



## NUTRACEUTICALS: INNOVATIVE RESEARCH AREA

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### Abstract

*Nutraceuticals is a diverse product category with various synonyms used internationally. The term 'nutraceutical' has been part of the industry for almost a decade. Unfortunately, it still seems to be held up in a scrambled web of complementary definitions, regulatory watchdogs and consumer confusion. For an effective regulatory policy framework, nutraceuticals need to move from a blurred idea with varied and sometimes conflicting definitions, to a sharply defined and quantifiable concept. In an effort to clarify the definition of nutraceuticals, three general concepts that should be included in a definition have been identified based on the some important definitions from literature. This article briefly discusses about the basic information about the nutraceuticals, its importance and developments.*

### I. INTRODUCTION

The principle, “*Let food be thy medicine, and medicine be thy food*”, advocated by Hippocrates (460–377 BC), the well recognized father of modern medicine, emphasize the association between nutrition and human health, and conceptualized the relationship between the use of appropriate foods for health and their therapeutic benefits.

The role of dietary active compounds in human nutrition is one of the most important areas of investigation with the findings having wide-ranging implications for consumers, health care providers, regulators, food producers, processors and distributors. Thus, the concept of ‘adequate nutrition’ is beginning to be replaced by ‘optimal nutrition’ with consumer belief increasing at an unprecedented pace.

The term “nutraceutical” combines the word “nutrient” (a nourishing food or food component) with “pharmaceutical” (a medical drug).. The term nutraceutical was coined in 1989 by **Stephen Defelice**, founder and chairman of foundation for innovation in medicine, an American organization which encourages medical health. According to him “a nutraceutical is any substance that is a food or a part of food and provides medical or health benefits, including the prevention and treatment of disease”. These include isolated nutrients dietary supplements and specific diets to genetically engineered designer food and herbal products.

The concept of nutraceutical was started from the survey in UK, Germany and France. However the term nutraceutical commonly used in market has no regulatory definition.

### II. NUTRACEUTICALS

Health ministry of Canada which defines Nutraceuticals as “ a product isolated or purified from the food generally sold in medicinal form not associated with food and demonstrated to have a physiological benefit and provide protection against chronological disease <sup>1</sup>.

Nutraceutical is a broad umbrella term. Nutraceuticals are food or food ingredients that provide medical or health benefits. The merging class of products blurs the line between food and medicine (Rishi, 2006).

Nutraceuticals may contain substances that are “natural” expressed intent of treatment or prevention of disease but may not be generally recognized as safe (Ross, 2000).

### **Categories of Nutraceuticals**

Nutraceuticals are non-specific biological therapies used to promote wellness, prevent malignant processes and control symptoms.

According to Hathcock (2001), the following are the categories of nutraceuticals.

- a) **Nutrients** - A constituent in a form and at a level that will help support the life of an animal. The chief classes of nutrients are proteins, fats, carbohydrates, minerals and vitamins and amino acids.
- b) **Dietary Supplement**- A product that contains one or more of the following dietary ingredients: vitamin, mineral, herb or other botanical, amino acid (protein) and also includes the diet as concentrates, constituents, extracts or metabolites of these compounds. It also includes the reagents derived from other sources (pyruvate, chondroitin sulphate, steroid hormone precursors) serving specific functions such as sports nutrition, weight-loss supplements and meal replacements.
- c) **Herbals**- Herbs or botanical products as concentrates and extracts. Herbals are as old as human civilization and they provide a complete storehouse of remedies to cure acute and chronic diseases. India has the oldest written tradition for the nature’s remedies called ‘Auyrveda’ which posses many effective means of ensuring health care. Numerous nutraceuticals are present in medicinal herbs of key components.

### **III. NUTRACEUTICALS AND FUNCTIONAL FOODS**

Today the exploration and exploitation of the disease fighting properties of a multitude of phytochemicals found in both food and nonfood plants have created a renaissance in human health and nutrition research. At the same time, many opportunities for the development of novel dietary products have been created. With all new fields of study come new terms. "*Nutraceuticals*" and "*functional foods*" are two new terms used to describe health-promoting foods or their extracted components.

In simple manner, Nutraceuticals are healthful products that are formulated and taken in dosage form (capsules, tinctures, or tablets). *Functional foods*, are products that are consumed as foods and not in dosage form.

In most of the developed countries, all functional foods must meet established requirements: they are:

- Prevent in their naturally occurring form, rather than a capsule, tablet or powder.
- Consumed in the diet as often as daily and
- Should regulate a biological process in hopes of controlling or preventing diseases.

Functional foods have been either enriched or fortified, a process called nutrification. This practice restores the nutrient content in a food back to similar levels from before the food was processed.

According to Kalra (2003) When food is being cooked or prepared using "scientific intelligence" with or without knowledge of how or why it is being used, the food is called "*functional food*". Thus, *functional food* provides the body with the required amount of vitamins, survival. When functional food aids in the prevention and treatment of disease and disorder other than anemia, it is called a nutraceuticals

Nutraceuticals is demonstrated to have a physiological benefit or provide protection against chronic disease, while the functional foods are defined broadly as foods that provide more than simple nutrition; they supply additional physiological benefit to the consumer. (Peter, 2002).

## **Nutraceuticals and Health**

Nutraceuticals are currently receiving recognition as being beneficial in coronary heart disease, obesity, diabetes, cancer, osteoporosis and other chronic and degenerative diseases such as Parkinson's and Alzheimer's diseases. Evidences indicate that the mechanistic actions of natural compounds involve a wide array of biological processes, including activation of antioxidant defenses, signal transduction pathways etc. It appears that these properties play a crucial role in the protection against the pathologies of numerous age-related or chronic disease. It is very imperative that the nutrients found in many foods, fruits and vegetables are responsible for the well documented health benefits.

### **1) Cardiovascular Diseases**

Worldwide, the burdens of chronic diseases like cardiovascular diseases, cancers, diabetes and obesity is rapidly increasing. In 2001, chronic diseases contributed approximately 59% of the 56.5 million total reported deaths in the world and 46% of the global burden of disease. Cardiovascular diseases (CVD) is the name for the group of disorders of the heart and blood vessels and include hypertension (high blood pressure), coronary heart disease (heart attack), cerebrovascular disease (stroke), heart failure, peripheral vascular disease, etc.

*Temple and Gladwin* (2003) noted that low intake of fruits and vegetables is associated with a high mortality in cardiovascular disease. Many research have identified majority of the CVD are preventable and controllable.

Nutraceuticals in the form of antioxidants, dietary fibers, omega-3 polyunsaturated fatty acids (n-3 PUFAs), vitamins, and minerals are recommended together with physical exercise for prevention and treatment of CVD.

Flavanoids in plants available as flavones (containing the flavonoid apigenin found in chamomile); flavanones (hesperidins - citrus fruits); flavonols (tea: quercetin, kaempferol and rutin) play a major role in curing the cardiovascular diseases.

*Majoa et al.*, (2005) reported that flavonoids protect the vascular system and strengthen the tiny capillaries that carry oxygen and essential nutrients to all cells.

Diet with inclusion of fruits and vegetables helps to reduce these diseases which occurs due to metabolism and lifestyle. Role of nutraceuticals in other diseases will be given in the proceeding part.

### **2) Diabetes**

Diabetes mellitus is characterized by abnormally high levels of blood glucose, either due to insufficient insulin production, or due to its ineffectiveness. Globally the total number of people with diabetes is projected to raise from 171 million in 2000 to 366 million in 2030 (*Wild et al.*, 2004).

*Baljit* (2007) noted that dietary fibers from psyllium have been used extensively both as pharmacological supplements, food ingredients, in processed food to aid weight reduction, for glucose control in diabetic patients and to reduce lipid levels in hyperlipidemia.

*Coleman et al.*, (2001) reported that Germans uses Lipoic acid (universal antioxidant) for treating diabetic neuropathy, as it is more effective long term dietary supplement for the prophylactic protection of diabetics from complications.

At last, *McCarthy* (2005) suggested that nutraceuticals with meaningful doses of combinations may substantially prevent and presumably could be marketed legally.

The above mentioned were the two common diseases prevailed, in these also nutraceuticals play a major role in preventing.

### **3) Obesity**

Obesity is one of the major lifestyle problems prevailing in developed and developing countries. Obesity is a complex condition, with serious social and psychological dimensions, affecting virtually all ages and socioeconomic groups.

Obesity occurs mainly due to lack of exercise and binge/over eating. In terms of energy, obesity arises due to an energy imbalance, it means energy intake exceed the energy expenditure. It is now commonly seen in adolescent children especially girls. Obesity leads to serious illness in future ie, it becomes the base for many life threatening diseases.

Hil and Peters (2002) suggested that developing functional foods for weight management may be a more attractive approach for dealing with the 61% of the population who are overweight or obese.

Kasbia, (2005) opined that nutraceuticals like conjugated linoleic acid (CLA), capsaicin, Momordica Charantia (MC), and Psyllium fiber possess potential antiobese properties. These will be suitable nutraceutical for obesity.

A study conducted by Wood gate and Conquer (2003) found that a blend of glucomannan, chitosan, fenugreek, G Sylvester, and vitamin C in the dietary supplement significantly reduced body weight and promoted fat loss in obese individuals.

The above three were the common problems/diseases in which nutraceuticals have effective role. These are the problems which occur to any age groups. Lets have a look at the old age.

### **Nutraceuticals and Geriatrics.**

Geriatrics is the term used for the category of old people. Old age is accompanied by many disorders physically, sociologically etc .The main disorders seen during old ages are muscles weakness and neuro related problems. Nutraceuticals contain herbs also. As old people are so trustful on these, nutraceuticals with herbs will more accept by these people. Nutraceuticals have a bigger role in alleviating the old age disorders.

Charu and Dhan (2015) suggested some nutrient/extracts such as antioxidants, plant polyphenols and catechins, carotenoids: lutene, plant stanols and sterols, B vitamins, Calcium and Vitamin D, omega-3 fatty acids, collagen, dietary fiber, prebiotics and probiotics, potassium, whey protein, zinc and coenzyme Q10.

#### **a) Alzheimer's Diseases**

Alzheimer's disease (AD), also called senile dementia of the Alzheimer type (SDAT), primary degenerative dementia of the Alzheimer's type (PDDAT), or simply Alzheimer's, is the most common form of dementia. The various nutraceuticals which are used to cure Alzheimer's disease is as follow:-

#### **b) Antioxidants**

A prominent theory of aging and chronic disease has been the free radical theory, in which a lifelong accumulation of cellular damage due to free radicals leads to an increased risk of disease and disability.

Antioxidants are very essential in the treatment of almost all diseases because most chronic diseases carry with them a great pact of oxidative stress. Oxidative stress plays a main role in neurodegenerative diseases such as Alzheimer's disease (AD), Parkinson's disease (PD), and Huntington's disease (HD).

A huge number of studies have found an association between high dietary antioxidant intake and a decreased risk of AD which is very imperative because preventing a disease is significantly easier than treating it.

Antioxidants act as peroxide decomposers (vitamin E), enzyme inhibitors, oxygen quenchers (vitamin E), and metal-chelating agents (transferritin).

Prakash and Gupta (2014) noted that enzymatic and non enzymatic antioxidants are able to detoxify free radical produced during intracellular and extracellular metabolism and also to ensure maximum intracellular protection, antioxidants are compartmentalized throughout the cell.

Raw fresh fruits and vegetables are of more importance than cooked, because of their high concentration and maximum absorption of antioxidants. Further researches are going on to identify the relationship between antioxidants and prevention of some diseases, such as cardiovascular disease and cancer.

The above discussed were important health aspects of nutraceuticals. Nutraceuticals play a key role in almost every diseases.

#### **IV. RESEARCH AND DEVELOPMENTS IN NUTRACEUTICALS**

Research is one of common process going in every field, its main purpose is to identify/develop a new process/product or to identify how the process/product have role in particular field. In food industry or medicinal industry, the primary aspect will be the standardisation of ingredients/processes related to this. So in nutaceuticals also researches are carrying out each day, as it is a tremendously progressing field and also its role on health. Developed countries are commonly carrying out researches in this field.

The greatest scientific need in nutraceuticals pertains to standardization of compounds and/or products, to carefully develop and execute clinical studies/trials to provide the basis for health claims for nutraceuticals that impact consumers as well as companies making strategic investments.

#### **Powerful market forces are fueling the interest in nutraceuticals:**

- Rapid advances in scientific knowledge supporting the vital role of diet in health and disease prevention.
- Skyrocketing health care costs.
- An aging population.
- Technical advances in the food industry that are allowing the development of health promoting foods that can be marketed to health-conscious consumers at a premium.
- The changing regulatory environment (Manisha *et al.*, 2010).

**Prasad *et al.*, (2012) stated the importance of research and development in nutraceuticals. They are:**

1. To test the safety, potency and purity of products.
2. To develop more effective and means of producing ingredients for use in products.
3. To develop testing methods for ensuring the consistency of the dosage of ingredients included in the company's products.
4. Develop the new products either by combining the existing ingredients used in nutritional supplements or identifying new ingredients that can be used in nutritional supplements.

Lakshmana *et al.*, (2012) noted that current research is focused on traditional herbal extracts. Investigators are more interested on examining claims linking these extracts with health enhancement



and prevention of chronic diseases. Additionally, it seeks to provide patients and physicians with much-needed safety and efficacy data.

### **Safety**

Safety of a nutraceutical product is easier to establish. Many nutraceuticals were used as alternative for both nutrition and medicine. Many manufactures make illegal claims without proper data to support their products safety and efficacy. Consumers need assurance that a product is safe and able to do what it says it does. Nutraceuticals should be safe for use as it is used for treating diseases.

### **Regulatory Aspects of Nutraceuticals**

Regulations/laws related to every minute particle in the world are compulsory. Imposition of regulations on certain items especially medicine and food (two things for sustaining life) are compulsory. According to these certain regulations only manufacturers are able to market their products. Another important aspect of regulations reflects on the labeling of the product. Nutritional labeling reveals the each and every aspect related to the product. Labeling reveals the safety of consuming the product. The regulations imposed will definitely vary among different countries.

Nutraceuticals have no official meaning and do not constitute a distinct category of foods; simply they are natural, consumers have been eating whole foods for thousands of years. As a result, the FDA regulates them in the same way they regulate all foods: The safety of ingredients must be assured in advance, and all claims must be substantiated, truthful and non misleading

Labeling, and strict control over formulations and branding are still not required for most products. Health claims on nutraceuticals serve to alert consumers as part of an overall healthy diet, which may reduce the risk of certain diseases.

Food manufacturers may use health claims to market their products, by providing information on healthful eating patterns that helps to reduce the risk of heart disease, cancer, osteoporosis, high blood pressure, dental cavities or certain birth defects. Health claims are different from structure/function claims, which also may appear on conventional food or dietary supplement labels.

Many academic, scientific and regulatory organizations are considering ways to establish the scientific basis to support claims (other than health claims) for the functional components of nutraceuticals. These are the five types of health-related statements allowed on food and dietary supplement labels:

- Nutrient-content claims indicate the presence of a specific nutrient at a certain level.
- Structure and function claims describe the effect of dietary components on the normal structure or function of the body.
- Dietary-guidance claims describe the health benefits of broad categories of foods.
- Qualified health claims convey a relationship between components in the diet and risk of disease, as approved by the FDA and supported by the weight of credible scientific evidence available.
- Health claims confirm a relationship between components in the diet and risk of disease or health condition, as approved by FDA and supported by significant scientific agreement.

The above said general health related informations should be available on every nutraceuticals. Label is the only source for the consumers to get correct information regarding the product. Misguidance through label is cheating to consumers.

The Food and Drugs administration of countries like The United States of America, Canada, European Union, China, and India have strict regulations on food and drugs in terms of manufacturing, servicing, marketing, and usage, but not having a complete regulation.

Despite the international movement within the industry, professional organizations, academia and health regulatory agencies add specific legal and scientific criterion to the definition and standards for nutraceuticals, within the United States the term is not regulated by FDA.

The detailed regulations on nutraceuticals, phytonutriton or phytotherapy, or nutritional therapy are carried out in consultation with experts who are able to identify the regulatory hurdles for these products and practices such as Good Manufacturing Practice (GMP) compliance, Generally recognized as safe (GRAS) status, analytical methods and its validation.

### **Indian Regulatory Aspects**

Foods for special dietary use are specifically processed or formulated to satisfy particular dietary requirements, which exist because of a physical or physiological condition or specific disease and disorder. These are presented as such where in the compositions of these foodstuffs must differ significantly from the Indian Standard (IS) composition of ordinary foods of comparable nature.

For decades, FDA regulated dietary supplements as foods to ensure that they were safe and that their labeling was truthful and not misleading. In 2006, the Indian government passed Food Safety and Standard Act to integrate and streamline the many regulations covering nutraceuticals, foods and dietary supplements. The Indian definition (as per Food Safety and Security Act passed in 2006) yet to implement.

### **Benefits of Regulations**

1. Allows greater legal security and more predicable environment.
2. Supports innovation (food and drink products).
3. Prevents unfair competition from manufactures using false or misleading claims.
4. If positive claims cannot be made, the regulation does not oblige anyone to make negative claims about the product. (Madhavan and Synal, 2005).

## **V. MARKETING TRENDS**

The functional beverages markets in India is relatively nascent at 24%. Indian nutraceuticals market in 2008, is estimated at USD 1.0 billion. Of these the functional foods markets is the largest with 54% market share followed closely by the dietary supplements markets which has a 32% market share. The functional foods and beverages categories consisting of nutrition fortified foods, sports and energy drinks, fortified juices and probiotic foods are growing faster, distribution occurs through FMCG channels as well as mass marketing.

The demand for nutraceutical ingredients has increased from 5.8% annually to \$ 15.5 billion. China and India are the fastest growing nutraceutical markets. Herbal and non-herbal extracts are used worldwide and widely used by medical professionals and increased from 6.5% annually to \$1.85 billion in 2010. Global demand for nutraceutical vitamin ingredients increased up to 4.6% annually to \$4.2 billion in 2010

Major companies marketing nutraceutical companies in India are GlaxoSmithKline consumer health care, Dabur India, Cadila Health Care EID parry's, Zandu pharmaceuticals, Himalaya Herbal Health Care, Amway, Sami labs, Elder Pharmaceuticals and Ranbaxy.

The Indian nutraceutical market is primarily dominated by pharmaceuticals and FMCG companies with very few pure play nutraceutical companies. Pharmaceuticals and FMCG players active in the nutraceutical space have diversified by introducing product extensions and developing variants under existing brand names. Many new players have announced aggressive investment plans (The Hindu, 2002).

According to Parasuram *et al.*, (2011) causes for the tremendous emergence of nutraceuticals market were :

- Dissatisfaction of consumers with high cost of drugs and conventional systems of health care are turning to unproven and untested natural product for treatment and prevention.
- Poor therapeutic alternatives for chronic diseases.
- Desire for personalized medicines.
- New focus on preventing medicines.
- Public perception that “ Natural is good”
- Use of nutraceuticals before long runs and routinely during a season of training may reduce the incidence of effusions, leading to less training days loss to swollen joints.
- Preparations that enhance meniscal healing, especially after surgical repair are sure to developed as the meniscus is the main protector of the knee joints.
- More than 40% of the Americans use alternative medical therapies, nutraceuticals account for major populations.

With the above reasons the nutraceuticals become the very fast developing market sector. Nutraceutical market is tremendously increasing day by day. This plays an important role in the maintenance of human health. Many researches are going day by day to identify new aspects in this field and how it can be used for human health.

## **VI. CURRENT SCENARIO OF NUTRACEUTICALS**

Ratnaparkhi *et al* (2015) noted that The Indian nutraceutical market valued at \$ 1,480 million in 2011. As per the statistical findings of report by Transparency Market Research (TMR), the international nutraceuticals market is prophesied to take home US\$278.96 bn by 2021 from US\$198.66 in 2016.

According to the report by business research and consulting firm, functional foods will be the quickest growing category followed by dietary supplements until 2015. However, dietary supplements specifically herbal and dietetic supplements will form the greatest opportunity areas for nutraceutical manufacturers that at present dietary supplements were the largest category accounting for 64 per cent of nutraceuticals market.

As per the study the global nutraceutical market was estimated to be \$ 149.5 billion in 2011 with US, Europe and Japan being the largest regional markets, accounting for nearly 93 per cent of the global nutraceutical demand. As these markets bears high per capita on nutraceutical products, nutraceutical manufacturers are looking at developing countries such as India and China as key growth regions to establish new areas of marketing and further developments.

Currently the Indian market is trying to incorporate traditional herbal ingredients (usually ayurvedic) into the nutraceutical portfolio. Key example is the chyawanprash supplements. The existence of alternative medicine in India, and the Indian consumer’s belief in them, could provide a platform for the nutraceutical industry to capitalize on.

### **Future of Nutraceuticals**

Increasing awareness levels about fitness and health, through media (now a days social medias also) are prompting the majority of people to lead healthier lifestyles, exercise more, and eat healthy. The expanding nutraceutical market indicates that users are more seeking minimally processed food with extra nutritional benefits and organoleptic value. Global nutraceutical markets are expanding very fastly. The emerging nutraceuticals industry seems to occupy the landscape in the new millennium. Its



tremendous growth has implications for the food, pharmaceutical, healthcare, and agricultural industries (Jim, 2002).

According to Jim (2002), Some incidence which probably occurs in the future are:

- Enzymes are another exciting frontier in the nutraceuticals. They are not much employed in this field. They are going to be hot area in the future.

Fermentation technology using microbes, for food developments becomes potential in the future.

Lutein and lycopene are the two most important carotenoid pigment. Lutein have role in age related disorders. Lutein has additional scientific support with regard to protective benefits against lung cancer, breast cancer and cervical cancer in women. Lycopene offers tremendous nutraceuticals properties.

Future use of nutraceuticals in these areas is exciting and opens an opportunity for extensive study of efficacy. There is an enormous concern for health care cost and the the impact.

## VII. CONCLUSION

The nutraceutical industry is growing at a rate far exceeding expansion in the food and pharmaceutical industries. In tomorrow's market, the most successful nutraceutical markets are likely to be those companies in which functional product are just a part of a broad line of goods satisfying both conventional and health value point. Future demand of nutraceutical depends on consumer perception of the relationship between diet and disease. A place for nutraceuticals in clinical practice is emerging, but important pharmaceutical and clinical issues need to be addressed by further research. When any new participant wants to enter the Indian nutraceutical market, it is very important to comply with the regulatory framework, so that the business run smoothly.

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