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Standardization of herbs and herbal products: The Present Need

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Abstract

Plant derived products are increasingly being sought out as medicinal products, nutraceuticals and cosmetics and are available in health food shops and pharmacies over the counter as self medication or also as drugs prescribed in the non-allopathic systems. According to the World Health Organization (WHO), about 80% of the world population still uses herbs and other traditional medicinesfor their primary health care needs. Herbal medicines widely used in health-care in both developed and developing countries are complex chemical mixtures prepared from plants and are limited in their effectiveness because they are poorly absorbed when taken orally. According to WHO guidelines, an herbs and their product needs to be standardized with respect to safety before launching it into the market. The present paper highlights some important guidelines to assess the medicinal plant.

Key-Words: Herbs, WHO, Standardization

Introduction

A major lacuna in Ayurveda is the lack of drug standardisation, information and quality control. Most of the Ayurvedic medicines are in the form of crude extracts which are a mixture of several ingredients and the active principles when isolated individually fail to give desired activity. This implies that the activity of the extract is the synergistic effect of it's varies components. In the absence of pharmacopeic data on the various plant extracts, it is not possible to isolate or standardize the active contents having the desired effects. Ayurvedic Pharmacopoeia compiled on modern lines and updated periodically is an urgent requirement. Research on the rationale and methodology of Ayurvedic medical practice; isolation of active constituents and their development into new therapeutics; standardisation and validation of known herbal medicines and other related aspects are needed.[12] These are some problems concerning the proper identity of a number of drug species. In many cases, a single plant species has several different commercial or medicinal names in different regions. Several distinct species are often used under the same drug name. Another problem relates to adulteration in the market samples.

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In other words, authentication of the botanical identity and ascertaining the genuineness of drug is great concern in practical situation. To some extent, it can be overcome by drug characterization which is done by estimating their active principles, recording the anatomical features under microscope and their curative effects by clinical trials. When the botanical identity of the plant is controversial, it is better to go for estimation of the therapeutic agent responsible for the curative effect ascribed to the species. The species rich in the ascribed compound should be taken as the genuine drug, those with relatively small amounts may be accepted as substitute of the original drug and those lacking the required constituents may be rejected.[3-5]

Need of QC of herbals

Quality control of the phytoproducts for human consumption and world market can be ensured by maintaining the quality of raw material adequacy of processing technology and quality of the finished products. Thus, the quality concept commences right from the choice of authentic and improved seeds (varieties) to the post harvest treatment of the raw material and to the process control for avoiding contamination. As such for developing phytoproducts, WHO's, Good Manufacturing Practice (GMP) must be followed to satisfy the ISO 9000 certification. Recently, ISO 14000 certification has also become necessary to safeguard the environment. This means

certifying that the product has been developed without inflicting ecological damage whatsoever.

In general, during the drug production process, the raw materials are subjected to macroscopic and microscopic examination and physicochemical parameters such as ash values, analysis of ash for major elements such as Sodium, Potassium and Calcium, alcohol soluble and water soluble extractive values and fluorescence analysis, quantitative estimation of phytoconstituents such as total tannins, total glycosides, total alkaloids, total resins and total sugars of the raw materials as well as the formulations was carried out. The formulations were also evaluated for the general parameters such as organoleptic properties, pH, viscosity, specific gravity, optical rotation and refractive index. High Performance Thin Layer Chromatography (HPTLC) technique was employed to obtain characteristic HPTLC fingerprints of the individual raw materials and formulations. Using the spectral patterns of the separated components, the presence of certain raw materials in the formulations could also be established. Batch to batch variation was also studied using HPTLC *fingerprinting* technique.[6]

The general scheme for quality assurance of crude drugs and raw materials as suggested by Pei-Gen and Hui-zhen[7] is given below.

Importance of quality assurance of crude drugs and raw material

- Guarantee the best final pharmaceutical products
- Environmental protection
- Sustainable utilization and development of natural resource

Criteria of good quality

- Good efficacy- high active ingredient, high yield
- Good safety-less toxicity and side effects, minimum pesticide residues, minimum heavy metals
- Purity
- Stability

Gene bank conservation

- Biodiversity conservation
- To store plant germplasm for future uses
- To make germplasm available to create new cultivars
- *In-situ* conservation- gene banks of medicinal and aromatic plants in Asia, *In-vitro* conservation
- Breeding

Biotechnology

- Plant cell culture eg. *Digitalis, Catharanthus*
- Hairy root culture eg. *Salvia, Glycyrrhiza uralensis, Datura stramoniun, Artemesia annua*
- Tissue culture eg. *Aloe, Crocus sativa, Mentha*
- Genetic engineering: Isolation and purification of an antifungal protein from *Phytolacca americana* against American ginseng pathogens and synthesis of its gene and expression in *E. coli.*

Suitable growth region: In order to get higher quality of crude drugs and raw materials selection of the most suitable growth region for relevant medicinal plant is quite important. According to the ecological conditions, flora and other criteria, several regions of crude drug development have been identified.

GAP: (Good Agrotechnological Practices): Large cultivation of medicinal plants relies upon strong and continuing research. Plant varieties with an abundance of desired constituents can be reproduced and improved upon under cultivation even in an entirely different area. Eg. Cultivation of American ginseng (*Panax quinquefolia*) in China. Attempt should be made to select appropriate region based on similar ecological conditions to introduce good cultivated variety, improve yield of the desired secondary metabolite and reduce the undesirable constituents.

Non polluted cultivation: In order to protect the environment, to sustainably utilise the resources and to get a good quality of crude drug, non-polluted agrotechnology is rapidly developed in recent years. These products are commonly called as "Green crude drugs" This involve biological control of insects and pathogens and use of botanical pesticides for the control of pest and diseases.

Post harvest technology: Right time harvesting, good processing, good storage, extraction or distillation, quality control.

Table 1: Gene banks of medicinal and aromatic plants in Asia

Country	Collection	Institutes
China	2500	IMPLAD Beijing and its 3 stations
India	1400	NBPGR, New Delhi; CIMAP Lucknow; AMPRS
Korea	850	Medicinal plants gardens
Malaysia	450	National Research Council and Kuala Lumpur city
		council gardens
Nepal	340	Royal Botanic Gardens
Philippines	220	University Herbal garden, Los Banos
Sri Lanka	200	Royal Botanic Garden, Kaudy
Thailand	100	Botanic Gardens

Quality control requirement of new preparation of traditional medicines

- Prescription and its basis
- Literature and research data of physico-chemical characteristic concerned with quality
- Preparation technology and its research references
- The draft of the quality standard and explanation of medicinal material, and medicament
- Literature and test data of initial stability for clinical research
- The reports of quality detection and hygiene standard detection of the preparation for clinical research
- Property and specification of the packing material of the medicament, design draft of the label and applied instructions

General requirement of quality control standard of medicament

- Quantitative determination of the effective compound or indicative component of 1-2 species of main medicinal materials in the prescription
- Qualitative identification of several to half of the medicinal materials in the prescription
- Determination of content of Pb, Cd, Hg, As and limit test of heavy metals in medicines
- Hygienic standard: bacteria < 1000/1gm, mould < 100/1gm, colibacillosis-nil
- Determination of pesticide residues (organic Cl and P) in the medicament

The general scheme for quality assessment of botanicals

The general scheme for quality assessment of botanicals as suggested[8] is as follows.

I. Assessment of crude plant materials

- General description of the plant
- Parts used
- Production of crude drugs-cultivation, harvesting, post-harvest handling, packing, storage.
- Quality specification: Chemical or chromatographic identification, foreign organic matter limit, ash content, acid insoluble ash content, water soluble extractive, alcohol soluble extract, moisture content, active constituent content, microbial limit, pesticide residue limit, heavy metal limit, likely contaminants, adulterants.

II. Assessment of finished products

- Tablets: Weight variation, disintegration time, identification of preservatives and active ingredients, determination of extractives in various solvents, microbial limit, heavy metals.
- Solutions: pH, identification of preservatives and active ingredients, alcohol content, microbial limit, Sodium Saccharic content.
- Infusions: Weight variations, identification of preservatives and active ingredients, determination of extractives in various solvents, microbial limit, heavy metals, Borax.

III. Chemical Standardisation methods: TLC/HPTLC, HPLC, GLC, FTIR

IV. Chemical Markers: Specification for raw materials, quality assurance in process control, standardisation of product, obtaining stability profiles, single marker vs. fingerprint.

V. Parameters of assay validation: Linearity, limits of quantification and detection, precision, robustness, recovery.

Complex and variable mixtures, choice of compounds to quantify, difficult sample preparation, lack of pure reference standards, lack of methods with adequate tolerances by analytical chemistry standards are some of the challenges in Chemical Standardisation of plant drugs.

International scheme for quality assurance of pharmaceutics

International scheme for quality assurance of pharmaceutics involves the following standard practices. GAP: Good Agricultural Practice, GLP: Good Laboratory Practice, GMP: Good Manufacturing Practice, GCP: Good Clinical Practice, GALP: Good Analytical/Automated Laboratory Practice

Quality has to be built into the whole process beginning from the selection of propagation material to the final product reaching the consumer. It is therefore a management system where all steps involved in the industrial utilization process have to be properly and strictly controlled to produce the desired quality products. The requirements for ISO 9000 certification have to be introduced and personnel trained so that enterprises could introduce the proper systems needed for certification. The control of the quality of the raw materials, finished products and of processes is an absolute necessity, if one is to produce goods for world markets and human use. Monographs have to be prepared for each product to include all specifications developed. Modern analytical techniques have to be extensively used to develop identity and quality parameters. The machinery and processes used in industries have to be validated to comply with international standards. It is imperative that the processed products comply with national and/or international specification. There is International Standard Organisation Specification (ISO) for many of the products. In addition, countries

and buyers can have their own requirements. Hence, the products could be tailor made to conform to the buyers' requirements. Sometimes the requirements of the buyers are more stringent and specific, demanding the application of good manufacturing procedures. Associated with quality management is the compliance with current good manufacturing practices.

WHO requirements of good manufacturing practices have to be introduced in every project as most developing countries fall very short of GMP. Without GMP products cannot be expected to be of required standards and quality. The concept of safety is almost non-existent in many developing countries. Safety requirements with respect to buildings, machinery and staff have to be introduced and if possible, safety manuals have to be prepared in order to focus the attention of the management and staff on these issues. Stringent requirements are being introduced presently to safeguard the environment, to reduce pollution caused by use of synthetic materials and to conserve the biodiversity. Hence eco-audit procedures will be required for safeguarding environmental damage. Organic production will reduce the risks of contamination of products and the environment with synthetic chemicals. In fact ISO 14000 requirements may have to be met in the future if the buyers insist on eco-labelling.[8]

Conclusion

Standardization of herbal drugs and their products comprises total information and controls to essentially guarantee consistent composition of all herbals including analytical operations for identification, markers and assay of active principles. Different countries define medicinal plants or products derived from them in different ways and have adopted different approaches to licensing, dispensing, manufacturing and trading to ensure their safety, quality and efficacy. Fingerprinting of herbal medicines is utilized for the authenticity and quality control of herbal medicines and herbal preparations. Moreover, all herbal products manufacturers must follow WHO guidelines for quality control. Further, the combination of qualitative fingerprinting and quantitative multicomponent analysis is a novel and rational method to address the key issues of quality control of herbal medicines.

References

1. Kumar, N., M. Abdul Khader, J. B. M., Rangaswami, P. and Irulappan, I. (1997). *Introduction to Spices, Plantation Crops, Medicinal and Aromatic Plants*. Oxford and IBH Publishing Co. Pvt. Ltd., New Delhi.
2. Dwivedi Sumeet (2009). QC of Herbals with special reference to standardization parameters: An overview; Abstract in National Seminar on ***Technological and Regulatory aspects of Herbal Drugs Analysis***, 7-Oct.,2009, Mandsaur, M.P.
3. Kumar, S., Shukla, Y. N., Lavania, U. C., Sharma, A. and Singh, A. K. (1997). Medicinal and Aromatic Plants: Prospects for India. *J. Med. Arom. Pl. Sc.* **19** (2):361-365.
4. Joy, P.P., Thomas, J., Mathew, S., and Skaria, B.P. (2001). Medicinal Plants. *Tropical Horticulture* Vol. 2. (eds. Bose, T.K., Kabir, J., Das, P. and Joy, P.P.). Naya Prokash, Calcutta, pp. 449-632.
5. Need of standardization of Ayurvedic herbs: Present status and future prospects; Abstract in National Seminar on ***Analytical Method Development and Biomedical Analysis,*** organized by B.R.Nahata College of Pharmacy, 28-29.Oct.2010, Mandsaur, M.P.
6. Haq, N. (1993). *Breeding and improvement of medicinal and aromatic plants*. In FAO, 1993.
7. Pei-Gen, X. and Hui-shen, C. (1997). *Quality assurance of crude drugs and raw materials.* In UNDP, 1997.
8. Kraisintu, K. (1997). *Industrial exploitation of indigenous medicinal and aromatic plants: Formulation and industrial utilization*. In UNDP.

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