

ABSTRACT

Facing the quandary of the modern medicine, medications from natural resources have been paid more and more attention worldwide once again. According to the development trends of the global healthcare requirement, nations from all over the world have been continuously relaxed the restraints on TCM. As the modernization of TCM promotes, the position of it has been enhanced globally, and it also has broad development prospects. However, since the medication mechanism of TCM is different from that of the Western Medicine, the major obstacle of TCM's internationalization is that it cannot meet the internationally well-acknowledged drug testing standard, therefore preventing it from entering the international market in the form of therapeutic drugs. Thus, evaluating and standardizing the quality of TCM has become the key issue.

This dissertation studies the development situation of plant medicine/TCM in the international market, thus determines the problems as well as opportunities of development of plant medicine/TCM in the international market. Meanwhile, this dissertation analyses the different requirements on plant medicine/TCM in the pharmacopoeias and/or drug standards from different countries/regions, and chooses three countries China, Japan, and Korea, which have similar culture background, to carry out a comparative analysis on their TCM quality standard. Seven crude drug which have the same original plant are chosen as examples from the pharmacopoeias of these three countries, standard testing methods and limitation value of these seven crude drugs are compared.

Combined with the key technologies of existing international commercial quality standard for TCM, this dissertation studies the frame of the key technologies for international commercial quality standard ,and designs and establishes the preliminary draft international commercial quality standard for two commonly used TCM, Panax notoginseng and Salvia, and practically optimizes the preparation and analytical technologies in quality control for these two TCM.

This dissertation independently and thoroughly analyzes the present situation and characteristics of Macau's TCM industry, as well as the significance of establishing TCM quality evaluation standard in promoting the leaping development of Macau's TCM industry, its industrial economic restructuring, and the development of medical technology industry in Macau.

Based on research, this dissertation reveals the great marketing potential of plant medicine/TCM in the international market, as well as the existing obstacles in the aspect of TCM quality control. It finds out the alterations of plant medicine/TCM quality control regulations, which is beneficial to the development of TCM, among state (regional) pharmacopoeias or drug standards in the world. This dissertation puts forward the framework of key techniques in international commercial quality standards for TCM, while designs and establishes the preliminary draft international commercial quality standard for TCM. Also, it gives suggestions on the formulation of TCM quality standard in Macau.

Keywords: TCM quality, quality control, commercial standard, Macau