Quality Control of CAM Products

Processing Control of Chinese Herbal Products: An Ultimate Approach for Quality Assurance

by Kam-Ming Ko & Ka-Ming Ng

Introduction

Over the past several thousand years, the practice of Traditional Chinese Medicine (TCM) has been playing an important role in safeguarding health in China. TCM, which adopts a holistic approach in the prevention and treatment of diseases, is regarded as a goldmine of healthcare knowledge for modern medicine. Living a nerve-wrecking city life, most people find the onset of therapeutic action produced by Chinese herbs too slow for relieving symptoms and/or the herbal decoction too inconvenient for use, not to mention the uncertainty regarding the chemical composition. The latter has raised serious concern on safety and efficacy of herbal preparations. On the contrary, by taking the readily available conventional drugs with well-defined chemical composition and efficacy as well as safety profile, the therapeutic action produced by Western medicine has a faster onset and a more credible reliability. Nevertheless, the practice of Western medicine is somehow inadequate in the prevention and treatment of chronic illnesses, particularly those related to old age. As a complement to Western medicine, TCM is found to be able to effectively ameliorate or even cure many, if not all, chronic illnesses. More importantly, the occurrence of side effects is relatively rare. While Western medicine remains as the mainstream in modern healthcare system, the acceptance of TCM, particularly its herbal application for preventive health, has been increasing among the populace in the developed countries.

Modernization of Chinese Herbal Products

During the course of Chinese civilization, the use of TCM-based herbal remedies for the prevention and treatment of diseases has stood the test of time. With recent advances in modern medicine, the efficacy and safety standards of TCM-based herbal products have been facing a lot of challenges. Therefore, modernization of TCM by establishing a proper scientific basis in terms of modern science and medicine for TCM-based herbal products is instrumental to revolutionize the Chinese herbal industry in the face of global challenge. One of the key objectives in modernization of TCM is to be able to produce a Chinese herbal product with consistent quality and efficacy in a large-scale processing plant. This is a major challenge for a number of reasons. First, most Chinese herbal formulas consist of multiple herbs, most of which have limited information on bioactive compounds. Second, the first problem is compounded by the fact that the amount of bioactive ingredients depends on whether the herb is wild or cultured, and on the season of the year when the plants are harvested. Third, the drug efficacy depends on how the formula is processed. For example, it is known that the composition of herbal decoction is different if the extraction is done with all herbs mixed together or separately with one
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herb at a time. With the myriad of bioactive compounds, it is impossible to obtain an identical composition, particularly in terms of minor components, in every batch of herbal product. Therefore, in addition to the chemical analysis of the major bioactive ingredients, bio-analysis of a product by functionally relevant assays is essential for ascertaining its efficacy. In order to achieve batch-to-batch consistency in manufacturing, the application of process system engineering concepts and techniques in processing herbal products represents an ultimate approach in quality assurance. Despite the variations in chemical compositions of raw herbs, a properly designed manufacturing process with adjustable operation parameters and bio-activity monitor will meet the pre-determined quality and efficacy requirement of the herbal product.

Process Design

Process design for quality assurance is an integral part of herbal product development (see figure). Based on phytochemical information of various component herbs and data from bench-scale engineering experiments, a manufacturing process with advanced processing technologies can be designed to meet specified quality requirements. These include solid-liquid extraction, liquid-liquid extraction, distillation, crystallization, chromatography as well as technologies for the manufacture of various dosage forms.1 A properly designed and controlled process provides a high quality product that is free of toxic impurities as well as consistent from batch to batch. Chemical and bio-activity analyses are adopted for monitoring the consistency of raw herbs, intermediates and finished products. If it is deemed necessary, information from experimental and/or clinical studies of the finished product can be used to modify the herbal formula and/or re-design the herbal processing, and the quality of the product in terms of safety and efficacy can be further improved.

Chemical and Bio-activity Consistency

With the advent of new methodology in chemical analysis, it is now feasible to assess the consistency of herbal product in terms of its chemical composition. However, the complex chemical nature of most herbal products limits the use of chemical analysis alone for efficacy assurance. To solve this problem, functionally relevant bio-activity assays could be used in conjunction with chemical analysis. While Chinese herbal products used for therapeutic purposes should be assessed by relevant pharmacological tests, as is the case for conventional drugs, the herbal product used for safeguarding health could generally be evaluated by measurements of antioxidant and immunomodulatory activities. In this regard, recent studies in our laboratory have shown that “Yang” and “Yin” Chinese tonifying herbs possess antioxidant and immunostimulatory activities, respectively.2 Interestingly, the “Yang-invigorating” herbs, most of which possess high antioxidant activities, are able to boost the energy status of the heart — a fundamental action of “Yang-invigoration” in Chinese medicine.3 Given that antioxidant and immunomodulation are the mainstay of preventive health, the measurement of antioxidant and immunomodulatory activities serves as a convenient means for bio-activity assessment of Chinese herbal health products.
Rising to the Challenges

The coming of age herbal health trend has offered enormous business opportunities for the Chinese herbal industry in Hong Kong SAR and the Mainland. However, without a substantial transformation in herbal processing technology for quality assurance, the Chinese herbal industry will not be able to capitalize on the profound traditional know-how and resource in TCM. Innovative approach should be adopted to assist the Chinese herbal industry to harness the tremendous business potential in the ever-growing herbal market in the global arena.

References


About the Authors

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