

STANDARDIZATION OF NUTRACEUTICALS WITH DEVELOPMENT OF SOPS OF NUTRACEUTICALS, HEALTH CLAIMS AND REGULARITY CONSIDERATION***¹Dr. Pooja Sahu, ²Dr. Shiromani Mishra and ³Dr. Surendra Kumar Sikarwar**^{*1,3}MD Scholar Final Year, Department of Dravyaguna, Govt. Dhanwantri Ayurveda College, Ujjain (M.P.)²Associated Professor, PG Department of Dravyaguna, Vigyana Ayurveda College, Ujjain (M.P.)***Corresponding Author: Dr. Pooja Sahu**

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Article Received on 05/11/2024

Article Revised on 25/11/2024

Article Accepted on 15/12/2024

ABSTRACT

Introduction: Nutraceuticals are a mix of "Nutrition" and "Pharmaceutical" and have grown from understanding how food affects health. They are substances in food that go beyond just giving nutrition and can also help prevent diseases or improve health. This article talks about how nutraceuticals and functional foods are regulated for health claims in India, the US, and Japan, as well as the challenges and market trends. An SOP is a set of instructions for doing tasks like operating equipment, cleaning, and inspecting. **Aims & objectives:** Standardization of nutraceuticals with development of standard operating procedures of ayurvedic nutraceuticals, and the food contains various nutritional components that show an impact on health condition in order to improve people's health and well-being. **Methodology:** An Ayurvedic approach for good nutraceuticals, Sops, and health claims on food products. **Result:** To develop standard operating procedures as per the WHO guideline for good manufacturing procedures (GMP). Health promoting and disease risk reduction based on evidence from literature and clinical data for the safety and efficacy of nutrients. **Discussion:** Now days, the Nutraceutical industry is growing at a constant yearly rate. The demand for Nutraceuticals now turns toward the development of Standardization of nutraceuticals (SOPs) of Ayurveda for the purpose of good preparation of this product. Nutraceuticals from the international market may claim to be organic combinations, and the lack of regulation may compromise the safety and safety and effectiveness of products.

KEYWORDS: Nutraceuticals, Ayurvedic nutraceuticals, Standardization, SOPs, Standard operating procedure.**INTRODUCTION**

According to Dr. Lockwood, a nutraceutical is like food or plants that can make you healthier. Nutraceuticals are safe food components that have been proven to have health benefits, such as preventing and treating diseases. These products are taken from food and sold in forms that are different from how we normally eat them. A nutraceutical helps to prevent chronic diseases by giving our bodies a boost. Thanks to new discoveries in medicine and nutrition, people are paying more attention to natural products and foods that are good for your health. This has led to new ideas like nutraceuticals, nutritional therapy, phytonutrients, and phytotherapy. Consumers are getting fed up with the expensive, high-tech approach to treating diseases in medicine. They are now looking for complementary or alternative products that can be beneficial. The red tape of managed care is making nutraceuticals especially attractive. Hippocrates said, "Let food be the medicine and medicine be the food" around 2,500 years ago, and this idea is still relevant today. "Acharya Kashyapa" also believes that food can act like medicine. However, there is still some

confusion about whether certain products should be considered food or medicine due to health claim systems and food safety regulations. It is challenging to prove the benefits of new products without consistent global rules and scientific evidence to back up health claims. To make sure the medicine is always the same and to set up rules for how it's made, the formula was tested in three batches in a lab using WHO's guidelines. The medicine was checked for things like how it looks under a microscope, ash value, moisture, pH levels, how long it takes to break down, how strong the pills are, if there are any harmful toxins, how much metal is in it, if there are any germs, and a special test called HPTLC. Following rules like SOPs is crucial in the medicine industry to make sure things are made the right way. Standard Operating Procedures are step-by-step guidelines for performing tasks such as operating equipment, cleaning, and inspecting. Some SOPs are used in conjunction with specific documents for manufacturing products. There are many benefits to using SOPs in local pharmacies. Pharmacists can demonstrate their professionalism and dedication by creating SOPs that detail all pharmacy

tasks while following laws and rules. These guidelines are important for upholding high standards and keeping everyone safe.

METHODS

STANDARDIZATION OF NUTRACEUTICALS IN AYURVEDA: The use of herbal products is growing rapidly worldwide. India is a leading center for studying natural herbs. Herbal drug technology is crucial for turning plants into Nutraceuticals, requiring a combination of modern scientific methods and traditional knowledge for quality control and standardization. WHO guidelines are very important for making sure herbal medicines are safe, effective, and good quality all around the world. Standardizing a nutraceutical means making sure it is the right thing, good quality, and pure at every step of its life. There are different ways to standardize compound drugs, like looking at them under a microscope, testing them physically and chemically, and using biological methods. The article talks about different methods used in chromatography, such as fingerprinting and quantifying multiple components. It also mentions hyphenated techniques like HPLC-MS and GC-MS, as well as the standardization of Bhasma.

DEVELOPMENT OF SOPs OF AYURVEDIC NUTRACEUTICALS: The World Health Organization's guidelines for good manufacturing practice (GMP) include standard operating procedures (SOPs). These SOPs are essential for planning, conducting, and monitoring clinical studies. To ensure the quality of each part of a research project, specific SOPs need to be created for each stage of the study. One crucial SOP is how to make an SOP, as it sets the standard format. The team involved in creating the SOPs should work together to evaluate and approve the procedures. If needed, specialized personnel can be hired to help with this process. In these situations, it's crucial for the team to know the industry well and communicate with the core group. They should be familiar with all the procedures and talk about each new SOP that's made. SOP has been explained in various ways by different authors. The US Environmental Protection Agency and the European Medicines Agency define it as "a written set of rules that show a regular and repeated task done by a company to ensure consistency in how a specific job is done." Standard Operating Procedures (SOPs) are rules that help people working in a certain place do tasks the right way. In the pharmaceutical field, following SOPs is

really important to make sure the final product is high quality and consistent, following the rules of good practice. SOPs are a key part of good manufacturing practices (GMP) and are widely used in the pharmaceutical industry. A Standard Operating Procedure (SOP) is a set of instructions for carrying out tasks like operating equipment, maintenance, cleaning, validation, cleaning the premises, controlling the environment, and sampling and inspection. Some SOPs can be used along with specific instructions for making products. By using SOPs in local pharmacies, we can enjoy many advantages and show that we are professional and responsible. Pharmacists need to create standard operating procedures (SOPs) for all the tasks they do at their pharmacy. These procedures should follow the rules and regulations, and pharmacists should always remember them when writing and following the SOPs.

HEALTH CLAIMS AND REGULARITY

CONSIDERATIONS: Three categories of claims are currently used on labels, for foods, and dietary supplements including nutraceuticals in most countries. Firstly, nutrient content claims, describe the percentage of a nutrient in a product relative to the daily value. Secondly, structure/function claims express the effect of a dietary supplement on the structure or function of the body and lastly the health claims describe the relationship between a food or bioactive ingredient and reduction in disease risk. The key factors for driving growth.

1. Demographics
2. Psychographics
3. Rising consumer interest in preventive health
4. Demand for more convenient formats
5. Innovations in food manufacturing

According to this regulation, health claims mean any message that implies the relationship between the content of nutrients or nutritional ingredients and specific disease conditions. The health claim concerning the article of food may be involved but not limited to.

- 1) Nutrient or nutritional function claim
- 2) Enhanced function claim
- 3) Disease risk reduction claims
- 4) Health maintenance claims
- 5) Immunity claims–increased resistance (Excluding vaccines)
- 6) Antiaging claims

Table: List of health claims permitted in India.

Nutrients	Health relation claims
Calcium, vitamin D/ calcium	Osteoporosis
Sodium	Hypertension
ALA (alpha-linolenic acid), Dietary Saturated fat	Blood cholesterol level
Potassium	Risk of hypertension
Oats, barley (beta-glucans)	Blood sugar
Phytosterol/stanol, Soluble dietary fiber	Lipid profile

Understanding each claim helps prevent wrong information and keeps consumers safe from false connections. The FDA's rules limit what functional food really means. Functional foods can only say they are good for you if they can prove it. Instead of looking for health claims, we should focus on the proof needed to make those claims. To be considered healthy, a functional food claim must meet FDA standards. Functional foods are those that have been proven to improve health by lowering the risk of certain diseases or positively impacting specific body functions. Companies often communicate the health benefits of functional foods through claims on their packaging. Overall, claims about improving health are more popular than claims about reducing disease risk. This mainly happens because there are not many studies that support those claims. A review article on qualified health claims shows that studies on health claims mainly focus on reducing the risk of getting sick, rather than on people who are already sick. The FDA will only look at evidence from studies that include people who have the disease mentioned in the health claim if it's scientifically okay to apply the findings to people who don't have the disease. This research focused on lycopene, a phytochemical in tomatoes, and how it may help reduce the risk of cancer. The study suggested that lycopene in tomatoes could lower the chances of getting cancer. However, the FDA decided that there wasn't enough proof to support this claim, so they didn't approve it. The FDA found very little reliable proof to support the idea that tomatoes and/or tomato sauce can help lower the risk of certain cancers like prostate, gastric, ovarian, and pancreatic cancers. However, they did say that if the health claims are worded carefully, they could be helpful to consumers.

RESULT

Ayurveda and modern nutraceutical ideas both focus on how food and herbs can keep us healthy and stop us from getting sick. Ayurveda looks at everything together, like what we eat, how we live, and the herbal supplements we take, to help us stay healthy and avoid getting sick. As more people are interested in natural and plant-based treatments, Ayurvedic nutraceuticals are becoming more important for keeping us healthy and preventing illnesses.

DISCUSSION

Ayurvedic health supplements focus on preventing illnesses, treating them, and taking care of the body after being sick. This includes focusing on what you eat, using therapies, and boosting immunity. The idea of Rasayan, tailored to each individual's needs, helps prevent the illness from coming back. Ayurvedic health supplements offer a special way of delivering medicine through formulas that help the body absorb the active ingredients better. Health authorities must make sure that all herbal medicines meet quality, safety, and effectiveness standards. The manufacturing and distribution processes must also follow GMP guidelines to maintain the quality of the products until they reach the consumer. Quality

control for herbal medicines involves not only analyzing active ingredients but also checking for pesticide residue, aflatoxins, heavy metals, and following good agricultural and manufacturing practices. It is important to develop techniques that combine traditional and modern evaluation methods. This will make the medicine better and encourage doctors to be more active in making sure it meets standards. Health statements for food labels should be controlled by the right people to approve them. In the U.S., you can't make claims about reducing the risk of getting sick. In the U.S. and Japan, you can make some health claims as long as they're backed up. But in India, it's not allowed, and the kind of claims you can make depends on the product. Health claim rules vary from one country to another, which makes it hard to create a standard product for the global market. With the food products market growing all over the world, health claim regulations are a tough challenge for everyone.

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