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STANDARDIZATION OF PLANT MATERIAL IN HERBAL PRODUCTS – A REVIEW

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Abstract
The plant drug used for treating various aliments is accepted across the herbal medicinal practitioner whereby more than 80% of the world population uses the herbal medicines. The increase in the utilities of herbal products leads to the rise in the adulteration of the products. Therefore, the protocol of the standarization for the plant material collection, transportation, handling, processing and production of herbal medicine is required.

Keywords: Phytochemicals, herbal medicine, standardization, quality control

Introduction

India is known for its traditional medicinal systems started with Ayurveda and later added Siddha and Unani system of curing. The Ayurvedic concept evolved between 2500 and 500 BC in India (Subhose et *al.*, 2005; Lone *et al.*, 2012). Humans recognized their dependence on nature for a healthy life and since that time humanity has depended on the diversity of plant resources for food, clothing, shelter and medicine to cure various ailments. Illness treated by using plants, animal parts, and minerals that were not part of their usual diet. Researchers of the time learned by trial and error to distinguish useful plants with beneficial effects whereby the knowledge of plant based drugs developed and passed gradually laying the base for many systems of traditional medicine all over the world. In some communities herbal medicine is still a central part of their medical system. Herbal medicines are being used by about 60 percent of the world's population (Ackerknecht, 1973). These medicines are not only used by the rural masses for their primary health care in developing countries but are also used in developed countries where modern medicines dominate.

Quality control and standardization of herbal medicines – concept and scope

Products made from botanicals, or plants,by means of simple processes involving harvesting, drying, and storage and used to treat diseases or to maintain health are called *herbal* products. The variability in various parameters is caused by differences in growth, altitudinal gradients, harvesting period, mode of transportation and storage conditions (Kunle *et al.*, 2012). Standardization of herbal medicines is the process of prescribing a set of standards wherein constant parameters, definitive qualitative and quantitative values shall carry an assurance of quality, efficacy, safety and reproducibility. It is the process of developing and agreeing upon technical standards of raw material, which shall lead to the process of prescribing a set of characteristics exhibited by the particular plant material (Pandey *et al.*, 2005). Hence, the standardization is a tool in the quality control.

Issues affecting the quality of herbal drugs. For instance:

1. Herbal drugs are usually mixtures of many phytochemical constituents.
2. The active constituents in most cases unknown.
3. Unavailability of reference compounds commercially.

4. Chemical variability of plant materials in natural state.
5. Existence of Chemo-varieties and chemo cultivars.
6. Variability of the source and quality of the raw material.

Standardization Perspective

The methods of harvesting, drying, storage, transportation and processing affect the quality of herbal medicine (Wani 2007; Parasuraman *et al.,* 2014). The cardinal responsibility of the regulatory authorities is to ensure the users purity, safety, potency and efficacy following various standards of quality prescribed for raw materials as well as finished products in pharmacopoeias, formularies and manufacturing operation for good manufacturing practices, good agriculture practices, good transportation and storage conditions. The quality of herbal medicine is the profile of the constituents in the final product ensuing the safety and quality (Patwardhan, 2014; Tade *et al.*, 2021). However, the quality control process in the the plant matrix of plant-based drugs is difficult to establish though modern analytical technique are expected to help in circumventing this problem. Batch to batch variation starts from the collection of raw material itself in the absence of any reference standard for identification (Parasuraman *et al.*, 2014). Hence, the process of standardization must encompass the entire field from the cultivation of medicinal plant to its final product's use.

Quality Control Of Raw Materials – Processes And Procedures

The quality standardization is the process of physicochemical evaluation of crude drug pertaining to the selection and handling of raw material (WHO, 2003; AOAC, 2005). It deals with the safety, efficacy, documentation of safety and risk based on experience, provision of product information to consumer and product promotion. The quality parameters are as under:

1. **Physical &Microscopic examination**: For Identification of right variety and identification of physical adulterants such as similar looking plants or plant parts.
2. **Foreign organic matter**: Removal of matter other than raw plant to obtain pure drug.
3. **Ash values**: For purity of crude drug's identity.
4. **Moisture content**: Checking moisture content helps in reducing the errors in estimation of the actual weight of drug material. For instiance, the low moisture means the better stability of the plant drug.
5. **Extractive values**: These are indicative weights of the extractable phytochemical constituents of crude drug under different solvents environment& temperature condition.
6. **Crude fibre**: For determining the woody material component.
7. **Qualitative chemical evaluation**: Phytochemical screening techniques involve botanical identification, extraction with suitable solvents at suitable temperature, purification, and characterization of the active constituents with the help of various chemical and analytical techniques. This also involves in identification of major phytochemical constituents as markers.
8. **Quantitative chemical evaluation**: To estimate the amount of the major classes of phytochemical constituents by applying various chemical and analytical techniques.

9. **Microbial assay**: This involves in establishing the absence or presence of potentially harmful microorganisms
10. **Toxicological studies**: It helps to determine the studies like pesticide residues, potentially toxic elements, LD50 etc.

The processes mentioned above involves wide array of scientific investigations, which include physical, chemical and biological evaluation employing various analytical techniques, methods and tools.

Conclusions

Plant materials are used in India as well as in whole world as home remedies, which is the beneficial aspect. Therefore, the guidelines for the quality assurance is essential internationally to get rid of the indiscriminate use herbs. Such initiative shall be a guiding principle for the global acceptance of its use. Thus, the following the WHO guidelines pave a universal approach for the herbal drug quality assurance.

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