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Review Article

A Holistic Review of WHO Guidelines on Herbal Medicines: Quality Control from Cultivation to Consumption

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A B S T R A C T

Herbal medicines remain a cornerstone of global healthcare, yet their quality, safety, and efficacy are highly dependent on stringent regulatory oversight. The World Health Organisation (WHO) has developed a series of guidelines addressing quality control across the herbal supply chain—from cultivation and harvesting to processing, manufacturing, and consumption. This review provides a holistic evaluation of these guidelines, highlighting their scope, strengths, and limitations. While WHO documents offer a broad, globally adaptable framework for Good Agricultural and Collection Practices (GACP), Good Manufacturing Practices (GMP), and quality testing, their advisory nature and lack of enforceability lead to variable adoption across regions. Moreover, many guidelines are dated and do not incorporate modern analytical advancements such as metabolomics, DNA barcoding, and AI-assisted quality assessment. In contrast, regional regulatory frameworks such as those of the European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA), China, and India (AYUSH) often provide more detailed specifications, pharmacopoeial standards, and enforceable quality benchmarks. This review critically compares WHO guidelines with such frameworks, identifies gaps, and emphasises the need for harmonisation and updates. Strengthening WHO guidance through integration with regional standards can ensure consistent global quality control and enhance the credibility of herbal medicines.

Keywords: Herbal medicines, Good Manufacturing Practices (GMP), Metabolomics

Introduction

Herbal medicine, also known as phytotherapy or botanical medicine, encompasses the use of plant-based remedies for preventive and therapeutic purposes. With roots deeply embedded in various traditional healing systems worldwide, herbal medicine has experienced a resurgence of interest in recent years due to its perceived safety, efficacy, and holistic approach to healthcare. In recent years, there has been a resurgence of interest in traditional herbal remedies, fuelled by the growing awareness of the limitations and side effects associated with conventional pharmaceuticals. Herbal plant extracts, derived from various parts of plants such as leaves, roots, flowers, and seeds, have been used for centuries in different cultures worldwide for their medicinal properties. These extracts contain a myriad of bioactive compounds that exhibit diverse pharmacological activities, making them a promising source for the development of novel therapeutics.[1]

Herbal remedies, dating back to the dawn of civilisation, have played a pivotal role in the history of human health and healing. Embedded in the cultural fabric of societies worldwide, the use of plants for medicinal purposes predates recorded history and has been an integral part of traditional healing practices across diverse cultures. The historical context of herbal remedies provides valuable insights into the evolution of healthcare and the enduring relationship between humans and plants. The historical context of herbal remedies underscores the enduring significance of plants in human health and healing.

From ancient civilisations to the modern era, herbal medicine has evolved in response to cultural, social, and scientific influences, yet its fundamental principles remain rooted in the healing power of nature. As we continue to explore the therapeutic potential of medicinal plants, it is essential to honour and preserve the traditional knowledge passed down through generations while embracing the opportunities for innovation and collaboration offered by modern science.[2]

Herbal medicine boasts a rich and ancient history, deeply rooted in the practices of civilisations like Mesopotamia, Egypt, China, India, Greece, and Rome, where it was intertwined with spiritual beliefs and empirical observations. Traditional healing systems such as TCM, Ayurveda, and Unani have historically relied on herbal remedies, with detailed classifications and formulations tailored to restore bodily balance. During the mediaeval period, herbal medicine flourished in Europe and the Islamic world, with significant advancements made by scholars like Avicenna. The Age of Exploration facilitated a global exchange of plants and herbal knowledge, enriching pharmacopoeias worldwide.[3]

In the modern era, scientific inquiry has revolutionised the study of herbal medicine. Pharmacognosy emerged, leading to the isolation of active compounds like aspirin from willow bark. Rigorous scientific validation through pharmacological studies and clinical trials is increasingly integrating herbal remedies into mainstream healthcare. Modern research focuses on elucidating mechanisms of action, identifying active compounds, and ensuring safety and efficacy through meticulous assessments, with regulatory bodies overseeing quality.[4] This has led to the integration of plants into conventional medicine as complementary or adjunctive therapies, offered in herbal medicine clinics and integrative healthcare centres. Pharmaceutical companies are also incorporating plant-derived compounds into modern medications, and research collaborations are bridging traditional knowledge with modern science.

Despite these advancements, challenges remain, including the need for standardisation and quality control in manufacturing processes, consistent regulation and safety measures across jurisdictions, and further rigorous research and evidence-based practice. Additionally, education and training for healthcare professionals and herbalists are crucial, as are efforts for sustainability and conservation of medicinal plant species to address the impact of increasing demand and environmental threats.[5].

The present review underscores that while WHO guidelines on herbal medicines provide a holistic framework covering cultivation, processing, and quality assurance, they remain largely descriptive and advisory in nature. Their generic approach facilitates global applicability but also creates ambiguity in implementation, particularly in countries with limited infrastructure. For instance, WHO recommendations on contaminant limits, stability studies, or advanced analytical methods often lack precise thresholds or validated protocols, leaving scope for inconsistent interpretation. Moreover, many guidelines have not been updated in line with emerging tools such as metabolomics, DNA barcoding, or AI-based quality assessment.

In contrast, other regulatory frameworks provide greater specificity. The European Medicines Agency (EMA) issues detailed herbal monographs and standardised quality benchmarks, while the United States emphasises Good Manufacturing Practices (GMP) and post-marketing surveillance under the FDA/DSHEA framework. China and India, through the Pharmacopoeia of PRC and AYUSH, respectively, integrate traditional evidence with modern analytical standards, offering more rigorous protocols for pesticide residues, heavy metals, and pharmacognostic authentication.

Thus, WHO guidelines are invaluable as a global baseline, but their limitations highlight the need for integration with regional pharmacopoeial standards. A critical comparative approach can bridge these gaps, fostering harmonisation and ensuring consistent quality and safety of herbal medicines worldwide.

Herbal Medication Products

Herbal medication products, also known as herbal remedies or botanical medicines, are medicinal products derived from plants or plant extracts. They have been used for centuries in various traditional healing systems around the world and continue to be popular due to their perceived natural origins and potential health benefits. Here's an overview of herbal medication products:[5-10]

- **Sources:** Herbal medication products are derived from various parts of plants, including leaves, roots, stems, flowers, seeds, and fruits. They may be obtained from a single plant species (monographs) or combinations of different plants (formulas).
- **Preparation:** Herbal medicines can be prepared in different forms, including:

- **Dried Herbs:** Whole or powdered plant material used to make teas, infusions, decoctions, or capsules.
- **Extracts:** Concentrated preparations obtained by extracting active compounds from plant material using solvents such as water, alcohol, or oil.
- **Tinctures:** Liquid extracts made by soaking plant material in alcohol or glycerine.
- **Ointments and Creams:** Topical preparations containing herbal extracts or oils for skin conditions.
- **Essential Oils:** Highly concentrated plant extracts used in aromatherapy or topical applications.
- **Traditional Use:** Herbal medication products have a long history of use in traditional healing systems such as Traditional Chinese Medicine (TCM), Ayurveda, and Native American medicine. They are often used to treat a wide range of health conditions, including digestive disorders, respiratory ailments, skin conditions, and musculoskeletal problems.
- **Health Benefits:** Herbal medicines are believed to exert their therapeutic effects through various mechanisms, including:
- **Phytochemicals:** Active compounds in plants such as alkaloids, flavonoids, terpenes, and phenolic compounds with medicinal properties.
- **Pharmacological Actions:** Herbal medicines may have anti-inflammatory, antioxidant, antimicrobial, analgesic, or immunomodulatory effects.
- **Holistic Approach:** Many herbal remedies are used holistically, addressing the physical, mental, and emotional aspects of health.[11]
- **Safety and Efficacy:** While herbal medicines are generally perceived as natural and safe, their safety and efficacy vary widely depending on factors such as plant species, preparation methods, dosage, and individual patient characteristics. Some herbal products may have adverse effects, interact with conventional medications, or contain contaminants or adulterants.
- **Regulatory Oversight:** Regulatory frameworks for herbal medication products vary between countries. In some regions, herbal medicines are regulated as dietary supplements or traditional medicines, while in others, they may be subject to more stringent pharmaceutical regulations. Regulatory authorities may require evidence of safety, quality, and efficacy before allowing herbal products to be marketed and sold.
- **Research and Evidence:** There is growing interest in scientific research on herbal medicines to evaluate their safety, efficacy, and mechanisms of action. Clinical trials, observational studies, and laboratory research contribute to the evidence base for herbal medication products, helping healthcare professionals make informed decisions about their use.[12]

Quality Control for Herbal Medication Products

Quality control for herbal medication products is vital to ensure safety, efficacy, and consistency. Crucial measures are required at every stage of production due to the natural origins and variability of plant materials.

- **Raw Material Identification and Authentication:** Proper identification and authentication of botanical raw materials are fundamental. This involves botanical examination, morphological and microscopic analysis, and chemical fingerprinting to confirm the identity of plant species and detect any adulteration.[13]
- **Standardisation:** Standardisation establishes specific quality parameters and ensures consistent levels of active constituents or marker compounds in herbal medicines. This is achieved through quantitative analysis, biological assays, chemical fingerprints, and total extractable content.
- **Identification:** Accurate identification of the botanical origin of herbal materials is essential for ensuring authenticity and preventing adulteration. Methods include macroscopic examination, microscopic examination, chemical analysis, and DNA barcoding.
- **Processing and Manufacturing Controls for Herbal Medicines:** Controls include raw material selection and handling, extraction and processing, formulation and standardisation, manufacturing practices, quality control testing, packaging and labelling, and quality assessment during processing.
- **Raw Material Evaluation:** This critical step involves assessing the identity, authenticity, purity, and quality of botanical raw materials. Techniques include botanical identification, microscopic examination, chemical profiling, and DNA barcoding.
- **Good Manufacturing Practices for Herbal Products:** GMP guidelines ensure quality, safety, and consistency in manufacturing processes. Key aspects include facility and equipment, personnel, raw material control, production controls, quality control, documentation and record-keeping, packaging and labelling, process control, and in-process testing.[14]
- **Process Control:** Process control involves monitoring and managing various aspects of production to ensure consistent quality, safety, and efficacy. Elements include standard operating procedures, process validation, process parameters, in-process testing, quality control checks, environmental controls, equipment calibration and maintenance, record-keeping and documentation, training and personnel competence, and sampling.[15]
- **In-Process Testing:** In-process testing is crucial for quality control in herbal product manufacturing. It involves the analysis and evaluation of product characteristics

at various stages of the manufacturing process to monitor and control quality, identify deviations, and ensure that products meet predefined specifications. Key aspects include physical tests, chemical tests, microbiological tests, sampling, testing methods, instrumentation, data analysis and documentation, and early detection of issues.

Quality Control Methods to Identify and Verify Herbs[16-20]

Several quality control methods are employed to accurately identify and verify herbs used in herbal medication products. These methods are essential for ensuring the authenticity, purity, and safety of herbal materials. Here are some commonly used techniques:

- **Macroscopic Examination:** Macroscopic examination involves visual inspection of the physical characteristics of herbs, including size, shape, colour, texture, and odour. It helps in identifying herbs based on their morphological features and distinguishing them from potential adulterants or substitutes.
- **Microscopic Examination:** Microscopic examination involves the use of a microscope to observe the cellular structure and tissue morphology of herbal materials. This technique can reveal diagnostic features such as the presence of specific cell types, trichomes, starch grains, crystals, or other anatomical structures characteristic of particular plant species.[21]
- **Thin-Layer Chromatography (TLC):** TLC is a chromatographic technique used for the separation and identification of chemical compounds in herbal extracts. It involves spotting the extract onto a thin layer of adsorbent material (e.g., silica gel) and developing the chromatogram using a suitable solvent system. Visualisation of separated compounds under UV light or after staining with specific reagents can aid in herb identification and authentication.[22-24]
- **High-Performance Thin-Layer Chromatography (HPTLC):** HPTLC is an advanced version of TLC that offers improved resolution, sensitivity, and reproducibility. It allows for the quantitative analysis of multiple compounds in herbal extracts and is often used for fingerprinting and quality control purposes.
- **High-Performance Liquid Chromatography (HPLC):** HPLC is a powerful analytical technique used for the separation, quantification, and identification of individual components in herbal extracts. It is particularly useful for analysing marker compounds or active constituents in herbs and comparing them to reference standards for authentication purposes.[25]
- **Gas Chromatography (GC):** GC is a chromatographic technique used for the separation and analysis of volatile and semi-volatile compounds in herbal materials. It is commonly used for the analysis of essential oils and volatile components of herbs, providing valuable information for identification and quality control.[26]
- **Mass Spectrometry (MS):** Mass spectrometry is a technique used for the identification and structural elucidation of chemical compounds based on their mass-to-charge ratio. Coupling MS with chromatographic techniques such as HPLC or GC (GC-MS) enhances the specificity and sensitivity of herbal material analysis, allowing for the identification of complex mixtures of compounds (Fig. 1).

DNA Barcoding: DNA barcoding involves the amplification and sequencing of specific DNA regions from herbal materials to identify plant species based on their genetic signatures. This molecular technique provides a reliable means of authentication, especially for processed or powdered herbs where morphological features may be absent or difficult to discern.[27-31]

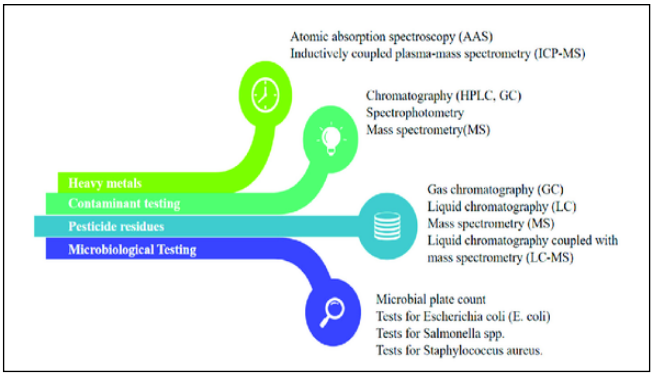

Figure 1.The quality control methods for contaminants, heavy metals, pesticide residues, and microbiology

Conclusion

WHO guidelines serve as a comprehensive framework for ensuring the safety, efficacy, and quality of herbal products throughout their lifecycle, from cultivation to consumption. Here's why adherence to these guidelines is crucial:

- **Safety Assurance:** By following WHO guidelines, manufacturers can implement practices that minimise the risks associated with herbal medicines, including contamination, adulteration, and variability in potency. This helps protect public health and ensures that consumers can use herbal products with confidence.
- **Efficacy Enhancement:** Quality control measures recommended by WHO contribute to the consistency and reliability of herbal medicines. Standardisation of production processes and the establishment of quality parameters help maintain the potency and efficacy of herbal products, leading to more predictable therapeutic outcomes.
- **Regulatory Compliance:** Adherence to WHO guidelines facilitates compliance with regulatory requirements

established by national authorities and international bodies. Regulatory agencies often refer to WHO guidelines when developing regulations for the manufacturing, distribution, and labelling of herbal medicines. Compliance with these guidelines helps manufacturers meet regulatory standards and gain market authorisation for their products.

- **Global Harmonisation:** WHO guidelines provide a harmonised approach to quality control practices, promoting consistency and uniformity in the assessment of herbal medicines worldwide. This facilitates international trade and ensures that products manufactured in one country meet quality standards accepted globally, fostering trust and confidence among consumers and healthcare professionals.
- **Continuous Improvement:** The systematic review highlights the ongoing efforts of WHO to review and update guidelines based on emerging scientific evidence and best practices. Adhering to these evolving guidelines encourages continuous improvement in quality control practices and fosters innovation in the herbal medicine industry.

References

1. Mirzaeian R, Sadoughi F, Tahmasebian S, Mojahedi M. The role of herbal medicines in health care quality and the related challenges. Journal of herbmed pharmacology. 2021 Jan 5;10(2):156-65.[Google Scholar]
2. Zhang M, Wang C, Zhang R, Chen Y, Zhang C, Heidi H, Li M. Comparison of the guidelines on good agricultural and collection practices in herbal medicine of the European Union, China, the WHO, and the United States of America. Pharmacological Research. 2021 May 1;167:105533.[Google Scholar]
3. Saggar S, Mir PA, Kumar N, Chawla A, Uppal J, Kaur A. Traditional and herbal medicines: opportunities and challenges. Pharmacognosy Research. 2022;14(2). [Google Scholar]
4. Li S, Han Q, Qiao C, Song J, Lung Cheng C, Xu H. Chemical markers for the quality control of herbal medicines: an overview. Chinese medicine. 2008 Jun 28;3(1):7. [Google Scholar]
5. Shi YH, Wang Y, Fu H, Xu Z, Zeng H, Zheng GQ. Chinese herbal medicine for headache: A systematic review and meta-analysis of high-quality randomized controlled trials. Phytomedicine. 2019 Apr 1;57:315-30.[Google Scholar]
6. World Health Organization. Regulatory situation of herbal medicines: a worldwide review.[Google Scholar]
7. Kumar V, Kumar V. An overview of herbal medicine. Int. J. Ph. Sci. 2009 May;1(1):1-20.[Google Scholar]
8. Alamgir AN. Herbal drugs: their collection, preservation, and preparation; evaluation, quality control, and standardization of herbal drugs. InTherapeutic Use of Medicinal Plants and Their Extracts: Volume 1: Pharmacognosy 2017 Sep 8 (pp. 453-495). Cham: Springer International Publishing.[Google Scholar]
9. Heyman HM, Meyer JJ. NMR-based metabolomics as a quality control tool for herbal products. South African Journal of Botany. 2012 Sep 1;82:21-32.[Google Scholar]
10. Gupta PD, Daswani PG, Birdi TJ. Approaches in fostering quality parameters for medicinal botanicals in the Indian context. Indian Journal of Pharmacology. 2014 Jul 1;46(4):363-71.[Google Scholar]
11. Pferschy-Wenzig EM, Bauer R. The relevance of pharmacognosy in pharmacological research on herbal medicinal products. Epilepsy & behavior. 2015 Nov 1;52:344-62.[Google Scholar]
12. Gouveia BG, Rijo P, Gonçalo TS, Reis CP. Good manufacturing practices for medicinal products for human use. Journal of Pharmacy and Bioallied Sciences. 2015 Apr 1;7(2):87-96.[Google Scholar]
13. Booker A, Johnston D, Heinrich M. Value chains of herbal medicines—Research needs and key challenges in the context of ethnopharmacology. Journal of ethnopharmacology. 2012 Apr 10;140(3):624-33.[Google Scholar]
14. Ekor M. The growing use of herbal medicines: issues relating to adverse reactions and challenges in monitoring safety. Frontiers in pharmacology. 2014 Jan 10;4:177.[Google Scholar]
15. Salgueiro L, Martins AP, Correia H. Raw materials: the importance of quality and safety. A review. Flavour and Fragrance Journal. 2010 Sep;25(5):253-71. [Google Scholar]
16. Mosihuzzaman M. Herbal medicine in healthcare-an overview. Natural product communications. 2012 Jun;7(6):1934578X1200700628.[Google Scholar]
17. Liu C, Guo DA, Liu L. Quality transitivity and traceability system of herbal medicine products based on quality markers. Phytomedicine. 2018 May 15;44:247-57. [Google Scholar]
18. Zhou X, Li CG, Chang D, Bensoussan A. Current status and major challenges to the safety and efficacy presented by Chinese herbal medicine. Medicines. 2019 Jan 18;6(1):14.[Google Scholar]
19. Gromek K, Drumond N, Simas P. Pharmacovigilance of herbal medicines. International Journal of Risk & Safety in Medicine. 2015 May;27(2):55-65.[Google Scholar]
20. Maina N, Kagira JM, Achila O, Karanja SM, Ngotho M. Herbal medicines in Kenya: a review of the toxicity and quality control issues. African Journal of Health Sciences. 2013;24(1):29-47.[Google Scholar]
21. Mukherjee PK, Bahadur S, Chaudhary SK, Kar A, Mukher-

jee K. Quality related safety issue-evidence-based validation of herbal medicine farm to pharma. InEvidence-based validation of herbal medicine 2015 Jan 1 (pp. 1-28). Elsevier.[Google Scholar]
22. Zhao Z, Xiao P, Xiao Y, Yuen JP. Quality assurance of Chinese herbal medicines (CHMs). Journal of Food and Drug Analysis. 2007;15(4):2.[Google Scholar]
23. El Hajj M, Holst L. Herbal medicine use during pregnancy: a review of the literature with a special focus on sub-Saharan Africa. Frontiers in pharmacology. 2020 Jun 9;11:866.[Google Scholar]
24. Sanzini E, Badea M, Dos Santos A, Restani P, Sievers H. Quality control of plant food supplements. Food & function. 2011;2(12):740-6.[Google Scholar]
25. Barkat MA, Goyal A, Barkat HA, Salauddin M, Pottoo FH, Anwer ET. Herbal medicine: Clinical perspective and regulatory status. Combinatorial chemistry & high throughput screening. 2021 Nov 1;24(10):1573-82.[Google Scholar]
26. van Wyk AS, Prinsloo G. Health, safety and quality concerns of plant-based traditional medicines and herbal remedies. South African Journal of Botany. 2020 Sep 1;133:54-62.[Google Scholar]
27. Mukherjee PK, Banerjee S, Gupta BD, Kar A. Evidence-based validation of herbal medicine: Translational approach. InEvidence-based validation of herbal medicine 2022 Jan 1 (pp. 1-41). Elsevier.[Google Scholar]
28. Liu WJ, editor. Traditional herbal medicine research methods: identification, analysis, bioassay, and pharmaceutical and clinical studies. John Wiley & Sons; 2011 Mar 29.[Google Scholar]
29. Jain T, Dubey D, Jain V, Dashora K. Regulatory status of traditional medicines in different countries: An overview. Research Journal of Pharmacy and Technology. 2011;4(7):1007-15.[Google Scholar]
30. Kosalec I, Cvek J, Tomic S. Contaminants of medicinal herbs and herbal products. Arhiv za higijenu rada i toksikologiju. 2009 Oct 1;60(4):485.[Google Scholar]
31. Jain SD, Shrivastava SK, Agrawal A, Gupta AK. WHO guidelines for quality control of herbal medicines: From cultivation to consumption.Internafional Journal of Pharmaceufical and Chemical Analysis. 2024;11(3):212-25.[Google Scholar]