

Standardization and Quality Control of Ayurvedic Polyherbal Formulations

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ABSTRACT

Ayurvedic polyherbal formulations are increasingly explored internationally as a budding field of therapeutic potential based on thousands of years of traditional medicinal practice. However, the absence of standardization protocol and stringent quality control measures is a significant barrier, and the adoption of their safe and effective use in western healthcare is a challenge. The goal of this review is to evaluate the standardization and quality control measures related to Ayurvedic polyherbal formulations. The review discusses the complexity of multi-component herbal mixtures, variability of raw material and absence of marker compounds and synergistic effects which make reproducibility more difficult. The review emphasizes the use of modern techniques including High-Performance Thin Layer Chromatography (HPTLC), Liquid Chromatography–Mass Spectrometry (LC-MS) methods, and microbiological analyses, all increasingly common approaches to assess the variance in products. While there have been advances in the use of HPTLC and LC-MS for standardization and quality control, many regulatory frameworks do not exist, and harmonized quality standards are absent. The review indicates a need for the traditional Ayurvedic approach and modern science to work collaboratively to develop standardized strategies. A successful collaborative effort would lead to increased global/consumer recognition, acceptance and contribution to enhanced public safety regarding the quality and efficacy of these established therapeutic preparations.

Key Words:

Ayurvedic medicine, Polyherbal formulations, Standardization, Quality control, Herbal drug evaluation, Phytochemical screening, Chromatographic techniques, Regulatory frameworks

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1. INTRODUCTION

Ayurveda, the ancient Indian system of medicine, has persisted through the ages and has been increasingly embraced by contemporary society for its holistic approach, individualized methods and use of herbal remedies. Central to Ayurvedic therapeutics are polyherbal formulations, which are complicated combinations – a blend of two or more plant-based substances, made to elicit synergistic, multi-targeted therapeutic effects. These polyherbal formulations are not arbitrary combinations. They are made following principles included in classical Ayurvedic texts like Charaka Samhita or Sushruta Samhita; and each component included is selected for its ability to increase efficacy, reduce toxicity or create balance among the doshas¹.

In recent decades, there has been a resurgence of interest in traditional medicine systems, particularly those that represent plant-based, sustainable, and culturally appropriate healthcare alternatives². Ayurvedic polyherbal formulations have started to appear increasingly in national and international markets and utilize the status as a treatment option for the management of chronic health conditions, facilitating immune boosting and general wellness. However, increased interest from the market and the subsequent integration of the Ayurvedic pharmaceuticals industry in the modern health-care sector poses a significant challenge of maintaining consumer trust and regulatory compliance; that is, a lack of standardized quality control protocols that meet the expectations of modern pharmaceuticals³.



Figure 1: Ayurvedic Polyherbs

Polyherbal formulations present a unique set of challenges compared to synthetic medicines which are normally recognized precisely and with a single active ingredient. Synthetic drugs have a long and detailed history of research and development and are typically understood in terms of their

“active ingredient” however Ayurvedic polyherbal formulations have dozens, if not hundreds, of phytoconstituents; each with the possibility of variation due to a multitude of factors such as the source of the plant, harvest time, processing, and storage conditions. Due to factors associated with herbal medicine, herbal medicines are potentially less efficacious, less safe, and less reproducible, which are major legal and ethical challenges for clinicians, regulators, and consumers⁴. Traditional quality control processes (organoleptic evaluation) and historical textual references to products are functions of assuring safety, however these evaluations alone do not meet the quantitative, reproducible, and evidence-based expectations in the modern pharmaceutical world⁵.

Health professionals will want to see at least some connection between traditional knowledge and modern scientific validity. More importantly ensuring consistency and safety, and defending its legitimacy as a product of global multiculturalism are essential to creating partnerships and integrating Ayurveda into globally provided health care systems. Critical aspects of addressing this uncertainty are to identify, assess, and define the challenges, quality control processes, regulatory systems and procedures, and opportunities in employing new analytical technologies for the standardization and regulation of Ayurvedic polyherbal formulation into evidence-based practice⁶. The relationship between ancient knowledge and modern science presents an opportunity for Indo-Canadian and potentially global partnerships for the acknowledgment of Ayurvedic medicine's contribution to modern health care and validation of its legitimacy to consumers and health care providers alike.

1.1. Background and Context

Ayurveda is one of the oldest healing traditions on the planet, and it believes in a personalized and preventive approach to health that is based on balance of the body's core energies: Vata, Pitta, and Kapha⁷. A major form of treatment in Ayurveda is using polyherbal treatment formulations where multiple medicinal plants are used in the same blend to provide greater therapeutic effect and less toxicity than would occur with individual herbs. These formulations are fundamentally based on empirical knowledge that has been passed down and improved over hundreds and hundreds of years. Since Ayurvedic herbs have been found to employ many different bioactive compounds, the combined action of the multiple bioactive could bring out effects that exceed the sum of the individual herbs, called synergism. Classic polyherbal formulations such as Triphala, Dashamoola, and Brahmi Ghrita serve as examples of synergistic polyherbal formulations and represent a central anchoring to ancient Ayurvedic medicine that remains used in formulations of contemporary Ayurveda⁸.

The ability to convert traditionally prepared products that can be manufactured consistently in scale and safely commercialized remains extremely elusive. Numerous factors including variability of raw material, lack of specified indicator or markers for the quality assessment of the herbal medicines, variability of manufacturing practices, all raise questions about the quality of the product and ultimately consumer safety.

1.2. Objectives of the Review

This review paper aims to:

- **To critically evaluate** the current practices involved in the standardization and quality control of Ayurvedic polyherbal formulations.
- **To analyze** the role of modern analytical techniques such as HPTLC, HPLC, LC-MS, and microbial testing in improving quality assurance.
- **To explore** the existing national and international regulatory standards (e.g., AYUSH, WHO) for herbal medicines and their implementation in the industry.

1.3. Importance of the Topic

With increasing global interest in herbal and natural healthcare solutions, Ayurvedic medicines particularly polyherbal formulations are now widely consumed outside India.

- **Expansion of Global Use** – Rising international demand for Ayurvedic polyherbal formulations reflects growing interest in herbal and natural healthcare solutions.
- **Concerns over Product Safety** – Variability in formulation quality, heavy metal contamination, microbial load, and inconsistent therapeutic effects pose serious health risks.
- **Regulatory Red Flags** – Inadequate quality control practices have triggered concern among scientific and regulatory communities worldwide.
- **Impact on Market Credibility** – Inconsistent product standards diminish consumer confidence and hinder global market acceptance of Ayurvedic medicines.
- **Need for Scientific Validation** – Development of standardized analytical protocols is essential to ensure product safety, efficacy, and reproducibility.
- **Integration of Tradition and Modernity** – Harmonizing traditional Ayurvedic knowledge with modern pharmaceutical quality standards is critical for global recognition.
- **Strengthening Clinical Utility** – Enhanced standardization and regulation will boost the credibility and therapeutic reliability of polyherbal formulations.

2. CONCEPT OF STANDARDIZATION IN AYURVEDIC FORMULATIONS

Standardization is an essential part of the development of pharmaceuticals; it underpins quality, safety and therapeutic reliability. In Ayurvedic medicine, standardization is particularly problematic because of the complexity of multi-ingredient dosage forms and the utilization of reported experiences or narratives rather than measurable endpoints⁹. As Ayurvedic medicine continues to gain recognition on the world stage, it is increasingly important that scientific methodologies are developed and adopted to standardize formulations without sacrificing the framework of traditional Ayurvedic medicine. This section will discuss the concept of standardization in Ayurveda as well as the importance of standardization in modern pharmaceutical systems.

2.1. Definition and Its Relevance to Traditional Systems of Medicine

Standardization, in Ayurvedic medicine, is the confirmation that a formulation has a consistent composition, quality, and preparation method consistent with the formulations described in classical Ayurvedic texts. When formulating an Ayurvedic product, standardization means establishing the identity, purity, concentration, and expected therapeutic action of the ingredients.

In traditional systems of medicine, formulations were standardized based on some combination of organoleptic qualities (color, taste, smell, ternary), source and development of herbs, and methods of preparation. Standards typically remained in the form of granthas, ancient scriptures, such as the Charaka Samhita, Sushruta samhita, and Bhaishajya Ratnavali. These texts provided rich explanatory detail about the author(s) philosophy of formulation, but did not offer the quantitative specification typical of modern pharmacopoeias, which like standardization in our contemporary societies provides a level playing field for consistency; demanding translations is challenging; we must commit to the effort in translating into our definitions ¹⁰.

2.2. Importance in Ensuring Safety, Efficacy, and Reproducibility

The primary objective of standardization is to ensure that Ayurvedic formulations are **safe for consumption, therapeutically effective, and consistent across production batches**. Without proper standardization, there is a high risk of:

- **Variability in therapeutic outcomes**, where the same formulation may produce different effects in different batches;
- **Adverse effects** due to contamination, adulteration, or incorrect proportions of ingredients;
- **Reduced patient confidence**, especially in global markets that demand regulatory clarity and consistency.

Standardization also supports clinical validation, allowing for Ayurvedic medicines to be tested in trials and for comparisons to be made with standard pharmaceuticals. Standardization is important to ensure Ayurveda fits into a more comprehensive framework of modern healthcare, and to lend legitimacy to significant regulatory bodies like WHO, FDA and EMA.

2.3. Differences in Classical Ayurvedic vs. Modern Pharmaceutical Perspectives on Formulation Consistency

A major conceptual divergence exists between traditional Ayurvedic philosophy and modern pharmaceutical science in how formulation consistency is defined and maintained:

- Classical Ayurveda focuses on a holistic, patient-centric approach. The formulation may be adjusted based on an individual's constitution (Prakriti), the disease state (Vikriti), seasonal variation (Ritu), and digestive power (Agni). Therefore, the same remedy might differ in composition or dosage depending on the patient and context.

- Modern pharmaceutical science, on the other hand, prioritizes chemical uniformity, batch reproducibility, and validated dosing. Each product must have a precisely quantified amount of active ingredients and meet specified physicochemical parameters. This approach often challenges the traditional flexibility of Ayurvedic practice.

Bridging these two perspectives requires innovative quality control systems that respect the philosophical essence of Ayurveda while meeting the regulatory expectations of modern medicine. Marker-based standardization, fingerprint profiling, and bioassay-guided evaluations are emerging as tools to help reconcile this gap.

3. CHALLENGES IN STANDARDIZING POLYHERBAL FORMULATIONS

Standardization of Ayurvedic polyherbal products has some major mismatches and challenges that do not happen in traditional medicines based on synthetic single-compound products. Polyherbal medicines have multiple plant-derived ingredients containing collections of phytochemicals that differ within and across the sources of, ingredients and seasons. Incorporating a multitude of species into formulations adds layers of complexity to demonstrating consistency, safety and efficacy, as it is easy to think of these ingredients and their historical uses as being a unit; however, traditional formulations are often segmented in on holistic principles and it is often not possible to reduce them to a fixed chemical profile, which makes the use of contemporary standardization tools very challenging. The following sections provide a summary of key hurdles for developing standardized polyherbal Ayurvedic products.

Table 1: Summary of Key Literature on Standardization and Quality Control of Ayurvedic Polyherbal Formulations

Author Name	Topic Covered	Research Study Title
PM et al. (2023) ¹¹	Highlighted the need for standardization of Ayurvedic formulations due to issues related to reproducibility, safety, and analytical validation.	Need of Standardization of Ayurveda Formulations
Bandhekar, P., & Kubde, S. ¹²	Discussed essential quality control parameters and emphasized the use of modern analytical techniques (e.g., HPTLC, HPLC) for authentication.	Quality Control of Ayurveda Formulations

Paul, T., & Kumar, K. J. (2024) ¹³	Focused on standardization of herbal medicines for managing lifestyle diseases and called for clinical and pharmacological validation.	Standardization of Herbal Medicines for Lifestyle Diseases
Mukherjee, P. K. (2019) ¹⁴	Provided comprehensive insights into quality control methods, including traditional, chromatographic, and toxicological approaches for herbal drugs.	Quality Control and Evaluation of Herbal Drugs: Evaluating Natural Products and Traditional Medicine
Chauhan et al. (2015) ¹⁵	Conducted pharmacognostical and physicochemical standardization of an Ayurvedic formulation (Yashtimadhu tablet), highlighting microscopic, organoleptic, and chemical parameters.	Pharmacognostical & Physicochemical Standardization of Yashtimadhu Tablet – An Ayurvedic Formulation

3.1. Complexity Due to Multiple Plant Components

Polyherbal formulations contain three or more plant sources, each of which contributes bioactive compounds with different therapeutic roles and these interactions may have a synergistic, antagonistic or additive effect where the overall effect is greater than the sum of its parts ¹⁶.

This complexity in biochemistry results in difficulties at recognising which compounds should be used as marker constituents in quality control. Further, the interaction between the compounds, whether during preparation (boiling, fermentation, grinding, etc.) or after preparation, can alter the chemical composition of the compounds making it difficult to define a reproducible standard of the preparation for the purposes of analytical study ¹⁷.

3.2. Variability in Raw Material Quality

Variations in environmental factors influence the quality of medicinal plants used in polyherbal formulations, specifically:

- Geographics (the type of soil, altitude, climate)
- Seasonal changes (harvest time, the stage of plant maturity)
- Post-harvest/curing processes (e.g., drying, storage)

These variations can result in considerable differences in the phytochemical profile of the same species of plant. The curcumin concentration in the turmeric (*Curcuma longa*) or the withanolide content in the *Withania somnifera* can be very different for the same plant, largely resulting from one or more of these three factors. Without stringent sourcing protocols and testing of the raw materials, this will result in variation in formulation quality, and ultimately therapeutic performance¹⁸.

3.3.Synergistic Effects Making It Difficult to Isolate Bioactive Markers

In polyherbal medicine, the therapeutic effect may not be achieved by one active component but rather by the synergistic effect of the different components. This complicates the choice of a compound(s) that are to be used as bioactive markers to standardize.

Contemporary quality control is usually performed through the marker-based analysis, however, when dealing with the polyherbal formulation, the isolation of one or two markers and the analysis of their presence and quantity may not reflect the actual product efficacy¹⁹. Further, the over-focus on individual markers can overlook the synergistic and multi-dimensional effects that are appreciated in Ayurvedic healing.

Such complexity necessitates multi-component fingerprinting methods (e.g. HPTLC, LC-MS) over single-compound quantification in order to reach significant and representative standardization.

3.4.Limitations in Existing Pharmacopoeial Monographs

Monographs Many single herbs have monographs in the Ayurvedic Pharmacopoeia of India (API) and other regulatory documents, but there is frequently little detailed advice on polyherbal formulas. Most of the time it is just confined to:

- Organoleptic and physicochemical parameters,
- Preliminary phytochemical tests,
- Basic microbial load and heavy metal limits.

Validated analytical techniques, defined marker compounds and standardized fingerprint profiles to complex formulations are often lacking. Consequently, manufacturers can use the conventional empirical approaches or their own standards, which creates discrepancies between brands and products²⁰.

Moreover, the issue of lack of international harmonization between Indian standards (e.g. AYUSH guidelines) and international ones (e.g. WHO, USP) further adds to the problem of acceptance of Ayurvedic products in the international markets.

4. METHODOLOGIES AND FINDINGS

The scientific assessment of Ayurvedic polyherbal formulation needs a multi-dimensional method consisting of physicochemical analysis, phytochemical screening, high-resolution chromatographic techniques and toxicological analyses. Such methodologies are needed to prove the conventional assertions, determine the quality parameters, and make sure of safety and efficacy. The most important analytical methods applied in quality control and standardization are listed in the following subsections, as well as the results of findings that have been reported in the recently published literature and studies.

4.1. Physicochemical Evaluation Techniques

Physicochemical analysis is a basic procedure of the quality review of Ayurvedic polyherbal formulations. Common parameters that are usually analyzed are moisture content, ash and acid insoluble ash, pH, and alcohol and water soluble extractive values. Moisture content is also very important because it establishes the water percentage in the sample and this directly influences shelf-life and microbial stability²¹. The total and acid-insoluble ash values show the existence of inorganic material or impurities, e.g. soil or sand. The importance of the pH value is that it determines how acidic or alkaline the formulation is, and this can determine the chemical stability and shelf-life of the product. The extractive values, which are calculated by the help of alcohol and water as solvents, give an estimate of the amount of active phytoconstituents contained in the formulation.

Table 2: Common Physicochemical Parameters Used for Standardization

Parameter	Purpose	Relevance
Moisture Content	Indicates water content in raw/formulated product	Affects microbial growth and shelf life
Total Ash Value	Measures total mineral content	Indicates presence of inorganic matter
Acid-Insoluble Ash	Detects non-physiological materials (e.g., sand)	Reflects contamination/adulteration
Water-Soluble Extractives	Measures bioactive compounds soluble in water	Reflects hydrophilic phytochemical content
Alcohol-Soluble Extractives	Measures alcohol-soluble compounds	Reflects lipophilic phytochemical content

pH	Indicates acidity/alkalinity	Affects formulation stability and absorption
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The results of different studies indicate that fluctuation of these physicochemical parameters is usually a result of unstable sourcing, inappropriate handling and poor processing of raw materials. High ash levels, e.g., can signify adulteration or contamination at the time of collection or storage. On the same note, the presence of too much moisture may foster the growth of microbes and cause the products to go bad thus raising the issue of consumer safety. These observations also highlight the importance of adopting and practicing Good Manufacturing Practices (GMP) in the supply chain, including the procurement of raw materials to the final formulation of Ayurvedic products to achieve uniformity, safety, and efficacy in Ayurvedic products²².

4.2. Phytochemical Screening

Phytochemical screening is an initial test to identify presence of major secondary metabolites, which may be the source of therapeutic action of Ayurvedic polyherbal formulations. Typical phytoconstituents that are tested are alkaloids, which are tested via Dragendorffs or Mayers reagent, tannins, which are tested by ferric chloride test, saponins, which are tested by froth formation test, flavonoids, which are tested by Shinoda test, and glycosides, which are tested by the Keller-Killiani test²³. These qualitative tests act as an initial guide to chemical composition of a formulation. Such preliminary tests are in many cases followed by quantitative estimations, which can be done by UV spectrophotometry or gravimetric analysis giving more accurate information about the concentration of active constituents.

Table 3: Phytochemical Constituents Commonly Screened in Polyherbal Formulations

Phytochemical Group	Test Used	Pharmacological Significance
Alkaloids	Dragendorff's / Mayer's test	Analgesic, antimalarial, hypotensive
Tannins	Ferric chloride test	Antioxidant, antimicrobial, astringent
Saponins	Froth test	Antioxidant, immune-stimulant
Flavonoids	Shinoda test	Anti-inflammatory, cardioprotective

Glycosides	Keller-Killiani test	Cardiotonic, laxative
Terpenoids	Salkowski test	Anti-inflammatory, antitumor

The results of research have always indicated that the level of phytoconstituents differs considerably even between commercial products and this is frequently caused by irregularity in the selection of raw materials, processing, or storage of the materials. This fluctuation does not only impact the therapeutic effectiveness of the formulations but also points at the difficulty of preserving product integrity and genuineness²⁴. Phytochemical screening is therefore important in detecting adulteration, the presence of major bioactive compounds and in the formulations that are acceptable in terms of quality. The noted discrepancies underline the necessity of uniform screening procedures and stricter regulatory control over the Ayurvedic production industry.

4.3. Chromatographic and Spectroscopic Methods

Chromatographic and spectroscopy techniques have emerged as an essential instrument in standardization and quality control of Ayurvedic polyherbal formulations. These techniques make possible the identification, quantitation and fingerprinting of complex mixtures of phytoconstituents. High-Performance Thin Layer Chromatography (HPTLC) is one of the most popular methods which are used to produce characteristic fingerprint profiles which can be used to ensure batch-to-batch reproducibility. High-Performance Liquid Chromatography (HPLC) is applied in the accurate determination of particular marker compounds. Gas Chromatography-Mass Spectrometry (GC-MS) is especially useful in the identification of volatile and semi-volatile constituents, whereas Liquid Chromatography -Mass Spectrometry (LC-MS) combines both the separation of compounds and the mass-based detection of compounds, which is ideal in the analysis of non-volatile bioactives. Structural elucidation of phytochemicals is done by Nuclear Magnetic Resonance (NMR) Spectroscopy, particularly where identity of compounds needs to be established.

The most important conclusions of different studies note that the most widely utilized method in the quality control of Ayurvedic products is HPTLC because it is cost effective and easy to use in fingerprinting. LC-MS and GC-MS have been known to give specific and detailed information on active constituents in complex matrices. Nevertheless, marker-based standardization is a major challenge in polyherbal formulations due to their multicomponent and synergistic properties despite the high-tech features of the tools. The existence of hundreds of interacting compounds where it is challenging to choose one marker or even a small set of markers that really signify therapeutic activity. Consequently, there is a growing trend of integrated analytical methods wherein several methods are used to come up with comprehensive chemical profiles, which provide a more comprehensive solution to the standardization of polyherbal products.

Table 4: Modern Analytical Techniques for Polyherbal Standardization²⁵

Technique	Purpose	Advantages	Limitations
HPTLC	Fingerprinting and identification	Quick, cost-effective	Less sensitive for complex markers
HPLC	Quantification of marker compounds	High precision and accuracy	Requires reference standards
GC-MS	Analysis of volatile/semi-volatile compounds	High specificity and sensitivity	Limited to volatile components
LC-MS	Identification of non-volatile compounds	Mass accuracy, structural info	High cost and complex operation
NMR	Structural elucidation	Detailed structure of phytochemicals	Requires pure and large samples

4.4. Microbiological and Toxicological Testing

The safety and acceptability of Ayurvedic polyherbal formulations is extremely important because microbiological and toxicological testing is essential and this is especially true in the international markets where the standards of contamination are highly regulated. The tests are meant to identify the presence of any harmful contaminants that could possibly be caused by poor sourcing, poor storage, or non-compliant production procedures. Microbial load testing determines the total number of bacteria and detects yeast and mold, which allows verifying the absence of pathogenic microorganisms in products. Atomic Absorption Spectroscopy (AAS) or Inductively Coupled Plasma Mass Spectrometry (ICP-MS) methods are applied to analyse the presence of toxic elements, including arsenic, lead, mercury, and cadmium. The testing of pesticide residues, usually done by gas chromatography, assists in screening of dangerous chemicals applied in the growth process. Also, aflatoxin is detected by ELISA method or High-Performance Liquid Chromatography (HPLC) method which can be contaminated by fungal growth in poor stored plant materials ²⁶.

Results of different studies have reported that many Ayurvedic formulations available commercially have unsafe amounts of heavy metals especially lead and arsenic. Such pollutants usually have their roots in the lack of standardization or poor control of raw materials sourcing. Also, microbial contamination such as molds and harmful bacteria has been common in the products that are not stored and packaged adequately ²⁷. These safety issues highlight the importance of strict quality monitoring, raw material traceability and strong regulatory oversight.

In the absence of such measures, the benefits that Ayurvedic products have on the therapeutic front could be negated by the safety hazards associated with it, thus restricting its credibility and adoptability in the local as well as global market²⁸.

5. DISCUSSION

Standardization and quality control of Ayurvedic polyherbal formulation plays an important role in establishing therapeutic efficacy, safety and batch-to-batch reproducibility. With the growing interest in traditional medicines all over the world, the scientific community turns more toward the ways of overcoming the limitations of the traditional practices and adapting them to the modern pharmaceutical standards²⁹. This discussion is based on some of the most important findings of the existing methodologies and shows the necessity of combining traditional wisdom and modern analytical tools, and reveals the existing research and regulatory gaps preventing the global recognition of these formulations³⁰.

5.1. Interpretation and Analysis

The review also indicated that physicochemical, preliminary phytochemical screening, chromatographic fingerprinting, microbial, and toxicological tests are some of the widely used methods of determining the quality of Ayurvedic polyherbal formulations. It has been observed that physicochemical parameters like moisture, pH, ash values and extractive values can be used as the basis of quality indicators but they are not always consistent because of variations in raw materials and conditions of processing³¹. Phytochemical screening enables the identification of important bioactive groups but is not quantitative in nature unless it is complemented either by spectrophotometric or chromatographic methods.

HPTLC and HPLC chromatographic techniques have become useful in producing reproducible fingerprints, and quantification of marker compounds, although GC-MS and LC-MS provide a greater level of information on complex phytochemical mixtures³². Nevertheless, the single-marker-compound-based standardization of polyherbal products is ineffective because of synergetic and multicomponent nature. Moreover, microbial and heavy metal pollution remains a significant preoccupation, as multiple studies have found unsafe amounts of pathogens, lead, arsenic, and pesticide residues in commercial samples, indicating regulatory enforcement and compliance with GMP³³.

5.2. Implications and Significance

- **Therapeutic Reliability:** Lack of standardization leads to inconsistent therapeutic outcomes, reducing reliability in clinical use.
- **Consumer Trust:** Variability and safety concerns undermine consumer confidence in Ayurvedic formulations.
- **Global Integration Challenges:** Absence of validated quality control protocols often results in rejection of Ayurvedic products by international regulatory authorities.

- **Public Health and Safety:** Advanced analytical techniques (e.g., HPTLC, LC-MS) improve product authentication, reduce adulteration, and enhance safety³⁴.
- **Industry Credibility:** Scientific validation and batch consistency help promote the credibility of the Ayurvedic pharmaceutical industry.
- **Economic Opportunities:** Standardization can facilitate global trade, attract investment, and boost exports of herbal and wellness products.
- **Innovation and Research:** Integration of traditional Ayurvedic knowledge with modern science encourages interdisciplinary research and educational initiatives.
- **Evidence-Based Ayurveda:** Moving toward scientifically supported practices can elevate Ayurveda from anecdotal tradition to a recognized and respected system of complementary medicine.

5.3.Gaps and Suggest Future Research Directions

- Integrative clinical trials to validate efficacy in patient populations.
- Systems biology approaches to understand interactions between multiple herbs.
- Development of polyherbal-specific quality control markers rather than relying on individual plant standards.
- Creation of a national/international database of validated formulations and analytical profiles.
- Policy frameworks that encourage collaboration between traditional practitioners and modern scientists.

6. CONCLUSION

As the world has been experiencing a growing need in natural and holistic healthcare products, Ayurvedic polyherbal formulations have found their way into the limelight³⁵. Although these formulations deeply exist within the Indian cultural and medicinal tradition, they have not been able to be widely utilized in the global market because of the problem in quality variability, lack of uniformity, and insufficient regulatory harmonization. This review has discussed the scientific and practical issues which entail the standardization of polyherbal Ayurvedic products, critically analyzing the methodology employed in all tests, the quality control systems and the necessity of incorporating the traditional knowledge with the modern pharmaceutical science³⁶.

6.1.Summary of Main Insights and Conclusions

The review points out that the rich repository of polyherbal therapeutic knowledge represented in Ayurveda presents a special challenge to standardization because of the inherent complexity of

multi-component formulations³⁷. The results show that the existing physicochemical testing, phytochemical screening, chromatographic profiling, and toxicological analysis although necessary is usually disjointed or applied differently³⁸. The standardization of marker compounds, as useful as it is, cannot perfectly express the synergistic effect of polyherbal formulations³⁹. Unreliable supply of raw materials, contamination, and the insufficient regulatory oversight also add to safety issues and a lack of credibility on a global level. However, incorporation of modern analytical methods (including HPTLC, HPLC, LC-MS, and NMR) into the classical Ayurveda is highly promising in coming up with holistic, reproducible and therapeutically sound formulations⁴⁰.

6.2.Reiteration of the Importance of the Review

- Highlights the urgency for developing scientifically validated and globally acceptable standardization protocols for Ayurvedic polyherbal formulations.
- Bridges the gap between ancient Ayurvedic wisdom and the modern scientific framework through a comparative and integrative approach.
- Provides insight into how traditional and modern systems can coexist to improve formulation safety, efficacy, and consumer trust.
- Supports the transition of Ayurveda from traditional practice to an evidence-based component of global healthcare systems.
- Promotes Ayurveda not merely as an alternative medicine but as a complementary therapeutic system backed by centuries of knowledge and modern validation.

6.3.Recommendations

To move forward effectively, the following key actions are recommended:

- Develop unified and polyherbal-specific monographs with well-defined analytical benchmarks.
- Promote collaborative clinical and pharmacokinetic research to validate efficacy and establish therapeutic dosing.
- Enhance regulatory harmonization by aligning AYUSH standards with international quality and safety frameworks (e.g., WHO, EMA).
- Strengthen traceability and GMP compliance throughout the supply chain to ensure consistency and safety.
- Invest in advanced infrastructure and training to support high-quality testing and personnel development.

- Create a national digital repository of validated formulations, quality standards, and clinical data.
- Adopt QR/barcode-based digital authentication systems to improve consumer trust and regulatory transparency.

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