

Is Your Herbal Practice Safe? Know the Clinical & Legal Standards



Galina V. Roofener

A.P., L.Ac., Dipl. Ac. (NCCAOM)®, Dipl. C.H. (NCCAOM)®

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Disclaimer

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- ▶ Author has no financial interests with any of the companies referred to in this presentation.
- ▶ Author has no intentions to promote a specific product or a company reflected in this presentation.
- ▶ All files reflected in this presentation are fully FDA compliant reflecting imaginary patients.
- ▶ This presentation is not intended to substitute legal advise, all information presented is for educational purposes only.

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Syllabus

COURSE LEARNING OUTCOMES: Through the successful completion of this course, each student will be able to:

- ▶ select quality herbs,
- ▶ questions to ask when selecting your vendor,
- ▶ select form of herbs (raw, patent, granules)
- ▶ record herbs in the SOAP to protect yourself legally
- ▶ calculate dose for a specific patient using different forms from different manufacturers
- ▶ collect and report adverse events

<https://www.asiantherapies.org/academy>

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Safety of Chinese herbal supplement brands?

From: Lu [REDACTED]@gmail.com)

To: gr@asiantherapies.org

Date: Friday, May 14, 2021, 12:26 AM EDT

Hello,

I have come across you many times in my research in the safety and efficacy of TCM. My practitioner prescribed me from the brand EverSpring and I have concerns about the safety and reputability of it. Are you aware of this brand or how I can confirm it's integrity? I do not mean to bother you for medical advice or anything of the sort, simply wish to learn how to approach this with caution!

Thank you



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The possible explanation of adverse reactions to Chinese herbs could be classified as follows:

1. *Wrong identification of herb*
2. *Contamination with heavy metals*
3. *Contamination with Western drugs*
4. Wrong use through self-medication
5. Administration of Chinese herbs in combination with Western drugs by practitioner not trained in Chinese Herbology
6. Wrong use of a herb, i.e. wrong diagnosis
7. *Ignoring possible allergens*

1-6 <http://www.scribd.com/doc/86928517/Safety-of-Chinese-Medicine-Giovanni-Maciocia#scribd>

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FDA Regulations for Chinese herbs

- Chinese Herbal Medicines ARE regulated by the FDA.
- Chinese Herbal Medicines are held to cGMP regulation under Title 21 CFR 111.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/complementary-and-alternative-medicine-products-and-their-regulation-food-and-drug-administration>



Medical Records Purpose

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Target Auditory: (this for whom you are writing notes for)

- Lawyer
- Insurance Auditor
- Your colleague for continuation of care
- Patient
- Researcher



Documentation Strategy:

- Accepted format: **SOAP** (Subjective, Objective, Assessment, Plan)
- SOAP is your legal defense tool. If you did not write it down it did not happen. **CYA!**
- This is your invoice, each item in it has its cost!
- SOAP does NOT limit what you do, it only outlines the structure HOW you write it down.

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SOAP

- @NAME@ a @AGE@ @SEX@ presents in the Traditional Herbal Medicine clinic.
- Patient identity confirmed by name and DOB; ***YES ***NO
- Today @TODAYDATE@ is initial visit ***In person ***Virtual/Telehealth
- Height: ***
- Weight: ***
- Allergies reviewed: ***NONE, Soy, Gluten, Latex, Shellfish, Citrus, Sesame, Tree nuts, Potato, Corn
- Medication reviewed: ***
- Supplements reviewed: ***

<https://www.asiantherapies.org/standard-terminology>

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Herbal vendor/pharmacy selection guidelines

- Quality of herbs
- Adherence to the FDA and USP guidelines for herbal compounding practices.
- Ease of prescription software use.
- Wide range of single herbs and formula options. available for custom formula compounding.
- Allergy warning on the label.
- Quick shipment options of custom and patent herbal formulas directly to the patient.
- Prescription pick up monitoring options.
- High customer service standards.
- Easily accessible professional support and communication

https://www.craneherb.com/shared/videos/cf_overview.aspx

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Best TCHM Compounding and Dispensing Practices

The screenshot shows the NCCAOM website with a navigation bar including: ADVOCACY / REGULATORY, CERTIFICATION, EDUCATION, RESOURCES, ABOUT, CONTACT, LOGIN. The main heading is "Chinese Herbal Compounding Safety Certificate of Qualification*". Below this, it introduces the NEW NCCAOM's Certificate of Qualification (COQ) with the following bullet points:

- Voluntary, online program;
- 10-module, assessment-based;
- In compliance with FDA Good Manufacturing (GMP) Guidelines.

It also states: "The program is open to all licensed acupuncturists and herbalists, students, lab technicians, herb pharmacy compounders and any other office staff who compound herbal formulas in their office or retail dispensaries." A badge image is shown with the text "CERTIFICATE OF NCCAOM QUALIFICATION" and "CHINESE HERBAL COMPOUNDING SAFETY". A green callout box says "Receive 10 NCCAOM PDA points and the NCCAOM CHCS COQ Badge on program completion." A "Help" button is visible in the bottom right corner.

- <https://www.nccaom.org/education/professional-development/>
- <https://www.nccaom.org/wp-content/uploads/pdf/Guidance%20-%20Best%20TCHM%20Compounding%20and%20Dispensing%20Practices%202017.pdf>

Prescription Label according to FDA standard

These statements have not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Take 6 capsules 2 times a day between meals. Days 3 thru day 14 of the cycle. Separate by 2 hours from the rest of your meds & supplements

Allergy Warning:
This herb prescription contains Du Zhong (Chao) (Eucommia (Dry-Fried)), which is a potential Latex allergen.



Gui Shao Di Huang Tang Mod.

Dosage: 6 caps 2 times per day for 14 days

Prescription # 10675593

Ms. Sarah Golden, LMT
7 Main St.
Oberlin, OH 44074

Prescribed: 4/27/15
Filled: 4/28/15
Discard after: 4/27/16

Prescriber:
Ms. Galina Roofener, L.Ac.
Cleveland Clinic - Chinese Herbal
Therapy Clinic
1950 Richmond Road TR2
Lyndhurst, OH 44124

158 capsules approx. 335 mg each

Herbal Supplement Facts
Serving Size 6 caps
Servings Per Container about 26

Amount Per Serving		% Daily Value	
Herbal Extract of:	Part	Pin Yin	
Latin Binomial			
Poriae Cocos Sclerotium	Sclerotium	Fu Ling	201 mg*
Alismatis Rhizoma	Stem	Ze Xie	168 mg*
Corni Officinalis Fructus	Fruit	Shan Zhu Yu	168 mg*
Dioscorea Batatis Rhizoma	Stem	Shan Yao	168 mg*
Angelicae Sinensis Radix	Root	Dang Gui (Shen)	168 mg*
Zizyphi Spinosi Semen	Seed	Suan Zao Ren	150 mg*
Rehmanniae Radix (cooked)	Root	Shu Di Huang	150 mg*
Moutan Radicis Cortex	Root Peel	Mu Dan Pi (Su)	150 mg*
Paoniae Lactiflorae Radix	Root	Bai Shao	150 mg*
Cuscutae Semen	Seed	Tu Si Zi	100 mg*
Eucommiae Ulmoidis Cortex	Bark	Du Zhong (Chao)	100 mg*
Atractylodis Macrocephalae Rhizoma	Stem	Bai Zhu	100 mg*
Proprietary Mixture			233 mg*

* Daily Value not established

Manufactured & distributed by
CRANE HERB PHARMACY
Mashpee, MA 02649
(508) 539-1700
www.CraneHerb.com

Herbal Supplement

Reproduced with permission from Crane Herb Pharmacy.

Manufacturing facilities and industry safety standards


Certifications:

- [TGA-PIC/S GMP](#) (Therapeutic Good Administration)
- [USDA-NOP](#) (United States Department of Agriculture, National Organic Program)
- [NSF-cGMP](#) (National Sanitation Foundation)
- [Kosher](#)
- [Halal](#)
- [ISO 9001:2008](#) (International Accredited Forum)
- [ISO 17025:2005](#) (Taiwan Accreditation Foundation)
- [GMP](#) (Good Manufacturing Practice)



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Appendix E: Single Herb COA - FDA & International Standards Compliant



香港藥業股份有限公司
KAISER PHARMACEUTICAL CO., LTD.
www.kaiser.com.hk


CERTIFICATE OF ANALYSIS

Product Name	4420 杏仁 / Xing Ren
English Name	Apricot Seed/Puriri Armeniacae Semen/Seed
Batch Number	G12030
Expiration Date	2020/4/28
Dosage Form	Granule
Manufacture Date	2016/4/29
Taste/Odor/Color	Astringent/ Normal/ Beige(U167 468)

Specification	Result
General Inspection	
Loss on Drying	< 12 % 2.40 %
Total Ash Content	< 6 % 1.40 %
Acid-Insoluble Ash Content	< 3 % 0.16 %
Water Extract	> 18 % 44.03 %
DH-Alcohol Extract	> 18 % 30.40 %
Heavy Metal	
Lead(Pb)	< 3.0ppm 0.001 ppm
Arsenic (As)	< 1.5ppm 0.02 ppm
Mercury(Hg)	< 0.2ppm 0.002 ppm
Cadmium(Cd)	< 0.5ppm 0.001 ppm
Microbiological Test	
Total Aerobic Microbial Count	< 1*10 ⁶ CFU/g 8* 10 ³ CFU/g
Total Yeast and Mold Count	< 1*10 ⁵ CFU/g <1* 10 ³ CFU/g
E. Coli	Absent in 10g Negative
Salmonella	Absent in 10g Negative
Staphylococcus Aureus	Absent in 10g Negative
Pesticides Residues	
Total BHC's	< 0.9ppm Complies
Total DDT's	< 1.0ppm Complies
Quintozene(PCNB)	< 1.0ppm Complies
TLC	Positive

2016/5/24

Lin Ying Sheng, Associate General Manager, Quality Control Department



This document is accurate to the best of our knowledge based upon general industry information, available scientific data, and customer requests. This report provides technical results for a specific sample and the report shall not be altered, modified, supplemented or abridged in any manner. Any violation of these conditions renders the report and its results void.

	KP	SunTen	TianJiang	Spring Wind	Blue Poppy
	Specification NSF-2015	Specification USP-36	Specification Chinese Pharm.	Specification Huisong Pharm.	Hill Pharm.
Expiration	4 years	3 years	manu. date	4 years	2 years
Name	Xing Ren	Xing Ren	Xing Ren	Xing Ren	Xing Ren
Concentration	5:1	5:1	5:1????	10:1	
Dosage Form	Granule	Fine Granule		Granule	water
Taste	Astringent	Bitter		normal taste	
Odor	Normal	Specific Aroma			
Color	Beige	Light Yellow	Light Yellow	normal color	Yellow Brown
Carrier	non GMO potato starch	Corn starch	maltodextrin 20%	20% Maltodextrin	
Heavy Metal					
Lead(Pb)	<3.0ppm 0.001ppm	10ppm 0.017ppm	<10 mg/kg 0.341 mg/kg	<3ppm 1.12ppm	<2.0 mg/kg 0.06 mg/kg
Arsenic(As)	<1.5ppm 0.02ppm	3ppm 0.019ppm	<5.0 mg/kg 0.248 mg/kg	<3ppm .16ppm	<3.0 mg/kg ND
Mercury(Hg)	<0.2ppm 0.002ppm	3ppm <0.006ppm	<0.1 mg/kg 0.032 mg/kg	<1ppm ND	<0.4 mg/kg 0.07 mg/kg
Cadmium(Cd)	<0.5ppm 0.001ppm	3ppm <0.003ppm	<1.0 mg/kg 0.013 mg/kg	<1ppm .06ppm	<0.8 mg/kg 0.08 mg/kg
Microbiologic Test					
Total Aerobic Microbial Count	<10,000 cfu/g 8,000cfu/g	10,000 cfu/g 2,000 cfu/g	<1,000 cfu/g 15 cfu/g	<1,000 cfu/g 45 cfu/g	<1,000 cfu/g 200 cfu/g
Total Yeast and Mold Count	<1,000 cfu/g <10cfu/g	1,000 cfu/g <10 cfu/g	<100 cfu/g <10cfu/g	<100 cfu/g 10 cfu/g	<100 cfu/g <10 cfu/g
E.Coli	absent in 10g negative	absent in 10g nil	absent in 1gm negative	absent 10g	absent 10g/g <.92 mpn/g <.10 mpn/g
Salmonella	absent in 10g negative	absent in 25g nil		absent 10g	absent 10g/g
Staphylococcus Aureus	absent in 10g negative				absent in 25g ND
Pesticides Residues					
Total BHCs	<0.9ppm complies			278 pesticide screen	<0.1 mg/kg ND
Total DDTs	<1.0ppm complies				<0.1 mg/kg ND
Quintozene (PCNB)	<1.0ppm complies				<0.1 mg/kg ND

Patent Yin Qiao San comparison

Brand	Vendor	Herbs Amount per dose	Dose /unit	Form & Dosage	Prep Method/ concentration	Fillers/Carriers	Allergy warning	Amazon
Yin Qiao	Kan	?	?? Drop	20-30 drops 2-3 x/day	water extract concentrate ???	Alcohol	no	YES
Yin Chiao Chientupien	SOLSTICE MEDICINE COMPANY	yes	?? tablet	2-4 tablet 2 x/day	(baked whole herbs) ???	Corn starch	no	YES
Yin Chiao Chien Tu Pien	Plum Flower	?	??	4 tablet 3 x/day	Extract ???	Dextrin, magnesium stearate, etc	YES: Contains soy	YES
Yin Qiao San	KPC	yes	0.5 gr capsule	4 capsules 3 x/day	water decocted concentrate(5:1)	Non GMO potato starch	YES: Contains soy	NO

www.amazon.com
www.craneherb.com
<https://www.mayway.com/yin-chiao-chieh-tu-tablets-extra-concentrated.html>
https://www.kanherb.com/cons_pi_trad_product.asp?productNameId=1575

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Patent Yin Qiao San content comparison from different manufacturers

Yin Chiao - Extra Concentrate [YC60] remove	Yin Qiao [YQ60] remove	Yin Qiao Jie Du [K002] remove	Yin Qiao San [C3870] remove																																																																																																																									
Product Code: YC60 Name: Yin Chiao - Extra Concentrate Pharmaceutical Name: Alternate Name: Yin Qiao San Japanese Name: Unit Size: 60 tabs Vendor: Golden Flower Chinese Herbs Product Line: Golden Flower Chinese Herbs (info) (products) Manufacturing Process: water decocted concentrate (7.5) Dosage: 2 tabs : 3X/day Practitioner Price: \$11.00 Add to Cart	Product Code: YQ60 Name: Yin Qiao Pharmaceutical Name: Alternate Name: Yin Qiao San Japanese Name: Unit Size: 60 tabs Vendor: Kan Herb Co. Product Line: Kan Traditionals (info) (products) Manufacturing Process: powder : steam cooked (non-conc) Dosage: 1-2 tabs: up to 4X/day Practitioner Price: \$8.81 Add to Cart Patient Price: Prescribe <i>Set patient in the Prescription List to view price.</i>	Product Code: K002 Name: Yin Qiao Jie Du Pharmaceutical Name: Alternate Name: Yin Qiao Formula Japanese Name: Unit Size: 100 Softgel caps Vendor: TCMzone,LLC Product Line: TCMzone (info) (products) Manufacturing Process: Dosage: 4 caps: 3X/day Practitioner Price: \$15.95 Add to Cart	Product Code: C3870 Name: Yin Qiao San 銀翹散 Pharmaceutical Name: Alternate Name: Lonicera & Forsythia Formula Japanese Name: Unit Size: 100 Vcaps Vendor: KPC Products Product Line: KPC Herbs (info) (products) Manufacturing Process: water decocted concentrate(5:1) Dosage: 4 caps: 3X/day Practitioner Price: \$10.50 Add to Cart																																																																																																																									
Yin Chiao - Extra Concentrate [YC240]	Yin Qiao [YQ300]	Yin Qiao Jie Du [K002]	Yin Qiao San (5:1) [3870]																																																																																																																									
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<https://www.craneherb.com/>

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Combined untargeted metabolomics profiling, global semi-quantitative analysis and pattern recognition for identification of chemical constituents and quality assessment of Chinese herbal medicine formula Yinqiaosan in four preparation forms (decoctions, granules, pills, and tablets)

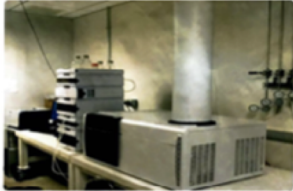
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Abstract

Yinqiaosan is a classic Chinese herbal medicine formula that has been used to treat various bacterial and viral infections by Chinese doctors for over two centuries. Here, we developed a comprehensive qualitative and quantitative method for identification, quantitation and quality assessment of chemical constituents in Yinqiaosan formula by four preparation forms (e.g., decoctions, granules, pills, and tablets). In this method, ultra-performance liquid chromatography quadrupole time-of-flight mass spectrometry (UPLC-QTOF-MS/MS) was used for integrated massomics profiling and global semi-quantitative analysis, and the acquired MS data were analyzed and compared by principal component analysis (PCA) for similarity and difference in chemical constituents. In this work, we were able to identify over a hundred chemical constituents from each preparation form using the available database, and quantitate them simultaneously using a single reference internal standard. The PCA and PLS-DA score plots showed distinct patterns for each Yinqiaosan preparation form. Among the forty-nine commonly identified compounds in the four Yinqiaosan preparation forms, sixteen were reported to have pharmacological activities, which could be used to investigate Yinqiaosan network pharmacology and help to understand the underlying mechanism of Yinqiaosan formula.

Instrumentation



Conclusion

A comprehensive high-throughput method for qualitative and quantitative analysis of Yinqiaosan formula. The chemical profiles of Yinqiaosan in four preparation forms were obtained, the commonly shared constituents were identified, and pharmacological active compounds were being sought. Perform semi-quantitative analysis for multi-components simultaneously using a single reference IS. The multivariate data analysis showed that the UPLC-MS/MS method developed were reliable and the chemical constituents in four Yinqiaosan preparation forms displayed unique pattern for product differentiation and recognition. This method may be useful in identification of chemical constituents and quality assessment not only for Yinqiaosan formula, but also for other CHM formulas.

Results

The representative retention times (RT) chromatograms of the retention blank and samples of various Yinqiaosan preparation forms in each product ion detector mode (A-E) are depicted as follows (Fig. 1).

The representative selected ion monitoring (SIM) chromatograms of six major compounds of Yinqiaosan along with the MS of a representative of 133 ions.

The Venn diagram of the chemical constituents found in each preparation form of the formula.

Summary of chemical constituents found in four Yinqiaosan preparation forms.

Visualization of multivariate data analysis: A) The PCA score plot, and B) the PLS-DA score plot of four Yinqiaosan preparation forms.

Figure 1

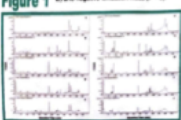


Figure 2




Figure 3




Figure 4





Table 1



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Serious Adverse Event Reporting Instructions - form 3500

SECTION C: SUSPECT PRODUCT(S)

- C1: Name
- C2: Dose, Frequency & Route Used
- C3: Therapy Dates
- C4: Diagnosis for Use
- C5: Event Abated After Use Stopped or Dose Reduced

C6: Lot #

C7: Expiration date -Include ONLY with all product problem reports and events involving human cells, tissues, and tissue and cellular-based products (HCT/Ps).

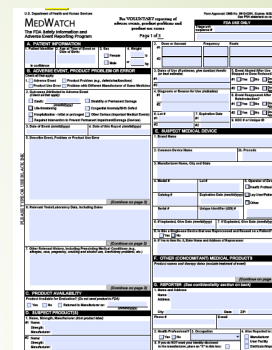
C8: Event Reappeared After Reintroduction

C9: NDC # or Unique ID - Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) must have a Unique ID number to track the product

C10: Concomitant Medical Products and Therapy Dates

<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=professional.reporting1>

<https://www.fda.gov/media/82655/download>



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Example of Patent TCHM record in the SOAP



<p>Ordered from 3rd party TCHM pharmacy</p> <p>TCM Rx Herbal Formula: (patent) Ge Xia Zhu Yu Tang KPC 5:1 concentrated water-extract granule Carrier: non-GMO Potato starch</p> <ul style="list-style-type: none"> ➤ Date Entered: July 11, 2021 9:40 AM ➤ Prescription Number: 13584344 <p>Dosage instruction:</p> <ul style="list-style-type: none"> ➤ Take 15 capsules with full glass of warm water ➤ 2 times a day, Separate from your med's and supplements by 1 hour ➤ Start on the 20th day of the cycle, stop on the 2nd day of the period 	<p>Off the shelf</p> <p>TCM Rx Herbal Formula: (patent) Ge Xia Zhu Yu Tang KPC 5:1 concentrated water-extract granule Carrier: non-GMO Potato starch</p> <ul style="list-style-type: none"> ➤ Lot: 2031 <p>Dosage instruction:</p> <ul style="list-style-type: none"> ➤ Take 15 capsules with full glass of warm water ➤ 2 times a day, Separate from your med's and supplements by 1 hour ➤ Start on the 20th day of the cycle, stop on the 2nd day of the period
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Factors affecting the dose of TCHM

- Patient weight
- Severity of complaint
- Length of complaint existence
- Functional or structural nature of complaint
- Amount of comorbidities
- Severity of comorbidities
- Medications
- Supplements
- Diet
- Gastrointestinal tract ability to absorb
- Lifestyle
- Herb concentration

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Age-to-Dose Dosing Guideline

Age	Recommended Daily Dosage
0 – 1 month	1/18 – 1/14 of adult dose
1 – 6 month	1/14 – 1/7 of adult dose
6 – 12 month	1/7 – 1/5 of adult dose
1 – 2 years	1/5 – 1/4 of adult dose
2 – 4 years	1/4 – 1/3 of adult dose
4 – 6 years	1/3 – 2/5 of adult dose
6 – 9 years	2/5 – 1/2 of adult dose
9 – 14 years	1/2 – 2/3 of adult dose
14 – 18 years	2/3 – full adult dose
18 – 60 years	adult dose
60 years and over	3/4 or less of adult dose

Weight-to-Dose Dosing Guideline

Weight	Recommended Daily Dosage
30 – 40 lbs	20% – 27% of adult dose
40 – 50 lbs	27% – 33% of adult dose
50 – 60 lbs	33% – 40% of adult dose
60 – 70 lbs	40% – 47% of adult dose
70 – 80 lbs	47% – 53% of adult dose
80 – 100 lbs	53% – 67% of adult dose
100 – 120 lbs	67% – 80% of adult dose
120 – 150 lbs	80% – 100% of adult dose
150 lbs	adult dose
150 – 200 lbs	100% – 133% of adult dose
200 – 250 lbs	133% – 167% of adult dose
250 – 300 lbs	167% – 200% of adult dose

Pin Yin	Common Name	Pharmaceutical Name	Parts (###, ##)	Pct	Patient Price
Lian Qiao	Forsythia	Forsythiae Fructus	11.00	14.67%	\$6.38
Jin Yin Hua	Lonicera Flower	Lonicerae Japonicae Flos	11.00	14.67%	\$15.31
Bo He	Mint	Menthae Herba	4.00	5.33%	\$1.49
Niu Bang Zi (Chao)	Arctium (Dry-Fried)	Arctii Lappae Fructus	10.00	13.33%	\$3.44
Jie Geng	Platycodon	Platycodi Radix	4.00	5.33%	\$2.38
Dan Dou Chi [subst]	Soybean-prepared (Soja)	Sojae Semen Praeparatum	4.00	5.33%	\$1.38
Gan Cao	Licorice	Glycyrrhizae Uralensis Radix	4.00	5.33%	\$1.60
Lu Gen	Phragmites	Phragmitis Rhizoma	19.00	25.33%	\$6.00
Jing Jie	Schizonepeta	Schizonepetae Herba	4.00	5.33%	\$1.38
Dan Zhu Ye	Lophatherum	Lophatheri Herba	4.00	5.33%	\$1.38
Total:			75.00	100%	\$40.74

* Potential allergen: Soy

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TCHM Rx TCM Style

Jin Yin Hua (Flos Lonicerae Japonicae)...9-15g
 Lian Qiao (Fructus Forsythiae Suspensae)...9-15g
 Jie Geng (Radix Platycodi Grandiflori)...3-6g
 Niu Bang Zi (Fructus Arctii Lappae)...9-12g
 Bo He (Herba Menthae Haplocalycis)...3-6g
 Dan Dou Chi (Semen Sojae praeparata)...3-6g
 Jing Jie (Herba Seu Flos Schizonepetae Tenuifoliae)...3-6g
 Dan Zhu Ye (Herba Lophatheri Gracilis)...3-6g
 Lu Gen (Rhizoma Phragmitis Communis recens)...15-30g
 Gan Cao (Radix Glycyrrhizae Uralensis)...3-6g

Total: 60 – 108g → average 75 gr → 5:1 extract = 15 gr a day
→ (Patent) 0.5 gr capsules = 30 capsules a day → 7- 8 capsules x 4 times a day (every 6 hours)
→ (Custom) 0.335 gr capsules = 45 capsules a day → 11- 12 capsules x 4 times a day (every 6 hours)

Reference: Benskey & Gamble 1993, Chinese Herbal Medicine Formulas and Strategies, Seattle Washington, Eastland Press Inc.

Contemporary TCHM Rx Style (modified Taiwanese Style)

Substance name	Main action	Chief complaint:
Metformin	drain damp	Increasing sense of anxiety, fearfulness, increasing heart rate
Glyburide	transform damp	Secondary complaint: Urinary urgency
Ozempic	warm the interior	Symptoms: Night sweats, Easy bruising, Retina inflammation/Uveitis, Nausea, Heartburn, neck tension, spasms along GB meridian/GB stones, alternating stool, neuropathy, recently lost weight
Rosuvastatin - Antihyperlipidemic	transform phlegm	
Valsartan - Antihypertensive	sedate Yang	
TCHM Rx		
Tian Wang Bu Xin Dan (5:1) 40.00%	nourish Yin/ harmonize Ht &K	
Dao Chi San (5:1) 30.00%	clear heat from the bladder & HT	
Huang Qin 3.00%	clear heat	
Bai He 3.00%	nourish Yin, calm Shen	
Xia Ku Cao 2.00%	clear Fire	
Mi Meng Hua 3.00%	clear Fire	
Chen Pi 9.00%	promote Qi movement	
Bai Zhu 6.00%	strengthen Sp	
Sheng Jiang 4.00%	protect stomach	
Nutraceutical Rx		
Ester-C® Bioflavonoids	cool blood	
Isotonix® Calcium Plus	anchor Shen	
Fish oil	nourish Yin	
Advanced Collagen	tonify blood	
Magnesium (Glycinate)	extinguish wind, stop tremors	
		Relevant Current Health History:
		1. Insufficiently controlled Diabetes Type 2
		2. Hypertension
		3. Hyperlipidemia
		1. ICD-10 Diagnosis: F41.9 Anxiety Disorder ICD-11 TM pattern: SF6L Heart and kidney systems disharmony pattern (TM1)
		2. ICD-10 Diagnosis: R30.0 Dysuria ICD-11 TM pattern: SF6E Small intestine excess heat pattern (TM1)
		TM Treatment Principle: Calm Shen, clear heat, nourish Ht and K Yin, harmonize Ht & K

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Measurable Reproducible Outcomes

<https://www.asiantherapies.org/modern-pulse-diagnosis>

Recorded: Tuesday, April 27, 2021 at 3:12:05 PM
Heart Rate: 101 BPM
Duration: 30s

Recorded: Saturday, May 15, 2021 at 6:08:58 AM
Heart Rate: 96 BPM
Duration: 30s

Recorded: Friday, June 4, 2021 at 6:22:28 AM
Heart Rate: 93 BPM
Duration: 30s

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Herbal safety

“An estimated incidence rate of adverse reactions varies from 1.8%–9.1% in clinical combination of herbs and drugs.”

Potential Herb-Drug Interaction in the Prevention of Cardiovascular Diseases during Integrated Traditional and Western Medicine Treatment
WANG Xiao-long (王肖龙), *Chinese Journal of Integrated Med* 2015
Jan;21(1):3-9

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Contraindications for Chinese Herbal Medicine

- If patient is on: Coumadin, Warfarin, Heparin, Interferon.
- Active Chemo – only with written referral of their oncologist. Share your notes with oncologist frequently!
- If patient has: Liver or Kidney failure (elevated liver enzymes or Creatinine)
Request LABS!



<https://professionalco-op.com/>

Pharmaceutical Drugs

Year	Death	Serious
1971	698	8,905
1981	1,284	5,985
1991	4,459	56,322
2001	23,777	146,297
2006	37,309	264,227
2011	98,469	572,992
2016	142,099	831,991
2018	196,749	1,107,848
2019	173,8757	1,159,948

Source: FDA Adverse Events Reporting System (FAERS) Public Dashboard

<https://fis.fda.gov/sense/app/d10be6bb-494e-4cd2-82e4-0135608ddc13/sheet/7a47a261-d58b-4203-a8aa-6d3021737452/state/analysis>

Chinese Herbs

Herb	Year	Death
Ma Huang (USA)	1995 - 2004	81
Guǎng Fáng Jì (Belgium)	1990 - 1994	102
Aconite (USA)	2017	1



Source: <http://https://www.citizen.org/article/petition-requesting-ban-of-ephedra/>
 J.L. Vandeherweghem. Misuse of Herbal Remedies: The Case of an Outbreak of Terminal Renal Failure in Belgium (Chinese Herbs Nephropathy). *The Journal of Alternative and Complementary Medicine* Vol. 4, No. 1
<https://www.cnn.com/2017/03/21/health/poisoned-herbal-tea-death-san-francisco/index.html>

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Chapter 14 b- Substances that stabilize and bind

Enters: Lu, LI, K, Sp, Ht.

Temperature: warm

Taste: sour, astringent, toxic

Caution: Excess conditions

Note: overdose may arrest Zhong Qi and lead to death

Action: relieve pain, Settle Shen, astringe Lung; astringe Large Intestine; stabilize lower Jiao

Indications: deficiency pain in the chest, abdomen, tendons, bones, and epigastrium; chronic cough d/t Lung Qi or Yin deficiency; chronic diarrhea or dysentery d/t Spleen Yin & Qi deficiency; chronic diarrhea or dysentery; polyuria, spermatorrhea, vaginal discharge d/t Instability of the lower Jiao.

Tongue: pale, swollen **Pulse:** floating, thready

Rationale: It suppresses Shen and contains Kidney Fear so allowing separation from pain, if overused it will disconnect Ht and Kidneys that may cause sleep disturbances and anxiety. Sour taste relaxes sinews so relieving pain. Astringent properties contain body fluids and Qi holding stool, urine and sperm. Prolonged use in high dose will cause Qi stagnation manifesting in dyspnea and constipation. Overdose will lead to constraint of Zhong Qi causing cardiac arrest and inability of Kidney to grasp Lung Qi leading to respiratory arrest.

Modifications: To counteract Qi stagnation add Chai Hu

Oxycodone

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<https://www.asiantherapies.org/principles-of-combining-tchm>

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FUTURE

Universal data – base

of herbal formula
side effects,
drug - herb interactions
and adverse effects
based on
research &
clinical observation



<https://www.asiantherapies.org/ae-reporting>