

NEED OF HERBAL DRUG STANDARDIZATION

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ABSTRACT

Majority of Ayurvedic practitioners uses traditional herbal preparations for their treatment purposes made by them. So it is necessary to improve safety of herbal drugs by developing certain quality control parameters & by following the WHO guidelines for herbal medicines. Our ancient books have mentioned many methods to standardize drug and also about adulteration. Now days, old methods are necessary but there are lots of limitations to these methods due to shortage of many drugs, unavailability or limited source, adulteration, lack of knowledge of drug identification and adverse effects of drugs etc.

Today physician is totally depending upon mediators for drug collection. Adulteration, substitution, ignorance of dealers creates problem. So there is need to standardize Ayurvedic herbal preparations.

There are different newer techniques to standardize raw drugs & finished products. This can be achieved only if herbal products are evaluated & analyzed using sophisticated modern techniques standardization such as UV visible, TLC, HPTLC, GCMS, Spectrofluorometric & other methods as Phyto-chemical constituents, fingerprinting content, appearance, pH, viscosity, refractive index, Saponification value & spread ability etc.

Controlled trails are necessary to establish safety, efficacy & manufacturing standards are required to ensure product quality.

Keywords: herbal drugs, safety, Authentication, techniques, controlled trails.

INTRODUCTION

Standardization of herbal formulations is essential to assess quality of drugs. It is based on the concentration of their active principles, physical, chemical, Phyto-chemical, and In-vitro, In-vivo parameters¹. The quality assessment of herbal formulations is important to justify their acceptability & safety. One of the major problems faced by the Ayurveda physicians is the unavailability of unique quality control parameters for herbal medicines and their formulations.

In India, the department of AYUSH Government of India launched a central scheme to develop standard operating procedures for the manufacturing process to develop pharmacopeia standards for Ayurvedic preparations². The subject of herbal drug standardization is massively wide and deep. There are so many contradictory theories on the subject of herbal medicines and their functions on 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.

SOME ANCIENT METHODS FOR STANDARDISATION:

Collection time³: Rutu, i.e. some drugs are seasonal as well as some parts of herb should collect in specific Rutu.

Desha: Availability of some drugs in specific area e.g. Himalaya, so geographical distribution is important one.

Nakshtra: Collection of some drugs should be done on specific Nakshtra.

Indications for using dry drugs & wet drugs.

WHO GUIDELINES FOR QUALITY STANDARDIZED HERBAL FORMULATIONS⁴

1) Quality control of crude drugs material, 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 ethno medical information and biological activity evaluations.

METHODS OF STANDARDISATION OF AYURVEDIC DRUGS⁵:

- Raw material standardization.
- In process standardization
- Finished product standardization.

1. RAW MATERIAL STANDARDIZATION:

This includes Authentication process in which following points should be considered. Area of the collection, parts of the plant collection, the regional situation, botanical identity, microscopic and histological analysis, 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 is as follows⁶:

- **Pharmacognostic evaluation-**

It includes Color, odor, taste, texture, size, shape, microscopically characters, Histological parameters etc.

- **Physico-chemical parameters:**

It includes foreign matter, Disintegration time, total ash, friability, acid-insoluble ash, hardness swelling and foaming index flow capacity, assay, flocculation, successive extractive values sedimentation, moisture content, alcohol content, Viscosity, pH etc.

- **Chemical parameters**

It includes limit tests, Chemical tests etc.

- **Chromatographic and spectroscopic analysis**

It includes TLC, HPLC, HPTLC, GC, UV, IR, FT-IR, AAS, LC-MS, GC-MS, fluorometry etc.

- **Microbiological parameters**

It includes the full content of viable, total mould count, total coli forms count.

2. IN PROCESS STANDARDIZATION⁷:

In Process preparation of Ayurveda formulation should have standard parameters. The manufacturing procedure should be described in detail. If other substances are added during manufacture in order to adjust the plant preparation to a certain level of active or characteristics constituents or, the added substances should be mentioned in the manufacturing procedures. A method for identification and, where possible, assay of the plant preparation should be added. If identification of an active principle is not possible, it should be sufficient to identify a characteristic substance or mixture of substances to ensure consistent quality of the preparation.

3. FINAL PRODUCT

Prepared drug should possess standard nature of characteristics. The manufacturing procedure and formula, including the amount of excipients, should be described in detail. A finished product specification should be defined to ensure consistent quality of the product. The finished product should comply with general requirements for particular dosage forms.

Stability:

The physical and chemical stability of the product in the container in which it is to be marketed should be tested under defined storage conditions shelf life should be established.

Safety assessment:

Herbal medicines are generally regarded as safe based on their long-standing effect. But the toxicity has been traced to contaminants and adulteration. However, some of the plants used in herbal medicines can also be highly toxic, so assessment of the safety of herbal products, therefore, is the first priority in herbal research.

DISCUSSION

In field of drug research there is large scope for Ayurvedic Researchers, as India is the major country and can 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. 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 advancement of analytical techniques will serve as a rapid and specific tool in the herbal research, thereby, allowing the manufacturers to set qual-

ity standards and specifications so as to seek marketing approval from regulatory authorities for therapeutic efficacy, safety and shelf- life of herbal drugs. The effective regulation and control of herbal medicines moving in international commerce also requires close liaison between national institutions that are able to keep under regular review all aspects of production and use of herbal medicines. As well as to conduct or sponsor evaluative studies of their efficacy, toxicity, safety, acceptability, cost and relative value compared with other drugs used in modern medicine.

CONCLUSION

Now a day's Ayurveda practitioners are totally depends upon mediators for drug collection. Proper identification of drug, adulteration, and availability are major problems faced by herbal industry. Actual availability of drug & finished products which are available in market; proportion of this is a big question mark. Some Ayurveda practitioners prepare their own medicines, so raw drugs used & quality of product which is prepared differs and it is questionable. So it is necessary to conduct uniform rules for preparing drug.

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