XXI IMEKO World Congress "Measurement in Research and Industry"
August 30 – September 4, 2015, Prague, Czech Republic

TRADITIONAL CHINESE MEDICINE REFERENCE MATERIALS

JUN LIU

National Institute of Metrology, Beijing, P.R.China, liujun@nim.ac.cn

Abstract – This paper will give an overview to the current definitions, classification and requirements that apply to reference materials used to analyse Traditional Chinese Medicine.

Keywords: reference materials, classification, requirements, Traditional Chinese Medicine

1. INTRODUCTION

With a history of 2000 to 3000 years, Traditional Chinese Medicine (TCM) has formed a unique system to diagnose and cure illness. And it has been gradually becoming a hot topic in the world. Concerns about the safety and quality of TCM have increased at both governmental and consumer levels. The Chinese government attaches great importance to and issued a series of laws and regulations, such as Chinese pharmacopoeia, the health ministry's ministerial standard, bureau awarded standards and local standards. Many consumers believe that TCM will improve their health and that these "natural" remedies are effective. Consumers today are interested in the information appearing on product labels. There are occasional reports of inaccurate labelling, adulteration, and contamination (with pesticides, heavy metals, or toxic botanicals). Manufacturers should establish specifications for identity, purity, strength, and composition; to set limits on contaminants and adulterants for every ingredient in their products; and to analyze both "materials in process" and finished products to determine whether specifications are met. ISO/IEC 17025 requirements laboratories to develop a quality assurance system to ensure that every analytical methods are validated with the best applicable means and are fit for the intended purposes. Reference materials (RMs) are used to calibrate and validate the testing methods that are applied within the framework of quality control throughout all of the stages in the production and manufacture of TCM. The quality of these RMs is therefore of prime importance to the quality and associated safety and efficacy of these products.

2. THE STATUS OF TCM RMS IN CHINA

2.1. Definition

TCM RMs agree with the requirements of the ISO Guides.

ISO Guide 30: 1992: Terms and definitions used in connection with reference materials.
ISO Guide 31: 2000: Reference materials – contents of certificates and labels.
ISO Guide 32: 1997: Calibration in analytical chemistry and use of certified reference materials.
ISO Guide 33: 2000: Uses of certified reference materials.
ISO Guide 34: 2000: General requirements for the competence of reference materials producers.
ISO Guide 35: 2006: Reference materials – general and statistical principles for certification.

ISO Guide 30: 1992 defines a reference material as follows: "Material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials." At the same time, a reference material can also be a defined individual substance.

Detailed quality requirements and technical principles are clearly regulated in the Pharmacopoeia.

2.2. Status quo

Studies on TCM RMs began in 1985 in China, table 1 shows the number of TCM RMs in "Chinese pharmacopoeia".

Table 1. The number of TCM RMs in "Chinese pharmacopoeia".

	Purity	Matrix	Extract
1985	60	16	0
1990	100	39	0
1995	143	94	0
2000	207	*156*	0
2005	282	218	11
2010	464	369	16

3. CLASSIFICATION

3.1. Purity RMs

Due to the complexity of natural ingredients, poor stability and low content, it is difficult to get a certain number of monomer composition extract. According to the purposes, purity RMs for Traditional Chinese Medicine mainly has 3 kinds:

(1) Used for the qualitative analysis

It is mainly used to identify by thin layer chromatography (TLC), gas chromatography in traditional Chinese medicine, Chinese medicine yinpian, extracts and Proprietary Chinese medicine which the purity should be above 95%.

(2) Used for quantitative analysis

These RMs are used in the methods of ultraviolet spectrophotometry (TLCs), a colorimetric method and thin layer chromatography ultraviolet spectrophotometry and thin layer scanning (TLCs) and HPLC, gas chromatography (GC) an so on which the purity is over 98%, i.e .the purity of monomer composition of raw material is over 99.5%.

(3) Used for the inspection of the impurities

According to the requirements, the RMs were used to check the impurities, distinguish kinds or toxic ingredients etc. which the purity should be fit for the purpose.

3.2 Natural-matrix RMs

These RMs have been identified for the native medicine which used for the confirmation of varieties, acquisition and collection of raw material, the qualitative analysis (such as TLCs) and quantitative analysis.

RMs should meet the requirements:

(1) Identification of varieties, each species must be in accordance with the provisions, identification of plant species;

(2) Raw material acquisition and collection: control medicinal material generally USES the mainstream of Chinese goods, meet the requirements of the GAP specification of cultivation of high quality Chinese herbal medicine;

(3) Pharmacognostic identification of medicinal properties, organization and the powder microscopic identification, identify medicinal material base of the original, must conform to the prescribed standards.

(4) Check items: according to the provisions of the standard to remove impurities;

(5) Tested items: thin layer selection criteria specified in the first test method, and then according to the extraction of medicinal ingredients is different from the standard test methods or expand conditions. Checked medicinal materials must be to check out the control or the chromatographic behavior of specimen with a consistent, the main chemical composition if there is a known chemical reference substance, should be consistent with the chemical reference substance chromatography spots. Content of 6 items: according to the prescribed standards for content determination, should comply with the prescribed standards.

3.3. Extract

This kind of RMs is not monomer composition which main composition is relatively fixed. Most of the raw material extracted from natural plant and animal.

Extract RMs should meet the requirements:

(1) The source of the raw material, extracted parts and preparation process should be conformed to the provisions;

(2) The main composition and content of relatively are fixed (TLC, HPLC, GC), and

(3) It should be consistent between physical and chemical characteristics in batch (solubility, relative density, refractive index, optical rotation, etc.

4. CHALLENGES

Developments in TCM science and technology lead to more challenges. The firstly challenge is the lack of reference materials for validation of analytical methods. Chinese Pharmacopoeia are constantly developing new monographs on TCM and TCM preparations and it will be a second challenge to select suitable purity, natural-matrix, extracts and authentic RMs to be applied in assays or system suitability tests. Thirdly, the crucial point in respect to the topic of RMs is their use for pharmacological and toxicological investigations. In a word, the quantity and quality of TCM RMs are not enough, and selection and use RMs are very important.

5. CONCLUSIONS

To meet the needs of analytical laboratories, manufacturers, and regulators, some actions should been taken:

(1) Increase the types and availability of TCM RMs;

(2) Develop methods of analysis for these materials;

(3) Strengthen the domestic and international technology exchange.