

Quality Control of Herbal Medicines and Their Related Products

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Main Issues in TCM Modernization

- **Safety – Heavy metals, Toxic compounds etc.**
 - Biological
 - Environmental
 - Chemical
- **Efficacy- proved by recognized approach**
- **Quality- controllable**
 - Standardization
 - Selection of marker compounds
 - Fingerprinting
 - Adulteration/misidentification
- **Mechanism- clarified**

TCM Quality Control

Availability of Adequate Supplies:

Authenticated Plant Materials
Reference Powders, Extracts
Marker Compounds
Actives, Known or Putative
Toxic Constituents, Known or Suspected
Misidentified Species
Contaminants/Adulterants

Methodology:

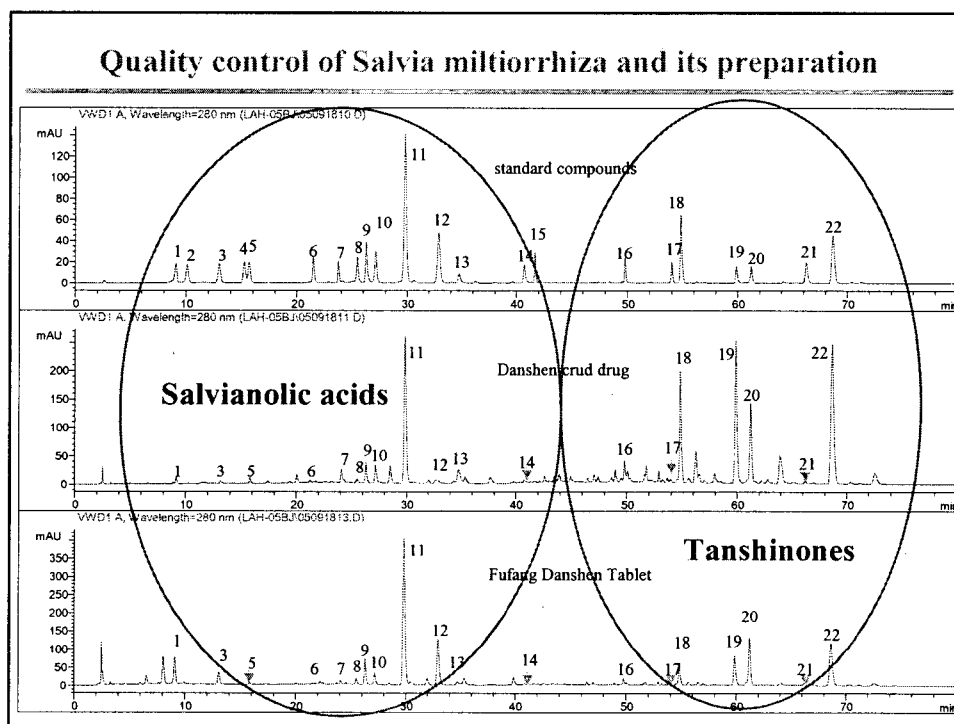
Fingerprint analysis
Multi-component quantitation

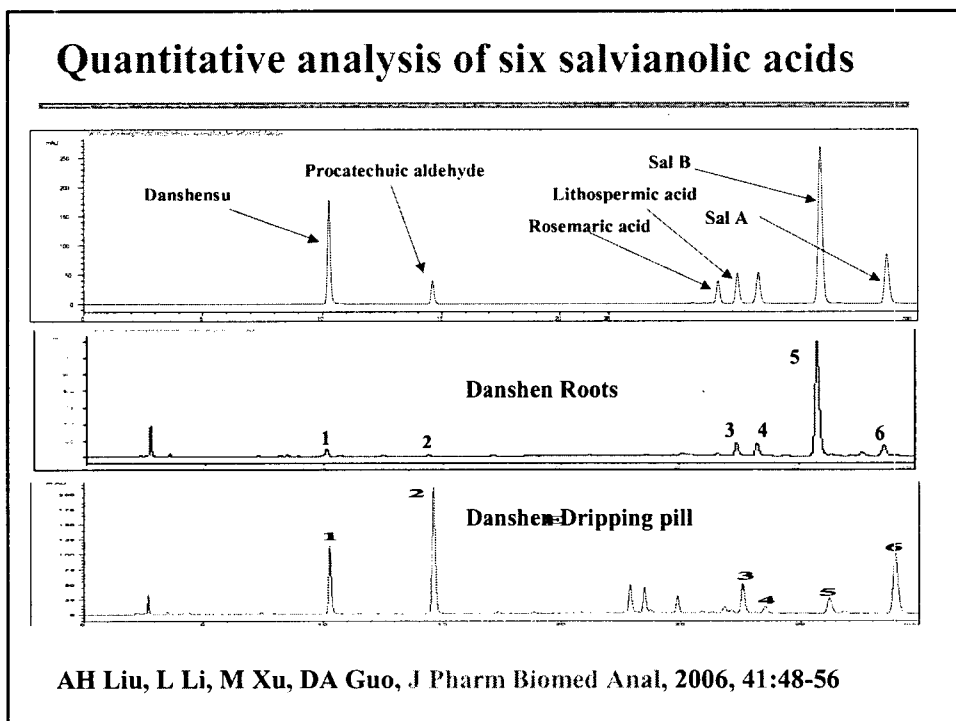
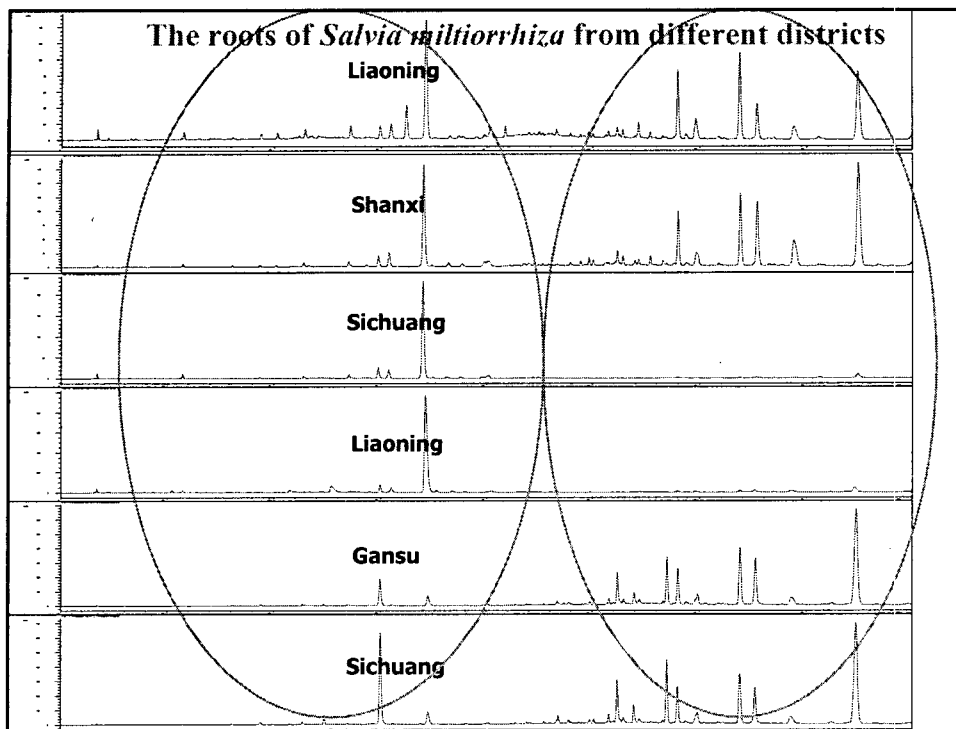
Fingerprint and Its Application

- **Biological fingerprints: DNA fingerprint, etc**
- **Chemical fingerprints:**
 - **Spectrometric fingerprints:**
UV, FTIR, NMR
 - **Chromatographic fingerprint**
 - * **Column chromatographic fingerprint**
HPLC, GC, CE, etc.
 - * **Planar chromatographic fingerprints**
Modern Thin Layer Chromatography

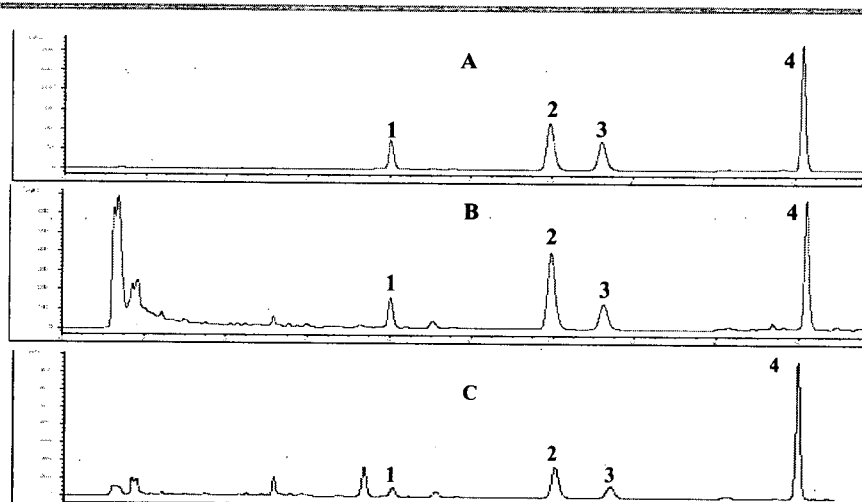
Fingerprint Practice in China

- Enforced in TCM injection preparation by SFDA of China in 2000;
- 74 TCM injections regulated by Fingerprints;
- Technical requirements regulates the fixed crude drug origin;
- A computer software developed to evaluate the similarity of fingerprints acquired.





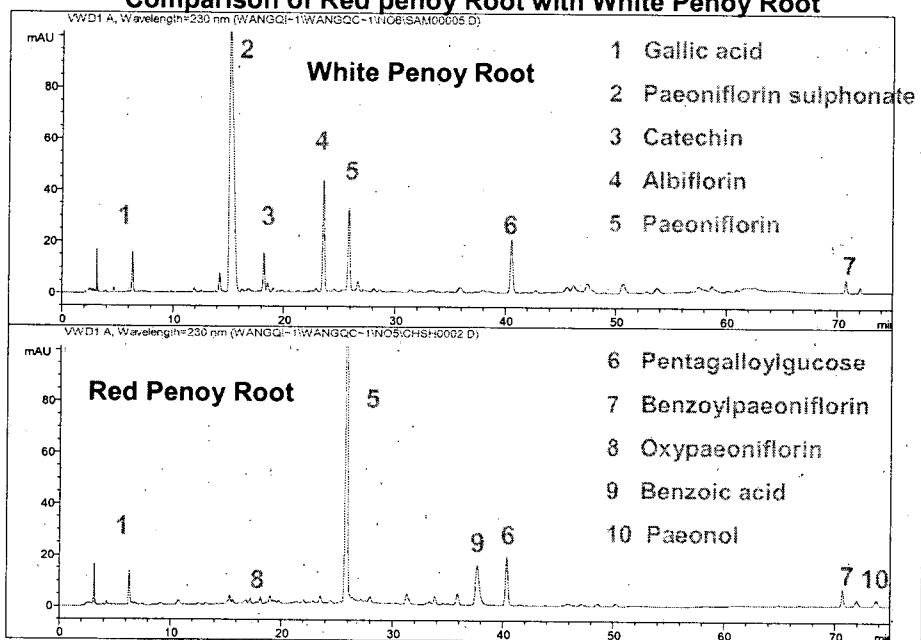
Quantitative analysis of four tanshinones



Representative HPLC chromatograms of (A) standard solution at medium concentration, (B) FDT (Xianzhi, Liaoning, China), (C) Danshen (Shanxi, China) 1, dihydrotanshinon I; 2, cryptotanshinone; 3, tanshinone I; 4, tanshinone IIA.

AH Liu, YH Lin, M Yang, JH Sun, H Guo, DA Guo J Pharmacy Pharm Sci, 2006, 9:1-9

Comparison of Red penoy Root with White Penoy Root



Q. Wang et al. Chromatographia, 2005, 62:581-588.