

An Overview on Herbal Drug Standardization

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Abstract

Herbal medicine has been utilized in many diseases from ancient time. 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. Standardization is an essential measurement for ensuring the quality control of the herbal drugs. These days various modern techniques for determination of Ash values, Extractive value, Swelling index, TLC, HPTLC etc., which are very essential to assess quality of herbal drugs, are being developed. The present article reviews the importance, scope of some standardization techniques for maintaining and assessing the quality and safety of the herbal drugs and herbal formulations.

Keywords

Herbal drugs, Standardization, Scope of Standardization, Standardization techniques



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INTRODUCTION

In ancient time, *Vaidyas* themselves used to collect drug, processed them according to therapeutic requirements. One of the major problems faced by the Ayurveda physicians these days is the unavailability of unique quality control parameters for herbal medicines and their formulations. Standardization of herbal drug and their formulations is an important step for the establishment of a consistent biological activity, a consistent chemical profile or simply a quality assurance program for production and manufacturing of herbal drugs. India can emerge as the major country and play the lead role in the production of standardization therapeutically effective Ayurvedic formulations. There are around 6000 herbal manufacturers in India. More than 4000 units are producing Ayurveda medicines and for that the Drugs and Cosmetics Act, 1940 are governed in India. and the provisions of the Act

are implemented by various state governments. The 1st Indian National Health Policy 1983 claims that India is the richest source of herbs and the drug should be standardized¹. In India, the department of AYUSH, Govt. of India launched a central scheme to develop standard operating procedures for the manufacturing process to develop Pharmacopeia standards for Ayurvedic preparations.² The subject of herbal drug standardization is massively wide and deep. "Standardization" expression is used to describe all measures, which are taken during the manufacturing process and quality control leading to a reproducible quality.³

ANCIENT METHODS FOR DRUG STANDARDIZATION⁴-

- 1) *Dravyasangrahal* (Collection time)- Some drugs are seasonal as well as specific part of herb should collect in specific *Rutu* (Season).
- 2) *Deshvichar*- Availability of some drugs in specific area. The

potency of drugs varies according to Desha. Drugs collected from Himalaya have greater therapeutic value.

- 3) *Dravyashodhan-* i.e. purification of herbal drugs before it is released for use without the fear of toxicity and contamination. E.g. Vastanabh, Gunja, Kuchla
- 4) Indications for using dry drugs and wet drugs.

WHO GUIDELINES FOR QUALITY STANDARDIZED HERBAL FORMULATIONS⁵

- 1) Quality control of crude drugs materials, plant preparations and finished products.
- 2) Stability assessment and shelf life.
- 3) Safety assessment documentation of safety based on experience or toxicological studies.
- 4) Assessment of efficacy by ethanomedical information and biological activity evaluation.

AN OVERVIEW OF THE PROCESS OF STANDARDIZATION⁶-

- 1) GSL (Good survey of literature)- Pass part data of raw plant drug.
- 2) GCP (Good clinical practice)- Study on the medicines part.
- 3) GHP (Good harvesting/handling practice)- Collection details.
- 4) GLP (Good laboratory practice)- Organoleptic evaluation of raw drugs.
- 5) GAP (Good agricultural practice) – Correct taxonomic identification and authentication.
- 6) GMT (Good marketing techniques) – Evaluation of chemical composition of drug.
- 7) GMP- Microscopic and Molecular examination.

DRUG STANDARDIZATION METHODS^{7,8}-

The standardization of crude drug material includes the following steps-

- 1) Macroscopic and Microscopic study

- 2) Foreign matter
- 3) Moisture content
- 4) Ash values
- 5) Extractives value
- 6) Swelling index
- 7) Foaming index
- 8) pH value
- 9) Spectrophotometry
- 10) TLC
- 11) HPTLC
- 12) Phytochemical analysis

1) Authentication- It involves macroscopic and microscopic study of herbal drug. Macroscopic identity of medicinal plant materials is based on evaluation of parameters like shape, size, colour, texture, odour, taste while microscopy includes qualitative, quantitative and microscopically measurements.

2) Foreign matter- Plant materials should be entirely free from visible signs of contamination by moulds or insects and other animal

contamination including animal excreta.

3) Moisture content- It is especially important for materials that absorb moisture easily or deteriorate quickly in the presence of water. Limits for water content should be set for every given plant material.

4) Ash values- It is used to determine foreign inorganic matter present as an impurity. The ash remaining following ignition of herbal drug materials and it is determined by three different methods such as Total ash, Acid insoluble ash, Water soluble ash.

5) Extractive values- It gives idea about the nature of the chemical constituents present in crude drugs. It is employed for material for which as yet no suitable chemical or biological assay exists.

6) Swelling index- It is useful in the evaluation of crude drugs containing mucilage.

7) Foaming index- Plant materials containing Saponins is evaluated by measuring the Foaming ability in term of foaming index.

8) pH values- The pH value conventionally represents the acidity or alkalinity of an aqueous solution of plant material.

9) Spectrophotometry- It is commonly applied instrumental technique for qualitative and quantitative analysis of drugs. The chemical constituents of drugs absorb light of different wavelength in different proportion when extracted in different solvents are measured.

10) TLC (Thin Layer Chromatography)- It is common fingerprint method. Particularly valuable for the qualitative determination of small amount of ingredients.

11)HPTLC (High performance thin layer chromatography)- This technique is widely employed in pharmaceutical industry in process

development, identification, detection of adulterants in herbal product.

12) Phytochemical analysis- The Phytochemical analysis of plant material used to know the broad chemical nature of the active principles such as alkaloids, proteins, lipids, reducing sugar, Tannins etc.

DISCUSSION AND CONCLUSION

Standardization is an important aspect for maintaining and assessing the quality safety of the herbal drugs and their formulations to attain the desire therapeutic effect. The subject of herbal drug standardization is massively wide and deep. The present article is provided an information and scope of some important techniques of standardization such as Ash value, Extractive value, Moisture content, Swelling index, Foaming index, Spectrophotometry, TLC, HPTLC etc.

In order to obtain quality oriented herbal products employment of Ayurvedic as well as modern techniques of Standardization are very necessary. An overview coverings latest development in the standardization of Ayurvedic drugs.

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