

Medicinal Plants And Its Standardization – A Global And Industrial Overview

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ABSTRACT

Over the last few decades the role of medicinal plants as a primary tool in the preservation of health and management of diseases is realized with great concern. Since the use of synthetic drug molecules that produce harmful side effects. Medicinal plants are commonly available in abundance, especially in the tropics. Plants are valuable for modern medicine in four basic ways, they are used as a source of direct therapeutic agents, serve as a raw material base for elaboration of more complex semisynthetic chemical compounds; the chemical structures derived from plant sources can be used as models for new synthetic compounds and finally medicinal plants can be used as taxonomic markers for the discovery of new compounds. Herbals have contributed significantly to allopathic medicinal armory. Some of the drugs used today (e.g., aspirin, codeine, morphine, vinblastine, vincristine, Pilocarpine, cocaine, atropine, emetine and ephedrine) have originated from medicinal plants (Bevill, R.L., *et al.*, 1999). It has been estimated that approximately one fourth of the prescriptions dispensed from community pharmacies in the United States contain one or more ingredients derived from plant origin (Blumenthal, M., *et al.*, 1998). Around 80% of all contemporary pharmaceuticals are derived directly or indirectly from plant sources. Quality control and standardization of herbal medicines involve several steps. However, the source and quality of raw materials play a pivotal role in guaranteeing the quality and stability of herbal preparations.

Key words: Medicinal plants, Standardization of herbal medicines, Quality control.

Introduction

India is sitting on a goldmine of well-recorded and traditionally well practiced knowledge of herbal medicine. This country is the largest producer of medicinal herbs and is rightly called the Botanical garden of the world. India officially recognizes over 3000 plants for their medicinal value. It is generally estimated that over 6000 plants in India are in use in traditional, folk and herbal, representing about 75% of the medicinal needs of the third world countries (Bauer, R & G. Tittel, 1996).

WHO has defined Herbal Medicine as a "Finished, labeled medicinal products that contain as active ingredients aerial or underground parts of plants, or other plant material, or combinations thereof whether in the crude state or as plant preparations. Plant material includes juices, gums, fatty oils, essential oils, and any other substances of this nature.

Herbal medicines may contain excipients in addition to the active ingredients. Medicines containing plant material combined with chemically defined active substances, including chemically defined, isolated constituents of plants are not considered to be herbal medicines. Exceptionally, in some countries herbal medicines may also contain, by tradition, natural organic or inorganic active ingredients which are not of plant origin". (Copper, j., S.J. Gunn, Carter, 1986).

Bio-prospecting and Bio-Piracy:

Bio-prospecting, at present, occurs in an environment of suspicions and growing tensions between the bio-piracy and rights of sharing benefits between the developing and developed countries. Most of the issues relating to the protection of the legal status for indigenous knowledge and compensation of the indigenous herbal practitioners for that knowledge are extremely complicated (Chaudhary, R.D., 1996). There are arguments for the present state of compensation or benefit sharing under the intellectual property rights, which is being considered a new legal form of bio-piracy by one group, whereas other groups argue that the intellectual property right is a legal tool to protect the rights of knowledge holders. (Calixto, J.B., 2000).

The Indian Protection of Plant Varieties and Farmers Rights Act of 2001 recognize the contribution of farmers who actively participate in the breeding programs. Furthermore, this act contains provisions for benefit sharing whereby local communities are acknowledged as a contributor of plants. (Chandra Prakash Kala, *et al.*, 2006)

Unfortunately, there is a wide gap between developed and developing nations such as India on patenting the products. For example, out of the 3,125,603 patents filed in 91 countries, only 301,177 or 9.6% are registered in developing countries while the rest is in industrialized countries. Of these, only 0.2% of the total and 2.3% of

those registered in developing countries belong to residents. In addition, 97.7% of the total patents filled thus far are in the name of non-residents, who apply solely to control export markets in developing countries. (Dubey, N.K., *et al.*, 2004; Eike reich, anne schibli, 2006)

Growing demand for herbal drugs:

The World Health Organization (WHO) has estimated the present demand for medicinal plants is approximately US \$14 billion per year. The demand for medicinal plant-based raw materials is growing at the rate of 15 to 25% annually and according to an estimate of WHO the demand for medicinal plants is likely to increase more than US \$5 trillion in 2050. In India, the medicinal plant-related trade is estimated to be approximately US \$1 billion per year. (Grünwald, J., 1995).

Issues Related to Botanicals:

The quality of herbal preparations is primarily affected by several factors, which includes Species differences, Organ specificity, Diurnal and seasonal variation, Environment, Field collection, Cultivation methods, Substitution, Adulteration, Processing, Manufacturing practices and Contamination-Mycotoxin elaboration in stored drug samples (Horie, y., Yamazaki, 1979). A number of intrinsic as well as extrinsic influences which greatly affect botanical quality have been analyzed to date.

Things to be considered for the development of medicinal plants sector:

- Document indigenous uses of medicinal plants,
- Certify raw material for quality control,
- Develop and improve the agro-technology for recognize and protect the customary laws of indigenous people,
- Prepare a clear policy for granting permits for cultivation within stipulated time
- Conduct regular research and training on better harvesting and processing techniques
- Investigate various pathological agents infecting medicinal plants,
- Setup a community-based management of medicinal plants farming and marketing,
- Analyze the market policies,
- Monitor and evaluate the status of medicinal plants with the assistance of local communities
- Conserve the critical habitats of rare medicinal plant species
- Share benefits judiciously arising from local people's knowledge on medicinal plants.

Standardization of Botanical Herbs and Quality of Botanical Preparations:

Plants contain several hundred constituents and some of them are present at very low concentrations. In spite of the modern chemical analytical procedures available, only rarely do phytochemical investigations succeed in isolating and characterizing all secondary metabolites present in the plant extract. Apart from this, plant constituents vary considerably depending on several factors that impair the quality control of phytotherapeutic agents. (Jablonski, D., 2004)

Quality control and standardization of herbal medicines involve several steps. However, the source and quality of raw materials play a pivotal role in guaranteeing the quality and stability of herbal preparations. Other factors such as the use of fresh plants, temperature, light exposure, water availability, nutrients, period and time of collection, method of collecting, drying, packing, storage and transportation of raw material, age and part of the plant collected, etc., can greatly affect the quality and consequently the therapeutic value of herbal medicines. Some plant constituents are heat labile and the plants containing them need to be dried at low temperatures.

Also, other active principles are destroyed by enzymatic processes that continue for long periods of time after plant collection. This explains why frequently the composition of herbal based drugs is quite variable.

As pointed out before, apart from these variable factors, others such as the method of extraction and contamination with microorganisms, heavy metals, pesticides, etc., can also interfere with the quality, safety and efficacy of herbal drugs. () For these reasons, pharmaceutical companies prefer using cultivated plants instead of wild-harvested plants because they show smaller variation in their constituents. Furthermore and certainly more relevant, when medicinal plants are produced by cultivation, the main secondary metabolites can be monitored and this permits definition of the best period for harvesting. (Koo, B., *et al.*, 2004)

Standardized Extract:

Extract refers to a concentrated preparation of active constituent of a medicinal herb. The concept of standardized extracts provides a solid platform for scientific validation of herbs. (Kokate, C.K., *et al.*, 1995). Extracts are of two types, which are active constituent extract and marker compound extract

Active constituent extract:

This regulates a specific biochemical constituent to a level that may not be naturally found in the plant. Concentrating 95% curcuminoids, for instance, in a standardized turmeric extract creates a product that while derived from the crude herb, is not expected to be naturally found concentrated at that level. This leaves only 5% of the other turmeric constituents with which the curcumin is combined. (Li, F., *et al.*, 1998)

Marker extract:

This type establishes that a specified amount of a marker compound is present in the finished product. It must be remembered that a marker does not represent the active constituents but is selected as a biochemical constituent characteristic of the plant. In many cases, if this process uniformly increases all plant constituents to an intended level.

Markers:

Markers constitute chemically defined constituents, which are used for control purpose. Markers may or may not have therapeutic activity. The markers can serve as a powerful tool in the finished form of herbal drug preparations which depends on the quantitative determination of the marker, when starting material selected. Marker compound are not necessarily active compounds, however if well chosen (They do not degrade under heat or other conditions that occur during processing) (Sethi, P.D., 1996).

Trends In Standardization:

The recent advances which occurred in the processes of purification, isolation and structure elucidation of naturally occurring substances have made it possible to establish appropriate strategies for the analysis of quality and the process of standardization of herbal preparations in order to maintain as much as possible the homogeneity of the plant extract. Among others, thin-layer chromatography, gas chromatography, high-performance liquid chromatography, mass spectrometry, infrared-spectrometry, ultraviolet/visible spectrometry, etc., used alone or in combination, can be successfully used for standardization and to control the quality of both the raw material and the finished herbal drugs. (Lazarowych, N.J. & P. Pekos, 1998).

The American Herbal Products Association (AHPA) published "Standardization of Botanical Products," that defines and discusses standardization of botanical products. As per AHPA standardization is defined as the complete body of information and controls that serves to optimize the batch-to-batch consistency of a botanical product. Standardization is achieved by reducing the inherent variation of natural product composition through quality assurance practices applied to agricultural and manufacturing processes. This in-depth work was undertaken in order to provide an authoritative reference on the subject and to help clear up misinformation regarding the use of standardization as applied to botanical products (Michel Tierra, L.A.C., 2005). For example, it has been said that standardized botanical products concentrate the key ingredients at the expense of or to the exclusion of others, require the use of highly toxic solvents in their manufacture, require more herb to make than a regular extract, and are products that are distinctly different from traditional preparations. (Leon Lachman, *et al.*, 1976)

The fact is that standardized extracts are not highly concentrated and do not target one particular compound, are not made with toxic solvents, use the same range of herb to extract as regular extracts, and contain the same broad spectrum of components as traditional preparations. (Sethi, P.D., 1996)

These products are essentially traditional extracts that have been tested for the presence of particular compounds. As AHPA's botanical standardization, standardization seeks to enhance the reproducibility of a product safety and efficacy. The process of assuring material of reasonable consistency involves careful production and selection of raw materials and the processes employed in product manufacture. These controls, along with sections on examinations and tests, documentations and records, product types and their development, are in the white paper, which should aid companies in their considerations of GMP requirements for botanical products. (Mashelkar, R.A., 2005).

Conclusion:

Herbal drug development is possible only through the development of standardized herbal products with reference to their active phytoconstituents present for commercialization, correct identification and supply of raw material and to avoid adulteration. Since some botanicals have undergone changes in their physical characteristics, the concept of active markers needs a flexible approach in favor of the complex nature of this material (Nautiyal, S., *et al.*, 2002; Mehrotra, M.N., 2006). The ultimate goal of ethnopharmacology must be to identify drugs to eliminate human illness by a thorough analysis of plants throughout the world.

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