

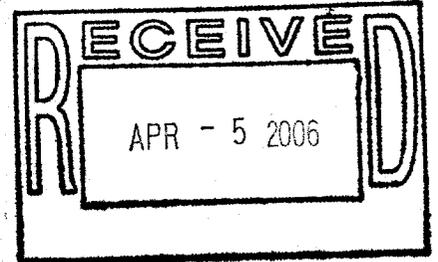
Memorandum

Date: **MAR 6 2006**

From: Consumer Safety Officer, Division of Dietary Supplement Programs, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305



Subject of the Notification: QRR-1

Firm: Shenzhen Qianrenren Sci. & Tech. Development Co., Ltd.

Date Received by FDA: December 7, 2005

90-Day Date: March 7, 2006

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

____Victoria Lutwak____

1995S-0316

RPT 323



5100 Paint Branch Parkway
Food and Drug Administration
College Park, Maryland 20740

FEB 17 2006

Renjing Tu, Executive Director
Shenzhen Qianrenren Sci. & Tech. Development Co., Ltd.
203, 85 Taining Road, Shenzhen, Guangdong
P.R. China 518029

Dear Mr. Renjing:

This is to inform you that the notification, dated November 25, 2005, you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on December 7, 2005. The notification concerns the substance called "QRR-1" which you assert is a new dietary ingredient.

According to your notification, "QRR-1" will be a combination of these nine herbal ingredients which are listed by their English names: _____ Radix Clematidis, _____ Radix Angelicae Pubescentis, _____ Rhizoma et Radix Notopterygii, _____ Radix Saposhnikoviae, _____ Radix Gentianae Macrophyllae, _____ Radix Angelicae Sinensis, _____ Rhizoma Chuanxiong, _____ Cortex Eucommiae, _____ Radix Achyranthis Bidentatae. The conditions of use that will be suggested or recommended on the label are the following: "Take - capsules _____ three times daily, after meal. Do not exceed recommended daily intake." "The total daily intake of 'QRR-1' is _____"

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C. 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

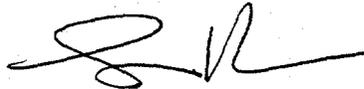
Your notification concerning "QRR-1" does not comply with the requirement of 21 CFR 190.6 and is incomplete. For example, the clinical study conducted with QRR-1 which you mention in your cover letter dated November 25, 2005, is not included in your notification.

FDA is unable to determine whether the scientific studies cited in your notice provide an adequate basis for a conclusion that the dietary supplement will reasonably be expected to be safe because the information contained in your notice is incomplete. If you market your product without submitting a notification that meets the requirements of 21 CFR 190.6 (<http://www.cfsan.fda.gov/~lrd/cfr190-6.html>), or market your product less than 75 days after submitting such a notification, your product is considered adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of December 7, 2005. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter please contact Linda Pellicore, Ph.D., at (301) 436-2375.

Sincerely yours,



Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety and Applied Nutrition

深圳市前仁人科技开发有限公司

地址: 深圳太宁路 85 号 203 邮编: 518020

电话: 0755-2903629

传真: 0755-2991361

Re: Pre-marketing Notification to US FDA on the new dietary ingredients of QRR-1

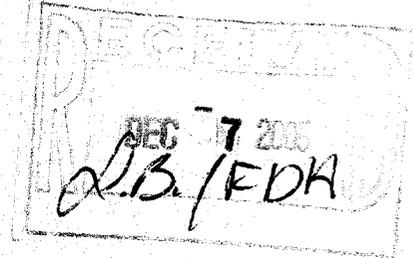
Division of Standards and Labeling Regulations

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)

Center for Food Safety and Applied Nutrition, FDA

5100 Paint Branch Parkway, College Park, MD, 20740-3835

Telephone Number: (301) 436-2371



Nov. 25, 2005

Dear Madam and/or sir,

We hereby present you information regarding patent pending QRR-1, a new dietary supplement, which we intend to market as a dietary supplement in US temporarily under the name of QRR-1.

QRR-1 contains 9 different herbals, which all has been used alone or in combination with other herbals for different purposes in China and other countries for centuries. Generally each individual herbal are safe in the traditional use. However, there are sporadic unexpected adverse effects while overdosing or misused. The dosage of the individual herbal in QRR-1 is weight below the recommended low end dosage by the Chinese Pharmacopoeia 2000.

QRR-1, the combination of the 9 herbals, has been used in China for more than 20 years. There was no significant side effect observed. In our clinical study, QRR-1 has potential to promote good health particularly on joints without significant side effect, hereby mitigating the needs for expensive chemical or biological drugs. Although the clinical studies aimed for efficacy, in combination with the toxicity information of the individual herbals, we conclude that QRR-1 is safe at the recommended dosage for human use.

We forward you herewith the Notification to US FDA on the new dietary supplement of QRR-1. QRR-1 will not be market in US for 75 days after you receive this notification.

Please contact us should you have any question regarding the enclosed Notification.

Sincerely yours,

Renjing Tu, Executive Director

Shenzhen Qianrenren Sci. & Tech. Development Co., Ltd.

203, 85 Taining Road, Shenzhen, P. R. China 518020

Email: renjing_tu@163.com

2005-8269
Aims

Encl. 2 copies of the notification.

Pre-market Notification to US FDA on the new dietary supplement:

QRR-1

Shenzhen Qianrenren Sci. & Tech. Development Co., Ltd.

Nov. 25, 2005

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1. The name and complete address of the manufacturer.....	3
or distributor of the dietary supplement that contains a new dietary ingredient, or of the new dietary ingredient;	
2. The name of the new dietary ingredient that is the.....	3
subject of the premarket notification, including the Latin binomial name (including the author) of any herb or other botanical;	
3. A description of the dietary supplement or dietary supplements that contain the new dietary ingredient including:	
(i) The level of the new dietary ingredient in the dietary supplement; and.....	3
(ii) The conditions of use recommended or suggested.....	4
in the labeling of the dietary supplement, or if no conditions of use are recommended or suggested in the labeling of the dietary supplement, the ordinary conditions of use of the supplement;	
4. The history of use or other evidence of safety establishing.....	4
that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe, including any citation to published articles or other evidence that is the basis on which the distributor or manufacturer of the dietary supplement that contains the new dietary ingredient has concluded that the new dietary supplement will reasonably be expected to be safe. Any reference to published information offered in support of the notification shall be accompanied by reprints or photostatic copies of such references. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation; and	
4.1 Publications	
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Chinese Medicine (2004) with translation	
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5. The signature of the person designated by the manufacturer.....	57
or distributor of the dietary supplement that contains a new dietary ingredient.	

1. The name and complete address of the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient, or of the new dietary ingredient

Shenzhen Qianrenren Sci. & Tech. Development Co., Ltd.
 203, 85 Taining Road, Shenzhen, Guangdong
 P. R. China 518020
 Email: renjing_tu@163.com

2. The name of the new dietary ingredient that is the subject of the premarket notification, including the Latin binomial name (including the author) of any herb or other botanical

Chinese	Pin Yin	English Name	Latin Name
威灵仙	Wei Ling Xian	Radix Clematidis	Clematis chinensis Osbeck Clematis hexapetala Pall. Clematis manshurica Rupr.
独活	Du Huo	Radix Angelicae Pubescentis	Angelica pubescens Maxim. F. biserrata Shan et Yuan
羌活	Qiang Huo	Rhizoma et Radix Notopterygii	Notopterygium incisum Ting ex H. T. Chang Notopterygium forbesii Boiss.
防风	Fang Feng	Radix Saposhnikoviae	Saposhnikovia divaricata (Turcz.) Schischk.
秦艽	Qin Jiao	Radix Gentianae Macrophyllae	Gentiana macrophylla Pall. Gentiana straminea Maxim. Gentiana crassicaulis Duthie ex Burk. Gentiana dahurica Fisch.
当归	Dang Gui	Radix Angelicae Sinensis	Angelica sinensis (Oliv.) Diels
川芎	Chuan Xiong	Rhizoma Chuanxiong	Ligusticum chuanxiong Hort.
杜仲	Du Zhong	Cortex Eucommiae	Eucommia ulmoides Oliv.
牛膝	Niu Xi	Radix Achyranthis Bidentatae	Achyranthes bidentata Bl.

3. A description of the dietary supplement or dietary supplements that contain the new dietary ingredient including:

- (i) The level of the new dietary ingredient in the dietary supplement; and

Chinese	Pin Yin	English Name	Dosage used	Dosage recommended in Chinese pharmacopoeia
威灵仙	Wei Ling Xian	Radix Clematidis		6-9g
独活	Du Huo	Radix Angelicae Pubescentis		3-9g
羌活	Qiang Huo	Rhizoma et Radix Notopterygii		3-9g
防风	Fang Feng	Radix Saposhnikoviae		4.5-9g
秦艽	Qin Jiao	Radix Gentianae Macrophyllae		3-9g
当归	Dang Gui	Radix Angelicae Sinensis		6-12g
川芎	Chuan Xiong	Rhizoma Chuanxiong		3-9g
杜仲	Du Zhong	Cortex Eucommiae		6-9g
牛膝	Niu Xi	Radix Achyranthis Bidentatae		4.5-9g

The total daily intake of QRR-1 is _____

(ii) The conditions of use recommended or suggested in the labeling of the dietary supplement, or if no conditions of use are recommended or suggested in the labeling of the dietary supplement, the ordinary conditions of use of the supplement;

The actual labeling is not yet defined. Following is the ordinary conditions of use of the supplement:

Take – capsules _____ three times daily, after meal. Do not exceed recommended daily intake.

Warning: Consult your health care professional prior to use if you have or suspect a medical condition or are taking prescription drugs. Do not use if you are pregnant or lactating. Not for use by individuals under the age of 18 years.

STORE IN A COOL, DRY PLACE. KEEP OUT OF REACH OF CHILDREN.

4. The history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe, including any citation to published articles or other evidence that is the basis on which the distributor or manufacturer of the dietary supplement that contains the new dietary ingredient has concluded that the new dietary supplement will reasonably be expected to be safe. Any reference to published information offered in support of the notification shall be accompanied by reprints or photostatic copies of such references. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation;

4.1 Radix Clematidis (威灵仙) -- is the dried root and rhizome of *Clematis chinensis* Osbeck, *Clematis hexapetala* Pall. or *Clematis manshuriac* Rupr. (Fam. Ranunculaceae). Chemical constituents: Anemonin, Anemonol, Coumarin, Kaempferol, Clematoside A, A', B and C.

History of Use:

The roots were obtained from the Jiansu, Anhui, Zhejiang, Shandong, Sichuan, Guangdong, and Fujian provinces of China. It was first listed in the Kai Bao Ben Cao(in year 973).

I. Route, schedules, and dose of administration

According to the Chinese Pharmacopia(2000), it is usually 6-9g.

II. Traditional geographical areas and populations in which such use occurred.

Since it was first listed in the Kai Bao Ben Cao(in year 973), it have been used mainly used

through out China by the Chinese population.

III. A description of similarities and/or differences between the traditional preparation and the proposed clinical formulation

It has been used for arthritis in alcohol infusion and powder, but not in the current set formula.

4.2 Radix Angelicae Pubescentis (独活) -- is the dried root and rhizome of *Angelica pubescens* Maxim. F. biserrata Shan et Yuan. (Fam. Umbelliferae). It is also called Pubescent angelica root. Chemical constituents: angelol, angelione, glabralactone, bergapten, osthol, umbelliferone, scopoletin, angelic acid, tiglic acid and palmitic acid, etc.

History of Use:

The roots were obtained from the Hubei, Sichuan and Jianxi provinces of China. It was first listed in the Shen Long Ben Cao Jing(around year 25-200).

I. Route, schedules, and dose of administration

According to the Chinese Pharmacopia(2000), it is usually 3-9g.

II. Traditional geographical areas and populations in which such use occurred.

Since it was first listed in the Shen Long Ben Cao Jing(around year 25-200), it have been used mainly used through out China by the Chinese population.

III. A description of similarities and/or differences between the traditional preparation and the proposed clinical formulation

It has been used for arthritis in alcohol infusion and powder, but not in the current set formula.

4.3 Rhizoma et Radix Notopterygii (羌活)—is the dried stem tubers of *Notopterygium incisum* Ting ex H. T. Chang and *Notopterygium forbesii* Boiss.

History of Use:

The tubers were collected in the Qinghai, Sichuan, Yuannan, Gansu, Hubei and Shanxi provinces of China. It was first listed in the Yao Xing Ben Cao(around year 627-649).

I. Route, schedules, and dose of administration

According to the Chinese Pharmacopia(2000), it is usually 3-9g.

II. Traditional geographical areas and populations in which such use occurred.

Since it was first listed in the Yao Xing Ben Cao(around year 627-649), it have been used mainly used through out China by the Chinese population.

III. A description of similarities and/or differences between the traditional preparation and the proposed clinical formulation

It has been used for arthritis in powder, but not in the current set formula.

4.4 Radix Saposhnikoviae (防风) -- dried root of *Saposhnikovia divaricata* (Turcz.) Schischk. (fam. Umbelliferae). Chemical constituents: deltoin, 5-O-methylvisamminol, 4'-O- β -glucosyl-5-O-methylvisamminol, psoralen, bergapten, xanthotoxin, imperatorin, cimifugin, prim-O-glucosylcimifugin, hamaudol, sec-O-glucosylhamaudol, etc.

History of Use:

The roots were obtained from the east-north of China, and inner mongulia, HeBei, Shangdong, Henan, Shangxi, Shanxi, and Hunan provinces of China. It was first listed in the Shen Long Ben Cao Jing(around year 25-200).

I. Route, schedules, and dose of administration

According to the Chinese Pharmacopia(2000), it is usually 4.5-9g.

II. Traditional geographical areas and populations in which such use occurred.

Since it was first listed in the Shen Long Ben Cao Jing(around year 25-200), it have been used mainly used through out China by the Chinese population.

III. A description of similarities and/or differences between the traditional preparation and the proposed clinical formulation

It has been used for arthritis in powder, but not in the current set formula.

4.5 Radix Gentianae Macrophyllae (秦艽) -- dried root of *Gentiana macrophylla* Pall., *Gentiana straminea* Maxim., *Gentiana crassicaulis* Duthie ex Burk. and *Gentiana dahurica* Fisch. (fam. Gentianaceae). Chemical constituents: Gentianine, Gentianidine, gentiopicroside, sweroside, swertiamarin, gentianal

History of Use:

The roots were obtained from the Helongjian, Liaolin, Inner Mongulia, Hebei, Shangxi, Shanxi, Henan, Ninxia, Gansu, Xinjiang, and Sichuan provinces of China. It was first listed in the Shen Long Ben Cao Jing(around year 25-200).

I. Route, schedules, and dose of administration

According to the Chinese Pharmacopoeia(2000), it is usually 3-9g.

II. Traditional geographical areas and populations in which such use occurred.

Since it was first listed in the Shen Long Ben Cao Jing(around year 25-200), it have been used mainly used through out China by the Chinese population.

III. A description of similarities and/or differences between the traditional preparation and the proposed clinical formulation

It has been used for arthritis in powder, but not in the current set formula.

4.6 Radix Angelicae Sinensis (当归) -- dried root of *Angelica sinensis* (Oliv.) Diels. family Umbelliferae. Chemical constituents: ligustilide, Butylidene phthalide, n-Valerophenone-o-carboxylic acid, Δ 2,4-Dihydrophthalic anhydride, scopoletin, umbelliferone, 7-hydroxycoumarin, carvacrol, falcarinol, etc.

History of Use:

The roots were obtained from the Gansu, Yuannan, Shanxi, Sichuan, Hubei and Guizhou provinces of China. It was first listed in the Shen Long Ben Cao Jing(around year 25-200).

I. Route, schedules, and dose of administration

According to the Chinese Pharmacopoeia(2000), it is usually 6-12g.

II. Traditional geographical areas and populations in which such use occurred.

Since it was first listed in the Shen Long Ben Cao Jing(around year 25-200), it have been used mainly used through out China by the Chinese population.

III. A description of similarities and/or differences between the traditional preparation and the proposed clinical formulation

It has been used for arthritis in powder, but not in the current set formula.

4.7 Rhizoma Chuanxiong (川芎) -- dried stem tubers of *Ligusticum chuanxiong* Hort. (Fam. Umbelliferae). Chemical constituents: mainly phthalides, such as 4-hydroxy-butylphthalide, ligustilide, butylidenephthalide, butylphthalide, neocnidilide, cnidilide, senkyunolide A, and others such as chuanxingzine, chuanxingol, tetramethylpyrazine, chrysophanol, sedanonic acid, etc.

History of Use:

The tubers were obtained from the Sichuan and Yuannan provinces of China. It was first listed in the Shen Long Ben Cao Jing(around year 25-200).

I. Route, schedules, and dose of administration

According to the Chinese Pharmacopia(2000), it is usually 3-9g.

II. Traditional geographical areas and populations in which such use occurred.

Since it was first listed in the Shen Long Ben Cao Jing(around year 25-200), it have been used mainly used through out China by the Chinese population.

III. A description of similarities and/or differences between the traditional prearastion and the proposed clinical formulation

It has been used for arthritis in powder, but not in the current set formula.

4.8 Cortex Eucommiae (杜仲) --is the dried bark of *Eucommia ulmoides* Oliv. (fam. Eucommiaceae). Chemical constituents: Gutta-percha, iridoids, aucubin, harpagide acetate, ulmoside, geniposide, geniposidic acid, etc.

History of Use:

The barks were obtained from the Sichuan, Shanxi, Hubei, Henan, Guizhou, Yunnan, Jianxi, Gansu, Hunan and guanxi provinces of China. It was first listed in the Shen Long Ben Cao Jing(around year 25-200).

I. Route, schedules, and dose of administration

According to the Chinese Pharmacopia(2000), it is usually 6-9 g.

II. Traditional geographical areas and populations in which such use occurred.

Since it was first listed in the Shen Long Ben Cao Jing(around year 25-200), it have been used mainly used through out China by the Chinese population.

III. A description of similarities and/or differences between the traditional prearastion and the proposed clinical formulation

It has been used for arthritis in powder, but not in the current set formula.

4.9 Radix Achyranthis Bidentatae (牛膝) -- dried root of *Achyranthes bidentata* Bl.(fam.

Amaranthaceae). Chemical constituents: Triterpenoid saponins, ecdysterone, inoteosterone, inokosterone, epicdysterone, and rubrosterone, etc.

History of Use:

The roots were obtained from the Henan province of China. It was first listed in the Shen Long Ben Cao Jing(around year 25-200).

I. Route, schedules, and dose of administration

According to the Chinese Pharmacopia(2000), it is usually 4.5-9g.

II. Traditional geographical areas and populations in which such use occurred.

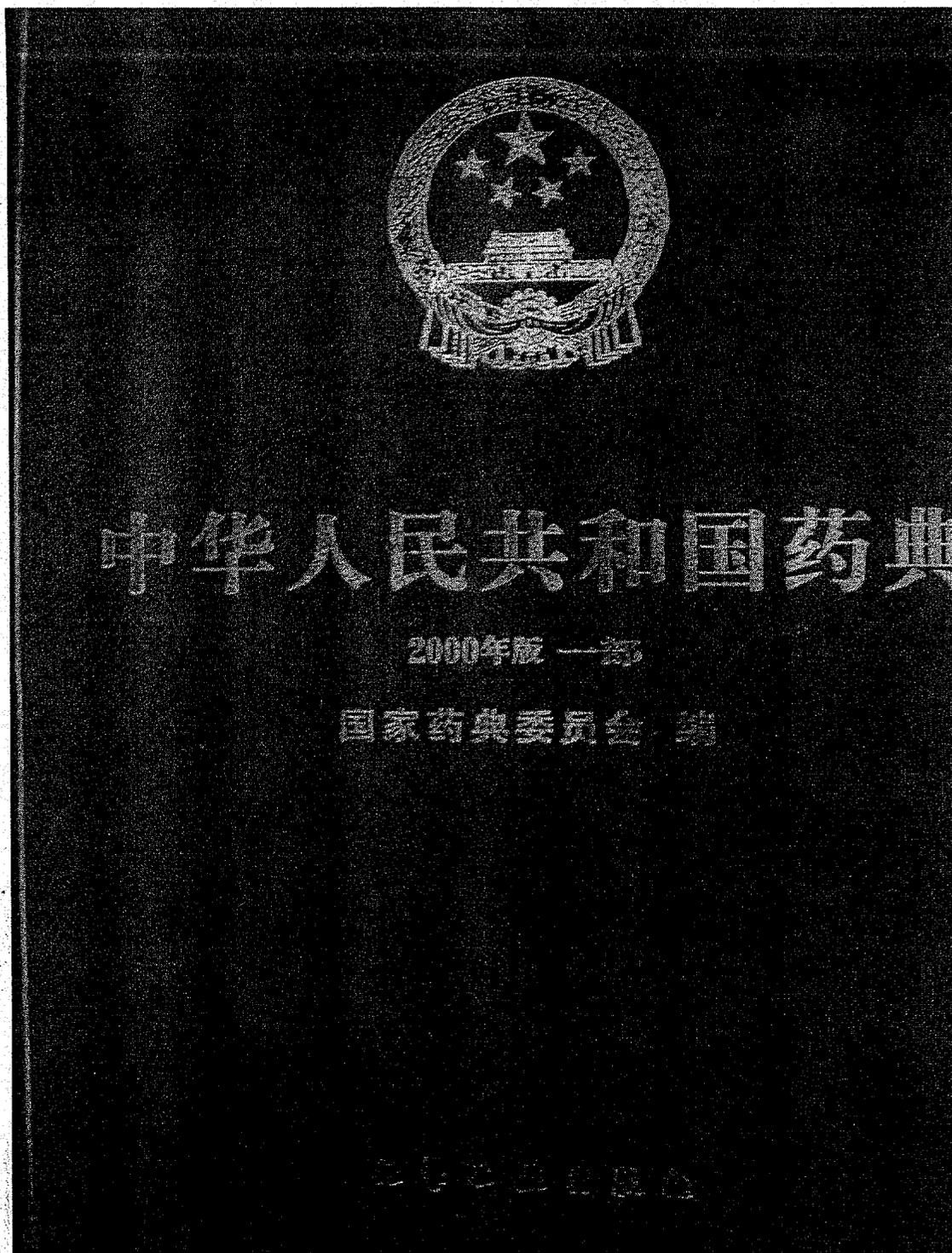
Since it was first listed in the Shen Long Ben Cao Jing(around year 25-200), it have been used mainly used through out China by the Chinese population.

III. A description of similarities and/or differences between the traditional preparastion and the proposed clinical formulation

It has been used for arthritis in powder, but not in the current set formula.

4.1 Publications

4.1.1. Chinese pharmacopeias(2000) dosage indicated



本品含鞣质性浸出物不得少于20%。

【检查】 总灰分 不得过8.0% (附录Ⅷ K)。
【浸出物】 鞣质性浸出物 取本品粉末约2g (过四号筛), 在五氧化二磷干燥器中放置48小时, 精密称定, 置100ml锥形瓶中, 加入乙醇50ml与玻璃珠数粒, 连接冷凝管, 加热至沸, 并保持微沸4小时, 取出, 用乙醚法滤取锥形瓶及玻璃珠, 滤液与滤液合并至100ml量瓶中, 加乙醇至刻度, 摇匀, 精密吸取50ml置已干燥恒重的蒸发皿中, 挥去乙醇, 置五氧化二磷干燥器中放置24小时, 迅速精密称定重量, 即得。

【含量测定】 取本品粗粉约1g (同时另取本品测定水分 (附录Ⅷ F第三法)), 精密称定, 置具塞锥形瓶中, 加乙醇20ml, 超声处理10分钟, 放冷, 过滤, 滤液置25ml量瓶中, 用少量乙醇分次洗残渣, 洗液并入同一量瓶中, 加乙醇至刻度, 摇匀, 作为供试品溶液。另取蛇床子素对照品适量, 精密称定, 加乙醇制成每1ml含1mg的溶液, 作为对照品溶液。照薄层色谱法 (附录Ⅵ B) 试验, 精密吸取供试品溶液20μl, 对照品溶液10μl与20μl, 分别交叉点于同一硅胶G薄层板上, 以苯-醋酸乙酯 (30:1) 为展开剂, 展开, 取出, 晾干, 置紫外光区 (365nm) 下检视定位。照薄层色谱法 (附录Ⅵ B薄层扫描法) 进行扫描, 波长λ=322nm, 入=670nm, 测定供试品吸收度积分值与对照品吸收度积分值, 计算, 即得。

本品按干燥品计算, 含蛇床子素 (C₁₅H₂₂O₂) 不得少于0.30%。

【炮制】 除去杂质, 洗净, 润透, 切薄片, 晒干或低温干燥。

【性味与归经】 辛、苦、微温。归肝、膀胱经。

【功能与主治】 祛风除湿; 通痹止痛。用于风湿痹痛, 腰膝疼痛, 少阴伏风头痛。

【用法与用量】 3~6g。

【贮藏】 置干燥处, 防潮, 防霉。

Dosage:

胆南星

Dandanxing
 ARISAEMA CUM BILE

本品为制天南星的细粉与牛、羊或猪胆汁经加工而成, 或为生天南星细粉与牛、羊或猪胆汁经发酵加工而成。

【性状】 本品呈方块状或圆柱状, 棕黄色、灰棕色或棕黑色, 质硬, 气微腥, 味苦。

【鉴别】 (1) 本品粉末淡黄棕色, 薄壁细胞类圆形, 充满糊化淀粉粒, 草酸钙针晶束长20~90nm, 偶见环状纤维直径6~10nm。

(2) 取本品粉末0.5g, 加水5ml, 搅拌, 过滤, 取滤液2ml置试管中, 加新制的鞣酸溶液 (C₁₂H₁₀O₆) 5ml, 振荡, 溶液即显棕红色环。

【性味与归经】 辛、苦、微平。归肺、肝、脾经。

【功能与主治】 清痰止咳; 息风定惊。用于痰热咳嗽, 咯痰黄稠, 中风痰迷, 癫狂痫病。

【用法与用量】 3~6g。

【贮藏】 置干燥处, 防潮, 防霉。

胖大海

Panghai
 SIMON-DUNALIAR-LYCHNOPHOBE

本品为胖大海的干燥果实。呈椭圆形或卵圆形, 长1.5~2.5cm, 直径1~1.5cm, 表面黄棕色或黄褐色, 有纵棱, 棱上具微细的网纹, 棱间有微细的沟纹, 顶端有微细的凹痕, 基部有微细的突起, 质硬, 气微, 味微甜。

本品为干燥的根及根茎。

根茎呈圆柱形，长2~4cm，直径1~2cm，基部较粗，皮孔红棕色，苞片外面密被淡黄色或淡黄绿色茸毛，有的最外层苞片茸毛已脱落而呈黑褐色，花被片10~12(15)，内外轮无显著差异。

【鉴别】(1)本品粉末呈绿色或淡黄绿色，非腺毛甚多，散在，多折断，完整者2~4细胞，亦有单细胞，壁厚1~13μm，基部细胞短而膨大，细胞壁加厚增厚似石细胞，石细胞多成群，呈椭圆形，有层状形成分枝状，壁厚6~20μm，孔沟不甚明显，胞腔中可见棕黄色分泌物。油细胞较多，类圆形，有的可见微小油滴，苞片表皮细胞扁方形，基周壁连珠状。

(2)取本品粗粉1g，加氯仿10ml，超声处理30分钟，滤过，滤液蒸干，残渣加氯仿2ml使溶解，作为供试品溶液。另取木兰脂素对照品，加甲醇制成每1ml含1mg的溶液，作为对照品溶液。照薄层色谱法(附录VI-B)试验，吸取上述两种溶液各2~10μl，分别点于同一以羧甲基纤维素钠为粘合剂的硅胶G薄层板上，以氯仿-乙酸乙酯(5:1)为展开剂，展开，取出，晾干，喷以10%硫酸乙醇溶液，在90℃加热至斑点显色清晰，供试品色谱中，在与对照品色谱相应的位置上，显相同的紫红色斑点。

【检查】水分 照水分测定法(附录IX H第四法)测定，不得过18.0%。

【含量测定】挥发油 照挥发油测定法(附录X F)测定。

本品含挥发油不得少于0.0%(ml/g)。

木兰脂素 照高效液相色谱法(附录VI D)测定。

色谱条件与系统适用性试验 用氨基键合硅胶为填充剂，乙腈-四氢呋喃-水(35:1:64)为流动相；检测波长为278nm，理论板数按木兰脂素峰计算应不低于9000。

对照品溶液的制备 精密称取在60℃减压干燥至恒重的木兰脂素对照品适量，加甲醇制成每1ml含木兰脂素0.1mg的溶液，即得。

供试品溶液的制备 取本品粗粉约1g，精密称定，置具塞锥形瓶中，精密加醋酸乙酯20ml，称定重量，浸泡30分钟，超声处理(功率250W，频率33kHz)30分钟，放冷，再称定重量，用甲醇补足减失的重量，摇匀，滤过，精密量取续滤液3ml，加于中性氧化铝柱(100~200目，2g，内径9mm，湿法装柱，用醋酸乙酯5ml预洗)上，用甲醇15ml洗脱，收集洗脱液，置25ml量瓶中，加甲醇至刻度，摇匀，用微孔滤膜(0.45μm)滤过，即得。

测定法 分别精密吸取对照品溶液与供试品溶液各4~10μl，注入液相色谱仪，测定，即得。

本品按干燥品计算，含木兰脂素(C₂₁H₂₄O₂)不得少于0.40%。

【性味与归经】辛，温。归肺、肾经。

【功能与主治】散风寒，通鼻窍。用于风寒头痛，鼻塞，鼻渊，鼻流浊涕。

【用法与用量】3~9g，外用适量。

【贮藏】置阴凉干燥处。

羌活

Qianghuo

RHIZOMA ET RADIX NOTOPTERYGII

本品为伞形科植物羌活 *Notopterygium incisum* Ting ex H. T. Chang 或宽叶羌活 *Notopterygium forbesii* Boiss. 的干燥根茎及根。春、秋二季采挖，除去须根及泥沙，晒干。

【性状】羌活，为圆柱状弯曲的根茎，长4~13cm，直径0.5~2.5cm，顶端具茎痕，表面棕褐色至黄褐色，外皮较厚处呈黄色，节间隆起，呈紧密隆起的环状，形似蚕，习称“蚕羌”；节间短者，形如竹节，习称“竹节羌”。根上有多数片状或瘤状突起的根根及棕色破碎鳞片。体轻，质脆，易折断，断面不平，有多数裂隙，皮部黄棕色至暗棕色，有棕色油点，木部黄白色，射线明显，髓部黄色至黄棕色，有少数油点。

宽叶羌活，为圆锥状根，根茎呈柱状，顶端具茎痕及叶柄残基，根茎圆锥形，有纵棱纹及皮孔，根

黄褐色，近根茎处有较密的环纹，长8~15cm，直径1~3cm，习称“条羌”。有的根茎粗大，不规则结节状，上部具数个茎基，根较细，习称“大头羌”。质松软，易折断，断面略平坦，皮部浅棕色，木部黄白色，气微，味淡。

【浸出物】 照醇溶性浸出物测定法项下的热浸法（附录X A）测定，用乙醇作溶剂，不得少于15.0%。

【含量测定】 照挥发油测定法（附录X D）测定。

本品含挥发油不得少于2.8%（ml/g）。

【炮制】 除去杂质，洗净，润透，切厚片，晒干。

【性味与归经】 辛、苦、温。归膀胱、肾经。

【功能与主治】 散寒，祛风，除湿，止痛。用于风寒感冒头痛，风湿痹痛，肩背酸痛。

【用法与用量】 3~9g。

【贮藏】 置阴凉干燥处，防蛀。

Dosage: —————

沙 苑 子

Shayuanzi

SEMEN ASTRAGALI COMPLANATI

本品为豆科植物扁茎黄芪 *Astragalus complanatus* R. Br. 的干燥成熟种子。秋末冬初果实成熟尚未开裂时采割植株，晒干，打下种子，除去杂质，晒干。

【性状】 本品略呈肾形而稍扁，长2~2.5mm，宽1.5~2mm，厚约1mm。表面光滑，褐绿色或灰褐色，沿一侧微凹处具圆形种脐，质坚硬，不易破碎。子叶2，淡黄色，胚根弯曲，长约1mm。无臭，味微甜，嚼之有豆腥味。

【鉴别】 取本品1g，捣碎，加乙醚10ml，置温水浴上回流10分钟，滤过，弃去醚液，药渣挥尽乙醚，加甲醇3ml，加热回流10分钟，滤过。取滤液1滴，点于色谱滤纸上，置紫外光灯（365nm）下观察，显紫红色荧光，再加甲醇2滴使斑点扩散，紫红色环内有一亮黄色环。

【炮制】 沙苑子 除去杂质，洗净，干燥。

盐沙苑子 取净沙苑子，照盐水炙法（附录I D）炒干。

【性味与归经】 甘，温。归肝、肾经。

【功能与主治】 温补肝肾，固精，缩尿，明目。用于肾虚腰痛，遗精早泄，白浊带下，小便余沥，眩暈耳鸣。

【用法与用量】 3~15g。

【贮藏】 置通风干燥处。

沙 棘

Shaji

FRUCTUS HIPPOPHAE

本品系蒙古族、藏族习用药材。为胡颓子科植物沙棘 *Hippophae rhamnoides* L. 的干燥成熟果实。秋季果实成熟或冻硬时采收，除去杂质，干燥或冻后干燥。

【性状】 本品自头状果序脱落，有的数个粘连，单个直径5~8mm，表面橙黄色或棕红色，皱缩。顶部有残存花柱。果实扁球形或扁圆形，果肉油润而柔软，种子扁卵形，长约4mm，宽约2mm，表面黄褐色，有光泽，中肋明显。果皮较硬，种仁乳白色，有油性，气微，味酸、甜。

【鉴别】 (1) 果实表面观：果皮表皮细胞多角形，垂周壁稍厚，表皮上密被毛状物，由100多个小细胞组成，排列成行，呈波状。气孔副细胞2个，呈T形。表皮细胞与副细胞均呈多角形，排列紧密，气孔副细胞2个，呈T形。表皮细胞与副细胞均呈多角形，排列紧密，气孔副细胞2个，呈T形。

【性味与归经】苦、寒。归肝、脾经。

【功能与主治】利水消肿，祛风止痛。用于水肿脚气，小便不利，湿痒疮毒，风湿痹痛，高血压。

【用法与用量】4.5g~9g。

【贮藏】置干燥处，防潮，防蛀。

防 风

Fangfeng

RADIX SAPOSHNIKOVIAE

本品为伞形科植物防风 *Saposhnikovia divaricata* (Turcz.) Schischk. 的干燥根。春、秋二季采挖未抽龙茎植株的根，除去须根及泥砂，晒干。

【性状】本品呈长圆锥形或长圆柱形，下部渐细，有的略弯曲，长15~30cm，直径0.5~2cm，表面灰棕色，粗糙，有纵皱纹，多数横皮孔及点状突起的细根痕，根头部有明显密集环纹，有的环纹上残存褐色毛状叶基。体轻，质脆，易折断，断面不平坦，皮部淡棕色，有裂隙，木部浅黄色，气特异，味微甘。

【鉴别】(1) 本品横切面，木栓层为5~30列细胞，皮层窄，有较大的椭圆形油室，韧皮部较宽，有多数类圆形油室，周壁分泌细胞1~5个，管胞内可见金黄色分泌物，射线多弯曲，外侧常成裂隙，形成层明显，木质部导管甚多，呈放射状排列，根头处有髓，薄壁组织中偶见石细胞。

粉末淡棕色，油室直径17~60 μ m，内含金黄色分泌物，射基维管束常伴有纤维束，网纹导管直径18~85 μ m，石细胞少见，黄绿色，长圆形或类长方形，壁较厚。

(2) 取本品粉末1g，加丙酮10ml，超声处理20分钟，滤过，滤液蒸干，残渣加乙醇1ml使溶解，作为供试品溶液。另取防风对照药材1g，同法制成对照药材溶液。再取升麻苷和5-O-甲基维斯阿米醇苷对照品，加乙醇制成每1ml各含1mg的混合溶液，作为对照品溶液。照薄层色谱法(附录V B)试验，吸取上述三种溶液各10 μ l，分别点于同一硅胶G₆₀薄层板上，以氯仿-甲醇(4:1)为展开剂，展开，取出，晾干，置紫外光灯(254nm)下检视。供试品色谱中，在与对照药材和对照品色谱相应的位置上，显相同颜色的斑点。

【浸出物】照醇溶性浸出物测定法项下的热浸法(附录A)测定，用乙醇作溶剂，不得少于13.0%。

【含量测定】照紫外-可见分光光度法(附录V D)测定。

色谱条件与系统适用性试验：用十八烷基硅烷键合硅胶为填充剂，甲醇-水(4:6)为流动相，检测波长为254nm，理论板数按升麻苷计算应不低于2000，按5-O-甲基维斯阿米醇苷计算应不低于2500。

对照品溶液的制备：分别取升麻苷及5-O-甲基维斯阿米醇苷对照品适量，精密称定，各加甲醇制成每1ml含升麻苷及5-O-甲基维斯阿米醇苷各50 μ g的溶液，即得。

供试品溶液的制备：取本品粉末约250mg(同时另取本品粉末测定水分(附录V E)第一法)，精密称定，置25ml具塞锥形瓶中，精密加入甲醇10ml，称定重量，水浴回流2小时，放凉，再称定重量，用甲醇补足减失的重量，超声10分钟，滤液用微孔滤膜(0.45 μ m)滤过，即得。

测定法：分别精密吸取上述两种对照品溶液各3 μ l与供试品溶液2 μ l注入液相色谱仪，测定，即得。本品以干燥品计，含升麻苷($C_{11}H_{16}O_5$)和5-O-甲基维斯阿米醇苷($C_{15}H_{20}O_6$)的总量不得少于

【炮制】除去不同规格的杂质，切厚片，干燥。

【性味与归经】苦、寒。归肝、脾经。

【功能与主治】祛风除湿，胜湿止痛。用于感冒头痛，风湿痹痛，筋骨疼痛，腰膝酸软。

【用法与用量】4.5g~9g。

【贮藏】置干燥处，防潮，防蛀。

Dosage: _____

的纤维束，断续排列成环，形成层亦在。木部部即由木化细胞组织，导管多单个散在，木纤维束成
形成层及内韧皮部，髓部木化纤维成束，周围薄壁细胞内含草酸钙方晶，散在髓部有纹孔。

【炮制】 除去杂质，洗净，润透，切段，干燥。

【性味与归经】 苦，微寒。归心、肝、肾经。

【功能与主治】 祛风通络，活血通脉，用于风湿痹痛，筋脉拘挛，腰膝酸痛，麻木，通经，止痛。

【用法与用量】 0.5~2g，外用研细适量，捣敷患处。

【贮藏】 置干燥处。

秦 艽

Qiancao

RADIX GENTIANAE MACROPHYLLAE

本品为龙胆科植物秦艽 *Gentiana macrophylla* Pall.、麻花秦艽 *Gentiana straminea* Maxim.、粗茎秦艽 *Gentiana crassicaulis* Durbin ex Burck. 或小秦艽 *Gentiana dahurica* Eisch. 的干燥根，前三种按性状不同分别习称“秦艽”和“麻花秦艽”，后一种习称“小秦艽”。春、秋二季采挖，除去泥沙，秦艽及麻花秦艽洗净，晒干，“发汗”至表面呈红黄色或灰黄色时，摊开晒干，或不给“发汗”直接晒干；小秦艽趁鲜时除去根头，晒干。

【性状】 秦艽 呈类圆柱形，上粗下细，扭曲不齐，长10~30cm，直径1~3cm，表面黄棕色或灰黄色，有纵沟或扭曲的纵皱纹，顶端有残存茎基及纤维状叶柄，质硬而脆，易折断，断面略呈纤维性，皮部黄色或棕黄色，木部黄色，气特异，味苦，微涩。

麻花秦艽 呈类圆锥形，多由数个圆锥形根膨大，直径可达7cm，表面棕褐色，粗糙，有纵沟至网状皱纹，质脆，易折断，断面多呈纤维状。

小秦艽 呈类圆锥形或类圆形，长3~15cm，直径0.2~1cm，表面棕黄色，主根通常1个，残存根茎有纤维状叶柄，下部多分枝，断面黄白色。

【鉴别】 (1) 取本品粗粉2g，加氯仿-甲醇-浓氨试液(75:25:5)混合液50ml，浸泡2小时，滤过，滤液置水浴上浓缩至约1ml，加10ml/L盐酸溶液2ml，继续除去氯仿，放冷，滤过，取滤液分置两支试管中，一管加稀氯化汞试液，即生成棕黄色沉淀，另一管加稀氯化钡试液，即生成棕红色沉淀。

(2) 取本品横切面，置紫外光灯(365nm)下观察，显黄白色或金黄色荧光。

【浸出物】 照醇溶性浸出物测定法项下的热浸法(附录A)测定，用乙醇作溶剂，不得少于24.0%。

【含量测定】 照高效液相色谱法(附录D)测定。
色谱条件与系统适用性试验：用十八烷基硅烷键合硅胶为填充剂，甲醇-水(1:1)为流动相，检测波长为285nm，理论板数按秦艽苷峰计算应不低于3000。

对照品溶液的制备：精密称取秦艽苷对照品适量，加甲醇制成每1ml含0.5mg的溶液，即得。
供试品溶液的制备：取本品粉末(过三号筛)约0.5g，同时另取本品测定水分(附录V)1.0g，精密称定，加甲醇20ml，超声处理30分钟，放冷，滤过，滤液减压回收至干，残渣用适量甲醇溶解，转移至20ml量瓶中，加甲醇至刻度，摇匀，精密量取1ml，置5ml量瓶中，加甲醇至刻度，即得。

测定法：分别精密量取对照品溶液与供试品溶液各10 μ l，注入液相色谱仪，测定，即得。
本品含秦艽苷(C₂₀H₂₅N₃O₆)不得少于0.3%。

【炮制】 除去杂质，洗净，润透，切段，干燥。

【性味与归经】 苦，微寒。归心、肝、肾经。

【功能与主治】 祛风通络，清虚热，用于风湿痹痛，筋脉拘挛，腰膝酸痛，骨蒸潮热，盗汗，自汗，多梦，遗精，带下，崩漏，胎动不安，血虚萎黄，心悸怔忡，失眠，健忘，小儿疳积。

【用法与用量】 0.5~2g，外用研细适量，捣敷患处。

【贮藏】 置干燥处。

Dosage:

【用法与用量】 3~9g。

【贮藏】 置通风干燥处。

秦 皮

Qinpi

CORTEX FRAXINI

本品为木犀科植物苦白蜡树 *Fraxinus rhynchophylla* Hance、白蜡树 *Fraxinus chinensis* Roxb.、尖叶白蜡树 *Fraxinus szaboana* Lingelsh. 或宿柱白蜡树 *Fraxinus stylosa* Lingelsh. 的干燥枝皮或干皮。春、秋季采收，晒干。

【性状】 枝皮，呈卷筒状或槽状，长 10~60cm，厚 1.5~3mm，外表面灰白色、灰棕色至黑棕色或稍带暗灰色，平坦或稍粗糙，并有灰白色圆点状皮孔及细斜皱纹，有的具分枝痕，内表面黄白色或棕色，平坦而较脆，断面纤维性，黄白色，无臭，味苦。

干皮，为长条状块片，厚 3~6mm，外表面灰棕色，具龟裂状沟纹及红棕色圆形或横长的皮孔，质坚硬，断面纤维性较强。

【鉴别】 (1) 取本品，加热水浸泡，浸出液在日光下可见碧蓝色荧光。

(2) 本品横切面，木栓层为 5~10 余列细胞，栓内层为数列多角形厚角细胞，皮层较宽，纤维及石细胞散在或成群，中柱鞘部位有石细胞及纤维束组成的环带，偶有间断，韧皮部射线宽 1~3 列细胞，纤维束及少数石细胞成层状排列，中间贯穿射线，形成“井”字形，薄壁细胞含草酸钙砂晶。

(3) 取本品粉末 1g，加乙醇 10ml，加热回流 10 分钟，放冷，滤过，滤液作为供试品溶液，另取秦皮甲素与秦皮乙素对照品，加乙醇制成每 1ml 各含 5mg 的混合溶液，作为对照品溶液，照薄层色谱法(附录 V B)试验，吸取上述两种溶液各 3 μ l，分别点于同一硅胶 G 薄层板上，以甲苯-醋酸乙酯-乙醇-甲酸(3:4:2:1)为展开剂，展开，取出，晾干，置紫外光灯(365nm)下检视，供试品色谱中，在与对照品色谱相应的位置上，显相同颜色的荧光斑点。

【含量测定】 对照品溶液的制备：精密称取经 60℃ 干燥至恒重的秦皮甲素对照品 20mg，置 10ml 量瓶中，加乙醇适量，振荡使溶解，必要时可做温加热，放冷，加乙醇至刻度，摇匀，即得。

标准曲线的制备：精密吸取对照品溶液 30 μ l、50 μ l、70 μ l、90 μ l 与 110 μ l，照薄层色谱法(附录 V B)试验，沿硅胶 G 薄层板的起始线分别点成 3~5cm 的长条(据点样量的多少而定)，以正丁醇-氯仿-甲苯-甲酸(3:1:1:1)为展开剂，展开，取出，晾干，置紫外光灯(365nm)下检视定位，分别刮取对照品条斑置具塞锥形瓶中，同时刮取同一薄层板下端与条斑等面积的硅胶 G 作为空白，置另一具塞锥形瓶中，各瓶均精密加入乙醇 10ml，45℃ 水浴加热 30 分钟，放冷，滤过，取续滤液，照分光光度法(附录 V A)，在 280nm 的波长处测定吸收度，以吸收度为纵坐标，浓度为横坐标，绘制标准曲线。

测定法：取本品粉末(过三号筛)约 1g，精密称定，置 50ml 具塞锥形瓶中，精密加入乙醇 10ml，称定重量，加热回流 30 分钟，放冷，再称定重量，用乙醇补足减失的重量，摇匀，滤过，取续滤液作为供试品溶液，照薄层色谱法(附录 V B)试验，精密吸取供试品溶液 50 μ l，沿硅胶 G 薄层板的起始线点成 5cm 的长条，另精密吸取对照品溶液 5 μ l，点于供试品条斑一侧间隔 1.5cm 处，作为对照，以正丁醇-氯仿-甲苯-甲酸(3:1:1:1)为展开剂，展开，取出，晾干，置紫外光灯(365nm)下检视，刮取与对照品色谱中相应位置上的供试品色谱中的条斑，照标准曲线的制备项下的方法，自“置具塞锥形瓶中”起，依法测定吸收度，从标准曲线上读出供试品溶液中秦皮甲素的量，计算，即得。

本品含秦皮甲素(C₁₅H₁₀O₅)不得少于 1.36%。

【炮制】 除去杂质，洗净，润透，切丝，晒干。

【性味与归经】 苦，寒。归肝、胆、大肠经。

【功能与主治】 清热燥湿，收涩，明目。用于热痢，泄泻，赤白带下，目赤肿痛，目生翳膜。

【用法与用量】 3~9g。外用适量。煎汤服。

【贮藏】 置通风干燥处。

【性状】 中柱韧皮部束与木质部束各19~27个，间隔排列，韧皮部束内侧有少数非木化纤维，木质部束导管径小，并有木纤维及管胞，导管类多角形，径向直径约至48 μ m，偶有导管深入至髓部，髓部散有少数短小纤维。

① 上木部 射线为3~6列细胞，韧皮部纤维木化，导管径向直径约至184 μ m，通常深入至髓部，与外韧皮部束作2~3轮状排列。

② 韧皮部 射线为3列细胞，细胞壁无横纹，其内层细胞的内壁特厚，皮层外侧散有纤维，类方形，部分木化，中柱韧皮部束36~40个，木质部束与管胞多角形，直径至107 μ m，其内侧与木纤维及木化的管胞细胞连接成环层。

③ 取本品粉末5g，加70%乙醇50ml，加热回流1小时，滤过，滤液蒸去乙醇，残渣加浓氨试液调节pH值至10~11，再加氯仿5ml，搅匀提取，分取氯仿层，蒸干，残渣加1%盐酸溶液5ml使溶解，滤过，滤液分为两份，一份中滴加碘化铋钾试液，生成橙红色沉淀；另一份中滴加钨钼酸试液，生成乳白色沉淀。

【浸出物】 照水溶性浸出物测定法项下热浸法（附录X A）测定，不得少于30.0%。

【炮制】 百部 除去杂质，洗净，润透，切厚片，干燥。

本品呈不规则厚片，或不规则条形斜片，表面灰白色，棕黄色，有深纵皱纹；切面灰白色，淡黄棕色或黄白色，角质样；皮部较厚，中柱扁缩，质韧，气微，味甘，苦。

【鉴别】 取百部片，照紫芥法（附录D）炒至不粘手。

加100g百部，用热蜜12.5kg。

本品形同百部片，表面棕黄色或褐棕色，略带焦斑，稍有粘性，味甜。

【性味与归经】 甘、苦，微温，归肺经。

【功能与主治】 润肺下气止咳，杀虫，用于新久咳嗽，肺痿咳嗽，百日咳；外用于头虱，体虱，蛲虫病，阴痒。蜜百部润肺止咳，用于阴痒咳嗽。

【用法与用量】 3~9g，外用适量，水煎或酒浸。

【贮藏】 置通风干燥处，防潮。

当 归

Donggui

RADIX ANGELICAE SINENSIS

本品为伞形科植物当归 *Angelica sinensis* (Oliv.) Diels 的干燥根。秋末采挖，除去须根及泥沙，沸水烫软后，捆成小把，上笼，用烟火慢慢烘干。

【性状】 本品略呈圆柱形，下部有支根3~5条或更多，长15~25cm，表面黄棕色至棕褐色，具纵皱纹、横纹及孔，根头（归头）直径1.5~3cm，具环纹，上端圆钝，有紫色或黄绿色的茎及叶鞘的残基；支根（归身）表面凹凸不平；支根（归尾）直径0.3~1cm，上粗下细，多扭曲，有少数须根。质柔韧，断面黄白色或淡黄棕色，皮部厚，有裂隙或多数棕色点状分泌腔，木部色较淡，形成层环黄棕色，有浓郁的香气，味甘，辛，微苦。

性状大，干枯无油或断面呈绿褐色者不可供药用。

【鉴别】 本品横切面：木栓层为数列细胞，皮层窄，有少数油室，韧皮部宽广，多裂隙，油室及油管类圆形，直径25~350 μ m，细胞较大，向内侧小，周围分泌细胞6~8个，形成层成环，木质部射线状排列，导管为散在的管胞，呈环状排列，薄壁细胞含淀粉粒。

粉末淡黄棕色，韧皮部呈纤维状，管胞厚，表面有细横纹的斜交网状纹理，有时可见菲薄的薄壁细胞及网状管胞，直径约至300 μ m，有时可见油管碎片。

【检查】 总灰分 不得过5.0%（附录K）。

重金属及有害元素 照铅、镉、砷、汞、铜测定法（附录K）。

【浸出物】 照醇溶性浸出物测定法项下的热浸法（附录A）测定，用50%乙醇作溶剂，不得少于

洗液与滤液合并，低温蒸干。残渣加氯仿2ml使溶解，转入分液漏斗中，用氯仿3ml分次洗涤容器，洗液并入分液漏斗中，用0.05mol/L硫酸溶液提取3次，每次5ml，酸液依次用同一氯仿10ml振荡洗涤，合并酸液，加氨试液调节pH值至9，再用氯仿提取3次，每次10ml，氯仿液依次用同一水20ml振荡洗涤，合并氯仿液，低温蒸干，残渣加无水乙醇适量使溶解，转入5ml量瓶中，用无水乙醇分次洗涤容器，洗涤液并入量瓶中，再加无水乙醇至刻度，摇匀，精密量取上述溶液及无水乙醇空白溶液各2.5ml，分别置25ml量瓶中，照标准曲线的制备项下的方法，自“各精密加入碱性硫酸羟胺试液1.5ml”起，依法测定吸光度，从标准曲线上读出供试品溶液中鞣型生物碱的重量(C₁₈H₁₅NO₇)，计算，即得。

本品含鞣型生物碱以乌头碱(C₁₈H₁₅NO₇)计，不得过0.15%。

【含量测定】取本品中粉10g，精密称定，照鞣型生物碱测定法项下的方法，自“加乙醚50ml”起至“洗液与滤液合并，低温蒸干”用乙醚-氯仿(3:1)的混合液代替乙醚。残渣加混合液5ml使溶解并蒸干，再加乙醚5ml使溶解，精密加入硫酸滴定液(0.01mol/L)15ml、水15ml与甲基红指示液3滴，用氢氧化钠滴定液(0.02mol/L)滴定至黄色，每1ml硫酸滴定液(0.01mol/L)相当于12.9mg的乌头碱(C₁₈H₁₅NO₇)。

本品含生物碱以乌头碱(C₁₈H₁₅NO₇)计，不得少于0.20%。

【性味与归经】辛、苦、热；有毒。归心、肝、肾、脾经。

【功能与主治】活血祛瘀。

【用法与用量】1.5~4g，宜先煎、久煎。

【注意】孕妇慎用。不宜与贝母类、半夏、白及、白蔹、天花粉、瓜蒌类同用。

【贮藏】置通风干燥处，防蛀。

川 芎

Chuanxiong

RHIZOMA CHUANXIONG

本品为伞形科植物川芎*Ligusticum chuanxiong* Hort. 的干燥根茎。夏季当茎上的节盘显著突出，并略带紫色时采挖，除去泥砂，晒干炕干，再去须根。

【性状】本品为不规则结节状团块，直径2~7cm，表面黄褐色，粗糙皱缩，有多数平行隆起的轮节，顶端有凹陷的类圆形茎痕，下侧及轮节上有多数小瘤状根痕，质坚实，不易折断，断面黄白色或灰黄色，散有黄棕色的油室，形成层呈波状环纹，气浓香，味苦、辛，稍有麻舌感，微回甜。

【鉴别】(1) 本品横切面：木栓层为10余列细胞，皮层狭窄，散有根迹维管束，其形成层明显，韧皮部宽，形成层环状或不规则多角形。木质部导管多角形或类圆形，大多单列或排成“V”形，偶有木纤维束，髓部较大，薄壁组织中散有多数油室，类圆形、椭圆形或形状不规则，淡黄棕色，靠近形成层的油室小，向外渐大，薄壁细胞中富含淀粉粒，有的薄壁细胞中含草酸钙晶体，呈类圆形团块或类簇晶状。

粉末淡黄棕色或灰棕色，淀粉粒较多，单粒椭圆形、长圆形、类圆形、卵圆形或肾形，直径5~15μm，长约21μm，脐点状、长槽状或人字状，偶见复粒，由2~4分粒组成。草酸钙晶体存在于薄壁细胞中，呈类圆形团块或类簇晶状，直径10~25μm，木栓细胞深黄棕色，常多层重叠，表面观呈多角形，壁薄，油室多已破碎，偶可见油室碎片，分泌细胞壁薄，含有较多的油滴，导管主为螺旋导管，亦有网纹及梯纹导管，直径14~50μm，有的螺旋导管增厚壁互相联结，似网状螺旋导管。

(2) 取本品粉末1g，加石油醚(30~60℃)5ml，放置10小时，时时振摇，静置，取上清液1ml，挥干后，残渣加乙醇1ml使溶解，再加2%3,5-二硝基苯甲酸的甲醇溶液2~3滴与甲醇饱和的氢氧化钾溶液2滴，显红色。

(3) 取本品粉末1g，加乙醚20ml，加热回流1小时，滤过，滤液挥干，残渣加醇液2ml使溶解，作为供试品溶液。另取川芎对照药材1g，同法制成对照药材溶液。照薄层色谱法(附录B)试验，吸取上述两种溶液各5~20μl，分别点于同一硅胶G薄层板上，以正己烷-氯仿(3:1)为展开剂，展开，晾干，置紫外光灯(365nm)下检视，供试品溶液中，在与对照药材溶液相应的位置上，显相同颜色的

【性状】

【检查】 总灰分 不得过 10% (附录 IX)

【炮制】 除去杂质，洗净，润透，切薄片，干燥

【性味与归经】 辛、温。归肺、胆、心包经

【功能与主治】 祛风行气，祛风止痛。用于风湿痹痛，筋骨疼痛，麻木脚气，腰膝酸痛，胸胁刺痛，跌打肿痛，头

【用法与用量】

【贮藏】 置阴凉干燥处，防霉

Dosage:

川 楝 子

Chuanlianzi

FRUCTUS TOOSENDAN

本品为楝科植物川楝 *Melia toosendan* Sieb. et Zucc. 的干燥成熟果实，冬季果实成熟时采收，除去杂质，干燥。

【性状】 本品呈类球形，直径 1.5~2cm，表面金黄色至棕黄色，略有光泽，少数凹陷或皱缩，具深棕色小点，顶端有花柱残存，基部凹陷，有果梗痕，外果被革质，与果肉间常成空腔，果肉松软，淡黄色，遇水潮湿则黏性，果核卵形或圆卵形，质坚硬，两端平截，有 6~8 条纵棱，剖分 5~8 室，每室含黑棕色长圆形的种子 1 粒，气特异，味微苦。

【炮制】 川楝子 除去杂质，用时捣碎

炒川楝子 取净川楝子，照炒法（附录 I D）炒至表面焦黄色

【性味与归经】 苦、寒。归肝、小肠、膀胱经

【功能与主治】 行气止痛，杀虫。用于胸胁、脘腹疼痛，疝痛，虫积腹痛

【用法与用量】 3~9g

【贮藏】 置通风干燥处，防霉

广 防 己

Guangfangji

RADIX ARISTOLOCHIAE FANGCHI

本品为马兜铃科植物广防己 *Aristolochia fangchi* A. C. Smith s. D. Chouet, S. M. Hwang 的干燥根，秋季采收，洗净，切段，干燥，切两半，晒干

【性状】 本品呈圆柱形或半圆柱形，略弯曲，长 6~13cm，直径 1.5~4cm，表面灰棕色，粗糙，有纵沟纹，除去粗皮后，表面较光滑，有纵沟纹，体重，质坚实，不易折断，断面粉性，有灰棕色与类白色相间的连续排列的同心环纹

【鉴别】 本品粉末：① 气孔副卫细胞，气孔副细胞 2~3 列，副细胞在细胞外环与纹孔层之间，具下壁加厚，纹孔层在气孔副细胞壁，少数石细胞散在，环纹层环不甚明显，木纤维束散在，② 木纤维束，直径 10~20μm，木纤维束壁厚 2~3μm，纤维直径约 20μm，壁较厚，纹孔层在纤维束壁，③ 木纤维束，直径 10~20μm，木纤维束壁厚 2~3μm，纤维直径约 20μm，壁较厚，纹孔层在纤维束壁

【检查】 本品粉末：① 气孔副卫细胞，气孔副细胞 2~3 列，副细胞在细胞外环与纹孔层之间，具下壁加厚，纹孔层在气孔副细胞壁，少数石细胞散在，环纹层环不甚明显，木纤维束散在，② 木纤维束，直径 10~20μm，木纤维束壁厚 2~3μm，纤维直径约 20μm，壁较厚，纹孔层在纤维束壁，③ 木纤维束，直径 10~20μm，木纤维束壁厚 2~3μm，纤维直径约 20μm，壁较厚，纹孔层在纤维束壁

【用法与用量】 3~9g

【贮藏】 置通风干燥处，防霉

炒牛蒡子 取净牛蒡子，照清炒法（附录 I D）炒至略鼓起，微有香气，用时捣碎。

【性味与归经】 辛、苦、寒。归肺、胃经。

【功能与主治】 疏散风热，宣肺透疹，解毒利咽。用于风热感冒，咳嗽痰多，麻疹，风疹，咽喉肿痛，疔瘡丹毒，痄腮疮毒。

【用法与用量】 6g~12g。

【贮藏】 置通风干燥处。

牛 蒡

Ngú

RADIX ACHYRANTHIS BIDENTATAE

本品为苋科植物牛蒡 *Achyranthes bidentata* Bl. 的干燥根，冬季茎叶枯萎时采挖，除去须根及泥沙，捆成小把，晒至半干后，将根切齐，晒干。

【性状】 本品呈细长圆柱形，稍弯曲，上端稍粗，下端较细，长 45~50 (90) cm，直径 0.4~1 cm，表面灰黄色或灰棕色，有略扭曲而细密的纵皱纹，稍长皮孔及稀疏的细根痕，质硬而脆，易折断，受潮则变柔软，断面平坦，灰棕色，微呈纤维样而泄潮，中心维管束木部较大，黄白色，其周围散有多数点状维管束，排列成 2~4 轮，气微，味微甜而稍苦。

【鉴别】 (1) 本品横切面，木栓层为数列细胞，皮层较窄，维管束断续排列成 2~4 轮，最外轮维管束较小，有时仅 1~2 数个导管，形成层无连接成环，向内维管束较大，木质部由导管、木纤维及木薄壁细胞组成，中心木质部束呈 2~3 轮，管胞细胞含草酸钙砂晶。

(2) 取本品粉末 2g，加乙醇 20ml，加热回流 45 分钟，静置，取上清液 10ml，加盐酸 1ml，加热回流 1 小时后浓缩至约 3ml，加水 10ml，用石油醚 (60~90℃) 20ml 提取，提取液蒸干，残渣加乙醇 2ml 使溶解，作为供试品溶液。另取齐墩果酸对照品，加乙醇制成每 1ml 含 1mg 的溶液，作为对照品溶液。照薄层色谱法（附录 B）试验，吸取供试品溶液 10~20μl，对照品溶液 10μl，分别点于同一以羧甲基纤维素钠为黏合剂的硅胶 G 薄层板上，以氯仿-甲酸 (40:1) 为展开剂，展开，取出，晾干，喷以磷钼钨试液，在 100℃ 加热至斑点显色清晰，供试品溶液与对照品溶液在相同位置处显相同的蓝色斑点。

【检查】 总灰分 不得过 9.0% (附录 B D)。

【炮制】 生蒡 除去杂质，洗净，润透，除去残根芦头，切段，晒干。

炒牛蒡 取净牛蒡根，照清炒法（附录 I D）炒干。

【性味与归经】 苦、寒。归肺、胃经。

【功能与主治】 补肝肾，益筋骨，宣散通经，引血下行。用于腰膝酸痛，筋骨无力，经闭不通，肝阳上亢。

【用法与用量】 6g~10g。

【注意】 孕妇慎用。

【贮藏】 置通风干燥处，防潮。

毛 苧 子

Móggēzǐ

FRUCTUS TERMINALIAE BILIBERITAE

本品为毛苧科植物毛苧 *Terminalia biliberrita* (L.) Merr. 的干燥成熟果实。

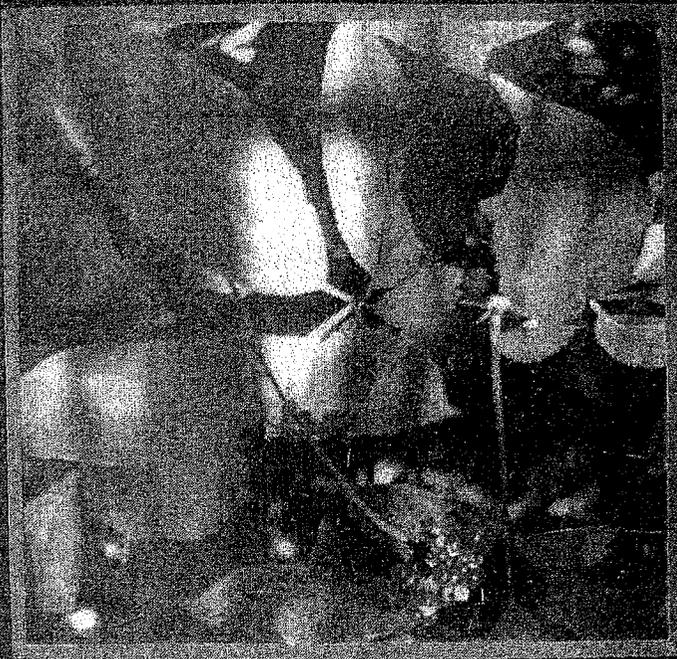
【性状】 本品呈椭圆形或卵圆形，长 1.5~2.5 cm，直径 0.8~1.2 cm，表面黄褐色或灰褐色，有细密的纵皱纹，顶端有宿萼，基部有宿柄，质硬，断面黄白色，微呈纤维状，气微，味微甜。

【鉴别】 本品横切面，果皮薄，中果皮厚，由多数薄壁细胞组成，散有少数油腺，气微，味微甜。

Dosage: _____

中药药理与临床

王本祥 主编



天津科技翻译出版公司

PHARMACOLOGY AND CLINIC OF CHINESE TRADITIONAL MEDICINE

... 用此煎液... 效

... 煎液... 效

【附注】

... 煎液... 效

... 煎液... 效

参考文献

1. ... 煎液... 效

2. ... 煎液... 效

3. ... 煎液... 效

4. ... 煎液... 效

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19. ... 煎液... 效

20. ... 煎液... 效

Radix Clematidis

1. Fresh Radix Clematidis caused one case of allergic dermatitis. Place pounded Fresh Radix Clematidis on the affect region. After 12 hours, the patient felt itches around neck. Erythema and blister appeared later. The symptom was released after taken cyproheptadine and Vc.
2. Radix Clematidis overdosing caused stomach bleeding. After boiling 70g Radix Clematidis, take the supernatant and add 250g yellow rice wine. It was taken at a draught before sleep. In the second day morning, the patient felt dizzy together with burning heat and pain sensation around stomach and kind of numbness of the extremities. The patient prepared and taken another medicine with 80 g Radix Clematidis by the same method. Around 4 pm in the afternoon, the patient felt the pain around stomach worsen and spitted blood. The bleeding might be associated with the ingredients like Anemonol, Sterone and Saponin, etc from Radix Clematidis in stimulating mucosa and anti-coagulating effect.
3. Radix Clematidis in combination with Radix Aconiti Lateralis Preparata causing toxic effect. Around 10 minutes after taken the combination of Radix Clematidis and Radix Aconiti Lateralis Preparata, 6 patients had distending epigastralagia, nausea and vomiting several times, cold sweat, acratia of extremities and dizziness. Around 6 hours later, the symptom was completely remised.

Our comments are:

The above mentioned cases of adverse reaction were mainly due to using Fresh Radix Clematidis, overdoing or in combination with known toxic herbals. Those situations are not in the recommended usage for QRR-1.

...注射用...每天 1.0g/kg 连用 5 日...形成的体外血栓,不但可延迟“雪...发生的时间,特异性血栓形成的时...血栓形成的时间,而且有使血栓长度...

...给小鼠口服...2.6g/kg,非小时后...延长 3 小时...3 小时作用消失...也与用药量呈正相关^[10]。独活在体外...部分溶解凝血因子^[11]。

...用现代生物分析法...研究证明,独活的二氯甲烷提取物...受体,血管紧张素 II 受体,钙通道阻滞...和胆碱收缩素受体均有抑制作...

...独活水提物...有抗心律失常...是其活性成分之一。给动物静脉注...10g/kg,可对抗乌头碱诱发的小鼠...引起的心律失常。给动...100mg/kg,5 分钟后,动作电位幅度...程缩短。

...*D. pubescens* Maxim.) 具有调节血管...受体,拮抗钙通道抑制剂...分别与降压和抗心率不齐有...

...甲氧基欧芹酚(costhol)可抑制角...足跖肿胀及乙酸引起的小鼠扭...50mg/kg,甲氧基欧芹酚的抗炎活...3±3.62%,比 10mg/kg 消炎痛的作用...61.2±5.14%,与 100mg/kg 阿司...

...1g,含提取物 83mg,相当于生药...49.8-99.6mg/kg 剂量给小鼠灌胃,可...的阈值和痛阈百分率,并明显...引起的小鼠扭体反应次数。上述...过敏反应也有抑制作用。给家兔...mg/kg 剂量的独活胶囊,可明显减少牛...的兔免疫球蛋白,提示独活胶囊有...调节作用。

...CFW 小鼠腹腔注射 40、50、50-...7-8 天,分别于注射后 1、2、3 天...细胞...40、50...及...水...。

...形花内酯对鼻咽癌 9RB 细胞的半数有效量(ED₅₀)为 33.0 μg/mL^[16]。

8. 抗胶原性关节炎 独活寄生汤灌胃治疗实验性小鼠胶原诱导性关节炎(CIA),发现其不能明显抑制小鼠 CIA 的发生,但能显著降低关节指数和抗 CI 抗体水平,同时该汤抑制模型小鼠内源性 IL-1β 的产生,提高 IFN-γ 水平,说明独活寄生汤对 CIA 的影响与对 IL-1β 和 IFN-γ 的调节有关^[17]。

9. 毒性 大鼠肌肉注射花椒毒素,香柑内酯的 LD₅₀ 分别为 160、943mg/kg^[18]。

【临床应用】

1. 关节炎 有人用独活寄生汤化裁(含独活、羌活、骨碎补、鸡血藤、青风藤、海风藤、威灵仙、杜仲等)治疗风湿性关节炎 52 例,显效 35 例,有效 15 例,无效 2 例,总有效率 96%^[1]。用独活汤(独活 60g,桑寄生 10g,秦艽 10g,防风 10g,威灵仙 30g,川牛膝 10g,桂枝 10g,细辛 10g,甘草 10g,当归 15g,金毛狗脊 15g,蜈蚣 3 条)加减,治疗髌骨关节炎,水煎服,每日 1 剂,15 天为 1 疗程。结果 1 个疗程临床治愈 10 例,2 个疗程治愈 25 例,2 个月治愈 8 例,显效 14 例,无效 5 例,总有效率 91.9%^[2]。

独活寄生汤加减治疗 55 例风湿痹,水煎服,每日 1 剂,15 天为 1 疗程。经 1-4 个疗程治疗后,55 例中 22 例治愈(关节疼痛消失,活动自如,停药后症状无复发),30 例有效(关节疼痛明显减轻,活动自如,停药后症状或有轻度复发),3 例无效(症状及体征无改善)^[2]。

2. 骨质增生症 以制刺膏(含独活、川乌、草乌、五加皮等,以铅丹和植物油按传统方法熬成)每次外敷 1-4 贴,每周更换 1 次,治疗 66 例骨质增生患者,显效 17 例,有效 40 例,总有效率为 86.4%,最少使用 3 次,最多使用 15 次^[3]。以热熨法加服独活寄生汤治疗 110 例患者,治愈 67 例,显效 30 例,有效 11 例,无效 2 例,总有效率 98.2%^[4]。

3. 坐骨神经痛 以独活艾果汤(含独活、艾叶、羌活、防风、白芍等)治疗坐骨神经痛患者 33 例,临床治愈 24 例,好转 8 例,无效 1 例,总有效率 98.2%^[5]。

4. 老年性膝痛 独活寄生汤加减治疗老年膝痛 33 例,每天 1 剂,水煎,分 2 次内服,15 天为 1 疗程,一般治疗 2-3 个疗程,全部有效,治疗结果,治愈 17 例,显效 10 例,有效 4 例,无效 2 例,总有效率 93.9%^[6]。

5. 骨性关节炎 独活寄生汤(独活、杜仲、桑寄生、

Modern Pharmacology and Clinic of Traditional Chinese Medicine(2004) translation

Radix Angelicae Pubescentis

Toxicity

The LD₅₀ for Xanthotoxin and Bergapten i.m. in rat are 160 and 945mg/kg respectively.

Our comments are:

In general, Radix Angelicae Pubescentis is safe to use in human for a long time. There was no LD₅₀ reported on Radix Angelicae Pubescentis.

Rhizoma et Radix Notopterygii

Toxicity

Taking the maximum concentration and allowable volume of the water soluble part of Rhizoma et Radix Notopterygii, p.o. 12g/kg in mice and observed for 72 hours. There was no abnormal reaction. There is another report that the maximum tolerance dose p.o. was 40g crude drug/kg; the maximum tolerance dose i.p. was 12.5g crude drug/kg. For ethanol extract of Rhizoma et Radix Notopterygii po, the maximum tolerance dose was 75g crude drug/kg. After 10ml/kg 2% injection of Rhizoma et Radix Notopterygii, which is about 125 times the clinical dosage, i.v. in rabbit, there was no abnormal reaction observed. The LD₅₀ for the essential oil of Rhizoma et Radix Notopterygii po in mice was 6.64ml/kg.

Modern Pharmacology and Clinic of Traditional Chinese Medicine(2004) translation

Radix Saposhnikoviae

Toxicity

The LD₅₀ of the decoction of Radix Saposhnikoviae p.o. for mice is 213.8±35.4g/kg, i.p. for mice are 37.18±8.36g/kg and 300.46±76.57g/kg.

The LD₅₀ of the water extract of Radix Saposhnikoviae i.p. for mice is 112.8±8.06g/kg. The LD₅₀ of the ethanol soaker of Radix Saposhnikoviae i.p. for mice is 11.8±1.90g/kg and i.s. for mice is 59.64±12.75g/kg. The LD₅₀ of the ethanol extract of Radix Saposhnikoviae i.p. for mice is 26.83±6.78g/kg, The LD₅₀ of the primary ethanol extract of Radix Saposhnikoviae i.p. for mice is 47.25±10.14g/kg.

Adverse reaction

There was a report on one case of allergic reaction caused by Radix Saposhnikoviae. It was disappeared after ceasing the drug. There was also a report on one case of allergic dermatitis caused by Radix Saposhnikoviae.

Modern Pharmacology and Clinic of Traditional Chinese Medicine(2004) translation

Radix Gentianae Macrophyllae

Acute Toxicity:

The LD₅₀ of Gentianine p.o. and i.p. for mice are 480.0±6.7 and 350.0±12.3mg/kg respectively, p.o. for rat is 420-520mg/kg, p.o. for dog is 240mg/kg or i.v. 80mg/kg. There was no significant adverse reaction observed after p.o. 100mg/kg once a day for three days in both monkey and cat.

Subacute toxicity

There was no change in appearance after Gentianine i.p for rats 50, 90 and 120 mg/kg, once a day for 4 days. However, at the pathologic sections, proteins were observed in glomerulus and renal tubules. Some animals had lung edema.

Adverse reaction

When using Gentianine for rheumatoid arthritis 100mg oral, there were some gastroenteric reaction, like nausea, vomiting etc.

Radix Angelicae Sinensis

Toxicity

The minimum lethal dose(MLD) of the liquid extract of Radix Angelicae Sinensis is 30-90g crude drug/kg. MLD of the liquid extract of the leaves of Radix Angelicae Sinensis is 100g crude drug/kg.

The LD₅₀ of Radix Angelicae Sinensis i.v. in mice is 100.6g/kg. The toxic reaction was crawl quietly, depressive respiration, and convulsively die. There was also reported that the LD₅₀ of Radix Angelicae Sinensis i.v. in mice is 80g/kg and 1.71g/kg for Sodium Ferulate. The essential oil of Radix Angelicae Sinensis i.v. 1 ml/kg can lower the blood pressure of anesthetic animal and depress the respiration. The ether extract of Radix Angelicae Sinensis has stronger toxicity, 0.06 and 0.02 ml/kg could cause dog and cat death respectively.

While in toxic death, there was large amount of watery secretion in the respiratory tract. Occasionally there was titanic convulsion, breath stop prior to heart beat.

Adverse reaction

Normally Radix Angelicae Sinensis is not toxic and there is very little adverse reaction in clinical application. Few patients took over dosed tincture and sedative of Radix Angelicae Sinensis, they felt fatigue and sleepy. Occasionally patients have skin itches, stomach upset, but both of them were quire minor.

While injecting the essential oil of Radix Angelicae Sinensis at some acupoints, there was some strong pain. It lasted for about 1 hour. Almost everyone had full body fever, very bad cold, headache, dry mouth, nausea, etc. Those symptoms were remised without treatment. While intravenous dripping, occasionally there was infusion reaction. There was a report on a case of allergic shock while injection at the acupoint with Compound Radix Angelicae Sinensis injection. There was another report of a case of asthma associated with Radix Angelicae Sinensis.

Rhizoma Chuanxiong

Toxicity

Using death as target, according to principal of drug accumulation, apparent pharmacokinetics parameters of orally and i.p. injecting the essential oil of Rhizoma Chuanxiong in mice were measured. The results are:

$LD_{50}(i.p.)=517.51\pm 90.01\text{mg/kg}$; Using 290mg/kg i.p. injecting, the apparent pharmacokinetical process of body remain amount fits in the type I open model, $Ke=0.466\text{h}^{-1}$, $t_{1/2}(ke)=1.5\text{h}$. $LD_{50}(\text{oral})=2982.37\pm 345.12\text{mg/kg}$. Using 1548mg/kg i.p. injecting, the apparent pharmacokinetical process of body remain amount fits in the type I open model, $Ke=0.24\text{h}^{-1}$, $t_{1/2}(ke)=2.8\text{h}$. For oral administration, the relative bioavailability is 17.5%. The LD_{50} of the water extract of Rhizoma Chuanxiong i.p. and i.m. in mice are 65.86 and 66.42g/kg. The LD_{50} of Chuanxiongzine i.v. in mice is 239mg/kg, while p.o. giving mice 5 or 10 mg/kg Chuanxiongzine daily for 4 weeks, there was no abnormality on body weight, blood test, liver and renal functions, and pathohistorical examinations. While p.o. rat 1.5 or 3 g/kg extract of Rhizoma Chuanxiong for 21 days, piloerection was observed after a week. There were bloody attachments around the nose. There were also salivation symptom. In the urine of higher dosage group, there was a significant increase in acetylated glucose aminidase activity. In blood, the Hb and red cell specific volume was significantly decreased, but platelet volume was significantly increased. The maximum hemolytic point and hemolytic end point were significantly decreased. In the biochemistry tests, phospholipids, total cholestol, α - amylases, Ca^{2+} were increased, and Total bilirubin, Lactate dehydrogenase, K^{+} , and Cl^{-} decreased. In liver, alkaline phosphatases, Glutamic-Oxalacetic Transaminase, Lactate dehydrogenase decreased. The histopathological test has not discovered any abnormality. The weight of livers in the both groups has increased.

Cortex Eucommiae

Toxicity

Each group of 6 Mice p.o. 15, 25, 50g/kg decoction of fried Cortex Eucommiae or 15g/kg decoction of Cortex Eucommiae, or 50g/kg ethanol extract of Cortex Eucommiae once per day for 5 days. There was no death occurred. The LD₅₀ for i.p. injecting the decoction of Cortex Eucommiae in mice was 17.30±0.52g/kg; Mice were intravenous injected with the 50g/kg decoction of Cortex Eucommiae or fried Cortex Eucommiae. In 5 days, there was one death among the 6 mice.

The subacute toxicity test has demonstrated that rat p.o. the 3.5g/kg water or 1.75g/kg ethanol extract of Cortex Eucommiae once a day for 21 days. There was no differences among all groups of the animals regarding appetites, blood test, liver function, and renal function in comparing with the normal control group. Dogs were i.p. 30ml 35% decoction once a day for 22 days. It was tested that there was no pathologic changes among liver, spleen, heart. However, there was slight degeneration on epithelial cells of renal tubules. There was similar observation with guinea pigs and rats.

The LD₅₀ for the water extract of the leaves of Cortex Eucommiae 8.64±0.59g/kg. Rats were p.o. 3.5g/kg or 1.75g/kg of the ethanol extract of the leaves of Cortex Eucommiae once a day for 21 days, there was no significant toxic effect observed.

Modern Pharmacology and Clinic of Traditional Chinese Medicine(2004) translation

Radix Achyranthis Bidentatae

Toxicity

The LD₅₀ is different among the Radix Achyranthis Bidentatae produced in different area while i.p. administration.

The LD₅₀ of ecdysterone i.p. in mice is 6.4g/kg; inokosterone is 7.8g/kg. While p.o. the LD₅₀ more than 9g/kg.

The 5% ether extract of (I) Radix Achyranthis Bidentatae, (II) alcohol treated Radix Achyranthis Bidentatae, (III) salt treated Radix Achyranthis Bidentatae (equivalent to 250 mg crude drug) can cause inflammatory reaction on mice ear skin. The ethanol extract of (I) has no effect on CHL cells in terms of chromosome mutation rate in the concentration between 0.04-125 mg/ml. While p.o. 15g/kg in mice and p.o. 10g/kg in pregnant mice, (I) (II) (III) have no effect on mice bone marrow cell micronucleus and early pregnancy.

Clinical study on Anti-Rheumatoid Arthritis Liquor (ARL)

Clinical Data

Subjects

40 patients with active rheumatoid arthritis, according to the classification criteria of the American Arthritis College, without other significant medical conditions were recruited. There 40 patients were recruited, 7 male and 33 female. Their ages were between 28-67 years old with average of 46.8 years old. The disease duration of the patients ranged from 0.4 to 13 years. All the patients had previously taken a variety of anti-rheumatic herbal medicine, but there was no improvement or just in relapse.

Treatment

40 patients assigned randomized to treatment with ARL or active control. Safety and compliance were monitored every 2 weeks with complete outcome evaluation at 4, 8 and 12 weeks. Observe group, 20 patients, was treated with ARL (30ml/d). It was taken before sleep or equally divided to be taken in the morning and evening. In the same time, active control group, 20 patients, was treated with the combination of Methotrexate (once a week, 7.5 mg), Mian IV (a TCM receipt contain 28 ingredients, house made medicine for RA in this hospital, one preparation per day) and one NSAID, such as Fenbid, Arthrotec, etc. The combination is one of the best treatments for RA in our clinic in terms of both safety and efficacy.

Outcome measurements

The outcome measurements for the both groups were divided to signs and symptoms, including: rest pain assessment, duration of morning stiffness, number of tender joint and the index of tenderness, number of swelling joints and the swelling index, grip strength, joint function, erythrocyte sedimentation rate, C reaction protein, and rheumatoid factor. The individual parameter improvement was calculated through the following formula:

Pre-treatment value-post treatment value

————— X100%

Pre-treatment value

The total improvement was used to compare the efficacy between the two groups. In order to accurately reflect the drug efficacy, 50% improvement, 75% improvement,

and 100% improvement (R50, R75 and R100) were used as statistical endpoint for efficacy.

The side effects were observed and recorded including stomach pain, stomach burning, headache, rash, drug tolerance, and hepatic and renal function, and blood routine tests, etc.

1.4 Statistics

t-test was used to analyze the significance of the differences between the observe group and active control group.

2. Results

All patients were completed the scheme. There was no dropout occurred.

2.1 Comparison of the treatment effects of the Herbal composition (ARL) and MTX, see the table 1.

Table 1. Comparison of the treatment effects of the Herbal composition(ARL) and MTX

Time(week)	Effect(improvement)	ARL(number(%))	MTX (number(%))
4	50%	5 (25) *	0
	75%	10 (50) *	0
	100%	5 (25) *	0
8	50%	2 (10) *	0
	75%	6 (30) *	0
	100%	12 (60) *	0
12	50%	1 (5) *	9 (45)
	75%	6 (30) *	0
	100%	13 (65) *	0
26	50%		8 (40)
	75%		10 (50)
	100%		0
52	50%		0
	75%		15 (75)
	100%		5 (25)

*, P (0.01)

2.2 Comparison of the time required for improvement of the Herbal composition(ARL) and MTX, see table 2.

During the drug administration periods of the both groups, there was significant gastrointestinal reaction, allergy, changes in hepatic and renal function and blood cytologic abnormality.

3. Discussion

Table 2. Comparison of the time required for improvement of ARL and MTX

Group	R50(week)	R75(week)	R100(week)
ARL	2.4±1.14*	3.2±0.90*	6.8±2.61*
MTX	15.2±5.43	27.7±10.5	47.2±10.7

*P<0.001

2.3 Side effects

During the observation periods of the both groups, there was no apparent gastrointestinal reaction, allergy, and changes in liver, kidney function and blood cytologic changes observed.

3. Discussion

Rheumatoid arthritis is a chronic inflammatory disease that primarily affects the joints and surrounding tissues but also affects other organ systems within the body. It is a systemic disorder.

Pharmacotherapy for RA consists of non-steroidal anti-inflammatory drugs (NSAIDs), disease-modifying anti-rheumatic drugs (DMARDs) and corticosteroids.

NSAIDs are generally prescribed as pain killer. Considerable progress has made as the recent introduction of the cyclo-oxygenase 2 (Cox-2) inhibitors which significantly reduce side effects usually accompanied with traditional NSAIDs. However, there is more and more cardiovascular concerns over COX-2 inhibitors.

There are several new DMARDs available on the market. There are Arava (leflunomide); tumor necrosis factor alfa (TNF) inhibitors, Remicade and Enbrel (etanercept); and interleukin-1 receptor alfa antagonist, Kineret. However, the efficacy and safety of those new launches are still raising concerns. Regarding the cost the efficacy, Methotrexate is still the most used DMARD for RA around the

world.

Methotrexate usually requires 12-24 weeks to show some clinical effect and long term usually 1-3 years administration. Because of long term administration, there are always somewhat toxic and side effects toward blood, liver and kidney, etc.

In this clinical trial, it was shown that ARL required shorter time to show clinical effectiveness. Four weeks after administration, it was able to make 50% RA patient to have 75% improvement on signs and symptoms (R75) and 25% RA patients to reach R100; Eight weeks after administration, 25% RA patients reached R75 and 60% RA patients reached R100. For the combination of oral methotrexate and NSAID, 12 weeks after administration, 45% RA patients reached R50; 26 weeks after administration, 40% RA patients reached R50 and 50% RA patients reached R75; 52 weeks after administration, 75% RA patients reached R75 and 25% RA patients reached R100. The efficacy differences between the two groups was extremely significant, $P < 0.01$.

For the time required to improve the signs and symptoms of RA patients, ARL required 1-4 weeks to reach R50, 3.2 weeks for R75, and 4-12 weeks for R100. In contrast, the combination of methotrexate and NSAID required 8-12 weeks to reach R50, 20-32 weeks for R75 and 52 weeks for R100.

Through our clinical observation, there were no severe toxic and side effects observed in the ARL group. The patients who were not used to drink alcohol can equally divide the amount of drug into two, and take them separately in the morning and evening.

4. Conclusion

Based on this clinical trial, ARL is a fast acting drug for RA, it is able to let 65% of patients reach R100. It is clear superior than the methotrexate and NSAID combination. However, her long term efficacy need to be further investigated.

Clinical study on Anti-Rheumatoid Arthritis Capsule (ARC)

Anti-Rheumatoid Arthritis Capsule (ARC) is a capsule made of the extract of several botanicals. In several decade clinical applications, it has been shown the efficacy and safety in the treatment of rheumatoid arthritis on a case by case basis.

In previous clinical trial, the basic efficacy and safety were observed of the alcohol solution of the drug. To assess the basic efficacy and side effect of ARC, the capsule form of the same drug, in RA patients, an open, randomized and active controlled clinical trial was carried out.

Outpatients with active rheumatoid arthritis, according to the classification criteria of the American Arthritis College, without other significant medical conditions were recruited. Patients assigned randomized to treatment with ARC or active control. Safety and compliance were monitored every 2 weeks with complete outcome evaluation at 4, 8, and 12 weeks.

36 typical active RA patients were selected and randomly divided into two groups. Observe group, 18 patients, was treated with ARC (4 capsules t.i.d., each capsule is about 0.3 g). In the mean time, active control group, 18 patients, was treated with the combination of Methotrexate (once a week, 10 mg), Folic acid (daily, 5 mg) and Arthrotec (b.i.d. 50 mg). The combination is one of the best treatments for RA in our clinic in terms of both safety and efficacy.

All the patients were treated and observed for 12 weeks. The improvement is denoted as either R50, R75 or R100 reflecting either an improvement to the 50%, 75%, or 100% level in the parameters based on the improvements of signs and symptoms including rest pain assessment, duration of morning stiffness, number of tender joint and the index of tenderness, number of swelling joints and the swelling index, grip strength, joint function, erythrocyte sedimentation rate, C reaction protein, and rheumatoid factor. From the outcome of the 36 patients treated with both ARC and active control, following results were recorded:

1. Four weeks after treatment, there was 44.5% patients achieved 50% response (R50) in the observe group; in the contrast, only 11.1% patients achieved R50 in the active control group. ($p < 0.01$).
2. Eight weeks after treatment, there was 33.3% patients achieved 75% response (R75) and 27.8% patients achieved R50 in the observe group; still only 11.1% patients achieved R50 in the active control group.
3. Twelve weeks after treatment, there was 33.3% patients achieved 100% response (R100), which is similar to the statue of complete clinical response and 61.1% patients achieved R75 in the observe group; there was 11.1% patients achieved R75 and 55.5% patients achieved R50 in the active control group. ($p < 0.01$).

4. During the observation, psychoneurological symptoms self-sensed by patients; gastrointestinal symptoms; blood pressure; routine blood and urine tests; liver and renal function test were performed. There was no abnormal reaction reported from both the patients and the lab test in the ARC group; however in the active control group, there are 3 patients complained about stomachalga.

Table I. The results of the trial.

Observation Period (weeks)	Improvement (%)	Observe Group Number(%)	MTX Group Number(%)
4	50	8(44.5)	2(11.1)
	75	0	0
	100	0	0
8	50	5(27.8)	2(11.1)
	75	6(33.3)	0
	100	0	0
12	50	0	10(55.5)
	75	11(61.1)	2(11.1)
	100	6(33.3)	0

Based on the preliminary results shown, it is indicated that ARC like ARL is effective for RA and lack of the severe side effects shown by other RA drugs. From the data shown, it indicates that ARC alone could be a potential promising new treatment for rheumatoid arthritis with good efficacy and safety.

A case study

The patient is a 53 years old male farmer with about 20 years RA history. At that time, only diclofenac rectal suppository was used. He has used many different drugs which he can not recall during his disease duration.

On 24 Feb, 2003, he was blood tested and hand picture taken.

ESR: 24mm/h, RF Ig G Ig M and Ig A: all negative. ASO: negative(50, normal<200IU/ml).

The patient complained long duration morning stiffness, rest pain, fatigue and apparent swelling on his hand. He was most of time staying in bed.

The patient started to take our herbal drug 70 ml/day besides the continuation of diclofenac rectal suppository.

On 3 March, 2003, as the swelling of his hands was remarkably shrunken, photo of his hands were taken.

On 19 May, 2003, the patient revisited and his blood was tested.

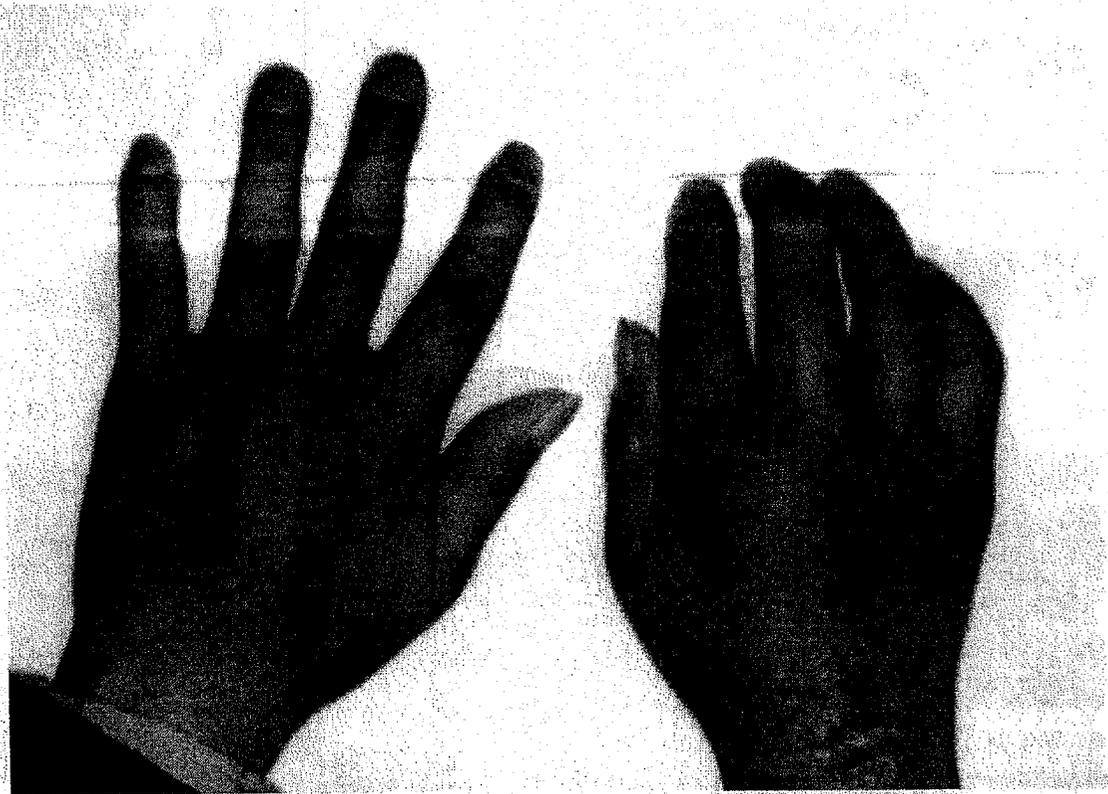
We were told that his morning stiffness disappeared. There is no pain and swollen joint in his hands. However, his knee was swelling and pain now, so diclofenac rectal suppository is continued. When stop using diclofenac, only knee joints are in pain.

He is now raising pigs.

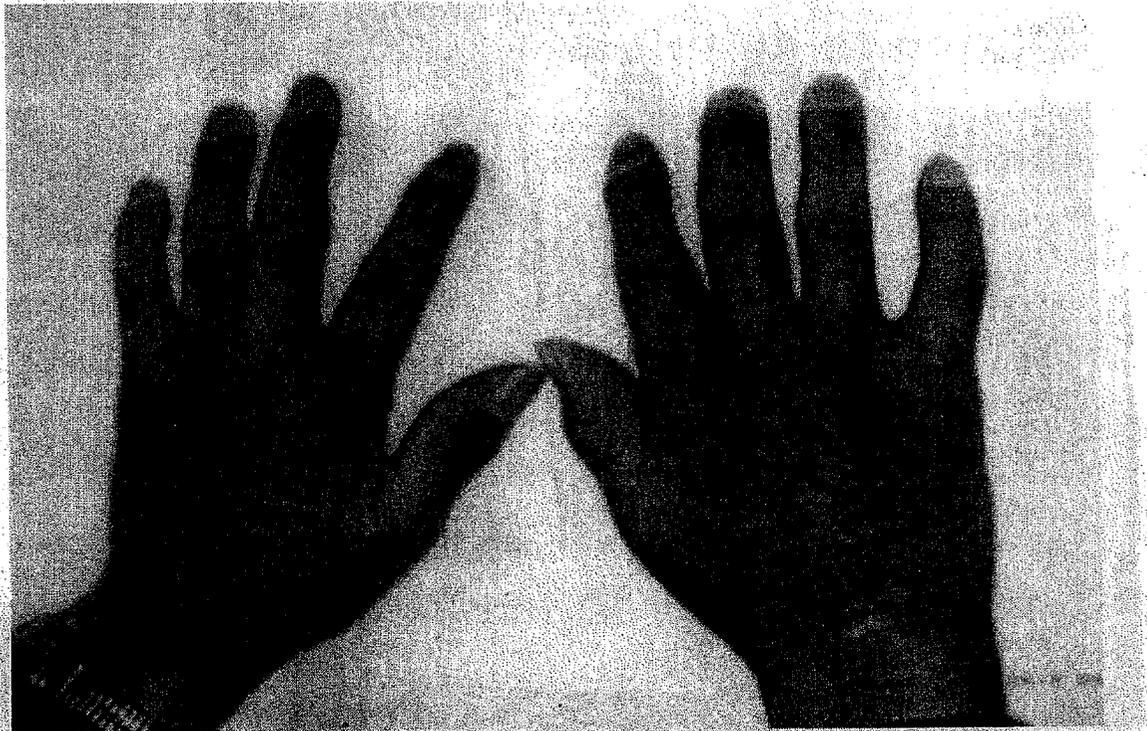
Blood test: RF: negative(10.9, normal <15IU/ml), ESR: 48(normal<15mm/h), Blood Uric acid: 649.5umol/L(normal: 150-420umol/L)

A week later, the herbal drug was discontinued.

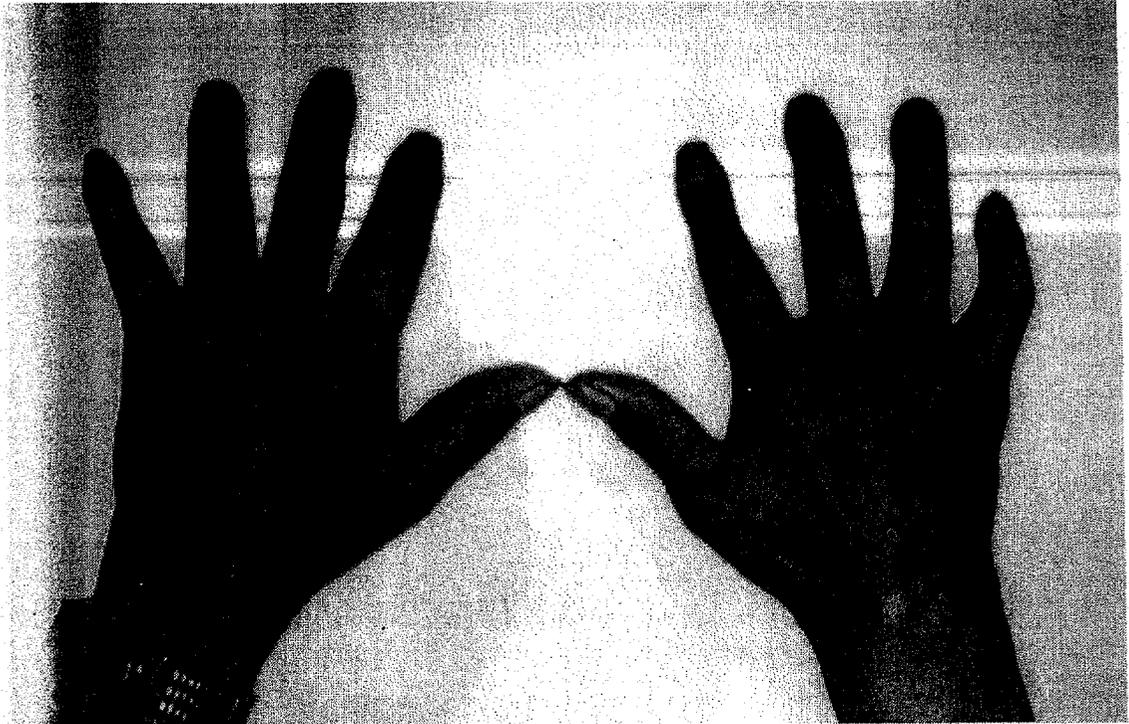
On August 8, 2003, we have taken the picture of the hands again(please see the attachment). We were told that his morning stiffness disappeared. There is no pain and swollen joint in his hands. However, his knee was swelling and pain now, so diclofenac rectal suppository is continued. When stop using diclofenac, only knee joints are in pain.



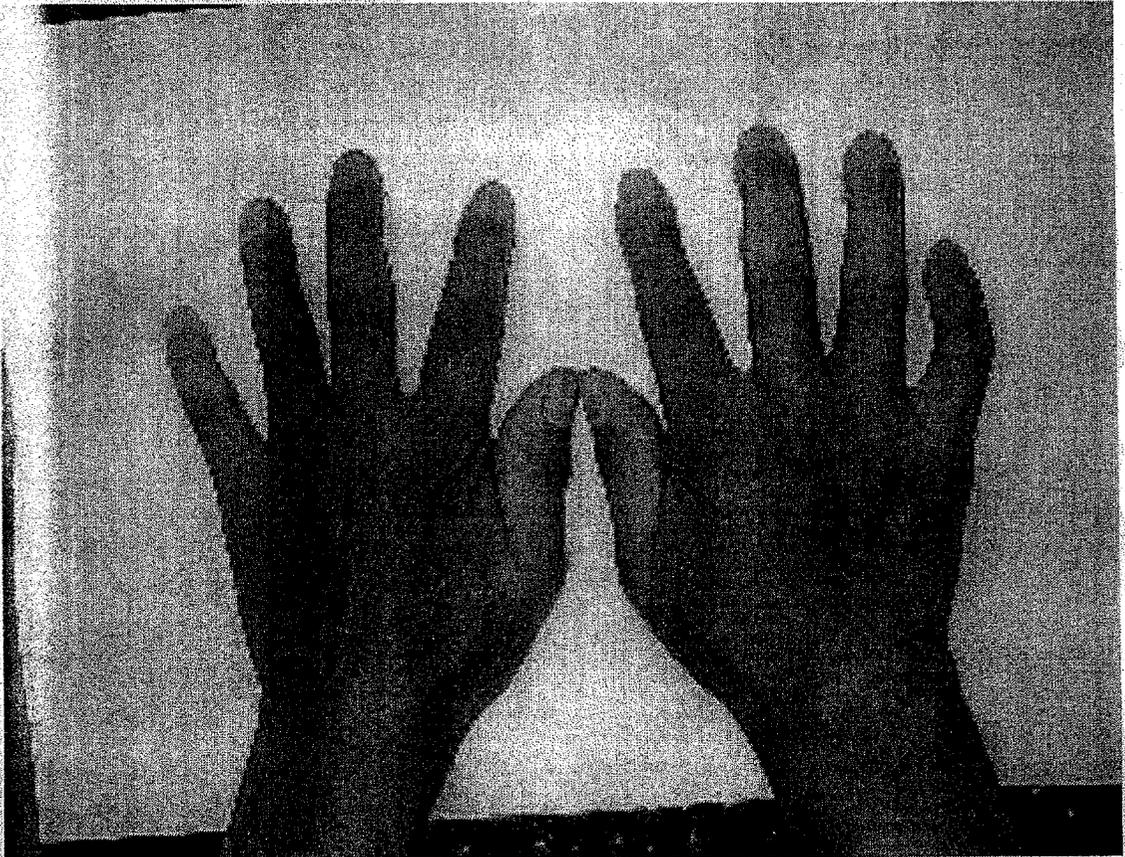
2003年2月24日(Feb. 24, 2003)



2003年3月3日(March 3, 2003)

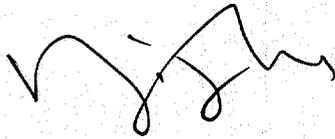


2003年5月19日(May 19, 2003)



2003年8月8日(Aug. 8, 2003)

5. The signature of the person designated by the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient.

A handwritten signature in black ink, appearing to be 'Renjing Tu', written in a cursive style.

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