The process of standardization of herbal raw drugs

Health & Medicine, Addiction

Medicinal plants have played an important role in a world health. Herbal drugs have been used since earliest times as medicines for the treatment of a variety of diseases. There is a growing focus on the importance of medicinal plants in the traditional health care systems. Phytotherapeutic agents or Phytomedicines are standardized herbal preparations consisting of complex mixtures of one or more plants which are used in most of the countries for the management of various diseases. Eighty percent of the world's population depends on herbal drugs and to either global it is vital to maintain its quality. The quality of herbal drugs is the sum of all the factors which contribute directly or indirectly to the safety. Standardization of drugs means confirmation of its identity and determination of its quality and purity. It is an important measurement for ensuring the quality control of the herbal drugs. It is a process of evaluating the quality and purity of herbal drug on the basis of various parameters like morphological, microscopical, physical, chemical and biological parameters. Standardization of herbal raw drugs contain passport data of raw plant drugs, botanical authentication, which contain microscopic and molecular examination, physical parameters like moisture content, ash value, extractive values etc. At the present due to advances in the crude drugs in the addition to its physical contants. A system to ensure that every packet of medicines that is being sold has the correct substances in the correct amount and will induce its therapeutic effect this is known as standardization.

Quality control

The quality control of the plant products is a general requirements to be fulfilled. A good quality assurance is necessary when dealing with the plant

products, intended to be released in market as drugs should be made to obtain and maintain the high quality of these plant products. To check any adulteration or non- deliberate mixing in the commercial batches, the specification must be laid down for each herb.

Who Guidelines for Standardization:

It is accepted worldwide that the standardization of herbal drugs is wide and deep. According to WHO, the herbal drug standardization is the process involved in the physicochemical evaluation of crude drugs that covers various aspects like the selection and handling of crude drug material, safety, efficacy and stability assessment of finished product formulation. The guidelines set by WHO for herbal drug standardization can be summarized as follows:

- Botanical evaluation: In this evaluation the sensory characters, foreign organic matter, microscopical evaluation and quantitative measurements are involved.
- Physicochemical parameters: In this evaluation the physical and chemical identity, chromatographic fingerprints, ash values, extractive values, moisture content, volatile oil content are included.
- Pharmacological parameters: This includes various biological activity profiles, bitterness values, swelling index, foaming index etc.
- Toxicological parameters: this includes determination of pesticide residues and heavy metals, etc.

Evaluation tools for herbal drug standardization

There are so many evaluation tools for the standardization of herbal drugs and their formulations. The following tools are used for evaluation:

1. Authentication: The most important step in the development of standardization of plant is authentication of a plant. Authentication of the plant is done by evaluating different parameters like biological source, family and the parts of collecting like leaf, flower, roots or steam, etc.
2. Macroscopical Evaluation: The Macroscopical evaluation is also known as morphological evaluation or organoleptic evaluation. In microscopical evaluation, the evaluation of drug done by color, shape, size, odor, taste and some other special features like touch and texture etc.
3. Microscopic evaluation: The microscopical evaluation is valuable for both powder and crude drugs. This evaluation can be categorized as: Qualitative and Quantitative microscopy.
4. Chemical Evaluation: The chemical nature of chemical constituents can be used as tool for analysis of the constituents. It involves the following steps:
5. Physical Methods: In this method, the some physical properties of drug may be determined, such as Moisture content, Swelling Index, Ash values, Viscosity, Density, Bitterness values, Solubility, Foaming Index, Specific gravity, etc.

Advanced Techniques for Standardization

Fingerprinting analysis is the advance technique for standardization. The Fingerprint analysis is the most powerful tool for quality control and standardization of herbal drugs. Fingerprinting is the process that determines the concentration of a set of characteristic chemical substances in the herbs. Advanced techniques for standardization include Chromatographic fingerprinting and DNA fingerprinting. The Chromatographic fingerprinting includes Thin layer chromatography (TLC), High Performance Thin Layer Chromatography (HPTLC), High Performance Liquid Chromatography (HPLC), Gas Chromatography (GC), etc., while DNA fingerprinting techniques includes Hybridization Based Methods, PCR Based Methods and Sequence Based Methods.

Need of standardization:

GMP for herbal industry is not well defined nor barest minimum standards of herbal product are maintained or regulated because modern system of medicine based on the sound experimental data, toxicity studies and human trails and pharmacopoeial standards on raw material or end products are available.

Need of the study of plants and their future prospects

Pharmacognosy has been developed rapidly due to this improvement made in the technology of isolation process which include the development of techniques such as column, paper, thin layer, gas liquid, HPLC and droplet counter current chromatography procedure. These methods have allowed the rapid isolation of substance which was previously difficult to obtain by classical procedure. The most important factor has been the development of

the new spectroscopic techniques, which has opened up whole new vistas in the exciting field.

Simultaneous advancement in the field of chemistry, biochemistry, biosynthesis and pharmacology has developed. Various active constituents have been isolated from the plant, which are used in modern medicine. With the advancement in synthetic organic chemistry, most of the active constituents of the plants used in medicine have been synthesized. However, in spite of phenomenal progress and appearance of antibiotics as major therapeutic agents, plants continue to provide basic raw material for some of the most important drug.

Since the indiscriminate use of synthetic drug and antibiotics has resulted in serious symptoms all over the world, the demand of the plant based raw materials for pharmaceuticals have increased enormously. Moreover, the synthetic drug and intermediary chemicals are extremely expensive. The World Health Organization (WHO) has emphasized the utilization of indigenous system of medicine based on the locally available raw materials that is a medicinal plant. Furthermore, approximately one third of all the drugs are plant-based and if bacteria and fungi are also included, nearly 60% of the pharmaceuticals are of plant origin. Our country is rich in large number of such plants that are either used directly or as a source of active principles in formulation of drug curing dreaded diseases. India is a rich source of medicinal plants which are distributed in almost all parts of the country. The herb collector and small traders collect the drug for manufacturing of Ayurvedic and Unani medicines. But there is a shortage of

these materials for maintaining the sustained supply of the plant based drug industries.

It is also not dependent only on natural resources to keep the wheel of industries running all the time in view of fast depleting natural wealth and this call for the domestication and cultivation of these plants as well as an increment in the drug production with uniformly high potency.

Inspire of the tremendous advancement in medicines, there are a number of diseases for which modern medicines have no cure. In such conditions, it treated only symptoms to provide relief to the patients. These include arthritic diseases, liver disorders, cancer, AIDS, etc. In recent trends have shown that plant drugs have the answer to such cases. Recently a number of formulations based on Ayurvedic medicines have come to the market for control of liver disorders and some of these have been found effective against these diseases. There is a considerable scope to screen such a plant for active constituent, which may be used in future for the treatment of such incurable diseases.

Challenges in the standardization of plant drugs

- Biological variations: Plants are rich sources of chemicals and potential sources of chemicals and potential sources of effective medicines, but the chemical constituents of plants vary depending on the species, variety and part of the plant, conditions of growth (soil, water and temperature) and age of the plant. This complexity and variations of chemical content make standardization essentials.

- Selection of markers: The major drawback associated with the process of standardizing a selection of markers. Most of standardized herbal extracts are not consistently standardized to one marker because it is not certain which of its constituents responsible for its therapeutic actions. Nettle root is standardized by one company to 5% amino acids by another to 8% sterols, and the third uses 35ppm scopoline. Echinacea can be standardized to three different constituents, i. e., echinoids polysaccharides or polybutylides. Moreover, any medicinal herb does not exhibit single biological activity, but has a long tradition of use in the treatment of various diseases and different constituents are responsible for different activities.
- Role of federal regulatory authorities (FRA): Lack of proper control of FRA results in marked Variation in strength of marked herbal formulations. Consumer report found that 25% of Ginseng products on health food store shelves did not contain any listed compounds, and the contents of the products varied widely. Another study commissioned by the Los Angeles times found that three of the ten different national brands of St. John’s Wort over the counter remedies, contained less than half the active ingredients claimed on the level and seven products contained between 75 to 135% of the active ingredients as labeled hypericin.
- Safety issues: In the United states, botanical products are marked as dietary supplements. Other countries treat the herbal preparation as drugs and to be registered these products to be tested to prove their safety and chemical efficacy. There is a general conception that herbs

are ‘ natural’ so these are completely safe. This is not true; the dangers of neutraceuticals are well documented. In 1994, use of Ephedra led to 39 deaths and 695 cases of serious illness, ranging from, insomnia, nervousness and arrhythmia to hypertension if used for a long time. Ginseng causes hypertension, gynecomastia and vaginal bleeding.

Solutions for problems associated with drug standardization

Control and monitor on growing conditions, harvesting time, part of plant harvested, absence of toxins, pesticides or other contaminants, drying methods, freshness and storage, processing, extraction solvents, whole extraction processes and analytical controls.

- Establishment of pharmacognostical standards as mentioned above.
- Biological evaluation on the bases.
- Isolation of biological active constituent(s) using bioactivity guided fractionation.
- Estimation of biological markers using HPLC HPTLC.
- Preparation of standardized formulation.
- Doses schedules.
- Controlled in the formulation and manufacture of dose form, packaging, storage and stability.
- Control of batch to batch variation.
- Control by FRA on finished products.