

Herbal Medicines and Herbal Medicinal Products- Quality and Safety

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The challenges are innumerable and enormous, making the global herbal market unsafe. This study seeks to enlighten physicians, pharmacists, consumers and stakeholders in herbal medicine on the need to establish quality parameters for collection, handling, processing and production of herbal medicine as well; as employ such parameters in ensuring the safety of the global herbal market. The processes of good quality assurance and standardization of herbal medicines and products is being discussed.

The use of herbs/herbal medicines for treating various ailments dates back several centuries. Usually, herbal medicine has relied on those traditions that may or may not be supported by empirical data. The belief that natural medicines are much safer than synthetic drugs has gained popularity in recent years led to maximum usage of herbal medicines. In most countries there is no universal regulatory system that insures the safety and activity of herbal medicines and herbal medicinal products (HMPs), e.g. main requirements on safety and efficacy according to European Medicine Agency are:

- No clinical tests and trials on safety and efficacy are required as long as sufficient safety data and plausible efficacy are demonstrated
- Involves assessment of mostly bibliographic safety and efficacy data
- Must have been used for at least 30 years, including at least 15 years within the EU

Evidence-based studies on the efficacy of HMPs are still frequently lacking. However, in recent years, data on evaluation of the therapeutic and toxic activities of HMPs are available. The advances in Natural Product Chemistry and analytical technology have led to discovery of a huge number of new active constituents. Pre-clinical studies for efficacy of HMPs are a constant challenge. The question of bioavailability for assessing to what degree and how fast compounds are absorbed after administration of HMPs and compared it with synthetic medicine. Of further interest is the elucidation of metabolic pathways for new active compounds and their analogues; the assessment of elimination routes and their kinetics. These analogues are more dangerous as their safety and efficacy are not determined. These data become an important issue to link data from pharmacological assays and clinical effects. Interactions of herbal medicinal products with synthetically derived drug products (Herb drug interaction) should be taken care of.

In the recent years with ever-growing commercialization in the field of herbal medicines, there has been an instant demand for quality control of the drugs used in this system. For this standardization is usually recommended as the solution to the problem.

Standardization of herbal drug(s) means adjustment of a herbal preparation to a defined quantity of its constituents with a known therapeutic effect³. Standardization ensures quality, quantity and therapeutic efficacy of each dose of ingredients in a predefined manner⁴. Good Manufacturing Practices (GMP) implementation is another requirement for the standardization of herbal formulations⁵⁻⁷. Such abundance of regulations

avoid batch to batch variations and minimize errors and increases the acceptance of polyherbal formulations⁸. The therapeutic efficacy in herbal medicines is generally attributed to the synergistic effect of the biologically active constituents which needs to be standardized.⁹In the present study an attempt has been made to study from Selection of Medicinal Plants; Good Agricultural Practices (GAP); Good Cultivation Practices (GCP); Good Field Collection Practices(GFCP); Technical Planning; population density; Geographical distribution; Topographical maps; collecting techniques & procedures; Source and Period of Collection; Identification; Storage; Chemical Standardisation; Assay; Current Good Manufacturing Practices (C GMP); Pre clinical studies to Clinical Approach; Good Marketing Practice (GMP), with special reference to maintain Standardisation at each and every stage and subsequent production of quality raw herbal products.

Different stages, i.e. Quality control studies of raw plant materials, Controlled studies of Method of Processing, Quality Control Studies of the finished product, Standardization procedures at each stage from birth of the plants up to its clinical application & marketing have been described. Special attention has been paid to the intentional adulteration of pharmaceutical medicines and their analogs.

Though a lot of studies have already been carried out on standardization of herbal medicines globally still there are many challenges one of the most commonly encountered problems is misconception that all naturals are safe; lack /non-availability of research data; complexity and inconsistency of formulations; lack of initiatives by manufacturers; flooding of proprietary products and volume of work involved; poor understanding of therapeutic activity; synergism offered by a mixture of constituents; adulteration with other medicines and potent chemical substance mistaken use of wrong species; incorrect dosing; misuse of herbal drugs by healthcare providers and consumers continuous efforts are being made to establish the newer and better techniques for standardization of herbal products.

Manufacturing of safe HMPs requires many main steps which are critical for the quality of the products being made. GMP must be in place at all stages of growth, from harvesting or growing herbs in the wild to manufacturing the final herbal product. This covers the determination of the composition of the herbal content, good handling during processing and formulation, prevention of pollution, proper handling and monitoring of the processes.

The chemical complexity is a key challenge in using plants as a source for medicines. Plants contain many constituents and many factors can affect the content and concentration, including environment, growing conditions, harvest time, and post-harvesting factors (such as storage and processing conditions). This attribute is important because not all constituents contribute equally to the pharmacological effects of a product. Under regulated agricultural conditions plants intended for registered HMPs are cultivated and harvested, requiring good agricultural practice (GAP). Where medicinal plants are harvested from the wild due to cultivation difficulties, good gathering practice (GCP) is required.

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