The Importance of Standardization and evaluation of herbal drugs

Dr. (Mrs.) Selvaluxmy Chelvendran
Principal Research Scientist, Herbal Technology
Section, Industrial Technology Institute, Colombo.

Traditional medicine is based on Ayurveda, Siddha and Unani medical systems. In almost all traditional medical systems, medicinal plants play a major role and constitute the backbone of traditional medicine. During the past decades, public interest in natural therapies has increased dramatically worldwide. Due to the high demand for herbal drugs, there is shortage of many drugs, unavailability or limited source, adulteration, lack of knowledge of source identification and the adverse effects of drugs were identified as the major problems in herbal drug industry. To overcome this problem herbal drug industries started using the alternative plants as substitutes for expensive and highly efficient raw materials to manufacture the drugs.

In the ancient time, the standardization of raw materials were carried out based on the collection time and parts of herb (Rutu), availability in specific areas (Desha) and collection of wet drug and dry drug on specific Nakshtra were considered.

According to the WHO guidelines the standardization of herbal drugs is based on the quality control of raw materials and finished products, stability assessment andshelf life, toxicologicalstudies and assessment of efficacy by ethno medical information and biological activity evaluations.

The source and quality of raw materials, storage, post-harvest handling and manufacturing process play a pivotal role in guaranteeing the quality and stability of such preparations.When developing the drug, the concentration of their active principles, physical, chemical and phytochemical, in-vitro and in-vivo parameters should be considered. The role of chemical and molecular markers to standardize the potency of such products is very importantto justify their acceptability and safety. Moreover, the levels of heavy metals, pesticide residues, mycotoxinsand microbiological limits which make these products harmful need to be critically evaluated before marketing.