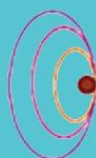




Ministry  
of  
Education



**NASTEC**  
National Science  
and  
Technology Commission

**Technical Report on  
Nutraceuticals and lead medicinal  
compounds derived from Sri Lankan bio resources**



**9<sup>th</sup> SRI LANKA BIENNIAL CONFERENCE ON  
SCIENCE & TECHNOLOGY  
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**23rd & 24th March 2023**

**Waters Edge, Battaramulla**

**NUTRACEUTICALS AND LEAD MEDICINAL  
COMPOUNDS FROM SRI LANKAN BIO  
RESOURCES**

9<sup>th</sup> Sri Lanka Biennial Conference on Science and Technology  
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## 1. Executive Summary

Nutraceuticals are products derived from food, plant or animal resources that possess medicinal properties and provide diverse health advantages. Sri Lanka has many bio-resources, such as cinnamon, turmeric, ginger, green tea, black pepper, and gotu kola, which possess nutraceutical properties. Sri Lanka's traditional knowledge of nutraceutical values of bioresources and health-food provides an added advantage for the development of new products and a better market share in the global nutraceutical industry.

The purpose of this technical report is to identify research needs to support the nutraceutical industry in Sri Lanka. The report aims to collect data on the global and Sri Lankan nutraceutical markets, constraints that hinder the progress of the nutraceutical industry, and research needs to develop the industry. The data collection was carried out through a literature review, data gathering from government institutions, and information collected from experts and nutraceutical companies. The report highlights the importance of understanding the current status of the industry to develop effective research strategies.

The collected information was categorized into sections that emphasized the research and development necessities for nutraceutical products. These categories encompassed the global and local market, raw material cultivation and post-harvest technology, compound identification, clinical trials, standardization, industrial research requirements, and the latest nutraceutical industry advancements.

The global nutraceuticals market experienced growth from USD 372 billion in 2022 to USD 409 billion in 2023, despite economic disruptions caused by the Russia-Ukraine conflict. Sri Lanka exported nutraceuticals and herbal products worth USD 36 million in 2022, with India, Netherlands, USA, Japan, and Australia being the primary export destinations. The import expenses amounted to USD 5.9 million, with Austria, India, Thailand, and Switzerland being the primary import sources for products including Herbal preparations for use as "Herbal teas", and "Nutraceutical" preparations, approved by the Director General of Health Services, Beverages put up for retail sales as "Energy Drinks" and Ayurveda / Herbal preparations: Schedule 01/02/03/04 preparations certified by the Commissioner of Ayurveda.

In the nutraceutical industry, the systematic cultivation and postharvest technology of plant raw materials are of utmost importance. The report highlights the significance of carefully selecting and cultivating plants from the wild, conducting trial cultivation and analytical procedures, developing proper storage techniques, and experimenting with trial propagation to develop high-yield varieties.

The report also highlights the importance of identifying active ingredients in herbal products targeting the global market. However, Sri Lanka lacks the necessary instruments, techniques and other infrastructure to achieve this goal. To develop herbal products for global markets, a research center with appropriate instruments, technical support staff, and facilities for in vitro assay developments and bioassay-guided isolations is necessary. Such a center could strengthen the herbal product industry and provide new potential lead compounds for various diseases.

The report also discusses the challenges and complexities in conducting clinical trials for nutraceuticals and herbal drugs, which require addressing various issues, including chemical-manufacturing-control, non-clinical, clinical, and ethical issues. Preclinical studies are important for predicting adverse drug reactions and establishing the mechanism of action. However, designing clinical trials for nutraceuticals is challenging due to their multi-ingredient composition. The World Health Organization has guidelines for conducting herbal drug-related clinical trials, and pharmacovigilance-based approaches that are necessary for identifying adverse drug reactions. Therefore, the report encourages proper trial conduction with expert nutraceutical and herbal trialists to develop quality and safe nutraceuticals.

In order to maintain the efficacy, quality, and safety of herbal products in Sri Lanka, standardization is important. The report outlines several quality parameters used for this purpose, including authentication of medicinal plants, identification of chemical constituents, physico-chemical parameters, determination of shelf life, microbial purity, determination of foreign matter, extractive values, heavy metals, total ash value, and pesticide residues. To guide the standardization of specific herbal products such as herbal capsules, herbal tea, soft candy, and herbal-fruit drinks/juices, etc., the Ayurveda Formulary Committee has prepared Standard Operating Procedures (SOPs).

The low levels of industrial research and development (R&D) investments in Sri Lanka, has resulted in limited innovative product development and technology transfers. Therefore, the report suggests encouraging and facilitating R&D within industries and introducing Industry-Institution partnerships protecting relevant intellectual properties. Additionally, there is a need for scaling up formulations developed at the R&D level at pilot plants or industrial production platforms before technology transfer or marketing. Also, there is limited availability of nutraceutical pilot plants in Sri Lanka. Therefore, it is suggested to strengthen such facilities to support the development of a sizable nutraceutical industry in the country.

Finally, the report outlines several issues in the nutraceutical industry and provides corresponding recommendations. These issues include the lack of policy decisions ensuring the efficacy of products, unavailability of standard profiles for raw materials, absence of a cost-

effective public laboratory for quality testing, lack of research and clinical evidence for export, and a shortage of skilled professionals in research laboratories and industries. The recommended solutions include encouraging in-vitro efficacy and clinical trials, promoting research for quality assurance, upgrading public laboratory facilities, incentivizing research and development partnerships, and enhancing human resource availability.

## 2. Introduction

Sri Lanka has a vast repository of endemic and indigenous bioresources, which are natural sources of pharmaceutical and nutraceutical compounds. Traditional Medicine employs around 2000 medicinal plants, many of which are indigenous to Sri Lanka. There are several research studies have been done on lead compounds including antioxidant, anti-inflammatory and antimicrobial properties of endemic plants that can be indicated for their potential to be used in drug development and other medical applications. Pharmaceutical and nutraceutical companies are on a rising trend to manufacture, import, and export nutraceuticals as they show less side effects and interactions with medicines.

The term "Nutraceutical" originated from the two words Nutrients and Pharmaceuticals. As the term implies these are food-derived products that exhibit health promoting properties. Furthermore, these nutraceuticals offer diverse health advantages that aid in the management and prevention of several health issues such as cancer, heart diseases, arthritis, neurological disorders, and more. They could also be used to improve immune response and decrease inflammation to enhance general health and wellness. Also, the surge in interest in natural and alternative healthcare procedures has resulted in the development and usage of nutraceuticals. There is a rich repository of indigenous bioresources in Sri Lanka, many of which possess nutraceutical properties. Additionally, the National Medicines Regulatory Authority (NMRA) regulates some nutraceuticals which play an essential role in this aspect. The NMRA regulates sales, importation, and distribution of nutraceuticals that obtained its registration. The Formulary Committee of the Department of Ayurveda registers the majority of nutraceuticals. Sri Lankan nutraceutical industries conform to global quality management systems, such as ISO 9001: 2015 and the good manufacturing practices (GMP), which outlines the criteria for a quality management system. These standards guarantee consistent manufacturing, packaging, and labeling of products. The industries regularly assess both finished products and raw materials to ensure they meet rigorous quality criteria. These assessments involve microbiological contamination, potency, and purity testing.

The Sri Lankan nutraceutical market now occupies a minor position compared to the entire global market. However, the nutraceutical industry is growing due to the country's unique biodiversity and the demand for natural health promoting products. The Export Development Board (EDB) is actively encouraging the export of nutraceutical products in order to improve foreign exchange revenues. Additionally, the National Science Foundation (NSF), Council for



Agricultural Research Policy (CARP), and the National Research Council (NRC) are responsible for funding scientific research and advancements in this area. The Industrial Technology Institute (ITI), other public research institutes, and the university system either alone or in partnership with the industry conduct research and development and provide technical support to small and medium scale nutraceutical industries.

The nutraceutical sector is continually evolving, and some recent advancements are reshaping its future. Nanotechnology is used to create nutraceutical nano formulations that improve the effectiveness and absorption of nutraceutical components. Nano encapsulation can improve the stability, solubility, and effectiveness of nutraceuticals within the body. Novel ingredients derived from bio-resources such as plants, algae, microbes, and other botanicals are presently utilized for developing nutraceutical formulations. Also, there is a demanding market for microbiome-based products, specifically targeting and regulating the gut microbiome. Additionally, personalized nutraceuticals result in the development of nutrition plans that are tailored to a particular person. Since Sri Lanka has a wealth of traditional knowledge on the health-food and nutraceutical values of its bioresources, it is an added advantage Sri Lanka has for a better market share in the global nutraceutical industry.

### 3. Methodology

The purpose of this technical report is to identify the research needs to support and strengthen the export-oriented nutraceutical industries in Sri Lanka.

Considering the above fact, collecting data and information on the below subjects are essential to understand the current country status;

1. **The nutraceutical product market on the global level** – to understand the global demand for nutraceutical and herbal products.

2. **The nutraceutical market in Sri Lanka** – to gain knowledge on where Sri Lanka stands compared to the global market.

-The nutraceutical import market of Sri Lanka

-The nutraceutical export market of Sri Lanka

3. **Constraints/barriers that are hindering the progress of the Sri Lankan nutraceutical industry** – to understand what types of constraints are preventing Sri Lankan nutraceutical production and export companies from gaining a lead on the global nutraceutical market.

4. **Research needs in the country to develop the nutraceutical industry** – to identify industry research needs relevant to the cultivation of raw materials, post-harvest issues, identification of compounds, standardization, quality control testing, clinical trials, etc.

The collection of above data and information was carried out using several methods:

01. Literature review on nutraceuticals, global market trends on nutraceutical products, traditional medicine research in the country, etc. via journal articles, books, online resources, etc.
02. Data gathering from Government institutions on the nutraceutical and herbal products import and export market in Sri Lanka - from Export Development Board, Department of Ayurveda, Sri Lanka Customs, etc.
03. Information gathering from scientists, academics, and government officials who are experts in the subject within the country - from Industrial Technology Institute, Faculty of Indigenous Medicine, Sri Lanka Institute of Biotechnology, Universities, etc.
04. Information gathering from nutraceutical and herbal product development and export companies in Sri Lanka, eg: Link Natural Products (Pvt) Ltd., Hettigoda Industries (Pvt) Ltd. (Siddhalepa), Beam Hela Osu (Pvt) Ltd., Ancient Nutraceuticals (Pvt) Ltd., etc. via a stakeholder meeting.

## 4. Results & Analysis

The data and information gathered were divided as per below sections, with each section emphasizing the research and development needs

- ❖ Current global and local nutraceutical product market
- ❖ Cultivation of raw materials and post-harvest technology
- ❖ An overview of research needs for the identification of compounds
- ❖ Clinical evaluation studies to establish efficacy and side effects
- ❖ Research needs for standardization
- ❖ Industrial research needs
- ❖ Research based on recent advancements in the nutraceutical industry
- ❖ Commercialization and market sustainability of nutraceuticals

### 4.1 Current global and local nutraceutical product market

As per nutraceutical market reports, the global nutraceuticals market grew from USD 372.27 billion in 2022 to USD 409.12 billion in 2023 at a compound annual growth rate (CAGR) of 9.9%. The Russia-Ukraine war disrupted the chances of global economic recovery from the COVID-19 pandemic, at least in the short term. The war between these two countries has led to economic sanctions on multiple countries, a surge in commodity prices, and supply chain disruptions, causing inflation across goods and services, and affecting many markets across the globe. The nutraceuticals market is expected to grow to USD 596.81 billion in 2027 at a CAGR of 9.9% [1][2].

As per the nutraceutical and related herbal product export and import data received from the Statistics Division of Sri Lanka Customs, Sri Lanka had an export revenue of USD 36.34 million from nutraceuticals and related herbal products in 2022, where the main exported countries were India, Netherlands, USA, Australia, Czech Republic, UK, Chile, etc. The import expenses were USD 5.85 million for 2022 with the main imported countries being Austria, India, Thailand, and Switzerland.

The export and import products that were considered to include "Nutraceutical" preparations, approved by the Director General of Health Services; Beverages approved as drugs by National Medicine Regulatory Authority (NMRA); Ayurveda / Herbal preparations: Schedule

01/02/03/04 preparations certified by the Commissioner of Ayurveda; Herbal preparations for use as "Herbal teas"; Beverages put up for retail sales as "Energy Drinks"; and Herbal based beverages.

#### **4.2 Cultivation and postharvest technology**

Plant raw materials are mostly obtained from the wild as systematic cultivation is very rare. There is some collection mainly of aromatic plants and spices through cultivation. If one needs to obtain a quality product using cultivated or wildy grown plant materials, quality has to built into the chain from the starting materials onwards. Hence cultivation or collection from the wild has to be selective and properly done. Cultivation can be done using seeds, cuttings or tissue cultured plantlets but using authenticated and selected plant sources. The following stages have to be followed: selection of the plant, authentication, cultivation, time of harvesting, disease and pest control, proper irrigation, collection, purification, drying if required, suitable packaging and proper storage.

After the selection of the plant, trial cultivation has to be done in plots to study the growth requirements and pest control and if required any fertilizer or pesticide use. After harvesting, proper procedures have to be used to clean the product, dry it and store until the time of use. Proper analytical procedures have then to be developed to get a good quality through testing.

Storage is another important factor. Storage conditions have to be developed to avoid deterioration due to moisture, temperature fluctuations, fungal contamination, insect infestation etc. These are very necessary as plant material starts degrading after harvesting. If the raw material is collected from the wild, economic mapping of autogenic flora has to be done.

Trial propagation for developing high yield varieties can also be done at this stage. Expiration dating of the raw materials has also to be undertaken in order to discard the deteriorated raw materials.

#### **4.3 An overview of research needs for the identification of compounds**

Detailed description of the active ingredients present is essential for any herbal product targeting a global market. However, identification of active ingredients of a herbal product is not that feasible in a country like Sri Lanka due to the lack of required instruments and identification techniques. Further, even for confirmation of the presence of known compounds, a standard library of natural products along with GCMS or LCMS has to be available. Hence

one research center with major instruments (LCMSMS, HPLC, GCMSMS and NMR) with experienced technical support staff is a major requirement, to develop herbal products for the global market. For endemic plants there would not be many publications on isolated compounds available. Hence, in vitro assay developments as well as facilities for bioassay guided isolations also need to be highly supported. These fundamental research needs could strengthen the herbal product industry as well as provide new potential lead compounds for many diseases.

#### **4.4 Pre-clinical and clinical evaluation studies to establish efficacy and side effects**

When undertaking a clinical trial of a nutraceutical or herbal drug, there are four issues that need to be addressed:

- (1) Chemical-manufacturing-control (CMC) issues
- (2) Non-clinical issues
- (3) Clinical issues
- (4) Ethical issues.

Studies of nutraceuticals face additional complexities in the research design process. These include the multi-ingredient composition of an intervention and the fact that typically substantial prior human use precedes its formal investigation. These features have important ramifications for CMC, non-clinical, clinical, and ethical issues.

Before the trial initiation process, exploratory preclinical studies including acute and chronic toxicity studies are important to predict adverse drug reactions, and also clarification of the possible mechanism of actions on nutraceuticals is essential for global recognition. Further standard toxicology parameters and safety including core battery studies are essential for novel nutraceuticals. In some instances, pre-clinical studies of dose determination studies have to be undertaken for the effective and safe usage of nutraceuticals. Further, stability studies of both accelerated and real-time are needed to establish the expiration dating of nutraceuticals.

Safe, effective, and high-quality medicines are developed and registered in most resource-efficient manner. But it is still difficult to apply these guidelines to nutraceuticals and herbal drug research. Nutraceuticals and herbal products' clinical trials may need a different approach or process to meet the recommendations, particularly considering the fact that many of the products have been in use for long periods.

In Sri Lanka, very few clinical trials have been conducted in herbal medicine development. Clinical trials require institutional ethical clearance, and trial registration in a World Health Organization-accepted trial registry before commencement and should adhere to the latest version of the Declaration of Helsinki with regard to good clinical practice (GCP). Investigators should achieve GCP training and certification before conducting a trial [3].

Despite sophisticated study designs and measurement tools, it is yet to create an innovative space for nutraceuticals in the healthcare system in Sri Lanka. The path is challenging due to the current hierarchies of scientific evidence and regulatory affairs. The role of the randomized, double-blind, placebo-controlled clinical trial (RCT) as a research approach functions well to characterize the benefits and risks of drugs but lacks the sensitivity to capture the efficacy and safety of nutraceuticals. While some facets of RCTs can be relevant and useful when applied to nutraceuticals, other aspects are limiting and potentially misleading when taken in their entirety [4]. But we encourage a proper trial conduction system with experts in herbal and nutraceutical trialists. There are some guidelines stipulated by the World Health Organization for herbal drug-related clinical trials [5]. A further pharmacovigilance-based approach is essential in marketed nutraceuticals to identify any adverse drug reactions and signal generations to avoid serious adverse reactions. Further recalling system is essential if any serious adverse reactions have occurred. We promote conducting clinical trials including the safety and efficacy for developing quality and safe nutraceuticals.

#### **4.5 Research needs for standardization**

Sri Lanka is blessed with remarkable biodiversity and identified as a biodiversity hotspot in the world with enormous numbers of medicinal plants and very high endemism among its flora. In order to maintain the quality, efficacy and safety of the herbal products, consistency of phytochemical constituents in herbal formulations should be assured. Several major problems such as inadequate availability of raw materials, use of poor-quality plant materials, adulteration using non effective plant materials, and lack of proper cultivation and propagation system of the medicinal plants, have been recognized by manufacturers of herbal products. Standardization of herbal products is not an easy task as above factors influence the bio-efficacy and the reproducibility of the therapeutic effect. Hence, it is essential to develop reliable and sensitive standardization methods to ensure the quality of herbal products using a combination of classical and modern analytical testing parameters.

In Sri Lanka, the quality of the product is assessed by traditional and modern quality parameters as specified in recognized pharmacopeias, monographs, WHO guidelines, Sri Lanka Standards (SLS) and any other recognized standards acceptable by the Department of Ayurveda. The herbal products shall be tested for quality in any independent laboratory accredited for that purpose by the Sri Lanka Accreditation Board (SLAB) or any other independent laboratory approved by the Department of Ayurveda. Ayurveda Formulary Committee of the Department of Ayurveda, Ministry of Indigenous Medicine is responsible for regulation of herbal products in the country and every formula of the herbal product should be approved by the Ayurveda Formulary Committee prior to issuance to the market for public consumption.

#### The list of quality parameters used for standardization of Herbal products

Herbal products can be a medicinal extract / fraction / item /formulation, a healthy food, a health supplement, a food supplement, a nutraceutical or a cosmeceutical product. The steps involved in standardization of herbal products are given below.

- **Authentication of medicinal plants**

Plant authentication is essential when preparing herbal products. Therefore, authentic specimens of plants should be available to serve as a reference and visual inspection helps to establish identity, purity and quality. DNA fingerprinting has been widely used in species identification of medicinal plants.

- **Identification of chemical constituents – TLC / HPTLC/ HPLC / GC**

Chemical constituents in herbal products are compared using Thin Layer Chromatography (TLC) as TLC is being employed extensively in the phytochemical evaluation of herbal products. TLC enables rapid qualitative analysis with minimum quantity of sample.

However, advanced chromatographic techniques, such as HPLC, HPTLC, LCMS, GCMS etc. help to obtain reliable chemical profiles for standardized therapeutically effective herbal formulations.

- **Physical parameters**

This is a qualitative evaluation of the herbal products and detailed botanical, macroscopic and microscopic descriptions of the herbal product are provided. A microscopic analysis assures the identity of the material and as an initial screening test

for impurities. Color, odor, appearance, clarity, viscosity, moisture content, pH, disintegration time, friability, hardness, flowability, flocculation, sedimentation and settling rate are considered as the physical parameters.

- **Determination of foreign matter**

Herbal product should be completely free from insects or molds, including visible and excreta contaminant such as stones, sand, harmful and poisonous foreign matter and chemical residues. Macroscopic evaluation can be used to determine the presence of foreign matter.

- **Determination of extractive values**

An extract of the herbal product is prepared using various solvents and this will provide the approximate quantity of the chemical constituents in the herbal products.

- **Determination of heavy metals**

Quantitative analysis of heavy metals in the herbal product is determined and the heavy metals such as Arsenic, mercury, lead, cadmium are considered to be contaminants of few herbal ingredients. AAS or ICPMS can be used to quantify the heavy metal content.

- **Determination of total ash value**

The residue after incineration of the herbal product is the total ash content of the crude drug, which simply represents inorganic salts, naturally found in drug or adhering to it or deliberately added to it, in the form of adulteration.

Three types of ash values: total ash, water soluble ash value and acid insoluble ash value.

- **Pesticides residue**

Herbal products are prone to contain pesticide residues, which gather from agricultural practices during cultivation and addition of fumigants during storage. The various methods are employed to measure pesticide residues by using GC, GC- MS, HPLC or LCMS.



## **Quality parameters used for standardization of specific herbal products in Sri Lanka**

Ayurveda Formulary Committee has prepared the Standard Operating Procedures (SOPs) to provide clear guidance and information on the procedure to be followed when standardization of specific herbal products including herbal capsules, herbal tea, soft candy (toffees and jelly-based candy), and herbal-fruit drinks / herbal-fruit juices (Table 01, Page 21).

### **4.6 Industrial research needs**

R&D at industrial level or investments made for research by the industries is extremely low in Sri Lanka. Therefore, innovative product development that could generate revenue to the country coming from industry is extremely limited although some product developments and technology transfers are happening via the state-owned research institutes and universities from the limited R&D investments available to them from the national budget. Therefore, it is important to encourage and facilitate R&D within industries, at least to some scale and support fine tuning and scaling up by the R&D institutions in the country. In such a value chain development process, the Industry-Institution partnerships should be introduced in order to protect intellectual properties of the industrialist by introducing strong legal bindings through MOU/MOA and NDAs. Further, the products developed at benchtop level need to be scaled up as the scaling up may not produce the same results the product needs to have. Therefore, the formulations developed at R&D level need to be scaled up at pilot plants or industrial production platforms before the product is ready for technology transfer or marketing. Pilot Plants or industrial production platforms for nutraceuticals are extremely limited in the country. Dedicated nutraceutical pilot plant is only available at ITI at present and it is also been installed. However, such facilities need to be strengthened in order to obtain maximum output for the development of a sizable nutraceutical industry in the country.

### **4.7 Research based on recent advancements in nutraceutical industry**

**Advanced delivery systems:** In order to improve the bioavailability, effectiveness, and absorption of nutraceuticals, advanced delivery techniques can be used. For instance, liposomes, microencapsulation, nanoparticles, and emulsions are examples of these techniques.

**Plant-based nutraceuticals:** This has grown in popularity in recent years as they adopt various improved health benefits such as chronic disease prevention. These are more sustainable, safer and environmentally friendly options for consumers that are shifting towards natural, sustainable, and personalized solutions to promote health and wellness.

**Personalized nutraceuticals:** This is a tailored nutritional plan based on genetics, lifestyle, and environmental factors to provide health benefits beyond basic nutrition aiming to improve overall wellness. There is recent ongoing research on the use of artificial intelligence and machine learning to monitor the effects of nutraceuticals in the body to develop precise and customized formulations for certain individuals.

**Gut microbiome-based nutraceutical:** The nutraceutical industry has recently witnessed a new area of progress known as gut microbiome-based nutraceuticals. The gut microbiome has influence on optimal digestion and absorption of nutrients by producing enzymes to breakdown food, regulating intestine permeability, etc. Therefore, gut microbiome-based nutraceuticals including prebiotics, probiotics, and postbiotics support gut microbiome health and balance for overall wellbeing.

#### **4.8 Commercialization and the market sustainability of Nutraceuticals**

There is a constant demand from the industry in recommending appropriate scientific protocols to be adopted in the process of commercialization and maintain the market sustainability of existing and novel nutraceuticals. This is a timely need for a potential growth in the nutraceutical market that needs serious attention in proposing viable model/s which cater the industry requirements by facilitating cost-effective, accurate, and reproducible outcome within an agreeable turnover time. It is suggestive to strengthen the network among the well-established facilities and each of established network should collectively dispatch their commitments in fulfilling the industry requirement for commercialization.

## 5. Conclusion

It is recommended that research in the below areas in nutraceuticals should be funded and supported;

- ❖ Cultivation of raw materials and post-harvest technology
- ❖ Identification of compounds
- ❖ Clinical trials
- ❖ Standardization
  - Authentication of medicinal plants
  - Identification of chemical constituents – TLC / HPTLC/ HPLC / GC
  - Physical parameters
  - Determination of foreign matter
  - Determination of extractive values
  - Determination of heavy metals
  - Determination of total ash value
  - Pesticides residue
- ❖ Industrial research
- ❖ Recent advancements in nutraceutical industry
  - Advanced delivery systems
  - Plant-based nutraceuticals
  - Personalized nutraceuticals
  - Gut microbiome-based nutraceuticals

## 6. Implications & Recommendations

**6.1. Issue:** Lack of policy decisions which ensures the efficacy of a nutraceutical product before introducing that product to the market

**Recommendation:** Encourage in-vitro and in-vivo efficacy, safety studies and clinical trials.

**6.2. Issue:** Inadequate standard phytochemical and pharmacopoeia profiles for herbal raw materials as well as the finished nutraceutical products to evaluate and regularize reproducibility and quality standards pre and post product development

**Recommendation:** Encourage research to ensure reproducibility and quality of raw materials and finished products, and ensure research to develop standards.

**6.3. Issue:** Inadequate laboratory facilities for quality testing of nutraceuticals

**Recommendation:** The Government should take the initiative to develop a system to establish ISO or/and internationally certified, state-of-the-art testing facilities with adequate capacity that would deliver timely reliable reports to the nutraceutical industries and other stakeholders in Sri Lanka.

**6.4. Issue:** Lack of research and clinical evidence in the process of nutraceutical product export

**Recommendation:** Establish a special scheme of R & D grants for public-private partnership (PPP) where Industries can collaborate with universities or public research institutes (PRI) and incentivize research to develop local nutraceutical industry.

**6.5. Issue:** Lack of skilled professional in research laboratories and industries

**Recommendation:** Enhancement of human resource availability.

**6.6. Issue:** Long delay in commercialization process of nutraceuticals

**Recommendation:** Establish network among well optimized facilities and identifying focal points within each network to facilitate industry requirements for commercialization.

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## 8. Figures & Tables

Table 1: Quality parameters used for standardization of specific herbal products in Sri Lanka

Herbal product	Quality parameters
Herbal capsule	<ol style="list-style-type: none"> <li>1) Identification of ingredients – TLC / HPLC / GC (any one appropriate method)</li> <li>2) Microbiological purity (total plate count, <i>E. coli</i>, <i>S. aureus</i>, <i>Salmonella</i>, <i>Pseudomonas</i>)</li> <li>3) Heavy metals (Hg, As, Cd, Pb)</li> <li>4) Moisture content (by using oven method) (if applicable)</li> <li>5) Coloring matter (if added)</li> <li>6) Pesticide residue: Organochlorine pesticides, Organophosphorus pesticides, Pyrethroids, Glyphosate</li> <li>7) Test for Aflatoxins (B<sub>1</sub>, B<sub>2</sub>, G<sub>1</sub>, G<sub>2</sub>)</li> </ol>
Herbal Tea	<ol style="list-style-type: none"> <li>1) Identification of ingredients – TLC / HPLC / GC (any one appropriate method)</li> <li>2) Microbiological purity (<i>E. coli</i>, <i>S. aureus</i>, <i>Salmonella</i>, <i>Pseudomonas</i>)</li> <li>3) Heavy metals (Hg, As, Cd, Pb)</li> <li>4) Moisture content</li> <li>5) Coloring matter (if added)</li> <li>6) Pesticide residue: Organochlorine pesticides, Organophosphorus pesticides, Pyrethroids, Glyphosate</li> <li>7) Test for Aflatoxins (B<sub>1</sub>, B<sub>2</sub>, G<sub>1</sub>, G<sub>2</sub>)</li> </ol>
Soft candy (toffees and jelly-based candy) (SLS 1575)	<ol style="list-style-type: none"> <li>1) General: appearance, colour, odour, free from dirt, shall not stick to wrappers (these parameters will be evaluated by the Technical Subcommittee; third-party lab reports are not mandatory)</li> <li>2) Identification of ingredients – TLC / HPLC / GC (any one appropriate method)</li> <li>3) Heavy metals (As, Cd, Pb, Sn, Cu)</li> </ol>

	<ol style="list-style-type: none"> <li>4) Microbiological purity (total plate count, <i>E. coli</i>, <i>S. aureus</i>, <i>Salmonella</i>, <i>Pseudomonas</i>)</li> <li>5) Moisture content</li> <li>6) Ash, sulphated</li> <li>7) Acid insoluble ash</li> <li>8) Reducing sugars</li> <li>9) Sucrose</li> <li>10) Fat content</li> <li>11) Sulphur dioxide</li> </ol>
<p>Herbal-fruit drinks / Herbal-fruit juices (SLS 729, SLS 1328)</p>	<ol style="list-style-type: none"> <li>1) Identification of ingredients – TLC / HPLC / GC (any one appropriate method)</li> <li>2) Total soluble solids content</li> <li>3) Acidity</li> <li>4) Sulphur dioxide content</li> <li>5) Benzoic acid content</li> <li>6) Sorbic acid content</li> <li>7) Microbiological purity (total plate count, yeasts &amp; moulds count, total coliform count)</li> <li>8) Pesticide residues (as for food)</li> <li>9) Heavy metals (As, Cd, Pb, Sn, Hg)</li> <li>10) Coloring matter (if added)</li> <li>11) Sugar content</li> </ol>

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- ❖ Prof. Kamal Perera, Dean, Faculty of Indigenous Medicine, University of Colombo
- ❖ Prof. Emeritus Tuley De Silva, Chancellor, Wayamba University of Sri Lanka, Former R&D Consultant, Link Natural Products (Pvt) Ltd
- ❖ Prof. Sirimal Premakumara, Chairman, Industrial Technology Institute (ITI)
- ❖ Dr. Susanthi Jayasinghe, Senior Lecturer, Faculty of Science, University of Peradeniya
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