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Comparative Studies of the Protein as Dietary Health Supplement: Regulatory Requirements and Nutritional Parameters

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ABSTRACT:

Health supplements do not belong to the huge domain of conventional foods and are considered as a separate category of foods: foods with health benefits and physiological effects. The general requirements of the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purposes, Functional Food, and Novel Food) Regulations, 2016 are discussed along with the regulations that specifically concern the formulation, manufacturing, and sale of health supplements. Among the numerous types of health supplements, protein supplements are focused upon, considering their wide consumption specifically among athletes and people who practise resistance training. The study highlights the current situation of health supplements with specific attention to the regulatory requirements for all aspects of their manufacturing in India including: their formulation, packaging, labelling, and sale. Further, major regulatory bodies worldwide are reviewed and compared with the regulations in India. The most consumed protein supplements are whey protein concentrate, whey protein isolate, casein, plant protein sources such as pea protein, soy protein concentrate, and isolate, and blends of two or more of such protein sources. From these, a sample of each: animal sourced protein (whey protein blend) and a plant-based protein (pea protein and rice protein blend) were chosen for a proximate analysis and determination of the amount of minerals present in them.

Keywords: Protein Supplement, FDA, ISO, AYUSH, FSSAI, Nutritional Content

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1. Introduction

The dietary health supplements are the ones which should be consumed above the age of five years. The supplement contains concentrated source of one or more nutrients mainly, amino acids, enzymes, minerals, protein, vitamins and other dietary substances, plants and botanicals, prebiotics, probiotics, and substances from animal origin providing nutritional and beneficial physiological effects, which are presented as such and are offered alone or in combination, but not as drugs (FSSAI, 2016). Such health supplements should be marketed in single use packaging as packaging as appropriate to maintain the integrity and quality of the product, or in dosage forms namely capsules, tablets, pills etc or other similar forms or in any form of liquid and powders designed to be taken in measured unit quantities. The main difficulty in discussing the regulation of dietary supplements is the lack of a global agreement on how to define this class of goods, which are known by different names in different countries, such as dietary supplements, Natural Health Products (NHPs), complementary medicines, or food supplements. For instance, a substance that is categorized as a dietary supplement and governed as food in the United States may be seen as a food supplement, therapeutic good (complementary medicine), or even a restricted substance in another country. Establishing uniform global standards for dietary supplements presents a considerable problem due to the wide range of definitions and regulatory frameworks. Another significant issue is that, while all regulatory scientists strive to protect consumers and enable them to make educated decisions about the products they use, the scientific barriers and regulatory frameworks in place to do so vary significantly from one nation to the next. Regulations governing dietary supplements can differ widely among nations, even those with comparable cultural histories, legal systems, and economic standing. Examples from English-speaking countries like Australia, Canada, and the USA can be used to highlight this. These countries share a lot of cultural and legal similarities, but their regulatory frameworks differ noticeably from one another (Dwyer et al 2018). Modern lifestyles, which are characterized by greater mechanization, decreased physical activity, and several socioeconomic conditions, have significantly contributed to the rising prevalence of noncommunicable diseases (NCDs) in the modern era. People are therefore becoming more conscious of the need to supplement their meals with more nourishment and better options. Supplements are becoming more popular to maintain an active lifestyle and to treat health problems. While regulatory bodies promote a balanced diet as a strategy to increase micronutrient intake, this guidance may not always be enough to meet each person's specific nutritional needs (Thakur and Modi, 2020; Thakur and Belwal 2022). The use of dietary supplements and herbal medicines gained from natural substances for enhanced quality of life, or their asserted benefits has increased worldwide (Mahady, 2001). Many herbal remedies and dietary supplements frequently depend on the principles and methods of traditional medicine. Consumers are usually encouraged to buy these goods by specific "health claims". However, there is a chance that people will mistakenly mistake these goods for real pharmaceuticals if they are not adequately educated or comprehend these claims. Health and safety risks to the customer could result from this. Before utilizing such supplements or herbal medicines, customers must be aware and seek professional advice (Moreira, 2014; Zhu et. al. 2019).

Foods that promote health have not only attracted customers but also have caught the eyes of researchers and medical nutrition professionals. Foods with additional health benefits, such as foods that contain bioactive substances, herbal supplements, and dietary supplements that contain a concentrated amount of nutrients are known to have a considerable effect on the human body (Boindala and Lewis, 2019). Food supplements are emerging as categories such as health supplements, functional foods, and nutraceuticals. These supplements are meant to

impart health benefits to the consumer. The global market for dietary supplements is estimated Fig 1.1 to be worth over 130 billion USD, and it has been expanding steadily for more than three decades (Zion Market Research 2017). The India dietary supplements market size reached INR 436.5 billion in 2022. Looking forward, IMARC Group expects the market to reach INR 958.1 billion by 2028, exhibiting a growth rate (CAGR) of 13.5% during 2023-2028 (IMARC, 2023). The increasing level of consumer health concern is the key factor propelling the Indian market for dietary supplements. Fig 1.2 Indian Dietary Supplement Market valued at USD 3924.44 million in FY2020, and with and predicted growth a CAGR of 16% until FY2027 (Research and Markets, 2021). People are now aware of the importance of nutritional supplements in bridging these nutritional gaps because conventional meals may not always be adequate. Rising disposable incomes, improvements in healthcare facilities, improved distribution networks, and other factors all support the expansion of this sector (IMARC, 2023)





Fig 1.2 Indian Market Supplement Pyramid, Research and Markets, 2020

Indian Dietary Su	pplement Market
Market forecast to gro	ow at a CAGR of 16.2%
	USD 11.6 Billion
USD 2.21 Billion	
2016	2027

2. Regulatory Framework for Health Supplements in India

Various regulatory frameworks for the health supplement industry have been highlighted below. Majorly all the supplementation industry has been governed by four major organisations- AYUSH, CODEX, FSSAI and FDA in Fig 1.3. Almost in every supplement, consumer choose they must see the logo and their nutritional content.



The varied climate of India offers the best conditions for growing a wide range of fruits and vegetables. India is only second to China in terms of production. In contrast to the USA, which is the world's largest market for nutraceuticals, a very small amount of agricultural goods in India are processed. The main causes of this gap are a lack of strict regulatory rules and a lack of knowledge about the health advantages of processing food products and further processing them into nutraceuticals and health supplements. (Bansal and Dhiman, 2019). The regulations are made more complicated in the Indian setting due to the diversity of food products, which includes medicinal products like health supplements made from plants, herbs, or unique substances. The pharmacologically active qualities of several of these substances raise the possibility of regulatory conflicts. Because of this, it is essential to create precise and unambiguous regulatory frameworks to guarantee the safety and effectiveness of these items (Boindala and Lewis 2019). All manufacturers must be accredited by ISO 22000 FSMS for food safety in addition to GMP certification to assess the standards of quality management systems & the safe practices of goods manufacturing (Banerjee, 2020). Fig. 1.4 illustrates the supplement pyramid based on different zones and their risk factors.



Fig 1.4 Supplement Pyramid as per Colour Zones and Risk Factors, Banerjee 2020

2.1 AYUSH

The use of plant and animal-derived products, vitamins, and minerals to treat specific diseases is regulated by the Department of Ayurveda, Yoga, Naturopathy, Unani, Siddha, and Homeopathy. AYUSH regulates the phytopharmaceutical drugs marketed under categories such as functional food, dietary supplement, traditional medicine, or a drug in any country.

The Drug and Cosmetic Act (D and C) of 1940 and the corresponding Rules of 1945 govern the use of herbal medications in India. The regulations governing Ayurvedic, Unani, and Siddha medications are clearly stated in these regulatory laws. The Department of AYUSH is the regulatory body in charge of these issues. It demands that any production or distribution of herbal medicines take place only after acquiring the required manufacturing license. Licensing, formulation design, manufacturing procedures, labelling, packaging, quality assurance, and exports of herbal medicines are all subject to the D and C Act's jurisdiction. The regulations for good manufacturing practices (GMP) that must be followed in the production of herbal medicines are outlined in Schedule "T" of the act. There are readily available official pharmacopoeias and formularies that determine the quality requirements for this medicine (Malik, 2013). A phytopharmaceutical drug is defined by AYUSH as a formulation with a minimum of four bioactive compounds or phytochemicals derived from a medicinal plant's extracts (Bhatt, 2016). Herbal products are referred to as traditional medicines, natural health products, health supplements, complementary medicines, etc. Countries have developed specific regulations concerning these products. About 80% of the global population currently relies mainly on herbal products for primary healthcare. (Mamta et.al., 2022).

2.2 FSSAI (Food Safety and Standard Authority of India)

The FSSAI regulations have become stringent; hence, the sale of such food products is strictly regulated to ensure food safety. The regulatory framework and its compliance in India have been active following the establishment of the Food Safety and Standards Act, 2006. After the FSSAI was established, the regulatory structure concerning functional foods, nutraceuticals, and dietary supplement has been evolving). According to FSSAI, functional foods, nutraceuticals, and health supplements, are the foods that are specially processed or formulated to meet dietary requirements that arise due to a particular physical or physiological condition or specific diseases and disorders (e.g., plants/botanicals or their extracts, minerals, vitamins, proteins, etc.). These products may be in the form of powders, granules, tablets, capsules, liquids, jelly, and other dosage forms. (FSSA, 2006). Health supplements shall contain a concentrated source of nutrient(s) namely, amino acids, enzymes, minerals, proteins, vitamins, plants or botanicals, prebiotics, probiotics, and substances from animal origin or other similar substances. These substances should have a known and established nutritional or beneficial physiological effect. Food additives in Food Safety and Standards (Food Product Standards and Food Additives), 2011. Table 2.2.1 the ingredients listed in Schedule I, Schedule II, Schedule III, Schedule IV, Schedule VI, Schedule VII, and Schedule VIII may be used in food for the purposes described in these regulations, if they comply with the requirements stated in these regulations.

Schedules	Ingredients specified in the Schedules	
Schedule I	Vitamins and minerals	
Schedule II	Amino acids	
Schedule IV	Plant or botanical ingredients	
Schedule VI	Proteins and enzymes	
Schedule VII	Strains as probiotics (live microbes)	
Schedule VIII	Prebiotic compounds	

Table 2.2.1 Schedule I, II, III, IV, VI, VII and VIII (Source: FSSAI 2016)

2.3 FDA (FOOD AND DRUG ADMINISTRATION)

The USA passed the DSHEA, that is, the Dietary Supplement Health and Education Act, 1994 (FDA, 2019a, FDA, 2019b; Denham, 2011; Hathcock, 2021; Ross, 2000), and defined

a dietary supplement as a product that contains a dietary ingredient, which can include vitamins, minerals, herbs, botanical ingredients, enzymes, probiotics, etc. in the form of concentrates, extracts, metabolites, or a combination of any of these categories. Dietary supplements are not meant for use in the form of conventional food or the only element of the diet or a meal. Dietary supplements are allowed to be sold in the form of tablets, pills, gummies, capsules, powders, etc. They may also take the same form as a category of conventional foods, such as bars, given that the product is not advertised as a conventional food. The products also need to be labelled as "Dietary Supplements". Under the DSHEA, FDA does not hold the authority to approve the dietary supplement product for sale unless it contains a new "dietary ingredient". The FD&C Act amended under the DSHEA holds the firm responsible for cases of adulteration or, misbranding in the sale of the product. The firm must also ensure that the health-related claims on the product label are not misleading. The intention of passing the DSHEA was to maintain a balance between making safe dietary supplements accessible to consumers so that they can maintain or improve their health; and giving the FDA the authority to act against firms that manufacture supplements with ingredients that are unsafe to consume, products with misleading claims, misbranding of the product, or adulterated products. (Frankos et.al., 2009).

3. Protein Supplements

Protein supplements contribute to a nutrient-dense diet and hence, an ideal fat-to-muscle ratio/body composition of muscle and fat. A significant portion of the public relies on protein supplements to substitute meals, lose weight, and/or for alleged health advantages. Protein supplements are not only available in powdered form which reconstitute after dissolving, but products such as RTE bars, protein milkshakes, extruded products, and proprietary foods such as breakfast cereals enriched with protein- are also highly acceptable by consumers. The high value of such RTE products is because of their ease of use. (Szydlowska et.al., 2022.) Consuming 20-30g total protein or 10g essential amino acids during or after exercise results in improved muscle protein synthesis and nitrogen balance. Consuming both, protein and carbohydrates during resistance exercise done for a prolonged number of hours enhances muscle protein synthesis during exercise (Karlund et al., 2019)

Exercise, particularly resistance exercise, and protein intake, both stimulate Muscle Protein Synthesis. These two factors work in synergy when protein is consumed before or after resistance exercise. However, most protein supplements do not contain any other essential nutrients that can contribute to a sustainable lifestyle (Samal and Samal, 2017). There is a wide variety of supplements available in the market. However, protein supplements have been consistently popular among people, especially the ones who practice resistance training. (Maughan, 2012). Milk protein concentrate powder had the lowest protein content among all (80.8%), whereas soy protein isolate powder had the highest protein content among all (91.1%). It was expected that the lowest content of protein was due to the residual lactose because of the process of isolation of dairy protein. The essential amino acid content in calcium caseinate powder, whey protein concentrate, and pea protein isolate was found to be the highest (Magda et. al. 2019). Animal-derived and plant-derived protein supplementation and its effects on the body composition of twenty-four college-aged men involved in resistance training, exercising 3 days per week were analysed and the result showed the difference between the concentrations of leucine in both rice and whey protein was observed. Rice protein contained 3.8g of leucine, whereas whey protein contained 5.5g of leucine. Amino acid mixtures that are rich in leucine are comparatively more efficient than only

leucine in improving muscle mass. This implies that the efficiency of leucine depends on other amino acids' presence (Joy, et. al. 2013).

This research has been planned for comparative studies on the protein supplement to have an idea about their health benefits and nutritional components.

4. Materials and Methods

4.1 Raw Material Processing

Two protein supplements were analysed for proximate analysis followed by a quantitative determination for four minerals namely sodium, magnesium, potassium, and calcium.

A whey protein supplement mixed with vitamins and minerals- "Pro Vit- X" by Aplomb Healthcare Ltd. This product contains the following ingredients: whey protein concentrate (37%), skimmed milk powder, maltodextrin, cocoa powder, chocolate flavouring, minerals (Magnesium oxide, sodium chloride, zinc sulphate, manganese sulphate, sodium selenite), vitamins (B3, B2, B7, B12, Retinyl acetate, Calcium D Pantothenate, and Pyridoxine hydrochloride).

A plant protein supplement- "TATA Gofit" by TATA Consumer Products is a blend of pea protein (65.2%), and brown rice protein (20%). The additional ingredients like additives were Cocoa powder (7%), Coffee powder (3%), natural and nature-identical flavouring substances, calcium carbonate, iodized salt, multienzyme complex, probiotic (*Bacillus coagulants*) (0.1%), stabilizer (INS 415), Artificial sweetener (INS 955). This product also claims that it is free from soy and lactose.

4.2 Proximate Analysis

Indian Standards by BIS (Bureau of Indian Standards) and Standard methods of the AOAC (Association of Official Analytical Chemists) were followed to conduct a proximate analysis of the samples, that included parameters such as protein, fat, and carbohydrate. Carbohydrate content was calculated mathematically using the amount of moisture, total ash, fat, and protein determined. The number of total sugars and added sugars were also determined. A comparative analysis was then, carried out between the results obtained.

Moisture content was determined by oven drying method which is the standard conventional method. Moisture content refers to the quantity of water contained in the food sample. It is expressed as the percentage of moisture based on total weight. The moisture content is expressed by the following formulae:

Moisture content (%) = $\frac{W_1 - W_2}{W_1}$

Where,

 $W_1 =$ Wet weight of the sample

 $W_2 = Dry$ weight of the sample

Ash was denoted the amount of minerals in the food sample. It is the inorganic material remaining as residue resulting after the sample is heated at high temperatures to remove the organic matter present in it.

Percentage of ash (%) = $\frac{W2-W}{W1-W} \times 100$

Where,

W = Weight of the empty crucible

 W_1 = Weight of the crucible containing sample.

 W_2 = Weight of the crucible with the ash

Protein was determined using the Kjeldahl method (IS-7219) by BIS is a three-step approach to the quantification of protein. It includes digestion- the conversion of the nitrogenous compounds presents in the sample into ammonia upon wet combustion in the presence of

catalysts and concentrated sulphuric acid, distillation- the ammonia is liberated from the resulting sample and is retained as ammonium sulphate in an acid of known strength followed by back titration of the received ammonia. The calculation results in the nitrogen content percentage, which when multiplied by a factor results in the total protein content percentage. The nitrogen percent is calculated by the following formula:

Nitrogen % = $\frac{(B-S) \times 1.4 \times N}{\text{weight of the sample } (g)}$

Where B = Volume of NaOH used for sample titration

S = Volume of NaOH used for blank titration

N = Normality of NaOH

The protein percentage was calculated by multiplying the nitrogen % by a factor which, in the case of this sample is considered as 6.25.

Hence, Protein % = Nitrogen % x 6.25

Fat was determined using the acid digestion method specified in AOAC 922.06. It is based on the principle of crude fat extraction from the sample with the help of a solvent that solubilizes the fat. This method is specific fat extraction method for products containing bound fat. Such type of fat is extracted by digesting the samples with concentrated acid and heat, followed by solvent extraction of fat using petroleum ether and diethyl ether.

The fat percentage is calculated using the formula-

Fat % = (W2 - W1) / Sample weight x 100

Where,

 W_2 = Weight of flat bottom flask containing the resultant fat.

 W_1 = Weight of empty flat bottom flask

Carbohydrate was calculated mathematically (following IS 1656 by BIS) by subtracting the sum of moisture, ash, fat, and protein % from 100. Energy, (in Kcal), was calculated as the sum of 9 times the fat %, and 4 times the carbohydrate and protein %.

Total sugar and added sugar in the samples was determined by following the Lane-Eynon method specified in the "FSSAI Manual of Methods of Analysis of Foods for Beverages, Sugar and Sugar Products and Confectionary Products" and IS 6287 by BIS. Total sugar content is determined by Fehling's test. The sample is digested with carrezes, inverted with HCl under heat, and titrated against Fehling's solution to obtain a red brick precipitate. Inversion is an important step in sugar analysis as it converts complex sugars into simpler ones and non-reducing sugars into reducing ones. Resulting in the determination of the total sugar percentage. The part of the sample that is not made to undergo inversion results in a reduced sugar percentage. The difference between both results in the added sugar percentage. Total sugar was calculated using the formula-

Total sugar percentage = $\frac{Fehling \, \prime \, s \, factor \, x \, Dilution \, (ml)x \, 100 \, x \, 100}{Sample \, weight \, x \, Aliquot \, volume \, x \, Titre \, value}$

Reducing sugar percentage = $\frac{Fehling \, \prime \, s \, factor \, x \, Dilution(ml) x \, 100}{Sample \, weight \, x \, Titre \, value}$

Added sugar percentage = (Total reducing sugar % - Reducing sugar %) x 0.95

4.3 Analysis of Minerals Using ICP-MS

ICP-MS is an instrument that works on the principle of mass divided by the ion's charge. **Sample preparation**- samples were digested thermally by the closed digestion method, for which a microwave digester was used. A control sample was also prepared. Microwave-assisted closed vessel digestion technique is adopted for sample digestion. **Digestion** is carried out in three different stages: Heating, holding, and cooling.

4.4 ICP-MS

The ICP-MS, which stands for Inductively Coupled Plasma Mass Spectrometry, is an elemental analysis technique. It uses an argon plasma- the ICP to ionize the sample which is then measured by the mass spectrometer- the MS, also known as the quadrupole mass analyser, based on the ratio of their mass over charge.

The digested sample is aerosolized and sprayed into a high-temperature plasma generated by argon gas which ionizes the droplets. These ionized droplets are detected and measured by the MS.(Wilschefski et.al., 2019).

Amount of Minerals (mg/100g)= (Sample concentration-Blank concentration) x Volume makeup x Dilution Sample weight

5. Results and Discussion

The analysis was conducted on plant-based protein "Gofit plant protein" by TATA and on whey protein Pro Vit- X" by Aplomb sample. The following standard methods were analysed in a comprehensive data.

5.1 Comparative Proximate Analysis of Plant Protein and Whey Protein

Carbohydrate content was calculated mathematically using the amount of moisture, total ash, fat, and protein determined. The number of total sugars and added sugars were also determined. A comparative analysis was then, carried out between the results obtained. Moisture content was determined by oven drying method which is the standard conventional method. Moisture content refers to the quantity of water contained in the food sample. It is expressed as the percentage of moisture based on total weight.

	Results per 100g		
Parameters	Plant protein	Whey protein	
Moisture (%)	5.30	3.76	
Ash (%)	4.11	4.10	
Protein (%)	70.63	38.28	
Fat (%)	6.34	1.73	
Carbohydrate (%)	13.63	52.13	
Energy (Kcal)	394.06	377.21	
Total sugar (%)	0	21.84	
Added sugar (%)	0	0	

Table 5.1	Results	of Pro	ximate	Analysis

Table 5.1 showed the proximate analysis of moisture, ash, protein, fat, carbohydrate, energy, total sugar, and added sugar per 100g of whey protein and a plant protein sample. The result showed that plant protein has a higher quantity of protein 70 percent, fat 6.34 percent in comparison to whey protein 38.28 percent and 52.13 percent respectively.

Whey protein has a higher carbohydrate 52.13 percent and total sugar content 21.84 percent in comparison to plant protein. Considering the amount of source of protein in both the protein supplements (approx. 85% in plant protein, and 37% whey protein concentrate in the whey protein supplement sample- owing to the higher protein concentration in the plant protein product), it cannot be concluded that a plant protein supplement is better than a whey protein one. However, product-wise, the former is a better choice than the latter- not just because of the higher protein concentration, but also zero percent of added sugars in it. An ingredient to focus on, despite several additives present in both products, is an artificial sweetener in the plant protein supplement, unlike the other one.





5.2 Minerals in Plant-Based Protein and Whey Protein

The results of the analysis are shown in Table 5.2, which also lists the number of samples analyzed, the concentrations of each mineral assessed on a wet weight basis, as well as the maximum and minimum values. It also shows the number of samples whose concentrations are higher than the quantification threshold for each element. The elements with the lowest mean concentrations were found to be while the minerals with the greatest concentrations were calcium (Ca), magnesium (Mg), potassium (K), and sodium (Na).

S.No.	Mineral	Result (mg/100g)		
		Plant protein	Whey protein	
1	Sodium	266.59	154.74	
2	Magnesium	32.74	95.96	
3	Potassium	137.05	324.45	
4	Calcium	195.22	234.47	

Table 5.2 Results	of Analysis	of Minerals in	Plant Protein	and Whey F	rotein
1 able 5.2 Results	of Analysis	or winerars in	I faint I fotein	and whey I	rotem

Table 5.2 analysed the content of minerals (sodium, magnesium, potassium, and calcium) in both samples. The result showed that whey protein contains a higher amount of calcium 234.47 mg, potassium 324.45 mg, and magnesium 95.96 mg. The plant protein supplement, on the other hand, had 32.74mg magnesium, 137.05 mg potassium, and 195.22 mg calcium. Plant protein has a higher amount of sodium (266.59 mg) than whey protein (154.74 mg). It's critical to recognize that results for some minerals exhibit significant variability. This variation is accepted as typical given that a variety of elements, including production and processing practices and the environment in which the whey was produced, affect the mineral content of foods. Additionally, the usage of salts as additions in these whey protein supplements can be blamed for the higher amounts of some minerals in addition to their biological source (Sanchez, 2013). Both their innate existence in biological sources and the deliberate addition of salts as additives in these whey protein supplements can be blamed for

the increased amounts of several minerals. For example, sodium hydro phosphate is used to improve flavour. Both potassium hydro phosphate and potassium citrate serve as pH buffers in a similar way. To preserve electrolyte balance, sodium and potassium chlorides are also added, while calcium phosphate acts as an anti-caking agent. The observed mineral content of the supplements is greatly influenced by these deliberate additions (Knapik, 2016)





6. Discussion

The two samples of protein are distinct in terms of composition, nutritive values, and target consumer group, although both belong to the same category, i.e., Health Supplements. By conducting the proximate analysis and mineral analysis of both samples, a comparative analysis can be derived that can be used to help us conclude as to which product is ideal for consumption by adults. Total moisture content percentage directly affects the shelf stability of foods. In the context of the two samples of protein supplements that are manufactured in powdered form, moisture content is determined.

A variation of 29 % is observed between the moisture content results of both samples. Ash content, that is the total mineral content or the total inorganic material present in the samples does not differ as much. A significant variation of 45.80 % is observed between the protein content of both samples. The plant protein sample contains a higher amount of protein than the whey protein one. The amount of protein sources added in the former is approximately 85 % whereas only 37 % in the latter. This factor of the product composition results in a significant variation in the protein content. The fat content in plant protein is approximately 5 times the fat content in whey protein. Since the total content of plant protein is lesser than whey protein. The results of the content of these macronutrients, namely, fat, protein, and carbohydrates directly affect the total calorific value of the sample. When conducting a comparative analysis of minerals in both samples, whey protein has added minerals, resulting in a higher concentration of magnesium, potassium, and calcium, except sodium.

Market Potential:

Nowadays there is a range of protein supplements, in the market offering different options based on their source, type and usage. These supplements can be categorized into animalbased varieties like whey, casein, fish, eggs, and others; as plant-based options such as soy, rice, pea protein powders or spirulina. They are further classified based on their form such as protein powders, protein bars or ready to drink products. Additionally, they are used for purposes like sports nutrition or functional foods. Among these product categories in the protein supplement market protein powders are expected to experience revenue growth in the coming years due to their advantages. Protein powders have a texture which makes them easy to package and carry around conveniently. Furthermore, there have been advancements in both research and commercial development within the protein powder segment recently. These developments are expected to impact the demand and overall market growth of this category. Additionally, there is a growing interest among fitness enthusiasts for plant-based products like protein bars and ready to drink beverages made from plants which has led to an increase in demand, for plant-based proteins.

Despite a lack of scientific evidence, consumers of varying activity levels consume protein supplements and believe in its' various positive features. There is lot of market potential with the protein supplements as the main used dietary health supplement. The U.S. protein supplements market size was valued at USD 7.70 billion in 2021 and is projected to grow from USD 8.29 billion in 2022 to USD 16.41 billion by 2029, exhibiting a CAGR of 10.26% during the forecast period. Since the market has immense potential but, the comparative assessments must be done on various nutritional parameters for the same, just to make the smarter and healthier choices by the individuals.

7. Conclusion

Customers are increasingly drawn to food supplements that contain healthy, natural components as they become more aware of the potential risks of overusing chemicals and their related negative effects. An increased awareness of the value of a healthy diet and a rising environmental conscience are the driving forces behind this change. As a result, a sizable number of dietary supplement producers emphasize the use of natural, eco-friendly, or renewable ingredients. The rising popularity of sports and fitness among India's millennial population. The advantages of whey protein, including those that encourage muscle building, lower inflammation, and improve general health, are major factors in the rising demand for it. These benefits fit in nicely with the goals of people trying to perform at their best physically. It also demonstrates adaptability in looking for other ways to keep up workout regimens. The rise in physical activity within this group is encouraging for the sports nutrition sector. It is projected that millennials will make up a sizeable portion of the market's consumer base. Current generation places a high value on total wellness and physical fitness.Additionally, their concerns about a variety of health issues, such as heart health, brain health, managing their weight, and keeping up their energy levels, point to a holistic approach to wellbeing. This is consistent with the general movement toward a balanced, healthy lifestyle that takes both physical and mental health into account.

8. References

- 1. Banerjee, S. (2018). Dietary Supplements Market in India is rapidly Growing: An Overview. IMS Management Journal. Vol 10(1)
- Bansal, R. and Dhiman, A (2019). Line of Progression: Indian Regulatory Framework for Nutraceuticals and Dietary Supplements. Applied Clinical Research, Clinical Trials & Regulatory Affairs. Vol 6(1): 46-61https://dx.doi.org/10.2174/2213476X06666190128150415
- 3. Bhatt, A. (2016). Phytopharmaceuticals: A new drug class regulated in India. Perspective Clinical Research, 7: 59-61
- 4. Boindala, S., & Lewis, J. I. (2019). The grand challenge of regulating health foods in India. *The Indian journal of medical research*, *150*(3), 248–25.

- 5. Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002.https://eur-lex.europa.eu/legal
 - content/EN/TXT/PDF/?uri=CELEX:32002L0046&from=EN.
- 6. Dwyer, J.T., Coates, P.M., Smith, M. (2018). Dietary Supplements: Regulatory Challenges and Research Resources. Nutrients. Vol 10(1): 41 DOI:10.3390/nu10010041
- 7. Federal Food, Drugs, and Cosmetics Act (FD&C Act) (2016). Dietary Supplement: New Dietary Ingredients (NDI) Notification Process.https://www.fda.gov/food/dietarysupplements/new-dietary-ingredient-ndi-notification-process
- 8. Federal Food, Drugs, and Cosmetics Act (FD&C Act) (2016). Dietary Supplement.https://www.fda.gov/food/dietary-supplements
- 9. Food Safety and Standards (Food product standards and food additives) Seventh Amendment Regulations. 2016. Available from: http://www.fssai.gov.in.
- Frankos, V.H., Street, D.A., and O'neill, R.K. (2010). FDA Regulation of Dietary Supplements and Requirements Regarding Adverse Event Reporting. Clinical Pharmacology & Therapeutics, Vol 87
- 11. Hathcock, J. (2001). Dietary Supplements: How are they used and regulated? The Journal of Nutrition. Vol. 131(3): 1114S-1117S DOI:https://doi.org/10.1093/jn/131.3.1114S
- 12. IMARC (2023). India Dietary Supplements Market: Industry Trends, Share, Size, Growth, Opportunity and Forecast 2023-2028. Available onhttps://www.imarcgroup.com/india-dietary-supplements-market/toc
- Joy, J. M., Lowery, R. P., Wilson, J. M., Purpura, M., De Souza, E. O., Wilson, S. & Jäger, R. (2013). The effects of 8 weeks of whey or rice protein supplementation on body composition and exercise performance. Nutrition Journal: 12(1), 1-7
- 14. Kårlund, A., Gómez-Gallego, C., Turpeinen, A. M., Palo-Oja, O. M., El-Nezami, H., & Kolehmainen, M. (2019). Protein supplements and their relationship with nutrition, microbiota composition and health: is more protein always better for sportspeople? *Nutrients*, *11*(4), 829
- Knapik, J.J., Steelman, R.A., Hoedebecke, S.S., Austin, K.G., Farina, E.K., Lieberman, H.R. (2016). Prevalence of Dietary Supplement Use by Athletes: Systematic Review and Meta-Analysis. Sports Medicine Vol. 46: 103-123 DOI: 10.1007/s40279-015-0387-7
- 16. Kołożyn-Krajewska, D. (2022). Development of Ready-to-Eat Organic Protein Snack Bars: Assessment of Selected Changes of Physicochemical Quality Parameters and Antioxidant Activity Changes during Storage. *Foods*, *11*(22), 3631
- 17. Mahady, G.B. (2001). Global Harmonization of Herbal Health Claims. American Society for Nutritional Sciences. Vol. 131: 1120S-1123S
- 18. Malik, V. (2013). Law Relating to Drugs and Cosmetics. 23rd Ed.
- Mamta, Pathania Singh (2021). Some Medicinal Herbs and Shrubs of District Solan (HP). International Journal for Research in Applied Science and Engineering Technology; 9(9) 248–54. DOI:http://dx.doi.org/10.22214/ijraset.2021.37957
- 20. Maughan, J R (2013). Quality Assurance Issues in the use of Dietary Supplements, with special reference to Protein Supplements. Journal of Nutrition Vol. 143(11) 1843S-1847S DOI: 10.3945/jn.113.176651
- 21. Moreira, D. L., Teixeira, S. S., Monteiro, M. H. D., De-Oliveira, A. C. A. X and Paumgartten, F. J. R. (2014). Traditional Use and Safety of Herbal Medicines. Revista Brasileira de Farmacognosia, Vol. 24: 248-257.
- 22. Research and Markets (2021). Indian Dietary Supplement Markets, By Product Type (Vitamin, Combination Dietary Supplement, Herbal Supplement, Fish Oil & Omega

Fatty Acid, Protein & Others), By Form, by distribution Channel, by Application, By End Use, By Region, Competition Forecast & Opportunities, FY2027).https://www.researchandmarkets.com/reports/5235681/india-dietary-supplement-market-by-product

- 23. Ross, S. (2000). Functional Foods: The Food and Drug Administration. The American Journal of Clinical Nutrition. Vol. 71(6): 1735S-1738S
- 24. Samal, J.R.K, and Samal, I.R. (2018). Protein Supplements: Pros and Cons. Journal of Dietary Supplements: 15(3), 365-371
- 25. Scanchez, O.A.J. (2013). SuplementaciónNutricional En La Actividad Físico-Deportiva: Análisis De La Calidad Del SuplementoProteicoConsumido. Universidad de Granada, Spain
- Szydłowska, A., Zielińska, D., Trząskowska, M., Neffe-Skocińska, K., Łepecka, A., Okoń, A., and Krajewska, D.K (2022). Development of Ready-to-Eat Organic Protein Snack Bars: Assessment of Selected Changes of Physiochemical Quality Parameters and Antioxidant Activity Changes during Storage. Vol. 11(22). doi: 10.3390/foods11223631
- 27. Thakur M, Belwal T (2022) Bioactive Components: A Sustainable System for Good Health and Well-Being, 1st edn. Springer Nature Singapore, Singapore
- 28. Thakur M, Modi VK (2020). Emerging Technologies in Food Science- focus on the developing world, SPRINGER Nature.
- 29. Wilschefski, S. C., & Baxter, M. R. (2019). Inductively Coupled Plasma Mass Spectrometry: Introduction to Analytical Aspects. *The Clinical biochemist. Reviews*: 40(3), 115–133
- 30. Zhu, J., Chen, M., Borlak, J. and Tong, W. (2019). The landscape of hepatobiliary adverse reactions across 53 herbal and dietary supplements reveals immune-mediated injury as a common cause of hepatitis. Archives of Toxicology Vol. 94: 273-29
- Zion Market Research (2017). Global dietary supplements market will reach USD 220.3 billion in 2022: Zion Market Research.https://globenewswire.com/newsrelease/2017/01/11/905073/0/en/Global-Dietary-Supplements-Market-will-reach-USD-220-3-Billion-in-2022-Zion-Market-Research.html.