INTRODUCTION

Nature has always stood as an outstanding benchmark to exemplify symbiotic phenomenon. It has enormous power and is a store house of remedies which can cure every ailment of man. Moreover, it has taken thousands years to accumulate knowledge related to drugs and due to man’s perpetual quest, we today have natural and effective means to ensure a better health care.1

The utilization of plant as medicaments has been recognized from ancient time to present day. Despite of the recent major advances in the world of medicines, plants significantly contribute to the health care system. As per World Health Organization (WHO), the herbal drugs and their associates have been defined in the following ways:

1. **Herbal Medicines** consist of herbs, finished herbal products and herbal preparations. However, herbal medicinal preparations may also consist of animal & mineral sources in addition to plant sources.

2. **Herbs** contain basic plant material, *i.e.* flowers, roots, leaves, fruit, stem, rhizomes, barks, wood, seeds or other parts of plants, which may be a whole plant, or its powdered/fragmented form.

In addition to herbs, herbal materials include dry powders, fixed oils, gums, fresh juices, resins, and essential oils. In a few countries, plant materials are processed through various procedures *viz.* roasting with honey, steaming, processing with alcoholic beverages, *etc.*

3. **Herbal preparation** forms the basis for completely finished products. They may consist of tinctures or extracts, powdered herbal materials, or fatty oils obtained from herbal materials. They are processed to obtain the active phytoconstituents through extraction, concentration, purification, fractionation and other biological/physical processes. Herbal preparations also consist of preparations made through heating herbal materials in honey, alcoholic beverages, and other materials.

4. **Finished herbal product** includes herbal formulations which are made from one or more than one herbs. If they include more than one herb, they can also be called “mixture herbal product”. Mixture herbal products and finished herbal products may also consist of excipients.
5. **Herbal formulations** are the formulation prepared from plant extracts and also contain suitable excipients. As these extracts contain active constituents, they are combined with excipients or a base to prepare a formulation, followed by its standardization using suitable methods. When more than two herbs are used in formulations, they are known as poly-herbal formulations.²

**Herbal Medicine: Market Potential in India**

In recent times there has been a change in worldwide trend from man-made to herbal medicine, which is also known as ‘Return to Nature’. Medicinal plants have been acknowledged for millennia and are greatly esteemed worldwide as an extreme source of potent medicinal agents for the cure & prevention of diseases. Nature has blessed our motherland with ample treasure of medicinal plants; that is why it has been called as Medicinal Garden of the Earth. Ancient civilizations such as India, South America, and Egypt, China etc. are still using many herbal remedies for the treatment of many ailments. India, in this regard, has a unique and important position in the globe, where numerous recognized and traditional systems of medicine such as Siddha, Ayurveda, Homeopathy, Unani, Naturopathy and Yoga are practiced for the better health care of community. There is no doubt that the herbal medicinal drugs are very much popular among urban and rural Indian community. The basis for their acceptability and popularity results from the minimal/ no adverse effect associated with these natural products. Demand for plant based food supplements, pharmaceuticals, health products, medicines, cosmetics, etc. is growing in developing as well as in developed countries. This is happening because of this increasing recognition that the herbal products have less/ no adverse effects, are non-toxic and easily accessible at reasonable price.

Nowadays, interest with plant based medicine is revived due to the increasing awareness of the health risks linked with the reckless use of current allopathic medicines. Moreover, the herbal drug industry is also developing very quickly in the global market. Unfortunately, India is still behind to mark its footprints in international business of herbal industry because lack of scientific approach in herbal drugs. Therefore, in order to open the floodgate for the growth of potential market in India, it is essential to focus on the market potential of herbal medicines.²
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Herbal Medicine: Indian Herbal Trade in World Scenario

The consumption of herbal medicines is in vogue and the market is also developing gradually. Indian herbal industry earns about Rs. 2,300 crores as adjacent to the pharmaceutical industry’s yield of Rs. 14,500 crores at a growth rate of 15%. In the last few years, India has been a substantial exporter of herbs and medicinal plants. Moreover, India is the second main manufacturer of castor seeds in the entire world, which produces approximately 125000 tonnes per year.3

Standardization of herbal formulations

In general, standardization is defined as a process of developing and implementing standards, based on some consensus, so as to maintain consistency. In other words, it can be said that herbal medicine’s standardization is the process of setting some standards and parameters for inherent characteristics, to attain an assurance of quality, efficacy, safety and reproducibility.

Standardization is used to describe and standardize all the measures which are important to be controlled during manufacturing followed by quality control resulting in a reproducible quality. It also includes the entire field of study from birth of a plant to its clinical application. Furthermore, “evaluation” of a drug refers to its identification followed by its quality and purity determination. It also includes determination of any adulteration. Standardization is undertaken by considering all the important aspects of a plant material, from its collection to its evaluation, including pharmacognostic, phytochemical, qualitative as well as quantitative. It also takes care of microbial load, toxicity, and biological activity.4 Table 1.1 represents a general protocol to standardization of herbal drugs.

Table 1.1. General protocol for quality control of herbal drugs

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<th>S. No.</th>
<th>Stages</th>
<th>Details</th>
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<tr>
<td>1</td>
<td>AUTHENTICATION</td>
<td>The first stage is to identify the plant species for its botanical verification through the presently accepted Latin botanical name and synonym. In the authentication the steps involved are macroscopic, taxonomic and microscopic studies. Regional status records, parts of the plant collected, collection, botanical identity i.e. morphology, taxonomical identity and histological analysis, microscopy.</td>
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<th><strong>PHYSICAL PARAMETERS</strong></th>
<th><strong>CHROMATOGRAPHIC AND SPECTROSCOPIC EVALUATION</strong></th>
<th><strong>PESTICIDE RESIDUE ANALYSIS</strong></th>
<th><strong>AFLATOXIN ANALYSIS</strong></th>
<th><strong>HEAVY METAL ANALYSIS</strong></th>
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<td>2</td>
<td>Physical tests which include organoleptic evaluation i.e. sensory characters like appearance, taste, and odor of crude drug, moisture content, viscosity, disintegration time, pH, hardness, friability, flow ability, ash value and sedimentation.</td>
<td>The Sophisticated modern techniques of standardization like spectroscopic UV-vis spectrophotometry, HPLC, HP-TLC, TLC, near infrared spectroscopy, NMR provides quantitative and semi quantitative information about the active ingredients or marker compounds present in the crude drug and herbal products. While fingerprinting of drug an important role is played by markers. Chromatographic fingerprints can also assess the quality of a drug.</td>
<td>Food and Agricultural Organization and WHO has set the standard limits of pesticides. Some common pesticides that can harm human body are BHC, DDT, aldrin and toxaphene which are analyzed.</td>
<td>Aflatoxins are group of toxic compounds which are produced by certain molds, particularly <em>Aspergillus flavus</em>. Aflatoxin is the strongest known naturally occurring carcinogen. Among 18 different types of aflatoxins which are identified, so far major members are aflatoxin B1, B2, G1 and G2.</td>
<td>Toxic metals like Zn, Cu and Fe and particularly As, Cd, Hg and Pb should be analyzed. While analyzing metals, their speciation should be taken into consideration.</td>
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**Need for quality audit and standardization of herbal formulations**

1. The standardization techniques and the concept of quality control used earlier were quite different from the techniques developed and used in today’s scenario.
2. Despite of the previous standardization methods, the evolution in the plants through the dynamic years may have led to changes in the methods of standardization.
3. The availability and supply of authentic raw material has become a big challenge which is mainly due to the high demands as compared to production.
4. Besides evolution, the physical and chemical properties of plants may have undergone change over time and due to changes in environmental factors.
5. Moreover, the variations can occur due to seasonal variation, ecotypic, genotypic and chemotypic variations. Moreover, drying and storage\conditions and the presence of xenobiotic also lead to variations.

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Commercialization of plants and their associated products has increased the urgency to standardize them. Moreover, the herbs-associated adverse events observed and reported in developed countries have warranted the requirement for herbal standardization and evaluation of safety and efficacy of medicinal plants and herbal products.

Internationally, there has been a revolution in the herbal medicine industry where more utilization of herbal medicines has been observed. It is mainly because of the shortcoming and the dangers associated with the modern medicines. The regulatory authorities must take the responsibility to ensure medication’s safety, purity, efficacy and potency. The regulatory authorities should strictly follow all standard parameters of quality as prescribed not only for raw materials, but for final products also in formularies, pharmacopoeias and good manufacturing practices imposed by statutory. These measures would reasonably apply to every type of preparation.

Although medicinal products are gaining popularity all over the world, the major hurdles in its acceptance is due to absence of a standard profile in terms of quality control. The herbal medicine’s quality can be ensured by the profile of its constituents, which further ensures its safety and efficacy in the form of final product. Despite the development of latest analytical techniques to assess the quality of the herbal formulation, it is very difficult to define parameters to control their quality and safety parameters. It is because of the inherent variability and complex nature of the constituents of plant-based preparations. In addition, the constituents responsible for the so-called therapeutic effects are not properly defined. Moreover, they are either unknown or just partially explained. The use of combination of several herbal ingredients commonly used in traditional practices has further complicated it.

The variation among batches occur right from the harvesting/ collection of plant as raw material itself due to lack of any reference/ standard which may help in their identification. These variations are more likely to multiply at the time of storage and processing. Therefore, standardization must include the complete area of study for herbal drugs and their products, i.e. from the cultivation of crude drugs to its clinical application. As plant preparations and herbal remedies obtained from them substantially represent a portion of international market, there is a need to develop nationally as well as internationally recognized guidelines for their quality assessment and quality control.5

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