PHARMACOPOEIAL SPECIFICATIONS FOR DIETARY SUPPLEMENTS AND NUTRACEUTICALS

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ABSTRACT

The United States Pharmacopoeia Convention (USP) has decided to have a separate panel of nutritionists and partner with the Indian scientific community to develop safety standards for the entire range of dietary and nutritional supplements currently not under strict control of any drug. or diet.Nutraceutical is a mixture of nutritious foods and medicines. Nutraceuticals are usually foods or food components that play a key role in conversion and preservation of the normal function of life that keeps people healthy. Dietary supplements For athletes to train hard Nutritional supplements are often seen as promoting flexibility in training, allowing for consistent and in-depth training by promoting recovery during training sessions,,reducing training disruption due to illness or injury, and improving competitive performance.Nutraceuticals is a fledgling industry in the Pharma industry. As people are more and more concerned about their health and diseases caused by malnutrition, the growth of the Nutraceuticals worldwide are inevitable. This article aims to provide the knowledge of pharmacopoeial specifications for Dietary supplements And Nutraceuticals.

Keywords: Dietary supplements, Nutrition, Nutraceuticals, Dietary fibre, food supplements.

INTRODUCTION

Dietary Supplements

Food Ingredients In the United States, food additives are defined as products (otherwise tobacco) intended to add to foods containing at least the following ingredients:
vitamins, minerals, herbs or botanicals (including herbal extracts or botanicals), amino acids, metabolite, any combination thereof. [1]

Nutraceuticals

The term 'nutraceutical' was coined from 'nutrition' and 'medicine' in 1989 by DeFelice and was originally defined as a diet (or part of a diet) that provides medical or health benefits, including prevention and treatment of diseases (Kalra EK, 2003).
Nutraceutical can be a naturally occurring nutrient such as spirulina, garlic, soy or a portion of foods such as omega-3 fats from salmon.They are also known as medical foods, nutritional supplements and dietary supplements.[2],[3]

Dietary supplements

Dietary supplements, such as the vitamin B supplement shown above, are usually sold in pill form. Dietary supplement is a product that contains nutrients found in liquid-based food products or capsule form. In the US,The Dietary Supplement Health and Education Act (DSHEA) of 1994 defined the term: "Dietary supplement is an oral product that contains" a dietary supplement intended to supplement the diet. "Dietary supplements" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glands, and metabolites. Dietary supplements can also be extracts or concentrated, and can be obtained in many ways such as pills, tablets, softgels, gelcaps, liquids, or powders. Dietary supplements do not need to be approved by the U.S. Food and Drug Administration (FDA) before marketing, but companies must register their production facilities with the FDA. With the exception of a few well-defined items,supplements can only be advertised to support body composition or function, and should not claim to cure a disease or condition, and should include the label:"These statements have not been finalized. by the Food and Drug Administration. This product is not intended to diagnose, cure or prevent any disease. "It achieves this goal through efficiency of such nutraceuticals in eliminating toxins in the body, avoiding vitamin and mineral deficiencies, and restoring healthy digestion and eating habits Combined on a regular basis

I. Chemical Constituents

a. Nutrients
b. Herbals

c. Phytochemicals

Phytochemicals are basically plant components that have specific biological functions in supporting human health, which function as follows.
1. Substrate for biochemical reactions.
2. Cofactors of enzymatic reactions.
3. Inhibitors of enzymatic reactions.
4. Absorbents bind and remove unwanted nutrients in the intestines.
5. Increase absorption and / or stability of essential nutrients.
6. Selective growth factor for beneficial bacteria.
7. Fermentation substrate for beneficial bacteria.
8. Selective inhibitors of deleterious intestinal bacteria.
9. Scavengers of reactive or toxic chemicals.
10. Muscles that irritate or antagonize cell space or intracellular receptors. [3]

II. Probiotic Microorganisms

They act to crowd out pathogens, such as yeasts, other bacteria and viruses that may otherwise cause disease and develop a mutually advantageous symbiosis with the human gastrointestinal tract. They have antimicrobial effect by altering the microflora, preventing bacterial attachment to the intestinal epithelium, competing with the elements needed for survival pathogen, producing antitoxin effect and reversing some of the effects of intestinal epithelium infections, such as secretory and neutrophil mutations. migration. Probiotics can treat lactose intolerance by producing a specific enzyme (ß-galactosidase) that can release lactose intolerance.

In the selection of probiotics options one should consider safety, functional and technical aspects as follows: Demonstrate potential health benefits.
• Probiotics should be of human origin.
• Generally gram positive organisms.
• It can survive after passing acid and gallstones.
• It can attach to human intestinal cells and grow in the intestines.
• May show antagonist action against pathogenic or carcinogenic bacteria.
• Proven health benefits proven clinically. [4]

III. Nutraceutical Enzymes

Enzymes are an essential part of life, without which our bodies would cease to function. Those people who are suffering from medical conditions such as hypoglycemia, blood sugar disorders, digestive problems and obesity, eliminate the symptoms by enzyme supplements to their diet.These enzymes are found in the sources of bacteria, plants and animals.

IV. Prebiotics

"Prebiotics" are a more recent addition to our vocabulary and are substances which when consumed are not digested by us. Instead, they act as a source of nutrients for good probiotic bacteria.This encourages the probiotic bacteria to grow in a favourable environment, which in turn reduces the chances that harmful microorganisms may start to grow in our digestive tract.Insulin is the most widely used prebiotic in digested foods. Essentially, it is a type of fibre obtained from the roots of plants such as chicory, Jerusalem artichoke, and even dandelions.[5]

Nutraceuticals

Classification of Nutraceuticals

Food sources used as nutraceuticals are all natural and can be classified as

1. Dietary Fiber
2. Probiotics
3. Prebiotics
4. Polyunsaturated fatty acids
5. Antioxidant vitamin

1. Dietary fibre

Dietary fiber (DF) contains undigested carbohydrates and lignin that is internal and strong in plants. Functional fiber (FF) contains isolated, Unprocessed carbohydrates have beneficial physiological effects on humans as shown in. Complete fiberis the sum of dietary and functional fiber. These definitions increase the phase and allow starch-resistant starch, oligosaccharides and other non-digestible carbohydrates to be included in the active fiber phase. Adequate dietary intake defined by Dietary Reference Intake (DRI) is 38 grams / day for adult males and 25 grams / day for adult females. There was not enough evidence to set a high tolerable level of dietary or functional fiber. The probiotics are living bacteria and yeasts that are good for your health, especially your digestive system. We often think of bacteria as the cause of disease. But your body is full of germs, good and bad. Probiotics are often called "good" or "useful" germs because they help keep your gut healthy. Probiotics are naturally found in your body. You can also find them in other foods and supplements. It has been around since the mid-1990s when people wanted to know more about probiotics and their health benefits. Doctors often suggest that they help with digestive problems. And because of their new popularity, you can find them in everything from yoghurt to chocolate.

2. Lactobacillus (probiotic.)

This may be the most common probiotic. This is the one you will find in yoghurt and other cooked foods. Different types can help with diarrhea and can help people who are unable to digest lactose, sugar in milk. Bifidobacterium can be found in other dairy products. It may help to reduce the symptoms of Irritable Bowel Syndrome (IBS) and other conditions.Probiotics help move food

through your gut. Researchers are still trying to determine which ones are best for certain health problems.
Some common conditions they treat are:

• Inflammatory bowel disease (IBD)
• Infectious diarrhea (caused by germs, germs, or parasites)
• Antibiotic-related diarrhea
• There are also studies that show that they help with problems in other parts of your body.
For example, some people claim to help with:
• Skin conditions, like eczema
• Urinary and vaginal health
• Preventing allergies and colds
• Oral health

3. Prebiotics

are substances that induce the growth or activity of microorganisms (e.g.,bacteria and fungi) that contribute to the well-being of their host.The most common example is in the intestinal tract, where prebiotics can alter the biological structure of the gut microbiome. However, in principle it is a more general term that can refer to other areas of the body as well. For example, certain hand moisturisers have been proposed to act like prebiotics to improve the activity or composition of skin microbiota (Patrick L et al., 2014). In diet, prebiotics are typically non- digestible, fiber compounds pass unchecked to the upper part of the gastrointestinal tract and promote the growth or function of beneficial bacteria that accumulate large intestines by acting as their substrate (Gibson GR et al., 1991). As part of an active diet, prebiotics, like probiotics, are mentally intermediate between diet and drugs. Depending on the area, they usually receive a moderate level of control tests, especially health claims made about them. Although all fiber prebiotics, not all fiber is prebiotic
The classification of a food ingredient as a prebiotic requires scientific demonstration that the ingredient (Jacob RA, 1995):
● Resists gastric acidity,hydrolysis by mammalian
● enzymes and absorption in the upper gastrointestinal tract
● Is fermented by the intestinal microflora
• Promotes selective growth and / or function
• intestinal bacteria that may be associated with health and wellness.

Health benefit of prebiotics

Data on the health effect of prebiotic diets are much more limited than dietary fiber. However,it has been suggested that prebiotic intake may:
• Reduce the spread and duration of antibiotic-associated diarrhea;
• Reduce inflammation and symptoms associated with tuberculosis;
• Have protective effects to prevent bowel cancer;

• Improving bioavailability and absorption of minerals, including calcium, magnesium, and possibly iron
• Lower some risk factors for cardiovascular disease
• Improve satiety and weight loss and prevent obesity. [6]

4.Polyunsaturated fatty acids

The group of poly-unsaturated fatty acids (PUFAs) is divided into two groups: omega-3 (n-3) and omega-6 (n-6) polyunsaturated fatty acids (PUFA), which differ in the area where for the first time double C.-bound is found. Two PUFAs are called fatty acids which are important because they cannot be synthesized in the human body and are essential for body integrity. Therefore, it should be found in food. Another linoleic acid (LA) also belongs to the n-6 family. Another α-linolenic acid (LNA) of the n-3 family. These essential parent compounds can be converted into the human body into long-chain acids (LC) but humans cannot convert n-3 and n-6 fatty acids.

5.Antioxidants

Damage to cells caused by free radicals is believed to play a key role in the aging process and in advancing disease. Antioxidants are our first line of defense against free radicals, and are essential for maintaining good health and well-being. Oxygen is a highly active atom that can be part of potentially harmful molecules commonly called "free radicals." Free radicals can invade healthy body cells, causing them to lose their structure and function. Antioxidants are able to stabilize, or block, free radicals before they attack cells. Antioxidants are essential for maintaining the cellular and systemic health and well-being. Humans have developed an extremely complex and complex antioxidant defense system. It includes a variety of components, both non-permanent and exogenous, that work collaboratively and synergistically to reduce free radicals (Liu LI et al., 2009). [7]

These components include:
• Nutrient-derived antioxidants like ascorbic acid
• (vitamin C), tocopherols and tocotrienols (vitamin E).
• carotenoids, and other compounds that are low in molecular weight
• such as glutathione and lipoic acid.
• Antioxidant enzymes, such as superoxide dismutase.
• glutathione peroxidase, and glutathione reductase
• catalyze free radical quenching reactions.
• Metal binding proteins, such as ferritin, lactoferrin.
• albumin, and ceruloplasmin sequester free iron, copper ions can cause oxidative reactions.
• Many other antioxidant phytonutrients are found in a variety of plant foods. [8]

Dietary Antioxidants
A. Vitamin C
B. Vitamin E

C. Beta carotene and other carotenoids

RATIONAL AND OBJECTIVE

Pharmacopoeial Specifications For Dietary Supplements And Nutraceuticals: The United States Pharmacopoeia Convention (USP) has decided to have a separate panel of nutritionists and partner with the Indian scientific community to develop safety standards for the entire range of dietary and nutritional supplements currently not under the strict control of any drug. or food. Domestic and international companies are competing for a position in the Indian 500 million food market, growing at 40% per year. The Central Food Technological Research Institute, Mysore, will be the largest USP-affiliated institution in this regard. The United States and Europe will be emerging markets for nutraceutical sales from India because of the large market base that already exists and consumers are looking for better and healthier options to prevent lifestyle-related diseases. The market power of the United States and European markets alone nutraceutical exports from India in 2013 will be $ 90 billion. Companies such as Amway India and Herbalife use high-level direct marketing to achieve innovation Although the Food Safety Act and the General Law 2006 define effective food / nutrition treatment, there are still other applicable laws; Appropriate guidelines and procedures are needed to gain momentum for effective national use. However, there is a need to clarify 0 and create a regulatory framework. If enforcement is effective in enforcing the Food Security Act and the General Law there is an opportunity to create greater opportunities in the active food or nutrition industry. grab a big pie at this global opportunity, Indian producers of nutritious products should come together to build a India marketing platform as a brand. There is a need for more cooperation in the field of production and research and development among Indian manufacturers. There should be communication between all parties, including policy makers, regulators, and producers.

Production, validation, research and development, and protection of intellectual property must be the same. There should be an extension of Indian standards such as Indian Pharmacopoeia so that the production of effective food / medicine can comply with your safety and quality standards. The Indian government still has to amend its laws regarding nutritional labeling like the U.S. Nutrition Labeling Education Act 1990 so that consumers are aware of the safe and healthy facts about active food / nutrition items. Collaborative efforts by government and the private sector on suitable law and assistance from food scientists indicate that there are many potential for processed foods in India in the future. there should be new marketing programs, increased validation and medical research, increased awareness due to media and government focus and greater corporate responsibility due to health awareness programs and new marketing and communication strategies, new research and development and product development skills. The passing of the Food Security Act and the General Law of 2006 was an important first step but much needed to be done to end the accumulation of old laws and regulations. Prior to FSSA, there were a number of laws and regulations governing food safety and standards. Nutraceuticals Collected Under PFA These standards will include details of ingredients, contaminants, pesticides, biological hazards, labels, and more. Everyone in the food industry is required to obtain a license or registration to be issued by the local authorities. Temporary shop owners are exempt from any license or registration that the Act will apply through state food safety commissions and local level officials. The law

empowers FSSAI and government food safety authorities to monitor and regulate food business operators. The food security commission of each state appoints a designated (DO) officer, who is not less than the level of a sub-district official, for a particular district. His duties include issuing or canceling licenses, preventing the sale of food items that violate certain standards, receiving reports and Offenses such as producing, selling, storing, or importing substandard or illegal food may result in fines. Offenses such as producing, distributing, selling, or importing unsafe food, resulting in injury, could result in a prison sentence. The penalty could be imprisonment if the offense causes death. Small-scale food producers, retailers, and temporary or retailers can be fined up to Rs 25000 if they violate the stated standards.

Food was classified as certified or patented. Later in 2006, all existing laws were consolidated into one law to ensure systematic and scientific advancement in the food processing industry.

Foods are classified under the following heads:
Food is categorized under the following headings:

- Novelic foods
- Organic foods
- Normal foods
- Foods used in special diets Active / nutritious foods / health ingredients.

The Food Safety and Standards Regulations 2011 promulgated in the Indian Gazette came into effect on August 5, 2011, to regulate the production, distribution, and sale of nutrients, active foods, and food additives in India [9]

Conclusions

The use of supplements is widespread in sports, although many of the ingredients used are almost ineffective. Athletes who take supplements should do so only after doing a careful cost analysis. Although these ingredients are often harmful, they are not always so.Regular iron supplementation, for example, can do more harm than good, and the risk of metal poisoning is very real. Athletes are therefore warned about the improper use of dietary supplements.Consumption of supplements may play a role when the diet or food choices are limited, or as a temporary remedy when a deficiency of the syndrome has been shown to exist. The use of supplements does not compensate for poor food choices.In a few additions, the evidence balance supports a beneficial effect on other types of applications; these supplements include creatine, caffeine and bicarbonate.There is no evidence that androste- nedione and the same prohormones are anabolic agents, and these ingredients may be a major health hazard. The risk of drug testing resulting from the use of sports ingredients contaminated with illicit combinations is also very real. Evidence of performance benefits should be strong enough to outweigh well-established risks .Nutraceuticals provide all the essential elements that should be present in a healthy human diet. From the above research it can be concluded that the various chemical components from natural sources can be obtained and processed into a variety of prepared, safe, stable conditions for the treatment and diagnosis of diseases. Nutraceuticals are

widely used in the food and pharmaceutical industries. Most nutraceuticals from minerals, animal origin or vegetable origin such as gamma terpinene, beta carotene, curcumine, limonene, eugenol, pinene, safranal, geraniol, alpine , caryophyllene, lycopene and silymarin. These sections are organized into volume forms such as headings, oral, etc. namely. creams, lotions, ointments, emulsions, number formulations, fragrances, microemulsions, SMEDDS, beads, tablets, emulgels, herbal formulas etc. are used in various stages such as antidiabetic, antibiotic , antimicrobial, anti-inflammatory, anti-cancer, protective, etc. Research results show that the demand and use of nutritious medicines now continues to increase due to safety, efficacy of treatment, structural stability.

The scope of supplement use

Limited information is available on the level of use of dietary supplements among athletes. The global supplement market in 2001 was estimated at US $ 46 billion, while the US supplement market in 2000 was estimated at US $ 16.7 billion (Financial Times, 19 April 2002).Athletes make up an important part of the overall market and a wide range of products are targeted at both active people and those who play competitive sports. Several supplementary use studies for athletes have been published, with a metalysis of 511 published a survey involving 10,274 male and female athletes showing a total prevalence of 46% use (Sobal and Marquart, 1994). The frequency of use, however, varies greatly between sports and among athletes of different ages, performance levels and cultural background. In some sports, especially power and energy, the use of additives is common. A report on supplement use among Norway's top 100 national competitions from various sports revealed that 84% tested using a specific type of micronutrient supplement (Ronsen et al., 1999). Many athletes in this study took a lot of supplements, although many had healthy eating habits that were described as ‘unsatisfactory’, meaning that these athletes could benefit greatly from paying attention to the food they ate. [10] Only a few studies have tried to estimate the frequency or amount of additional use, but it seems common for athletes to exceed the recommended dosage of ingredients. This may be due to the feeling that ‘much is better’ or because team players or opponents are known to use high doses. In some cases, for example creatine, the dose recommended by other providers may be significantly higher than the maximum effective dose. On the other hand, the value of additives in some preparations may be much less than the amount spent on effective laboratory studies, especially when expensive ingredients are involved. Consumption rates by individual athletes suggest that some may consume large quantities of different ingredients on a regular basis and that the amounts used may be higher than those shown to be safe. Many people believe that ‘natural’ supplements are harmless, but taking too much of these ingredients over a long period of time can be harmful. Iron, zinc and other metals are often used in amounts that are known to be harmful. It may seem that athletes - and often those who are important - are often unaware of the dangers. [11] Many studies have failed to determine the reasons for the use of supplements by athletes, the basic information in any attempt to change the behavior of athletes. In one study, attitudes toward food supplement use were assessed in 1737 young people (14-19 years) men and women (58% men, 42% women) high school athletes (Perko, 2000). Coaches, parents, doctors, sports coaches, and peers all contributed to the decision to take supplements. There was a positive relationship between behavior and commonly

thought behaviors, but knowledge about the effects of supplements was limited. Other studies found no correlation between the frequency of use of supplements and gender, race, marital status, educational background, eating habits or training status. [12]

Commonly cited reasons for supplement use include:
• . to compensate for an inadequate diet;
•. to meet the extraordinary needs of hard training or constant competition
• . to benefit performance
• . to keep up with team-mates or opponents; recommended by coach, parent or other influential individual.

However, even when athletes are informed on the basis of biochemical estimates that their diet is adequate or that their body condition is normal (e.g. iron), the use of additives persists, suggesting that the decision to use supplements is. is not logical. [13]

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