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Herbal Drugs in India And Their Standardization

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ABSTRACT

Herbal medicines are the oldest remedies known to mankind. Herbs had been used by all cultures throughout history but India has one of the oldest, richest and most diverse cultural living traditions associated with the use of medicinal plants. In the present scenario, the demand for herbal products is growing exponentially throughout the world and major pharmaceutical companies are currently conducting extensive research on plant materials for their potential medicinal value. In many journals, national and international, we find an increasing number of research publications based on herbal drugs. Many analysis-based studies regarding pharmacological research in India have been conducted in the past. Out of these, one study has shown an upward trend in indigenous drug research but there are only few studies on the exclusive analysis of herbal drug research in India. Therefore, the present review was done to analyze the recent trends of herbal drug and their standardization in India.

Keywords: Herbal medicines, Ayurveda, Medicinal plants, potential medicinal value.

1. INTRODUCTION

Since ancient times a number of Indian medicinal plants have been used globally. There are many references to Indian medicinal plants and trade in spices in a number of historical documents. Herbal medicine has been used in India for thousands of years and is increasingly been used worldwide during the last few decades as evidenced by rapidly growing global and national markets of herbal drugs. Due to high prices and harmful side effects of synthetic drugs, people rely more on herbal drugs and this trend is growing, not only in developing countries but in developed countries too. India has 2.4% of world's area with 8% of global biodiversity. The forests of India are estimated to harbour 90% of India's medicinal plants diversity in the wide range of forest types that occur. The diverse approaches to herbal drugs have led to interesting hits and novel activities, which need further in depth drug development efforts, both as herbal as well as new single molecule drugs. Examples of successful companies, such as Himalaya Drug Company (HDC), Emami, Aswini, Ayur, Dabur, Chodayil Pharma, etc., that have patented their herbal and ayurvedic products in India and abroad^{1,2}.

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1.1 Advantages of Herbal Medicine

1. Herbal medicine have long history of use and better patient tolerance as well as acceptance.
2. Medicinal plants have a renewable source, which is our only hope for sustainable supplies of cheaper medicines for the world growing population.
3. Availability of medicinal plants is not a problem especially in developing countries like India having rich agro-climatic, cultural and ethnic biodiversity.
4. The cultivation and processing of medicinal herbs and herbal products is environmental friendly.
5. Prolong and apparently uneventful use of herbal medicines may offer testimony of their safety and efficacy.
6. Through out the world, herbal medicine has provided many of the most potent medicines to the vast arsenal of drugs available to modern medical science, both in crude form and as a pure chemical upon which modern medicines are structured.

1.2 Limitations of Herbal Medicines

The prominent limitations of herbal medicines can be summarized as follow

1.2.1 Ineffective in acute medical care

As may be observed, herbal medicines are not varying effective to treat any acute illness. As most of the medicines are designed to work at molecular level of physiology, the drug takes its time to deliver the results.

1.2.2 Inadequate standardization and lack of quality specifications

This is the most often criticized aspect of herbal medicines. One important fact is that a herbal medicines. One important fact is that a herbal preparation is administered for its holistic value. Standardization of herbal drugs by known marker compounds may not be complete answer.

1.2.3 Lack of scientific data

Literature on herbal medicines, lack of scientific data in support of the medicinal activity claimed and their safety and efficacy assumed. Hence there is a need to incorporate certain parameters of the pharmacological evaluation of moderns on modern lines^{3,4,5}.

2. HERBAL DRUG STANDARDIZATION AND EVALUATION

In recent years, there has been great demand for plant derived products in developed countries. These products are increasingly being sought out as medicinal products, nutraceuticals and cosmetics. There are around 6000 herbal manufacturers in India. More than 4000 units are producing Ayurveda medicines. Due to lack of infrastructures, skilled manpower reliable methods and stringent regulatory laws most of these manufacturers produce their product on very tentative basis. In order to have a good coordination between the quality of raw materials, in process materials and the final products, it has become essential to develop reliable, specific and sensitive quality control methods using a combination of classical and modern instrumental method of analysis. Standardization is an essential measurement for ensuring the quality control of the herbal drugs. "Evaluation" of a drug means confirmation of its identity and determination of its quality and purity and detection of its nature of adulteration.

Standardization of herbal drugs is not an easy task as numerous factors influence the bio efficacy and reproducible therapeutic effect. In order to obtain quality oriented herbal products, care should be taken right from the proper identification of plants, season and area of collection and their extraction and purification process and rationalizing the combination in case of polyherbal drugs⁶.

3. NEED OF STANDARDIZATION

The quality control of crude drugs and herbal formulations is of paramount importance in justifying their acceptability in modern system of medicine. But one of the major problems faced by the herbal drug industry is nonavailability of rigid quality control profile for herbal material and their formulations. Quality controls of synthetic drug offer no problems with very well defined parameters of analysis. In contrast, herbal products represent a number of unique problems when quality aspects are considered. These are because of the nature of the herbal ingredients present therein, which are complex mixtures of different secondary metabolites that can vary considerably depending on environmental and generic factors. Thus batch to batch variation starts from the collection of raw material itself in the absence of any reference standard for identification. These variations multiply during storage and further processing.

The task of lying down standards for quality control of herbal crude and their formulation involves biological evaluation

for a particular disease area, chemical profiling of the material and laying down specification for the finished product. Therefore, in case of herbal drugs and product, the word "Standardization" should encompass entire field of study from cultivation of medicinal plant to its clinical application.

4. METHOD OF STANDARDIZATION

The Standardization of crude drug materials includes the following steps

4.1 Macro and Microscopic Examination

For Identification of right variety and search of adulterants.

4.2 Foreign Organic Matter

Remove of matter other than source plant to get the drug in pure form.

4.3 Ash Values

It is criteria to judge the identity and purity of crude drug - Total ash, sulfated ash, water soluble ash and acid insoluble ash etc.

4.4 Moisture Content

To check moisture content helps prevent degradation of product.

4.5 Extractive Values

These are indicating the approximate measure of chemical constituents of crude drug.

4.6 Crude Fiber

To determine excessive woody material Criteria for judging purity.

4.7 Qualitative Chemical Evaluation

It covers identification and characterization of crude drug with respect to photochemical constituent.

4.8 Chromatographic Examination

Include identification of crude drug based on use of major chemical constituent as marker.

4.9 Qualitative Chemical Evaluation

Criteria to estimate amount the major class of constituents.

4.10 Toxicological Studies

Pesticide residue, potentially toxic elements, and Microbial count approach to minimize their effect in final product.

4.11 Physical evaluation

Each monograph contains detailed botanical, macroscopic and microscopic descriptions of the physical characteristics of each plant that can be used to insure both identity and purity.

4.12 Microscopic evaluation

Microscopic analyses of plants are invaluable for assuring the identity of the material and as an initial screening test for impurities. Ideally, submitted materials should be in their whole or semi-whole (cut) form for microscopic assessment.

4.13 Chemical evaluation

A chemical method for evaluation covers the isolation, identification and purification. Chemical analysis of the drug is done to assess the potency of vegetable and animal source material in terms of their active principles.

4.14 Biological evaluation

Pharmacological activity of certain drugs has been applied to evaluate and standardize them. The assays on living animal and on their intact or isolated organs can indicate the strength of the drug or their preparations. All living organism are used, these assays are known as Biological assays or Bioassay.

4.15 Analytical Methods

Critical to compliance with any monograph standard is the need for appropriate analytical methods for determining identity, quality, and relative potency. There are a plethora of analytical methods available.

4.16 Chromatographic Characterization

Chromatographic separations can be carried out using a variety of supports, including immobilized silica on glass plates (thin layer chromatography), very sensitive High Performance Thin Layer Chromatography (HPTLC), volatile gases (gas chromatography), paper (paper chromatography) and liquids which may incorporate hydrophilic, insoluble molecules (liquid chromatography).

4.17 Purity Determination

Each monograph includes standards of purity and other qualitative assessments which include when appropriate: foreign matter, ash, acid-insoluble ash, moisture content, loss of moisture on drying, and extractives.

4.18 Quantitative Analysis

The primary goal of the method(s) is to provide validated methods to be used for the quantization of the compound(s) most correlated with pharmacological activity or qualitative markers as determined by the primary pharmacological literature, constituent declaration in product labeling, and a survey of experts. [7, 8, 9, 10]

5. INTERNATIONAL MARKET SCENARIO OF TRADITIONAL HERBAL PRODUCTS

A huge opportunity in the international market awaits the ingenious Indian pharmaceuticals, to be availed through innovation, patents and trademarks. India has enormous resources of medicinal and herbal plants. The pre-historic knowledge of Ayurveda and its applications to cure illnesses effectively has not been explored fully by India. If this happens successfully, India could gain a very significant competitive edge in the global market, especially in the pharma, beauty care and healthcare segments. There is a lot of scope for India to achieve global leadership through export of quality produce and products from medicinal and aromatic plants. But India seems to be lagging behind and is ranked third in the herbal medicine category, with less than 2% of global market share, while China occupies nearly 30% of the market. The major reasons may be:

- Globally, Chinese herbs are more preferred probably because of the research which the western countries are conducting on these herbs. As in India, the medicinal herbs hardly undergo 'double blind trials' to establish their real usefulness. The scientific base for Indian herbal medicines is lacking.
- China has been willing to actively export its medical system. Under government sponsorship, China produced translated books and sent them to America. By contrast, the Indian government is not involved in export of Ayurveda and few Indian writers have made an effort to have their books published for an American audience.
- The most heavily promoted traditional Ayurvedic practice is Panchakarma (a purification procedure). In the USA, it is offered as a several day event (requiring the person to make a major change in their normal schedule and habits) that has a high expense leaving it open only to the wealthy. In contrast, an acupuncture session usually lasts

about half an hour and can be fit into most schedules, and it has a modest cost per session.

- Further, the quality of herbal materials from China has been better than those from India in many instances (due to differences in quality control procedures). Quality control, standardization, scientific methods of production and evaluation were completely missing in India. China has successfully overcome such difficulties by modernizing its traditional medicine profession with government-sponsored GAPs and Good Manufacturing Practices (GMPs). [11, 12, 13, 14]

6. CONCLUSION AND FUTURE PROSPECTS

In India more than 70% of the population uses herbal drugs for their health. There is a vast experience-based evidence for many of these drugs. There are also a number of Institutes/Universities in India carrying our research on herbal drugs and medicinal plants. Using 'reverse pharmacological' approach, several Institutes carry out basic and clinical research on the potential health benefits of herbal drugs. There are many successful examples in this direction. These herbal drugs and Indian medicinal plants are also rich sources of beneficial compounds including antioxidants and components that can be used in functional foods. Newer approaches utilizing collaborative research and modern technology in combination with established traditional health principles will yield rich dividends in the near future in improving health, especially among people who do not have access to the use of costlier western systems of medicine.

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