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Editorial Open Access

Amalgamation of Chemistry and Biology to Overcome Bottlenecks in Standardization of Ayurvedic Medicines

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Editorial

Use of traditional single drugs and their formulations has increased tremendously over the past few decades. The trend is more likely to continue in years to come because of the rapid globalization of herbal medicines. Standardization is very important to ensure that the products marketed show consistency in composition and repeatability of the therapeutic efficacy in the clinical settings. If the benefits of the formulation cannot be repeated from batch to batch it will have adverse impact on the acceptability of the formulations at both national and global level. However, unlike the single pure synthetic products used in allopathic practice, Ayurvedic medicines are mainly plant based drugs. Medicinal plant based products represent complex biological mixtures and achieving a reproducible pharmaceutical quality would be a very challenging task.

Standardization can be defined as the process of prescribing a set of standards or inherent characteristics, constant parameters, definitive qualitative and quantitative values that carry an assurance of quality, efficacy, safety and reproducibility. It is the process of developing and agreeing upon technical standards. Specific standards are worked out by experimentation and observations, which would lead to the process of prescribing a set of characteristics exhibited by the particular medicine (Kunle et al. 2012). Several set of monographs have been prepared and used as part of herbal pharmacopoeia in different parts of the world. For example 525 quantitative monographs based on chemical markers have been documented in Chinese Pharmacopoeia (2005). In India under the Department of Ayush eleven volumes of Ayurvedic Pharmacopoeia of India (API) have been published in two parts. In these volumes the emphasis is on characterization of the plant material through simple parameters. This includes correct identification of the plant material, organoleptic evaluation, quantitative evaluation of certain prescribed physicochemical parameters, and chromatographic finger printing. Assessment of samples for the presence of xenobiotics (mainly pesticides), heavy metals and microbial contaminants has been advised. Indian Drugs Manufacturers Association (IDMA) in collaboration with Regional Research Laboratory (RRL) Jammu has published two volumes of Indian Herbal Pharmacopoeia; ICMR has published a series of volumes (13 till date) related to standardization under the heading "Quality standards of Indian Medicinal Plants".

In Ayurveda, there are many formulations which are used for the treatment of various diseases in humans. The knowledge on cytotoxicity of some of the plant products which are used in the treatment of diseases is still not known. It is laborious and very difficult to study the toxic effect of each ingredient using in vivo condition. To overcome this problem, in vitro animal cell culture techniques are used. In animal cell culture, cytotoxicity of different plant product can be screened using normal and cancerous cell lines derived from various cells of human origin and other mammalian origin cells.

The currently available protocols even with chemical finger printing can only indicate that the proper plant source has been used for drug preparation but cannot ensure that the product would produce desired biological activity. Further it is inadequate to address standardization requirement of multi-component formulations which are the mainstay of Ayurveda and other Indian Medicines. This requires employment of latest advances made in the field of chemistry and biology to evolve an integrated approach with emphasis on chemical fingerprinting linked to bio-response finger printing. Evolving internationally acceptable protocol would help in great expansion of trade in Indian drugs and practice at the global level besides providing a mechanism for strict quality control program. This will be one of the major steps towards global acceptance of Ayurvedic practice.