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Original Article

Quality Assurance in Herbal Medicines: Regulatory framework and Modern Standardization approaches

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Abstract

The growing global use of herbal medicines necessitates robust quality assurance (QA) systems to ensure their safety, efficacy, and consistency. Herbal products are complex, multi-component preparations whose quality is influenced by factors such as geographical origin, cultivation, harvesting, processing, and storage conditions. In addition, adulteration, substitution, contamination, and inconsistent labeling pose significant risks to consumer safety and therapeutic reliability[1]. Quality assurance in herbal medicines involves systematic control of raw materials, manufacturing processes, and finished products in compliance with regulatory and pharmacopoeial standards. Standardization is central to QA, ensuring the identity, purity, composition, and biological activity of herbal materials. Evaluation methods include macroscopic and microscopic examination, physicochemical testing, phyto-chemical screening, biological assays, and advanced analytical techniques such as chromatography and spectroscopy for authentication and detection of adulterants. Effective integration of modern analytical tools with established regulatory frameworks is essential to achieve reproducible quality and maintain public confidence. Strengthening QA practices in herbal medicine production is therefore critical for safeguarding public health and supporting the global acceptance of herbal therapeutics.

Keywords: *Quality assurance, Herbal medicines, Standardization, Analytical methods, Regulatory compliance*

Introduction

1. Growth of the Herbal Industry

Due to growing consumer desire for natural and plant-based medicines, the global herbal medicine market has grown significantly in recent years. Herbal medications are frequently used to prevent illness, treat chronic illnesses, and promote general wellness. Their price, perceived safety, and compatibility with holistic treatment systems have all increased consumer demand. The global herbal medicine industry is expected to increase at a significant compound annual growth rate, from its estimated USD 77.45 billion in 2023 to over USD 300 billion by 2032, according to recent market reports. The most popular dose forms are still capsules and tablets because of their precision, stability, and ease of use. Thanks to growing healthcare. Thanks to growing healthcare awareness and traditional medical systems, the Asia-Pacific region dominates the market. However, in order to guarantee safety, effectiveness, and consumer confidence, strong quality assurance and standardization procedures are also critically needed, as highlighted by the quick industrial expansion.

2. Need of Quality Assurance in Herbal Medicines

Ensuring the quality, safety, and consistency of herbal medications is becoming increasingly difficult as their use grows. Consumers' and healthcare professionals' trust can be damaged by inconsistent active chemical levels and possible safety concerns brought on by inadequate quality control.

a. Challenges in Quality control of Herbal Pharmaceuticals

Quality control of herbal drugs is particularly challenging due to the complex nature of plant-based materials and the diverse range of chemical compositions they include.

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Herbal medicines, as opposed to manufactured medications, contain a range of active substances, the quantities of which differ depending on the climate, soil type, harvesting season, harvesting time, and processing methods.

1. Adulteration and substitution Adulteration is one of the most common issues with the quality of herbal drugs. Because several plant species have similar morphologies, economic adulteration may occur accidently or on purpose. Comparability in appearance Comparability of color Using the incorrect botanical source Carelessness during collection and supply chain management Efficacy and safety are significantly impacted by incorrect plant identification.
2. Inadequate Standardization Global regulatory standards for herbal medications are not consistent. Disparities in national pharmacopoeial standards and regulatory frameworks result in inconsistencies in: quality of raw materials Methods of manufacturing Final product details Batch-to-batch variance is still a big issue.
3. Changes in Chemical Composition Different therapeutic plants have different chemical profiles because Environmental elements (soil, climate, and altitude) Time of harvesting Conditions for storage Techniques for processing Maintaining constant potency and therapeutic activity is challenging because of this fluctuation.
4. Problems with Stability and Shelf-Life Typical herbal preparations include: Chemical compositions that are complex Light, temperature, and moisture sensitivity Setting up appropriate storage conditions might be challenging. Stability testing is difficult but necessary to guarantee the safety and effectiveness of products over time.
5. Limited Clinical and Pharmacokinetic Information In contrast to synthetic medications, many natural products don't have: Sufficient pharmacokinetic evidence Assessment of toxicology extensive clinical trials This restricts the efficacy and safety of scientific confirmation[6].
6. Difficulties with Evaluation Techniques
7. Challenges in Qualitative Evaluation Evaluation of organoleptic properties (color, taste, texture, and odor) Analysis of morphology and microscopy Identification of adulterants and replacements Expertise is needed for these techniques, which might not always identify complex adulteration.

The Difficulties of Quantitative Evaluation Finding the active ingredients The application of techniques like the leaf constants and Lycopodium spore method Advanced analytical procedures are required. Because there are several active chemicals, chemical profiling can be challenging.

Regulatory and Ethical Concerns Variations

In the adoption of regulations around the world Inadequate standardization of guidelines The difficulties in carrying out randomized controlled trials Because herbal products have a unique flavor, smell, and look, it is challenging to construct placebo-controlled experiments.

GMP and Manufacturing Issues:

GMP, or good manufacturing practices Adequate documentation In the herbal industries, controlled processing parameters are crucial yet frequently applied inconsistently.

Aim of Review is "To evaluate and ensure quality assurance parameters of selected herbal tablets in accordance with WHO and pharmacopoeial guidelines."

3. **Regulatory Framework for Herbal medicines [1TO 4]:**

Different nations and organizations have different regulatory frameworks for herbal medicines, which reflect differences in legislative frameworks, approaches to quality assurance, and healthcare priorities. Key distinctions and similarities between GMP regulations, quality standards, and assessment techniques are highlighted in a comparative perspective.

Regulatory Body/ Region	Scope and focus	GMP/QA Requirements	Enforceability	Remarks
WHO (Global)	Provides global guidelines for herbal medicines quality and safety	Good Agricultural & Collection practices (GMP), quality testing, contaminant limits Advisory/ Non-binding	Advisory/ non-binding	Serves as a global baseline; flexible implementation; limited updates for modern analytical tools (DNA barcoding, metabolomics)
EMA (Europe)	Herbal medicinal products & traditional herbal medicinal products	Detailed herbal monographs, standard quality benchmarks, stability testing, safety evaluation, batch documentation	Enforced under EU law	High specificity for herbal products; clear pharmacopoeial standards
FDA (USA)	Herbal products regulated as dietary supplements	GMP for dietary supplements, manufacturing controls, labeling, post-marketing serveillance	Enforced under FDA regulations	Focus on manufacturing compliance; limited pre-market efficacy requirements

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CFDA (China)	Herbal and Traditional Chinese medicines	GMP integrating traditional practices with modern pharmaceutical standards; limits for contaminants and heavy metals	Enforceable	Incorporates traditional evidence; evaluates both raw materials and finished products
AYUSH/ India Drug and cosmetic Act, 1940	Ayurvedic, Unani, Siddha and other traditional herbal products	Pharmacopoeial standards, GMP compliance, raw material authentication, safety testing	Enforceable	Emphasizes integration of traditional knowledge with modern QA methods

The comparative study emphasizes the necessity of unified international standards that combine conventional wisdom with contemporary analytical and GMP procedures. Improving regulatory alignment can help herbal medications maintain uniform quality assurance, boost product reputation, and ease international trade.

Standardization of medicinal herbs and products

The phyto-chemical components found in herbal formulations can change depending on the climate, soil composition, and growing region; these factors all act as barriers to standardization. The gradual growth in herbal medication adulteration and substitution is caused by the expansion of deforestation. The safety and effectiveness of the medication are harmed by this adulteration and substitution.

Adulteration, substitution, and lack of skilled personnel contribute significantly to the unavailability of genuine herbal drugs. Therefore, advanced quality control techniques and well-defined standards are essential to ensure the safety, efficacy, purity, and consistency of herbal products. Standardization involves evaluating the qualitative and quantitative characteristics of herbs according to established pharmacopoeial parameters.

Authentication relies on organoleptic evaluation, macroscopic and microscopic examination, and assessment of physicochemical parameters such as moisture content and ash values. These methods help detect adulterants, confirm identity, and ensure purity. Phyto-chemical screening and identification of key secondary metabolites—including alkaloids, tannins, glycosides, saponins, and flavonoids—further support quality assurance.

Modern chromatographic and spectroscopic techniques strengthen the scientific validation of Ayurveda and traditional herbal medicines. Guidelines established by the World Health Organization provide a framework for standardized evaluation, ensuring the quality, safety, and global acceptance of herbal drugs.

Identification/ authentication of cultivated medicinal plants

1. **Selection of medicinal plants**

Choice of therapeutic plants Whenever possible, the species or botanical variation chosen for cultivation should match those listed in the end-user's country's national pharmacopoeia or suggested by other official national sources. The choice of species or botanical variants listed in the pharmacopoeia or other authoritative documents of other nations should be taken into consideration in the absence of such national publications. The species or botanical variation chosen for cultivation in newly introduced medicinal plants should be identified and recorded as the source material utilized or described in the native country's traditional medicine.

2. **Botanical identity**

It is important to confirm and document the botanical identity, or scientific name (genus, species, subspecies/variety, author, and family), of every medicinal plant being grown. The English and local common names should also be noted if they are available. When necessary, additional pertinent details like the cultivar name, ecotype, chemotype, or phenotype may also be given. The name of the cultivar and the provider should be given for cultivars that are sold commercially. When landraces are gathered, reproduced, spread, and cultivated in a particular area, documentation of the locally identified line should be preserved, along with the source seeds, plants, or propagation materials' origin.

3. **Specimens**

If a medical plant is first registered in a producer's country or there is dispute about its authenticity, a voucher botanical should be used in accordance with WHO standards on appropriate farming and collection procedures for medicinal plants. Submit a specimen to a regional or national herbarium for identification. Where possible, a genetic pattern should be compared to that of a genuine specimen. The registration file should include documentation proving the botanical identification.

4. **DNA barcoding**

DNA barcoding is a molecular authentication technique that involves sequencing standardized DNA sections such as rbcL, matK, and ITS. The acquired sequence is compared to reference databases to ensure botanical identity. This approach is particularly beneficial for detecting adulteration and substitution in powdered or processed herbal materials that cannot be morphologically identified. Although it requires specialized laboratory facilities, DNA barcoding considerably improves traceability, regulatory compliance, and quality assurance of herbal raw materials.

Characterizing herbs and herbal products using thermal analysis

Because the components of the herbals are complex, unique procedures and tactics are used to verify the quality, purity, and integrity of the herbals. Thermal techniques such as thermogravimetric analysis (TGA) and

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differential thermal analysis (DTA) have the following characteristics: high sensitivity, reproducibility, determination of mass and enthalpy variation, thermal stability of the samples, and quick reaction to variations in results.

Thermal analysis is a valuable tool for characterizing herbal extracts and drug products. Techniques such as TGA, DTA, DTG, and DSC are used to assess raw material quality, purity, moisture content, thermal stability, degradation behavior, and drug–excipient compatibility. These methods operate within a temperature range of approximately 25–1000 °C and measure mass loss and thermal transitions (endothermic and exothermic changes) during heating.

Kinetic parameters—including reaction order (n), activation energy (Ea), frequency factor (A), and rate constant (k)—are calculated using the Arrhenius equation:

Ln k=In A−Ea/RT [OR] k(T)= A.$e^{-Ea/RT}$

where, A= frequency factor,

K= rate constant,

Ea= activation energy and

R= gas constant (8.3a4Jk^{-1} mol^{-1})

As temperature increases, the rate constant (k) increases, accelerating degradation. Activation energy (Ea) is the minimum energy required to initiate a thermal process. A decrease in particle size increases surface area and instability, which lowers activation energy and enhances the rate of thermal degradation.

Thermal studies also aid in evaluating stability under isothermal and non-isothermal conditions and help determine safe disposal methods by analyzing degradation behavior and potential.

Fingerprint Data Analysis Using Chemometric Approaches

When quality markers of herbal medicines (HMs) are unknown, combining chemical fingerprinting with chemometrics is the preferred method for quality assessment. Instrumental techniques like LC-MS/MS and ^{1}H-NMR generate chemical profiles that reveal similarities and differences between samples, enabling classification into categories such as authentic or adulterated. However, the presence of numerous unknown chemical components makes data analysis challenging. Chemometrics—using statistical and mathematical tools to analyze chemical data—helps manage these complex datasets and allows accurate identification even when characteristic constituents vary in concentration

The International Chemometrics Society defines chemometrics as the science of linking chemical measurements to properties of interest (e.g., concentration) through mathematical or statistical methods. It is widely applied to spectroscopic and chromatographic data. Among chemometric techniques, classification approaches are most common in HM fingerprinting, aiming to relate chemical measurements to discrete sample categories). Key methods include exploratory data analysis and pattern recognition, both supervised and unsupervised. These techniques can reduce data complexity and provide insight into chemical datasets. Additionally, multivariate calibration methods such as principal component regression, partial least squares regression (PLSR), and multiple linear regression are often used to build predictive models for analytes of interest.

Physicochemical Parameters

1. **Ash Values**

The ash of any organic material is made up of their non-volatile inorganic components. Incineration of crude drug in controlled manner results in an ash residue of an inorganic material (metallic salts and silica). This value varies in wide limits and is therefore an important parameter for the purpose of evaluation of crude drugs.

2. **Extractive values**

This method determines amount of active constituent in given quantity of medicinal plant material, when extracted with solvents. It is helpful for those substances for which no assay method is available.

The extraction of any crude drug with a particular solvent yields a solutions containing different phyto-constituents. The composition of phyto-constituent in that particular solvents always depended on nature of drug and solvent used. It has following types depending upon solvent used.

- Determination of water soluble extractive
- Determination of Alcohol soluble extractive
- Solvent Hexane soluble extractive
- Volatile Ether soluble extractive
- Non volatile Ether soluble extractive

3. **Moisture content/ Loss on drying**

Moisture is an inevitable component of crude drugs, which has to eliminated as much as possible. The crude drug preparation from harvested drug plants involves cleaning or garbling to remove soil or other unwanted parts followed by drying which plays important role in the quality as well as purity of material. The main objective of drying fresh material is to aid their preservation, to check enzymatic or hydrolytic reactions that might after the chemical composition of drug, to reduce their weight and bulk and to facilitate subsequent comminution.

Methods for determination of moisture content include the loss on drying, volumetric azeotropic distillation method and the titrimetric Karl Fischer method. Which method is to be applied depends upon the constituents and nature of drug.

4. **Foreign matter**

Foreign matter means any unwanted material present in herbal drugs, such as insects, dust, or other plant parts. It is determined by manual separation and expressed in percentage. Controlling foreign material is essential to ensure purity, safety, and compliance with pharmacopoeial standards.

Phytochemical screening

Phytochemical screening is a primary qualitative analytical method, used to identify the presence of various bioactive constituents in herbal drugs. These phytoconstituents, such as alkaloids, flavonoids, tannins, glycosides, saponins, and terpenoids, which are responsible for the therapeutic activity of medicinal plants. Therefore, phytochemical screening plays a important role in the standardization, quality control, and evaluation of herbal

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medicines. It also helps in identifying active constituents, ensuring consistency and quality, supporting pharmacological activity and detecting adulteration and substitution.

There are varies phytochemical tests:

- Alkaloids- Dragerndorff's/ Mayer's test
- Flavonoids- Shinoda test
- Saponins- Froth test
- Tannins- Ferric chloride test
- Glycosides- Kelle-killani test
- Terpenoids- Salkowski test,etc.

Microscopy

Microscopic examination is an essential method for authentication and quality control of herbal drugs. It studies cellular structure and diagnostic features using suitable samples preparation, staining and the mounting techniques. The transverse section and powder microscopy are used to identify key characteristics such as stomata, trichomes, fibers, and crystals, which helps in detection of adulteration and ensuring purity.

Advanced Analytical Techniques

1. **HPLC**

It is important to establish the standardized manufacturing procedures and suitable analytical tools to framework for quality control in herbals. Among these tools, HPLC is a separation tool which is used to evaluate and assay of finished products.

2. **Gas Chromatography- Mass spectroscopy (GC-MS)**

Gas Chromatography- Mass spectroscopy (GC-MS) is a powerful analytical technique used for separation, identification, and quantification of volatile and semi-volatile compounds in herbal drugs. In this method, the samples is vaporized and carried with in inert gas through a chromatographic column, where on the basis of their volatility and interaction components are separated. The separated components are then detected by mass spectrometer, which provides structural information based on mass-to-charge (m/z) ratios.

3. **Liquid chromatography- Mass Spectrometry LC-MS)**

Liquid Chromatography- Mass Spectroscopy (LC-MS) is an advanced analytical technique mainly used for the analysis of non-volatile, thermally unstable and high molecular weight compounds in herbal medicines. In LC-MS, compounds re first separated using liquid chromatography based on their polarity and chemical properties., followed by detection using mass spectrometry for precise identification and quantification.

Contamination Testing and Safety Evaluation

Contamination testing checks herbal medicines (HMs) and natural products for harmful substances like microbes, pesticides, myco-toxins, and heavy metals**.** Metals such as lead (Pb), mercury (Hg), arsenic (As), and cadmium (Cd) can build up in plants from soil, water, or during processing and can be dangerous if consumed.

Common methods to detect contaminants include:

- **Atomic Absorption Spectroscopy (AAS)** – used to measure heavy metals like Pb, Hg, Cd, and As.
- **Inductively Coupled Plasma Mass Spectrometry (ICP-MS)** – a very sensitive method that can detect multiple metals at very low levels.
- **Chromatography and mass spectrometry (HPLC, GC-MS, LC-MS/MS)** – used to find pesticides, mycotoxins, and leftover solvents.
- **Microbial tests** – check for bacteria and fungi, including *E. coli* and *Salmonella.*

Safety evaluation combines these tests with toxicology studies to make sure the product is safe. This involves identifying toxic compounds, measuring their amounts, assessing the risk of exposure, and ensuring the product meets safety standards set by WHO, FDA, EMA**,** or official pharmacopeias.

Using a combination of chemical fingerprinting, statistical analysis (chemometrics), and contamination testing provides a complete approach to confirm the quality, authenticity, and safety of herbal medicines, even when the main active compounds are unknown or vary between samples.

Discussion

The increasing global use of herbal medicines highlights the need for effective quality assurance systems to ensure their safety, efficacy, and consistency. In this review, key aspects such as crude drug authentication, standardization, microscopic evaluation, phytochemical screening and advanced analytical techniques have been discussed.

Traditional evaluation methods, including microscopy and physicochemical analysis, are simple and cost-effective methods but limits sensitivity. In contrast, modern techniques such as GC-MS and LC-MS has more accuracy for identification and quantification of phyto-constituents, improving the reliability of quality assessment.

However, the challenges associated such as adulteration, variability in chemical composition, and lack of harmonized regulatory standards affects the quality of herbal medicines. Therefore, an integrated approach combining conventional methods with advanced analytical tools is essential to ensure the quality, safety, and global acceptance of herbal drugs.

Conclusion

Quality assurance is an essential to ensure the safety, efficacy and consistency of herbal medicines. The integration of traditional evaluation methods with modern analytical techniques such as HPLC, GC-MS, and LC-MS improves the reliability of herbal drug standardization. Despites it advancements, it has challenges like adulteration, variability in composition, and lack of global regulatory harmonization still persist. Therefore, a comprehensive and integrated approach is necessary to keep consistency in quality and enhance the global acceptance of herbal medicines.

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Conflicts of interest

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