

CHINESE MEDICINE TESTING – APPLYING MODERN SCIENCE TO TRADITION

AUTHOR: ANDY TONG, CUSTOMER SERVICE AND TECHNICAL MANAGER, SGS LIFE SCIENCE SERVICES, SHANGHAI, CHINA

Traditional Chinese Medicines (TCMs), principally composed of herbal preparations, are used widely to prevent, diagnose and treat diseases. TCM preparations potentially contain herbs, shell, animal bone, and/or minerals in varying combinations. The goal of taking such preparations is to nourish the body, thus restoring balance of energy, body and spirit.

The use of TCMs dates back about 3,000 years. By 200 BC, TCMs were firmly established as options for maintaining or improving health, and by the first century AD, a listing of medicinal herbs and herbal formulations had been developed.

The earliest existing text on TCMs, the book *Shen Nong Ben Cao Jing* (“Ben” means root and “Cao” means shoot), was written sometime during the Qin and Han Dynasties (221 BC – 220 AD). This book was based on the work of medical experts who gathered a plethora of information before the Qin Dynasty. The book covered 365 types of medicine, some of which are still used in contemporary medicine. The *Shen Nong Ben Cao Jing* laid the foundation for the establishment of eastern medicine.

Li Shi-Zhen authored the classic book on TCMs during the Ming Dynasty (1152–1578). This work lists nearly 2,000 herbs and extracts. By 2010, the latest edition of *The Pharmacopoeia of the People’s Republic of China* now lists approximately 2,165 single herbs or extracts and complex formulations¹.

With the increase in popularity of herb-based medicines, many TCMs are sold worldwide either individually or as a formulation component. These TCMs and herbal formulas are often available

in health food stores, some pharmacies, and at herbal medicine practitioner offices. The global market for herbal medicines is estimated to be worth United States Dollars (USD) \$60 billion annually according to the World Health Organization (WHO)². In China alone, there are more than 4,000 Traditional Chinese Medicine manufacturers, 43 dosage forms and more than 5,000 varieties in the market. The total annual output of TCMs in China tops USD \$8.4 billion³. The export of raw materials and medicines is worth on the order of USD \$600 million to China, exporting to more than 130 countries. Similarly, the TCM market in Korea is estimated at USD \$1 billion⁴.

Some herbs or extracts are believed to play a role in prevention and treatment of cancer and other diseases when combined with conventional treatment. However, more research is needed to determine the effectiveness of these individual substances. Some herbs and herbal formulations have been evaluated in animal, laboratory, and human studies in both the East and West with wide-ranging results (see Table 1).

Evidence from randomized clinical trials indicate that some TCMs may contribute to longer survival rates, reduced side effects, and lower risk of recurrence

for some cancers, especially when combined with conventional treatment.

REGULATIONS

Given the tremendous size of the TCM market, many governments have enacted regulations for TCM practice in order to ensure product consistency and patient safety.

In China, synthesis of medicinal herbs using Western techniques has led to the successful integration of East and West medicine. Artemisinin is the most successful case.

In most European countries, the main component of TCM preparations is strictly controlled, but inclusion of multiple other components is permitted. Furthermore, the use of TCMs in Europe is limited by prescription from a physician, making the market and management standardized and controllable. In 2004, the European Union (EU) formed a new government panel to investigate the safety of herbal medicines. The Committee on Herbal Medicinal Products holds its meeting every two months under new EU legislation designed to protect consumers. One of the goals of the panel is to harmonize regulation of the herbal product industry across the EU.

TABLE 1: PLANT-DERIVED MEDICINAL COMPOUNDS: A REPRESENTATIVE SAMPLE

TYPE	COMPOUND	SOURCE	DISEASE TREATED/USE
Alkaloid	Camptothecin	<i>Camptotheca acuminata</i>	Breast, colon cancer, etc.
	Colchine	<i>Colchicum autumnale</i>	Antitumor agent, gout
	Irinotecan	<i>Camptotheca acuminata</i>	Anticancer, antitumor
	Quinine	<i>Cinchona ledgeriana</i>	Antimalarial, antipyretic
	Reserpine	<i>Rauvolfia serpentina</i>	Antihypertensive, tranquilizer
	Theobromine	<i>Theobroma cacao</i>	Diuretic
Glycoside	Etoposide	<i>Podophyllum peltatum</i>	Antitumor agent
	Digitalin	<i>Digitalis purpurea</i>	Cardiotonic
Terpenoid	Docetaxel (Taxotere)	<i>Taxus sp.</i>	Antitumor agent
	Artemisinin	<i>Artemisia annua</i>	Antimalarial
	Paclitaxel (Taxol)	<i>Taxus sp.</i>	Breast, colon cancer, etc.

In the US, TCMs are encompassed by the phrase Complementary and Alternative Medicine (CAM). The US Federal Drug Administration (US-FDA) regulates herbal and other dietary supplements as foods or nutraceuticals rather than as drugs. A nutraceutical is defined as any substance that may be considered a food or part of a food and provides medical or health benefits, including preventing and treating disease. The preparation of TCMs in the US does not have to meet the same strict standards as drugs or over-the-counter medications with respect to proof of safety, effectiveness and what the US-FDA refers to as Good Manufacturing Practices (GMPs). In general, the laws governing the marketing and sale of foods (including supplements) are less strict than the laws governing drugs. Importantly, the manufacturer of foods does not have to prove supplement quality.

CHALLENGES AND QUALITY CONTROL

The use of TCMs in therapy has been assessed in only a few clinical trials that have followed methodologies considered

adequate by modern Western medical researchers. Therefore, the effectiveness of the tested TCMs is considered poorly documented. Research results vary widely depending on the specific herb, but several have shown activity against cancer cells in laboratory cell cultures and in some lab animals⁵. Many of these studies, however, are published only in Chinese, making it difficult for English-only scientists to assess the results. Furthermore, some of them do not list the specific herbs tested or describe the study methodology in enough detail to determine whether they are comparable to those used in Western clinical research.

Because of the variety of herbs used in TCM, the potential exists for negative interactions with prescribed drugs. Some herbal preparations contain other ingredients that are not always identified. The US-FDA has issued a statement warning diabetics to avoid several specific brands of TCM products because they illegally contain the prescription diabetes drugs glyburide and phenformin. US-FDA warnings have been issued for PC-SPES (TCM compound prescription or TCM compound formulations) and production

of these products was suspended due to inclusion of prescription drugs: indomethacin, diethylstilbestrol, valium and warfarin⁷.

The California Department of Health found that nearly one-third of TCMs tested were contaminated with toxic metals such as mercury, arsenic and lead. Concerns about TCM products have been raised in other countries as well. As the TCM industry becomes increasingly regulated, testing of raw materials, as well as intermediate and finished products is becoming increasingly important⁶.

In China, several agencies exist that manage and control TCM quality, including the State Food and Drug Administration (SFDA) and the State Administration of Traditional Chinese Medicine (SATCM). Good Agricultural Practice of Medicinal Plants and Animals (GAP) is the main regulatory agency governing the cultivation of plants used for TCMs. The Chinese Pharmacopoeia 2010 edition (Ch.P.2010) Volume I is the official test standard for TCMs. Ch.P.2010 Volume I requires that TCMs undergo various types of testing depending on type. For crude medicinal

material, testing attributes include: appearance; powder identification; thin layer chromatography (TLC)-mediated identification; loss on drying; total sulphated ash; heavy metal impurities (lead, cadmium, arsenic, mercury and copper); pesticide residues; and assay of main components. TMC extracts require similar tests. Conversely, for TMC preparations, the number and quality of testing attributes is significantly greater, as is the level of control over tests. For injectionables, additional attributes tested include: formulations, preparation, related-substance identification, abnormal toxicity test and hemolysis.

SGS'S EXPERTISE ON TCM TESTING

Key platforms for TCM testing include:

1. Routine tests (SGS Life Science Services, Shanghai)

Routine test for TCM crude material, extracts and preparation according to Ch.P. 2010 or other standard methods, including appearance, powder identification, TLC identification, loss on drying, total sulphated ash, heavy metals or element impurities, pesticide residue, chromatograph finger-print, related substances, abnormal toxicity test, assay of main components and others.

2. Professional testing services (SGS Life Science Services, Shanghai)

SGS has successfully developed pesticide residue test procedures thus far for ginkgo leaf and radix sophorae flavescentis according to EP 7.0 and USP 36. Peppermint oil chromatograph finger-print and inductively coupled plasma-mass spectrometry (ICP-MS) for centelia total glucosides have been validated according to Ch.P. 2010 volume I. Furthermore, SGS can provide services to develop a TCM quality standard for any given herbal or formulation based upon client requirements.

3. Adulteration and counterfeit drugs testing (SGS Life Science Services, Taiwan)

Common services include Medicine Adulteration test and Counterfeit Drug testing using several advanced techniques, including high-performance liquid chromatography (HPLC), HPLC-MS/MS, gas chromatography-mass spectrometry (GC-MS), and others. Capabilities include qualitative analysis of 9 diet drugs, 22 erectile dysfunction drugs and other 224 medicines, using TCMs.

SGS Life Science Services laboratories aid Chinese Medicine manufacturers in ensuring the quality and competitiveness of their products by leveraging the knowledge, experience, and expertise in the Quality Control Testing of pharmaceutical and biopharmaceutical drug products.

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CONTACT INFORMATION

EUROPE

BELGIUM

+32 10 42 11 11
be.pharmaqc@sgs.com

FRANCE (PARIS)

+33 1 41 06 95 93
fr.pharmaqc@sgs.com

FRANCE (POITIERS)

+33 (0) 5 49 57 04 04
clinicalresearch@sgs.com

GERMANY (BERLIN)

+49 30 3460 7500
de.pharmaqc@sgs.com

GERMANY (FREIBURG)

+49 761 6116 7760
de.m-scan@sgs.com

GERMANY (TAUNUSSTEIN)

+49 6128 744 245
de.pharmaqc@sgs.com

ITALY (LIVORNO)

+39 0586 852591
it.pharmaqc@sgs.com

SWITZERLAND (GENEVA)

+41 22 794 8374
ch.m-scan@sgs.com

UK (GLASGOW)

+44 141 952 0022
biosafety@sgs.com

UK (WOKINGHAM)

+44 (0) 1189 896940
uk.m-scan@sgs.com

ASIA

INDIA (CHENNAI)

+91 44 2254 2601
in.pharmaqc@sgs.com

INDIA (MUMBAI)

+91 22 6457 2540 45
in.pharmaqc@sgs.com

SINGAPORE

+65 677 53 034
sg.pharmaqc@sgs.com

CHINA

+86 21 6115 2197
cn.pharmaqc@sgs.com

TAIWAN

+886 2 2299 3279 ext 2500
tw.pharmaqc@sgs.com

NORTH AMERICA

CANADA

+ 1 905 364 3757
ca.pharmaqc@sgs.com

USA (FAIRFIELD, NJ)

+ 1 888 747 8782
us.pharmaqc@sgs.com

USA (LINCOLNSHIRE, IL)

+1 847 821 8900
us.pharmaqc@sgs.com

USA (WEST CHESTER, PA)

+ 1 610 696 8210
us.m-scan@sgs.com

WWW.SGS.COM/LIFESCIENCE