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Aspects of Quality for Herbal Medication Standardization and Control According to Analytical Methods

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Abstract: *Quality, defined as compliance to criteria and meeting customer wants, is very important for pharmaceuticals, and particularly difficult for herbal drugs. The World Health Organization (WHO) has promoted pharmaceutical quality since its creation, as stated by its charter. [1]The World Health Assembly has frequently emphasized the need to ensure the quality of medicinal plant products using contemporary control techniques and appropriate standards. [2]This document provides tests for assessing the quality of medicinal plant materials and is intended for national medication quality control laboratories in poor nations.*

Keywords: Quality aspects, Analytical technique, Herbal drug

I. INTRODUCTION

Humans are primarily concerned with quality in all facets of life. Given that pharmaceuticals are intended to promote human health, their quality is crucial when it comes to the drugs that people use. Strict rules and regulations govern the quality control of medications made from synthetic chemicals. [3]Before being marketed and used by patients and customers, they must pass a number of series tests and quality control inspections. Because of the strict regulations, the quality of pharmaceuticals that are created synthetically is maintained at a level that guarantees the goods' safety and effectiveness.

[4]Quality is paramount in pharmaceuticals due to their impact on human well-being. Synthetic chemical pharmaceuticals are subject to stringent regulations and multiple quality control tests, ensuring safety and efficacy.2 However, herbal medicinal products, derived from plant resources, face less strict regulations compared to synthetic drugs. This disparity contributes to a decline in the quality of herbal products through adulteration, spurious drugs, and substitution, potentially leading to hazardous health effects for consumers. Therefore, robust quality control for herbal drugs and products is essential for public health.

[5]Because herbal products are used extensively throughout the world for medical treatment, quality control is essential. Using both qualitative (UV, IR) and quantitative (HP-TLC, HP- LC, SFC, thermal analysis, ICP-MS, LC-MS, GC-MS) approaches, this entails standardization and phytochemical inquiry.[6] In order to guarantee the effectiveness and safety of herbal materials and products—a difficult but crucial undertaking in pharmaceutical research—the increasing demand for herbal pharmaceuticals calls for stringent quality control standards, similar to those for synthetic drugs.

GENRAL INTRODUCTION OF QUALITY ASPECTS

The pharmaceutical industry emphasizes quality control to guarantee drug safety, efficacy, and consistency amidst evolving agents and analytical techniques. [7]Understanding herbal drugs is crucial for applying these advanced quality control tools. Traditional medicine, encompassing diverse practices, often utilizes plant-based medicines. Plants serve as a principal source of therapeutic compounds, with herbal drugs referring to unprocessed plant parts and herbal preparations to processed forms like extracts. [8]The increasing involvement of major pharmaceutical companies in herbal drugs highlights the need for enhanced botanical quality control.

Herbal drugs are medicinal plant materials in their crude or unprocessed form, including various plant parts. [9]Raw materials in a general sense are plants used for flavoring, fragrance, or medicinal purposes, distinct from food

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vegetables. Herbal formulations are prepared products derived from herbs, with or without excipients, and exist in various physical forms like liquids, solids, or semi-solids.

Evaluations of safety are documented and grounded in practical experience or toxicological research.

Adulteration of botanical preparations is a significant issue, driven by over-exploitation, habitat loss, and the endangerment of medicinal plants, leading to substitution with inferior materials, artificial substances, or cheaper plant parts. Herbal products may also contain undisclosed pharmaceuticals and heavy metals. 10While agrochemicals can contaminate crude plant material, the mechanisms of action, pharmacokinetics, and drug-drug interactions of many herbs remain poorly understood. Reports of adverse effects from herbal preparations underscore the need for national regulation, registration, and safety monitoring. Clinicians should not recommend herbal remedies without established efficacy, yet their appeal to patients persists, necessitating direct patient inquiry and robust quality control for botanicals.

[11]The need for quality control and standardization of herbal products stems from:

• Differences in historical standardization technologies and concepts.
• Potential evolutionary changes in plant material identity over time.
• Challenges in sourcing genuine raw materials due to commercialization.
• Alterations in botanical properties caused by environmental factors and time.

These factors negatively impact the quality of crude drugs and subsequent formulations. The concept of quality, as defined by various standards and experts, generally revolves around fulfilling requirements, defect reduction, fitness for use, uniformity, and satisfying stated or implied needs while being free of deficiencies.

QALITY CONTROL OF HARBAL DRUG

Herbal medical goods, derived from plant resources for human health, require quality monitoring comparable to chemically manufactured medications. [12]Current regulatory standards for herbals are less stringent than for synthetic drugs, leading to quality degradation through adulteration and substitution, which poses health risks to consumers. 13To ensure the quality of herbal drugs, optimization, phytochemical research, and various quality control instruments are employed, necessitating both qualitative and quantitative metrics. Analytical techniques such as UV spectroscopy, HPLC, LC-MS, TLC, and HPTLC are used for quality control. Pharmacopoeial quality control features include product identification, detection of adulterants and substituents, purity assessment, and assay of pharmaceutical constituents.

Standardization, the practice of comparing herbal properties to defined criteria, is crucial. The contamination, and chromatographic/spectroscopic evaluations. Modern analytical methods are vital for the global acceptance of traditional medicines like Ayurveda, with pharmacognostic assessment providing scientific validation. Organoleptic tests, coupled with physicochemical research and pharmacognostic strategies, ensure authenticity and standardization. Microscopical evaluation aids in identifying adulterants and confirming pure herbal materials, and is beneficial for characterizing unorganized crude drugs like terpenoids and flavonoids. Detailed analysis of parameters such as microscopic features, shape, size, moisture content, ash value, and chemical constituents is important.14 Pharmacopoeial monographs also serve as validation tools for herbal material formulation development. Due to their inherent complexity, unique procedures, including thermal analysis techniques like Thermo gravimetric Analysis (TGA) and Differential Thermal Analysis (DTA), are used to verify the quality, purity, and integrity of herbal products by measuring thermal stability and enthalpy fluctuations.

The Pharmaceutical Manufacturers Association defines quality as encompassing all factors contributing to a product's safety, effectiveness, and acceptability. Standardization, through manufacturing processes and quality control, ensures reproducible product quality. The WHO emphasizes the need for standardization and quality control of herbal medicines, advocating for national standards, technical guidelines, and methodologies for evaluating their safety, efficacy, and quality. The development of national pharmacopoeias and monographs for medicinal plants, along with their cultivation and sustainable use, is also crucial, as botanicals present unique challenges compared to synthetic drugs due to their complex nature and lack of established reference standards.

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Challenges in herbal product standardization include plant identity, adulteration, storage, and transport issues. [15]The lack of standardized quality control profiles hinders global acceptance. Polyherbal formulations, often containing numerous ingredients in liquid or semi-solid forms, are particularly difficult to standardize, with limited official standards available. Their unique processing methods create complex mixtures that are hard to analyze.

[16]Germany requires physicians to have herbal medicine training and conducts extensive research, including double-blind, placebo-controlled trials. German physicians widely recommend and patients use herbal medicines, with manufacturers adhering to purity and pharmaceutical activity standards. Commission E, responsible for overseeing herbal medicines, has published 387 monographs detailing their safety and efficacy. Other European countries also have policies for rational oversight of herbal medicines.

[17]In the United States, herbs are regulated as either dietary supplements with minimal safety and efficacy standards or as drugs requiring rigorous testing. A balanced approach for the

U.S. would involve acknowledging the historical use of herbal medicines, examining data from various sources and countries, enforcing strict production standards, ensuring absolute safety, and classifying efficacy based on evidence. The translated Commission E monographs could significantly benefit patients and physicians in the U.S.

HERBAL AND TRADITIONAL MEDICINE NEEDS TO BE STANDARDIZED

Standardizing herbal extracts is crucial for controlling double-blind clinical trials and ensuring product quality, reliability, and the use of correct plant species. 6This standardization provides uniformity and defined active ingredient concentrations, making herbal products more acceptable to medical professionals accustomed to pharmaceutical standards.[18] Experts like Dr. Rudolf Bauer emphasize that standardization and pharmaceutical-grade verification are necessary for phytopharmaceuticals to be considered legitimate medicines. Contrary to popular belief, the demand for standardized herbal products is centuries old, with historical definitions focusing on consistent extraction ratios, recipes, or processes, rather than solely on specific active ingredient levels as often marketed today.

Concept of validation

Validation is defined by the USFDA as documented evidence providing a high degree of assurance that a specific process will consistently produce a product meeting predefined specifications and quality attributes. Initially viewed as a waste of time and money in the pharmaceutical industry, validation is now understood as an investment yielding quality products. While widely applied in synthetic drug manufacturing, the concept of validation has been less thoroughly studied and applied to herbal drug manufacturing. Although international regulations like USFDA, MCC, MHRA, and TGA address validation in pharmaceutical manufacturing, only WHO explicitly applies it to herbal drug production, and even then, to a limited extent. 6Consequently, the authors aim to emphasize the concept and propose a validation model for herbal drug manufacturing, contrasting it with the simple, commonly used model for synthetic drugs.

The proposed model outlines a process for manufacturing herbal drugs, emphasizing a reverse-direction validation approach.[19] This process begins by defining the desired quality attributes of the final product, including identity, strength, safety, purity, and efficacy. For a herbal tablet (Gutika), these attributes translate to specific characteristics such as shape, packaging, dosage strength (e.g., 500mg/tablet), safety for manufacturers and consumers, purity levels (e.g., 99.9%), and therapeutic effectiveness. Following the definition of output requirements, process parameters are established, covering steps like mixing duration, granulation type and time, compression pressure and duration, and final packaging. Finally, inputs are defined, encompassing personnel, equipment, raw materials, packaging materials, and environmental conditions (temperature, air changes). While applicable to herbal drugs, the model has limitations concerning synthetic drugs, particularly in vendor certification. For herbal drugs, validation must extend beyond vendor certification to manufacturer certification, a more challenging but necessary step.

Factor affecting quality of harbal

Quality control (QC) methods are essential for ensuring the validity of manufactured commodities, including herbal mixtures, and for maintaining the reputation of medicinal plants. Advancements in analytical procedures have

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significantly improved the quality of herbal products by enhancing factors such as harvesting, cultivation, storage, active ingredient stability, and product purity.20 Key variables influencing the quality of herbal ingredients include genetic variations between or within species, often linked to geographic origin; environmental elements like cultivation conditions, altitude, and climate; and harvesting time, as ingredient concentrations can fluctuate daily or throughout a plant's life cycle.

[21]Plant part utilized: Generally speaking, the active compounds in plants vary depending on the part of the plant, and it is not uncommon for a herbal product to contain plant parts that are not normally employed. There are other instances where plant material that has been extracted and then "exhausted" is used as an adulterant to increase the weight of a batch of herbal substances.

o Post-harvest factors: Treatment procedures and storage circumstances can have a significant impact on the quality of a herbal ingredient. Following harvest, drying methods may result in the loss of thermo-labile active substances, and inappropriate storage might result in microbial infection.

Standardization of medicinal herbs and products

Standardization of medicinal herbs and products is crucial due to variations in growing conditions, which affect phytochemical constituents and present obstacles to consistent quality. Adulteration and substitution of herbal drugs, exacerbated by deforestation, compromise their safety and efficacy. [22]Overcoming these challenges and ensuring the availability of genuine herbal drugs requires advanced quality control techniques and suitable standards. Standardization confirms the identity, quality, and purity of herbs and herbal products, assessing freshness and overall quality through preliminary identification, physical, chemical, and biological properties.

[23]Pharmacopoeial aspects of quality control involve identifying substances, adulterants, substitutes, assessing material purity, and assaying active chemical constituents.

Standardization is the process of measuring qualitative and quantitative values against set standards. The WHO provides guidelines for standardization methods and procedures based on evaluation parameters such as organoleptic properties, ash values, moisture content, microbial contamination, and chromatographic and spectroscopic evaluations.

Modern analytical techniques are essential for the global acceptance of Ayurveda and traditional herbs, requiring comprehensive pharmacognostical assessment for scientific validation of quality. [24]Authentication and standardization necessitate organoleptic tests, physicochemical studies, and pharmacognostical schemes. Microscopic and macroscopic studies are vital for identifying adulterants and authenticating genuine herbs, while the identification of secondary metabolites like alkaloids, tannins, glycosides, saponins, and flavonoids serves as a useful tool for standardization. Future studies will utilize microscopic investigation (qualitative and quantitative), macroscopic observation (shape and markings), identification of adulterants and genuine drugs, physicochemical parameters (moisture content, acid insoluble ash, water soluble ash), and pharmacognostical schemes for herb authentication.

HP-TLC analysis method for quality control of herbal botanical formulations

High-Performance Thin-Layer Chromatography (HPTLC) is employed for the identification and quality control of herbal plants and formulations, yielding qualitative and quantitative results by comparing peak profiles and intensities with reference standards. [25]This technique provides information on marker compound identification, percentage of purity, and minimum content. Pharmacognostic, phytochemical, and physicochemical tests are used for preliminary identification of adulteration and substitutes, functioning as quantitative tests. HPTLC is favored for the accurate and simple quantitative estimation of phytochemicals. It allows for the evaluation of varying properties and phytochemical components in samples collected from different geographical and climatic conditions. HPTLC facilitates comparative studies of herbal drugs and formulations through simultaneous application of samples and standards on the same plate, enabling visual detection even at microliter concentrations.

High-Performance Thin-Layer Chromatography (HP-TLC) is an analytical technique employed for the quality control of herbal botanical formulations. This method allows for the separation, identification, and quantification of active compounds within these complex mixtures, ensuring consistency and efficacy.

Plant formulations are analyzed using the HP-LC analytical technique for quality control.

The identification of active compounds in herbal extracts is a challenging task in modern discovery. Traditional isolation methods are slow, tedious, and can diminish compound activity. High-Performance Liquid Chromatography

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(HPLC) is employed to overcome these drawbacks by accurately identifying multiple compounds. HPLC is also crucial for quality assurance of herbal medicines, enabling estimation of chemical components and standardization through marker profiles, which addresses issues related to the safety and efficacy of active essentials in complex formulations.
[26]HPLC is a valuable technique for the qualification, quantification, and authentication aspects of herb quality control, especially for separating components in polyherbal formulations. Factors such as harvesting season, drying techniques, plant origin, heavy metals, and microbial content can affect herb quality and pose challenges to quality control.
HPLC serves as a beneficial tool for standardizing complex traditional herbal products by quantitatively and qualitatively estimating active chemical and biological markers. It is also an effective method for analyzing thermo-labile substances and poly-component medicinal herbal products, with techniques like RP-HPLC offering high reproducibility and automation for identifying multiple constituents in botanical preparations. Sampling techniques like liquid-liquid partitioning and solid-extraction are used to reduce matrix complexity, which can otherwise lead to co-elution of multi-component herbal marker compounds during HPLC analysis.

II. CONCLUSION

Novel formulations of herbal products used in traditional medicine require standardization for safety, efficacy, and potency. Quality control examination of herbs, regulated through proper norms, ensures the development of high-quality products, leading to safer use, effective treatment, and improved well-being for society.Plant materials constitute a significant portion of the global medicine market, utilized worldwide in various forms from home remedies to pharmaceutical raw materials. Ensuring the safety, quality, and efficacy of medicinal plants and herbal products is a critical concern. The advancement of the herbal industry, particularly in India, hinges on collaboration between drug regulatory bodies, scientists, and industries.
Standardization of methodologies and the collection of quality control data for safety and efficacy are essential for understanding herbal medication use. The development of globally accepted norms is crucial for evaluating the quality of these products.

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