

STANDARDIZATION OF HERBAL PREPARATIONS: SCIENTIFIC APPROACH FOR CONVENTIONAL HERBAL MEDICINE

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Introduction

Herbal medicine is still the mainstay of about 80% of the world population for their primary healthcare. Plant based medicines are accepted as therapeutic agents for many diseases such as diabetes, arthritis, liver diseases, cardiovascular diseases, infections etc. Currently, herbal medicine is increasingly becoming popular among the developed countries with the more apparent manifestations of side effects of modern drugs. Herbal drugs have intrinsic

worth over modern drugs for their perceived efficacy, low cost and low incidence of side effects. The desired benefits of herbal drugs rely on the correct plant material, quality of preparation, correct dosage, time period of administration etc. Phytochemicals or the active ingredients responsible for the bioactivities greatly vary with genetic variation, climatic and environmental factors, method of preparation, storage etc. (Thus, maintaining the quality and consistency of herbal formulations has become a challenge. Evaluation of a herbal product does not necessarily require purifying the active constituent unlike in allopathic medicine. Instead the best approach would be the analysis of the active ingredients in the herbal mixture and maintaining the quality and purity of such preparations by standardization.

In most countries, herbal products are formulated and launched to the market without proper scientific evaluation. Though it is believed that herbal products are less toxic, untested preparations could lead to severe side effects, especially where substitution or adulterations are encountered. Thus, it is evident that the herbal medicine industry requires strict guidelines and regulations to maintain the quality standards of herbal preparations. In 1992, WHO recognized this issue and formulated a set of guidelines for quality control and standardization of medicinal plants (WHO,1993).



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Standardization of herbal formulations

Standardization of herbal products referred to as “confirmation of its identity and determination of its quality and purity” is with a clear objective to provide general test methods for correct botanical evaluation and identification of medicinal plants, widely used in traditional and home remedies (WHO,1998). Today, standardization has become a fundamental requirement of industries and other organizations dealing with herbal products. It is also a timely requirement to make the general public aware about the quality standards of raw herbal products they use in their day to day life, with an emphasis to minimize the side effects of contaminated or adulterated plant material. Although, some of the herbal formulations are well documented in pharmacopeias, chemical standards have not been mentioned. Thought, the standardization of herbal preparations is not an easy task. The following guidelines will help to ensure the purity, quality, safety and reproducibility of herbal preparations.

General testing parameters for characterization and Standardization of Herbal medicine

Standardization of herbal raw drugs include passport data of raw plant material, botanical authentication, macroscopic & microscopic examination, identification of chemical composition by various chromatographic techniques and biological activity of the whole plant.

1. Botanical

- General information- Geographical location, harvesting time, harvesting procedure- To minimize the variations of active constituents in plants
- Gross morphology -Macro and microscopic examination of plant material. For identification of correct variety and search of adulterants
- Organoleptic evaluation – colour, odour, taste, texture etc to confirm the identity of the preparation



Figure: Schematic diagram of standardization of herbal plant material (WHO,1998)

2. Physical

- Foreign matter evaluation- this involves removal of matter other than source plant to get the drug in pure form.
- Ash values – Will help to judge the identity and purity of the crude drug
- Water/moisture content – reduce the error when estimating the weight of the preparation
- Extractive value – these are indicative weights of the extractable chemical constituents
- Crude fibre content – helps to determine the woody material component.

3. Chemical

- Chemical analysis - Qualitative and Quantitative chemical evaluation. This encompasses the identification and characterization of the crude drug with respect to active constituent for known and unknown constituents
- Chromatographic examination - Identification of crude drugs based on the major chemical constituent as markers
- Photometric analysis

4. Biological

- Pesticides – herbal drugs are liable to contain pesticide residues that accumulate from agricultural practice
- Heavy metals – contamination by heavy metals such as mercury, lead, copper, cadmium and arsenic in herbal remedies can cause adverse effects. Atomic adsorption spectrophotometry (AAS) can be used to measure the heavy metal contamination.
- Aflatoxins- Aflatoxins in herbal drugs can be dangerous to health even if these are absorbed in minute amounts. Aflatoxin producing fungi can build up during storage. Proper cleanup methods are required and TLC can be used to test the toxic contamination.
- Microbial purity –medicinal plants may be contaminated with a broad variety of microbes such as virus, bacteria and fungi. Also, medicinal plants can be contaminated by poor methods of harvesting, drying, handling, storage. Therefore, it is important to test for microbial contaminations.
- Radioactivity – radioactive contamination is a concern only in areas where nuclear accidents were reported. Naturally occurring radionuclides are not of much concern.

5. Bioactivities

- a) Toxicological studies-help to determine the potentially harmful substances
- b) Pharmacological activities- evaluate specific activities of the preparation
- c) Other specific activities

In general, all the above mentioned parameters confirm the quality and purity of a herbal preparation.

Recent approaches in herbal drug standardization

The traditional approach towards standardization is insufficient for the current global market.

Hence, there is need for more advanced techniques for standardization. The new era of herbal drug standardization includes molecular approaches in addition to the conventional methods.

1. DNA fingerprinting

Correct identification and quality assurance of raw plant material is a prerequisite for quality herbal preparation. DNA analysis has proved to be an important tool in herbal drug standardization. This technique is useful for the identification of phytochemically indistinguishable genuine drugs from substituted or adulterated drugs. There are hybridization-based methods, polymerase chain reaction (PCR) –based methods and sequencing methods for DNA fingerprinting.

2. Chromatographic fingerprinting

This technique has been widely used in pharmaceutical industry for isolating and purification of herbal compounds. Recently, it has become one of the most powerful methods to quality control herbal drugs. In addition to the conventional HPLC, Liquid Chromatography- Mass Spectroscopy (LC-MS), Gas chromatography (GC-MS) Gas chromatography flame ionization detector (GC-FID), Supercritical fluid chromatography (SFC) and capillary electrophoresis have emerged as novel chemical techniques of standardization of herbal drugs (Schaneberg et al, 2004).

Future aspects

Maintaining quality of a herbal formulation requires careful monitoring of the process from the collection of plants to the finished packaged product. It is recommended that the relevant stakeholders should follow a more universal approach for standardization of herbal formulation placing emphasis on the WHO guidelines. Development of herbal

monographs using various quality standards is also encouraged to minimize the quality breach. The applications of high-technology oriented advanced hyphenated techniques will serve as rapid and unambiguous tools in herbal research, thereby, upgrade the entire pharmaceutical industry as well as benefit people around the world.

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The intuitive mind is a sacred gift and the rational mind is a faithful servant. We have created a society that honours the servant and has forgotten the gift.

Albert Einstein (1879-1955)