

The Standardization and Quality Control of Herbal Remedies

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Abstract

The use of herbal remedies in modern medicine is becoming more well-known and widely accepted. It is well-known that more than 80% of the global population relies on herbal remedies and products for a healthy lifestyle, even if the majority of these uses are unconventional. Additionally, the methods for ensuring the high quality and standardization of herbal remedies were covered.

Keywords:- Herbal medicine, standardization, quality control.

INTRODUCTION

An herb is any plant or part of a plant that is prized for its aromatic, culinary, medicinal, or flavourful qualities. Herbs may be seen as natural factories that synthesize various chemical substances. Herbal treatments or medications are made from parts of plants or unrefined plant extracts that contain many ingredients, which typically have a synergistic effect when combined. Herbal medicine, often known as herbalism, is the practice of using the medicinal or therapeutic qualities of plants or herbal remedies. Their primary sources are the plant's leaves, roots, bark, seeds, and flowers, however they may come from anywhere. They may be consumed, ingested, imbibed, breathed, or topically administered to the skin. Many of the medicinal qualities of plants are due to the wide variety of bio chemicals found in plants, and herbal remedies often include these compounds. Chemicals with therapeutic properties are often termed as "active ingredients" or "active principles". There are a number of factors that affect their existence, including the plant species, harvest season, soil type, and herb preparation process.

In the last ten years, both developing and industrialized countries have seen an increase in

public interest and acceptance of natural treatments. Because of financial constraints and limited access to modern medical procedures, around 80% of the global population uses herbal medicine as their primary method of healthcare. This is particularly true in poorer nations. Within these societies, conventional medical procedures are often seen as an essential component of their cultural heritage. In Western societies, individuals are drawn to herbal remedies for several reasons, with the primary motivation being the belief that, like to our predecessors, these treatments would enhance our overall well-being. Herbal remedies are often seen as a judicious and temperate method of promoting healing. Consumers that use herbal products for self-care and purchase them without a prescription contribute billions of dollars to the industry. Consequently, they constitute a significant component of the worldwide illicit drug trade. In order to get the intended advantage from herbal remedies, a person must adhere to the prescribed dosage for certain duration. Although most herbal medicines are believed to be safe to ingest, it's worth noting that certain plants, like many biologically active

compounds, have the potential to be poisonous and cause unwanted side effects.

The genetic, cultural, and environmental variables that contribute to the variety of ingredients in herbs or herbal preparations have increased the complexity of using herbal treatments beyond what would have been expected. For instance, it might be difficult to regulate and check the quality of different batches of the product, the active ingredients can be diverse and sometimes unknown, and raw materials can be difficult to get and of high quality. There is a lack of mandatory safety and toxicological testing and comprehensive scientific evaluation of herbal products before they hit the market in many nations. There is a lack of efficient infrastructure to oversee production procedures and ensure adherence to quality standards. Consumers have the ability to purchase herbal remedies without needing a prescription and may not be aware of the possible dangers associated with a substandard product. Consequently, maintaining a well-defined and consistent composition of the medicine is crucial in order to manufacture a high-quality medication. Ensuring consistent quality of goods is crucial for the survival and development of the sector due to the variable and affected nature of plant-based products.

Literature and Review

Alinia-Ahandani, Ebrahim & Rafeie, Farjad (2023) Heavy metals are naturally present chemical components that may be found in soil and water. Although they are essential for many biological functions, they may be harmful to humans when present in large quantities. Medicinal plants, used for their medicinal attributes, have the potential to accumulate heavy metals in the soil. The bioaccumulation of heavy metals in medicinal plants presents a substantial hazard to human well-being, given that these plants are often ingested as herbal medicines or nutritional supplements. Neurological deficits and other serious health problems are possible outcomes of heavy metal exposure, which may occur with lead, mercury, cadmium, and arsenic, renal dysfunction, cancer, and developmental issues. Hence, it is crucial to guarantee that medicinal plants are cultivated in regions devoid of or with little

heavy metal pollution. Furthermore, it is essential to use appropriate processing methods to eliminate any remaining traces of heavy metals before to ingestion. This review article aims to examine and evaluate scholarly studies pertaining to the presence of heavy metals in medicinal plants.

Opuni, Kwabena & Kretchy, James-Paul & Agyabeng, Kofi (2023) there has been a meteoric rise in the usage of herbal medicinal products (HMPs) among LMICs. Therefore, the potential contamination of these items poses a substantial public health risk. This comprehensive study sought to ascertain the occurrence, varieties, and concentrations of impurities in HMPs originating from Latin American and Caribbean nations (LMICs). We followed the "Preferred Reporting Items for Systematic Reviews and Meta-Analyses" (PRISMA) standards for reporting our findings, and our search terms were suitable. The analysis included a total of 91 peer-reviewed studies, spanning from 1982 to 2021, originating from 28 distinct nations across four continents. The pollutants identified in the 91 articles included metals, microbiological agents, mycotoxins, pesticides, and residual solvents. Among these, metals were the most prevalent (56.0%, 51/91), followed by microbial agents (27.5%, 25/91), and mycotoxins (18.7%, 17/91). Approximately 16.4% (1236 out of 7518) of the samples exceeded the legal limits for pollutant levels. The samples that were analyzed for microbiological contaminants had the largest percentage (46.4%, 482 out of 1039) of pollutants that exceeded the limit set by regulations. This was followed by mycotoxins, with 25.8% (109 out of 423) surpassing the limit, and metals, with 14.3% (591 out of 4128) exceeding the limit. The percentage of samples above the regulation limit for average non-essential metal contamination levels was 57.6% (377 out of 655), 18.3% (88 out of 480), 10.7% (24 out of 225), and 11.3% (29 out of 257) for Pb, Cd, Hg, and As, respectively. The most prevalent bacterial species identified were *Escherichia coli*, accounting for 52.3% (10 out of 19 samples), followed by *Salmonella* species, which accounted for 42.1% (8 out of 19 samples). The assessment indicated that over 90% of *Candida albicans* and over 80% of

molds above the mandated regulatory thresholds. The intake of HMPs has significant health repercussions for both consumers and patients. Consequently, In order to improve the lives of people in low- and middle-income countries and lessen the dangers to their health, it is critical to establish and strictly implement regulations that regulate HMPs.

Oladeji, Oluwaseun &Kopaopa, Boikanyo (2023) Many Indian cultures understand and accept the potential of plants as a medicine for a wide range of illnesses, including cancer. Some people, particularly those who are already vulnerable, may be at risk from the presence of high levels of heavy metals in plant materials. The purpose of this study is to determine the concentrations of heavy metals in medicinal plant samples used to treat skin cancer. Additionally, it seeks to assess the potential health hazards posed by these adults in the city of Pretoria, South Africa, who are exposed to heavy metals. With the exception of mercury, which had concentrations below the allowed limit, all of the heavy metals tested had levels above it. There may be health hazards to using these medicinal plants for an extended period of time, although there are currently no documented non-carcinogenic health problems linked with heavy metals since their Hazard Quotient (THQ) is less than 1. As part of our study, we looked at the HI values indicated that the ingestion route is the main source of risk. The values were more than 1, suggesting that the long-term use of a specific herbal preparation containing heavy metal contamination may represent a health risk. Our study's findings highlight the critical need of regularly testing medicinal plants supplied to patients by herbal shops for heavy metal levels.

Atitsogbey, Patience &Kyereh, Emmanuel (2023) Green leafy vegetables, including cocoyam leaves, spinach, amaranths, roselle leaves, and lettuce, are a significant component of Ghanaian cuisine. These vegetables are rich in essential vitamins, along with important bioactive compounds. Regrettably, the techniques used by the majority of value chain participants in Ghana throughout the Diseases, heavy metals, and pesticide residues may contaminate these nutrient-rich vegetables during production, transportation, and handling.

The public's concerns about the quality and safety of these green leafy vegetables have so grown. Learning about the current thinking on the hazards of pesticides, heavy metals, and diseases in green vegetables and their effects on consumer health is crucial for identifying effective measures to enhance practices and protect human well-being. There has been consistent detection of iron, copper, manganese, zinc, cadmium, chromium, lead, and zinc in the leaves of green vegetables from several cities in Ghana. There is evidence of pesticide residues from synthetic pyrethroid, organophosphorus, and organ chlorine. The tainted green leafy veggies from Ghana by microbes, heavy metals, and pesticide residues were found to be considerable both on the farms and in the markets. Therefore, it is essential to implement mitigation strategies to effectively reduce ... order to safeguard the public's health from the contamination of these veggies as they go through the whole food chain.

Kaur, Gurleen (2023) The use of herbal remedies for the treatment of illnesses may be traced back to the period between 6,000 and 4,000 BCE in India. There is a vast collection of Vedic literature that provides detailed explanations of the constituents of medicinal plants and their effects on the human body. The sexual element between spouses has undergone changes as a result of industrialization. Sexual intercourse is a fundamental need for human existence, and people seek various medical systems to preserve or enhance it. Ayurveda, the ancient Indian system of medicine, is the primary method due to its safety, lack of side effects, and ability to not only treat diseases but also improve general health. Therefore, herbal aphrodisiacs, known as Vajikarna in Ayurveda, have been the preferred option of therapy in modern times for addressing sexual issues. Alongside the advantages, there is a downside associated with the potential contamination of heavy metals, given that these products are derived from plants. These contaminations may arise from atmospheric dust, pesticide application, and the presence of harmful compounds in the air, soil, and water. Hence, it is crucial to identify the existence of harmful substances, which is closely monitored according to Gathering and Agricultural Best

Practices (GACP). The need of herbal aphrodisiacs and the problem of contamination with harmful ingredients are both brought to light in this review. Elements evaluated by these methods in various parts of the world are detailed in a table. Finding herbal medicines with high concentrations of heavy metals will be the main focus.

STANDARDIZATION OF HERBAL MEDICINES

Herbal medicine, traditional medicine has been around for a very long time and universally practiced type of healthcare across all civilizations throughout time. Primitive people acknowledged their need on the natural world for a sound existence, and ever since, mankind has relied on the wide range of plant resources for sustenance, attire, housing, and medicinal remedies for many afflictions. Primitive people relied on their innate instincts, discerning taste, and accumulated knowledge to address ailments via the use of plants, animal components, and minerals that were not often consumed as part of their regular diet. Early humans acquired knowledge via a process of experimentation to differentiate between plants that were helpful and those that were poisonous or inert. They also discovered the most effective mixtures and techniques of processing to get reliable and optimum outcomes. In ancient societies, tribal communities diligently gathered data on plants and formulated precise herbal pharmacopias. The burial site of a Neanderthal man was unearthed in a cave in northern Iraq in 1960, providing archaeologists with solid evidence of the usage of herbal remedies some sixty thousand years ago. Throughout the majority of the twentieth century, a significant portion of the medicinal resources used in modern medicine originated from the traditional knowledge of indigenous populations. The acquisition of information about plant-based pharmaceuticals progressed incrementally and was subsequently transmitted, so becoming the basis for several conventional medical systems worldwide. Herbal medicine is an integral component of the medical system in many societies. Medicinal plants are extensively dispersed worldwide, with the highest concentration found in tropical regions. Approximately 25% of contemporary

pharmaceuticals are believed to be originated from higher plants, either directly or indirectly. Herbal medicine has facilitated the identification of several novel pharmaceuticals and non-pharmaceutical compounds.

In general, all medications, regardless of whether they are synthetic or derived from plants, must meet the fundamental criteria being effective while also being safe. The term "herbal drugs" describes phytopharmaceuticals, which are substances derived from plants or plant parts by uncomplicated procedures such as harvesting, drying, and storage. Therefore, they have the ability to undergo changes. These variations may also be attributed to disparities in growth, geographical positioning, and timing of harvest. For herbal medicines to be standardized, they must meet certain requirements about their quality, efficacy, safety, and repeatability. These requirements include uniform parameters, clear qualitative and quantitative values, and a set of intrinsic qualities. It involves the creation and consensus-building of technical standards. The process of determining specific criteria for herbal medicine involves conducting experiments and making observations. These efforts aim to establish a set of qualities that the medication should possess. Standardization is a crucial instrument used in the process of quality control. The quality of herbal pharmaceuticals is frequently affected by many issues that do not often apply to synthetic drugs. As an example:

1. Herbal medications often consist of a combination of many ingredients.
2. The active principle(s) is (are) often unidentified in most situations.
3. Commercial availability of selective analytical techniques or reference substances may be limited.
4. Plant materials have inherent chemical and natural variability.
5. There are many types of plants that have been specifically bred or cultivated for their chemical properties, known as chemo-varieties and chemo cultivars.
6. The raw material originates from many sources and has varied quality.

Several variables, including the methods used for harvesting, affect the quality of herbs, drying, storage, shipping, and processing. These factors include the selection of extraction technique, solvent polarity, and the stability of the contents. Currently, there are no established governmental criteria for herbal remedies. The firms doing formulation testing have their own criteria, many of which are still in the early stage. Currently, it is very challenging to accurately detect the existence of all the components as asserted in a given formulation. Therefore, the primary objective is to develop a parameter that can accurately detect the presence of all the ingredients. This can be achieved by employing chromatographic and spectrophotometric techniques, as well as evaluating the physicochemical properties to establish a pattern for identifying the different ingredients. These approaches may be used to quantitatively estimate bioactive groups of chemicals such as alkaloids, flavonoids, polyphenolic components, or specific compounds.

A LOOK AT THE NECESSITY FOR UNIFORMITY FROM THE VIEWPOINTS OF BOTH PRODUCERS AND CONSUMERS

From a worldwide standpoint, there is a growing trend towards the use of herbal therapy due to the increasing recognition of the risks and limitations associated with contemporary treatment. The primary duty of regulatory bodies is to ensure that customers get medicine that assures purity, safety, potency, and effectiveness. The quality standards outlined in pharmacopoeias, formularies, and production processes for both inputs and outputs are rigorously enforced by the regulatory bodies as mandated by good manufacturing practices. These techniques are universally applicable to all forms of medicines, regardless of whether they are part of the contemporary system of medicine or one of the old systems.

Despite the growing global popularity of herbal products, a major obstacle to their adoption is the absence of a standardized quality control profile. The final product's efficacy and safety as a herbal medication are affected by the quality of its constituents. Nevertheless, the

intricate composition and intrinsic inconsistency of the substances used in herbal remedies, which makes it difficult to establish standards for quality assurance, despite the potential assistance of contemporary analytical techniques in overcoming this issue. On top of that, the ingredients that are supposed to have a therapeutic effect are not always named or only partly explained. The use of a variety of herbal compounds in traditional medicine adds more complexity to the situation. A typical product often contains up to five distinct botanical components. The variance from one batch to another originates from the raw material gathering process itself, since there is no reference standard available for identification. The proliferation of these variants occurs during storage and subsequent processing. Therefore, when it comes to herbal treatments and goods, it is important to ensure that standardization covers the full spectrum of research, starting with the cultivation of medicinal plants all the way to their clinical use.

A significant chunk of the world's commerce is devoted to plants and herbal medicines made from them. Therefore, it is essential to have globally accepted rules for assessing and controlling their quality.

PROTOCOLS FOR THE STANDARDIZATION AND QUALITY ASSURANCE OF HERBAL CRUDE PHARMACEUTICALS

Herbal product quality control and standardization is defined by the World Health Organization as the method of methodically assessing the physical and chemical properties of medicinal plants in their unprocessed state. A number of steps comprise this process, including picking and managing raw materials with care, reviewing the final product for soundness, effectiveness, and security, recording security and risk factors according to prior encounters, informing consumers, and advertising the product. There is usually an emphasis on quality indicators like:

1. Using a microscope and other forms of magnification: This can help you determine the exact kind and rule out any filler.

2. In order to get the drug in its most pure form, this method entails extracting elements other than the original plant material, which is known as foreign organic matter.

3. There is a number of ash values used to identify and assess the purity of crude medicines. These include total ash, sulphated ash, water-soluble ash, and acid-insoluble ash.

4. **Moisture content:** Assessing the moisture content aids in minimizing inaccuracies in determining the true weight of the pharmacological substance. Reduced moisture content indicates enhanced resistance to product deterioration.

5. **Extractive values:** The chemical components of the crude medicine that may be extracted in different solvent conditions are represented by the following weights.

6. **Crude fibre:** This aids in identifying the presence of lignocellulosic material, and serves as a standard for assessing its purity.

7. **Qualitative chemical evaluation:** This pertains to the identification and characterisation of raw medicinal substances in terms of their phytochemical components. In order to isolate the active ingredients, it employs a battery of analytical procedures. One method of phytochemical screening is the identification of plants, extracting their active ingredients using appropriate solvents, purifying them, and characterizing their medicinal significance.

8. **Chromatographic examination:** Identify the crude medicine by examining the primary chemical elements that serve as indicators.

9. **Quantitative chemical evaluation:** To assess the quantity of the primary categories of components.

10. **Toxicological studies:** The levels of pesticide residues and other potentially harmful substances may be evaluated, and animal safety tests like the LD50 and Microbial assay can be used to establish the presence or absence of harmful microbes.

The procedures include a diverse range of scientific inquiries, including physical, chemical, and biological assessments using a

variety of analytical techniques and instruments. The diverse objectives of such inquiry in ensuring the quality of herbal products are as multifaceted as the methods used.

Physical evaluation

Every monograph includes comprehensive description of each plant's physical characteristics at the macroscopic, microscopic, and botanical levels which serve to guarantee both its authenticity and purity. Every description is supplemented by meticulous graphics and digital photographs that provide visual evidence of precisely specified material.

Microscopic evaluation

A comprehensive physical examination is necessary to get a complete and precise characterisation of plant material. Verifying the material's validity and performing an initial screening test for pollutants are both facilitated by microscopic studies of plants.

Chemical evaluation

This include the processes of screening, isolating, identifying, and purifying the chemical constituents. The medicine undergoes chemical analysis to evaluate the effectiveness of the plant material in relation to its active components. Colorimetric assays are one possible component of chemical screening and testing, which aids in identifying the drug ingredient and detecting any adulterants.

Biological evaluation

Some drugs' efficacy has been determined by studying their pharmacological activities. Drug or drug preparation potency may be determined by assays performed on live animals and their whole or isolated organs. Biological assays or bioassays are common terms for these kinds of testing.

Purity determination

As mentioned before, all of the monographs include purity standards and other qualitative indications.

Conclusion

Herbal plants have been used as medicinal remedies for centuries. Scientists have mixed several plants to create synergistic effects or

numerous effects, due to their ongoing interest in studying the medicinal potential of herbals. Subsequently, the herbal compositions have acquired significance. One significant advantage of these formulations is their great effectiveness and few side effects. The growth and development of a number of variables affect plants, including geographical location, climate, harvesting practices, and irrigation methods. These factors also have an impact on the quality, effectiveness, and safety of the plants. Hence, it is necessary to establish a uniform standard for both the plants and the formulations created via any possible combination of them.

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