



Available online at SciVerse ScienceDirect  
**Chinese Herbal Medicines (CHM)**

ISSN 1674-6384

Journal homepage: [www.tiprpress.com](http://www.tiprpress.com) E-mail: [chm@tiprpress.com](mailto:chm@tiprpress.com)



## Editorial

# Quality Marker Concept Inspires the Quality Research of Traditional Chinese Medicines

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DOI: 10.1016/S1674-6384(17)60069-8

Traditional Chinese medicines (TCMs) have been used in China for thousands of years for the treatment of various diseases, highly treated as the Chinese cultural heritage. It has played the pivotal role in maintaining the health of Chinese people and even the entire globe. In the past 20 years, TCMs scientific research and industry have witnessed rapid development and growth. The TCMs industrial gross output has reached 780 billion RMB in 2015. Over the past decades, TCMs have been gaining increasing global acceptance in such developed communities as American and European countries (Normile, 2003; Stephen et al, 2004).

However, the TCM quality control system has not been fully established to cover the entire production chain of TCM products from the field cultivation, collection, processing, and manufacturing process to the final formulation. TCMs quality standards are mainly reflected in the TCMs compendium of *Chinese Pharmacopoeia* but from which one can see that majority of the Chinese crude drugs and decoction slices are still short of holistic quality standards in which some are even lack of quantitative markers specified. This quality control model clearly does not fit for the quality assessment of TCMs complex system. The main challenges for the TCMs quality research and elaboration of quality standards fall into the four aspects: a) analysis and characterization of the chemical components in TCMs herbs especially in TCMs compound formulas; b) single marker approach for quality control is not suitable for TCMs multiple component system, hence, development of a comprehensive quality model is the necessity; c) clarification of active or even effective components in TCMs; and d) elaboration of scientific, practical and feasible quality standards. To meet the afore-mentioned challenges, a holistic and feasible approach should be developed for the proper quality control of TCMs crude drugs, decoction slices and finished products (Guo et al, 2015).

In the perspective article of "A New Concept on Quality Marker for Quality Assessment and Process Control of Chinese Medicines" [CHM, 2017, 9(1): 3-13], Liu et al

described a new concept of quality marker (Q-marker) for the quality assessment and standard elaboration of TCMs. In the proposed new Q-marker concept, the definition of Q-marker as well as the relevant methods was discussed on the basis of biosynthetic pathways of secondary metabolites and source of biological active components. According to the authors, Q-marker is defined as the chemical component(s) with the following four features as: 1) Q-marker exists naturally in herbs, decoction slices, extracts, and finished formulations; 2) Q-marker should be analyzed through either qualitative or quantitative approaches; 3) Q-marker should be identified by considering and closely associated with such TCM theories as King (*Jun*), minister (*Chen*), assistant (*Zuo*), and guide (*Shi*), and TCM compatibility, as well as the modern pharmacological research results; 4) Q-marker is a chemical substance with the feature of transferability and traceability in the process of production and preparation. This definition of Q-marker clearly indicated that the establishment of Q-markers should meet the four requirements so that the TCMs quality could be assessed. A four-stage process to determine the Q-markers, as well as the pathways of improving quality of TCMs were also proposed covering the preparation of standard decoction, fingerprint development, biological effect evaluation and determination of quantitative and qualitative Q-markers.

In alignment with this new concept of Q-marker, several typical TCMs herbs were practiced for the development of quality control method or pharmacopoeia standards. *Corydalis Rhizoma* is commonly used Chinese herbal medicine with alkaloids as its major components. By specific biosynthesis pathway analysis of the chemical composition, as well as the potency, efficacy, pharmacodynamics, pharmacokinetics and network pharmacological analysis, the biological activity of its main alkaloids were confirmed. Through qualitative identification and quantitative analysis of 11 batches of samples of *Corydalis Rhizoma*, similarity analysis and principal component analysis, fingerprint control methods were established. Finally, seven alkaloidal

compounds including tetrahydropalmatine, corydaline, coptisine, palmatine, dehydrocorydaline, tetrahydrojatrorrhizine, and protopine have been selected as Q-markers for the elaboration of quality standard of the herb (Zhang et al, 2016). Similarly, five chemical saponin markers were established for the quality standard of *Panax Notoginseng Radix* (Yao et al, 2015), and 10 triterpenoids markers used for the development of pharmacopoeia quality standard of *Ganoderma lucidum* (Da et al, 2012). This concept was also confirmed to be equally suitable for the development of quality standard of compound formulas. Brucine and strychnine occurring in King herb of "Biqi Capsule" were proved to be the suitable Q-markers of the product (Xu et al, 2009).

The Q-marker is a brand new concept not only for the quality assessment and control of TCMs but also for other herbal medicine systems which shares similar features of multiple components. The definition, steps, and basic principle to establish Q-markers are defined and several successful examples are practiced and it can be promisingly to predict that this new concept will inspire the future TCM quality research and also greatly improve the quality of the TCM quality standard. But before it is widely accepted and universally applied in herbal quality standard development, in depth research needs to be performed in a case-by-case manner for different TCMs to clarify the suitable Q-markers for each herb and herbal products. It is also worth to mention that integration of traditional Chinese herbal theory with such modern science as natural products chemistry, chromatographic analysis, network pharmacology, systems biology, etc. is essential for the determination and validation of reasonable, scientific, and practical Q-markers. It is firmly

believed that Q-marker concept will change the paradigm of TCM quality control pattern, and hence to drastically improve the quality control capability of TCMs for the better serving Chinese people and all mankind at large.

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