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Harnessing the potential: Exploring the significance of nutraceuticals in the medicinal plant industry

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Abstract

The utilization of medicinal plants for therapeutic purposes has a rich history dating back centuries. In recent years, the focus has shifted towards nutraceuticals derived from medicinal plants, which offer a promising avenue for promoting health and well-being. This article aims to explore the significance of nutraceuticals in the medicinal plant industry, shedding light on their potential benefits and applications. We delve into the unique characteristics of nutraceuticals, their extraction and formulation processes, and their diverse mechanisms of action. Furthermore, we discuss the increasing demand for nutraceutical-based products and the implications for the medicinal plant industry. The article also addresses the challenges and opportunities associated with nutraceutical research, including quality control, standardization, and regulatory considerations. This comprehensive overview provides valuable insights into the field and paves the way for further advancements in nutraceutical research and the sustainable utilization of medicinal plants.

Keywords: Nutraceuticals, nutrition, herbal supplements, FSSAI

Introduction

Nutraceuticals are a modern approach to food science. The area of possible use can be called "beyond the diet, but before the drugs". According to World Health Organization (WHO), nutraceuticals are, "food or part of a food that provides medical or health benefits, including the prevention or treatment of disease" [1]. Contrary to the global expansion of the nutraceutical industry; the major problem is that there is uncertainty about the potential effectiveness of these products. However, food composition has been tested and verified as people become increasingly aware of health-related issues and how food can directly or indirectly be responsible for maintaining proper health and preventing diseases (figure: 1) [2].

Scope and opportunities of nutraceutical market

Nutraceuticals and dietary supplements are sold in India under the name of "fast-moving health care goods" (FMHG). There is a growing awareness of the importance of nutrition and diet for long-term good health. It is the best possible solution for the management of lifestyle diseases. Factors that increase the demand for nutrition include a rise in medical management costs, increased life expectancy, and increased health awareness.

In 2018, the global nutraceutical market was valued at USD 252,535.4 million, and it is expected to grow to \$465,709.8 million by 2027. Currently, the trending nutraceutical market is, it is used as a preventive measure to minimize the occurrence of chronic and other diseases such as cancer, obesity, diabetes, allergies, Alzheimer's, immune-inflammatory diseases, and Parkinson's disease [3]. Markets of nutraceuticals have seen significant evolution in recent years, with the emergencies of newer technologies like nanotechnology, and the development of advanced procedures or instruments that facilitate both quantitative and qualitative analysis.

Increased demand for nutraceuticals

The wide supportive evident growth of the nutraceuticals market is linked to their consumption as a preventative for certain complex clinical conditions, and one of their most traced advantages is their lower health risks compared to synthetic drugs. Manufacturers are actually contributing greatly by introducing multiple nutraceutical products aimed at improving function, building muscles, repair, and damage to the body. The beauty segment is also growing at a very fast rate in India and nutraceuticals have created great inroads into the market [4].

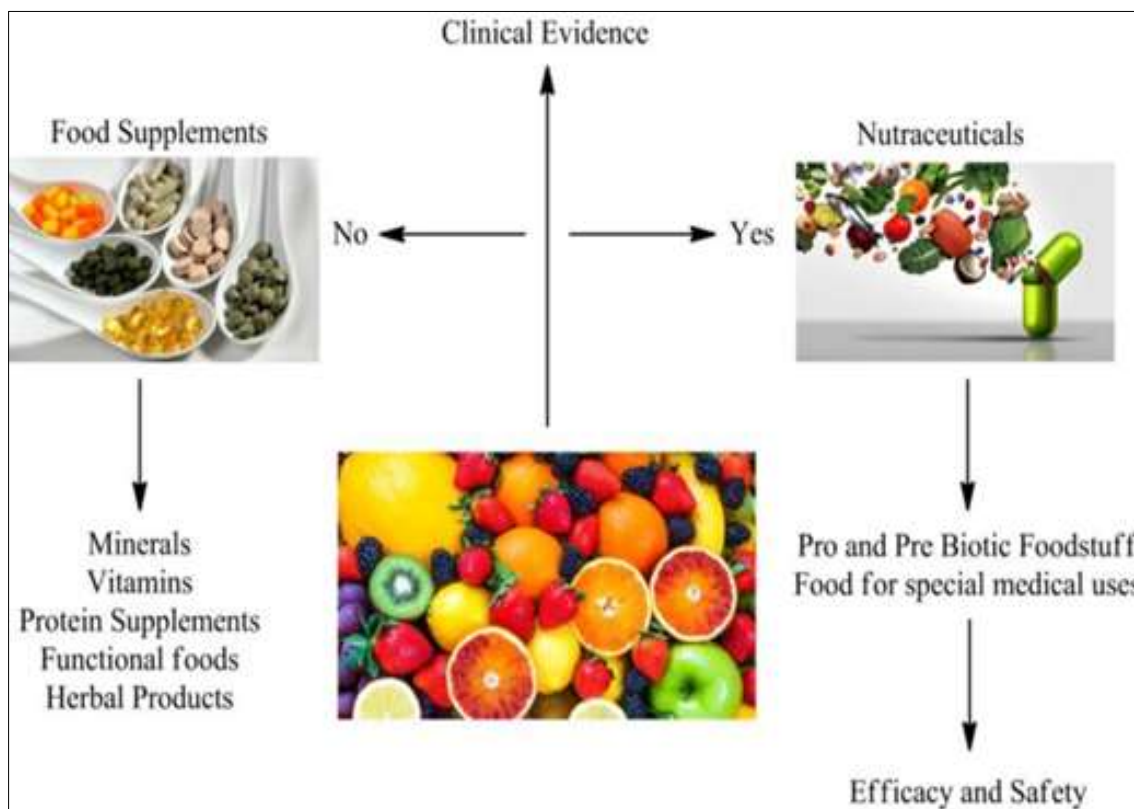


Fig 1: How food can directly or indirectly be responsible for maintaining proper health and preventing diseases

Regulations

The Government of India amended an old law on the prevention of food adulteration (PFA) and enacted the Food Safety and Standards Act (FSSA). In addition, the manufacturers had to abide by many other laws, such as the Fruit Products Order 1955 (FPO), Vegetable Oils Products (regulation) Order (VOP)1988, Agricultural Produce (Grading and Marking) Act of 1937, and the General Grading and Marking Rules of 1986 and 1988 (AGMARK) [4].

The Food Safety and Standard Act 2006 aims to establish a reference point for all matters relating to Food Safety and Standards. Food Safety and Standard Act 2006 consists of 12 chapters. Chapter IV, Article 22 of the act addresses nutraceuticals, functional food, dietary supplements, and the

need to regulate these products. Food Safety and Standards Regulations 2016 (health supplements, food for special dietary use, food for special medical purposes, functional foods, and novel foods. This regulation has been amended as of September 6, 2021. Section 22 of the Food Safety and Standards Act 2006 deals with ingredients that can be used in the preparation of nutraceutical preparations. The preparations may include; plants or botanicals in the form of powder, or hydroalcoholic extract. minerals, vitamins or proteins, substances of animal origin that can be formulated as powders, granules, tablets, capsules, liquids, jelly, etc. No claim should be raised to cure or mitigate any specific disease. It does not include a narcotic drug or a psychotropic substance [5].

Table 1: Important schedules related to nutraceuticals [5].

Schedules	Content	Examples
Schedule IV	List of plants or botanical ingredients	<i>Camellia sinensis</i> , <i>Capsicum annum</i> L. var. annum, <i>Glycyrrhiza glabra</i> L.
Schedule VI	List of ingredients used as nutraceuticals	Part A: e.g.: spirulina, selenium yeast, <i>Piper nigrum</i> Part B: eg: <i>Allium sativum</i> , aloe-vera
Schedule VII	List of strains as Probiotics	Eg. <i>Lactobacillus acidophilus</i> , <i>Lactobacillus casei</i>
Schedule VIII	List of prebiotic compounds	Eg. polydextose, soya bean oligosaccharides, insulin
Schedule VF	List of food additives used	e.g., Acacia gum

Phytochemicals as a source of nutraceutical

Phytochemicals are non-nutritive plant chemicals with defensive or disease-protective properties. Their dietary intake may promote health benefits. It includes foods, such as whole grains, beans, fruits, vegetables and herbs. Phytochemicals with nutraceutical properties present in food are of enormous significance due to their beneficial effects on human health since they offer protection against numerous diseases or disorders such as cancers, coronary heart disease, diabetes, high blood pressure, inflammation, microbial, viral and parasitic infections, psychotic diseases, spasmodic

conditions, ulcers, osteoporosis and associated disorders [6].

Selection of a drug

Any of the ingredients listed in Schedules I, II, III, IV, VI, VII, and VIII may be used in the formulation of these products, according to the Food Safety Standards Authority of India (FSSAI). A drug is chosen based on various criteria such as drug-drug, drug-food, drug- disease interaction, toxicity, and so on. The act also specifies the types of drugs that may be used and the plant parts that may be used.

Table 2: Common herbs used as health food

sSl no;	Herb	Health benefits
1	Brahmi	Improve attention and information processing, reduce symptoms of ADHD.
2	Turmeric	Antiseptic, boost immune system
3	Liquorice root	Prevent nausea, stomach ulcer
4	Cardamom	Prevent stomach ulcer
5	Peppermint	Manage IBD
6	Holy basil	Fight infections, boost immunity
7	Ginger	Anti-inflammatory properties, nausea
8	Fenugreek	Improve blood sugar level
9	Coriander	IBS, constipation, diarrhoea, nausea
10	Cumin	Prevent cancer, diabetes, asthma, improve digestion
11	Nutmeg	Antidepressant, improve digestion, for diarrhoea
12	Onion	Decrease blood sugar level, prevent inflammation
13	Garlic	Reduce CVD, antitumor, anti-microbial
14	Aloe Vera	Curing wound, boost immune system
15	Amla	Antifungal, reduce hair fall, cure sore throat

In case of botanicals, the botanical's name must be determined. The plant parts used in the botanical preparation shall be ascertained, such as root, rhizome, tuber, bulb, stem, bark, leaves, flower, fruit, seed, etc. The botanical identification shall be confirmed by the following methods: Macroscopic and microscopic evaluation, chromatographic and spectroscopic methods, and other characteristic assays; physical tests; etc. One should investigate potential interactions of the selected drugs with any other drug, food, or herb, as well as other ingredients in the formula, solubility in various solvents, and so on [5].

Methods of Extraction used

- Soxhlet extraction by using hot menstruum for effective extraction of constituents
- Sonication, by the use of ultrasonic sound waves to agitate particles in a given solution. Thereby accelerates the dissolution of a solid into a liquid.
- Percolation, by the slow passage of suitable solvent through a column of drug.
- Maceration, the process of extracting a drug by allowing it to stand in contact with a solvent for certain days.
- Infusion, the process of extracting chemical compounds or flavours from plant material in a solvent such as water, oil or alcohol, by allowing the material to remain suspended in the solvent over time.
- Decoction, is used especially for water-soluble and thermostable constituents.
- Pulverization, the method of reducing solid substances to a fine powder by combining them with a suitable solvent which can be removed easily by the end of the process [6, 7].

Examples of some Additives used and mentioned in Nutraceutical regulation

- **Sweetening agent:** Sucrose, mannitol
- **Binding agent, disintegrant:** Starch, Gelatine, Sodium glycolate
- **Buffering agent:** Tartaric acid, Citric acid
- **Diluents:** Lactose, Mannitol
- **Vehicle, humectants:** Propylene glycol
- **Preservative:** Methylparaben

Incorporation of various nutraceuticals into herbal formulation

Nutraceuticals includes substances with established nutritional functions such as vitamins, minerals, amino acids and fatty acids, herbs or botanical products, dietary

supplements. Currently, numerous studies are being conducted to develop these herbals into various nutraceutical formulations that improve health. Nutrients, herbal supplements, and herbal formulations has proved to be an alternative to modern medicine in the treatment and prevention of diseases.

Nutraceuticals can be formulated into various dosage forms like tablet, capsules, liquids, granules, jellies etc. As per section 22 of FSS act, only plant or botanical extracts using water, ethyl alcohol, hydro alcoholic extract can be used. While using a combination of ingredients, it should be studied for synergistic or antagonistic interactions, impact on stability, bioavailability, safety and efficacy of these products. E.g.: chewable gummy tablets, polyherbal health drink, herbal lozenges, energy bars, herbal biscuits.

Parameters to assess the genuineness of the product

The common parameters used to determine the genuineness of nutraceutical formulations, includes:

1. Organoleptic, physical, chemical and microbiological parameters
2. The final product must not permit microbiological growth
3. Fat stability (e.g. Oxidation/rancidity in fish or vegetable oils)
4. Monitor physical changes on storage (appearance, hardness)
5. No interactions between ingredients have noted.
6. The stability of the finished product, i.e. the stability of the product after opening the pack and during the expected consumption period [8].

Parameters to assess the safety

All manufacturers should comply with Current Good Manufacturing Practices (cGMP) to ensure safety, quality products for consumers. The goal of nutraceutical regulations to follow cGMP in order to provide consumers with safe, effective and high-quality products. To ensure the safety of the product it should start from the selection of raw materials itself. Nutraceutical regulations have been focused on safety and labelling, with a lesser emphasis (As compared to pharmaceuticals) on product claims and intended use. Increased regulations related to quality and safety of these products will benefit the industry as a whole and help mitigate the risk of regulatory backlash.

In order to perform products assessment as per Indian regulatory definition, it is of utmost importance to examine each active ingredient and additive in the context of permissibility, standards and dosage of vitamins /minerals

allowed as per the therapeutic, prophylactic or recommended daily allowance for Indians^[9,10].

Challenges and constraints of nutraceutical industry in India

Several challenges associated with the development of nutraceuticals are often ignored because of a lack of authoritative control. These challenges include identification of the authentic source of raw materials, purity of the compound, presence of other active compounds, quality, lack of experimental evidence, false advertising, contamination with heavy metals, and interactions between supplements and drugs. Various challenges to market expansion include;

- Minimal acceptance of the products: People accept it as a diet rather than a medicine.
- Lack of awareness about the products: There is a wide range of products available in the market, but the population is not aware of the right product.
- Proper regulations for nutraceutical as pharmaceutical is not followed
- Expensive
- Lack of studies regarding the Pharmacokinetic (PK) data.
- Exact mechanism of action is not well established.
- Lack of regularized system for setting up manufacturing plant and aid for the globalization of the nutraceutical sector.
- A separate approach with specific advertising, composition, positioning, price, and distribution is required for a holistic approach to the Indian market.
- The route of administration is mostly oral, and another route of administration is less established.
- Other routes of administration for humans should be explored further to improve bioavailability and efficacy.
- Nutraceuticals cannot claim to be a substitute for actual food, but only a dietary supplement^[11].

Safety and Efficacy

Generally, nutraceuticals have a lower incidence of reporting safety and efficacy issues as compared to conventional pharmaceutical drugs. The majority of nutraceuticals on the market are safe for human consumption and only in some instances may cause harm because some ingredients may have toxic effects on human health. They also cause safety issues due to pharmacological changes, and quality issues like misidentification of the plants, adulteration during manufacture, pharmacological issues like drug-food interaction, drug-drug interaction, and nutraceutical-pharmaceutical interaction. Eg: pyrrolizidine alkaloids are among the most toxic alkaloids present in several plants which are hepatotoxic and have carcinogenic effects^[12]. Understanding of the pharmacokinetic behaviour of every drug is extremely important for understanding of safety profile (Toxico-kinetics), onset of action, required dose, and dose frequency. However, as per regulations of the European Union, these herbal agents must prove scientific evidence for safety, efficacy, and quality before being licensed for use by the public. Dietary supplements need to be monitored by nutravigilance for quality, the active ingredient, purity and any adverse reactions.

Future prospectives

Over the last 20 years, there has been a rapid increase in the use of nutraceuticals. The marked side effects and ineffectiveness of modern pharmaceuticals have also compelled people to look for nutraceuticals as alternative

therapies. The global nutraceuticals market size was valued at USD 454.55 billion in 2021 and is expected to expand at a compound annual growth rate (CAGR) of 9.0% from 2021 to 2030. Manufacturers of nutraceuticals are also frequently launching new products into the market to expand the nutraceutical industry, and pharmaceutical companies are turning to marketing nutraceuticals. Eg: The drug company “Novartis” has also launched functional food for the health of consumer in the market and pharmacies.

To implement evidence-based practice for nutraceuticals, there is a need to generate more clinical evidence, which includes Clinical trials, observational studies, Meta-analysis, and Real-World Evidence studies. The current Covid-19 pandemic has also created a lot of awareness regarding the need for immunity to fight against diseases, and the need for immunity boosters has increased^[13,14].

Conflict of interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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