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ENSURING AUTHENTICITY OF HERBAL DRUGS: A COMPREHENSIVE REVIEW ON SUBSTITUTION AND ADULTERATION

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ABSTRACT

Background: Herbal drugs form an important component of traditional systems like *Ayurveda* and are widely used due to their therapeutic efficacy and natural origin. However, variability in raw materials, processing methods, and environmental factors often affects their quality, safety, and effectiveness. Lack of proper standardisation leads to issues such as adulteration, contamination, and inconsistency in herbal formulations. **Aim:** To critically review the concept, importance, methods, and challenges involved in the standardisation of herbal drugs. **Objectives:** To understand the need for standardisation of herbal drugs. To study different parameters used in quality evaluation. To analyze modern and classical approaches for standardisation. To identify issues related to adulteration and variability. **Materials and Methods:** This study is based on a comprehensive review of literature collected from classical Ayurvedic texts such as *Charaka Samhita*, *Sushruta Samhita*, and *Ashtanga Hridaya*, along with published research articles, WHO guidelines, pharmacognosy textbooks, and review papers. Relevant data were compiled and critically analyzed focusing on identification, authentication, physicochemical, phytochemical, chromatographic, and microbiological evaluation methods used in herbal drug standardisation. **Results:** The review highlights that standardisation of herbal drugs involves multiple parameters

including organoleptic, microscopic, physicochemical, and phytochemical evaluation. Advanced techniques such as TLC, HPTLC, HPLC, and GC-MS play a crucial role in identification and quality control. WHO guidelines emphasize assessment of identity, purity, safety, and efficacy at all stages from raw material to finished product. Despite available methods, challenges like adulteration, lack of uniform standards, and variability in plant sources continue to affect quality assurance. **Conclusion:** Standardisation is essential to ensure the safety, efficacy, and consistency of herbal drugs. Integration of traditional knowledge with modern analytical techniques and strict regulatory guidelines is necessary for improving global acceptance and therapeutic reliability of herbal medicines.

Keywords: Herbal drug, Standardisation, Quality control, Pharmacognosy, Phytochemical evaluation, Adulteration

INTRODUCTION

Herbal drugs have been used since ancient times as an essential part of traditional systems like *Ayurveda*, where treatment is based on maintaining balance of *Dosha*,[1] *Dhatu*,[2] and *Mala*.[3] Plants have served as a primary source of medicine for the management of various diseases, and even today a significant proportion of the global population depends on herbal remedies for healthcare. The knowledge of medicinal plants has been passed through generations and forms the foundation of many traditional healing systems. Modern research also supports that a considerable number of drugs are derived directly or indirectly from plant sources.[4]

In recent decades, there has been a growing global interest in herbal medicines due to their perceived safety, affordability, and minimal side effects.[5] Herbal formulations are widely used in both developing and developed countries, and they play an important role in primary healthcare systems. However, despite their popularity, the quality and consistency of herbal drugs remain a major concern.[6] Variability in plant species, geographical origin, seasonal changes, and processing techniques can significantly influence the chemical composition and therapeutic efficacy of herbal products.

One of the major challenges associated with herbal medicines is the lack of proper standardisation. Issues such as adulteration, substitution, contamination with heavy metals, pesticides, and microbial load can compromise the safety and effectiveness of herbal drugs.[6] According to WHO, standardisation and quality control involve evaluation of identity, purity, safety, and efficacy of herbal materials and finished products. Without proper authentication

and validation, herbal products cannot be considered scientifically reliable or therapeutically consistent.[7]

Therefore, standardisation of herbal drugs has become a critical requirement in the present era. It involves a comprehensive evaluation through pharmacognostical, physicochemical, phytochemical, and microbiological parameters, along with advanced analytical techniques such as chromatography and spectroscopy. Proper standardisation ensures uniform quality, prevents adulteration, and enhances global acceptance of herbal medicines.[8] It also helps in bridging the gap between traditional knowledge and modern scientific validation, making herbal therapy more reliable and acceptable in contemporary healthcare systems.

AIM AND OBJECTIVES

Aim:

To critically review the concept, importance, methods, and challenges involved in the standardisation of herbal drugs.

Objectives:

- To understand the need for standardisation of herbal drugs.
- To study different parameters used in quality evaluation.
- To analyze modern and classical approaches for standardisation
- To identify issues related to adulteration and variability.

MATERIAL AND METHODS

This study is a critical review based on detailed literature analysis of herbal drug standardisation. Relevant data were collected from published review articles, including *Standardization of Herbal Formulations: An Overview* and *Standardization of Herbal Drugs – An Overview*, along with WHO guidelines, pharmacognosy textbooks, and research papers. The collected information was systematically compiled and analyzed focusing on various standardisation parameters such as authentication, organoleptic and microscopic evaluation, physicochemical tests (ash value, moisture content, extractive values), phytochemical screening, chromatographic techniques (TLC, HPTLC, HPLC), and microbiological assessment. Emphasis was given to quality control measures ensuring identity, purity, safety, and efficacy of herbal drugs, and the findings were critically evaluated to understand current practices and challenges in standardisation.

STANDARDISATION OF HERBAL DRUG

Standardisation of herbal drug refers to the process of establishing definite quality parameters for a crude drug, herbal preparation, or finished herbal formulation so that its identity, purity, safety, and efficacy remain consistent. In simple words, it means making sure that the herbal drug being used is genuine, free from contamination, therapeutically reliable, and uniform from batch to batch. The reviewed articles explain that standardisation is not limited to one laboratory test. It is a broad scientific process that includes correct identification of the plant, evaluation of raw material, study of chemical composition, detection of adulteration, and assessment of contaminants and biological activity. This makes standardisation the foundation of quality control in herbal medicine [10]

Importance of Standardisation in Herbal Medicine

Herbal medicines are widely used because of their natural origin, traditional acceptance, and therapeutic value. At the same time, one major problem with herbal drugs is that their composition may vary greatly depending on plant species, climate, geographical source, season of collection, soil conditions, storage, transportation, and processing methods. Such variation can directly affect the quality and action of the drug. The reviewed literature clearly shows that without standardisation, the same herbal drug may differ in strength, purity, and safety in different samples.[11] That is why standardisation becomes necessary to ensure that the patient receives a drug of reliable quality every time. It also helps in increasing the scientific credibility and global acceptance of herbal medicines

Standardisation as a Tool for Identity, Purity, Safety, and Efficacy

A properly standardised herbal drug must satisfy four basic quality requirements: identity, purity, safety, and efficacy. Identity means the drug should be the correct plant material and the correct part of that plant. Purity means it should not contain foreign matter, substitutes, adulterants, or unwanted contaminants. Safety means the drug should be free from harmful levels of microorganisms, pesticides, aflatoxins, radioactive material, and toxic heavy metals. Efficacy means the drug should contain the necessary active or marker constituents in appropriate amount so that it can produce the expected therapeutic action.[12] The reviewed articles repeatedly emphasize that all four dimensions must be evaluated together because quality in herbal medicine is not determined by appearance alone or by one chemical test alone

WHO Perspective on Standardisation

The concept of standardisation becomes clearer through the WHO approach discussed in the reviewed papers. According to WHO, quality control and standardisation of herbal drugs involve the physicochemical evaluation of crude drugs, safety and stability assessment of finished products, proper documentation, and provision of reliable product information to consumers.[13] The WHO framework does not treat quality as a single final test. Instead, it considers quality as a chain that starts from cultivation and collection of raw material and continues up to packaging, storage, labelling, and finished product evaluation. This approach is very important because a high-quality final herbal product cannot be prepared from poor-quality raw material. Therefore, WHO guidelines connect agriculture, pharmacognosy, phytochemistry, microbiology, pharmaceutical processing, and regulatory control into one integrated system [14]

Need for Standardisation in the Present Era

In the present time, the use of herbal products has increased in both traditional and modern healthcare settings. However, this growing use has also increased the risk of spurious products, poor manufacturing practices, and misleading labelling. The articles reviewed explain that many herbal products enter the market without proper authentication or full quality evaluation. This creates problems such as batch-to-batch inconsistency, reduced therapeutic effect, and possible toxicity. Standardisation therefore becomes essential not only for academic or industrial purposes, but also for public health protection. It ensures that herbal medicines are not judged only by traditional reputation, but also by reproducible scientific parameters. This is especially important when herbal drugs are used on a large scale or for chronic diseases.[15]

Factors Responsible for Variation in Herbal Drugs

A conceptual understanding of standardisation is incomplete without knowing why herbal drugs vary so much. The reviewed literature notes several major factors. These include identity of the plant, ecotypic and genotypic variation, seasonal and geographical differences, stage and time of collection, use of fresh or dried plant material, drying conditions, storage conditions, exposure to light and temperature, packing and transportation methods, and contamination during handling. Even the age of the plant and the specific part collected may change the phytochemical profile. Some active constituents are heat labile, some are destroyed by enzymes after collection, and some vary according to season.[16] Because of this,

two samples sold under the same name may not be chemically or therapeutically equivalent. Standardisation is therefore needed to control this natural and technical variability as much as possible

Stages Involved in Standardisation

The reviewed paper on herbal formulations describes standardisation as a multistage process. It begins with literature survey and correct taxonomic identification of the crude drug. This is followed by proper agricultural and collection practices, collection details such as place and developmental stage, organoleptic evaluation, and microscopic or molecular examination. After this comes chemical composition study and assessment of shelf life and biological activity of the crude drug. For herbal formulations, the process extends further into good manufacturing practice, toxicity evaluation, chemical profiling, pharmacodynamic and pharmacokinetic considerations, dosage determination, stability evaluation, therapeutic merit, and proper presentation and packing. This staged concept is very useful because it shows that standardisation is not a single lab event but a systematic quality pathway from source to finished dosage form.[17]

Authentication of Raw Material

Authentication is the first and most important step in standardisation. If the raw material itself is wrong, then no later test can make the product correct. Authentication includes confirmation of botanical identity, taxonomical classification, regional status, stage of collection, and the specific plant part used. The reviewed literature highlights that macroscopic, microscopic, histological, and taxonomic methods are all useful here. Voucher specimens and authenticated reference samples are especially important for confirming identity. This stage helps to avoid substitution and ensures that the drug actually comes from the claimed source plant. In herbal medicine, this is crucial because many crude drugs look similar in the market, and misidentification can lead to therapeutic failure or toxicity.[18]

Organoleptic and Macroscopic Evaluation

Organoleptic evaluation refers to the use of sense organs to assess the drug. This includes colour, odour, taste, texture, fracture, shape, size, and general appearance. Macroscopic characters are often the first screening tools in crude drug identification. They are especially helpful for whole plant parts and for quick market-level assessment.[19] The reviewed

literature points out that these characters give initial clues about genuineness and possible adulteration. Though organoleptic examination is simple, it remains extremely valuable because it provides a rapid and traditional basis of quality assessment before advanced instrumental testing is done

Microscopic Evaluation

Microscopic evaluation is used to study the internal structure of plant material and the diagnostic features seen in powdered or whole drug samples. The reviewed papers mention characteristics such as stomatal number, stomatal index, palisade ratio, vein-islet number, trichomes, calcium oxalate crystals, starch grains, fibres, and lignified tissues. Chemical reagents may also be used during microscopy for better identification of tissue components. Microscopy is especially important for powdered crude drugs, where external morphology is lost. It helps in confirming authenticity and detecting adulteration or substitution. Conceptually, microscopic evaluation bridges traditional pharmacognosy with modern scientific verification.[20]

Physicochemical Evaluation

Physicochemical evaluation forms a major part of standardisation. It includes determination of ash values, extractive values, moisture content, volatile matter, density, viscosity, specific gravity, swelling index, foaming index, bitterness value, refractive index, melting point, and loss on drying. Ash values help in assessing purity and inorganic content, especially in powdered drugs. Extractive values indicate the number of active constituents soluble in particular solvents. Moisture content is important because excess moisture promotes deterioration, microbial growth, and instability. These tests provide measurable, reproducible parameters that can be compared from batch to batch. In conceptual terms, physicochemical testing converts the quality of a herbal drug from a subjective impression into objective numerical data.[21]

Foreign Matter and Purity Assessment

Purity assessment means ensuring that the crude drug contains only the intended plant material and not unwanted matter. Foreign matter may include soil, stones, insect parts, animal excreta, stems of other plants, or deliberate admixture of other drugs. The reviewed literature treats foreign matter as a key standardisation parameter because even a genuine plant drug loses quality if contaminated with extraneous material. Removal and quantification of foreign matter is therefore necessary to obtain the drug in pure form and to

protect consumer safety.[22] This aspect is especially relevant in market samples where cleaning and handling may be poor

Phytochemical Standardisation

Phytochemical standardisation focuses on the chemical constituents present in the herbal drug. According to the reviewed papers, this includes preliminary testing for major classes of compounds, quantification of groups such as alkaloids, phenolics, triterpenoids, and tannins, and establishment of fingerprint profiles. It may also include multiple marker-based profiles and quantification of important constituents. The aim is not only to detect compounds but to understand whether the chemical profile supports the expected therapeutic value. Where the active principle is known, standardisation may be based on that constituent.[23] Where it is unknown or too complex, marker compounds and fingerprint patterns are used. This makes phytochemical evaluation one of the most scientifically powerful parts of standardisation

Chromatographic and Instrumental Methods

Modern analytical methods have greatly strengthened herbal drug standardisation. The reviewed articles mention thin-layer chromatography, gas chromatography, high-performance liquid chromatography, ultraviolet-visible spectrometry, infrared spectrometry, mass spectrometry, and nuclear magnetic resonance spectroscopy as useful tools for the identification and control of herbal drugs. WHO-based approaches also give importance to TLC, HPTLC, HPLC, and GC fingerprinting.[24] These methods help in detecting marker compounds, identifying adulteration, comparing samples, and building characteristic chemical fingerprints. In many cases, when individual active principles are not fully known, the chromatographic fingerprint itself becomes a quality identity of the herbal drug. Conceptually, instrumental methods provide the scientific reproducibility needed for wider regulatory acceptance of herbal medicines

Biological and Pharmacological Evaluation

The reviewed literature explains that standardisation should not stop at physical and chemical testing alone. Biological and pharmacological evaluation may also be needed to confirm the activity of the drug. Such evaluation can include assays on living animals, isolated organs, and other biological models to indicate the strength or therapeutic action of the drug. This is especially important when the herb contains multiple constituents and its action cannot be explained by one single chemical marker. Conceptually, pharmacological

standardisation helps in linking laboratory quality with therapeutic usefulness, which is ultimately the practical goal of herbal medicine.[25]

Microbiological Evaluation

Microbial contamination is an important concern in herbal drug quality. Medicinal plants may carry bacteria, moulds, and other microorganisms from soil, water, atmosphere, harvesting conditions, or storage practices. The reviewed papers emphasize the need to test total microbial load and specific pathogens such as *E. coli*, *Salmonella* spp., *Staphylococcus aureus*, and *Pseudomonas aeruginosa*.[26] Aflatoxins produced by fungi are also a major concern. Microbiological evaluation therefore becomes essential for safety assessment. This part of standardisation is especially important for crude plant materials and formulations that are stored for long periods or prepared under non-sterile conditions

Toxicological Evaluation and Contaminant Testing

A herbal drug may be natural, but that does not automatically make it safe. The reviewed papers clearly note the importance of testing for pesticide residues, heavy metals such as lead, cadmium, mercury, and arsenic, aflatoxins, and even radioactive contamination where relevant. Toxicological studies may also include animal safety studies and determination of harmful effects. This part of standardisation is critical because contamination may occur during cultivation, processing, storage, or preservation.[27] Therefore, safety testing is not optional in herbal standardisation. It is central to responsible use of herbal medicines in modern healthcare settings

Validation of Analytical Methods

Another important conceptual component is validation. The reviewed literature explains that an analytical method used for herbal standardisation must be proven suitable for its intended purpose. Validation generally includes specificity, linearity, accuracy, precision, range, detection limit, and quantitation limit, depending on the method. This concept is important because results are meaningful only when the method itself is reliable. In herbal drug analysis, validation also depends on the availability of authenticated reference materials and suitable standards for chromatographic comparison.[28] So, validation is what converts an analytical procedure into an accepted scientific method for quality control

Assessment of Stability and Shelf Life

Quality is not fixed only at the time of manufacture. It must remain stable during storage. The reviewed literature explains that physical and chemical stability under defined storage

conditions should be tested and the shelf life should be established. This is essential because herbal drugs may degrade over time due to moisture, light, oxidation, microbial growth, or changes in constituents. Standardisation therefore includes stability assessment so that the consumer gets an effective and safe product throughout its marketed life. This becomes especially important for powdered materials, extracts, and liquid preparations.[29]

Assessment of Finished Product and Labelling

The final herbal product should possess standard characteristics and comply with requirements related to its dosage form. The manufacturing procedure, ingredients, excipients, and product specifications should be clearly defined. The reviewed paper also stresses the importance of labelling. A proper label should include the name of the drug, manufacturer, batch number, expiry date if applicable, dosage instructions, and assurance of quality standards. This is conceptually important because even a well-prepared product may be misused if consumer information is incomplete or misleading. Thus, standardisation extends beyond laboratory science into pharmaceutical presentation and responsible communication.[30]

Role of Good Practices in Standardisation

The reviewed sources strongly support good agricultural practices, good storage practices, good laboratory practices, and good manufacturing practices. This is a very important conceptual point. Standardisation is not achieved only by testing the final product and rejecting bad batches. It is achieved more effectively when quality is built into the drug at every stage, from cultivation to manufacturing. Good practices reduce variability and contamination before they occur.[31] This preventive approach is scientifically and economically better than depending only on end-product correction

Challenges in Standardisation of Herbal Drugs

Despite advances in analytical science, standardisation of herbal drugs still faces many challenges. Herbal materials are chemically complex and often contain multiple active or interacting constituents. In many cases, the exact active principle is not fully known. Natural variation, market adulteration, substitution, contamination, poor storage, and lack of universal regulatory enforcement further complicate the process. The reviewed literature also points out that the word “standardized” on a label may not always guarantee real quality because legal and practical control may be inadequate.[32] These challenges show that herbal drug standardisation is not merely a technical procedure but also a regulatory and ethical responsibility

Relevance of Standardisation to *Ayurveda*

In the context of *Ayurveda*, standardisation has special relevance because Ayurvedic drugs are traditionally judged by properties such as *Rasa*, *Guna*, *Virya*, *Vipaka*, and therapeutic effect. One reviewed article also connects standardisation with these classical quality concepts and with factors such as *Desha*, collection practices, storage, processing, *Matra*, and *Yukta* application. This shows that standardisation is not foreign to traditional thought. Rather, modern standardisation can be seen as a scientific extension of the classical concern for proper source, collection, processing, and use of drugs.[33] Thus, standardisation helps bring traditional Ayurvedic wisdom into a scientifically validated and globally understandable framework

Overall Understanding

From the reviewed literature, it becomes clear that standardisation of herbal drug is a comprehensive quality assurance system rather than a single test or narrow laboratory procedure. It begins with correct plant identity and extends through collection, processing, physicochemical study, phytochemical profiling, contamination testing, biological evaluation, validation, stability testing, finished product control, and proper labelling. Its main purpose is to ensure that the herbal drug is genuine, pure, safe, effective, and consistent. In the present era, where herbal drugs are increasingly used worldwide, standardisation is essential for therapeutic reliability, patient safety, and scientific acceptance. It stands as the central bridge between traditional herbal knowledge and modern pharmaceutical quality control.[34]

SCIENTIFIC INVESTIGATIONS

- **Physical Evaluation:**

Physical evaluation includes detailed botanical, macroscopic, and microscopic examination of herbal drugs. It helps in correct identification of plant material through observable features and structural characteristics. Microscopic analysis acts as an important initial screening tool to confirm identity and detect impurities or adulterants in crude drugs.[35]

- **Chemical Evaluation:**

Chemical evaluation is carried out to determine the potency of herbal drugs by analyzing their active constituents. It includes processes like screening, isolation, identification, and

purification of phytochemicals. This evaluation helps in confirming drug identity, detecting adulteration, and ensuring the presence of therapeutically active components.[36]

• Biological Evaluation:

Biological evaluation assesses the pharmacological activity of herbal drugs. It involves testing on living systems such as animals or isolated organs to determine the therapeutic strength and efficacy of the drug. This method provides functional validation of the drug's action.[37]

PARAMETERS TO BE ASSESSED FOR STANDARDISATION

• Macroscopic and Microscopic Examination:

Used for identification of correct plant species and detection of adulterants through morphological and cellular characteristics.

• Foreign Organic Matter:

Ensures removal of extraneous materials like soil, dust, insects, or other plant parts to maintain purity.

• Ash Value:

Indicates the presence of inorganic matter and helps in assessing purity and quality, especially in powdered drugs.

• Moisture Content:

Determines the amount of water present in the drug. Low moisture content ensures better stability and prevents degradation.

• Extractive Values:

Reflect the amount of active constituent's extractable in different solvents, indicating the chemical nature of the drug.

• Crude Fibre:

Helps in determining the woody content and serves as a parameter for purity evaluation.

• Qualitative Chemical Evaluation:

Involves identification and characterization of phytoconstituents using various analytical techniques. It includes extraction, isolation, and detection of active principles responsible for therapeutic action.

WHO GUIDELINES FOR QUALITY STANDARDIZED HERBAL FORMULATIONS

• Quality Control of Raw Materials:

Ensures proper identification, authentication, and selection of plant material. Includes evaluation of botanical origin, purity, and absence of adulteration or contamination.

• Good Agricultural Practices (GAP):

Focuses on proper cultivation, harvesting time, geographical conditions, and use of pesticides to maintain quality of medicinal plants.

• Good Storage Practices (GSP):

Maintains quality during storage by controlling moisture, temperature, light exposure, and preventing microbial contamination.

• Good Manufacturing Practices (GMP):

Ensures standard procedures during preparation, processing, packaging, and labeling of herbal formulations to achieve batch-to-batch consistency.

• Physicochemical Evaluation:

Includes parameters like ash value, moisture content, extractive values, and other physical constants to assess purity and quality.

• Phytochemical Evaluation:

Involves qualitative and quantitative analysis of active constituents and establishment of chemical fingerprint profiles.

• Chromatographic Analysis:

Use of techniques such as TLC, HPTLC, HPLC, and GC for identification, standardisation, and detection of adulterants.

• Microbiological Evaluation:

Assessment of microbial load and detection of pathogens such as *E. coli*, *Salmonella*, and fungi to ensure safety.

• Toxicological Evaluation:

Detection of harmful substances such as heavy metals (lead, mercury, arsenic), pesticide residues, and aflatoxins.

• Stability Studies:

Determination of shelf life and stability of herbal formulations under defined storage conditions.

• Safety Assessment:

Evaluation of toxicity through experimental and clinical data to ensure safe use.

• Efficacy Assessment:

Validation of therapeutic effects through pharmacological studies, clinical trials, and traditional evidence.

• Standardisation of Finished Product:

Includes evaluation of dosage form, uniformity, pH, viscosity, disintegration time, and overall quality parameters.

• Documentation and Record Keeping:

Proper documentation of all processes, quality checks, and test results for traceability and regulatory compliance.

• Labelling Requirements:

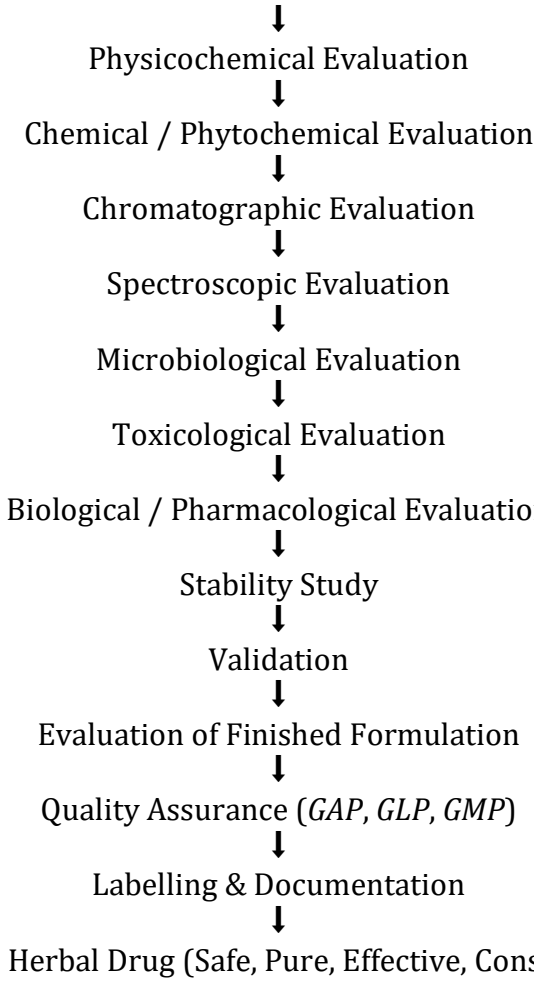
Clear labeling including drug name, batch number, manufacturing and expiry dates, dosage, indications, and storage instructions.

• Regulatory Compliance:

Adherence to WHO guidelines, pharmacopoeial standards, and national regulatory requirements for herbal medicines.

STANDARDISATION OF HERBAL DRUG (FLOW CHART – ARROW BY ARROW)

Collection & Authentication
↓
Preparation of Crude Drug
↓
Standardisation / Evaluation (Quality Assessment)
↓
Physical Evaluation (Organoleptic + Macroscopic + Microscopic)



RESULT AND FINDINGS

• Standardisation of herbal drugs is a systematic and multi-step process that ensures consistent quality, safety, and therapeutic efficacy.

• Authentication and proper identification of plant material were found to be the most critical initial steps to avoid substitution and adulteration.

• Organoleptic, macroscopic, and microscopic evaluations provide primary and reliable methods for identification of crude drugs.

• Physicochemical parameters such as ash value, moisture content, and extractive values are essential indicators of purity, stability, and quality.

• Phytochemical screening confirms the presence of active constituents responsible for pharmacological activity.

• Advanced analytical techniques like TLC, HPTLC, HPLC, and spectroscopic methods help in developing fingerprint profiles and ensuring batch-to-batch consistency.

• Microbiological evaluation revealed the importance of controlling contamination by bacteria, fungi, and pathogens.

• Toxicological analysis highlights the need to monitor heavy metals, pesticide residues, and aflatoxins to ensure safety.

• Biological and pharmacological studies validate the therapeutic efficacy of herbal drugs.

• WHO guidelines emphasize quality control at all stages, from raw material selection to finished product evaluation.

• Variability in herbal drugs is influenced by environmental, geographical, and processing factors.

• Proper implementation of quality control practices like *GAP*, *GLP*, and *GMP* significantly improves the reliability of herbal formulations.

• Overall, standardisation enhances global acceptance, scientific validation, and therapeutic reliability of herbal medicines.

DISCUSSION

Standardisation of herbal drugs is essential to ensure consistent quality, safety, and therapeutic efficacy. The present findings highlight that variability in plant sources, geographical conditions, seasonal factors, and processing methods significantly affects the composition and activity of herbal drugs. Without proper standardisation, issues like adulteration, substitution, and inconsistency may arise, leading to unreliable clinical outcomes. Therefore, basic evaluation methods such as organoleptic, macroscopic, and microscopic studies play a crucial role in the initial identification and authentication of crude drugs.[38]

The discussion also emphasizes the importance of physicochemical and phytochemical evaluation in determining the purity and potency of herbal materials. Parameters like ash value, moisture content, and extractive values provide measurable indicators of quality, while phytochemical screening confirms the presence of active constituents. Advanced analytical techniques such as TLC, HPTLC, HPLC, and spectroscopic methods have strengthened the scientific basis of herbal drug standardisation by enabling accurate identification and fingerprint profiling. Additionally, microbiological and toxicological

evaluations are vital to ensure safety by detecting contaminants like pathogens, heavy metals, pesticides, and aflatoxins.[39]

Furthermore, adherence to WHO guidelines and quality control practices such as *GAP*, *GLP*, and *GMP* is necessary for maintaining standards at every stage, from cultivation to finished product. Despite the availability of these guidelines, challenges such as lack of uniform regulatory enforcement and limited awareness still persist. Hence, integration of traditional principles of *Ayurveda* with modern scientific validation is required to improve reliability, global acceptance, and therapeutic effectiveness of herbal drugs.[40]

CONCLUSION

Standardisation of herbal drugs is a crucial process to ensure their identity, purity, safety, and therapeutic efficacy in modern healthcare. The present study highlights that a combination of classical evaluation methods and modern analytical techniques is necessary for proper quality assessment. Despite advancements, challenges such as variability, adulteration, and lack of strict regulatory implementation still exist. Therefore, integration of traditional principles of *Ayurveda* with scientific validation, along with adherence to WHO guidelines and quality control practices like *GAP*, *GLP*, and *GMP*, is essential to achieve consistent quality, enhance global acceptance, and ensure safe and effective use of herbal medicines.

CONFLICT OF INTEREST -NIL

SOURCE OF SUPPORT -NONE

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