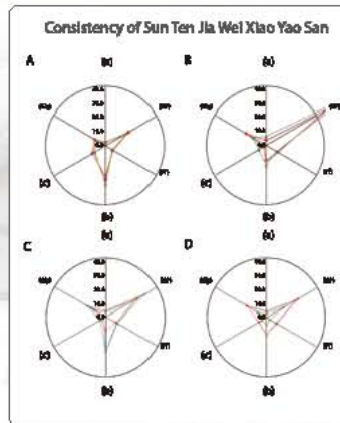


Constituent Verification

HPLC fingerprinting is used to analyze the quantity of marker compounds in source materials and final products and to track the variance of these compounds among different batches. Batch-to-batch consistency of the marker compounds in different batches of the same product can then be easily compared when displayed in a radar graph. The lower the variance among different production batches, the higher the consistency of the quality in the final product. The chart to the right illustrates Sun Ten's batch-to-batch consistency by comparing the consistency of three batches of Sun Ten's Jia Wei Xiao Yao San with three-batch comparisons of the same formula from three other manufacturers.



HPLC Radar Graph of Three Selected Batches of Jia Wei Xiao Yao San Produced by Different Manufacturers.

A: Sun Ten
 B-C: Other Brand
 B: Geniposide (GFI) is very high in three batches but the quantity of remaining markers is not consistent in other batches
 C & D: Quantity of all markers is not consistent among batches

Professional Credibility

Sun Ten is proud of the number and quality of its certifications. Manufacturing certifications testify to the quality of a manufacturer's operation. This includes the quality of the facility, the organization of its operations, its adherence to important procedures, and the organization's implementation and tracking of quality and safety controls. Since each country has distinct standards of excellence and certification, the professional credibility of a distinguished global facility is illustrated by the various certifications they attain from those regions that strictly enforce high standards of quality and safety.



Pharmaceutical GMP
 Therapeutic Goods Administration
 AUSTRALIA



Pharmaceutical GMP
 Ministry of Health Labor & Welfare
 JAPAN



Dietary Supplement GMP
 Natural Product Association
 UNITED STATES



Pharmaceutical GMP
 Department of Health
 TAIWAN



ISO 9001:2000
 British Standard Institute
 UNITED KINGDOM



Authenticity Quality Experience Safety Consistency Transparency

順天堂藥廠股份有限公司
 SUN TEN PHARMACEUTICAL CO., LTD.

3F, No. 207, Sec. 3, Beldin Rd., Xindian Dist., New Taipei City, Taiwan, R.O.C.
 Tel: +886-2-8978-5599 | Fax: +886-2-8913-2338 | suntenglobal.com
marketing@sunten.com.tw



The Essence of Concentrated Herbal Extracts

中藥精華 · 盡在順天

Awarded the highest compliance category of
 Australia's TGA PIC/S GMP Certification

About Sun Ten

Sun Ten Pharmaceutical Company Ltd. was founded by Dr. Hong-yen Hsu in Taipei, Taiwan in 1946. In 1975, Sun Ten began exporting to Japan and was the first herb extract manufacturer in Taiwan whose products qualified for reimbursement through the Japanese Health Insurance Plan. In 1996, the Malaysian Drug Control Administration issued an import drug license to Sun Ten products. With establishment of Sun Ten Pharmaceutical MFG (M) SDN BHD in Malaysia, Sun Ten entered the Malaysian and Singaporean markets. In 2013, Sun Ten received the highest-ranking GMP certification (A1 TGA PIC/S) from the Australian Therapeutic Goods Administration. This world-class manufacturing standard is comparable to that required of manufacturers of western pharmaceuticals.

For nearly seven decades, Sun Ten has produced the highest quality herb extracts; manufacturing for, and exporting to more than 20 countries including the United States, Canada, Japan, Malaysia, Singapore, Australia, Switzerland, Germany and England. Sun Ten products are held in high regard by professional Chinese Medicine practitioners and end-users throughout the world. We continue to meet the unique specifications mandated by each government, ensuring product safety and quality and establishing ourselves as a leading world-class manufacturer of herbal products.

Authenticated Source Herbal Materials

All of Sun Ten's source herbs are obtained from private growers and suppliers whose products meet our strict quality specifications. We secure these resources by maintaining long term relationships with our suppliers and regularly purchasing qualifying crops from them. We avoid purchasing materials directly from the public market because herbs purchased in that setting can be unreliable and often have inferior constituent content. In addition, they tend to have issues such as species identification errors, unsafe heavy metal and pesticide contamination and introduction of unwanted weight enhancers or toxic material. Sun Ten does not accept any source materials that do not meet our unyielding quality standards.

Authenticity

Prior to acquisition each herb purchased by Sun Ten undergoes thorough examination to ensure that it is the correct plant material from the correct plant. Unfortunately, misidentification of herb material is still widespread and care must be taken with each purchase. Sun Ten uses the Pharmacopoeia of People's Republic of China as the reference standard by which to determine the correct species. Both organoleptic and analytical scientific methods are used to confirm species identification and proper plant part.

Herb Sourcing Team

Sun Ten established the Herb Sourcing Team to ensure that all source materials are the proper plant and correct plant part and to assess the quality and purity of each incoming herb. The Herb Sourcing Team also is responsible for proper handling and storage of source materials.



Manufacturing Excellence

Sun Ten is a leading manufacturer of Chinese herb formula and single herb products. As a manufacturer, we also function as a full service OEM/private-label manufacturer specializing in Chinese herb extract products. Sun Ten also has the experience, resources and scientific infrastructure to manufacture products that meet the detailed specifications necessary for scientific studies.



Decoction



Concentration



Spray Drying



Tableting



Safety & Quality

The following Quality Control tests are routinely executed to ensure the safety and quality of our products:

- ✓ **Macroscopic (visual and organoleptic) inspection** authenticates the herb species and herb part.
- ✓ **HPLC/PDA** assures product potency and batch consistency by quantifying the content of marker components.
- ✓ **Microscopic examination** authenticates the herb species by histological examination and comparison with a certified reference standard specimen.
- ✓ **Microbiological testing** assesses product for yeast, mold and pathogenic microorganisms to ensure product safety.
- ✓ **TLC** verifies the herb species by comparing its unique analytical identification with a certified reference standard herb.
- ✓ **HPLC/ELSD** determines the quality of Rehmannia (Di Huang) by analyzing its S to M saccharide ratio.
- ✓ **ICP/MS** measures heavy metals to ensure products meet the safety specifications of the target market.
- ✓ **HPLC/FD** measures aflatoxins to ensure product safety.
- ✓ **GC/MS** screens for pesticide residue to ensure product safety.
- ✓ **LC/MS** screens for the existence of aristolochic acid to ensure product safety.

COA

A Certificate of Analysis for every production batch is approved and issued by the Head of Quality Assurance to ensure that Sun Ten's products meet international safety and quality standards.

