A Comprehensive Review of Herbal Medicine Standardization

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Abstract:

The use of herbal products is expanding quickly on a global scale. Science based on natural herbs is centered on India. Herbal drug technology is the process of turning plant components into pharmaceuticals, with a focus on quality assurance and standardization through a blend of cutting-edge scientific methods and conventional wisdom. Global harmonization depends on the World Health Organization's (WHO) precise rules for evaluating the quality, safety, and efficacy of herbal medicines. Ensuring a drug's identification, quality, and purity over its entire lifecycle is the goal of standardization. This study includes approaches that are utilized in the standardization of compound pharmaceuticals, both finished and crude, including physical, chemical, biological, microscopic, and macroscopic procedures. Along with the standardization of bhasma, it also covers chromatographic techniques, comprehensive methodologies like fingerprinting and multi-component quantification, and hyphenated techniques like HPLC-MS and GC-MS.

Keywords: Herbal medicine, Herbal products, Quality control, Quality assessment, Bhasma standardization

INTRODUCTION

Since ancient times and still now, natural resources have been the main source of medicines. Worldwide people are quite knowledgeable about the natural resources they depend on, including a great deal of botanical knowledge. About 85% of people on the planet receive their healthcare from traditional medicine. (Peter & De Smet, 2002) To avoid major health problems, plants and their products must be assured to be safe, of high quality, and effective. Medical plurality characterizes healthcare in India; Ayurveda is still more common than contemporary medicine, especially for the treatment of chronic illnesses. (Waxler-Morrison, 1988)

The World Health Organization defines traditional medicine as a broad category of medical procedures, methods, information, and beliefs. These comprise manual methods, exercises, spiritual treatments, plant, animal, and mineral-based medications, which can be used alone or in conjunction to promote health and to cure, diagnose, or prevent disease. As per their particular definitions, the WHO has additionally defined a number of words connected to herbal medications.

Herbal medicines come in many forms: herbs, herbal ingredients, herbal preparations, and completed herbal products. Distinct countries and traditions may have somewhat distinct phrasing. Generally

speaking, herbs are unprocessed plant components including leaves, flowers, fruits, seeds, stems, wood, bark, roots, rhizomes, or other entire, broken, or powdered plant parts. This term is expanded upon to cover fresh juices, gums, fixed oils, essential oils, resins, and dry powders of herbs. Some areas steam, roast, or stir-bake these components with things like honey or alcoholic beverages.

The foundation of finished herbal products, herbal preparations might comprise extracts, tinctures, comminuted or powdered herbal ingredients, and fatty oils made from herbs. These preparations are made by means of physical and biological procedures including extraction, fractionation, purification, concentration, and others. In order to get the intended result, they can also entail steeping or heating herbal components in honey, alcoholic beverages, or other substances.

Comprising herbal preparations made from one or more herbs, finished herbal goods are formulations. Use of several herbs is referred to as "mixture herbal products." These items could contain active botanical components together with excipients. natural medications are not, however, formulations that include chemically defined active ingredients, such as synthetic chemicals or isolated components from natural sources.

Many traditional medical systems, including Chinese medicine, Ayurveda, Unani, Naturopathy, Osteopathy, and Homeopathy, make considerable use of herbal medications. (World Health Organization, 2000)

Standardization

Plant-based goods have become much more popular in industrialized nations in recent years. Applications for these substances as nutraceuticals, cosmetics, and medical goods are growing. (Sagar Bhanu, Zafar, & Panwar, 2005) Development of sensitive, detailed, and dependable quality control techniques is necessary to guarantee high standards from raw materials to finished goods. This is fusing contemporary and classical instrumental analysis techniques. Consistent quality control of herbal medicines is mostly dependent on standardization.(Patel, Patel, & Goyal, 2006)

Standardizing herbal medications means setting uniform standards and particular qualitative and quantitative values that guarantee their efficacy, safety, and repeatability (Kunle, Egharevba, Ahmadu, & O Peter, 2012). By use of experimentation and observation, technical standards are established to specify the properties of every medication. Ensuring the quality control of herbal goods mostly depends on standardization. (Waldesch, Konigswinter, & Remagen, 2003)

The American Herbal Product Association states that standardization seeks to reduce natural product composition variances by means of quality control procedures in manufacturing and agriculture. This guarantees the adequate constancy of content in herbal goods.

Everything from plant culture to clinical use that results in uniform product quality is covered by the term "standardization" in manufacturing and quality control. It could entail combining many herbal medications or preparations or adding excipients to make herbal preparations contain particular ingredients. (Bhutani, 2003)

Herbal medicines are "evaluated" by identity verification, purity and quality determination, and adulteration detection. This all-encompassing procedure guarantees that herbal medications satisfy established criteria and are appropriate for therapeutic application. (Kokate, Purohit, & Gokhale, 2005)

Herbal medicine standards need to include a number of important elements that raise the general caliber of the medications. These consist of making sure the sample is correctly identified, assessing its sensory qualities (organoleptic evaluation), doing pharmacognostic tests, determining volatile components, doing quantitative tests like extractive values and ash, doing phytochemical analyses, looking for xenobiotics, determining microbial contamination, determining toxicity levels, and looking at biological activity.

Among these, the phytochemical profile is very important since it affects the efficacy of herbal medications directly. Quality of herbal medications is ensured by fingerprint profiles, which are essential tools in determining the phytochemical consistency. Furthermore improving the evaluation of sample quality is the quantification of particular marker chemicals.

These all-inclusive techniques guarantee that herbal medicines satisfy predetermined criteria of consistency, safety, and efficacy, therefore enabling their use in therapeutic settings. (Nikam *et. al.* 2012)

The need for standardization

Traditionally, vaidyas provided individualized treatment to individuals by customizing medicines to meet their specific needs. The knowledge of Rishis, Vaidyas, and Hakims was valued in traditional medical systems for its ability to maintain quality control. Modern, objective criteria must be established in order to address issues like shelf life, remote distribution, and the economic feasibility of large-scale production. The public's knowledge of potency and its adverse consequences is expanding. Researchers, manufacturers, and regulators must carefully employ scientific methods to ensure consistent quality and safety of traditional herbal products in order to gain public trust and integrate them into mainstream healthcare. (Wani, 2007)

1. The concept of standards and technology were very different when traditional medicines were invented.
2. The dynamic process of evolution during the last millennium may have altered the identity of plant material.
3. The procurement of authentic raw materials has grown more difficult as a result of commercialization.
4. Environmental influences and time may have changed a botanical's properties. (Patwardhan, 2000)

Many factors cause the raw materials utilized in herbal products to vary significantly. Plant identity and seasonal fluctuations that impact collection periods are important factors. (Dixit & Yadav, 2008)

Significant influences are also played by changes in ecotypic, genotypic, and chemotypic traits as well as drying and storage conditions. Variability in product quality and the concentration of plant chemicals across different batches is caused by a variety of factors, including harvesting methods, manufacturing processes (such as selection, drying, purification, and extraction), and environmental conditions (such as sunlight, rainfall, altitude, temperature, and soil quality). The chemical makeup of plants can be impacted by ecological variables such as microbial infections and insect damage, which can change secondary metabolites. Different portions of the same plant (such as the roots, stems, and leaves) may have different amounts of the same chemical components. Depending on the plant component and stage of ripeness employed, diurnal variations (e.g., paclitaxel, opium alkaloids) and seasonal changes further add to the diversity observed in herbal medicines, influencing both therapeutic effectiveness and possible toxicity. (Anna & Stephen, 1997)

There is a lot of variance in products made by different manufacturers, and it is difficult to regulate every element affecting the chemical composition of plants (Michael, 1999; Shinde et al., 2009). Setting quality control measures is challenging since plant-based medications contain complex and naturally variable ingredients. It is anticipated that contemporary analytical methods will lessen this difficulty. Furthermore, it's common for the therapeutic ingredients accountable for purported results to be poorly known or only partially described. Establishing quality control standards is made more difficult by the fact that many herbal formulations, particularly traditional polyherbal formulations, are either liquid or semisolid. Frequently, official guidelines for these formulations are absent. The distinct processing techniques employed in their production turn simple herbs into intricate combinations, making it challenging to separate, recognize, and evaluate their constituent parts.

Herbal product standardization falls into two primary categories. The active components extract comes first, where the therapeutic benefits of established biochemical principles are used. Second, even while the active principle itself is not entirely understood, a characteristic component can be utilized as a marker to indicate the presence of other therapeutic biochemical compounds (Khalid, 2009). This is known as a marker extract. Standardization based just on isolated chemicals, however, has drawbacks since it ignores the potential for synergistic benefits or buffering properties that the herb's entire contents may offer, which may assist lessen adverse effects.

The process of standardizing conventional medicine starts with the gathering of raw materials and continues all the way to clinical implementation. In conventional medicine, the combined action of a substance's chemical components is responsible for its therapeutic efficacy. As a result, guaranteeing quality and purity necessitates assessing the drug's full profile rather than just certain features. The name, botanical and geographic origins, organoleptic qualities, morphology, anatomy, physical attributes, chemical composition, and biological activities of the medicine must all be included in this thorough approach to standardization.

The World Health Organization places a strong emphasis on the use of both qualitative and quantitative techniques for sample characterization, chemical marker or biomarker quantification, and fingerprint profile establishment. It makes sense to quantify the main active component once it is identified. A particular marker material that is distinct to the botanical can be chosen for analytical

purposes in situations where the active elements influencing therapeutic efficacy are not entirely recognized.

The references listed in pharmacopoeias are used to verify the validity, excellence, and purity of herbal medications. These publications provide standards for clinical practice and provide an overview of the conventional and traditional medicinal applications of plants. Herbal descriptions, botanical data, laboratory analysis, medicinal indications, and details on possible medication interactions are all included in pharmacopoeial monographs. Additionally, pharmacopoeias establish numerical criteria for the physical, analytic, and structural properties of pharmaceuticals (WHO, 2002).

Conventional approaches for standardizing crude drug formulation

Standardising herbal raw medicines requires thorough procedures to guarantee their uniformity and quality. Starting with a medico-botanical survey and botanical verification via macroscopic inspection, "passport data" for raw plant medications is established. The identification procedure includes the whole pharmacognostical profile and follows established pharmacopoeial testing procedures. (Ministry of AYUSH, Government of India, 2008)

Sensory evaluation parameters including shape, size, color, texture, odor, and taste help to identify therapeutic plant materials macroscopically. Examination under a microscope improves identification accuracy even further, and developments in light and scanning electron microscopes are essential to the standardization of herbal medications.

Preliminary testing for different chemical groups, measurement of particular chemical components (e.g., alkaloids, phenolics, triterpenic acids, tannins), development of fingerprint profiles, creation of multi-marker-based fingerprint profiles, and quantification of important chemical components necessary for quality assessment are all part of phytochemical evaluation.

Furthermore important are safety assessments, which include measuring biological activity, microbiological limits, aflatoxins, pesticide residues, and heavy metal profiling to guarantee therapeutic efficacy and safety requirements are fulfilled (Calixto & Barz, 2000).

STANDARDIZATION OF HERBAL/ POLYHERBAL FORMULATION

Herbal formulas are standardized when they are made with raw materials obtained from several sources and the chemical effectiveness of multiple batches of the formulation is compared. Superior clinical efficacy batches are chosen by careful assessment of standard physical, chemical, and pharmacological factors. The whole production process is validated and the safety and quality of the end product are guaranteed by this selection procedure. (Sharma *et al.*, 2009)

In polyherbal formulations, which blend several plants to provide the intended medicinal benefits, batch-to-batch differences are greatly reduced by standardization. It increases these formulations' dependability in clinical use by ensuring their safety, efficacy, quality, and acceptability. (Ahmad *et al.,* 2006)

Standardizing herbal formulation calls for the application of Good Manufacturing Practices. (WHO, 1996) Furthermore, it is thought necessary to investigate a number of aspects including pharmacodynamics, pharmacokinetics, dose, stability, self-life, toxicity assessment, and chemical profiling of the herbal formulations. Equally significant in the standardization of herbal medicines are heavy metal contaminations and Good Agricultural Practices (GAP) (Bauer, 1998)

Herbal medications are often given in ancient medical systems as ethanol extracts or water decoctions. Genuine medical plant parts must be devoid of impurities including heavy metals, microorganisms, pesticides, and radioactive materials. Usually, the process entails extracting the medicinal plant once or more times with a solvent or via techniques mentioned in old writings. After that, the extract is tested biologically on models of experimental animals.

Together with fingerprint analysis, the bioactive extract should be standardized according to its active principles or main constituents. The bioactive extract has to be stabilized in order to have a minimum one-year shelf life. After thereafter, the stabilized extract is subjected to restricted or regulated safety testing. Its therapeutic profile becomes clearer when one understands its probable mode of action. When the WHO certifies that the safe and stable herbal extract has been well-documented in traditional medical systems, it can be sold.

Limited clinical trial may be carried out to confirm its therapeutic potential even more. Using this method, herbal remedies should be prescribed or sold over-the-counter depending on the particulars of the illness. (Ansari, 2005; Bele & Khale, 2011)

WHO Recommendations for Standardized Herbal Formulations of High Quality

1) Quality control encompasses the evaluation of crude drug materials, plant preparations, and finished products.
2) Stability assessment and determination of shelf life are crucial aspects.
3) Safety assessment involves documenting safety based on experience or toxicological studies.
4) Efficacy assessment includes ethnomedical information and evaluations of biological activity.

Bioactive extracts should be standardized based on active principles or major compounds, complemented by chromatographic fingerprints (TLC, HPTLC, HPLC, and GC).

In general, all medicines, whether synthetic or of plant origin, must meet the fundamental requirements of safety and effectiveness. (WHO, 2002; EMEA, 2005)The term 'herbal drugs' refers to plants or plant parts that have been processed into phytopharmaceuticals through procedures such as harvesting, drying, and storage. (EMEA, 1998)

1. Quality Control of Herbal Drugs -

The phrase "quality control" describes the procedures used to preserve a manufactured product's validity and quality. Three key pharmacopeial features serve as the foundation for quality control in general:

a. **Authenticity or identity:** the product should only include one plant

b. **Purity:** Only herbs should be present as contaminants.

c. **Assay or Content:** The active ingredients must be included within the specified bounds.

Examining herbal constituents both macroscopic and microscopic is part of identity verification. Furthermore necessary to guarantee batch-to-batch consistency are chromatographic techniques and chemical testing like color reactions or precipitation tests. Through the identification of profiles of common plant components such as flavonoids, alkaloids, and terpenes, chromatographic methods can provide a "fingerprint" of herbal substances.

Identity and purity must be established by assessing factors like preparation type, sensory qualities, physical constants, adulteration, pollutants, moisture content, ash content, and solvent residues. Samples from vouchers are dependable sources of reference. Plants' physical appearance changes brought on by illnesses can result in a wrong identification. (WHO, 1998; De Smet, 1999)

A safe usage of herbal medications depends on their purity, which is determined by evaluating things like ash values, foreign matter (like other herbs), and heavy metals. Along with photometric analysis, Thin Layer Chromatography (TLC), High Performance Liquid Chromatography (HPLC), High Performance Thin Layer Chromatography (HPTLC), and Gas Chromatography (GC), modern purity evaluation also includes testing for microbial contamination, aflatoxins, radioactivity, and pesticide residues. Through these techniques, the composition of herbal remedies is guaranteed constant.

Various methods like "normalization versus standardization" are used to guarantee uniformity and quality control depending on whether the active components of a herbal product are known or unknown. Particularly difficult is content or assay verification for herbal medications whose active ingredients are unknown. Assays in such situations are frequently markers or percentage extractable materials using a particular solvent; these techniques are generally included in pharmacopeias. (WHO, 1996; WHO, 1998)

Modern chemical analytical methods such ultraviolet/visible spectroscopy (UV/VIS), Thin Layer Chromatography (TLC), High Performance Liquid Chromatography (HPLC), High Performance Thin Layer Chromatography (HPTLC), Gas Chromatography (GC), mass spectrometry (MS), or combinations like GC/MS can be used to precisely identify and quantify herbal drugs with known active components or markers (e.g., sennosides in senna or alkylamides in Echinacea). These techniques provide trustworthy evaluation of the consistency and content of herbal remedies. (Watson, 1999)

2. Evaluation of Stability and Shelf Life

Long-term and apparently trouble-free usage of natural compounds frequently offers proof of their safety. Periodically, though, studies on the toxicity of widely used natural compounds have revealed hitherto unidentified hazards including teratogenicity, carcinogenicity, and systemic toxicity. The findings must be quickly and precisely reported to regulatory agencies. They ought to be able to act

quickly to such warnings by removing or changing the permits for goods that have these dubious ingredients. Substances may occasionally need to be categorized to allow for solely medical prescription use.

Quality Assessment

Good manufacturing processes should guide every step of the process.

Crude Plant Material

Along with a thorough description of the plant part used, active components, and distinguishing characteristics, the botanical definition should make explicit the genus, species, and authority.

There should be content restrictions set for these components where practical. There need to be established or limited standards for foreign materials, contaminants, and microbiological content. Certificate specimens, which stand in for every batch of processed plant material, are to be verified by a licenced botanist and kept for a minimum of 10 years. Every batch should be given a lot number, which has to be visible on the packaging.

Preparations of Plants

The manufacturing procedure has to be thoroughly recorded. Should further materials be added throughout production to modify the plant preparation to particular concentrations of active or distinctive components, or for any other reason, the manufacturing processes must make this obvious. Included should be a way to recognize and, if practical, measure the plant preparation. When it is impossible to identify an active principle, a characteristic substance or mixture of chemicals will suffice to ensure the product's constant quality.

Finished Product

The production process and formula, together with the quantity of excipients, ought to be thoroughly explained. Definition of a finished product specification is necessary to guarantee constant quality of the product. The final result has to meet the general specifications for specific dosage types.

Stability

The shelf-life should be determined and the product's physical and chemical stability in the container it is to be marketed in should be evaluated under specified storage circumstances**.**

3. Assessment of Safety:

Because herbal medicines have long been used in many cultures, they are usually regarded as safe. Serious side effects from using herbal remedies have been reported, though. Many times, adulteration and pollutants were blamed for these negative consequences. Still, some of the plants utilized in herbal remedies can be quite dangerous. All things considered, if not carefully assessed, herbal medications run the danger of side effects and combinations with other medications and diet.

The most important thing in herbal research is to guarantee the safety of herbal products. There are

many ways to evaluate their safety. Usually, two main causes of the harmful effects of herbal remedies are the intrinsic toxicity of plant components and substances and the contamination caused by production procedures.

Evaluation of the harmful effects of plant components in herbal preparations requires thorough phytochemical and pharmacological research. Based on past usage in many civilizations, it is generally believed that the use of hazardous plant components has been mostly discontinued. Many times, misidentification or overdosing of particular ingredients is blamed for recent toxicological concerns. (ICDRA, 1991)

Because of things like habitat loss, overuse of some plants, and forest fragmentation—all of which have made many therapeutic plants rare or endangered—adulteration of botanical remedies is a major worry. These problems together with the expensive raw materials add to the lack of real medications and promote adulteration. Adulteration can be replacing real plants with cheaper plants, artificially produced chemicals, exhausted medications, or other vegetative elements. (Mukherjee, 2002)
Several reports suggest that heavy metals and unidentified medications are included in many herbal products. (Robert et al., 2004) A deliberate use of medicinal adulterants is another possibility. Complicating matters further are agrochemicals used in plant protection. Furthermore poorly known are the pharmacokinetics, mechanisms of action, and medication interactions of many plants. More and more instances of fatalities or negative effects from herbal preparations highlight how urgently national regulation, registration of herbal medications, and safety monitoring must be established. Like drugs shown to be successful through extensive research, doctors must not prescribe or suggest herbal treatments without verified efficacy based on rigorous scientific investigations. (De Smet, 2002)

Assessment of Toxicity

The analysis by itself is unlikely to disclose the contributions to toxicity itself, hence toxicology testing will also be necessary. The dosage of an herbal remedy is crucial in determining its toxicity. (TDR, 2005) One or more of the following methods are used in toxicity assessment: in vitro, in vivo, cell line, and micro-array and other contemporary methods, standardization, and methods to suitably simulate toxicity.

4. Assessment of Efficacy

Though their effectiveness is now evaluated using normal clinical trial techniques, herbal medications are fundamentally different from conventional pharmaceutical treatments. Usually, clinical results such as better health status, pain relief, increased appetite and weight, lower blood pressure, smaller tumors, and better quality of life are used to assess the effectiveness of these trials. Results from laboratory or diagnostic tests include things like lower blood glucose, higher hemoglobin, less opacity in imaging tests, and better electrocardiograms.

Standardizing the method for herbalists and gathering prospective data calls for interventional

designs that, when well organized, mimic single-blind randomized trials. While less exacting than double-blind studies, these designs can be the best ones for quick assessment of herbal products both economically and biologically. But uniformity can be difficult to include into current legal systems, and ethical issues need to be properly handled.

Although randomized clinical trials—especially double-blind trials—are difficult to carry out for herbal therapy, they are not totally out of the question for determining effectiveness. Such trials can be supported by case series investigations, which offer enough scientific and ethical validity; yet, their acceptance would necessitate a change in the conventional medicine approach to medication evaluation.

Herbal medicine standardized and quality controlled through a wide range of scientific studies including physical, chemical, and biological evaluation using different analytical techniques and instruments.

Physical Evaluation: Each monograph includes detailed botanical, macroscopic, and microscopic descriptions accompanied by illustrations and photographic images to accurately identify the material. Microscopic analysis serves as an initial screening test for impurities.

Chemical Evaluation: This involves analyzing the drug to assess the potency of its active principles. It includes screening, isolating, identifying, and purifying chemical components to verify the identity of the drug substance and detect possible adulteration.

Biological Evaluation: Pharmacological assays are employed to evaluate and standardize certain drugs. These assays, conducted on living animals or their organs, indicate the potency of the drug or its preparations.

Analytical Methods: These methods are crucial for determining the identity, quality, and relative potency of herbal drugs.

Preparing samples is the first and most important stage in creating analytical procedures for botanical and herbal products. Usually, to produce a homogeneous sample, this procedure includes pre-washing, drying or freeze-drying of plant components, and grinding. Along with getting the sample ready, these procedures improve the kinetics of the constituents' extraction. Among the techniques often employed in pharmacopoeial monographs are Soxhlet extraction, reflux heating, and sonication. But these techniques can take a long time, need for a lot of organic solvents, and have inferior extraction efficiency. New approaches are always being looked for in order to solve these problems. Target chemicals can differ in polarity and heat stability, hence selecting an extraction technique needs to be done carefully. To reduce the amount of organic solvent needed and increase the effectiveness of extracting particular components from plant materials, new methods including microwave-assisted extraction (MAE), supercritical fluid extraction (SFE), accelerated solvent extraction (ASE), or pressurized liquid extraction (PLE) have been developed.

Chromatography

Separating specific components within herbal mixes and evaluating their bioactivity is made possible

in large part by chromatography. This is accomplished by use of a variety of chromatographic methods, such as capillary electrophoresis (CE), gas chromatography (GC), thin-layer chromatography (TLC), and paper chromatography (PC).

Because TLC can assess herbal extracts fast and with little sample preparation, it is commonly used in phytochemical analysis. Data on resolved chemicals are provided both qualitatively and semi-quantitatively. Using chromatograms, retention factors (Rf), band colors, absorption spectra, and peak profiles upon derivatization with various chemicals, TLC fingerprinting generates a unique fingerprint profile for each sample.

By use of a photodiode array detector with different mobile phases, HPLC fingerprinting similarly captures chromatograms, peak retention periods, and absorption spectra. GC is used especially to create fingerprint profiles of the fixed and volatile oils included in herbal medications. (Liang *et al.,* 2004; Ong, 2002)

Low-pressure HPLC (usually less than 5 bar) and high-pressure HPLC (more than 20 bar) are the two types of preparative HPLC; they are used for different purposes in the separation and purification of chemicals from herbal extracts. (Chimezie *et al.,* 2008)

With less mobile phase needed than with HPLC, HPTLC has been investigated for the simultaneous study of several components in complicated formulations. (Thoppil *et al.,* 2001) In the pharmaceutical sector, it finds adulterants in herbal products, pesticide residues and mycotoxins, and guarantees quality control of herbs and health foods. (Jiang *et al.,* 2010)

For several phases of drug development, LC-MS is now the method of choice. It finds reference markers, therefore standardizing the chemical makeup of aqueous herbal extracts. Drug discovery, toxicity research, and pharmacokinetics all gain from the increased speed and sensitivity of LC-NMR detection.(Soni & Naved, 2010) Real-time data collecting during chromatography made possible by online LC-NMR increases detection efficiency. (Patil & Rajani, 2010)

Mass spectrometers with quick scans and gas chromatography equipment interface readily. Low flow rate capillary columns supply MS ionization chambers directly. Commonly used as the most basic mass detector in GC is the Ion Trap Detector. (Zhang & Ye, 2009)

Because of their sensitivity, stability, and efficiency—especially when combined with mass spectrometry for qualitative analysis of complex compounds—GC and GC-MS are well recognized for the examination of volatile components of herbal medications. (Guo *et al.,* 2006)

Some of the best aspects of gas and liquid chromatography are combined in supercritical fluid chromatography. SFC makes it possible to separate and identify a class of substances that liquid or gas chromatography cannot easily handle. Application of SFC has been made to several natural products, medications, food, and pesticides. (Matthew & Henry, 2006)

The main technique used historically to preliminary identify distinct components has been UV absorption. But other detectors are also employed for certain purposes: fluorescence (FD), flame

ionization (FID), electron capture (ECD), refractive index (RI), and evaporative light scattering (ELSD). These techniques make it possible to measure the chemical elements in herbal and plant materials.

Mass spectrometry (MS) detection is now made easier by software and computational developments. This approach not only finds peaks of chromatographically separated mixtures but also integrates nuclear magnetic resonance spectroscopy (LC–UV–MS–NMR), multistage MS, and UV detection (by photodiode array) for molecular description. (Guliyeva *et al.,* 2004; Hostettmann & Wolfender, 1999)

NMR metabonomics has been a potent technique recently when combined with chemometrics such as simulated independent modeling of class analogy (SIMCA) and principal component analysis (PCA). Compared to conventional NMR or HPLC, high-field NMR offers a non-reductive fingerprinting technique for thorough chemical composition characterization of samples with a far greater resolution. (Belton *et al.,* 1998; Frederich *et al.*, 2004; Choi *et al.,* 2004; Hylands *et al.,* 2004)

(Belton et al., 1998; Frederich et al., 2004; Choi et al., 2004a; Hylands et al., 2004) One of the criteria in pharmacopoeias is also the existence of harmful metals. Atomic absorption spectrometry (AAS) is the main method in most analyses used to identify and measure the elements.

Many instruments have been created presently based on the same idea, such inductively coupled plasma-optical emission spectrometry (ICP-OES). Mass spectrometry-based detection and quantification have also been made feasible by inductively coupled plasma-mass spectrometry (ICP-MS). (Mosihuzzaman & Choudhary, 2008)

STANDARDIZATION OF BHASMAS

Metals include zinc, lead, gold, silver, tin, copper, and metal alloys as well as minerals like gems, coral, mica, and others are the sources of bhasmas. They are made by the process of calcining these materials following their purification and detoxification with mineral preparations or herbal juices. (Kapoor, 2010) Often taken with milk, butter, honey, or ghee to lessen any possible negative effects of the metals and improve their compatibility inside the body, hasmas are widely used in Ayurvedic medicine to treat a variety of chronic diseases. (Kumar et al., 2006)

While the Drug and Cosmetics Act mentions many traditional literature that Ayurvedic practitioners (vaidyas) might consult for their preparation, the Ayurvedic Formulary of India describes several techniques for making bhasmas from specific metals.(Department of Health, Ministry of health & Family welfare, Delhi, 1978) For several single herbal medications, the Indian government has set pharmacopoeial standards; work to standardize classical composite formulations in different research facilities is still in progress. Standardization of both the production method and the finished product is essential. The phase spot test is one of the methods the Central Council for Research in Ayurvedic Sciences (CCRAS) has created to help detect and evaluate bhasmas. (Central Council for Research in Ayurveda and Siddha, 1991)

Contemporary physicochemical characterisation of bhasmas has been greatly aided by sophisticated data analysis methods and cutting-edge testing equipment. These investigations have thoroughly examined the chemical composition and crystalline structure of intermediates and end products as well as different preparation techniques for the same metal.

Several analytical methods have been instrumental in these studies:

- **Atomic Absorption Spectrophotometry (AAS)**: Measures the absorption of specific wavelengths of electromagnetic radiation by atoms, allowing quantitative estimation of elements present.
- **Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES)**: Uses plasma to excite atoms, which then emit characteristic electromagnetic radiation that can be used to quantify element concentrations in a sample.
- **X-ray Diffraction (XRD)**: Provides information on the crystallographic structure of materials, distinguishing between crystalline and amorphous forms and revealing details about chemical composition and physical properties.
- **pHmetry**: Measures the acidity or alkalinity of a solution, providing insights into the chemical environment during preparation.

The quality and consistency of bhasma preparations are assessed in part by the determination of elements like particle size distribution and crystal structure made possible by these methods. Such tools allow Standard Operating Procedures (SOPs) for bhasma preparation to be improved and standardized. (Tripathi, 2006)

A standardised procedure ought to distinguish between bhasmas derived from minerals and herbs that are not possibly harmful and those that are. Ensuring safety and effectiveness in Ayurvedic treatments as well as regulatory compliance depend on this distinction.

DNA FINGERPRINTING TECHNIQUE

Standardizing herbal medications now depends heavily on DNA analysis. This method is very important in identifying real medications from ones that appear same in phytochemicals but have been altered or tampered with. DNA fingerprinting depends on the genetic consistency of the plant species, unlike phytochemical analysis which might differ depending on the plant component used, physiology, and environmental conditions. (Shikha & Mishra, 2009)

The idea of DNA fingerprinting has grown in favor recently to determine the ancestry of microbes, plants, and animals. Because plants may vary greatly even within the same genus and species, genotypic categorization is especially useful in herbal therapy.

The capacity of DNA fingerprinting to identify adulterants even in processed samples is one of its main advantages in herbal medicine authenticity. This capacity checks that intact genomic DNA from plant materials exists during all processing phases, so guaranteeing the legitimacy of the medication. (Mihalov *et al.,* 2000)

Because DNA fingerprinting provides intact genomic DNA specificity, it has another important use in commercial herbal medicines. This skill is essential to identify adulterants even in processed samples of herbal products. (Lazarowych & Pekos, 1998) Crucially involved in this process are DNA markers, which are DNA fragments with known positions on chromosomes.

Because these markers can generate normal, working proteins to replace faulty ones, they are

extremely useful for identifying cells, people, or species. DNA markers are especially helpful in herbal therapy to identify real herbs from synthetic medications. For example, it has been effective to distinguish Cannabis sativa and Arabidopsis thaliana L. Heyne from their tampered-with species using ISSR (Inter Simple Sequence Repeat) markers.

This application emphasizes the value of DNA fingerprinting for preserving the genuineness and high caliber of herbal medications and guaranteeing that customers get goods that satisfy exacting requirements for purity and effectiveness. (Usha *et al.,* 2010)

CONCLUSION

The growing interest in traditional herbal treatments is driving a fast expansion in the Indian herbal sector. But along with this increase have come worries about the efficacy and safety of herbal remedies. More sophisticated methods in standardisation are desperately needed to address these issues.

Herbal research depends on analytical technique developments since they give producers quick and precise means to set quality criteria and norms. These requirements guarantee the therapeutic effectiveness, safety, and shelf life of herbal medications and are necessary for obtaining regulatory authority marketing approval.

Ensuring that herbal pharmaceutical products meet exacting requirements throughout their production and distribution processes is mostly the responsibility of national health authorities. Maintenance of product quality and safety up to the end user depends especially on adherence to Good Manufacturing Practices (GMP).

Not only are analytical techniques for active ingredients established, but other important aspects such pesticide residues, aflatoxin levels, heavy metal contamination, and compliance with Good Agricultural Practices (GAP) and GMP are also addressed in the quality control of herbal medications. Enhancing drug quality and motivating practitioners to actively participate in the standardization process will result from balancing conventional and current evaluation techniques.

In general, the growing herbal sector depends on the creation and application of these methods to protect the safety, effectiveness, and quality of herbal medications.

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