several chemical components, and can contain up to 50

active chemicals, accounting for 70-90 percent of the formula.

- There are no active ingredients or excipients in this product.
- Nutraceutical nature Botanicals and extracts might vary dependent on geography, season, and other circumstances, posing issues in terms of particle size, flow, compressibility, moisture sensitivity, ingredient interaction, content homogeneity, and quality control (QC) testing.
- The quantity of each ingredient must be sufficient to ensure adequate delivery of the beneficial substances. Because the dose size of the active constituent is big, there is little room in the final formulation for excipients.
- -In comparison to pharmaceutical formulations, nutraceutical formulations typically contain more active ingredients in higher concentrations. Excipient space is generally limited due to dosage size limitations.

Liquid dosage form-

Phytoconstituents, fatty acids, flavonoids, volatile oils, and other nutraceuticals make up the majority of nutraceuticals. These components have a number of issues.

- These components' solubility. Carotenoids, for example.
- The components' long-term stability. Coenzyme Q10 and Omega 3 fatty acids are two examples. The low stability of bacteria in the GI tract, as well as the resulting loss of viability due to high acidity and bile salt concentrations, make oral delivery of probiotics difficult.
- The bioavailability and permeability of these substances. Curcumin is an excellent example. It even hampered the absorption of the lipophilic antioxidant coenzyme Q10.
- Low aqueous solubility and slow dissolution rate in GI fluids furnished by its highly lipophilic character (log P=21).
- Permeability is limited by its large molecular weight (863).

Psychological challenges-

Manufacturers of nutraceuticals must first isolate the items and treat them differently than functional foods.

- Tailoring items to the tastes and preferences of domestic consumers. Vegetarianism, Halal or Hindu dietary practises, traditional cures, flavour and formulation preferences reflecting social and cultural variety, or a refusal to acknowledge functional benefits in basic foods are just a few examples.
- Selecting a study population can be tricky. (Depends on age, disease, and other factors.)

Market scenario of nutraceuticals

The nutraceuticals market has grown at an exponential rate in industrialised and health-conscious countries around the world during the last decade (Pushpangadan et al., 2004). Among other countries, the United States of America and Japan have well-developed nutraceutical markets. As a result, the population of these countries' disposable income is gradually increasing (Ahmad et al., 2011). In the sphere of nutraceutical markets, Brazil, China, and India have shown enormous promise among developed nations. China and India have established themselves as important sources of natural raw ingredients for these nutraceutical sectors. The global nutraceutical market was valued at over $250 billion in 2018. Nutraceutical foods were the largest market segment in 2007, with a value of 39.9 billion USD, rising to 56.7 billion USD by 2013 (Kakkar et al., 2016). While nutraceuticals supplements ranked second in market share in 2007, with 39 billion dollars, this figure has risen to almost 48.8 billion dollars in 2013. Beverages, which are classified as nutraceuticals, were worth 38.4 billion dollars in 2007 and 71.3 billion dollars in 2013. The market capitalization of nutraceuticals has risen year after year, reaching 285.2 billion dollars. Despite the

growing industry, nutraceuticals have increased the average life span of adults (over 60 years old) who had previously perished as a result of numerous lifestyle conditions. The Indian nutraceutical market has a market share of 4 billion dollars in 2015, and it is predicted to grow to roughly 10 billion dollars by 2022. The entry of ayurvedic products from various companies like Patanjali, AYUSH, Dabur etc. in the nutraceuticals market have been fueled the growth in the last couple of years (Espín et al., 2007).

Regulatory requirements for India entry

Because India's nutraceutical rules are still developing, some of the information may be contradictory or unclear. However, things must be streamlined in order for the Indian industry to take shape. Product evaluation, real product analysis, obtaining licencing, and establishing India-specific health and label claims are some of the most critical aspects to focus on in order to enter the Indian nutraceutical market. (Bhowmik et al., 2013)

1. Product evaluation: The classification of formulations in India is extremely complicated. As a result, precision in carving a specific amount for each ingredient and the mix of elements becomes extremely important. It is critical to analyse each active component and additive in the context of permissibility, standards, and amount of vitamins/minerals authorised as per the therapeutic, prophylactic, or recommended daily allowance for Indians in order to appraise a product according to Indian legislation.

The Central Government wants to implement a regulatory enforcement structure and procedures in the Food Safety and Standards Rules, 2011. The hierarchy starts with the commissioner of food safety and extends to a variety of officers such as designated officers, food safety officers, food analysts, and others who will be involved in the product analysis process at various stages.

Various steps in the product analysis include-

- Developing extracts of documents and authenticating the same by the concerned authority
- Sample collection (in the presence of witnesses)
- Sample dispatch to the concerned authority (different processes for bulk package and single package)
- Food analysis
- If analysis is not complete within the stipulated period of time, further action plan by the designated officer
- Adjudication proceedings (holding enquiry, appeal procedure, hearing, etc.)

2. Licenses: Though the new FSSA claims to make the licencing and registration of nutraceuticals easier, the actual process differs depending on a variety of factors. Depending on the actual product state, a number of licences (about 4 - 5) may be necessary to get a product registered in India. The food importer will be required to provide a number of documents to the government body, as well as registration application dossiers. Interlink provides regulatory support for various licencing procedures through its regulatory product line

- Import licensing
- Manufacturing licensing
- Marketing licensing

3. Health and label claims: While entering the Indian market, developing health and label claims that are relevant to Indian regulatory rules is a crucial factor to consider. Clients from all over the world, as well as those within the United States, have a variety of questions. About-

- India specific labelling and packaging requirements
- Packaging of the consignment composition of the consignment and approach to market the same
- Need for sample material and declaration for registration

- Label content and claim
- Structure-function claim Based on the regulatory assessment of the product, India-specific label content and claims needs to be developed. New entrant should also consider the requirements to be met, to make specific product claims.

CONCLUSION

In terms of growth, the nutraceutical industry is beating the food and pharmaceutical industries. The most successful nutraceutical companies in the future will most likely be those whose functional products are just one part of a bigger line of commodities that satisfy both conventional and health-related needs. Future nutraceutical demand will be determined by consumers' perceptions of the relationship between diet and diseaseAlthough nutraceuticals hold great promise in the promotion of human health and disease prevention, health professionals, nutritionists, and regulatory toxicologists should collaborate strategically to plan appropriate regulation that will provide mankind with the greatest health and therapeutic benefit. To scientifically confirm nutraceuticals in various medical diseases, long-term clinical research are required. Another topic that should be considered is the interaction of nutraceuticals with diet and medications. The impact of different processing methods on nutraceutical biological availability and effectiveness is still unknown. Nutraceuticals, like medicines, should be subject to strict regulatory oversight.

REFERENCES

Sohaimy, S. A. E. (2012). Functional food and Nutraceuticals-Modern Approach to Food Sciences. *World Applied Science Journal. 20*(5), 691-708.

Zhao, J. (2007). Nutraceuticals, Nutrition Therapy, Phytonutrients, and phytotherapy for improvement of human health: A perspective on plant biotechnology application. *Recent Pat Biotechnol. 1*, 75-97.

Prabu, S. L., Suriyaprakash, T. N., Kumar, C. D., & Kumar, S. S. (2012). Nutraceuticala and their medicinal importance. *Int J Health Applied Sci. 1*, 47-53.

Bieselsk, H. K. (2001). Nutraceuticals: the link between nutrition and medicine. In: Nutraceuticals in Health and Disease Prevention. *Marcel Deckker. 2*, 1–26.

Healthcare Packaging (2019). The global market for nutraceuticals is set for robust growth. Available:https://www.healthcarepackaging.com/markets/Nutraceuticals-functional/article/13296428/the-global-market-for-nutraceuticals-set-for-robust-growth. Retrieved 6 January 2020.

Gupta, S., & Chauhan, M. K. An Overview of Nutraceuticals:Current Scenario. *Journal of Basic and Clinical Pharmacy*. 1-14.

Takayuki, S. K., & Kazuki & Fereidoon, S. (2008). Functional Food and health. In the Proceedings of the ACS Symposium. 993.

Chanda, S., & Tiwari, R. K. (2019). Nutraceuticals Inspiring the Current Therapy for Lifestyle Diseases. Advances in Pharmacological and Pharmaceutical Sciences. 1-10.

Allen, L. V. (1997). Nutritional Products, In: Covington, T. R., Berardi, R. R., & Young, L. L. Editors. Handbook of Nonprescription Drugs. Washington DC: American Pharmaceutical Association.

Ehrlich, S. D. (2009). Peppermint (Mentha Piperita), Private Practice Specializing in Complementary and Alternative Medicine, Review, VeriMed Healthcare Network, Phoenix, AZ, USA.

Holzapfel, W. H., Haberer, P., Geisen, R., Bjorkroth, J., & Schillinger, U.

(2001). Taxonomy and important features of probiotic microorganisms in food and nutrition, *The American Journal of Clinical Nutrition. 73*(2), 365S–373S.

Casey, C. F., Slawson, D. C., & Neal, L. R. (2010). "Vitamin D supplementation in infants, children, and adolescents," *American Family Physician, 81*(6), 745–748.

Gosslau, A., & Chen, K. Y. (2004). Nutraceuticals, apoptosis, and disease prevention. *Nutrition. 20*(1), 95.

Shahidi, F. (2009). Nutraceuticals and functional foods: whole versus processed foods. *Trends in Food Science & Technology. 20*(9), 376-387.

Kalia, A. N. (2005). Textbook of industrial pharmacognosy. New Delhi: CBS Publisher and Distributor; 204-8.

Zhao, J. (2007). Nutraceuticals, Nutritional Therapy, Phytonutrients, and Phytotherapy for Improvement of Human Health: A Perspective on Plant Biotechnology Application, Bentham Science Publishers, Available from: http://www.benthamscience.com/biot/samples/biot1-1/Zhao.pdf.

Verma, G. (2016). *International Journal of Pharmacy & Therapeutics, 7*(4), 152-160.

Anwar, F., Latif, S., Ashraf, M., & Gilani, A. H. (2007). Moringa oleifera: a food plant with multiple medicinal uses. *Phytother Res, 21*(1), 17-25.

Verma, G. (2016). *International Journal of Pharmacy & Therapeutics, 7*(4), 152-160.

Avrelija, C. (2010). The Role of Functional Foods, Nutraceuticals, and Food Supplements in Intestinal Health, *Nutrients, 2,* 611-625.

Ajit, S. (2012). Nutraceuticals- critical supplement for building a healthy India, Ernst and Young, FICCI task force on nutraceuticals; 1-80.

Sarin, R., Sharma, M., Singh, R., & Kumar, S. (2012). Nutraceuticals; Review, *International Research Journal Pharmacy, 3*(4), 95-99.

Rajasekaran, A., Sivagnanam, G., & Xavier, R. (2008). Nutraceuticals as therapeutic agents: A Review. *Research J. Pharm. and Tech. 1*(4), 328-340.

Ajit, S. (2012). Nutraceuticals- critical supplement for building a healthy India, Ernst and Young, FICCI task force on nutraceuticals; 1-80.

Siddiqui, R. A. (2020). Nutraceuticals and Nutrition Supplements: Challenges and Opportunities. *Nutrients. 12*, 1593.

Chaudhari, S. P. & Powar, P. V. (2017). Nutraceuticals:A Review. *World Journal of Pharmacy and Pharmaceutical Sciences. 6*(8), 68-739.

Pushpangadan, P., George, V., Sreedevi, P., Bincy, A. J., & Anzar, S. (2004). Aswany Functional foods and nutraceuticals with special focus on mother and child care. *Annals of Phyto Medicine. 3*(1), 4-24.

Ahmad, M. F., Ashraf, S. A., Ahmad, F. A., Ansari, J. A., & Siddiquee, M. R. A. (2011). Nutraceutical market and its regulation. *Am J Food Technol. 6*(5), 342-34.

Kakkar, V., Modgill, N., & Kumar, M. (2016). From nutraceuticals to nanoceuticals. In Nanoscience in Food and Agriculture. Springer, *Cham. 3*, 183-198.

Espín, J. C., García-Conesa, M. T., & Tomás-Barberán, F. A. (2007). Nutraceuticals: facts and fiction. *Phytochemistry. 68*(22-24), 2986-3008.

Bhowmik, D., & Gopinath, H. (2013). Nutraceutical –A Bright Scope and Opportunity of Indian Healthcare Market. *The Pharma Innovation. 1*(11), 29-41.

Pariharm, S. & Sharma, D. (2021). Cynodondactylon: A Review of Pharmacological Activities. *Sch Acad J Pharm, Nov 10*(11), 183-189.

Pariharm, S., & Sharma, D. (2021). "Navagraha(Nine Planets) Plants: The Traditional Uses And The Therapeutic Potential Of Nine Sacred Plants of India That Symbolises Nine Planets", *International Journal of Research and Analytical Reviews, 8*(4), Page No pp. 96-108.

Chirania, A., & Sharma, D. (2021). Pharmacological Activity of Macrotyloma uniflorumA Review, *Int. J. Pharm. & Biomed. Rese. 8*(4), 1-5. DOI: http://dx.doi.org/10.18782/2394-3726.1115.

Sharma, D., & Gupta, S. (2018). Anticancer Activity of Crocus Sativus: A Review", *International Journal of Research and Analytical Reviews (IJRAR), 5*(4), Page No pp. 851-854.

Gupta, S., Kumar, S., & Sharma, D. (2018). "Ribes Fasciculatum: A Review of Pharmacological Activities", *International Journal of Research and Analytical Reviews, 5*(4), Page No pp.458-462.

Sharma, D., & Kosankar, V. K. (2018). Green Tea in Green World an updated review; *PharmaTutor; 6*(3), 9-16; http://dx.doi.org/10.29161/PT.v6.i3.2018.9