International Standard Serial Number (ISSN): 2249-6807

International Journal of Institutional Pharmacy and Life Sciences 5(4): July-August 2015

INTERNATIONAL JOURNAL OF INSTITUTIONAL PHARMACY AND LIFE SCIENCES

Pharmaceutical Sciences

Review Article……!!!

Received: 19-05-2015; Revised: 19-07-2015; Accepted: 20-07-2015

A REVIEW ON STANDARDIZATION OF HERBAL DRUGS

Mali Ajay R*, Salunkhe Vijay R, Nikam Vishal T

Department of Quality Assurance, Rajarambapu College of Pharmacy, Kasegaon, Tal. Walwa, Dist. Sangli, Maharashtra, India.

Keywords:

WHO, Herbal formulation, Standardization, Quality control, Nanoherbal drugs, Phytosomes, DNA markers

For Correspondence:

Mali Ajay R

Department of Quality Assurance, Rajarambapu College of Pharmacy, Kasegaon, Tal. Walwa, Dist. Sangli, Maharashtra, India

E-mail:

1490ajaymali@gmail.com

ABSTRACT

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. Pharmacological properties of an herbal formulation depend on phytochemial constituents present there in. Development of authentic analytical methods which can reliably profile the phytochemical composition, including quantitative analyses of market/bioactive compounds and other major constituents, is a major challenge to scientists. An overview covering various techniques employed in extraction and characterization of herbal medicines as well as herbal nanomedicines standardization is reported. In addition, phytosomes increased bioavailability, bhasma as ametal nanobarrier drug delivery system, potential of metabolomics in the development of improved phytotherapeutic agents, DNA based molecular markers in adulterants, and SCAR markers for authentification and discrimination if herbs from their adulterants are reported. Nanotechnology based herbal drugs possess improved solubility and enhanced bioavailability.

INTRODUCTION

Within the context of increased herbal medicines use and lack of effective regulatory control, the safety of herbal medicines has become a key priority issue. Herbal drug technology is used for converting botanical materials into medicines, where standardization and quality control with proper integration of modern scientific techniques and traditional knowledge is important. The new Pharmacognosy includes all the aspects of drug development and discovery, where biotechnology-driven applications play an important role Scientifically validated and technologically standardized herbal medicines may be derived using a safe path of reverse pharmacology approach based on traditional knowledge database. This may play a vital role in drug discovery, development and therapeutics, in addition to dealing with a typical Western bias against Ayurveda.

WHO Guidelines for Herbal Drug Standardization and Evaluation

The WHO guidelines for herbal drugs can be summarized as follows:-

• **Identity of the drug**: Botanical evaluation- sensory characters, foreign organic matter, microscopical, histological, histochemical evaluation, quantitative measurements etc.

Physicochemical character of the drug: Physical and chemical identity, chromatographic fingerprints, ash values, extractive values, moisture content, volatile oil and alkaloidal assays, quantitative estimation protocols etc.

• **Pharmacological parameters**, biological activity profiles, bitterness values, hemolytic index, astringency, swelling factor, foaming index etc.

• **Toxicity details** :- pesticide residues, heavy metals, microbial contamination like total viable count, pathogens like E.coli, Salmonalla, P.aeroginosa, S. aureus, Enterobacteria etc.

• **Microbial contamination**.

• **Radioactive contamination.**

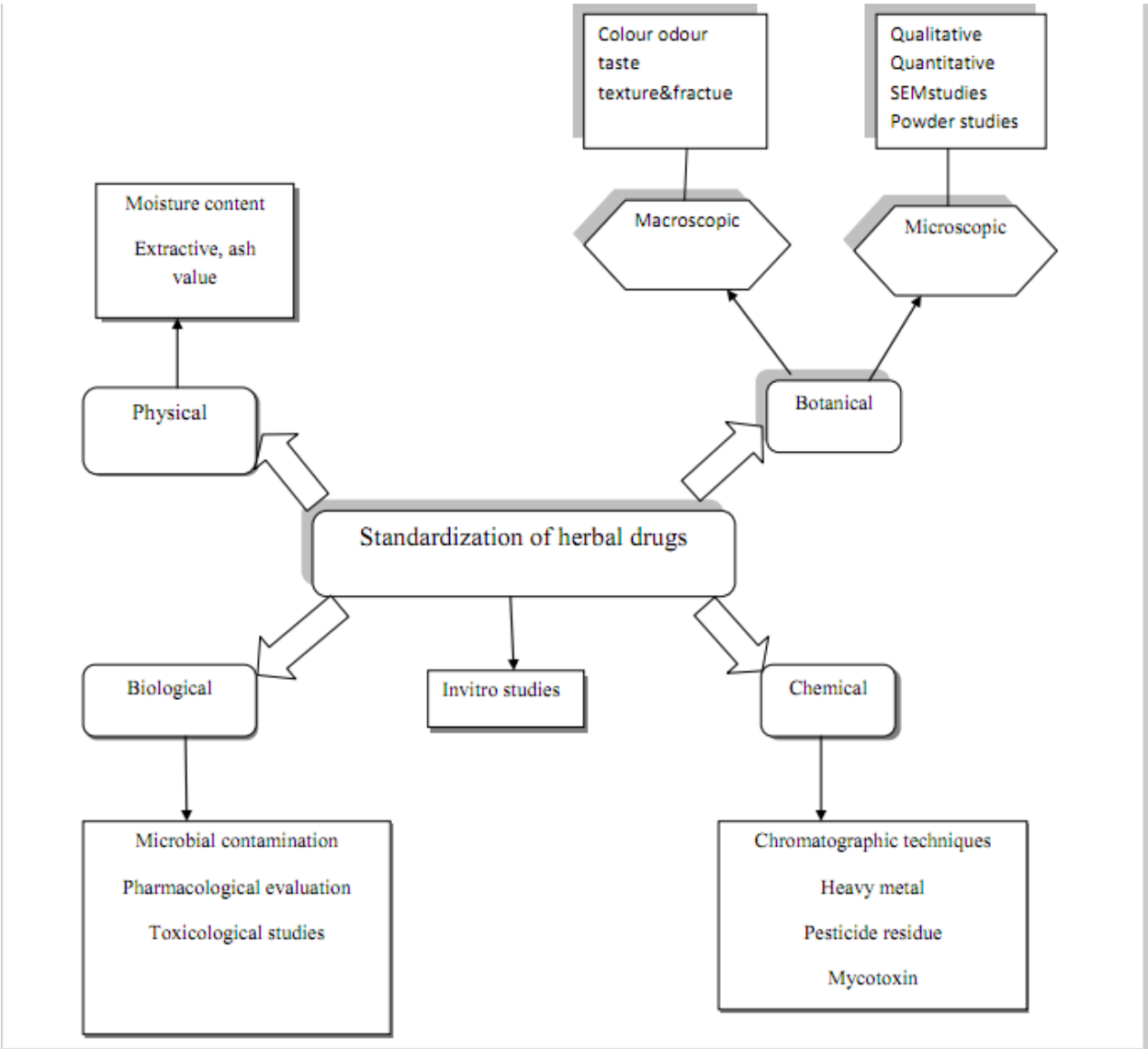

Figure 1. A schematic representation of herbal drug standardization

METHODOLOGY

Methodology is divided into following for the better indulgent:

1. Process standardization
2. Rasausadhis standardization
3. Overview on herbal drug standardization
4. Polyherbal standardization
5. DNA fingerprinting technique
6. Techniques in extraction of herbals
7. Phytosomes/ pharmacosomes: A novel drug delivery system for herbal drugs
8. Instrumental techniques for herbal drug standardization & identification
9. Herbal nanomedicines standardization

Marker compounds as "chemically defined constituents of a herbal drug which are of interest for control purposes, independent of whether they have any therapeutic activity or not"

Marker compounds are pure, single isolated compounds, secondary metabolites mostly with terpene, steroid, alkaloid, flavonoid, aromatic & heteroaromatic frameworks having alcoholic, carbonyl, olefinic, acid, ester & amide functionalities. Marker compounds of ingredients not necessarily the markers for formulations. Some undergo transformations and decompose, vanish or generate new markers. Marker compounds specific to Multiherbal

Markers are categorized in to two classes:

(1**) DNA markers** are reliable for informative polymorphisms as the genetic composition is unique for each species and is not affected by age, physiological conditions as well as environmental factors. DNA can be extracted from fresh or dried organic tissue of the botanical material; hence the physical form of the sample for assessment does not restrict detection .

(2) **Chemical markers** generally refer to biochemical constituents, including primary and secondary metabolites and other macromolecules such as nucleic acids .

DNA Markers: Various types of DNA-based molecular techniques are utilized to evaluate DNA polymorphism. These are hybridization-based methods, Polymerase Chain Reaction (PCR)-based methods and sequencing-based methods.

Applications of molecular markers in herbal drug technology:

DNA-based molecular markers have proved their utility in fields like taxonomy, physiology, embryology, genetics, etc.

• **Genetic variation/genotyping**: RAPD-based molecular markers [10] have been found to be useful in differentiating different accessions of Taxus wallichiana, neem, Juniperus communis L., Codonopsis pilosula, Allium schoenoprasum L., Andrographis paniculatacollected from different geographical regions. Interspecies variation has been studied using RFLP and RAPD in different genera such as Glycerrhiza, Echinacea, Curcuma and Arabidopsis. RAPD has served as a tool for the detection of variability in Jojoba (Simmondsia chinensis L. Schneider), Vitis vinifera L. and tea (Camellia sinesis).

• **Authentication of medicinal plants**: Sequence Characterized Amplified Region (SCAR), AP–PCR, RAPD and RFLP have been successfully applied for differentiation of these plants and to detect substitution by other closely related species. Certain rare and expensive medicinal plant species are often adulterated or substituted by morphologically similar, easily

available or less expensive species. For example, Swertia chirata is frequently adulterated or substituted by the cheaper Andrographis paniculata. Marker assisted selection of desirable chemo types: AFLP analysis has been found to be useful in predicting phytochemical markers in cultivated Echinacea purpureagermplasm and some related wild species DNA profiling has been used to detect the phylogenetic relationship among Acorus calamus chemotypes differing in their essentialoil composition.

• **Medicinal plant breeding**: Molecular markers have been used as a tool to verify sexual and apomictic offspring of intraspecific crosses in Hypericum perforatum, a well known antihelminthic and diuretic.

• **Applications in foods and nutraceuticals**: Roundup ready soybeans, maize and cecropin, capsicum have been successfully discriminated from non-GM products using primers specific for inserted genes and crop endogenous genes.

Chemical markers

The European Medicines Agency (EMEA) defines chemical markers as chemically defined constituents or groups of constituents of an herbal medicinal product which are of interest for quality control purposes regardless whether they possess any therapeutic activity Applications of chemical markers

• Identification of adulterants- An adulterant of gamboges was differentiated from the authentic sample by an HPLC-UV method using eight caged xanthones as chemical markers.

• Differentiation of herbal medicines with multiple sources

• Determination of the best harvesting time

• Confirmation of collection sites

• Assessment of processing methods

• Quality evaluation of herbal parts

• Identification and quantitative determination of proprietary products

• Stability test of proprietary products- Stability test is used to evaluate product quality over time and determine recommended shelf life.

• Diagnosis of herbal intoxication- Toxic components may be used as chemical markers in screening methods, e.g. rapid diagnosis of acute hidden aconite poisoning in urine samples by HPLC-MS.

• Lead compounds for new drug discovery- The components responsible for the therapeutic effects may be investigated as lead compounds for new drug discovery.

Chromatographic and **Spectroscopic technologies** are still two main methods for establishing the fingerprint, including TLC, HPLC, GC, CE, IR, NIR, NMR, as well as DNA fingerprinting. Nowadays, more and more hyphenated technologies are used such as GC-MS, HPLC-MS, HPLC-DAD-MS, and LC-NMR. Especially, the hyphenation of MS with HPLC or GC has been a very useful means to the chemical constituents' analysis, quality control and metabolite studies, etc. [23-27]. Sometimes, a single fingerprint is inadequate for the effective analysis of complex herbal medicine, so multiple chromatographic fingerprints with different test conditions in the same or different separation principles have been proposed.

CONCLUSION

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. These guidelines for the assessment of herbal medicines are intended to facilitate the work of regulatory authorities, scientific bodies and industry in the development, assessment and registration of such products. The assessment should reflect the scientific knowledge gathered in that field. Such assessment could be the basis for future classification of herbal medicines in different parts of the world. Other types of traditional medicines in addition to herbal products may be assessed in a similar way.

ACKOWNLEDGEMENT

We express sincere thanks to the Principal and Vice-Principal of Rajarambapu College of Pharmacy, Kasegaon to providing necessary facilities to carry out the research work.

REFERENCES

1. Sapna Shrikumar, Ravi T.K., Pharmacognosy Reviews, 2007, Vol 1(1).
2. Peter Goldman, Herbal Medicines Today and the Roots of Modern Pharmacology, Academia Clinic, 2001.
3. Pulok K. Mukherjee, Atul Wahil, Drug Information Journal, 2006; Vol. 40, 131–139.
4. K.K. Bhutani. Finger-Printing of Ayurvedic Drugs, The Eastern Pharmacist, 2000; 21-26.
5. Indian Herbal Pharmacopoeia, Indian Drug Manufacturers' Association, Mumbai, 2002.
6. British Herbal Pharmacopoeia, British Herbal Medicine Association, 1996.
7. Quality Control Methods for Medicinal Plant Materials, WHO, Geneva, 1998
8. Satheesh Madhavi NN, Kumud Upadhya, Asha Bishti. Phytochemical screening and standardization of poly herbal formulation for Dyslipidemia. Indian journal of physiology and pharmacology, 2011; 3(3).
9. Sunita Panchawat, Sisodia Nema RK. Standardization and evaluation of herbal drug formulations, 2010.