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Herbs: Puríty & Potency

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Herbs: Purity & Potency

Medicinal herbs travel from seed to the medical practitioner's office. Here, we explore how purity, potency, and sustainability are impacted by this journey. From seed to bottle, we look at farming practices, extraction techniques, protection of endangered flora and fauna, quality certifications and testing, traceability, herbal medicine research, and methods for verifying the geo-authenticity of herbal medicines. Ultimately, this entire chain affects the ability of medicinal herbs to deliver positive patient outcomes.

This continuing education course is a multimedia experience with two major components. This eBook is one component, the other is a video, please view the video at the following link:

https://youtu.be/XEWFykQT5ic



The following is an alternate link if the above link does not function: https://www.youtube.com/watch?v=XEWFykQT5ic

At HealthCMi, we reached out to Dr. Teresa Williams Zhang, Ph.D. and Dr. Ann Wang, CMD, L.Ac. to ensure that we have the most accurate and up-to-date scientific information. Dr. Williams, Ph.D. received her B.S. from the Massachusetts Institute of Technology (MIT) and her M.S. and Ph.D. degrees from the University of California at Berkeley. She is currently VP of operations at Treasure of the East, which provides herbal medicines from Tianjiang.

Dr. Ann Wang, CMD, L.Ac. is the founder and director of the Integrative Medicine Center (Ithaca, NY) and is a medical consultant for Treasure of the East. She received her medical degree in Chinese medicine from Shandong University of Traditional Chinese Medicine. Previously, she was Chief Medical Administrator of the Chinese State Administration of Traditional Chinese Medicine, adjunct professor of the China Academy of Chinese Medical Sciences, and a faculty member at Cornell University. She is one the first overseas practitioners to be awarded the title of Doctor of Chinese Medicine, Physician in Chief by the World Federation of Chinese Medicine Societies. She is also a member of the Presidential Council of the World Federation of Chinese Medicine Societies.

Dr. Wang's adventure in Chinese medicine brought her back to China decades ago because she started having difficulty getting clinical results with herbal medicines. After determining that many raw and packaged herbal medicines lacked adequate potency, she ventured to China and investigated the issue. Over-farming, stripping of wild herb species from the land, pollution, and other issues heavily impacted the herbal medicine industry.



Variety of Herbs

Tianjiang & Treasure of the East

Dr. Wang, L.Ac. found a small research company that was producing quality herbal medicines. Since that time, that little company (Tianjiang) has grown into a multi-billion dollar enterprise supplying over 8,000 hospitals across Asia with medicinal herbs. She started Treasure of the East in the USA, which provides herbs from Tianjiang. Since that time, her clinical successes with herbal medicines have returned. Her hypothesis was correct and it was the lack of herbal medicine potency that was impacting patient outcomes.

Dr. Wang, L.Ac. notes that there are two important aspects to herbal medicine: inheritance, innovation. She notes that we have inherited a great treasure of Chinese medicine and the focus is on continuing to innovate the resources and improve availability.

China Pharmaceutical University

This history is important because Tianjiang created an educational consortium with China Pharmaceutical University's Department of Genetics and Breeding, that specializes in Chinese medicinal herb cultivation. This resulted in the first publication of a work that identified the historically correct species of Chinese medicinal herbs, confirmed by various testing methods, including TLC (thin-layer chromatography). In this way, correct seed stocks are identified and maintained. That work is entitled *TLC Atlas of Concentrated Granule Prescription*. The following pictures are from a two volume set:





Seeds

The *TLC Atlas* allows for determining exact botanical identity. Herb producers throughout China and the Chinese government have adopted the *TLC Atlas* as a definitive standard of Chinese herbal medicine identification. Using TLC and mass spectrometer multi-constituent testing, Tianjiang (in partnership with China Pharmaceutical University) has differentiated specific herb varieties with the greatest concentrations of therapeutic components.

Several decades ago, this level of determining herbal authenticity was unavailable. However, the nascent Chinese herbal medicine industry has grown significantly enough to document this important information.

Requirements for testing and maintenance of seeds is an active process, involving many moving parts. This requires a significant amount of labor because the quality of seeds may deteriorate over time for any given crop and careful attention to seed breeding must be continually applied and tested. In the case of Tianjiang, they developed a standard to address this issue for their cultivation base: Good Agricultural Practice (GAP). This requires active involvement of the China Pharmaceutical University (中国药科大学) to maintain and

develop seed stocks. The focus is on maintaining a seed bank with the truest adherence to traditional Chinese medicine functions.

Prior to development of the aforementioned standards (using scientific equipment) herbalists were often limited to plant and seed identification by means of organoleptic inspection. Now, organoleptic inspection (taste, sight, smell, touch, etc...) is only one aspect of identification.

Planting

Dr. Wang notes that after three cycles of planting a medicinal herb crop in one region, efficacy often diminishes and pest control issues emerge. Specific farming practices are implemented by Tianjiang to address this important issue and to ensure continued potency and purity of herbal medicines.

Daodi

Daodi regions are the first choice for growing herbs, unless potency and purity are superior in other regions. The term daodi is similar to the French term *terrior* (environmental conditions, including soil and climate, for growing grapes).

Daodi has a broader scope in that the term also includes individual herb organoleptic qualities and clinical efficacy. Daodi refers to the traditional regions and conditions that specific species of herbs are planted, grown, harvested, processed, and then subsequently produce clinical results. The term geo-authenticity applies to regional specificity for daodi herbs. Pao zhi (medicinal processing) is an important aspect of daodi. From seed to clinical results, daodi covers specific parameters for the production and processing of herbs.

Chemical Continuance

Tianjiang tests crops across different regions to determine the ideal planting conditions that produce effective herbs. They discovered that some regions produce better, more potent, herbs than others. This is the concept of chemical continuance, which includes where to grow an herb based on the regions that produce the greatest concentrations of active components.



Bai He

Purity & Sustainability

The HealthCMi research for this course focused on Tianjiang's seed to bottle process because, over the years, they have developed high standards in Chinese medicinal herb production. In our examination of their processes, we learned that there is a highly regulated and controlled system to test for pesticide residues, heavy metals, bacterial levels, aflatoxins, sulfur dioxide, lead, cadmium, mercury, copper, and other potential contaminants. The advanced scientific testing methods allow for a pure herbal product. It is recommended that acupuncturist/ herbalists only use herbs that have undergone extensive testing, such as the methods used at Tianjiang.

Whatever herbal supplier you choose, ensure that production is in accordance with Good Manufacture Practice (GMP). Tianjiang is GMP compliant and uses ISO Class 6 clean rooms for processing. Another important, and sometimes overlooked, part of processing is using only filtered water. Tianjiang uses filtered water in their automated herb processing and filtering.

Tianjiang never uses banned endangered species and receives certificates from CITES (Convention on International Trade in Endangered Species of Wild Fauna and Flora) to ensure that herbs come from sustainable sources and never from the wild. As licensed acupuncturists, we are often keenly aware of the issue surrounding animals, but the same issues exist for herbs.

Tianjiang develops seeds and plants, including Tian Ma, Rou Cong Rong, Bai Ji, and Bei Sha Shen. These protected and endangered plants, if stripped from the wild, could potentially go extinct. The efforts of Tianjiang in maintaining seed banks and appropriate planting regions preserves the legacy and existence of many herbal medicines.

Tianjiang maintains a direct relationship with farmers. In the same way, the company maintains partnerships with China Pharmaceutical University and over 25 additional research and herbal medicine related institutions. In many ways, it takes a community, working together, to provide quality herbal medicines.

Advanced farming practices is an important contribution to the preservation of herbs. Tiangjiang owns approximately 70 farms and contracts with hundreds of other farms to ensure sustainability, GMP (Good Manufacturing Practices) certification, and adherence to Good Agricultural Practice (GAP). This also helps maintain ISO (International Organization for Standardization) certification for quality measurements, calibration, environmental management, and testing.

These standards are why Tianjiang supplies over 8,000 hospital herbal medicine granule pharmacies across Asia. At HealthCMi, we do not have a financial relationship with Tianjiang; however, we are featuring this company because it represents an important standard for the herbal medicine community.

Traceability

Having a direct relationship with company owned farms, testing centers, processing facilities, and independent farms allows for tracking and accountability. For Tianjiang, they use a QR code for herbal medicine batches to ensure traceability, which encompasses the following data:

- Farmer record
- Origin environment
- Planting management
- · Field management
- Harvest management
- Processing management
- Storage management
- Transfer/transportation management
- Sales management and warehouse management

The QR code information shows where herbs are grown, when they were harvested, identification of specific batches, and even includes the packing date. Treasure of the East sells Tianjiang herbs in the USA and complies with FDA regulations with a bar coding system that links to the Tianjiang safety tracing system.



Variety of Herbs

Processing & Extraction

When many of us started practicing acupuncture and herbal medicine decades ago, unified production standards for herbal medicines did not exist. Many herbs that we purchased contained sulfur dioxide and other contaminants because our suppliers bought herbs in open air markets that lacked quality controls.

Traceability was almost completely unavailable. It got to the point where we were not getting results from herbs, which previously were very helpful to patients. At HealthCMi, we recall when Tian Ma became ineffective and simultaneously endangered. Thankfully, Tianjiang maintains Tian Ma in the seed bank, along with many other herbs, and cultivates herbs in appropriate regions for both potency and purity.

Dr. Wang, L.Ac. notes that there are many intricacies that must be observed when producing herbal medicines, with exact controls. This is

part of **optimal parameter development**. This includes growing, processing, and testing procedures and standards.

Volatile Oil Capture

One important example is the location of processing facilities. For example, the active ingredients in Bo He (volatile oils) are best preserved when the herbs are processed fresh. As a result, Tianjiang built a processing facility near the farms that grow the herbs to achieve fresh processing. In addition, special extraction techniques capture the volatile oils and ensure that they are in the herbal granules at completion of processing.

Dry Granulation & Optimal Parameters

Tianjiang uses a dry granulation technique, which is superior to wet spray. Dry granulation does not require an excipient and can be achieved at low temperatures, thereby preserving the active ingredients in many herbs.

Tianjiang sets optimal parameters based on variables such as temperature, pressure, length of time, and number of extractions. These parameters have been repeatedly tested in several ways. For example, HPLC (high-performance liquid chromatography) is used to measure the active ingredients in herbs before and after processing to ensure that the active ingredients are preserved and not destroyed.

Also, some active ingredients cannot be fully extracted in one process and must be cooked three times to achieve the best results, as in the case of Huang Qin. If that wasn't enough to figure out, the pressure, temperature, and length of time at each cooking is different.

This is a massive undertaking because each herb must be tested under a variety of processing conditions (temperature, pressure, length of time, number of extractions, etc...). After a myriad of conditions are tested, the optimal method of extraction (HPLC verified) for each herb is standardized. This helps produce the **maximum potent chemical constituents**.



Zi Su Ye

Low Temperature Extract

Many of us enjoy oils, such as olive oil, that are cold pressed. This process prevents degradation of the oil. Herbal medicines contain many oils and other ingredients that require low temperature extraction. Often, boiling herbs destroys many active ingredients. The history of the importance of low temperature extraction is well documented in Chinese medicine history. Next, we take a look at a discovery based on this important variable in herbal medicine processing.

Dr. Tu Youyou

Dr. Tu Youyou (Chinese Academy of Chinese Medical Sciences) received both the Nobel Prize in Medicine and the Lasker-DeBakey Clinical Medical Research Award for developing an herbal based cure for malaria. During the Vietnam War, troops were suffering from malaria. Dr. Tu Youyou headed Project 523, a top secret Chinese military project seeking the cure for malaria in the late 1960s.

By 1972, Dr. Tu Youyou's team extracted Qinghaosu (artemisinin) from Qing Hao (Artemisia annua) and successfully isolated a cure for malaria. Qinghaosu is safe for human consumption but is lethal to Plasmodia, the parasitic protozoans responsible for malaria.

Dr. Tu Youyou investigated the efficacy of Qing Hao for the treatment of malaria because it was already in use for that purpose among traditional Chinese medicine herbalist-acupuncturists for at least 1,600 years. In the year 340 CE, Ge Hong included Qing Hao as a cure for malaria in the classic work the *Handbook of Prescriptions for Emergencies*. Ge Hong included specific directions to extract Qing Hao in cold water and to wring out the juice. Dr. Tu Youyou was familiar with this Chinese medicine classic text.

Dr. Tu Youyou then applied modern extraction techniques to concentrate the herb Qing Hao. Instead of using conventional high temperature water concentration methods, Dr. Tu Youyou used a low temperature ether extraction method to preserve the active ingredients. It was confirmed that Ge Hong was correct and Qing Hao degrades at high temperatures.

Dr. Tu Youyou made several other important findings. She identified that Qing Hao leaves contain the most significant amount of active ingredients. She also determined the optimal time to harvest the plant to sustain maximum yields. In the process, she also removed acidic portions of the concentrate that did not provide anti-malarial benefits. As a result, the final concentrate was safe, potent, and effective. Qinghaosu rapidly reduces fevers and eliminates blood-borne parasites in patients with malaria.

Separate And Combined Extraction

In our interview with Dr. Williams, Ph.D. and Dr. Wang, L.Ac., we inquired about decocting herbal formulas either separately for each herb or whether or not a full formula is decocted in the same batch. For all Treasure of the East formulas, each individual herb is extracted separately and then later combined into a formula. Naturally, our question was, which method is better?

There are two major levels of testing that determine the answer. The first level is measuring the level of active ingredients in the raw herbs before and after processing. The next level is to test the actual formula in clinical trials to determine real world efficaciousness. The research teams at Tianjiang and associated research institutions determined that this question can only be answered by testing each formula, which accounts for a vast amount of research from Tianjiang.

Tianjiang/Treasure of the East uses the separate herb method and not the combined herb method for extraction and dry granulation. The data supports this direction and the separate herb method allows for strict variable controls in all levels of testing. There are both historical and scientific precedents for choosing this method of formulation.

A major reason for choosing the separate herb method is that this process allows for strict control of temperature, pressure, length of time, and number of extractions for each individual herb. The combined technique would preclude the use of the individual specialty techniques required for each herb. Tianjiang developed standard for individual extraction of herbs and combining them into formulas using extensive pharmacology studies and clinical trials. As this is a continuing effort of investigation by herbal medicine producers, we will highlight developments in extraction and combination methods in the HealthCMi newsroom. In summary, the separate method allows for verification of efficacy; however, standards could potentially be developed for the combined method as well.

Capsules, Granules, Powder

Tianjiang features three major forms of herbs: capsules, granules, and concentrated powder. Capsules are convenient, granules offer better absorption and improved efficacy, and concentrated powders are often used to make customized formulas in large batches. Concentrated powders are extracted herbs prior to granulation. Granules dissolve easily in hot water and capsules contain granules.

At HealthCMi, we find the distinct advantage of capsules is the benefit of easy patient compliance. However, granules dissolved in hot water offer better absorption. The method of intake ultimately affects efficaciousness and this same principle also applies to pharmaceuticals.

> The physical form of a drug substance is of great importance as it directly affects the manner in which the material is formulated and presented to the consumer. It also influences more fundamental characteristics such as solubility and dissolution rate, which, in turn, affect bioavailability.¹

^{1.} Hart, M.L., Do, D.P., Ansari, R.A. and Rizvi, S.A.A., 2013. Brief overview of various approaches to enhance drug solubility.

J. Dev. Drugs, 2(3), pp.1-7.

Research

The following is an example of herbal medicine research. At HealthCMi.com, visit the news section to view more research like this on acupuncture and herbal medicine.

COVID-19, Herbs, & Patient Outcomes

Acupuncture and Chinese herbal medicine for the treatment of COVID-19 patients is safe and effective. Researchers determined that specific herbal formulas demonstrate purity, potency, and efficacy. In addition, acupuncture treatments address signs and symptoms including coughing, fatigue, and fevers. In this article, we highlight essential herbal medicine findings.

Researchers from the University of Texas Health Science Center (Houston) and other healthcare centers reviewed the work of Sun et al. Published in the *The American Journal of Emergency Medicine*, the findings indicate that alternative therapies are potentially useful interventions for patients with COVID-19. The doctors from Texas note that, in China, Chinese medicine "is an essential part of the armamentarium to treat these [COVID-19] patients," and that this approach to integrative medicine may facilitate treatment at ports of entry for patients, which are often emergency rooms. [1]

This report was based on a meta-analysis by Sun et al. In a randomized controlled clinical trial analysis of COVID-19 patients with pneumonia, a total of 681 participants across 7 studies were examined. The researchers conclude that the addition of Chinese medicine to conventional care improves clinical efficacy. Importantly, Chinese medicine "significantly increased viral nucleic acid negative conversion rate." [2]

The researchers made three additional important discoveries. Chinese medicine "prominently reduced pulmonary inflammation," "improved host immune function," and did not increase the adverse effect rate. [3] The researchers confirm that for COVID-19 patients, Chinese medicine "exhibited superior performance" for improving the "clinical effective rate, viral nucleic acid negative conversion rate, remission rate of pulmonary inflammation, and biochemical markers." [4]

The researchers discarded studies with risk bias and sorted for low risk bias for inclusion in the meta-analysis. Results were based on quantifiable outcomes, including chest CT scans and remission rates from pulmonary inflammation based on CT scans and biochemical marker improvements (e.g., WBC, IL-6, lymphocyte ratios).

Another meta-analysis of 2,275 COVID-19 patients confirms these findings. The researchers determined that Chinese medicine (e.g. acupuncture, herbs) is standard medical care in China and that Chinese herbal medicine was one of the most frequently applied forms of Chinese medicine. The most common herbs used across 18 randomized controlled trials were: Gan Cao, Huang Qin, Ban Xia, Lian Qiao, Ku Xing Ren.

The research team compared Chinese herbal medicine with conventional medicine. Patients in the Chinese medicine group received either Chinese medicine monotherapy or Chinese medicine combined with conventional medicine. Patients in the conventional medicine group received conventional medicine monotherapy or conventional medicine plus a placebo instead of real Chinese medicine.

The research team determined that Chinese medicine significantly improved patient outcomes. The researchers note, "Our meta-analyses found that comparing CHM [Chinese herbal medicine] group and conventional western medicine group, CHM group has improvements in several clinical parameters including lung CT, clinical cure rate, ranging from mild to critical cases, length of hospital stay, total score of clinical symptoms, fever reduction time, symptom score of fever, number of cough reduction cases, symptom score of cough, number of fatigue reduction cases, symptom score of fatigue, disappearing time of fatigue, TCM syndrome, viral nucleic acid testing, and inflammatory biomarkers (C-reactive protein)." [5] They added that no severe adverse effects resulted from the use of Chinese herbal medicine.

The research team carefully documented methods of quantification and types of herbal formulas used. Some of the formulas reviewed were: Qingfie Touxie Fuzheng, Shufeng Jiedu capsules, Lianhua Qingwen capsules, Xuanfei Zhisou mixture, Shuang Huang Lian oral liquid, Yu Ping Feng granules, Gan Lu Xiao Du Dan, Ma Xing Shi Gan Tang, Chai Ling Ping Wei decoction, Hao Qin Qing Dan decoction, Huo Pu Xia Ling decoction, Qi Wei decoction, Xuebing injection, Tanreqing injection, Sheng Mai injection, Shenfu injection, Tou Jie Qu Wen granules, Jin Hua Qing Gan granules, Re Yan Ning mixture, Shu Feng Jie Du capsules, Lianhua Qing Ke granules, and many custom and standardized herbal formulas to address specific conditions, including pneumonia.

Here, we highlight one of the formulations examined in the study. The formula was devised for the treatment of severe pneumonia and was given the name: Powerful Pneumonia #1 Formulation. The herbs in the formula were: Chai Hu, Huang Qin, Ban Xia, Bing Lang, Cao Guo, Gua Lou, Gan Cao, Hu Zhang, Huang Lian, Zhi Shi, Zhe Bei Mu, Jie Geng, Bai Bu, Qian Hu, Zi Wan, Kuan Dong Hua, Huo Xiang, Pei Lan. We see the treatment strategy addresses damp-heat, external wind-heat, shaoyang stage illness, and heat-toxins. Notably, herbs for the treatment of toxic phlegm and coughing are present. In other formulations, herbs such as Bai Shao, Dang Shen, and Hong Jing Tian are included to address severe fatigue and low blood oxygen levels.

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2. Sun, Chun-Yang, Ya-Lei Sun, and Xin-Min Li. "The role of Chinese medicine in COVID-19 pneumonia: A systematic review and meta-analysis." The American Journal of Emergency Medicine (2020).

3. Ibid.

4. Ibid.

5. Xiong, Xingjiang, Pengqian Wang, Kelei Su, William C. Cho, and Yanwei Xing. "Chinese herbal medicine for coronavirus disease 2019: a systematic review and meta-analysis." Pharmacological Research (2020): 105056.



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