Quality control of Botanicals – Needs, Difficulties and Logical approach

All over the world there is an awareness that synthetic drugs, while playing a very useful role in healthcare, have accompanying serious toxicities which often gets highlighted in the lay media creating fear regarding their use. It is also understood at the same time that for many countries the healthcare systems cannot afford costly synthetic drugs and hence there is a need to complement the modern system with indigenous system of medicines. Industries are also trying to exploit the 'back to nature' trend for reaping profits. The lack of price control, unlike that of synthetic medicines coupled with an inadequate controls for these plant based products, have brought many entrepreneurs to manufacture plant based formulations claiming a variety of therapeutic actions and applications. There are no effective standardization procedures for majority of the natural drugs and their formulations. Few manufacturers may be setting their own standards for their products. Various countries have some official books /pharmacopoeias to address the issue as regard to authenticity and purity of botanicals used in healthcare, but the standards laid down are not adequate or find it difficult to implement. Therefore, there is need to do more and also extend this activity to formulations.

Herbal drug technology includes all the steps that are involved in converting botanicals into medicines, where standardization and quality control with proper integration of modern scientific techniques and traditional knowledge will remain important.

Quality assurance of the starting material is, therefore, an essential prerequisite to ensure reproducible quality of herbal medicine, which contributes to its safety and efficacy.

Factors for continued popularity of botanicals:

i. Traditional systems of medicine continue to be practiced because *a.* ready availability in rural areas and less accessible regions in developing countries, *b.* shortage of practioners of modern medicine in those areas and their tendency do not cater to rural areas, *c.* Socio-cultural reason, and *d.* emotional attachment to traditional medicines.

ii. Plant derived drugs and pharmaceutical aids form an important segment of the modern pharmacopoeias and since commercially feasible synthetic methods are not likely to become available for many of these, these plant will continue to remain in demand.

iii. Unlike petrochemicals (basis of synthetic medicines) plants are renewable source.

iv. General belief that botanicals are safe i.e. free from side effects and toxicities.

v. Some of the important modern drugs or their intermediates are still being obtained from plant source, for diseases for which modern drugs are inadequate.

Difficulties encountered in standardization of botanicals:

i. Lack of thorough knowledge and information about the correct plant species to be used and its constituent/s.

ii. Being natural the active constituents varies depending upon the time and season in which it is collected and other uncontrollable factors.

iii. Adulteration and substitution also make the matter more complicated.

Logical approach to assure quality of botanicals:
In order to reduce the variability in botanicals

i. Establish correct identity of botanical material

ii. Identify chemical composition of the drug, if not major constituents which can act as marker for chemical evaluation.

iii. Use cultivated plants which show greater consistency rather than wild plants which often are heterogeneous.

In recent years, advancement made in the field of Pharmacognosy, Phytochemistry, Cultivation of Botanicals and Instrumentation techniques for analysis can be of great help in tackling these problems.