

NUTRACEUTICAL PRODUCT DESIGN BY INGREDIENT SCIENCE

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With the changing times and with the recent pandemic outbreak, the awareness amongst the population is increasing and everyone is getting into adopting healthier habits. This can be marked as an era of Health Revolution in history of mankind. Especially in India, which comes with a rich background of Ayurveda and our household 'Dadima ka Nuske' we have all adopted certain habits for healthier living like having a glass of Turmeric Milk, a spoon of Honey & Lemon in the morning with warm water or a cup of Curd with our meals.

What are these? These are basically the traditional forms of modern adopted nutraceuticals. In simple terms, nutraceuticals are generally natural ingredients derived from sources such as animals, plants and microbial organisms which provide various health benefits. These are essentials that provide the functional benefits of completing the nutritional needs for a healthy living.

Ingredient Market

The Global Nutraceutical Ingredients market is valued at USD 162.1 billion in 2020 and is expected to reach USD 227.5 billion by 2025, with a CAGR of 7.0% from 2020 to 2025. The growth of the market is driven by factors such as growth in the demand for fortified foods, supplements and nutraceuticals owing to the increasing health consciousness amongst consumers.

The Asia Pacific nutraceutical ingredients market is completely driven by India largely, which accounted for nearly 31.5% of the market share in 2019. Our nation is projected to be the fastest-growing country for nutraceutical ingredients due to changing lifestyles, dietary patterns and growing awareness about nutrition. Consumers in the country are now willing to spend an additional amount for fortified products, which has increasingly helped manufacturers of nutraceutical ingredients to find a substantial market opportunity.

Ingredients Driven Product Development

Nutraceutical ingredient is the major component for developing



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Ranjitha Balakrishnan comes with an experience of more than 12 years in the area of Health, Wellness & Fitness. She has been dedicated to the Nutraceutical industry in the areas of Business Development, Strategic Initiatives & Regulatory Compliances. During these years in the industry, Ranjitha has successfully launched various Nutraceutical Products, right from Ideation, Conceptualization and commercialization with various pharmaceutical & nutraceutical companies in India. Her specialization includes Business Development, In - Licensing, Regulatory, Technical Compliances, Dossier development, Client Relationship management, Strong Competency in New Product Development & Market Research for Nutraceutical/ Health & Dietary Supplement/ Probiotics. Her recent achievement, marks a feather in the success of one of the Fastest growing Health & Wellness Company, wherein she has got products like Astaxanthin, Whey Protein Isolate and BCAA, Informed Sports Certified, which is the Apex certification for the Quality & Safety of the products in the World.

the product for a specific health benefit. While designing the product, studying properties of the ingredients and the health benefits of the active component can help design the right product with the right dose for its effectiveness. Focus on the ingredient supported with clinical studies and either single ingredient or with combination of ingredients that complement the effect makes an excellent product. For eg- Curcumin (an active ingredient from turmeric) when combined with Bioperine (Piperine) helps in enhancing the absorption of curcumin and works the best for Joint care management, Astaxanthin when combined with Tocotrienols provides wonderful benefits for skin health.

Generally, the nutraceutical products that are seen in the market are a combination of multivitamins, natural extracts, herbal extracts, amino acids, etc. positioned for different health categories. Although designing a single ingredient or a combination of complementary ingredients set at the right dose of its active components will provide a product that works for its expected & stated benefits.

Key Factors to be considered while selecting Nutraceutical Ingredients:

1. Transparency and Traceability
Ingredients used in the product should be easily traced to their source starting from farming to the finished products. The ingredient manufacturer should be transparent about the entire cycle from farming to harvesting, extraction, purification and manufacturing of the finished ingredient. This makes the ingredient trustable for its safety and quality.
2. Standardized to Active Ingredients
Standardization of active ingredients is consistent in producing measurable high quality ingredients using standardized processes. In case of branded ingredients like KSM 66® Ashwagandha, BioSolve Curcumin™, EVNoI Max™ Tocotrienols, AstaReal® Astaxanthin, Megashine-O® Flaxseed Oil and such others have unique manufacturing techniques which standardizes the concentration of the ingredient at a specific effective dose. Such standardized ingredients have better absorption and are highly efficacious when compared to non-standardized ingredients owing to superior results.
3. Clinically Researched Ingredients

While selecting an ingredient, having fully established scientific dossiers and clinical studies gets an edge over other generic ingredients. These studies support the effectiveness of the ingredient with evidence based trials. A clinically researched ingredient definitely works the best of its expected result and health benefit with the set dose. AstaReal® is one such ingredient backed with more than 60 clinical studies at set dose for skin health, Liver detoxification, Muscle recovery, Brain health, Eye health working on each cell of the body. A simplified matrix to summarize the clinical studies can be used for quick mapping and understanding of a researched ingredient.

| Ingredient Scientific Study Matrix * | |
|--------------------------------------|---|
| Type of Study | Human Study/Animal Study |
| Nature of the Study | Double Blinded/ Open |
| No of Subjects | xx |
| Indication | Eye Health, Antioxidant, Derma, Liver Health, etc |
| Duration | xx weeks |

| | |
|--------------|---|
| Formulation | Either Single or in Combination |
| Dose | -mg |
| Summary | Background and Objectives: Study Design: Results: |
| Outcome | Conclusion of the study |
| Claim if Any | Health Claims |
| Journal | Journal Name |
| Hyperlink | Web Link of the Study |

*Developed by NISA™ (Nutraworks Intelligence Scientific Alliance)

4. Clean, Safe & Qualified Ingredients

Along with the number of clinical studies and the scientific rationalization, the purity, safety and quality of the ingredient is equally important. Impurities from the extraction process or excipients can be of concern sometimes with the ingredients that are being used. Also the safety limits of per dose is to be considered while designing the product. Ensuring that the ingredients are free of harmful chemicals, doping substances or any other banned substances is very critical for the consumer's safety. Various certifications like Halal, Kosher, Informed Choice, Organic Certification from NPOP (National Programme on Organic Production), and claims like Vegan, GMO Free, Gluten Free etc. plays an important role in maintaining the Quality standards of the ingredients.

5. Informed Consumer Intelligence

The consumer has to be informed about all the elements of the product. Knowing the efficacy of the product is important, along with knowing the safety limits and assurance of no harmful effects, is important for building confidence in the minds of consumers. The Ingredient manufacturers should keep the consumer informed and educated about these parameters through various programs like Informed Consumer Choice, organized by Expert Nutraceutical Advocacy Council (ENAC)®

6. Ingredient compliance as per the regulation

The Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods and Novel Foods) Regulations, 2016 has defined the ingredients that are allowed to be used while formulating the product. ENAC® has been in the forefront for release of this regulation and is continuously submitting various representations in support of the industry.

Below table highlights some of the key ingredients under each category that are popularly used.

7. Ingredient Pricing

While developing any product, one of the decision making parameters is to check the viability of the ingredient from the commercial perspective. Ingredient pricing should be such that it is feasible as well as strong from the point of effectiveness. Promoting *Atmannirbhar* (home-grown) ingredients, working on scientific studies on these ingredients and establishing the same will help provide better commercials.

Importance of Nutraceutical Ingredients

Traditionally we have known a lot of remedies and 'at home' table solutions for developing a healthy lifestyle. But over the years, the quality of the feed that is produced is degraded. The kind of nutritious food that our ancestors ate are not the same as what we get these days. In such times, getting all our Macro and Micro Nutrients for the efficient functioning of the body is a critical factor.

1g of protein per kilogram of the body weight should be consumed for the right functioning and maintaining energy throughout the day. Your muscles will be stronger when they are fed with the right amount of protein. Our regular foods, especially for vegetarians, do not provide such amounts of protein. So, an external source like Whey Protein or Plant proteins should be added to the daily regimen.

Daily replenishment of Calcium, Magnesium, Zinc, Vitamin B complex, Vitamin D, Vitamin E, Biotin and other such micro nutrients are essential. Micro nutrients play a very vital role in the proper functioning of the body and hence is it very important to consume them in the right quantities daily.

Natural antioxidants like Astaxanthin (6000 times stronger than Vitamin C), Glutathione, Tocotrienols, Grape seed extract, Citrus bioflavonoids, and other popularly known Vitamin C, Vitamin E are vital. Antioxidants are substances that may protect your cells against free radicals and can play a vital role in keeping heart disease, cancer and other diseases at bay.

Omega 3s are not naturally produced in the body but are an incredibly important ingredient for the functioning of the body. Omega 3 helps in maintaining a healthy heart, keeps the cholesterol in check and supports the development of the brain.

| Ingredient Classification under FSS Regulation, 2016 | | | | |
|--|--------------------|----------------------------------|-----------------------------|---------------------------|
| Multivitamin & Mineral | Nutraceuticals | Plant & Botanicals | Probiotics | Prebiotics |
| Vitamin A | Astaxanthin | Ashwagandha | Lactobacillus acidophilus | Inulin |
| Vitamin C | Glutathione | Green tea extract | Lactobacillus reuteri | Fructo-oligosaccharides |
| Vitamin D | Tocotrienol | Gingko biloba extract | Lactobacillus plantarum | Maltitol |
| Vitamin E | Citrus | Curcuma longa (Turmeric) | Lactobacillus casei | Polydextrose |
| Vitamin B complex | Bioflavonoids | Moringa oleifera (Drumstick) | Lactobacillus paracasei | Isomaltulose |
| Vitamin K | Lycopene | Bilberry extract | Lactobacillus rhamnosus | Gluco-oligosaccharides |
| Magnesium | Lutein | Silymarin extract (Milk Thistle) | Bifidobacterium lactis | Xylo-oligosaccharides |
| Calcium | Zeaxanthin | Spirulina | Bifidobacterium bifidum | Galacto-oligosaccharides |
| Phosphorous | Flaxseed oil | Boswellia serrata | Bifidobacterium longum | Soybean oligosaccharides |
| Iron | Fish oil | Emblica officinalis (Amla) | Staphylococcus thermophilus | Isomalto-oligosaccharides |
| Selenium | Resveratrol | Evening Primrose oil | Saccharomyces cerevisiae | Inositol |
| | Collagen peptides | Aloe vera | | |
| | Grape seed extract | | | |
| | Black Garlic | | | |
| | Fenugreek | | | |

These are just a few of the ingredients. You may refer to FSSR copy for other ingredients under each category