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Review Article

WHO guidelines for quality control of herbal medicines: From cultivation to consumption

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ABSTRACT

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. By following WHO guidelines, manufacturers can implement practices that minimize 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. Quality control measures recommended by WHO contribute to the consistency and reliability of herbal medicines.

Standardization of production processes and the establishment of quality parameters help maintain the potency and efficacy of herbal products, leading to more predictable therapeutic outcomes. 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 labeling of herbal medicines. Compliance with these guidelines helps manufacturers meet regulatory standards and gain market authorization for their products. WHO guidelines provide a harmonized 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. 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.

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1. 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

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1.1. Historical context

Herbal remedies, dating back to the dawn of civilization, 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.²

From ancient civilizations 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 honor and preserve the traditional knowledge passed down through generations while embracing the opportunities for innovation and collaboration offered by modern science.

1.2. Ancient civilizations

In ancient Mesopotamia, Egypt, China, India, Greece, and Rome, herbal medicine was deeply intertwined with spiritual beliefs, cultural traditions, and empirical observations. Sumerian clay tablets dating back to 3000 BCE contain records of herbal prescriptions, while ancient Egyptian papyri such as the Ebers Papyrus (circa 1550 BCE) and the Edwin Smith Papyrus (circa 1600 BCE) document extensive herbal knowledge and medical treatments.

2. Traditional Healing Systems

Traditional healing systems such as Traditional Chinese Medicine (TCM), Ayurveda, Unani, and Native American medicine have relied heavily on herbal remedies to promote health and treat various ailments. In TCM, herbs are classified according to their energetic properties and organ systems, and formulations are tailored to restore balance and harmony within the body.³

3. Medieval Europe and the Islamic Golden Age

During the medieval period, herbal medicine flourished in Europe and the Islamic world, with monasteries serving as centers of herbal knowledge and cultivation. Herbalists and apothecaries collected, cultivated, and prepared medicinal plants, often drawing upon the wisdom of ancient texts such as the works of Dioscorides and Galen.

4. The Islamic Golden

Age witnessed significant advancements in herbal medicine, with scholars such as Avicenna (Ibn Sina) compiling comprehensive pharmacopoeias and conducting systematic studies on the medicinal properties of plants.⁴

5. Colonialism and Global Exchange

The Age of Exploration and colonialism facilitated the exchange of plants and herbal knowledge between different continents, leading to the globalization of herbal medicine. European explorers and colonizers documented the medicinal plants encountered in the Americas, Africa, and Asia, while indigenous healers shared their traditional remedies with newcomers.

6. Modern Era and Scientific Validation

In the modern era, the advent of scientific inquiry and technological advancements revolutionized the study of herbal medicine. Pharmacognosy, the scientific discipline dedicated to the study of medicinal plants, emerged as researchers began to identify and isolate active compounds from herbs. The discovery of aspirin from willow bark and quinine from cinchona bark exemplifies the successful translation of traditional herbal remedies into modern pharmaceuticals.

7. Chemical Complexity and Pharmacological Diversity of Plants

Plants represent a vast reservoir of bioactive compounds, each with unique chemical structures and pharmacological properties. The chemical complexity and pharmacological diversity of plants contribute to their multifaceted therapeutic potential and have profound implications for human health and medicine. Plants produce an extensive array of bioactive compounds through primary and secondary metabolic pathways. These compounds include alkaloids, flavonoids, terpenoids, phenolics, polysaccharides, glycosides, and many others. Each class of compounds possesses distinct chemical properties and biological activities, allowing plants to interact with their environment and defend against pathogens, predators, and environmental stressors.^{5–7}

7.1. Alkaloids

Alkaloids are nitrogen-containing compounds found in various plant species and exhibit diverse pharmacological activities. Examples include morphine and codeine from opium poppy (*Papaver somniferum*), caffeine from coffee beans (*Coffea arabica*), and nicotine from tobacco (*Nicotiana tabacum*). Alkaloids can act as analgesics, stimulants, sedatives, or toxins, depending on their chemical structure and dosage.

7.2. Flavonoids

Flavonoids are polyphenolic compounds found in fruits, vegetables, grains, tea, and medicinal herbs. They are renowned for their antioxidant, anti-inflammatory, anti-cancer, and cardioprotective properties. Common flavonoids

include quercetin, kaempferol, catechins, and anthocyanins, which exert their effects through scavenging free radicals, modulating enzyme activity, and influencing cellular signaling pathways.⁸

7.3. Terpenoids

Terpenoids, also known as isoprenoids, are a diverse class of compounds synthesized from isoprene units. They are abundant in essential oils and resinous exudates of plants and exhibit a wide range of biological activities. Examples include menthol from peppermint (*Mentha piperita*), artemisinin from sweet wormwood (*Artemisia annua*), and taxol from the Pacific yew tree (*Taxus brevifolia*). Terpenoids possess antimicrobial, anti-inflammatory, antiparasitic, and anticancer properties.

7.4. Phenolics

Phenolic compounds are aromatic secondary metabolites found in fruits, vegetables, nuts, seeds, and herbs. They include phenolic acids, flavonoids, tannins, lignans, and stilbenes, among others. Phenolics are renowned for their antioxidant properties and play a crucial role in protecting plants from oxidative stress and UV radiation. They also exhibit anti-inflammatory, antimicrobial, cardioprotective, and neuroprotective effects in humans.

7.5. Polysaccharides

Polysaccharides are complex carbohydrates composed of long chains of monosaccharide units. They are abundant in plants, particularly in fruits, vegetables, grains, and medicinal mushrooms. Polysaccharides such as β -glucans, pectins, and fructans possess immunomodulatory, anti-inflammatory, antioxidant, and antitumor activities. They interact with immune cells, promote the production of cytokines and antibodies, and enhance the body's defense mechanisms against infections and cancer.⁹

8. Modern Perspectives and Scientific Validation of Plants^{10–12}

In recent decades, there has been a resurgence of interest in harnessing the therapeutic potential of plants, driven by advances in scientific research and a growing recognition of the limitations and side effects associated with conventional pharmaceuticals. Modern perspectives on plants emphasize their diverse pharmacological properties, bioactive compounds, and therapeutic applications, which are increasingly validated through rigorous scientific inquiry.

9. Pharmacological Validation

Advancements in analytical techniques, molecular biology, and pharmacology have enabled researchers to elucidate the

mechanisms of action of bioactive compounds present in plants. Through *in vitro* studies, animal models, and clinical trials, scientists have validated the pharmacological activities of plant-derived compounds, including antioxidant, anti-inflammatory, antimicrobial, anticancer, neuroprotective, cardioprotective, and immunomodulatory effects. This scientific validation provides empirical evidence supporting the traditional uses of medicinal plants and informs the development of evidence-based herbal medicine.

10. Identification of Active Compounds

Modern analytical methods, such as chromatography, mass spectrometry, and nuclear magnetic resonance spectroscopy, allow for the identification and quantification of bioactive compounds in plant extracts. By isolating and characterizing active constituents, researchers can determine their chemical structures, elucidate their pharmacological properties, and optimize extraction methods to maximize their therapeutic potential. This chemical profiling contributes to the standardization of herbal products and ensures consistency in quality and efficacy.¹³

11. Mechanistic Insights

Studies investigating the molecular mechanisms underlying the pharmacological effects of plant derived compounds have provided valuable insights into their mode of action. These compounds interact with specific receptors, enzymes, signaling pathways, and cellular processes to exert their therapeutic effects. For example, flavonoids may modulate inflammatory mediators, terpenoids may induce apoptosis in cancer cells, and polysaccharides may enhance immune function. Understanding these mechanisms allows for the rational design of herbal formulations and the development of targeted therapies for various health conditions.

12. Safety and Efficacy Assessments¹⁴

The safety and efficacy of plant-derived medicines are subject to rigorous evaluation through preclinical and clinical studies. Toxicological assessments ensure that herbal remedies are safe for human consumption and do not pose undue risks of adverse effects or toxicity. Clinical trials evaluate the therapeutic efficacy of herbal interventions in human populations, providing valuable evidence regarding their effectiveness for specific indications. Regulatory agencies, such as the FDA and EMA, oversee the approval and regulation of herbal products to ensure quality, safety, and efficacy standards are met.

13. Integration with Conventional Medicine

Increasingly, herbal medicine is being integrated into conventional medical practice as complementary or adjunctive therapies. Healthcare providers recognize the value of incorporating evidence-based herbal remedies into treatment protocols, particularly for conditions where conventional treatments may be inadequate or associated with side effects. Integrative medicine approaches, which combine conventional therapies with complementary modalities, offer patients a comprehensive and personalized approach to healthcare, leveraging the benefits of both systems.^{15–17}

14. Integration of Plants with Conventional Medicine

The integration of plants with conventional medicine represents a significant paradigm shift in healthcare, emphasizing a holistic approach that combines the strengths of both traditional and modern therapeutic modalities. This integration is driven by growing recognition of the therapeutic potential of plant-derived compounds, as well as the limitations and side effects associated with conventional pharmaceuticals. Here, we explore the various ways in which plants are being integrated into conventional medical practice:

15. Complementary Therapies

Plants are increasingly used as complementary therapies alongside conventional treatments to enhance efficacy, minimize side effects, and improve overall patient outcomes. For example, cancer patients undergoing chemotherapy may experience side effects such as nausea, vomiting, and fatigue, which can be alleviated with the use of herbal remedies such as ginger (*Zingiber officinale*) for nausea and ginseng (*Panax ginseng*) for fatigue.¹⁸

16. Adjunctive Treatments

Plants are also utilized as adjunctive treatments in conjunction with conventional therapies to address specific health concerns or enhance therapeutic effects. For instance, herbal supplements containing ingredients such as St. John's wort (*Hypericum perforatum*) or omega-3 fatty acids may be prescribed alongside antidepressant medications to augment the treatment of depression.

17. Herbal Medicine Clinics

Herbal medicine clinics, often staffed by trained herbalists or integrative healthcare practitioners, offer comprehensive consultations and personalized treatment plans that incorporate both herbal remedies and conventional therapies. These clinics provide patients with access to evidence-based herbal interventions while ensuring coordinated care and monitoring of treatment outcomes.

18. Integrative Healthcare Centers

Integrative healthcare centers provide a multidisciplinary approach to patient care, integrating conventional medicine with complementary and alternative modalities, including herbal medicine. These centers offer a range of services such as acupuncture, massage therapy, nutritional counseling, and herbal consultations, with an emphasis on holistic wellness and patient-centered care.

19. Herbal Formulations in Pharmaceuticals

Pharmaceutical companies are increasingly recognizing the therapeutic potential of plant-derived compounds and incorporating them into conventional medications. For example, the anti-inflammatory drug aspirin was originally derived from willow bark (*Salix* spp.), while the anticancer drug paclitaxel (Taxol) is derived from the Pacific yew tree (*Taxus brevifolia*). By harnessing the bioactive constituents of plants, pharmaceutical formulations can be optimized for safety, efficacy, and standardized dosing.

20. Research Collaborations

Collaborations between researchers in the fields of herbal medicine and conventional medicine facilitate the translation of traditional herbal remedies into evidence-based therapies. These collaborations involve preclinical studies, clinical trials, and pharmacological investigations aimed at elucidating the mechanisms of action, safety profiles, and therapeutic potentials of plant-derived compounds. By bridging the gap between traditional knowledge and modern science, research collaborations pave the way for the development of novel treatments and therapies.¹⁹

21. Challenges and Future Directions of Herbal Medicine

As herbal medicine gains recognition and popularity in modern healthcare, several challenges and opportunities emerge that shape its future trajectory. Addressing these challenges and leveraging future directions will be essential for maximizing the potential of herbal medicine and integrating it more seamlessly into mainstream healthcare systems.

22. Standardization and Quality Control

One of the primary challenges in herbal medicine is the lack of standardized manufacturing processes and quality control measures for herbal products. Variability in plant species, growing conditions, harvesting methods, and extraction techniques can result in inconsistencies in the composition and potency of herbal remedies. Establishing standardized protocols for cultivation, harvesting, processing, and formulation of herbal products is crucial for ensuring

quality, safety, and efficacy.

23. Regulation and Safety

Regulatory frameworks governing herbal medicine vary widely across different jurisdictions, leading to disparities in safety standards, labeling requirements, and marketing practices. Strengthening regulatory oversight and enforcing quality assurance measures are essential for protecting consumer safety and preventing adulteration, contamination, and mislabeling of herbal products. Collaborative efforts between regulatory agencies, industry stakeholders, and healthcare providers are needed to establish evidence-based guidelines and standards for the production and sale of herbal remedies

24. Research and Evidence-Based Practice

Despite growing interest in herbal medicine, there is still a need for rigorous scientific research to validate the efficacy, safety, and mechanisms of action of herbal remedies. Conducting well-designed clinical trials, pharmacological studies, and systematic reviews is essential for generating high-quality evidence to support the use of herbal interventions in clinical practice. Collaborative research initiatives involving interdisciplinary teams of scientists, healthcare professionals, and traditional healers can help bridge the gap between traditional knowledge and modern science.^{20,21}

25. Education and Training

Training programs for healthcare professionals, herbalists, and traditional healers play a vital role in promoting evidence-based practice and ensuring the safe and appropriate use of herbal remedies. Integrating education on herbal medicine into medical, nursing, and pharmacy curricula can enhance healthcare providers' understanding of herbal pharmacology, interactions, and therapeutic applications. Additionally, providing continuing education opportunities and certification programs for herbal practitioners can improve standards of practice and patient care.

26. Sustainability and Conservation

The increasing demand for medicinal plants poses challenges related to sustainability, biodiversity conservation, and environmental stewardship. Overharvesting, habitat destruction, climate change, and illegal trade threaten the long-term viability of many medicinal plant species. Adopting sustainable harvesting practices, promoting cultivation of medicinal plants in botanical gardens and agroforestry systems, and supporting community-based conservation initiatives are essential for preserving plant biodiversity and ensuring the availability

of medicinal plants for future generations.²²

27. Need of Study

The need for a systematic review on WHO guidelines for quality control of herbal medicines arises from several important considerations:

1. **Global Relevance and Impact:** WHO guidelines serve as a cornerstone for global health standards and policies. Given the widespread use of herbal medicines across different cultures and healthcare systems, a systematic review of WHO guidelines in this area is crucial to ensure their relevance, applicability, and effectiveness on a global scale.
2. **Quality Assurance and Safety:** Herbal medicines are often perceived as natural and safe, but concerns about quality, purity, and safety remain significant. A systematic review can help assess the adequacy of WHO guidelines in addressing these concerns and enhancing quality assurance measures to safeguard public health.
3. **Standardization and Harmonization:** There is a need for standardization and harmonization of quality control practices for herbal medicines to facilitate trade, ensure product consistency, and minimize risks associated with variability and adulteration. By systematically reviewing WHO guidelines, inconsistencies can be identified, and efforts toward harmonization can be promoted.
4. **Regulatory Compliance and Capacity Building:** Many countries lack robust regulatory frameworks and technical capacity for quality control of herbal medicines.
5. **A systematic review can help identify gaps in WHO guidelines that may hinder regulatory compliance and capacity building efforts, thus guiding targeted interventions and resource allocation.**
6. **Evidence-Based Practice and Decision Making:** Healthcare professionals, policymakers, and regulators rely on evidence-based guidelines to make informed decisions regarding the use, regulation, and prescription of herbal medicines. A systematic review can synthesize the available evidence and provide insights into best practices for quality control based on WHO recommendations.
7. **Consumer Confidence and Trust:** Ensuring the quality and safety of herbal medicines is essential for building consumer confidence and trust. By critically evaluating WHO guidelines, stakeholders can gain assurance that appropriate quality control measures are in place, thereby enhancing the credibility and acceptance of herbal medicines among consumers.
8. **Research Prioritization and Future Directions:** Identifying research gaps and priorities is crucial for

advancing the field of herbal medicine quality control. A systematic review can highlight areas where further research is needed to strengthen

9. WHO guidelines, improve analytical methodologies, and address emerging challenges in quality control.
10. Overall, conducting a systematic review on WHO guidelines for quality control of herbal medicines is essential for promoting evidence-based practices, protecting public health, and advancing global efforts to ensure the quality, safety, and efficacy of herbal medicines.

28. 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:²³

Sources: Herbal medication products are derived from various parts of plants, including leaves, roots, and 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.

1. (a) **Extracts:** Concentrated preparations obtained by extracting active compounds from plant material using solvents such as water, alcohol, or oil.
- (b) **Tinctures:** Liquid extracts made by soaking plant material in alcohol or glycerin.
- (c) **Ointments and Creams:** Topical preparations containing herbal extracts or oils for skin conditions.
- (d) **Essential Oils:** Highly concentrated plant extracts used in aromatherapy or topical applications.
- (e) **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.

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.

29. Quality Control for Herbal Medication Products^{24–27}

Quality control for herbal medication products is essential to ensure their safety, efficacy, and consistency. Given the natural origins of these products and the variability in plant materials, quality control measures are crucial at every stage of production. Here are quality control processes for herbal medication products:

Raw Material Identification and Authentication: Proper identification and authentication of botanical raw materials are fundamental to ensuring product quality.

This involves botanical examination, morphological and microscopic analysis, and chemical fingerprinting to confirm the identity of plant species and detect any adulteration.

29.1. Standardization

Standardization involves establishing specific quality parameters and ensuring consistent levels of active constituents or marker compounds in herbal medicines. This ensures that each batch of the product meets predefined quality standards. Standardization is typically achieved through the following methods:

Quantitative Analysis: Quantifying the content of specific active compounds or marker compounds in herbal extracts using analytical techniques such as high-performance liquid chromatography (HPLC), gas chromatography (GC), or mass spectrometry (MS).

Biological Assays: Assessing the biological activity or pharmacological effects of herbal medicines through in vitro or in vivo assays to determine their potency and efficacy.

Chemical Fingerprints: Creating characteristic chromatographic fingerprints of herbal extracts using techniques such as high-performance thin-layer chromatography (HPTLC) or HPLC with diode array detection (HPLC-DAD). These fingerprints serve as reference profiles for batch-to-batch consistency and authentication.

Total Extractable Content: Determining the total extractable content of herbal materials to ensure that the extraction process efficiently extracts the desired constituents from the plant material.

29.2. Identification

Identification involves accurately identifying the botanical origin of herbal materials to ensure authenticity and prevent adulteration. Various methods are used for the identification of herbs:

Macroscopic Examination: Visual inspection of the physical characteristics of herbal materials, including size, shape, color, texture, and odor, to identify characteristic features indicative of specific plant species.

Microscopic Examination: Microscopic analysis of cellular structures and tissue morphology of herbal materials using a microscope to detect characteristic diagnostic features unique to particular plant species.

Chemical Analysis: Analyzing the chemical composition of herbal materials using techniques such as chromatography (e.g., TLC, HPLC) and spectroscopy (e.g., infrared spectroscopy, nuclear magnetic resonance spectroscopy) to identify specific chemical markers or metabolites.

DNA Barcoding: Amplifying and sequencing specific DNA regions from herbal materials to identify plant species based on their genetic signatures. DNA barcoding provides a reliable method for species-level identification, especially for processed or powdered herbal materials where morphological features may be absent.

30. Processing and Manufacturing Controls for Herbal Medicines^{28–31}

Processing and manufacturing controls for herbal medicines are essential to ensure the consistency, quality, and safety of the final products. These controls encompass a range

of practices and procedures implemented throughout the manufacturing process. Here's an overview:

31. Raw Material Selection and Handling

Quality Assurance: Establish criteria for the selection of raw materials, including botanical identity, purity, and potency. Conduct supplier audits and quality assessments to ensure the reliability and consistency of raw material sources.

Storage Conditions: Implement proper storage conditions for raw materials to prevent contamination, degradation, or loss of potency. This may include controlling temperature, humidity, light exposure, and ventilation in designated storage areas.

32. Extraction and Processing

32.1. Extraction methods

Select appropriate extraction methods (e.g., maceration, percolation, distillation, Soxhlet extraction) based on the properties of the herbal materials and the desired constituents to be extracted.

32.2. Process controls

Implement process controls to ensure consistency and reproducibility of extraction processes. Monitor parameters such as extraction time, temperature, solvent-to-material ratio, and agitation to optimize extraction efficiency and maintain product quality.

32.3. Solvent residues

Monitor and control solvent residues to ensure compliance with safety regulations. Employ techniques such as evaporation, filtration, or solvent recovery to remove residual solvents from herbal extracts.

33. Formulation and Standardization

33.1. Formulation

Develop standardized formulations for herbal medicines based on predetermined ratios of active constituents or marker compounds. This helps ensure consistency in potency and efficacy across different batches.

33.2. Standardization

Implement methods for standardizing herbal products to ensure consistent levels of active ingredients or bioactive compounds. This may involve quantifying specific constituents using analytical techniques such as chromatography (e.g., HPLC, TLC) or spectroscopy (e.g., UV-Vis).

33.3. Manufacturing practices

Good Manufacturing Practices (GMP): Adhere to GMP guidelines to ensure quality, safety, and consistency in

manufacturing processes. This includes maintaining clean and sanitary facilities, proper equipment calibration and maintenance, personnel training, and documentation of all manufacturing activities.

Batch Control: Implement batch control systems to track and trace individual batches of herbal medicines throughout the manufacturing process. Assign unique batch numbers and maintain detailed batch records documenting raw material usage, processing parameters, quality control testing results, and packaging information.

34. Quality Control Testing

In-process Testing: Conduct in-process testing at various stages of manufacturing to monitor critical parameters and ensure product quality. This may include testing for moisture content, particle size distribution, pH, viscosity, or other relevant properties.

Finished Product Testing: Perform comprehensive quality control testing on finished herbal medicines to verify compliance with specifications and regulatory requirements.

This may include assays for identity, purity, potency, microbial contamination, heavy metals, solvent residues, and other quality parameters.

35. Packaging and Labeling

Packaging Materials: Use appropriate packaging materials that are compatible with herbal products and provide adequate protection against contamination, moisture, light, and oxidation.

Labeling Requirements: Ensure compliance with labeling requirements for herbal medicines, including accurate product identification, ingredient listing, dosage instructions, expiration date, batch number, manufacturer information, and any relevant warnings or precautions.

36. Quality Assessment During Processing

36.1. Raw material evaluation

Raw material evaluation is a critical step in the quality control process for herbal medicines. It involves assessing the identity, authenticity, purity, and quality of the botanical raw materials used in the production of herbal products. Here's an overview of the key aspects of raw material evaluation:

1. (a) **Identity and Authenticity:** Botanical Identification: Confirm the botanical identity of raw herbal materials by comparing their morphological characteristics, such as size, shape, color, texture, and odor, with authenticated reference samples or botanical monographs.
Microscopic Examination: Conduct microscopic examination of plant tissues and cellular structures to identify diagnostic features

characteristic of specific botanical species. This may involve preparing thin sections of plant material and observing them under a microscope.

- (b) **Chemical Profiling:** Analyze the chemical composition of raw materials using techniques such as chromatography (e.g., TLC, HPLC) or spectroscopy (e.g., UV-Vis, IR) to identify characteristic chemical markers or metabolites indicative of botanical identity.
- (c) **DNA Barcoding:** Employ DNA barcoding techniques to amplify and sequence specific DNA regions from raw herbal materials, allowing for species-level identification based on genetic signatures. DNA barcoding provides a reliable method for verifying botanical authenticity, especially for processed or powdered materials.
- (d) **Purity Assessment: Extraneous Matter:** Evaluate the presence of extraneous matter, such as dirt, debris, insects, and other contaminants, in raw herbal materials through visual inspection, sieving, or other physical methods. Remove any foreign materials to ensure product purity.

Heavy Metals: Test for heavy metal contamination in raw materials using analytical methods such as atomic absorption spectroscopy (AAS) or inductively coupled plasma mass spectrometry (ICP-MS). Heavy metal levels should comply with established safety limits to prevent health risks.

Pesticide Residues: Analyze raw materials for pesticide residues using chromatographic techniques (e.g., GC-MS, LC-MS/MS) to ensure compliance with regulatory standards. Pesticide levels should be below established maximum residue limits (MRLs) to ensure product safety.

Microbial Contamination: Assess microbial contamination levels in raw materials by testing for total aerobic microbial count, yeast and mold count, and specific pathogens using appropriate microbiological methods. Microbial levels should meet specified microbiological safety standards to prevent spoilage and ensure product safety.

36.2. Quality assurance

Supplier Qualification: Evaluate the reliability and consistency of raw material suppliers through supplier audits, quality assessments, and verification of Good

37. Agricultural and Collection Practices (GACP)

Traceability: Establish traceability systems to track and document the origin, cultivation, harvesting, and handling of raw materials throughout the supply chain.

Maintain detailed records of raw material sourcing and procurement to ensure product traceability and transparency.

38. Good Manufacturing Practices for Herbal Products

Good Manufacturing Practices (GMP) for herbal products are a set of quality assurance guidelines and procedures designed to ensure that herbal medicines are consistently produced and controlled to meet quality standards appropriate for their intended use. Here are key aspects of GMP for herbal products:

39. Facility and Equipment³²

1. (a) **Facility Design:** Design and maintain manufacturing facilities in accordance with sanitary and hygienic principles to prevent contamination and ensure product safety.
- (b) **Equipment Calibration:** Calibrate and maintain manufacturing equipment to ensure accuracy and reliability in production processes. Equipment used for extraction, blending, granulation, drying, and packaging should be properly maintained and validated.
- (c) **Personnel: Training:** Provide comprehensive training programs for personnel involved in herbal product manufacturing, covering topics such as GMP principles, hygiene practices, equipment operation, and quality control procedures.
- (d) **Hygiene Practices:** Enforce strict personal hygiene practices among manufacturing personnel, including proper handwashing, use of protective clothing (e.g., gloves, hairnets), and adherence to cleanliness standards.

40. Raw Material Control

Supplier Qualification: Qualify and audit raw material suppliers to ensure the reliability, consistency, and quality of herbal raw materials. Establish supplier agreements and conduct periodic assessments to monitor supplier performance.

Receipt and Inspection: Inspect incoming raw materials for identity, purity, and quality before acceptance. Reject or quarantine materials that do not meet established specifications or quality standards.

41. Production Controls

Batch Records: Maintain detailed batch records documenting all production activities, including raw material usage, processing steps, in-process testing, quality control checks, and packaging operations.

Process Validation: Validate manufacturing processes to ensure consistency, reproducibility, and reliability in product quality. Conduct process validation studies for critical manufacturing processes and equipment.

Cleaning and Sanitization: Implement cleaning and sanitization procedures for equipment, utensils, and manufacturing areas to prevent cross-contamination and ensure product safety.

41.1. Quality control

In-process Testing: Perform in-process testing at various stages of manufacturing to monitor critical parameters and ensure product quality. This may include testing for moisture content, particle size, density, and other relevant properties.

Finished Product Testing: Conduct comprehensive quality control testing on finished herbal products to verify compliance with specifications and regulatory requirements. This may include assays for identity, potency, purity, microbial contamination, heavy metals, and other quality parameters.

42. Documentation and Record-Keeping:^{33,34}

Documentation Control: Establish document control procedures to ensure the accuracy, completeness, and integrity of manufacturing records, including batch records, standard operating procedures (SOPs), specifications, and quality control documents.

Record Retention: Maintain records of all manufacturing activities, quality control tests, deviations, and corrective actions taken. Retain records for a specified period as required by regulatory authorities.

43. Packaging and Labeling

Packaging Controls: Implement controls to ensure the cleanliness, integrity, and suitability of packaging materials for herbal products. Use packaging materials that provide adequate protection against contamination, moisture, light, and oxidation.

Labeling Compliance: Ensure compliance with labeling requirements for herbal products, including accurate product identification, ingredient listing, dosage instructions, expiration date, batch number, manufacturer information, and any relevant warnings or precautions.

43.1. Process control

Process control in the manufacturing of herbal products involves monitoring and managing various aspects of production to ensure consistent quality, safety, and efficacy. Here are key elements of process control in the manufacturing of herbal products:

44. Standard Operating Procedures (SOPs)

1. Develop and implement SOPs for all critical manufacturing processes, including extraction, blending, granulation, drying, milling, and packaging.

2. SOPs outline the step-by-step procedures, parameters, and requirements for each process to ensure consistency and reproducibility.
3. Process Validation:
4. Validate critical manufacturing processes to ensure that they consistently produce herbal products of the desired quality.
5. Conduct process validation studies to demonstrate that manufacturing processes are capable of meeting predetermined specifications and quality standards.
6. Process Parameters:
7. Define and monitor critical process parameters such as temperature, pressure, time, flow rate, pH, and agitation speed.
8. Establish acceptable ranges for process parameters based on product specifications and quality requirements.
9. In-process Testing:
10. Perform in-process testing at various stages of manufacturing to monitor and control product quality.
11. Test for critical parameters such as moisture content, particle size, density, viscosity, and pH to ensure that products meet specifications.
12. Quality Control Checks:
13. Implement quality control checks to verify the identity, purity, potency, and safety of raw materials, intermediates, and finished products.
14. Conduct tests for identity, potency, purity, microbial contamination, heavy metals, and other quality attributes as per established procedures.
15. Environmental Controls:
16. Maintain appropriate environmental conditions in manufacturing areas to prevent contamination and ensure product safety.
17. Control factors such as temperature, humidity, air quality, and cleanliness to minimize the risk of microbial contamination and cross-contamination.

45. Equipment Calibration and Maintenance

Calibrate and maintain manufacturing equipment to ensure accuracy, reliability, and consistency in production processes.

Regularly inspect, clean, and sanitize equipment to prevent product contamination and ensure product quality.

46. Record-Keeping and Documentation

Maintain detailed records of all manufacturing activities, process parameters, in-process testing results, and quality control checks.

Document deviations, corrective actions, and any changes to manufacturing processes or procedures to ensure traceability and accountability.

47. Training and Personnel Competence

Provide training to manufacturing personnel on proper process control procedures, equipment operation, and quality control practices.

Ensure that personnel are competent to perform their assigned tasks and responsibilities

in accordance with established SOPs and quality standards.

47.1. In-process testing

In-process testing is a crucial component of quality control in the manufacturing of herbal products. 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. Here are key aspects of in-process testing:

47.2. Purpose

Monitor Critical Parameters: In-process testing helps monitor critical parameters such as physical properties, chemical composition, and microbial contamination levels during manufacturing.

Control Process Variability: By testing at multiple points throughout the production process, manufacturers can identify and control variability, ensuring consistent quality and reducing the risk of defects.

Early Detection of Issues: In-process testing allows for the early detection of issues or deviations from specifications, enabling timely corrective actions to be taken before production continues.

47.3. Types of in-process testing

Physical Tests: Measure physical properties such as particle size, moisture content, density, viscosity, hardness, and friability. These tests ensure that the product meets specific physical characteristics required for its intended use.

Chemical Tests: Analyze chemical composition, potency, and purity of the product.

This may involve quantifying active compounds, marker compounds, or other chemical constituents using techniques such as chromatography (e.g., HPLC, TLC) or spectroscopy (e.g., UV-Vis, IR).

Microbiological Tests: Assess microbial contamination levels to ensure compliance with microbiological safety standards. This includes testing for total aerobic microbial count, yeast and mold count, and specific pathogens using appropriate microbiological methods.

47.4. Sampling

Representative Sampling: Ensure that samples taken for in-process testing are representative of the entire batch or lot

being manufactured. Use appropriate sampling techniques and sample sizes to obtain accurate and reliable results.

Sampling Plan: Develop a sampling plan that specifies the sampling points, frequency, and methods for in-process testing. Sampling points may include raw materials, intermediates, and finished products at various stages of production.

47.5. Testing methods

Validated Methods: Use validated testing methods that are accurate, reliable, and suitable for the intended purpose. Ensure that testing methods are properly validated according to established guidelines and standards.

Instrumentation: Employ appropriate instrumentation and equipment for in-process testing, calibrated and maintained according to established procedures. This includes laboratory instruments, analytical equipment, and testing devices.

48. Data Analysis and Documentation

Data Interpretation: Analyze in-process testing results to assess compliance with specifications and identify any deviations or trends that may require corrective action.

Documentation: Document all in-process testing activities, including test results, observations, and any corrective actions taken. Maintain detailed records as part of batch documentation and quality control documentation.

49. Quality Control Methods to Identify and Verify Herbs

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, color, texture, and odor. 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.

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. Visualization of separated compounds under UV light or after staining with specific reagents can aid in herb identification and authentication.

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.^{26,27}

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 analyzing marker compounds or active constituents in herbs and comparing them to reference standards for authentication purposes.

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.²⁸

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.

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.

50. Discussion

A systematic review on WHO guidelines for quality control of herbal medicines, spanning from cultivation to consumption, presents a comprehensive assessment of the standards and recommendations established by the World Health Organization (WHO) to ensure the safety, efficacy, and quality of herbal products. Let's delve into a discussion on this topic:

51. Scope and Importance

The review outlines the significance of WHO guidelines in providing a global framework for quality control practices across the entire herbal medicine supply chain, from cultivation and harvesting to manufacturing, distribution, and consumption.

It highlights the importance of quality control measures in herbal medicine production to address concerns related to adulteration, contamination, variability in potency, and lack of standardization.

52. Cultivation and Harvesting Practices

The review examines WHO guidelines related to good agricultural and collection practices (GACP) for medicinal plants, emphasizing sustainable cultivation methods, genetic authenticity, proper harvesting techniques, and avoidance of environmental contaminants.

It discusses the role of GACP in ensuring the quality and safety of herbal raw materials, including the importance of selecting suitable planting sites, using authentic plant material, implementing organic farming practices, and minimizing pesticide use.

53. Processing and Manufacturing Controls

The review explores WHO guidelines on good manufacturing practices (GMP) for herbal products, focusing on quality control measures implemented during extraction, processing, formulation, and packaging.

It discusses the necessity of GMP compliance to ensure consistency, purity, and potency of herbal medicines, including requirements for facility design, equipment calibration, personnel training, process validation, and quality assurance procedures.

54. Standardization and Quality Parameters:^{35–37}

The review examines WHO recommendations for standardization of herbal medicines, including methods for quantifying active constituents, establishing quality parameters, and implementing analytical testing techniques.

It discusses the challenges associated with standardization due to the complexity and variability of herbal materials, as well as the importance of chemical profiling, chromatographic fingerprinting, and bioassays for ensuring product quality and consistency.

55. Regulatory Compliance and Post-Market Surveillance

The review addresses WHO guidelines on regulatory requirements for herbal medicines, including product registration, licensing, labeling, and compliance with pharmacovigilance systems for post-market surveillance.

It emphasizes the need for regulatory authorities to enforce adherence to WHO guidelines to protect public health, promote consumer safety, and prevent misleading claims or adulteration in the herbal medicine market.

56. Challenges and Future Directions

The review identifies challenges and gaps in current WHO guidelines, such as the need for harmonization of standards, improved methods for authentication and quality control, and greater collaboration between regulatory agencies, industry stakeholders, and traditional medicine practitioners.

It suggests areas for future research and development, including advancements in analytical techniques, standardization methods, botanical authentication, and evidence-based validation of traditional herbal remedies.

WHO guidelines for quality control of herbal medicines offers valuable insights into the regulatory framework, best practices, and challenges in ensuring the safety and efficacy of herbal products from cultivation to consumption. By promoting adherence to WHO guidelines and addressing gaps in quality control measures, stakeholders can enhance the quality, integrity, and accessibility of herbal medicines for global healthcare delivery.^{39–40}

57. 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 minimize 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.

Standardization 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 labeling of herbal medicines. Compliance with these guidelines helps manufacturers meet regulatory standards and gain market authorization for their products.

Global Harmonization: WHO guidelines provide a harmonized 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.

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59. Conflict of Interest

None.

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