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**A REVIEW ON VARIOUS APPROACHES OF SELECTION OF HERBAL
RAW MATERIAL, PROCESSING AND ITS CHARACTERIZATION FOR
THE FORMULATION OF HERBAL MEDICINAL PRODUCTS**

MAURYA VB* AND KUMAR R

Institute of Pharmacy, V.B.S. Purvanchal University, Jaunpur, UP, India

*Corresponding Author: Vijay Bahadur Maurya: E Mail: maurya6479@gmail.com, Mobile No:
+917388873288

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ABSTRACT

Herbs are deficit the woody stem and oftentimes are seasonal and extensively aerial portions die back at the terminal of each growing season. Herbs may be annuals, biennials and few are perennials. The other parts of these herbaceous plants including bark, seed, root, rhizome and fruit which are used in dried form are called spices. The standardization of herbal products became necessary to industrial production under defined conditions, using so-called Good Manufacturing Practices (GMP) and this can be achieved by understanding the growth conditions, the time of harvesting, the manner of extraction or other preparation of material so that a reliable active ingredient can be offered to people. Herbal materials are used to maintain health and treat the disease. However, adulteration of herbal medicine remains a major concern for their safety and efficacy. Many medicinal plants have similar macro structural morphology among species within the same genus, where as some others are under differentiated using vernacular names. Adulterated, counterfeit and substituted products pose serious safety issues.

Keywords: Herbs, Herbal medicine, Chemodiversity, Metabolomics, Capillary electrophoresis

INTRODUCTION

Herbs are plant or plant material that is used from thousands of year for culinary, cosmetic, medicative and spiritual concern around the globe. They are either fresh or dried leaf or flowering parts of low growing plants having soft stem [1]. Herbs are deficit the woody stem and oftentimes are seasonal and extensively aerial portions die back at the terminal of each growing season [2]. Herbs may be annuals, biennials and few are perennials [3]. The other parts of these herbaceous plants including bark, seed, root, rhizome and fruit which are used in dried form are called spices [4]. Culinary herbs are usually referred as spices and provide the specific color, fragrance and taste to food for example thyme, parsley, coriander, dill, bay leaves, curcuma, ginger etc. [5]. Herbs for cosmetic purpose are used to improve the personnel appeal in the form of mixture, paste, mask, cream, lipstick and fragrances like aloe-vera, calendula, lavender, rosemary, chamomile etc [6]. Herbs of medicinal importance are used to treat or cure different ailments for example turmeric, flax seed, st john's wort, cannabis. The spiritually valuable herbs in different religion are myrrh, turmeric, cannabis, basil etc.

HERBAL MEDICINE: Herbal medicine is the oldest system of medicine for the

maintenance of health [7] and based on the knowledge of indigenous plants in different culture. Although herbal medicine were used from ancient time in different part of world but now its acceptability is rapidly growing in developed countries due to belief of consumer that the herbal products have less adverse effect than synthetic drugs [8]. Today we are using the ancient information of plants to make it safer, effective and suitable type of dosage form to enhance the compliance. In the different – different region and culture herbal medicine from a plant may uses different parts and techniques to prepare dosage which change its activity outcome [9].

Some of these popular traditional system of herbal medicine are, traditional Chinese medicine use by Chinese people from ancient time, although it was usually based on animal origin but also consist plant based materials and were used some types of processing like stir frying, soaking in vinegar and alcohol [10]. Kampo is the Japanese traditional medicine system [11] based on herbs and mostly influenced by Chinese traditional system. The 14th edition of Japanese pharmacopoeia lists 165 herbal ingredients that are used in kampo medicine [12] and were standardized for chemical

constituents. The Indian system of traditional medicine which were based on plant materials are *Ayurveda*, *Siddha* and *Unani*.

HERBAL MEDICINAL PRODUCTS:

Herbal medicine referred as plant materials that involve whole plant or parts of plants or plant extract used to prevent or cure the ailment [13]. Consumers have reported positive attitudes towards these products, in large part because they believe them to be of 'natural' rather than 'synthetic' origin, they believe that such products are more likely to be safe than synthetic drugs, they are considered as a part of healthy lifestyle, and they can help to avoid unnecessary contact with conventional 'western' medicine [14].

The standardization of herbal products became necessary to industrial production under defined conditions, using so-called Good Manufacturing Practices (GMP) and this can be achieved by understanding the growth conditions, the time of harvesting, the manner of extraction or other preparation of material so that a reliable active ingredient can be offered to people [15]. The monographs on selected herbs are available from a number of sources, including the European Scientific Cooperative on Phytotherapy, German Commission, and the World Health Organization. The WHO monographs,

describe the herb itself by a number of criteria (including synonyms and vernacular names) and the herb part commonly used, its geographical distribution, tests used to identify and characterize the herb including macroscopic and microscopic examination and purity testing, the active principles, dosage forms and dosing, medicinal uses, pharmacology, contra-indications and adverse reactions [16].

HERBAL DRUG PREPARATION:

Herbal preparations are the basis for finished herbal products and may include comminuted or powdered herbal materials, or extracts, tinctures and fatty oils, expressed juices and processed exudates of herbal materials [17]. They are produced with the aid of extraction, distillation, expression, fractionation, purification, concentration, fermentation or other physical or biological processes [18]. They also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials [19].

SOURCES OF HERB: It is estimated that 500000 plant species exist worldwide, among which 287655 species are indentified [20]. Approximately 72000 – 77000 plants are utilized for medicinal purpose. WHO estimates that 70 - 80% world population living in Africa, India and other developing

nation rely on traditional health system for primary healthcare. In India 8000 plants are considered to be of medicinal value. 70-90% of medicinal herb species are collected from wild sources [21]. India is a land of immense biodiversity in which two out of eight hot spots of the world is located here and due to varied climatic zone from alpine in Himalaya to tropical wet in south and arid in Rajasthan [22]. Such climatic conditions have given rise to rich and varied flora in the Indian subcontinent. 77% of medicinal plants are collected from their natural sources including 12% in temperate forest, 40% in tropical forest, 25% roadside and 20% are cultivated.

SELECTION OF HERBAL MATERIAL

1-Ethnomedicinal Approaches: This is based on the fact that plant is already being used for some purpose like medicinally, insecticide, or cultural by the group of population. The testing of plant extract and any isolated compound can be guided by what the plant is traditionally used for and any possible result would serve to validate the use of plant. The ethnomedicinal approach allows for an increased possibility of finding an active compound as well as documenting and preventing local knowledge [23].

2-Ecological Approach: This includes the biodiversity, chemodiversity, apparency, chemical defense and phylogenetic theory. The various ecological characteristics such as climate, soil, habitat, geography, phytosociology are important to indicate the active compounds [24]. The plants in their endemic are full of bioactive while diminished when domesticated. The phylogenetic theory assumed that closely related species would share a similar bioactive [25]. The chemical defense theory postulated that young leaves showed greater activity than the mature and older leaves. It was further postulated that mature leaves of slow growing shade tolerant species showed better light conditions. The apparency theory discussed that the herbs and annuals need to small amount of toxic chemicals to defend themselves while biannual and perennials used quantitatively less toxic chemicals. This suggests that for prospecting new bioactive compounds should prefer herbs and annuals [26].

3-Random Approach: In this plants are screened without any criteria for their biological efficacy. The plant parts are undergoes to routine extraction and systematic bioassay. The massive biological screening of randomly selected plants and following the isolation and activity study

without any prejudicial become productive [27].

4-Metabolomics: It helps in the rapid analysis of plant extract and can give a good indication of the active constituents present in a particular plant extract. Metabolomics allows for the profiling of the entire metabolome or a specific fraction tested for biological activity. The concentration and characteristic of chemical constituent can be determined and statistical analysis used to link compound with physiological activity [28, 29].

IDENTIFICATION AND AUTHENTICATION OF HERBAL

MATERIAL: Herbal materials are used to maintain health and treat the disease. However, adulteration of herbal medicine remains a major concern for their safety and efficacy. Many medicinal plants have similar macro structural morphology among species within the same genus, where as some others are under differentiated using vernacular names. Adulterated, counterfeit and substituted products pose serious safety issues [30]. Plant species are usually authenticated by their phenotype morphological characteristics and done by professional taxonomist. Misidentification and substitution leads to potential health risk. Thus a reliable method for species

identification of herbal material is critical for the enforcement of good manufacturing practices and to avoid safety and efficacy issues.

In the case of herbal material, there may be misidentification of the collected plant, adulteration with other species, or contamination with extraneous ingredients. From the perspective of a regulatory action, these cases may range from simple misleading labeling to frank poisoning due to toxic contaminants. Authentication tools may range widely, depending on the plant and processes involved, from a straight forward botanical or morphological identification of a plant to genetic or chemical approaches. Each identification method uses different techniques, some of prior information and skill to achieve proper authentication of herbal product.

The initial step in the identification and authentication of herbal materials follows classical botanical methodologies for collection and documentation of the plant at its source. Vital information such as the proper latin binomial nomenclature of the plant (vs. the common name), the name of the person who collected it, the date of collection, the location of the collection site per global positioning, geographical description, a unique collection number/code,

a list of the plant part(s) collected, habitat information, organoleptic characteristics and processing steps like drying method, time, and temperature, as well as a visual representative image of the plant both in the field and after harvest. The authentication and characterization [31] of bulk plant material as well as plant material that have been dried and ground can be facilitated by following techniques:

1- Macroscopic Techniques: That may be examined to aid in identification/authentication include traits such as woody, semi-wood or herbaceous; leaf size, shape and morphology for e.g., leaf margins entire, undulate, dentate, serrate, lobed; inflorescence characteristics, such as type of inflorescence for e.g., spike, raceme, panicle, cyme, corymb, helicoid cyme, head; floral morphology for e.g., epigynous, perigynous, hypogynous; stamen number and shape; number of carpels per ovary; number of seeds per carpel; root characteristics, including surface texture, type corm, bulb, rhizome, and tissue layering banding patterns. Macroscopic techniques may be used to discriminate between the desired plant species and plant

part and morphologically similar, yet distinguishable, species that could occur as potential adulterants [32].

2- Microscopic Techniques: It may be especially useful when attempting to establish authenticity or adulteration in a sample of plant material that has been ground and in which most macroscopic characteristics are difficult to distinguish. A microscopic approach utilizes techniques such as scanning electron microscopy to analyze characteristics such as the presence or absence of hairs (trichomes), oil glands, canals, particular cell types, seed or pollen morphology, and vascular traces [33].

3- Analytical Chromatographic Techniques: This is one of the most reliable and applicable authentication method based on analytical chemical techniques like thin layer chromatography (TLC), high performance liquid chromatography (HPLC), capillary electrophoresis (CE), and gas chromatography (GC) with a suitable detection mode. However, for an analytical authentication method to be considered valid, the investigators are required to utilize a statistically

significant representative set of authenticated reference samples so that it can be identified and established. The identified and selected “marker” compounds that make up the analytical fingerprint should be unique to the selected species.

a) Thin Layer Chromatography

(TLC): TLC is frequently used for the analysis of herbal medicines to provide first characteristic fingerprints of herbs. TLC is rather simple and can be employed for multiple sample analysis. For each plate, more than 30 spots of samples can be studied simultaneously in one time. The advantages of using TLC to construct the fingerprint of herbal medicines are its simplicity, versatility, high velocity, specific sensitivity, simple sample preparation and its economy. Thus TLC is a convenient method to determine the quality and possible adulteration of herbal products [34].

b) High Performance Liquid Chromatography (HPLC):

HPLC is a popular method for the analysis of herbal medicines, because it is easy to learn and use and is not limited by the volatility or stability of the sample compound. In general HPLC can be used to analyze almost all the compounds in herbal medicines [35].

c) Capillary Electrophoresis (CE):

Capillary electrophoresis allows an efficient way to document the purity/complexity of a sample and can handle virtually every link of charged sample components ranging from simple inorganic ions to DNA. Capillary electrophoresis is promising for the separation and analysis of active ingredients in herbal medicines, since it needs only small amounts of standards and can analyze samples rapidly with a very good separation activity [36].

d) Gas Chromatography (GC):

The gas chromatography of the volatile oil gives a reasonable fingerprint and can be used to identify the plant. The extraction of the volatile oil is relatively

straight forward and can be standardized and the components can be readily identified using GC-MS analysis. The advantages of gas chromatography clearly lie in its high sensitivity of detection for almost all the volatile chemical compounds [37].

4- Chemometric Metabolomics

Techniques: These techniques utilized the broad Spectrum analysis and the entire chemical profile has been extracted from the sample is studied.

a) GC–Mass Spectroscopy: The volatile components of a complex plant extract are injected into the GC-Mass Spectroscopy system; the resultant separated peaks are then identified by their specific mass, and the ratios of the identified peaks provide the basis for statistical analyses that can cluster the “like” samples into grouped populations [38].

b) Proton Nuclear Magnetic Resonance (H-NMR): This methodology uses statistical analyses to evaluate and cluster all the peaks within the proton spectrum of, typically, a whole

extract of a plant sample. H-NMR identity testing of a whole extract can provide a valuable tool for understanding the full chemical profile of a given sample. Although this is not required for identification purposes, it is desirable from a scientific standpoint that one have an understanding as to what compounds are providing the signals for the unique fingerprint that is generated [39].

c) Infrared (IR) Spectroscopy:

This methodology uses for ascertaining the authenticity of plant samples through the use of near-IR (NIR ~4,000–12,500 cm^{-1}), mid-IR/Fourier transform IR (FT-IR ~400–4,000 cm^{-1}), and FT-Raman (~ 400– 4,000 cm^{-1}) spectrum analysis. These IR methods rely on the various vibrational, stretching, wagging, and bending actions that are present within all the molecules that are contained in a botanical sample. NIR provides ease of use for a quick evaluation of raw materials; however, this method falls short of providing an

accurate analytical method for authentication purposes because it does not provide a high enough resolution of individual identifying peaks to accomplish this task. In addition, NIR analysis can be affected by signals related to water content. FT-IR analysis provides a more in-depth spectroscopic resolution of the fingerprint peaks than NIR does, but the FT-IR spectrogram can also be significantly affected by residual water signals. Unlike NIR and FT-IR, which rely on absorbance of IR signals, FT-Raman spectroscopy relies on measuring the resultant scattering of a specific wavelength of light. This allows for the removal of inordinate water peaks and conferment the ability to perform measurements even through some types of packaging materials. Both FT-IR and FT-Raman IR techniques can be highly useful tools for identification purposes, but one should have a thorough understanding of what each representative fingerprint peak

signifies with regard to the constituents of the sample [40].

5- Genetic Finger Printing Technique:

Genetic differences at the DNA level can be successfully used to identify species or to characterize isolates within a species. These differences can be detected using a variety of molecular biological techniques. The lack of sequence data and the limited knowledge of the genetic diversity present in many of the plant species are significant obstacles to the development of simple and reliable genetic identification markers. However, with the proper scientific background experiments, genetic profiling can be used for various purposes, including varietal identification, detection and characterization of contaminants, and/or identification of the geographical origin of a sample. These methods can be adapted to efficient high-throughput analyses with easily transferable technology to provide a valuable new tool for authentication purposes. DNA should be isolated using established techniques or validated commercially available kits, and the acquired

genetic information should be stored in a database for ready access and for comparison purposes [41, 42].

PROCESSING OF HERBAL RAW

MATERIAL: Processing is the distinct steps of preparing herbal materials and herbal preparations for therapeutic application. The process concerns not only ensuring the quality of the herbal materials and preparations produced, but also their safety and efficacy in clinical settings. In the case of processing herbs into herbal materials, three major sequence of processing are associated, included the “primary”, “secondary” and “special” processes [43].

Primary Processing: Most of herbal plants are handled by production facilities at the place of origin. There it is collected from source directly i.e. Former or wild plant collectors. It is intended to free them from foreign materials and other contaminants, and the process includes are sorting, washing, and drying [44, 45].

A. Sorting: Raw herbal plant materials should be inspected and sorted prior to primary processing. The inspection may include:

- 1- Visual inspection for cross-contamination by untargeted medicinal plants and/or plant parts.
- 2- Visual inspection for foreign matter.

3- Organoleptic evaluation, such as: appearance, damage, size, color, odor and possibly taste.

B. Washing: Raw herbal plant materials should properly washes to remove any adherent dirt.

C. Drying: When medicinal plant materials are prepared for use in dry form, the moisture content of the material should be kept as low as possible in order to reduce damage from mould and other microbial infestation. Medicinal plants can be dried in a number of ways:

- 1- In the open air (shaded from direct sunlight).
- 2- Placed in thin layers on drying frames, wire-screened rooms or buildings.
- 3- By direct sunlight, if appropriate.
- 4- In drying ovens/rooms and solar dryers.
- 5- By indirect fire, baking, lyophilization, microwave, or infrared devices.

The temperature and humidity should be controlled to avoid damage to the active chemical constituents and have a considerable impact on the quality of the resulting medicinal plant materials. For example, shade drying is preferred to

maintain or minimize loss of color of leaves and flowers; and lower temperatures should be employed in the case of medicinal plant materials containing volatile substances.

Secondary Processing: This is the next step associated with transforming the primary processed herbs into herbal materials by various additional procedures in addition to aging/sweating, baking/roasting, boiling/steaming, and stir-frying [46].

Special Processing: This is an expansion of the secondary process, which employs a specialized method to treat selected herbs to:

- 1- Mitigate their toxicity.
- 2- Improve the purity of the plant part being employed.
- 3- Alter and modify their therapeutic activity.
- 4- Reduce drying time.
- 5- Prevent damage from mould, other microorganisms and insects

Common specific processing practices include pre-selection, peeling the skins of roots and rhizomes, boiling in water, steaming, soaking, pickling, distillation, fumigation, roasting, natural fermentation, treatment with lime and chopping. Processing procedures involving the formation of certain shapes, bundling and special drying may also have an impact on

the quality of the medicinal plant materials [46].

CONCLUSION: Herbal material may be misidentification of the collected plant, adulteration with other species, or contamination with extraneous ingredients. From the perspective of a regulatory action, these cases may range from simple misleading, labeling to frank poisoning due to toxic contaminants. Authentication tools may range widely, depending on the plant and processes involved, from a straight forward botanical or morphological identification of a plant to genetic or chemical approaches. Plant species are authenticated by their phenotype morphological characteristics and done by professional taxonomist. Misidentification and substitution leads to potential health risk. Thus a reliable method for species identification of herbal material is critical for the enforcement of good manufacturing practices and to avoid safety and efficacy issues.

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