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Standardization of Herbal Medicine: A Concise Review

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Abstract

The medicinal plants have enormous commercial potentials throughout the world. In addition, they are also the source of chemical intermediate needed for the production of some drugs. As the risks and the deficiencies of modern medicine have started getting more apparent, majority of formulation are prepared from herbs. In the global perspective herbal medicines and products has been enjoying renascence among the clients owing to its natural origin and lesser side effects for healthy living. The medicaments however, suffer from lack of standardization parameters and proper documentation based on scientific screening procedures. The main limitation is the lack of standardization of raw materials, of processing methods and of the final products, dosage formulation, and the nonexistence of criteria for quality control. Along with increased interest in herbal medicine there has been an explosion in the amount of literature on the subject and quality control is of utmost essential in this respect over the world. Herbal medicines are not a simple task since many factors influence the biological efficacy and reproducible therapeutic effect. Standardized herbal products of consistent quality and containing well-defined constituents are required for reliable clinical trials and to provide consistent beneficial therapeutic effects. Quality control measures covers; many aspects of drug manufacture, distribution and, sale is not restricted to final product analysis either regulatory or otherwise, while engaging in this chore, it must be realized that some of the Quality control practices that work excellently either modern drug may not be appropriate with Herbal drugs.

Keywords: Standardization, Quality control, Medicinal plants, Crude drug

1. Introduction

The traditional medicine is widely used for various human ailments. The usage of herbal medicine could be even traced right from the beginning of mankind. Man tried to know about the plants around him to satisfy his basic needs such as food, shelter and clothing. All plants in this planet are important because of its medicinal qualities. Traditional system of medicines has become significantly more popular all over the globe because of the effective and curative nature for chronic disease with less toxicity. Herbal medicines are not a simple task since many factors influence the biological efficacy and reproducible therapeutic effect [1, 2].

Standardization of herbal formulations is essential in order to assess of quality drugs, based on the concentration of their active principles, physical, chemical, phyto-chemical, standardization, and In-vitro, In-vivo parameters. The quality assessment of herbal formulations is of paramount importance in order to justify their acceptability in modern system of medicine [3]. One of the major problems faced by the herbal industry is the unavailability of rigid quality control profiles for herbal materials and their formulations. In India, the department of Ayush, Government of India, launched a central scheme to develop a standard operating procedures for the manufacturing process to develop pharmacopeial standards for ayurvedic preparations. The subject of herbal drug standardization is massively wide and deep. There is so much to know and so many seemingly contradictory theories on the subject of herbal medicines and their relationship with human physiology and mental function. India needs to explore the medicinally important plants. This can be achieved only if the herbal products are evaluated and analyzed using sophisticated modern techniques of standardization [2, 4].

As per WHO definition, there are three kinds of herbal medicines: Raw plant material, processed plant material and medicinal herbal products. Herbal drugs are finished labeled products that contain active ingredients such as aerial or underground parts of plant or other plant material or combination thereof, whether in the crude state or as plant preparations. The use of herbal medicines has increased remarkably in line with the global trend of people returning to natural therapies [5, 6]. According to an estimate of the World Health Organization (WHO), about 80% of the world population still uses herbs and other traditional medicines for their primary health care needs. The World Health Organization (WHO) has appreciated the importance of medicinal plants for public health care in developing nations and has evolved guidelines to support the member states in their efforts to formulate national policies on traditional medicine and to study their potential usefulness including evaluation, safety, and efficacy.

Most of the traditional systems of medicine are effective but they lack of standardization. So, there is a need to develop a standardization technique. Central Council of research in *Ayurveda* and *Siddha* has given preliminary guidelines for standardizing these conventional formulations. For the uniformity of batches in production of herbal formulations it is necessary to develop methods for evaluation. Standardization of drugs means confirmation of its identity and determination of its quality and purity. Initially the crude drugs were identified by comparison only with the standard description available [2, 6, 7].

Substitution and Misidentification of Herbal Substances

Risks associated with herbal medicine products were first reported for medicinal plants of the Asteraceae family, *Hypericin* and *Aristolochia* genus, and kava-kava. A number of cases of inadvertent or deliberate substitution of the constituents of Chinese herbal preparations are cited in the literature. For example, Siberian ginseng (*Eleutherococcus senticosus*), American ginseng (*Panax quinquefolium*), and Japanese ginseng (*Panax pseudo ginseng*) have been substituted for Korean or Chinese ginseng (*Panax ginseng*). Sometimes the substitute has a much greater toxicity than the original material. Examples of substitution resulting in an adverse effect include reported cases of hepatitis with jin bu huan, renal fibrosis due to *Aristolochia fangchi*, and podophyllin poisoning due to *Podophyllum emod* [2, 8, 9].

Requirement of Standardization of Herbal Drug:

In recent years there is a spurt in the interest regarding survival of Ayurvedic forms of medication. In the global perspective, there is a shift towards the use of medicine of herbal origin, as the dangers and the shortcoming of modern medicine have started getting more apparent. It is the cardinal responsibility of the regulatory authorities to ensure that the consumers get the medication, which guaranteed the purity, Safety, potency and efficacy. This duty is discharged by regulatory authorities by rigidity following various standards of quality prescribed for raw materials and finished products in pharmacopoeias controlling manufacturing formula through the use of formularies and manufacturing operation through statutory imposed “Good manufacturing practices”. Herbal products has been enjoying renaissance among the customers throughout the world. The quality of herbal medicine i.e. the profile of the constituents in the final product has implication in efficacy and safety. Due to complex nature and inherent variability of the constituents of the plant based drugs, it is difficult to establish quality control parameter and modern analytical technique are expected to help in circumventing this problem. The quality control of crude drugs and herbal formulations is of paramount importance in justifying their acceptability in modern system of medicine.

But one of the major problems faced by herbal drug industry is non-availability of rigid quality control profile for herbal material and their formulations. The task of lying down standard for quality control of herbal crude drug and their formulation involves biological evaluation for particular disease area, chemical profiling of the material and lying down specification for the finished product. Therefore, in case of herbal drugs and product, the word "standardization" should encompass entire field of study from cultivation of medicinal plant to its clinical application. Plant material and herbal remedies derived from them represent substantial portion of global market and in this respect internationally recognized guidelines for their quality control are necessary. WHO has emphasized the need to ensure quality control of medicinal plant products by using modern technique and by applying suitable parameters and standards. In order to overcome certain inevitable shortcoming of the Pharmacopoeial monograph other quality control measures must be explored [4, 10, 11].

Steps Involved in Standardization of Raw Materials:

Authentication- Each and every step has to be authenticated, area of the collection, parts of the plant collection, the regional situation, as phytomorphology botanical identity, microscopic and histological analysis(characteristic features of cell walls, cell contents, starch grains, calcium oxalate crystals, hairs, fibers, vessels etc.) Several studies of the histological parameters are list of palisade ratio, vein islet number, vein termination, stomatal number, stomatal index, trichomes, stomata, quantitative microscopy, taxonomic identity, foreign matter. Loss on drying, swelling index, foaming index, ash values and extractive values, Chromatographic and spectroscopic evaluation, Determination of heavy metals, pesticide residues, Microbial contamination, Radioactive contamination. The parameter stability of herbal formulations that includes pharmacognostic parameters, physico-chemical parameters, phyto-chemical parameters, microbiological assay and chromatographic analysis:

1. **Pharmacognostic evaluation:** It includes color, odor, taste, texture, size, shape, microscopical characters, and histological parameters.
2. **Physico-chemical parameters:** It includes foreign matter, total ash, acid-insoluble ash, swelling and foaming index, assay, successive extractive values, moisture content, viscosity, PH, Disintegration time, friability, hardness, flow capacity, flocculation, sedimentation, alcohol content.
3. **Chemical parameters:** It includes limit tests, chemical tests etc.
4. **Chromatographic and spectroscopic analysis:** It includes TLC, HPLC, HPTLC, GC, UV, IR, FT-IR, AAS, LC-MS, GC-MS, fluorimetry etc.
5. **Microbiological parameters:** It includes the full content of viable, total mould count, total coliforms count. Limiters can be used as a quantitative tool or semi-quantitative to determine and control the amount of impurities, such as reagents used in the extraction of various herbs, impurities ships directly from the manufacturing and solvents etc [2, 8, 12].

Current Regulations for Standardization of Herbal Drugs

Several pharmacopoeias like Pharmacopoeia Committee, Chinese Herbal Pharmacopoeia, United States Herbal Pharmacopoeia, British Herbal Pharmacopoeia, British Herbal Compendium, Japanese Standards for Herbal Medicine and the Ayurvedic Pharmacopoeia of India (API). Lay down monograph for herbs and herbal products to maintain their quality in their respective nations. Government of India too has brought out Ayurvedic Pharmacopoeia of India, which recommends basic quality parameters for eighty common Ayurvedic herbal drugs. World Health Organization (WHO) encourages, recommends and promotes traditional/herbal remedies in national healthcare programmes because these drugs are easily available at low cost, safe and people have faith in them. The WHO assembly in number of resolutions has emphasized the need to ensure quality control of medicinal plant products by using modern techniques and applying suitable standards [10, 13, 14].

WHO Guidelines for Quality Standardized Herbal formulations

The bioactive extract should be standardized on the basis of active principles or major compounds along with the chromatographic fingerprints (TLC, HPTLC, HPLC and GC). The standardization of crude drug materials includes the following steps:

a. Authentication (Stage of collection, parts of the plant collected, regional status, botanical identity like phyto-morphology, microscopical and histological analysis, taxonomical identity etc.)
b. Foreign matter (herbs collected should be free from soil, insect parts or animal excreta etc.)
c. Organoleptic evaluation (sensory characters – colour, taste, appearance, odour, feel of the drug etc.)
d. Tissues of diagnostic importance present in the drug powder.
e. Ash values and extractive values.
f. Moisture content
g. Volatile matter
h. Determination of heavy metals e.g. cadmium, lead, arsenic, etc.
i. Chromatographic and spectroscopic evaluation: TLC, HPTLC, HPLC methods will provide qualitative and semi quantitative information about the main active constituents present in the crude drug. The quality of the drug can also be assessed on the basis of the spectroscopic fingerprint.

j. Pesticide residue: WHO and FAO (Food and Agricultural Organization) set limits of pesticides, which are usually present in the herbs. These pesticides are mixed with the herbs during the time of cultivation. Mainly pesticides like DDT, BHC, toxaphene, aldrin cause serious side-effects in human beings if the crude drugs are mixed with these agents.

k. Microbial contamination: Usually medicinal plants containing bacteria and moulds are coming from soil and atmosphere. Analysis of the limits of *E. coli* and moulds clearly throws light towards the harvesting and production practices. The substance known as aflatoxins will produce serious side-effects if consumed along with the crude drugs. Aflatoxins should be completely removed or should not be present.

l. Radioactive contamination: Microbial growth in herbals is usually avoided by irradiation. This process may sterilize the plant material but the radioactivity hazard should be taken into account. The radioactivity of the plant samples should be checked accordingly to the guidelines of International Atomic Energy (IAE) in Vienna and that of WHO.

In order to obtain quality oriented herbal products care should be taken right from the proper identification of plants; season and area of collection, extraction, isolation and verification process [2, 14, 15]. Chemical and instrumental analyses are routinely used for analyzing synthetic drugs to confirm its authenticity. In the case of herbal drugs, however the scene is different especially for polyherbal formulation, as there is no chemical or analytical method available. Therefore biological-screening methods can be adopted for routine checkup of herbal drugs and formulations. In the case of herbal drugs, the quality of raw materials and products can be furnished by regular pharmacognostic identifications and phyto-chemical analysis. The herbal formulations in general can be standardized schematically as to formulate the medicament using raw materials collected from different localities and a comparative chemical efficacy of different batches of formulation are to be observed. The preparations with better clinical efficacy are to be selected. After all the routine physical, chemical and pharmacological parameters are to be checked for all the batches to select the final finished product and to validate the whole manufacturing process.

Microbiological parameters include total viable content, total mould count, total enterobacteria and their count. Limiters can be utilized as a quantitative or semi quantitative tool to ascertain and control the amount of impurities like the reagents used during abstraction of various herbs, impurities coming directly from the manufacturing vessels, impurities from the solvents, etc. The stability parameter for the herbal formulations includes physical parameters, chemical parameters and microbiological parameters. Physical parameters include colour, appearance, odour, clarity, viscosity, moisture content, pH, disintegration time, friability, hardness, flow ability, flocculation, sedimentation, settling rate and ash values etc. Chemical parameter includes limit tests, extractive values, chemical assays, etc. Chromatographic analysis of herbals can be done using TLC, HPLC, HPTLC and GC, UV, Fluorimetry, GC-MS, etc [16, 17].

2. Conclusion

In the last few decades there has been an exponential growth in the field of herbal medicine and tremendous budge towards the use of medicine of herbal origin. Recently there is a squirt in the interest regarding survival of ayurvedic formulations. In the herbal boom worldwide, it is estimated that high quality phytomedicines will provide safe and effective medication. India can emerge as the major country and play the lead role in production of standardized, therapeutically effective ayurvedic formulation. India needs to explore the medicinally important plants. This can be achieved only if the herbal products are evaluated and analyzed using sophisticated modern techniques of standardization such as UV-visible, TLC, HPLC, HPTLC, GC-MS, spectrofluorimetric and other methods. Recent advances in science and researches proves the use of modern sophisticated instrument is a necessary tool for making pure, tested, valuable natural drugs.

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