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Evaluation and Quality Control of Herbal Drugs in Contemporary Era

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ABSTRACT
In the modern era, the assessment and monitoring of herbal medicines have become crucial aspects of quality control. The evaluation of herbal drugs is important to ensure their safety, effectiveness, and acceptability. Currently, the field of herbal drugs and formulations is rapidly advancing and there is still much to discover regarding their standardization. Herbal medicines face challenges due to the absence of standardized parameters. The modern era emphasizes the need for standardized protocols and rigorous testing procedures to maintain the quality and integrity of herbal drugs. To graduate quality, safety and effectiveness of herbal medicines, it is essential to implement regulations and adopt modern and appropriate good manufacturing practice (GMP) standards.
KEYWORDS: Herbal drug, quality control, standardization

I. INTRODUCTION

Geographical location and time of harvesting are important factors in the standardization of herbal medicines. Traditional medicine is widely used for various ailments and has quantities of quality, efficacy and safety. Standard herbal formulations are necessary to assess the quality of herbal drug based on their active principles. However there are several problems in the quality assessment of herbal formulations. Herbal drugs are usually mixture with unknown active principles and selective analytical methods may not be available commercially. Additionally plant materials are chemically and naturally variable and different chemo-varieties and chemo cultivars exist. The unavailability of rigid quality control profiles for herbal materials and their formulations is the major problem in the herbal pharmaceutical industry. Standardization of herbal drug and product should cover the entire process from cultivation to clinical application. The World Health Organization emphasizes the use of modern techniques and suitable parameters and standards for quality control of medicinal plant products.

Need of standardization

In recent years, there has been a growing interest in the survival of ayurvedic medicines. Globally there is shift towards using herbal medicines due to the increase awareness of the dangers and limitations of modern medicines. The majority of ayurvedic formulations are made from herbs.

Regulatory authorities have a crucible role in ensuring that consumers receive medicines that are pure, safe, potent and effective. They achieve this by strictly adhering to quality standards for raw materials and finished products as outlined in pharmacopoeias. Manufacturing process are controlled through the use of formularies and adherence to statutory "Good Manufacturing Practices."

Standardization of herbal drugs

Standardization of herbal medicines involves verifying its identity and assessing its quality, purity, and identifying any adulterants through different methods such as morphological, microscopic, physical, chemical and biological examination.

All medicines, whether systemic or from plant, must meet safety and effectiveness requirements. Herbal drugs are made from plants through simple process like harvesting and drying which can lead to variability due to factor like growth and location.

The quality of herbs is influenced by how they are harvested, dried, stored, transported and processed. Official standards for herbal preparations are lacking. Manufacturers testing their formulations have their own essential parameters. Identifying all ingredients in a formulation is currently difficult. Developing parameters to detect all ingredients are essential. Spectrophotometric and chromatographic methods can be used for this purpose.

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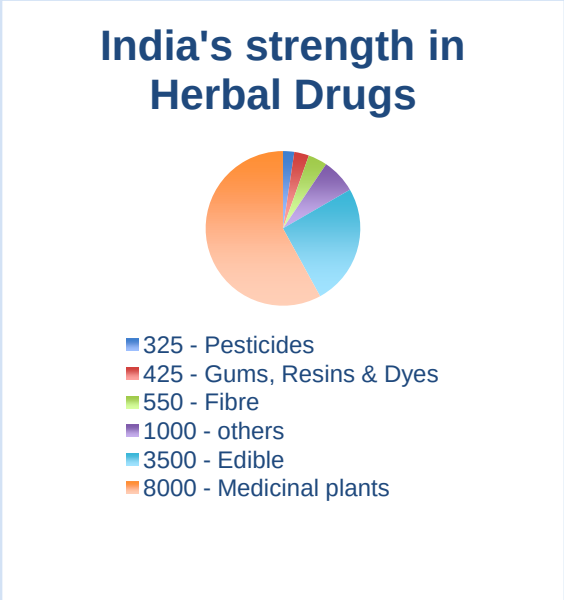


Need of quality control

The modern medical system relies on solid experimental data, toxicity studies, and human clinical studies. However, there is a lack of pharmaceutical standards for raw material and finished products. The herbal industry also lack well defined cGMP standards and minimum standards for medicinal plant products. This absence of quality standards results in different harmful effect ranging from mild to severe, including liver toxicity and even death. Therefore it is important to have tools that can determine the identity, purity, and quality of herbal ingredients. The World Health Organisation has establish specific guidelines for assessing the safety, efficacy and quality of herbal medicines. To produce high quality herbal products, it is essential to properly identify the plants, consider the season and area of collection, and ensure the extraction and purification of poly herbal drugs.

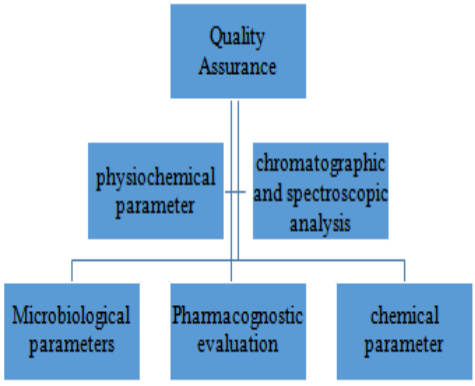
WHO Guidelines for quality control of herbal formulations

1. Evaluating stability and shelf life of a product.
2. Checking the quality of raw materials, plant preparations, and final products.
3. Ensuring safety through documentation of experience or toxicological studies.
4. Assessing effectiveness using ethno medical information and biological activity evaluations.

The biological extract needs to be standardized on the basis on active component or major compound, as well as chromatographic fingerprints like TLC, HPTLC, HPLC, And GC.

Quality assurance of herbal crude drug

WHO states that quality control of herbal products involves evaluating the physical and chemical properties of raw materials, ensuring safety, efficacy, and stability of the final product, documenting safety and risks, providing consumer information, and promoting the product. Authentication is crucial at every stage including collection area, plant parts, botanical and taxonomic identity, analysis of foreign matter, ash values, heavy metals, pesticide residue, microbial and radioactive contamination, and stability parameters of herbal formulations.



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Pharmacognostic evaluations
It includes taste, odour, colour, shape, size and histological characteristics.

Chemical parameters
It includes chemical test, limit tests etc.

Physico – chemical properties
It includes total ash, acid insoluble ash, sweeling foreign matter, assay, extractive values, moisture content, pH, viscosity, sedimentation, alcohol content, disintegration time.

Chromatographic and Spectroscopic analysis
It includes HPLC, HPTLC, UV, AAS, IR, TLC, LC-MS AND GC-MS etc.

Microbiological parameter
It includes the full content of viable, total mould count, total coliforms count.

Factors affecting quality control of herbal drugs

Foreign matter

Herbal medicines must only be made form the specified plant part, without any others parts of the same plant or other plants. They should be clean from mold, insets, excreta, sands, stones, harmful substances, and chemical residues. Animal matter like insects and unseen microbial contaminants that can create toxins are also possible contaminants. Foreign matter can be identified through macroscopic examination, and TLC may be necessary to detect chemical residues.

Microscopic evaluation

Microscopic evaluation is crucial in the quality control of herbal drugs. It helps in identifying herbs, detecting foreign matter and adulterants, and analysing small fragment of crude or powdered drugs. A simple visual evaluation can ensure that the correct species and plant parts are being used. In some cases, microscopic analysis is necessary to determine species and specific part of plant.

Ash content

To find ash content, the plant material is burned and the remaining ash is calculated as total and acid insoluble ash. Total ash shows the total material left after burning, including ash from the plant and acid insoluble ash. Acid insoluble ash is what's left after boiling the total ash with dilute hydrochloric acid, and burning the remaining insoluble matter. This method is used to measure the silica content, particularly in sand and siliceous earth. Water soluble ash is the difference in weight between total ash and residue after treatment of total ash with water.

Formula to determine ash content:

1. % Total ash = $\frac{\text{Ash weight}}{\text{Weight of sample}} \times 100$

2. % Acid Insoluble ash = $\frac{\text{Acid insoluble ash weight}}{\text{Weight of sample}} \times 100$

3. % Water soluble ash = $\frac{\text{Total ash weight – water insoluble residue in total ash}}{\text{Weight of sample}} \times 100$

Heavy metals

The presence of heavy metals like mercury, lead, copper, cadmium and arsenic in herbal remedies can be cause by various factors, including environmental pollution. This contamination can have significant health risks for users and should be limited. To determine the potential intake of these toxic metals, their level in the product and the recommended dosage need to be considered. Many pharmacopoeias provides simple tests for heavy metal detection. The amount of heavy metals present can be estimated by comparing it to the standard. When the metals are present in the small amounts or when qualitative analysis is required, instrumental methods such as AAS (absorption spectrophotometry), ICP (inductively coupled plasma), NAA (neutron activation analysis) are commonly used.

Microbial contamination

Medicinal plants can contain various types of bacteria, fungi and viruses due to environmental factors affecting the quality of herbal products. Bacteria and molds are commonly found in herbal drugs, originating from the soil. Improper harvesting, cleaning and storage methods can lead to additional contamination including Escherichia coli and Salmonella spp. Laboratory procedures for testing microbial contamination are outlined in pharmacopoeia and WHO guidelines, with specific limit value provided. Tests typically includes total aerobic microbial count, total fungal count, total Entero – bacteriaceae count and presence of specific bacteria like E. coli and Salmonella spp. European Pharmacopoeia mandates that herbal preparations

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should be free from Escherichia coli and Salmonella spp.

Radioactive contamination

A nuclear accident can lead to dangerous contamination. The WHO along with other organizations has created guidelines for dealing with widespread contamination from radionuclides after major nuclear accidents. The health from naturally occurring radioactive contamination are generally not a concern, but those from accidents like Chernobyl and Fukushima can be serious depending on the specific radionuclide, contamination level, and amount consumed. Considering the typical amount of herbal medicine consumed the risk is low. Currently, there are no proposed limits for radioactive contaminations.

Validation

The validation of herbal products is a significant concern for public health in both developed and resource poor countries. Despite the presence of guidelines from individual countries and the WHO, government agencies do not have control over this issue. It is crucial to ensure scientific validation and regular monitoring of the quality and effectiveness of herbal products if they are being marketed as therapeutic agents. Official pharmacopoeia have monographs that set standard for herbal drugs, provide definite standards and validated analytical procedures. The purpose of qualitative chemical examination is to identify and separate the active ingredients. TLC and HPLC are the primary analytical techniques employed. LC–MS can be used for mode characterization when necessary. In situations where active ingredients are unknown, the quality of plant extracted can be evaluated using 'fingerprint' chromatogram.

II. CONCLUSION

When it comes to herbal products, it is necessary to standardize the new formulations for safety, effectiveness, and strength. It is necessary to evaluate and analyse herbal products using advanced techniques like UV- visible, TLC, HPLC, GC-MS and others methods. This will ultimately result in safer use, effective treatment, and the desired strength of product and reduces the quality issues of the medicines.

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