

# 中药配方颗粒 研究与中药汤剂发展

## The Research on Single Concentrated Herb Granule and the Development of Herb Decoction

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### 一. 内容提要

#### Abstract

利用现代分析检测技术，对500余种中药材进行分析研究，建立药材和配方颗粒质量控制标准；在遵循中药汤剂煎煮特色的基础上，利用现代先进的制药技术，对中药材进行全成分提取，形成浓缩颗粒剂型；实现中药汤剂：标准、可控、安全、高效、免煎、方便。

By adopting advance analysis techniques to category over five hundred herbal medical ingredients, construct in term of quality control and fingerprint standardization on both raw herbs and concentrated herbs granule. According to the decoction in characteristics of herb, the contents of raw ingredients are fully extracted by modern pharmaceutical techniques, and ready to make concentrated herbs granule. Specifications of herb decoction: standardsable, controllable, safe, effective, without further decoction and convenient.

### 二. “中药配方颗粒”的定义

#### The Definition on Single Concentrated Herb Granules (SCHG)

中药配方颗粒是用符合炮制规范的中药饮片为原料，经现代工业提取、浓缩、干燥、制粒而成的纯中药产品系列。其性味、功效与原中药饮片一致，用其替代中药饮片供中医临床辨证施治、调配汤药。既保持了传统饮片汤药的药性、药效，又具有不需煎煮、直接冲服、服用量小、高效卫生等优点。

SCHG are made with quality selected prepared Medicinal Herbs”, which go through the modern manufacturing process of extracting, concentrating, drying and granulating. The taste and effectiveness of SCHG are identical to the original “Prepared Medicinal Herbs”, research and testing shown that “Prepared Medicinal Herbs” can be substituted and used in TCM clinic. SCHG preserved the original characteristic and effectiveness of “Prepared Medicinal Herbs”, while introduced others benefit - such as non-decoction, direct intake, fewer and precise dosage, guaranteed effectiveness, hygienic, and safe for storage.

### 三. 研究开发背景

#### Background of the Research

中药剂型众多，传统的有汤剂、膏剂、丹剂、丸剂、散剂等，现代的有胶囊剂、片剂、针剂、口服液等。但最常用的剂型仍然是中药饮片汤剂，因为汤剂最能体现中医辨证论治的治疗思想。随着社会的不断发展，传统汤剂的临用现煎用药方式已逐步表现。出其“不方便性”和疗效的“不确定性”，在一定程度上限制了中药汤剂的临床应用以及中医药发展。

汤剂使用的不方便性：体积大，不方便携带和保存；煎煮费时，服用量大；旅行和工作时无法煎煮服用；中医急诊用药受限等。

汤剂疗效的不确定性：中药饮片质量受品种、产地、采收季节、炮制等因素影响；服用者的煎煮方法和条件无法统一；中药饮片质量无统一评判标准等。

为此，在1993年，国家卫生部、国家食品药品监督管理局等有关部门联合决定开展中药配方颗粒研究，进行中药汤剂改革。广东省中医研究所、广东一方制药有限公司成为该国家项目的研究开发定点单位。

There are many varieties of TCM. In tradition - there are decoctions, intments, pellets, pills and powders. In the new generation – there are capsules, tablets, injections and oral liquid are also available. Nevertheless the most commonly use is still the “herbal decoction” because it can reflect extensively in the TCM theory during treatment toward various kind of syndrome. While the modern society moving-on, the traditional decoction gradually shows its “inconvenience” and “curative uncertainty”. To some extent, it limits the clinical applications of herb decoction and the development of TCM.

#### The Disadvantages of Decoction Application:

Inconvenience to carry and store due to large in volume; time consuming when decoction; in-taking large volume when decocted; impossible to decoct during journey or at work; limited applications in TCM emergency treatment.

#### The Uncertainty of Treatment of Decoction Application:

The quality of “Prepared Medicinal Herbs” is affected by variety, origins, harvest season and preparation techniques. The way of decoction & treatment cannot be control and standardize. There are no uniform standards to TCM Prepared Medicinal Herbs.

In 1993, the Chinese State Health Ministry, the State Food And Drug Administration and other related Departments decided to carry out research on Single Concentrated Herb Granules in order to reform TCM decoction. Thus Guangdong TCM Research Institute and Guangdong Yifang Pharmaceutical Co., Ltd. have been appointed by the Government to leads the TCM Research & Development Project.

## 四. 主要研究开发内容

### Major R & D Contents

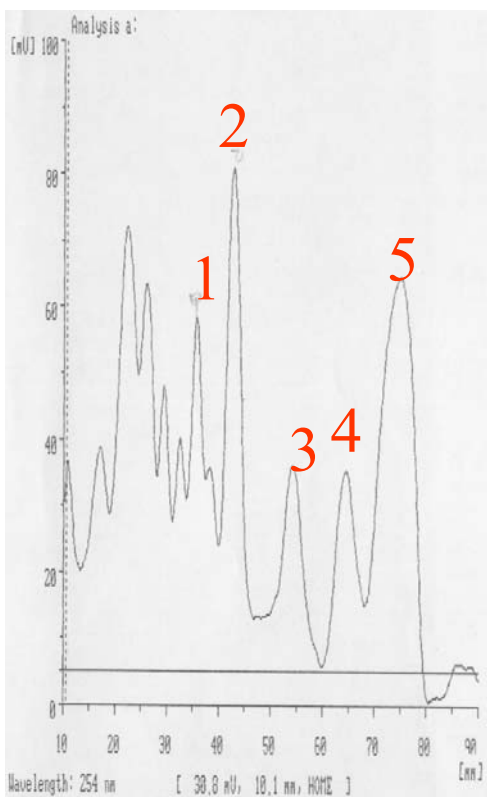
1. 中药材质量控制
2. 生产工艺
3. 成品质量标准
4. 稳定性研究
5. 化学成分比较
6. 药效学比较
7. 临床疗效比较

#### ★ 中药材的质量控制研究

- 1) 采用现代分析技术和设备、按照中国药典的检验要求，对中药材（包括饮片）进行品种鉴别、真伪鉴定、含量测定等，建立中药材指纹图谱鉴别体系。如：对川黄柏和关黄柏、南五味子与北五味的品种鉴别；黄芪、制川乌、酸枣仁等真伪鉴定等。

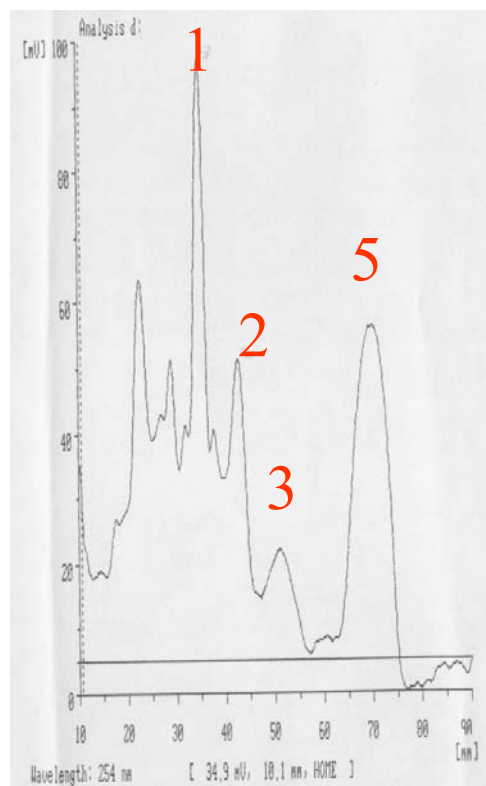
北五味子薄层扫描图

The TLCS Drawing of Chinese Magnoliavine Fruit



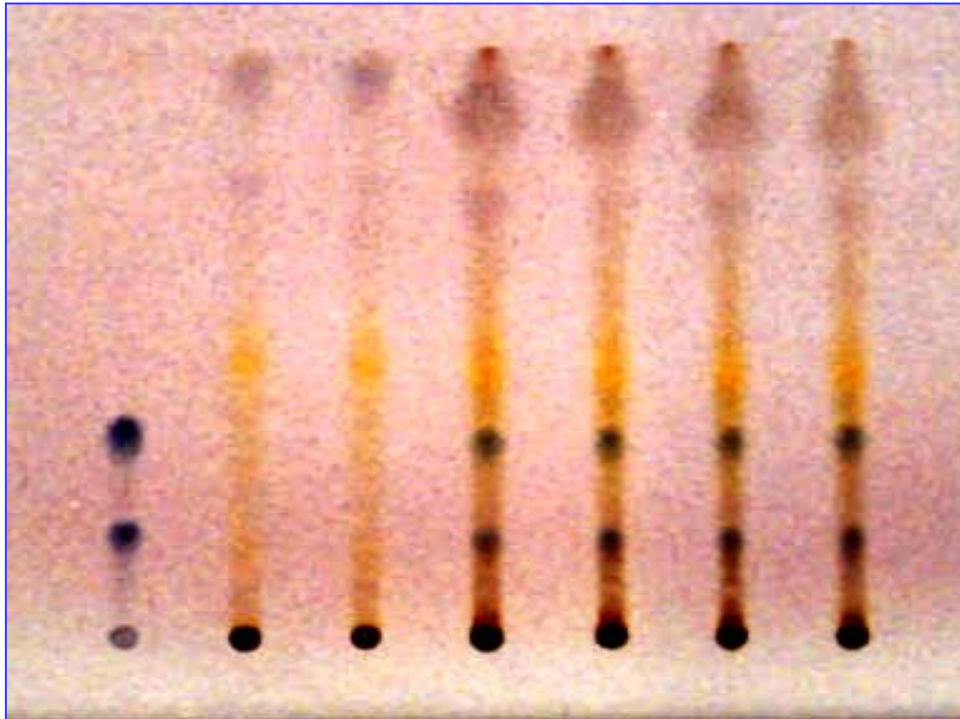
五味子薄层扫描图

The TLCS Drawing of South Chinese Magnoliavine Fruit



## 酸枣仁药材薄层鉴别图

The TLC Identification of Suan Zao Ren



1 2 3 4 5 6 7

- 1、酸枣仁皂甙a,b Saponin a b    2-3、伪品药材 False Herb  
4-5、酸枣仁药材 Raw Herb        6-7、配方颗粒 Concentrated herb

2). 确定的基础上，根据中国药典要求进行药材化学成分含量测定、优劣评价。

### ★ 生产工艺研究

1). 工艺研究总的方针是处理好继承与创新的关系，就是根据中药的不同药性，用不同的技术设备和工艺条件充分体现传统汤剂科学的煎煮方法。如先煎、后下、文火、武火等。结合现代的最新研究成果，对部分品种采用特殊工艺进行加工处理。

2). 主要技术研究要求

- 根据汤剂的特点，主要用水煎煮提取，辅以其它技术；
- 含挥发性成分药材，先提取挥发油，再用水煎煮提取；
- 含脂溶性有效成分的药材，用水煎煮提取，结合超临界CO<sub>2</sub>萃取或乙醇提取；
- 含有效成分对热敏感的药材，采用动态低温或乙醇提取。
- 中医习惯用研粉服用的药材，采用超细粉碎技术。

★ 中药配方颗粒质量标准研究

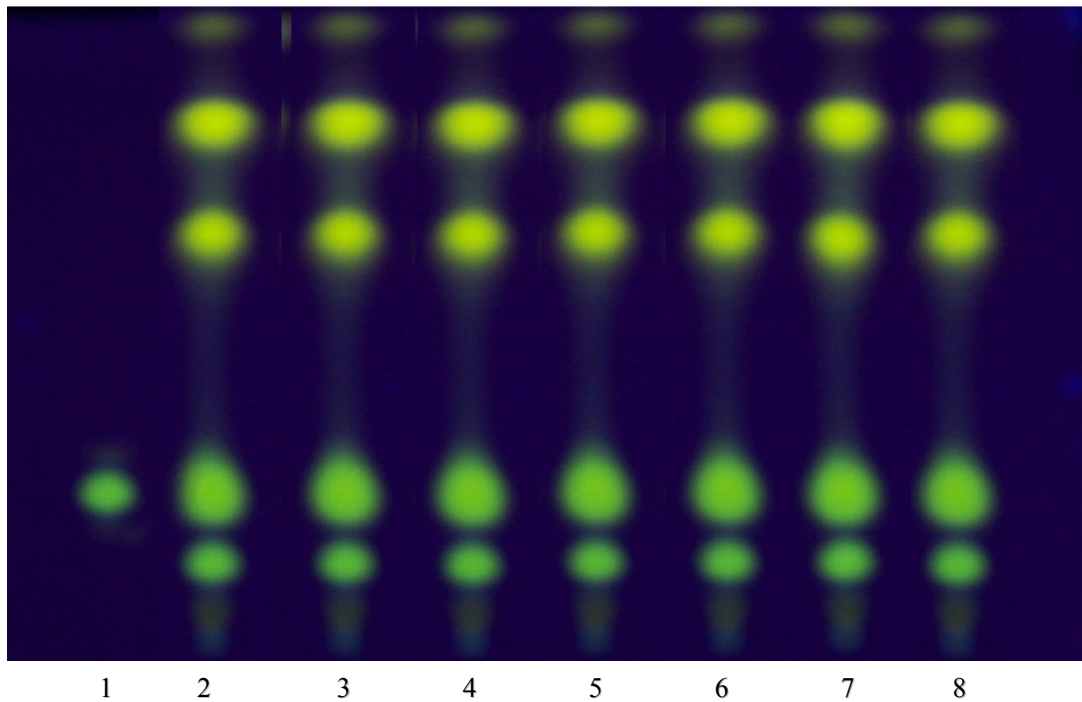
1) 主要研究内容

- a) 性状
- b) 鉴别：薄层色谱、紫外等
- c) 检查：水份、粒度、溶化性、装量差异、卫生学、重金属、农药残留等；
- d) 浸出物测定：醇溶性、水溶性；
- e) 含量测定
- f) 成品稳定性研究

▼ 鉴别

黄连配方颗粒薄层色谱图

The TLC Drawing of Huang Lian Concentrated Granule

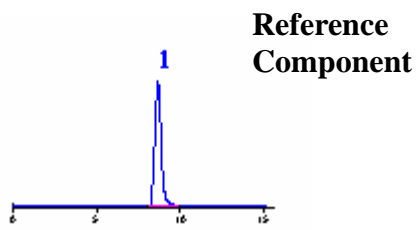


- 1 盐酸小檗碱对照Reference Component 2 黄连对照药材Reference herb  
3~8 黄连配方颗粒Concentrated Granule

▼ 含量测定

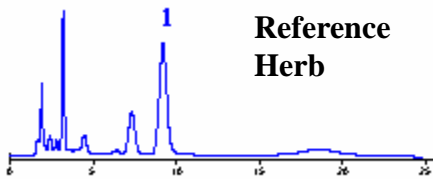
白芍配方颗粒含量测定

The Content Determination of Baishao Concentrated Granule

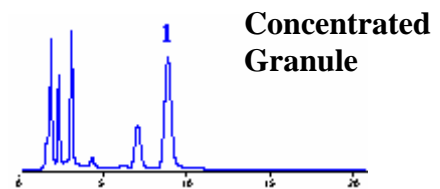


芍药苷含量不少于3.0%  
Shaoyao Glycoside contents not less  
Than 3.0%

芍药苷对照品



白芍对照药材



白芍配方颗粒

▼ 成品稳定性研究

1. Quality Control of Raw Herbs
2. Production Technique

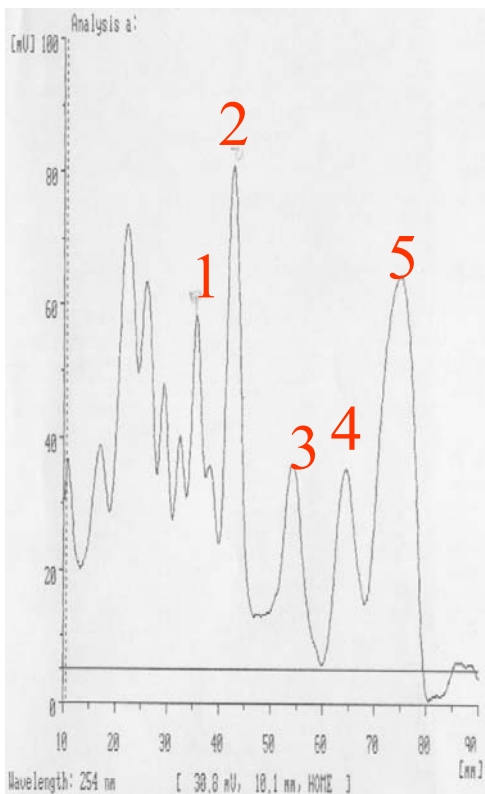
3. Quality Standardization of Products
4. Stability Control
5. Comparison of Chemical Components
6. Comparison of Medicinal Efficiency
7. Comparison of Clinical Efficiency

★ Research on Quality Control of Raw Herbs

1) The System of TCM Fingerprint Illustration was set up according to the inspection requirement of Chinese Pharmacopoeia. By using modern analytical techniques and facilities, to evaluate and identify the substance and origin of the raw herbs. Such as: The species identification between Chuan Huangbo and Guan Huangbo, also between southern Chinese Magnoliavine Fruit and northern Chinese Magnoliavine Fruit. The authenticity of Milkvetch Root, Prepared Common Monkshood Mother Root and Spine Date Seed.

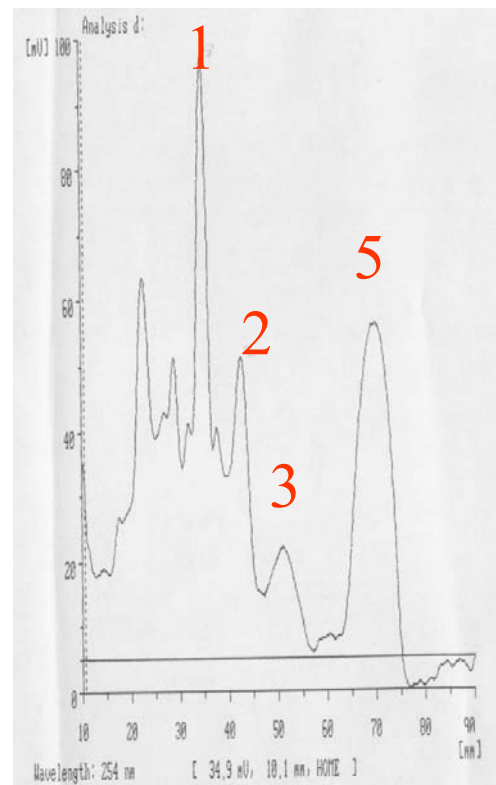
**北五味子薄层扫描图**

**The TLCS Drawing of Chinese Magnoliavine Fruit**



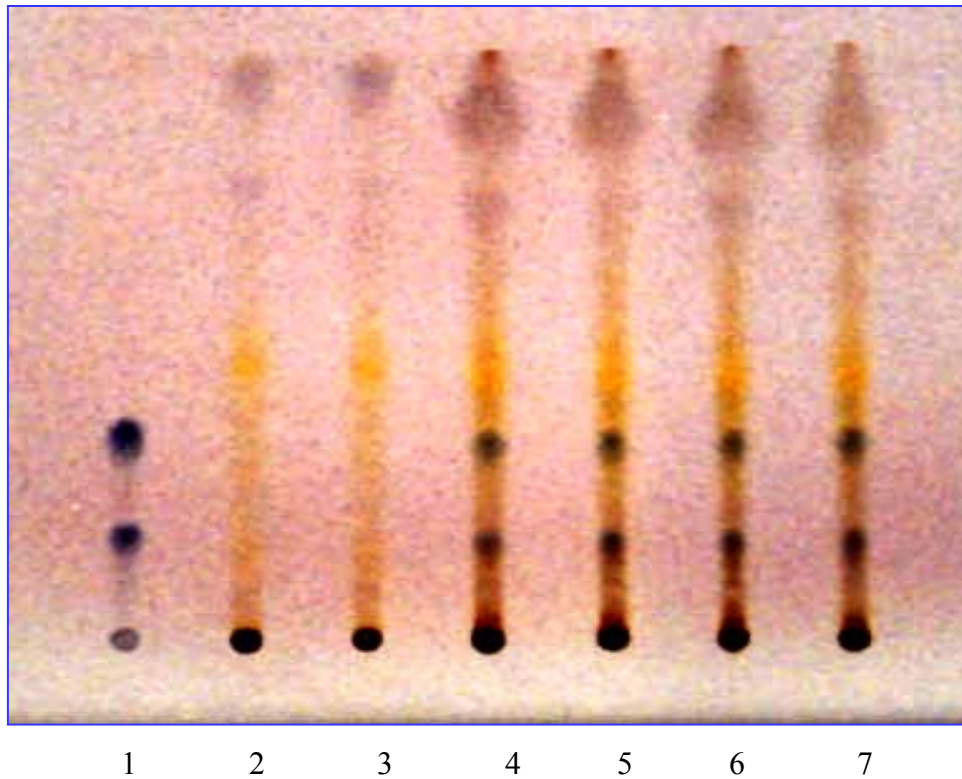
**南五味子薄层扫描图**

**The TLCS Drawing of South Chinese Magnoliavine Fruit**



## 酸枣仁药材薄层鉴别图

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4-5、酸枣仁药材 Raw Herb        6-7、配方颗粒 Concentrated herb

2) Upon confirmation of species, the chemical contents of herbs are tested and evaluated according to Chinese Pharmacopoeia.

### ★ The Research on Production Technique

- 1) The guideline on Production Technique is to harmonize the relationship between inheritance and creative. This fully reflected in the Science Of Traditional Decoction through applying and using different techniques and

facilities according to the medicinal property of individual herbs. Such as sequence of decoction, variety of roasting/boiling technique. In addition some herbs are being processed through new and specialise technological method.

## 2) The Requirement on Major Technique Research

- a) According to the characteristic of decoction, decoct with water is the principal method, other specialized techniques are also applied during decoction.
- b) Volatile Oil will be extracted from raw herbs containing vaporize substance prior decocted with water.
- c) The raw herbs containing oily substance are extracted through water with the combination of Mass Critical CO<sub>2</sub> Extraction or Ethanol Extraction.
- d) The raw herbs containing heat sensitive substance are extracted through Dynamic Low Temperature Extraction or Ethanol Extraction.
- e) The Super Fine Grinding technique is applied for the herbs usually taken in powders.

## □ The Research on Standard for Quality of Single Concentrated Herb Granules

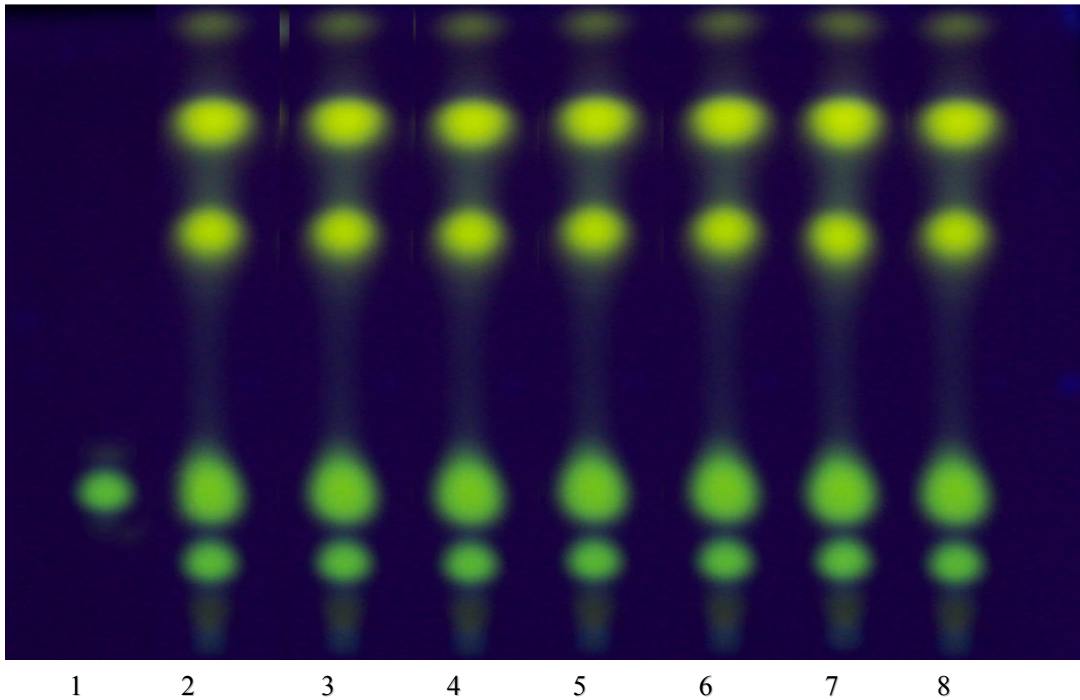
### 1) Major Research Contents

- a) Description
- b) Identification: TLC, UV.
- c) Inspection: water content, granularity, solubility, packing diversity, hygienic, heavy metal and residue of pesticide.
- d) Determination on the soaked content: ethanol and water solubility.
- e) Determination on content
- f) The Research on Stability of Finished Product

▼ Identification

黄连配方颗粒薄层色谱图

The TLC Drawing of Huang Lian Concentrated Granule

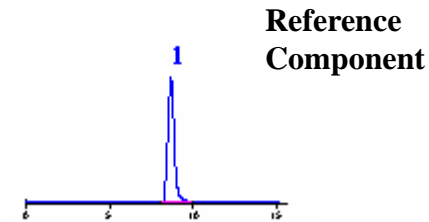


1 盐酸小檗碱对照Reference Component 2 黄连对照药材Reference herb  
3~8 黄连配方颗粒Concentrated Granule

▼ Determination on Content

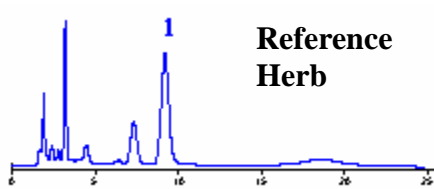
白芍配方颗粒含量测定

The Content Determination of Baishao Concentrated Granule

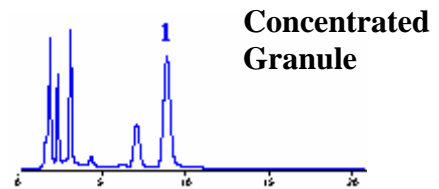


芍药苷含量不少于3.0%  
Shaoyao Glycoside contents not less Than 3.0%

芍药苷对照品



白芍对照药材



白芍配方颗粒

▼ The Research on Stability of Finished Product

五 药配方颗粒研究成果及意义

The Research Achievements & Indications on Single Concentrated

## Herb Granule

1. 适应现代社会发展的需要，实现了中药科学化、标准化；
2. 有利于保护中药资源：中药配方颗粒采用现代制药技术，合理有效地提取中药材药用成份，降低中药材消耗，保护中药资源；
3. 有利于配制中药新的制剂：中药配方颗粒已对中药材进行了全成分提取，可用于中药其它剂型如胶囊、片剂、口服等制剂生产的原料药；(四)
4. 有利于推进中药产业化进程：中药汤剂应用具有巨大的潜在市场，中药配方颗粒的应用大力推动了中药汤剂的发展，有利于促进中药产业化发展；
5. 有利于中药国际化进程：中药配方颗粒的应用使中药更加安全、有效、可控、方便，符合国际医疗保健用药要求，有利于加速中医药国际化进程。

1. Meeting the Demands of Modern Society; we determine and driven the TCM to be standardized in a measurable scientific way.
2. Ideal to protect the Herbal Resources: Modern pharmaceutical technology is made full use on manufacturing concentrated herbs; the substance of raw herbs are extracted reasonably and effectively; this help reduce consumptions on raw herbs and to protect its resources.
3. Beneficial for preparing new TCM products: All substances from raw herbs have been fully extracted for Single Concentrated Herbs. It can also be used for other TCM medicinal application like capsule, tablet and oral liquid, etc.
4. Beneficial for developing TCM into an Industrial Market: The application of TCM decoction has potential huge market. Because of its format (dispensable sachet), it gives accountability as well as end-to-end quality assurance, which are the fundamental building block for TCM Industrialization.
5. En route as TCM Internationalization:  
The application of Concentrated Herb Granules (CHG) in Dispensable Sachet gives TCM a new meaning. It benefits from - safe, effective, controllable and convenience, which furthermore compliance with the demands of international medical treatment and health care authority.

The use of dispensable sachet in TCM department in Hong Kong Hospital Authority is a prime example.

**谢 谢 ！**

**THANK YOU!**