DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUL 30 1999

Mr. Yueming Shi
President
China Shanxi ZhengZhong Group Co., Ltd.
130 Shuangta West Street
(Jinguang Building)
Taiyuan, Shanxi 030012
CHINA

Dear Mr. Shi:

This is in response to your letter of July 26, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that China Shanxi ZhengZhong Group Co., Ltd. is making the following statements, among others, for the product **"Chinese Joint Complex:"**

"Controls swelling"
"Ease discomfort"
"Control increased body temperature"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The claims that you are making for this product suggest that it is intended to treat, prevent, or mitigate disease, in that it is intended to treat, prevent, or mitigate joint disorders and febrile states. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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We also note that your product contains Stephania root. FDA is aware of serious adverse events associated with the use traditional chinese medicines labeled as containing Stephania, but which instead contained Aristolochia species as a contaminant or mistakenly in place of Stephania. Aristolochia species contain aristolochic acids, which are genotoxic carcinogens and are associated with interstitial nephropathy. FDA expects that a manufacturer using Stephania in a dietary supplement or that is importing traditional chinese medicines into the United States and intends to market them as dietary supplements has taken necessary action to ensure that its products do not contain Aristolochia species.

Please contact us if we may be of further assistance.

Sincerely,

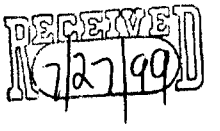
Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, San Francisco District Office, Compliance Branch, HFR-PA140

cc:
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (file)
HFS-450 (r/f, file, OSN#58642)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
HFV-229 (Benz)
GCF-1 (Barnett, Nickerson, Dorsey)
r/d:HFS-456:RMoore:7/27/99
revised per LLarsen:7/30/99
f/t:rjm:HFS-456:7/30/99:66255.adv:disc39

July 26, 1999

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St., S.W.
Washington, DC 20204



Dear Sir or Madam:

This notification is being filed pursuant to section 403(r)(6) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 343(r)(6), and in accordance with the requirements of 21 C.F.R. § 101.93. China Shanxi ZhengZhong Group Co., Ltd., 130 Shuangta West Street (Jinguang Building), Taiyuan, Shanxi 030012, China, plans to market a dietary supplement bearing the following statements on the label and/or in the labeling:

Name of supplement: Chinese Joint Complex

Dietary ingredients: Phellodendron Bark (Huang-Bai)

Prunus armeniaca (seed)

Stemona sessilfolia (root)

Job's Tears (seed)

Pinellia (Ban-Xia) (rhizome)

Forsythia (Lian-Qiao) (fruit)

Stephania Root (Fang-Ji)

Tetrapanax papyriferus (medulla)

Siegesbeckia glabrescens (herb)

Shrubby Sophora (Ku-Shen) (root)

Tripterygium wilfordii (root)

Glycyrrhiza glabra (root)

Also see docket 97S-0163

Structure/function statements:

1. **For joint health**—This statement is the subject of Chinese Joint Complex, and the Chinese Joint Complex ingredients Job's Tears (seed), Stephania Root (Fang-Ji), Siegesbeckia glabrescens (herb), and Tripterygium wilfordii (root).

2. **Helps maintain healthy, mobile joint function and connective tissue health**—This statement is the subject of Chinese Joint Complex, and the Chinese Joint Complex ingredients Job's Tears (seed), Stephania Root (Fang-Ji), Siegesbeckia glabrescens (herb), and Tripterygium wilfordii (root).

3. **Promotes joint flexibility**—This statement is the subject of Chinese Joint Complex, and the Chinese Joint Complex ingredients Job's Tears (seed), Stephania Root (Fang-Ji), Siegesbeckia glabrescens (herb), and Tripterygium wilfordii (root).

4. **Controls swelling**— This statement is the subject of Chinese Joint Complex, and the Chinese Joint Complex ingredients Job's Tears (seed), Stephania Root (Fang-Ji), Forsythia (Lian-Qiao) (fruit), Tetrapanax papyriferus (medulla), Glycyrrhiza glabra (root), and Tripterygium wilfordii (root).

5. **Ease discomfort**—This statement is the subject of Chinese Joint Complex, and the Chinese Joint Complex ingredients Siegesbeckia glabrescens (herb), Stephania Root (Fang-Ji), and Tripterygium wilfordii (root).

6. **Control increased body temperature**—This statement is the subject of Chinese Joint Complex, and the Chinese Joint Complex ingredients Forsythia (Lian-Qiao) (fruit), Phellodendron Bark (Huang-Bai), Shrubby Sophora (Ku-Shen) (root), Tetrapanax papyriferus (medulla), and Glycyrrhiza glabra (root).

Summary of Substantiation:

The claims "for joint health," "helps maintain healthy, mobile joint function and connective tissue health," "promotes joint flexibility," "controls swelling," "ease discomfort," and "control increased body temperature" for Chinese Joint Complex, are based on, and supported by,

reference to authoritative scientific literature and the long marketing history for Chinese Joint Complex in the People's Republic of China.

The Pharmacopoeia of the People's Republic of China, which is approved by the Ministry of Public Health of the People's Republic of China, states the following actions and indications for the component ingredients of Chinese Joint Complex (see attached):

- Job's Tears (seed) (listed as semen coicis): Action—to alleviate arthritis; Indications—arthritis with contracture of joints;

- Stephania Root (Fang-Ji) (listed as radix stephaniae tetrandrae): Action—to relieve rheumatic conditions; Indications—edema with rheumatic arthritis;

- Siegesbeckia glabrescens (herb) (listed as herba siegesbeckiae): Action—to relieve rheumatic conditions, to improve the motility of joints, etc.; Indications—rheumatic arthralgia with aching and weakness of the loins and knees, and numbness of the limbs;

- Forsythia (Lian-Qiao) (fruit) (listed as fructus forsythiae): Action—to remove toxic heat; Indications—febrile diseases at the early stage and at the stage with high fever, dire thirst, delirium, and maculation;

- Phellodendron Bark (Huang-Bai) (listed as cortex phellodendri): Action—to remove *damp-heat*, quench *fire*, counteract toxicity, and relieve consumptive fever; Indications—consumptive fever and night sweating;

- Glycyrrhiza glabra (root) (listed as radix glycyrrhizae): Action—to remove heat and counteract toxicity; and

- Tetrapanax papyriferus (medulla) (listed as medulla tetrapanacis): Action—to remove heat.

In addition, The Pharmacology of Chinese Herbs, Second Edition, a highly regarded resource for scientists interested in herbal medicine, states the following actions and indications for the component ingredients of Chinese Joint Complex (see attached):

- Stephania Root (Fang-Ji): Actions—anti-inflammatory, anti-hypersensitivity, and relieving pain; Therapeutic Uses—in the treatment of arthritis;

- Shrubby Sophora (Ku-Shen) (root): Therapeutic Uses—to remove "heat" and dampness from the body;

- Glycyrrhiza glabra (root): Actions—anti-inflammation; Therapeutic Uses—remove "heat" and toxic substances;

- Phellodendron Bark (Huang-Bai): Therapeutic Uses—to purge intensive "heat," and to remove "dampness" and toxic substances;

- Forsythia (Lian-Qiao) (fruit) (listed as fructus forsythiae): Action—anti-inflammatory properties and can lower body temperature;

- Tripterygium wilfordii (root): Actions—anti-inflammatory effect, inhibits proliferation of peripheral blood mononuclear cells of rheumatic arthritis patients, improvement of stiffness, walking, and hand grasping strength, and reduction of inflammation index;

- Siegesbeckia glabrescens (herb): Uses—arthritis and rheumatism; and

- Job's Tears (seed) (listed as Coix lacryma-jobi L.): Uses—antirheumatic, arthritis, and inflammation.

The findings of numerous *in vitro*, animal, and human studies involving the Chinese Joint Complex ingredients also support the above claims:

- Forsythia (Lian-Qiao) (fruit) (also referred to as Forsythia suspensa Vahl) has demonstrated an anti-inflammatory effect in mice;[1/]

- Job's Tears (seed) (also referred to as Coix lachryma-jobi var.) has demonstrated an anti-inflammatory effect in rats;[2/]

- Stephania Root (Fang-Ji) (also referred to as Stephania tetrandrae S. Moore) has demonstrated an anti-inflammatory effect in rats;[3/]

- Tetrapanax papyriferus (medulla) (also referred to as Tetrapanax papyriferum) has demonstrated an anti-inflammatory effect in rats;[4/] and

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1/ Ozaki Y *et. al.*, *Antiinflammatory Effect of Forsythia Suspensa Vahl and Its Active Fraction,* BIOL-PHARM-BULL Aug; 20(8): 861-4 (1997).

2/ Otsuka H *et. al.*, *Anti-inflammatory Activity of Benzoxazinoids From Roots of Coix Lachryma-jobi Var. Ma-yeun,* J NAT PROD Jan-Feb; 51(1): 74-9 (1988).

3/ Kobayashi S. *et. al.*, *Inhibitory Effects of Tetrandrine on Angiogenesis in Adjuvant-induced Chronic Inflammation and Tube Formation of Vascular Endothelial Cells,* BIOL PHARM BULL Apr;21(4):346-9 (1998).

4/ Sugishita E. *et. al.*, *Studies on the Mechanism of Anti-inflammatory Activities of*

(continued...)

- Tripterygium wilfordii (root) has demonstrated through numerous *in vitro*,[5] animal,[6] and human[7] studies to be an effective treatment for rheumatoid arthritis and its symptoms.

4/(...continued)
Papyriogenin A and Papyriogenin C, J PHARMACOBIODYN May;6(5):287-94 (1983); Sugishita E. *et. al.*, *Structure-activity Studies of Some Oleanane Triterpenoid Glycosides and Their Related Compounds From the Leaves of Tetrapanax Papyriferum on Anti-inflammatory Activities*, J PHARMACOBIODYN Jun;5(6):379-87 (1982).

5/ Chou CT *et. al.*, *The Inhibitory Effect of Common Traditional Anti-Rheumatic Herb Formulas on Prostaglandin E and Interleukin 2 In Vitro: A Comparative Study With Tripterygium Wilfordii*, J ETHNOPHARMACOL Sep;62(2):167-71 (1998).

6/ *See e.g.*, Asano K. *et. al.*, *Suppressive Effects of Tripterygium Wilfordii Hook F., A Traditional Chinese Medicine, On Collagen Arthritis In Mice*, IMMUNOPHARMACOLOGY May; 39(2): 117-26 (1998); Gu WZ *et. al.*, *Inhibition of Type II Collagen-Induced Arthritis In Rats By Triptolide*, INT J IMMUNOPHARMACOL Aug;20(8):389-400 (1998); Ren L. *et. al.*, *The Effects of Tripterygium Wilfordii Extract on Adjuvant Arthritis in Rats*, FUKUOKA-IGAKU-ZASSHI Jan; 86(1): 6-11 (1995); Gu WZ *et. al.*, *Inhibition of Type II Collagen Induced Arthritis In Mice By An Immunosuppressive Extract of Tripterygium Wilfordii Hook F.*, J-RHEUMATOL May; 19(5): 682-8 (1992);

7/ *See e.g.*, Tao XL *et. al.*, *A Prospective, Controlled, Double-blind, Cross-over Study of Tripterygium Wilfordii Hook F in Treatment of Rheumatoid Arthritis*, MED-J-ENGL May; 102(5): 327-32 (1989); Zeng X *et. al.*, *The Effects Of A Single Active Ingredient (T4) Of Tripterygium Wilfordii Hook On The Production Of Tumor Necrosis Factor By The Peripheral Blood Mononuclear Cells And Synovium Cells Of Rheumatoid Arthritis Patients*, CHUNG KUO I HSUEH KO HSUEH YUAN HSUEH PAO Apr;18(2):138-42 (1996); Li RL *et. al.*, *Clinical and experimental study on sustained release tablet of Tripterygium wilfordii in treating rheumatoid arthritis*, CHUNG KUO CHUNG HSI I CHIEH HO TSA CHIH Jan;16(1):10-3 (1996); QP *et. al.*, *Effects of Tripchlorolide (T4) of Tripterygium Wilfordii Hook on the Production of Prostaglandin E2 by Synovial Cells of Rheumatoid Arthritis*, YAO-HSUEH-HSUEH-PAO 29(10): 790-2 (1994); Ye WH, *Mechanism of Treating Rheumatoid Arthritis With Polyglycosides of Tripterygium Wilfordii Hook (T II). III. Study on Inhibitory Effect of T II on In Vitro Ig Secreted by Peripheral Blood Mononuclear Cells From Normal Controls and RA Patients*, CHUNG-KUO-I-HSUEH-KO-HSUEH-YUAN-HSUEH-PAO Jun; 12(3): 217-22 (1990); Tao XL, *Mechanism of Treating Rheumatoid Arthritis With Tripterygium Wilfordii Hook. II. Effect on PGE2 Secretion*, CHUNG-KUO-I-HSUEH-KO-HSUEH-YUAN-HSUEH-PAO Feb; 11(1): 36-40 (1989).

In addition, Chinese Joint Complex has been used by over 100,000 individuals and for over 20 years in China for the improvement of joint health, maintenance of healthy, mobile joint function and connective tissue health, control of swelling, reduction of discomfort, and control of increased body temperature.

Therefore, the proposed claims "for joint health," "helps maintain healthy, mobile joint function and connective tissue health," "promotes joint flexibility," "controls swelling," "ease discomfort," and "control increased body temperature" are proper and supportable for Chinese Joint Complex.

The undersigned certifies that the information presented and contained in this notification is complete and accurate, and that China Shanxi ZhengZhong Group Co., Ltd. has substantiation that each structure/function statement is truthful and not misleading.

Sincerely,

Yueming Shi
President, China Shanxi ZhengZhong Group Co., Ltd.

Attachments

PHARMACOPOEIA OF THE PEOPLE'S REPUBLIC OF CHINA

(English Edition 1997)
Volume I

Compiled by The Pharmacopoeia Commission of PRC

CHEMICAL INDUSTRY PRESS
BEIJING, CHINA

PHARMACOPOEIA OF THE PEOPLE'S REPUBLIC OF CHINA

(English Edition 1997)
Volume I

This Pharmacopoeia is the English version edited from Pharmacopoeia of the People's Republic of China 1995 edition. The Chinese edition is approved by the Ministry of Public Health of the People's Republic of China to be effective from April 1, 1996, in accordance with the official document WYF (95) 77.

(京)新登字 039 号

图书在版编目(CIP)数据

中华人民共和国药典 一部：英文版/郭济贤主编.
北京：化学工业出版社，1997.12
ISBN 7-5025-2062-7

Ⅰ.中… Ⅱ.郭… Ⅲ.药典-中国-英文 Ⅳ.R921.2

中国版本图书馆 CIP 数据核字(97)第 22567 号

Compiled by The Pharmacopoeia Commission of PRC

ISBN 7-5025-2062-7 / R·28

Published by the Chemical Industry Press
No.3, Huixinli, Chaoyang Dist., Beijing, China, 100029

Printed in the People's Republic of China

Contents

der reflux for 15 minutes. Allow to cool, transfer to a separator. Separate the chloroform layer and shake with 10 ml of sodium hydroxide TS, allow to stand; a red colour is produced in aqueous layer. If a brown colour is produced, add 1～2 drops of hydrogen peroxide TS to the separated aqueous layer and heat for 4 minutes in a water bath, a red colour is produced.

(2) Macerate 1 g of the powder with 10 ml of methanol for 1 hour, filter, evaporate the filtrate to dryness, dissolve the residue with 10 ml of water, add 1 ml of hydrochloric acid, heat on a water bath for 30 minutes, cool immediately, extracted with two quantities, each of 20 ml, of ether, combined the test solution, evaporate to dryness, dissolve the residue with 1 ml of chloroform as the test solution. Dissolve emodin and chrysophanol CRS with ethanol to produce a solution containing each of 1 mg per ml as the references solution. Carry out the method for thin layer chromatography(Appendix Ⅵ B), using silica gel H containing sodium carboxymethylcellulose as the coating substance and petroleum ether (30～60℃)-ethyl formate-formic acid(15:5:1)as the mobile phase. After developing and removal of the plate, dry it in air, examinze under ultra-violet light (365 nm). The orange fluroscent spots in the chromatogram obtained with the test solution correspond in positon and colour to the spots in the chromatogram obtained with the reference solution. The spots turn to red on exposure to ammonia vapour.

Processing *Semen Cassiae* Eliminate foreign matter, wash clean and dry. Break into pieces before use.

Semen Cassiae (stir-fried) Stir-fry the clean Semen Cassiae as described under the method for simple stir-frying (Appendix Ⅱ D) until slightly scented. Break into pieces before use.

Action To remove *heat* from the *liver*, to improve eyesight, and to relax bowels.

Indications Inflammation of the eye with pain, photophobia and lacrimination; headache, dizziness, blurred vision and constipation.

Usage and dosage 9～15 g.

Storage Preserve in a dry place.

Semen Celosiae (青葙子, Qingxiangzi)

Feather Cockscomb Seed

Feather Cockscomb Seed is the dried ripe seed of *Celosia argentea* L. (Fam. Amaranthaceae). The plant is cut up or the infructescence is picked up in autumn when the fruit is ripe, dried in the sun, and the seed is gathered and removed from foreign matter.

Description Oblate, a few rounded-reniform, 1～1.5 mm in diameter. Externally black or reddish-black, lustrous, somewhat raised at middle, with a hilum on the slightly dented lateral side. Testa thin and brittle. Odourless; tasteless.

Foreign matter Not more than 2% (Appendix Ⅸ A).

Action To remove *heat* from the *liver*, and to clear the eye of corneal opacity.

Indications Redness of the eye and dizziness due to excessive *heat* or *fire* in the *liver*; nebula with blurred vision.

Usage and dosage 9～15 g.

Storage Preserve in a dry place.

Semen Citri Reticulatae (桔核, Juhe)

Tangerine Seed

Tangerine Seed is the dried ripe seed of *Citrus reticulata* Blanco and its other cultivats (Fam. Rutaceae). The drug is collected after the fruit ripened, washed clean, and dried in the sun.

Description Slightly ovoid, 8～12 mm long, 4～6 mm in diameter. Externally pale yellowish-white or pale greyish-white, smoothy, with raphe line on one side, one end obtuse-rounded and the other end acuminate and small stalk-shaped. Testa thin, tenacious; endotesta thin, pale brown, cotyledons 2, yellowish-green, oily. Odour, slight; taste, bitter.

Identification Transverse section: Epidermal cells of testa consisting of rows of mucilage cells, with 1 row of palisade-arranged sclerenchymatous cells underneath, outer walls even or with a tail-like convex at the upper end, cell walls lignified, pitted and uneven in thickness; cells of pigment layer containing orange-yellow or yellowish-brown contents and prisms of calcium oxalate, 7～16 μm in diameter. Endosperm cells 3～4 rows, some cell walls beaded, containing oil droplets. Cotyledon cells containing fine clusters or prisms of calcium oxalate, oil droplets and rosette crystals of hesperidin.

Processing *Semen Citri Reticulatae* Eliminate foreign matter, wash clean and dry. Break into pieces before use.

Semen Citri Reticulatae (processed with salt) Stir-fry the clean Semen Citri Reticulatae as described under the method for stir-frying with salt (Appendix Ⅱ D) to dryness and break into pieces before use.

Action To regulate the flow of *qi*, cause subsidence of nodulation, and relieve pain.

Indications Hernia; painful swelling of the testis; mastitis with formation of painful nodules.

Usage and dosage 3～9 g.

Storage Preserve in a dry place, protected from mould and moth.

[redacted] (薏苡仁, Yiyiren)

Coix Seed

Coix Seed is the dried ripe kernel of *Coix lacryma-jobi* L. var. *ma-yuen* (Roman.) Stapf (Fam. Gramineae). The plant is collected in autumn when the fruit is ripe and dried in the sun. The fruit is picked up, dried in the sun, and the kernel is separated from the shell, yellowish-brown coat, and foreign matter.

Description Broad ovoid or elongated-elliptical, 4～8 mm long, 3～6 mm wide. Externally milky white, smooth, occasionally with yellowish-brown testa. One end obtusely

rounded, the other end relatively broad and slightly dented with 1 pale brown dotted hilum. Dorsal surface rounded and protruding; ventral surface having 1 relatively broad and deep longitudinal furrow. Texture hard, fracture white and starchy. Odour, slight; taste, slightly sweet.

Identification Powder: Whitish. Starch granules numerous, simple granule subrounded or polyhedral, 2～20 μm in diameter, hilum stellate; compound granules seldom visible, usually consisting of 2～3 components. On adding iodine TS, the starch showing a brownish-red colour.

Processing *Semen Coicis* Eliminate foreign matter.

Semen Coicis (stir-fried) Stir-fry the clean Semen Coicis as described under the method for stir-frying with bran (Appendix Ⅱ D) until a pale yellow colour is produced.

Action To invigorate the *spleen* function and promote diuresis, to alleviate arthritis, to arrest diarrhea, to remove heat and facilitate the drainage of pus.

Indications Edema, oliguria; arthritis with contracture of joints; diarrhea due to diminished function of the *spleen*; lung abscess, appendicitis; verruca plana.

Usage and dosage 9～30 g.

Storage Preserve in a ventilated and dry place, protected from moth.

Semen Crotonis Pulveratum (巴豆霜, Badoushuang)

Defatted Croton Seed Powder

Defatted Croton Seed Powder is a processed product of Croton Seed.

Processing Treat the clean Croton Seed as described under the method for frost-like powder (Appendix Ⅱ D), or pulverize the seed and determine its content of fatty oil, add sufficient starch to make the fatty oil content in compliance with the requirement and mix well.

Description A pale yellow, lax powder, homogeneous in size, oily in appearance.

Identification Complies with the tests for Identification described under Fructus Crotonis.

Assay Heat under reflux about 5 g of the powder, accurately weighed, in a Soxhlet's extractor with 100 ml of ether for 6～8 hours to exhaust fatty oil. Transfer the extract to the evaporating dish dried to constant weight, remove the ether at a low temperature on a water bath. Dry the residue at 100℃ for 1 hour, cool, and weigh accurately.
It contains 18%～20% of fatty oil.

Action To cause drastic purgation, to relieve edema, and to soothe the throat.

Indications Constipation and indigestion due to accumulation of cold; ascites and edema with oliguria and constipation; inflammation of the throat.

Usage and dosage 0.1～0.3 g; mostly used for making pills or powder.

Precaution Contraindicated in pregnany. Incompatible with Semen Pharbitidis.

Storage Preserve in a cool and dry place.

Semen Cuscutae (菟丝子, Tusizi)

Dodder Seed

Dodder Seed is the dried ripe seed of *Cuscuta chinensis* Lam. (Fam. Convolvulaceae). The plant is collected in autumn when the fruit is ripe, dried in the sun, the seed is collected and removed from foreign matter.

Description Subspherical, 1～1.5 mm in diameter. Externally greyish-brown or yellowish-brown, with numerous fine projecting dots, a slightly sunken linear raphe at one end. Texture hard, difficult to break with finger. Odour, slight; taste, weak.

Identification Macerate a small quantity in boiling water, a mucilage is produced on the surface; boil until the testa is broken, yellowish-white silky rotary embryo is revealed.

Total ash Not more than 10.0% (Appendix Ⅸ K).

Processing *Semen Cuscutae* Eilminate foreign matter, wash clean, dry in the sun.

Semen Cuscutae (stir-fried with salt-water) Stir-fry the clean Semen Cuscutae as described under the method for stir-frying with salt-water (Appendix Ⅱ D) until the seeds become slightly convex.
Externally brownish-yellow, broken and slightly aromatic. A mucilage is produced on the surface after macerating the processed Semen Cuscutae in an appropriate quantity of boiling water. A yellow to dark brown curved and rotary embryo is revealed after boiling.

Action To arrest seminal discharge and abnormal urination, prevent abortion, improve eyesight and relieve diarrhea by replenishing and tonifying the *liver* and the *kidney*.

Indications Impotence, seminal emission, dripping of urine after urination, enuresis, frequent urination, aching and weakness of the loins and knees, blurred vision and tinnitus; threatened abortion due to hypofunction of the *kidney*; diarrhea due to hypofunction of the *spleen* and the *kidney*; external use for vitiligo.

Usage and dosage 6～12 g, appropriate quantity for external use.

Storage Preserve in a ventilated and dry place.

Semen Euphorbiae (千金子, Qianjinzi)

Caper Euphorbia Seed

Caper Euphorbia Seed is the dried ripe seed of *Euphorbia lathyris* L. (Fam. Euphorbiaceae). The drug is collected in summer and autumn when the fruit is ripe, removed from foreign matter, and dried.

Description Ellipsoidal or ovoid, about 5 mm long, 4 mm in diameter. Externally greyish-brown, with irregular reticulated wrinkles, greyish-black in the dents of reticulated pits, forming fine spots. A longitudinally furrowed

several to more than 10 layers of cells. Cortex narrow. Sieve tube groups of phloem distinct. Cambium in a ring. Xylem well developed, medullar rays broad, more than 10 cells wide. Parenchymatous cells containing sand crystals of calcium oxalate, mainly in ray cells.
(2) Macerate 1 g of the powder in 10 ml of dehydrated ethanol for 15 minutes and filter. Examine 2 ml of the filtrate under an ultra-violet light (365 nm); a brilliant blue and slight purple fluorescence is shown.

Acid-insoluble ash Not more than 5.0% (Appendix IX K).

Processing Eliminate foreign matter, wash clean, soften thoroughly, cut into thick pieces, and dry.

Action To relieve fever in *deficiency* conditions.

Indications Fever due to *deficiency* of *yin*, consumptive fever, fever in infantile malnutrition.

Usage and dosage 3～9 g.

Storage Preserve in a ventilated dry place, protected from moth.

Radix Stemonae
(百部, Baibu)

Stemona Root

Stemona Root is the dried root tuber of *Stemona sessilifolia* (Miq.) Miq., *Stemona japonica* (Bl.) Miq. or *Stemona tuberosa* Lour. (Fam. Stemonaceae). The drug is collected in summer and autumn, removed from rootlet, washed clean, treated with boiling water for a moment or steamed until the centre of the cut surface is devoid of a white core, and dried in the sun.

Description *Root of Stemona sessilifolia* Fusiform, the upper end relatively slender, shrunken and curved, 5～12 cm long, 0.5～1 cm in diameter. Externally yellowish-white or pale brownish-yellow, with irregular longitudinal deep furrows, and occasionally transverse wrinkles. Texture fragile, easily broken, fracture even, horny, pale yellowish-brown or yellowish-white, bark broad, stele compressed. Odour, slight; taste, sweet and bitter.

Root of Stomona japonica Two ends slightly thinned, externally mostly with irregular longitudianl folds and transverse wrinkls.

Root of Stemona tuberosa Long fusiform or long slat-shaped, 8～24 cm long, 0.8～2 cm in diameter. Externally yellowish-brown to greyish-brown, with shallow longitudinal wrinkles or irregular longitudinal furrows. Texture compact, fracture yellowish-white or dark brown, stele large, pith whitish.

Identification (1) Transverse section:

Root of Stemona sessilifolia Velamen of 3～4 layers of cells, walls suberized and lignified with dense and fine striations. Cortex relatively broad. In stele phloem bundles and xylem bundles 19～27, respectively, arranged altenatively, with a few non-lignified fibres in the inner side of phloem bundles; xylem bundles with 2～5 vessels, xylem fibres and tracheids, vessels subpolygonal, 48 μm in diameter, radially, occasionally penetrating into the pith. A few small fibres scattered in pith.

Root of Stemona japonica Velamen of 3～6 layers of cells. Phloem fibres lignified. Vessels up to 184 μm in diameter, radially, usually penetrating into pith, arranged in 2～3 whorls.

Root of Stemona tuberosa Velamen of 3 layers of cells, walls without fine striations, the inner walls of the inner layers heavily thickened. Fibres scattered in the outer part of cortex, subsquare, with slightly lignified walls. In stele, phloem bundles 36～40. Vessels in xylem bundles rounded-polygonal, up to 107 μm in diameter. The inner sides of xylem bundles linked up with xylem fibres and slightly lignified parenchymatous cells into a ring.
(2) Heat under refulux 5 g of the powder with 50 ml of 70% ethanol for 1 hour, filter, evaporate the filtrate to remove ethanol. To the residue add concentrated ammonia TS, adjust to pH 10～11, extract with 5 ml of chloroform. Evaporate the chloroform solution to dryness, dissolve the residue in 5 ml of 1% hydrochloric acid solution and filter. Separate the filtrate into two portions. To one protion add 1 drop of potassium iodobismuthaste TS, an orange-red precipitate is produced; to another portion add 1 drop of silicotungstic acid TS, a milky-white precipitate is produced.

Extractives Carry out the hot extraction method described under the determination of water-soluble extractives (Appendix X A), not less than 50.0%.

Processing *Radix Stemonae* Eliminate foreign matter, wash clean, soften thoroughly, cut into thick slices, and dry.
Occurring in irregular thick slices or irregular slat-shaped oblique slices; externally greyish-white or brownish-yellow, deep wrinkled longitudinally; cut surface greyish-white, pale yellowish-brown or yellowish-white, horny; bark relatively thick, stele compressed. Texture flexible and soft. Odour slight; taste sweet and bitter.

Radix Stemonae (Stir-fried with honey) Stir-fry the slices of Radix Stemonae as described under the method for stir-frying with honey (Appendix II D) until it is not sticky to fingers, using 12.5 kg of refined honey for 100 kg of Radix Stemonae.
The form similar to the slice of Radix Stemonae, but externally brownish-yellow or brown, with less burnt specks, slightly sticky. Taste sweet.

Action To moisten the *lung* and relieve cough, and to kill insects and worms.

Radix Stemonae (Stir-fried with honey) To moisten the *lung* and relieve cough.

Indications Acute and chronic cough, cough in phthisis, whooping cough; external use: for pediculosis capitis, pediculosis corporis, oxyruiasis, pudendal itching.

Radix Stemonae (Stir-fried with honey) cough in phthisis.

Usage and dosage 3～9 g; for external use, appropriate quantity to be decocted with water or infused in wine.

Storage Preserve in a ventilated dry place, protected from moisture.

[redacted]drae
(防己, Fangji)

Fourstamen Stephania Root

Fourstamen Stephania Root is the dried root of *Stephania tetrandria* S. Moore (Fam. Menisper-

maceae). The drug is collected in autumn, washed clean, removed from the outer coarse bark, half-dried in the sun, cut into section; the large one is cut longitudinally; and dried.

Description Irregularly cylindrical, semi-cylindrical or lump-shaped, mostly tortuous, 5～10 cm long, 1～5 cm in diameter. Externally greyish-yellow, usually exhibiting deeply depresessed transverse grooves and appearing as knotty-knobby at the curved part. Texture heavy and compact, fracture even, greyish-white, starchy, sparsely. Odour, slight; taste, bitter.

Identification (1) Transverse section: Remaining cork sometimes visible. Cortex scattered with stone cells groups, usually arranged tagentially. Phloem relatively broad. Cambium in a ring. The greater part occupied by xylem, rays wide; vessels rare, radially arranged, accompanied by wood fibres. Parenchymatous cells filled with starch granules and a few minute rod-shaped crystals of calcium oxalate.

(2) Heat about 2 g of the powder with 20 ml of sulfuric acid solution (0.5 mol/L) for 10 minutes and filter, adjust the filtrate to pH 9 by adding ammonia TS, tranfer to a separator and extract with 25 ml of benzene. Evaporate 5 ml of benzene extract to dryness and add several drops of molybdo-sulfuric acid TS to the residue, a violet colour is produced which gradually becomes a green to dirty green colour and deepens on standing.

(3) Heat under reflux 1 g of the powder with 15 ml of ethanol for 1 hour, cool, filter and evaporate the filtrate to dryness. Dissolve the residue in 5 ml of ethanol as the test solution. Dissolve tetrandrine CRS and fangchinoline CRS in chloroform to produce a mixture containing 1 mg of each per ml as the reference solution. Carry out the method for thin layer chromatography (Appendix Ⅵ B), using silica gel G as the coating substance and chlorofrom-acetone-methanol (6:1:1) as the mobile phase. Apply separately to the plate 5 μl of each of the two solutions. After developing and removal of the plate, dry it in air, and spray with dilute potassium iodobismuthate TS. The spots due to tetrandrine and fangchinoline in the chromatogram obtianed with the test solution correspond in position and colour with the spots in the chromatogram obtianed with the reference solution.

Assay Weigh accurately about 1 g of the powder (through No.3 sieve), previously dried at 80℃ for 4 hours, to a Soxhlet's extractor, add 6 drops of concentrated ammonia solution, stand for 1 hour, then add a quantity of chloroform and heat under reflux on a water bath for about 6 hours. After recovering of chloroform on a water bath, cool and disssolve the residue in absolute ethanol, transfer to a 2 ml volumetric flask, add absolute ethanol to volumn, mix well as the test solution. Dissolve tetrandrine CRS in chloroform to produce a solution containing 2 mg of per ml as the reference solution. Carry out the method for thin layer chromatogram (Appendix Ⅵ B), using silica gel G as the coating substance and chloroform-acetone-methanol-concentrated ammania (20:3:2:0.1) as the mobil phase. Apply accurately in strip to the plate 100 μl of the test solution and 10 μl of the reference solution beside. After developing and removal of the plate, exposure immediately under ultra-violet light (365 nm) for about 10 minutes. Scarpe off the strip of the test preparation corresponding in position with the reference spot, and scarpe off equal area of silica gel G on the same plate as a blank. Packed to two column (0.7 cm × 10 cm). Carry out the method for column chromatography (Appendix Ⅵ C), elute with 30 ml of methanol, collect the eluate in an evaporating dish and evaporate to dryness on a water bath. Allow to cool, add accurately 10 ml of hydrochloric acid solution (0.1 mol/L) and dissolve the residue completely. Carry out the method for spectrophotometry (Appendix Ⅴ A), measure the absorbance of the resulting solution at 280 nm. Calculate the content of $C_{38}H_{42}N_2O_6$, taking 113 as the value of A (1%, 1 cm).

It contains not less than 0.7% of tetrandrine ($C_{38}H_{42}N_2O_6$), calculated on the dried drug at 80℃ for 4 hours.

Processing Eliminate foreign matter, soak briefly, wash clean, soften thoroughly, cut into thick slices, and dry. Occurring in subrounded or broken thick slices, edges rather dark in colour, cut surface greyish-white, starchy, with sparse radial striations. Odour slight; taste bitter.

Action To cause diuresis and to relieve rheumatic conditions.

Indications Edema with oilguria; eczema; rheumatic arthritis; hypertension.

Usage and dosage 4.5～9 g.

Storage Preserve in a dry place, protected from mould and moth.

Radix Tinosporae (金果榄, Jinguolan)

Tinospora Root

Tinospora Root is the dried root tuber of *Tinospora sagittata* (Oliv.) Gagnep. or *Tinospora capillipes* Gagnep. (Fam. Menispermaceae). The drug is collected in autumn and winter, removed from rootlet, washed clean, and dried in the sun.

Description Irregular masses, 5～10 cm long, 3～6 cm in diameter. Externally brownish-yellow or brownish, rugged, deeply wrinkled. Texture hard, uneasily broken, transversely cut surface yellowish-white when dissected, showing vessels in groups, arranged somewhat radially. Odourless; taste bitter.

Processing Eliminate foreign matter, soak, soften thoroughly, cut into thick slices, and dry.

Action To remove *toxic heat*, to cure sore throat and to relieve pain.

Indications Swelling and pain of the throat, carbuncles and boils; diarrhea, dysentery; epigastric pain of *heat* type.

Usage and dosage 3～9 g; for external use, appropriate quantity to be ground into powder and insufflated into the throat, or to be ground together with vinegar and applied topically.

Storage Preserve in a dry place, protected from moth.

Radix Trichosanthis (天花粉, Tianhuafen)

Snakegourd Root

Snakegourd Root is the dried root of *Trichosanthes kirilowii* Maxim. or *Trichosanthes rosthornii* Harms (Fam. Cucurbitaceae). The drug is col-

Herba Selaginellae
(卷柏, Juanbai)

Spikemoss

Spikemoss is the dried herb of *Selaginella tamariscina* (Beauv.) Spring or *Selaginella pulvinata* (Hook. et Grev.) Maxim. (Fam. Selaginellaceae). The drug is collected all the year round, removed from fibrous root and soil, and dried in the sun.

Description *Herb of Selaginella tamariscina* Crumpled into fisted masses, 3～10 cm long. Branches fascicled, flat and branched, green or brownish-yellow, curved inward, densely growing scaly leaflets, long-aristate at the apex, central leaves (ventral leaves) 2 lines, ovate-oblong, arranged obliquely upward, margin membranous, irregularly serrulate. Dorsal leaves (lateral leaves), membranous margin of dorsal surface frequently brownish-black. Fibrous roots remained at the base brown, scattered or clustered in short rods. Texture fragile, easily broken. Odourless; taste, weak.

Herb of Selaginella pulvinata Basically similar to *Selaginella tamariscina*, but most of fibrous roots scattered. Central leaves (ventral leaves) 2 lines, ovate-lanceolate, arranged straightly upward. Leaves unsymmetrical, the inner side relatively straight, the outer side frequently thickened by folding inward, entire.

Processing *Herba Selaginellae* Eliminate remained fibrous roots and foreign matter, wash clean, cut into sections, and dry in the sun.

Herba Selaginellae (carbonized) Stir-fry the clean Herba Selaginellae as described under the method for carbonizing by stir-frying (Appendix Ⅱ D) until a charred black colour is produced externally.

Action To promote blood circulation and to stimulate menstrual discharge.
Herba Selaginellae (carbonized): To remove *blood stasis* and to arrest bleeding.

Indications Amenorrhea, dysmenorrhea, mass formation in the abdomen.
Herba Selaginellae (carbonized): Spitting of blood, abnormal uterine bleeding, hematochezia, prolapse of rectum.

Usage and dosage 4.5～9 g.

Precaution Used with caution in pregnancy.

Storage Preserve in a dry place.

Herba Siege[redacted]
(豨莶草, Xixiancao)

Siegesbeckia Herb

Siegesbeckia Herb is the dried aerial part of *Siegesbeckia orientalis* L., *Siegesbeckia pubescens* Makino or *Siegesbeckia glabrescens* Makino. (Fam. Compositae). The drug is collected in summer and autumn before or at flowering stage, removed from foreign matter, and dried in the sun.

Description Stems subsquare, frequently branched, 30～110 cm long, 0.3～1 cm in diameter; externally greyish-green, yellowish-brown or purplish-brown, with longitudinal furrows and fine longitudinal striations, covered with grey pubescences; nodes distinct, slightly swollen; texture fragile, easily broken, fracture yellowish-white or green; pith broad, whitish, hollowed. Leaves opposite, lamina frequently crumpled and rolled, when whole, ovate, greyish-green, margin obtusely serrate; both surfaces with white pubescences, trinervious. Some showing yellow capitulum; involucre spatulate. Odour, slight; taste, slightly bitter.

Processing *Herba Siegesbeckiae* Eliminate foreign matter, wash, soften slightly, cut into sections, and dry.

Herba Siegesbeckiae (processed with wine) Steam the sections of *Herba Siegesbeckiae* thoroughly as described under the method for steaming with wine (Appendix Ⅱ D), using 20 kg of yellow rice wine per 100 kg of *Herba Siegesbeckiae*.

Action To relieve rheumatic conditions, to improve the motility of joints, and to counteract toxicity.

Indications Rheumatic arthralgia with aching and weakness of the loins and knees, and numbness of the limbs; hemiplegia; rubella, sores with exudation.

Usage and dosage 9～12 g.

Storage Preserve in a ventilated dry place.

Preparation Siegesbeckia Pills.

Herba Spirodelae
(浮萍, Fuping)

Common Ducksmeat Herb

Common Ducksmeat Herb is the dried whole plant of *Spirodela polyrrhiza* (L.) Scheid. (Fam. Lemnaceae). The drug is collected from June to September, washed clean, removed from foreign matter, and dried in the sun.

Description Flat thallophyte, ovoid or ovate, 2～5 mm in diameter on the long side. The upper surface pale green to greyish-green, with a small pit on the side, margin entire or slightly curved. The lower surface purple to purplish-brown, with several fibrous roots. Texture light, easily broken when twisted. Odour, slight; taste, weak.

Action To dispel *wind-heat*, to promote eruption, and to cause diuresis.

Indications Measles without adequate eruption, urticaria with itching; edema with oliguria.

Usage and dosage 3～9 g; for external use, appropriate quantity to be decocted for washing or immersion.

Storage Preserve in a ventilated dry place, protected from moisture.

Herba Swertiae Mileensis
(青叶胆, Qingyedan)

Mile Swertia Herb

Mile Swertia Herb is the dried whole plant of

the apex and a yellow-tomentose fruit stalk at the base. Texture hard and fragile. Transverse section showing 5-locular ovary, each locule possessing 1～2 yellowish seeds. Odour, strong aromatic; taste, pungent and bitter.

Identification (1) Powder: Brown. Non-glandular hairs 2～6 celled, 140～350 μm long, warts obvious, some lumina containing brownish-yellow to brownish-red contents. Glandular hairs with a 7～14 celled head, elliptical, usually containing yellowish-brown contents, and a 2～5 celled stalk. Clusters of calcium oxalate frequently found, 10～25 μm in diameter; prisms occasional found. Stone cells subrounded or rectangular, 35～70 μm in diameter, with large lumina. Pale yellow fragments of oil cavities sometimes visible.
(2) To 0.5 g of the powder add 10 ml of hydrochloric acid solution (1→100), shake vigorously for several minutes, filter. To 2 ml of the filtrate add 1 drop of mercuric potassium iodide TS and shake well, a yellowish-white precipitate is produced. To another 1 ml of the filtrate add gradually 2 ml of *p*-dimethyl-aminobenzaldehyde TS and heat on a water bath, a reddish-brown colour ring is produced at the junction of the two liquids.

Processing *Fructus Evodiae* Eliminate foreign matter.

Fructus Evodiae (prepared) Pound Radix Glycyrrhizae to pieces and decoct in a proper amount of water. Remove the residue, add clean Fructus Evodiae in a covered container to absorb the decoction entirely. Stir-fry until partially dry and then dry in the sun. To each 100 kg of Fructus Evodiae add 6 kg of Radix Glycyrrhizae in the processing.

Action To dispel *cold* and alleviate pain, to relieve vomiting, and to check diarrhea.

Indications Headache accompanied by retching and cold limbs; abdominal colic; weakness and edema of the legs; abdominal pain during menstruation; epigastric distension and pain with vomiting and acid regurgitation; diarrhea occurring before dawn daily; hypertension. External use for ulcers in the mouth.

Usage and dosage 1.5～4.5 g; appropriate quantity for external use.

Storage Preserve in a cool and dry place.

Fructus Foeniculi
(小茴香, Xiaohuixiang)

Fennel

Fennel is the dried ripe fruit of *Foeniculum vulgare* Mill. (Fam. Umbelliferae). The plant is cut in autumn when the fruit nearly ripe, dried in the sun, and then the drug is tapped off and removed from foreign matter.

Description Cremocarp, cylindrical, some slightly curved, 4～8 mm long, 1.5～2.5 mm in diameter. Externally yellowish-green or pale yellow, tapering slightly towards both ends, apex bearing remains of yellowish-brown projecting stylopodium, sometimes having a small fruit stalk at the base. Mericarp elongated-elliptical, with each dorsal surface bearing five ribs and commissural surface flattened and broad. Transverse section showing a pentagonal, the four sides of dorsal surface nearly equal in length. Odour, characteristically aromatic; taste, slightly sweet and pungent.

Identification Transverse section of mericarp: Exocarp consisting of 1 layer of flattened cells, covered cutile at outside. Mesocarp with 5 ribs each containing a vascular bundle surrounded by numerous lignified reticulate cells. Vittae 6, of 4 situated in the dorsal, with a large, elliptical and brown vitta between every 2 ribs, and 2 commissural. Endocarp consisting of 1 layer of flattened thin-walled cells varying in length. The testa cells compressed and elongated, containing brown contents. Endosperm cells polygonal, filled with aleurone grains, each embedding a minute cluster of calcium oxalate.

Foreign matter Not more than 4.0% (Appendix IX A).

Total ash Not more than 10.0% (Appendix IX K).

Processing *Fructus Foeniculi* Eliminate foreign matter.

Fructus foeniculi (processed with salt) Stir-fry the clean Fructus Foeniculi as described under the method for processing with salt-water (Appendix II D) to yellowish.

Action To dispel *cold* and relieve pain, to regulate the stomach function.
Fructus foeniculi (processed with salt): To dispel *cold* from the interior and relieve pain

Indications Scrotal hernia with pain and cold extremities; dysmenorrhea with lower abdominal pain and cold sensation; distending pain in the epigastrium with anorexia, vomiting and diarrhea; hydrocele of tunica vaginalis.
Fructus Foeniculi (processed with salt): Scrotal hernia with pain and cold extremities; dysmenorrhea with abdominal pain caused by cold.

Usage and dosage 3～6 g.

Storage Preserve in a cool and dry place.

Fructus Forsythiae
(连翘, Lianqiao)

Weeping Forsythia Capsule

Weeping Forsythia Capsule is the dried fruit of *Forsythia suspensa* (Thunb.) Vahl (Fam. Oleaceae). The drug is collected in autumn when nearly ripe and still greenish, removed from foreign matter, steamed thoroughly and dried in the sun (known as "Qingqiao"); or the drug is collected when fully ripe, dried, and removed from foreign matter (known as "Laoqiao")

Description Long ovoid to ovoid, slightly compressed, 1.5～2.5 cm long, 0.5～1.3 cm in diameter. Externally with irregular longitudinal wrinkles, numerous raised small maculaters, and a longitudinal furrow on each of the two surfaces. Apex acute, bearing a small fruit stalk or its scar at the base. "Qingqiao" mostly indehiscent, externally greenish-brown, with less small greyish-white maculates, texture hard; seeds numerous, yellowish-green, slender, winged at one side. "Laoqiao" dehiscent from apex or to two segments, outer surface yellowish-brown or reddish-brown, inner surface mostly pale yellowish-brown, smooth, with a longitudinal septum. Texture brittle; seeds brown, mostly fallen off. Odour, slightly aromatic; taste, bitter.

Identification (1) Transverse section of pericarp: Exocarp consisting of 1 row of epidermal cells, with thickened outer and lateral walls and covered with cuticle. Mesocarp composed of vascular bundles scattered in parenchyma at the

outer side, and many layers of stone cells at the inner side, elongated, subrounded or oblong, wall thickness variable, mostly tagentially parqueted and extended to the cells of the septum; endocarp consisting of 1 layer of parenchymatous cells.

(2) Extract 1 g of the powder in a Soxhlet's extractor with ether until the liquid becomes colorless. Transfer ether to a separating funnel, wash the ether with three 15 ml portions of 5% sodium carbonate solution, discard the washings. Extract the ether with three 20 ml portions of 1% sodium hydroxide, acidify the combined solution of sodium hydroxide with dilute hydrochloric acid and extract with three 20 ml portions of ether. Evaporate the combined ether to dryness, dissolve the residue in 1 ml ethanol and use it as the test solution. Prepare a solution of Fructus Forsythiae reference drug in the same Way as the reference drug solution. Carry out the method for thin layer chromatography (Appendix Ⅵ B), using silica gel G as the coating substance and cyclohexane-chloroform-benzene-methanol(5:3:5:1) as the mobile phase. Apply separately 5 μl of each of the above two solutions to the plate. After developing and removal of the plate, dry it in air, spray with 5% ferric chloride solution acidified with hydrochloric acid, dry with hot blowing until the colour of spots appear clearly. The spot in the chromatogram obtained with the test solution corresponds in position and colour to the spot in the chromatogram obtained with the reference drug solution.

Foreign matters Not more than 3% for green Fructus Forsythiae(known as"Qingqiao"), not more than 9% for brown Fructus Forsythiae(Known as"Laoqiao")(Appendix Ⅸ K).

Total ash Not more than 4%(Appendix Ⅸ K).

Extractives Carry out the method for determination of extractives, cold maceration method(Appendix Ⅹ A), using 65% ethanol as the solvent; not less than 30.0% for green Fructose Forsythiae(known as"Qingqiao"); not less than 16.0% for brown Fructus Forsythiae(Known as"Laoqiao").

Action To remove toxic heat, to cause subsidence of sweeling, and to eliminate nodulation.

Indications Carbuncles, boils, lymphadenitis, mastitis, erysipelas; upper respiratory infection; febrile diseases at the early stage and at the stage with high fever, dire thirst, delirium and maculation; acute urinary infection with oliguria.

Usage and dosage 6～15 g.

Storage Preserve in a dry place.

Fructus Galangae (红豆蔻, Hongdoukou)

Galanga Galangal Fruit

Galanga Galangal Fruit is the fruit of *Alpinia galanga* Willd. (Fam. Zingiberaceae). The drug is collected in autumn when the fruit is turning red, removed from foreign matter, and dried in the sun.

Description Long spherical, slightly narrow in the middle, 0.7～1.2 cm long, 5～7 mm in diameter. Externally reddish-brown or dark red, somewhat shrunken, apex with yellowish-white tubular persistent calyx, base with a fruit stalk scar. Pericarp thin, easily broken. Seeds 6, oblate or triangular-polygonal, blackish-brown or reddish-brown, covered with a yellowish-white membranous aril, endosperm greyish-white. Odour, aromatic; taste, pungent.

Identification (1) Transverse section of seed: Aril consisting of 4～7 rows of cells, rounded or tangetially elongated, with slightly thickened walls. The outer part of testa consisting of 1～5 rows of unlignified and thick-walled fibres, rounded or polygonal, 13～45 μm in diameter, and 1 row of flattened, yellowish-brown or dark brown pigment cells beneath them; oil cells, 1 row, square or rectangular, 16～45 μm in diameter; pigment layer consisting of 3～5 rows of cells containing reddish-brown contents; tegmen consisting of 1 row of thick-walled palisade cells, about 65 μm long, 30 μm wide, yellowish-brown or reddish-brown, the inner walls and lateral walls adjacent to inner side strongly thickened, lumina containing a silica mass. The cells of perisperm filled with masses of starch granules and occasionally containing small prisms of calcium oxolate. The cells of endosperm containing aleurone grains and oil droplets.

(2) To 1 g of the pulverized sample, add 20 ml of ether, ultrasonicate for 10 minutes, and filter. Wash the residue with a quantity of 10 ml of ether, filter, combine the filtrates, and evaporate to dryness. Dissolve the residue with 1 ml of ethyl acetate as the test solution. Produce a solution of 1 g of Fructus Galangae reference drug in the same manner as the reference drug solution. Carry out the method for thin layer chromatography (Appendix Ⅵ B), using silica gel GF_{254} as the coating substance and *n*-hexane-ethyl acetate (85:15) as the mobile phase. Apply separately to the plate 5～10 μl of each of two solutions. After developing and removal of the plate, dry it in air, and examine under ultra-violet light (254 nm). The three spots with fluorescence in chromatogram obtained with the test solution correspond in position and colour obtained with the reference solution. Then spray with a 5% solution of vanillin in sulfuric acid, and heat at 105℃ for 5～10 minutes. The three spots with fluorescence in the chromatogram obtained with the test solution correspond in position and colour obtained with the reference drug solution.

Assay Weigh accurately a quantity of seeds, carry out the method for determination of volatile oil(Appendix Ⅹ D). The seeds contain not less than 0.4% (ml/mg) of volatile oil.

Processing Eliminate foreign matter. Break to pieces before use.

Action To dispel *damp-cold*, to invigorate the function of the *spleen*, and to promote digestion.

Indications Epigastric pain accompanied by cold sensation; retention of undigested food with abdominal distension, vomiting and diarrhea; excessive alcohol drinking.

Usage and dosage 3～6 g.

Storage preserve in a cool and dry place.

Fructus Gardeniae (栀子, Zhizi)

Cape Jasmine Fruit

Cape Jasmine Fruit is the dried ripe fruit of *Gardenia jasminoides* Ellis (Fam. Rubiaceae). The drug is collected from September to November when it turns reddish-yellow, removed from the

Action To remove *heat* from blood, to activate blood circulation and eliminate *blood stasis*.

Indications Eruptions in epidemic diseases; spitting of blood, epistaxis; consumptive fever occurring at night and subsiding in the morning without sweating; amenorrhea, dysmeorrhea; carbuncles and sores; traumatic injuries.

Usage and dosage 6～12 g.

Storage Preserve in a cool and dry place.

Cortex Periplocae
(香加皮, Xiangjiapi)

Chinese Silkvine Root-bark

Chinese Silkvine Root-bark is the dried root bark of *Periploca sepium* Bge. (Fam. Araliaceae). The root is collected in spring and autumn, the root bark is stripped off, and dried in the sun.

Description Quilled, channelled, a few pieced irregularly, 3～10 cm long, 1～2 cm in diameter, 2～4 mm thick. Outer surface greyish-brown or yellowish-brown, cork soft and loose, often scaly, easily exfoliated; inner surface pale yellow or pale yellowish-brown, relatively smooth, with fine longitudinal striations. Texture light and fragile, easily broken, fracture uneven, yellowish-white. Odour, characteristic and aromatic; taste, bitter.

Identification (1) Powder: Pale brown. Prisms of calcium oxalate rare, 9～20 μm in diameter. Stone cells rectangular or subpolygonal, 24～70 μm in diameter. Laticiferous tubes containing colourless oily granules. Cork cells brownish-yellow, polygonal. Starch granules numerous, simple granules subrounded or oblong, 3～11 μm in diameter; compound granules composed of 2～6 components.

(2) Distill 10 g of the powder with 150 ml of water in a 250 ml flask, the odour of distillate characteristic and aromatic. Transfer 10 ml of the distillate to two test tubes. To one test tube add 1 drop of 1% ferric chloride solution, a brownish-red colour is produced. To another one add 5 ml of saturated solution of hydrazine sulfate and a few crystals of sodium acetate, warm gently and cool, a pale yellowish-green precipitate is produced. Examine under ultra-violet light (365 nm), the precipitate shows a strong yellow fluorescence.

(3) Heat under reflux 1 g of the powder with 10 ml of ethanol for 1 hour, filter. Transfer the filtrate to a 25 ml volumetric flask, and dilute with ethanol to volume. Transfer 1 ml of the ethanol solution to a 20 ml volumetric flask, dilute with ethanol to volume. Carry out the method for spectrophotometry (Appendix V A), the light absorption exhibits a maximum at 278 nm.

(4) To 2 g of the powder add 30 ml of methanol, heat under reflux on a water bath for 1 hour, and filter. Evaporate the filtrate to dryness, and dissolve the residue in 2 ml of methanol as the test solution. Dissolve 4-methoxy salicylic aldehyde CRS in methanol to produce a solution containing 1 mg per ml as the reference solution. Carry out the method for thin-layer chromatography (Appendix VI B), using silica gel G as the coating substance and petroleum ether (60～90℃)-ethyl acetate-glacial acetic acid (20:3:0.5) as the mobile phase. Apply separately 2 μl of each of the two solutions to the plate. After developing and removal of the plate, dry it in air. Spray with dinitrophenylhydrazine TS. The spot in the chromatogram obtained with the test solution corresponds in position and colour to the spot in the chromatogram obtained with the reference solution.

Assay Carry out the method for high performance liquid chromatography (Appendix VI D).

Chromatographic system and system suitability Use octadecylsilane bonded silica gel as the stationary phase and methanol-water-acetic acid (70:30:2) as the mobile phase. The wavelength of the detector is 278nm. The number of theoretical plates of the column is not less than 1000, calculated with the reference to the peak of 4-methoxyl salicylic aldehyde. The resolution factor between the peaks of 4-methoxyl salicylic aldehyde and internal standard complies with the related requirements.

Internal standard solution Dissolve a quantity of *n*-butyl-*p*-hydroxybenzoate, accurately weighed, in 60% methanol to produce a solution containing 6mg per ml as the internal stardand solution.

Procedure Weigh accurately a quantity of 4-methoxyl salicylic aldehyde CRS in an amber volumetric flask, dissolve and dilute with 60% methanol to produce a solution containing 1mg per ml. Accurately measure 4 ml of the solution and 2 ml of the internal standard solution in a 25 ml volumetric flask, dilute with 60% methanol to volume, and mix well. Inject 20 μl into the column and plot the chromatogram. Accurately weigh 250 ～ 500 mg of the coarse power, dried at 60℃ for 4 hours, in a 50 ml flask. Add 15 ml of 60% methanol, heat under reflux on a water bath for 1.5hours, and filter. Transfer filtrate to a 25 ml volumetric flask, wash the container with 60% methanol, filter the washings to the same flask, add accurately 2 ml of the internal standard solution, dilute with 60% methanol to volume, and mix well. Filter through a membrane filter (0.5 μm in pore size), and use the filtrate as the test solution. Inject 20 μl into the column, measure the peak area and calculate the content with corrected intemal standard method.

It contains not less than 0.20% of 4-methoxyl salicylic aldehyde ($C_8H_8O_3$) on the dried basis at 60℃ for 4 hours.

Processing Eliminate foreign matter, wash clean, soften thoroughly, cut into thick slices and dry in the sun.

Action To relieve rheumatic conditions and to strengthen tendons and bones.

Indications Rheumatic arthritis with aching and weakness of the loins and knees, cardiac palpitation, shortness of breath and edema of the lower extremities.

Usage and dosage 3～6 g.

Precaution Overdosage should be avoided because of its toxicity.

Storage Preserve in a cool and dry place.

Cortex Phellodendri
(黃柏, Huangbo)

Amur Cork-tree

Amur Cork-tree is the dried bark of *Phellodendron chinense* Schneid. or *Phellodendron amurense* Rupr. (Fam. Rutaceae). The former is commonly called "Chuan huangbo" and the latter "Guan huangbo". The drug is collected, removed from coarse bark, and dried in the sun.

Description *Chuan huangbo* Tabular or shallowly channelled, varying in length and width, 3～6 mm thick. Outer surface yellowish-brown, even or longitudinally furrowed, some showing scars of lenticels, and remains of greyish-

brown coarse bark. Inner surface dark yellow or pale brown, with fine longitudinal ridges. Texture light and hard, fracture fibrous, showing lobelike layers, dark yellow. Odour, slight; taste, very bitter, viscous after chewing.

Guan huangbo 2～4 mm thick. Outer surface yellowish-green or pale brownish-yellow, relatively even with irregular longitudinal fissures, scars of lenticels small and infrequently visible, occasionally remaining greyish-white coarse bark. Inner surface yellow or yellowish-brown. Texture light and relatively hard, fracture bright yellow or yellowish-green.

Identification (1) Powder: Greenish-yellow or yellow. Fibres bright yellow, 16～38 μm in diameter, often in bundles, surrounded by parenchymatous cells containing prisms of calcium oxalate, forming crystal fibres; the walls of crystal cells lignified and thickened. Stone cells bright yellow, subrounded or fusiform, 35～128 μm in diameter, some branched, sharp at the top, walls thickened with striations distinct. Prisms of calcium oxalate up to 24 μm in diameter.

(2) To 1 g of the powder, add 10 ml of ether, shake well, filter and evaporate the filtrate to dryness. Dissolve the residue in 1 ml of glacial acetic acid, add 1 drop of sulfuric acid and allow to stand; a purplish-brown colour is produced.

(3) Heat under reflux 0.1 g of the powder with 5 ml of methanol for 15 minutes on a water bath and filter. To the filtrate add methanol to produce a 5 ml solution as the test solution. Prepare a solution of Cortex Phellodendri reference drug in the same manner as the referenc drug solution. Dissolve berberin hydrochloride CRS in methanol to produce a solution containing 0.5 mg per ml as the reference solution. Carry out the method for thin layer chromatography (Appendix Ⅵ B), using silica G as the coating substance and benzene-ethylacetate-isopropanol-concentrated ammonia TS(6:3:1.5:0.5)as the mobile phase. Apply separately to the plate 1 μl of each of the three solutions. After developing and removal of the plate, dry it in air and examinze under ultra-violet light(365 nm). The fluorescent spots in the chromatogram obtained with the test solution correspond in position and colour to the spots in the chromatogram obtained with the reference drug solution. The yellow fluorescent spot in the chromatogram obtained with the test solution corresponds in position and colour to the spot in the chromatogram obtained with the reference solution.

Processing *Cortex Phellodendri* Eliminate foreign matter, spray with water, soften thoroughly, cut into slivers and dry.

Cortex Phellodendri (processed with salt) Stir-fry the slivers of Cortex Phellodendri as described under the method for stir-frying with salt water (Appendix Ⅱ D) to dryness.

Cortex Phellodendri (carbonized) Stir-fry the slivers of Cortex Phellodendri as described under the method for carbonizing by stir-frying (Appendix Ⅱ D) until the surface becomes charred-black.

Action To remove *damp-heat*, quench *fire*, counteract toxicity, and relieve consumptive fever.
Cortex Phellodendri (processed with salt): To nourish *yin* and reduce *fire*.

Indications Dysentery, jaunice and morbid leukorrhea caused by *damp-heat*; urinary infection; weakness and edema of legs; consumptive fever and night sweating; seminal emission; sores and skin infection with local redness and swelling; eczema with itching.

Cortex Phellowdendri (processed with salt): Night sweating and consumptive fever due to exuberant *fire* secondary to *deficiency of yin*.

Usage and dosage 3～12 g; appropriate quantity for external use.

Storage Preserve in a ventilated and dry place, protected from moisture.

Cortex Pseudolaricis (土荆皮, Tujingpi)

Golden Larch Bark

Golden Larch Bark is the dried root bark or stem bark near the root of *Pseudolarix kaempferi* Gord. (Fam. Pinaceae). The drug is collected in summer, and dried in the sun.

Description Root bark irregularly long slat-shaped, twisted and slightly rolled, variable in size, 2～5 mm thick. Outer surface greyish-yellow, rough, wrinkled and greyish-white transversely lenticellate and the rugged external tissues frequently scaling off, with reddish-brown exposed surface. Inner surface yellowish-brown to reddish-brown, even, with fine longitudinal striations. Texture flexible, fracture splintery, easily detachable in flakes. Odour, slight; taste, bitter and astringent. Stem bark in flattish pieces, up to about 8 mm thick, the rugged external tissues relatively thick, the outer surface cracked and the inner surface relatively rough.

Identification Powder: Pale brown or brownish-red. Stone cells abundant, subrectangular, subrounded or irregularly branched, 30～96 μm in diameter, containing yellowish-brown masses. Most sieve cells in bundles, 20～40 μm in diameter, numerous elliptical sieve areas scattered over the side walls, Mucilage cells subrounded, 100～300 μm in diameter. Resin cells longitudinally connected into tubeform, containing reddish-brown to yellowish-brown resinous matter, sometimes with prisms of calcium oxalate embedded in them. Walls of cork cells slightly thick, some of them lignified and pitted.

Processing Wash clean, soften slightly, cut into slivers and dry in the sun.

Action To kill parasites and relieve itching.

Indications Scabies and tinea.

Usage and dosage Appropriate quantity soaked with vinegar or wine, or ground into powder and mixed with water to be applied topically.

Storage Preserve in a dry place.

Crinis Carbonisatus (血余炭, Xueyutan)

Carbonized Hair

Carbonized Hair is the carbonized human hair. The hair is removed from foreign matter, washed with soda water, rinsed clean with water, dried in the sun, carbonized by calcining, cooled in air.

Description In irregular pieces, black, lustrous, with many

Processing Soften thoroughly, cut into thin slices, and dry. Break to pieces before use.

Action Replenish vital essence, promote blood circulation and relieve collapse. To reinforce *qi* and to stanch bleeding.

Indications Collpase tendency due to asthenia, cool limbs and weak pulse. *Qi* cannot control blood, uterine bleeding, cardiac failure and cardiogenic shock.

Usage and dosage 3～9 g.

Precaution Incompatible with Rhizoma et Radix Veratri.

Storage Preserve in well closed containers, stored in a cool and dry place, protected from moth.

Radix Glehniae
(北沙参, Beishashen)

Coastal Glehnia Root

Coastal Glehnia Root is the dried root of *Glehnia littoralis* Fr. Schmidt ex Miq. (Fam. Umbelliferae). The drug is collected in summer and autumn, removed from rootlet, washed clean, dried slightly in the air, treated with boiling water, peeled and dried, or dried immediately directly after washing.

Description Slenderly cylindrical, branching occasionally, 15～45 cm long, 0.4～1.2 cm in diameter. Externally yellowish-white, slightly rough, occasionally with patches of cork adhering, or yellowish-brown when unpeeled, finely wrinkled longitudinally, and with brownish-yellow spotted rootlet scars. Top usually with yellowish-brown remains of rhizome. The upper part somewhat thin, the middle part relatively thick, and the lower part tapering. Texture fragile, easily broken, fracture yellowish-white in bark and yellow in wood. Odour, characteristic; taste, sweetish.

Identification Transverse section: Cortex of several layers of parenchymatous cells, scattered with secretory canals. Cork visible when unpeeled. Phloem broad, rays distinct, sieve tube groups collapsed in the outer part and appearing as a narrow band; secretory canals scattered, 20～65 μm in diameter, containing yellow-brown secretion, surrounded by 5～8 secretory cells. Cambium in a ring. Xylem rays 2～5 cells wide; most vessels arranged in V-shape; parenchymatous cells containing gelatinized starch granules.

Processing Remove remains of stems and foreign matter, soften slightly, cut into sections, and dry.

Action To replenish *yin* of the *lung* and stomach, remove *heat* from the *lung*, and promote fluid secretion.

Indications Dry cough caused by *heat* in the *lung*; bloody sputum in phthisis; thirst in febrile diseases.

Usage and dosage 4.5～9 g.

Precaution Incompatible with Rhizoma et Radix Veratri.

Storage Preserve in a ventilated and dry place, protected from moth.

[redacted]
(甘草, Gancao)

Liquorice Root

Liquorice Root is the dried root and rhizome of *Glycyrrhiza uralensis* Fisch, *Glycyrrhiza inflata* Bat. or *Glycyrrhiza glabra* L. (Fam. Leguminosae). The drug is collected in spring and autumn, removed from rootlet, and dried in the sun.

Description *Root of Glycyrrhiza uralensis* Roots cylindrical, 2～100 cm long, 0.6～3.5 cm in diameter. The outer bark loose or tight. Externally reddish-brown or greyish-brown, obviously longitudinally wrinkled, furrowed, lenticellate, and with sparse rootlet scars. Texture compact, fracture slightly fibrous, yellowish-white, starchy, cambium ring distinct, rays radiate, some with clefts. Rhizomes cylindrical, externally with bud scars, pith present in the centre of fracture. Odour, slight; taste, sweet and characteristic.

Root of Glycyrrhiza inflata Roots and rhizomes woody and stout, some branched, the out bark rough, mostly greyish-brown. Texture compact, more lignified fibres and less starchy. Rhizomes with more and large adventitious buds.

Root of Glycyrrhiza glabra Texture of root and rhizomes relatively compact, some branched, the outer bark not rough, mostly greyish-brown, lenticels small and indistinct.

Identification (1) Transverse section: Cork consisting of several layers of brown cells. Cortex relatively narrow. Phloem rays broad, mostly curved, frequently with clefts; most phloem fibres in bundles, unlignified or slightly lignified, surrounded by parenchymatous cells containing prisms of calcium oxatate; sieve tube tissue often pressed to be collapsed. Fascicular cambium distinct. Xylem rays 3～5 cells wide; vessels frequent, up to 160 μm in diameter; xylem fibres in boundles, surrounded by parenchymatous cells containing prisms of calcium oxalate. Roots without pith at the centre; rhizomes possessing pith at the centre.
Powder: Brownish-yellow. Fibres in bundles, 8～14 μm in diameter, thick-walled, slightly lignified, surrounded by parenchymatous cells containing prisms of calcium oxalate, forming crystal fibres. Prisms of calcium oxalate frequent. Bordered pitted vessels large, reticulated vessels rare. Cork cells reddish-brown, polygonal, slightly lignified.
(2) To 1 g of the powder add 40 ml of ether, heat under reflux on a water bath for 1 hour, filter. Heat the residue under refuex in 30 ml of methanol on a water bath for 1 hour and filter. Evaporate the filtrate to dryness and dissolve the residue in 40 ml of water. Extract the aqueous solution with 3 quantities, each of 20 ml, of *n*-butanol. Combine the *n*-butanol solution, wash with water for 3 times and evaporate on a water bath to dryness, dissolve the residue in 5 ml of methanol as the test solution. Prepare a solution of Radix Glycyrrhizae reference drug in the same manner as the reference drug solution. Dissolve ammonium glycyrrhizate CRS in methanol to produce a solution containing 2 mg per ml as the reference solution. Carry out the method for thin layer chromatography (Appendix VI B), using silica gel G containing 1% solution of sodium hydroxide as the coating substance and ethyl acetate-methanol-glacial acetic acid-water (30:2:2:4) as the mobile phase. Apply separately to the plate 1～2 μl of each of

the three solutions. After developing and removal of the plate, dry it in air. Spray with 10% solution of sulfuric acid in ethanol. Heat at 105℃ to visualize clearly, and examine under ultra-violet light (365 nm). The fluorescent spot in the chromatogram obtained with test solution corresponds in position and colour to the spot obtained with the reference drug solution; the orange-yellow fluorescent spot in the chromatogram obtained with the test solution corresponds in position and colour to the spot in the chromatogram obtained with the reference solution.

Water Carry out the method for Determination of water (Appendix Ⅸ H, method 1), not more than 12.0%.

Total ash Not more than 7.0% (Appendix Ⅸ K).

Acid-insoluble ash Not more than 2.0% (Appendix Ⅸ K).

Processing Eliminate foreign matter, wash clean, soften thoroughly, cut into thick slices and dry.

Action To reinforce the function of the *spleen* and replenish *qi*, to remove *heat* and counteract toxicity, to dispel *phlegm* and relieve cough, to alleviate spasmodic pain, and to moderate drug actions.
Radix Glycyrrhizae (processed with honey) To reinforce the function of the *spleen* and replenish *qi*, and to restore the normal cardiac rhythm.

Indications Weakness of the *spleen* and the *stomach* marked by lassitude and weakness; cardiac palpitation and shortness of breath; cough with much *phlegm*; spasmodic pain in the epigastrium, abdomen and limbs; carbuncles and sores. It is often used for reducing the toxic or drastic actions of other drugs.
Radix Glycyrrhizae (processed with honey) Weakness of the *spleen* and the *stomach* with lassitude and lack of strength; arrhythmia.

Usage and dosage 1.5～9 g.

Precaution Incompatible with Radix Euphorbiae Pekinensis, Flos Genkwa and Radix Kansui.

Storage Preserve in a ventilated and dry place, protected from moth.

Preparation Liquorice Extract.

Radix Glycyrrhizae Preparata (炙甘草, Zhigancao)

Prepared Liauorice Root

The drug is the processed Radix Glycyrrhizae.

procedure Stir-fry the slices of Radix Glycyrrhize as described under the method for stir-frying with honey (Appendix Ⅱ D) until it becomes yellow to deep yellow and not stichy to the fingers, take out and cool in the air.

Description Occurring in subrounded or elliptical slices, externally reddish-brown or greyish-brown, slightly lustrous, cut surface yellow to deep yellow, cambium ring distinct, rays radiate. Texture slightly stichy. Odour, with agreeable burnt smelling; taste, sweet.

Identification Carry out the method as described under Identification test (2) in the monograph of Radix glycyrrhizae, it shows the same result.

Water Carry out the method for Determination of water (Appendix Ⅸ H, method 1). Not more than 10.0%.

Total ash Not more than 5.0% (Appendix Ⅸ K).

Acid-insoluble ash Not more than 1.0% (Appendix Ⅸ K).

Action To invigorate the function of *spleen* and stomach, to reinforce *qi* and promote blood circulation.

Indications Deficiency of *spleen* and stomach, lassitude, palpitation, arrhythmia.

Usage and dosage As described under Radix Glycyrrhizae.

Precaution As described under Radix Glycyrrhizae.

Radix Hedysari (红芪, Hongqi)

Manyinflorescenced Sweetvetch Root

Manyinflorescenced Sweetvetch Root is the dried root of *Hedysarum polybotrys* Hand. -Mazz. (Fam. Leguminosae). The drug is collected in spring and autumn, removed from rootlet and root stock, and dried in the sun.

Description Cylindrical, few-branched, upper end slightly thick, 10～50 cm long, 0.6～2 cm in diameter. Externally reddish-brown of grey tint, with longitudinal wrinkles, transversely elongated lenticels and a few rootlet scars, outer layer easily stripped off, the exposed layer yellowish. Texture hard and tough, fracture fibrous and starchy, yellowish-white in bark and yellowish-brown in wood, rays radial, cambium ring brownish. Odour slight; taste sweetish, slightly bean-like on chewing.

Identification Transverse section: Cork consisting of 6～8 layers of cells. Cortex narrow, with 2～4 layers of collenchymatous cells at the outside. Phloem broader, cleft outside, fibres in bundles scattered, with thickened walls, slightly lignified; phloem rays often curved outside. Cambium in a ring. Vessels in xylem singly scattered or 2～3 grouped, surrounded by wood fibres. Fibre bundles surrounded by parenchymatous cells containing prisms of calcium oxalate.
Powder: Yellowish-brown. Fibres in bundles, 5～22 μm in diameter, with thickened walls, slightly lignified, surrounded by a sheath of parenchymatous cells containing calcium oxalate prisms, forming crystal fibres, the walls of crystal cells unevenly thickened. Prisms of calcium oxalate 7～14 μm in diameter, up to 22 μm long. Bordered pitted vessels up to 145 μm in diameter. Starch granules simple or compound, subrounded or ovoid-rounded, 2～19 μm in diameter; compound of 2～8 components.

Extractives Carry out the method for Determination of ethanol-soluble extractives (Appendix Ⅹ A, the hot extraction method), using 45% ethanol as the solvent, not less than 30.0%.

Processing *Radix Hydrysari* Eliminate foreign matter, grade according to size, wash clean, soften thoroughly, cut into thick slices, and dry.

Action To reinforce *qi* and strengthen the superficial resistance, to cause diuresis, and to promote the drainage of pus and the growth of new tissue.

Indications *Deficiency of qi* with lack of strength, anorexia and loose stools; sinking of the *spleen qi* marked by protracted diarrhea and prolapse of the rectum; hematochezia and abnormal uterine bleeding; spontaneous sweating due to weakened superficial resistance; edema due to *deficiency of qi*; abscess or boil difficult to burst; anemia; diabetes mellitus; albuminuria in chronic nephritis.

Usage and dosage 9～30 g.

Medulla Junci (*carbonized*) Calcine the clean Medulla Junci as described under the method for carbonizing by calcining (Appendix Ⅱ D).

Action To eliminate excess *fire* in the *heart*, and to induce diuresis.

Indications Fidgetness and insomnia with oliguria and painful difficult urination or with ulceration in the mouth or on the tongue.

Usage and dosage 1～3 g.

Storage Preserve in a dry place.

Medulla Stachyuri
Medulla Helwingiae
(小通草, Xiaotongcao)

Stachyurus or Japanese Helwingia Pith

Stachyurus or Japanese Helwingia Pith is the dried stem pith of *Stachyurus himalaicus* Hook. f. et Thoms., *Stachyurus chinensis* Franch. (Fam. Stachyuraceae) or *Helwingia japonica* (Thunb.) Dietr. (Fam. Cornaceae). The stem is collected in autumn, cut into sections, the pith is taken out when fresh, arranged and dried in the sun.

Description *Pith of Stachyurus Chinensis and Stachyurus himalaicus*: Cylindrical, 30～50 cm long, 0.5～1 cm in diameter. Externally white or pale yellow, without striations. Texture light, lax and soft, deformed when kneaded, elastic, easily broken, fracture even and without a hollow, silvery. Unctuous on touching after soaking. Odourless and tasteless.

Pith of Helwingia japonice: Surface with shallow, longitudinal striations. Texture relatively hard, uneasily deformed when kneaded. No unctuous on touching after soaking.

Identification Transverse section: *Pith of Stachyurus Chinensis and Stachyurus himalaicus* All composed of rounded, elliptical or polygonal parenchymatous cells, sparsely pitted; mucilage cells scattered. *Pith of Stachyurus chinensis* with a few clusters of calcium oxalate, and *Pith of Stachyurus himalaicus* without clusters.

Pith of Helwingia japonice Parenchymatous cells with relativaly distinct pits, containing colourless liquid drops and a few clusters of calcium oxalate; mucilage cells absent.

Processing Eliminate foreign matter and cut into sections.

Action To remove *heat*, to cause diuresis, and to promote lactation.

Indications Oliguria, urinary infection; galactostasis.

Usage and dosage 2.5～4.5 g.

Storage Preserve in a dry place.

[redacted]
(通草, Tongcao)

Ricepaperplant Pith

Ricepaperplant Pith is the dried stem pith of *Tetrapanax papyriferus* (Hook.) K. Koch (Fam. Araliaceae). The stem is collected in autumn and cut into sections. The pith is taken out when fresh, arranged, and dried in the sun.

Description Cylindrical, 20～40 cm long, 1～2.5 cm in diameter. Externally white or pale yellow, with shallow longitudinal furrows. Texture light, soft and loose, with slight elasticity, easily broken, fracture even, with silvery lustre, and with a hollow, 0.3～1.5 cm in diameter, or translucent membrane in the middle part, arranged in scalariform in longitudinally cut surface, while solid ones visible occasionally. Odourless and tasteless.

Identification Transverse section: All composed of elliptic, subrounded or subpolygonal parenchymatous cells. The outer cells relatively small, pits obvious. Some cells containing clusters of calcium oxalate, 15～64 μm in diameter.

Processing Eliminate foreign matter, cut into thick slices.

Action To remove *heat*, to induce diuresis, and to stimulate the flow of milk.

Indications Dysuria with difficult painful urination; edema and oliguria; lack of milk secretion.

Usage and dosage 3～5 g.

Storage Preserve in a dry place.

Mel
(蜂蜜, Fengmi)

Honey

Honey is a saccharine fluid deposited by *Apis cerana* Fabricus or *Apis mellifera* Linnaeus (Fam. Apidae). The drug is collected from spring to autumn, and filtered.

Description Translucent, lustrous and viscid, white to pale yellow or orange yellow to yellowish-brown, white granular crystals gradually separated out on keeping or on cooling. Odour, aromatic; taste, very sweet.

Relative density Dissolve any crystal on a water bath at a temperature below 60℃, if the crystal has separated out in the samples examined, mix well. Cool to 25℃ and carry out the method for the determination of relative density (Appendix Ⅶ A), not less than 1.349.

Acidity Mix 10 g with 50 ml of freshly boiled and cooled water, add 2 drops of phenolphthalein IS and 4 ml of sodium hydroxide solution (0.1 mol/L), and a pink colour is produced, persisting for 10 seconds.

Starch and dextrin Boil 2 g with 10 ml of water, cool, add 1 drop of iodine TS, and no blue, green or reddish-brown colour is produced.

5-(hydroxyl methyl) furfural: Place 5.0 g, weighed accurately, into a 50 ml volumetric flask, add 0.5 ml of each of 15 % potassium ferrocynide solution and 30 % zinc acetate solution, dilute with water to volume (add 1 drop of ethanol if the froth is produced), and mix well. Filter with the dry filter paper, discard the initial filtrate, and transfer separately 5 ml of each of the filtrate, measured accurately, to two tubes with stopper. To one tube add 5.0 ml of water and mix well as the test solution. To another tube add 5.0 ml of 0.2% sodium hydrogen sulfite solution as the blank solution. Carry out the method for spetrophotometry (Appendix Ⅴ A), and measure the absorbance at 284 nm and 336 nm.

The value of subtraction between two absorbances is not

The PHARMACOLOGY *of* CHINESE HERBS

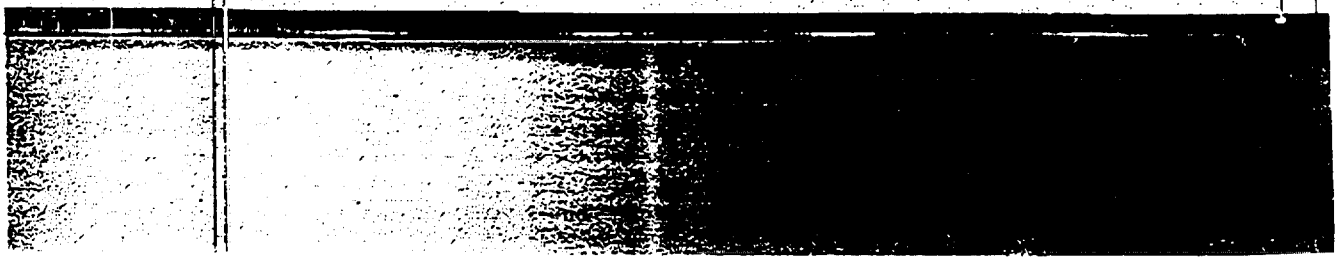
Second Edition

Kee Chang Huang

CRC Press
Boca Raton London New York Washington, D.C.

Catalog record is available from the Library of Congress

No claim to original U.S. Government works
International Standard Book Number 0-8493-1665-0
Printed in the United States of America 1 2 3 4 5 6 7 8 9 0
Printed on acid-free paper



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1665
ISBN 0-8493-1665-0
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James A. Duke, *co-author of Medicinal Plants of China, is a renowned ethnobotanist, who has travelled widely in that country.*

Born in Birmingham, Alabama, in 1929, he graduated from the University of North Carolina, and undertook post-doctoral work at Washington University, and the Missouri Botanical Garden. From 1963-65, he was with the U.S. Department of Agriculture. From 1965-71, he was with Batelle Columbus Laboratories, for whom he undertook ecological and ethnological studies in Panama and Colombia. In 1971 he returned to the Department of Agriculture to undertake crop diversification and medicinal plant studies in developing countries. A key figure in the "Herbal Renaissance," he received the Cutty Sark Award in 1981. He is currently Chief, Germplasm Resources, at the Department of Agriculture in Beltsville, Maryland.

The author of more than 100 scientific publications, his other books include ***A Handbook of Legumes of World Economic Importance, Medicinal Plants of the Bible,*** *and* ***A Culinary Herbal.***

Edward S. Ayensu, *co-author of Medicinal Plants of China, is also editor of the series "Medicinal Plants of the World," to which it belongs. He has travelled to China several times, visiting different regions of the country.*

One of the world's eminent botanists and tropical biologists, who obtained his doctorate degree from the University of London, Professor Ayensu, a Ghanaian, is Director of the Smithsonian's Office of Biological Conservation, and was formerly Chairman of the Institution's Botany Department. He is a Fellow of the Ghana Academy of Arts and Sciences, and a Foreign Fellow of the Indian National Science Academy. He belongs to many professional organizations, including the Linnean Society of London. He serves as Secretary General of the International Union of Biological Sciences, and is also a member of the W.H.O Panel on Traditional Medicine.

Among his research interests are tropical biology and ecology, and science and technology, especially in developing countries. He has authored ***Medicinal Plants of West Africa, Medicinal Plants of the West Indies,*** and other works.

Cover photo by Edward S. Ayensu
The Sacred Lotus
Pinyin name: liān zi
Nelumbo nucifera
(See page 458)

MEDICINAL PLANTS of CHINA

Vol. 1

James A. Duke
Edward S. Ayensu

REFERENCE PUBLICATIONS, INC.

FANG JI (防己) OR HAN FANG JI (漢防己)

The dried tuberous root of *Stephania tetrandra* S. Moore (Menispermaceae)

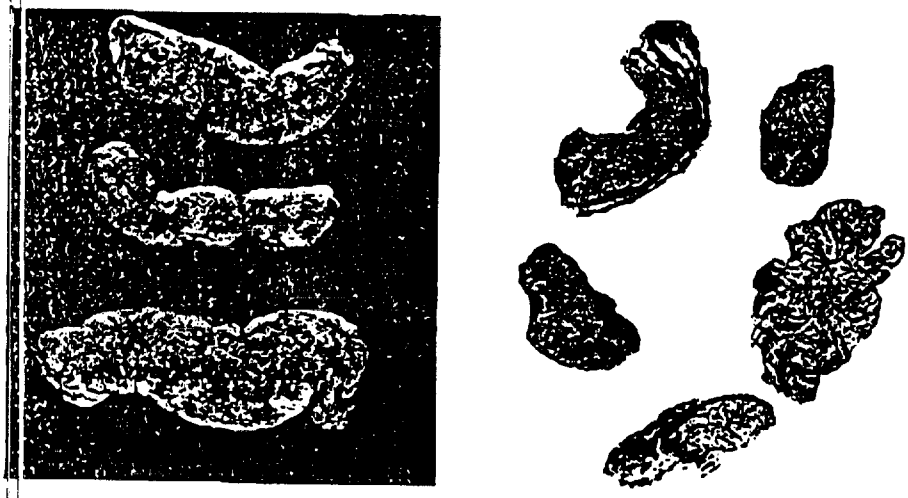


Figure 8.1 (A) *Fan Ji*; (B) *Mu Fang Ji*.

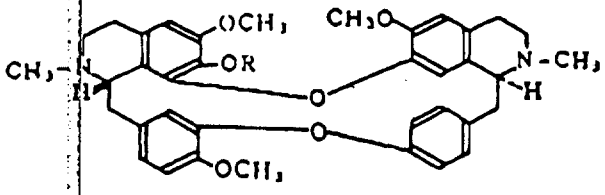
Chemistry: The total alkaloid content of this herb is between 1.5 to 2.3%. The primary alkaloids found are *d*-tetrandrine (汉防己碱, approximately 1%), fangchinoline (0.5%), and cyclanoline (0.1%).

Table 8.1 Known Components Isolated from Different *Fang Ji*

Name of *Fang Ji*	Major components	Chemical formula	Melting point (°C)
Han Fang Ji	Tetrandrine	$C_{38}H_{42}O_6N_2$	217
Stephania tetrandra	Demethyltetrandrine	$C_{37}H_{40}O_6N_2$	241–242
Mu Fang Ji (Kong Fang	Mufangchine A	$C_{32}H_{24}O_{13}N_2$	278–280
Ji, Ting Fang Ji)	Mufangchine B	$C_{14}H_{33}O_{11}N$	232–233
Cocculus thunbergii	(Mufangchine)		
Japanese *Han Fang Ji*	Sinomenine	$C_{19}H_{23}O_4N$	162, 182
Sinomenium acutum	Disinomenine	$(C_{19}H_{22}O_4N)_2 \cdot 2CH_3OH$	222
	Sinactine	$C_{20}H_{21}O_4N$	174
	Acutumine	$C_{20(21)}H_{27}O_8N$	240
	Diversine	$C_{20}H_{27}O_5N$	80–93
	Tuduranine	$C_{18}H_{29}O_3N$	125
Japanese *Mu Fang Ji*	Trilobine	$C_{36}H_{36}O_3N_2$	235
Cocculus trilobus	Isotrilobine	$C_{36}H_{36}O_3N_2$	215

It should be pointed out once again that Chinese herbal terminology is very confusing. Chinese *Fang Ji*, as described here, is generally called *Han Fang Ji* (汉防己) and differs considerably from Japanese *Fang Ji* (日本防己), which is derived from the root of *Sinomenium acutum* Rehder et Wilson. The latter contains the alkaloids sinomenine and disinomenine, which are phenanthrene derivatives similar to morphine.

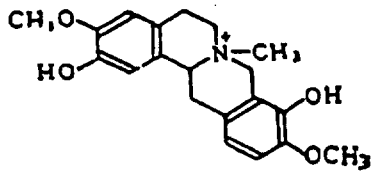
Japanese *Mu Fang Ji* (日本木防己) is the root of *Cocculus trilobus*, which contains the alkaloids triboline and isotrilobine. Both have structures very similar to tetrandrine, a *d*-tubocurarine-like substance (see Table 8.1).



R =

d-Tetrandrine CH_3

Fangchinoline H



Cyclanoline

Actions: The herb has a curare-like action. Methylated tetrandrine and metetrandrine iodine were found to be 4 times more potent than *d*-tubocurarine in their ability to block the depolarizing action of acetycholine on the NMJ.

Fang Ji has anti-inflammatory and antihypersensitivity actions. The herb has a direct stimulatory effect on adrenal corticosterone secretion. Feng et al.[8] reported that sinomenenine exerts a marked immunosuppressive effect and significantly decreases the ratio of cGMP/cAMP of plasma in mice.

The herb has analgesic properties. Japanese *Fang Ji* and sinomenine are as effective as morphine in relieving pain.

Fang Ji, especially *d*-tetrandrine, displays antiarrhythmic effects; its action is similar to quinidine (see Chapter 3).

Toxicity: Overdose may cause respiratory paralysis. Therapeutic doses, however, have little effect on the heart or respiration. Occasionally, patients may develop cyanosis and excess sweating.

The LD_{50} of metetrandrine in mice is 1.3 mg/kg (i.v.), ten times greater than that of *d*-tubocararine.

Therapeutic Uses: Popular prescriptions of *Fang Ji* include use as a diuretic, antiphlogistic, and antirheumatic.

As an adjuvant in anesthesia for abdominal operations, metetrandrine has been used in combination with acupuncture to obtain a good anesthetic effect. The dose used is 0.8 mg/kg administered intramuscularly, or diluted to 5 to 10 ml with isotonic glucose solution for intravenous injection. It usually takes 2 to 5 min to produce complete muscle relaxation, which will last for 40 min. In some cases, a drop in blood pressure has been observed.

In the treatment of arthritis and neuralgia, the standard dose is 6 to 12 g daily; if *d*-tetrandrine tablets (0.02 g) are used, the dose is 1 to 2 tablets t.i.d. Tetrandrine is also used as an antiarrhythmic agent to replace quinidine.

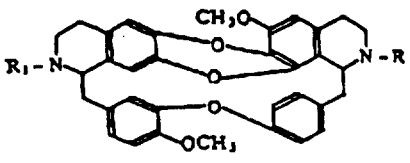
MU FANG JI (木防己)

The dried root of *Coculus thunbergii*;

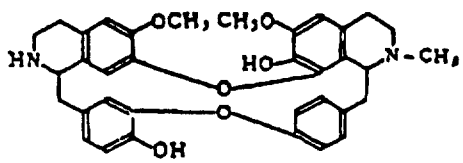
JAPANESE MU FANG JI (日本木防己)

The dried root of *Cocculus trilobus* (Thunb.)

Chemistry: The root or rhizome contains several alkaloids. The major ones are magnoflorine ($C_{20}H_{24}O_4N$, approximately 0.41%), trilobine, homotrilobine, etc. Their structures are shown as follows:



	R =	R_1 =
Trilobine	H	CH_3
Homotrilobine	CH_3	CH_3



Trilobamine

3

ANTIARRHYTHMIC HERBS

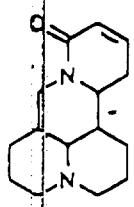
Figure 3.1 *Ku Seng* (the dry root).

KU SENG (苦參)

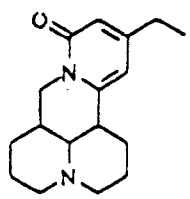
The dried root of *Sophora flavescens* Ait. (Leguminosae)

Chemistry: This root contains several alkaloids, which are the major active principles responsible for the antiarrhythmic effect. These include:

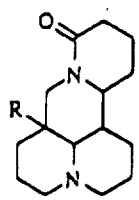
- *d*-matrine
- *d*-oxymatrine
- *d*-sophoranol
- cytisine
- *l*-anagyrine
- *l*-baptifoline
- *l*-methylcytisine
- *l*-13-ethylsophoramine
- trifolirhizin
- norkurarinone
- kuraridin



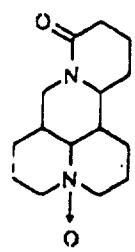
l-Sophocarpine



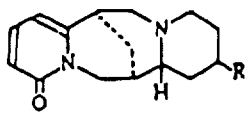
Ethylsophoramine



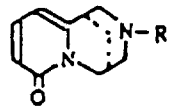
d-Matrine R =H
d-Sophoranol R = OH



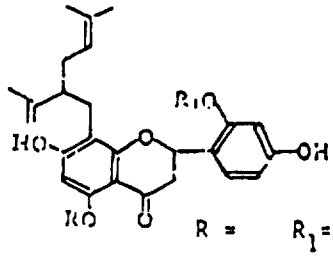
d-Oxymatrine



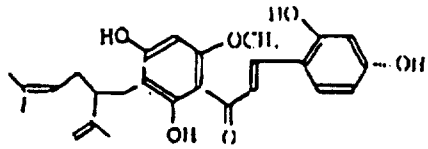
	R=
l-Anagyrine	H
l-Baptifoline	OH



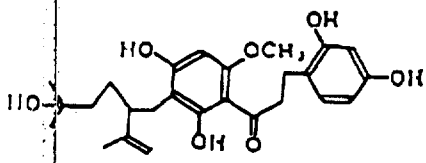
	R =
l-Methylcytisine	CH_3
Cytisine	H



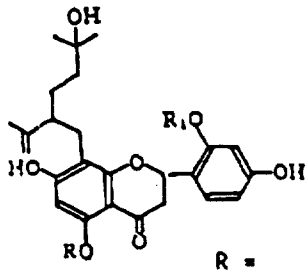
	R =	R_1 =
Kurarinone	CH_3	H
Norkurarinone	H	H
Isokurarinone	H	CH_3



Kuraridin



Kuraridinol



	R =	R_1 =
Kurarinol	CH_3	H
Neokurarinol	CH_3	CH_3

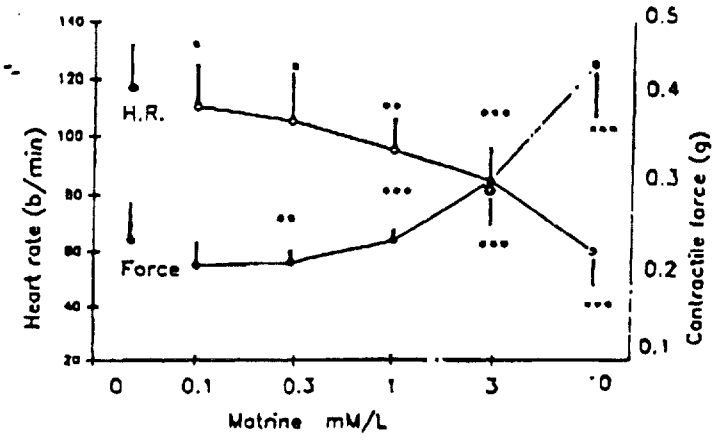


Figure 3.2 Effect of matrine on heart rate and myocardial contraction. (From Xin, H. B. and Lin, S. F., *Acta Pharmacol. Sin.*, 8, 501, 1987. With permission.)

Actions: Ku Seng's primary use is as an antiarrhthymic. It slows the heart rate, increases cardiac conduction time, and decreases myocardial excitability. Such effects are not influenced by atropine nor β-adrenergic agents. Cats which received an intravenous injection of 100% *Ku Seng* solution at 1 ml/kg showed a decrease in heart rate and a simultaneous increase in coronary blood flow.

Studies showed that *d*-matrine exerted an antiarrhythmic action on animals by a direct inhibiting effect on atrial muscle. On guinea pig atrial muscle fiber, *d*-matrine produced a negative chronotropic and a positive inotropic effect. The agent also reduced the maximal driving frequency and inhibited the automaticity of the left atrial muscles.[30] Results are illustrated in Figure 3.2.

In another animal experiment, *d*-matrine exhibited a significant antiarrhythmic effect on arrthythmias induced by aconitine, $BaCl_2$, or coronary ligation.

In mice, *d*-matrine was found to have a protective effect on lipopolysaccharide-induced nephritis. Hu et al.[15] reported that this principle can inhibit splenocyte proliferation and the release of interleukin IL-1 and IL-6 *in vitro*.

It has been found that oxymatrin can raise the cytoplasmic Ca^{2+} levels and decrease cAMP concentration of human lymphocytes, but with no effect on cGMP nor on Ca^{2+} uptake.[25]

Other properties of *Ku Seng* allow its use as an antiasthmatic, an expectorant, a diuretic, and a natriuretic. *Ku Seng* also increases leukocyte count, and has exhibited antibacterial and anticancer properties. Chen et al. showed that *Ku Seng* exerts an inhibitory effect on biosynthesis of virus protein, resulting in a reduction of virus replication.[4]

Matrine derivatives also have an anti-inflammatory effect and can inhibit the increased vascular permeability induced by histamine.

Oxymatrine is less absorbed from the intestine than matrine. When it is given orally or by intramuscular injection, it is mainly transformed into *d*-matrine, which is excreted in the urine. Approximately 24% of the dose is eliminated within 24 h.

Toxicity: In mice, a *Ku Seng* decoction had an LD_{50} of 43 ± 2.2 g/kg; for the [illegible] mg/kg [illegible] matrine was reported to be 72.1 mg/kg in mice (i.v.).

Primary adverse effects are gastrointestinal disturbances, including gastric pain, nausea, vomiting, and constipation.

Therapeutic Uses: Clinically, oxymatrine is effective in treating allergic contact dermatitis by inhibiting degranulation of mast cells.

Ku Seng is used in Chinese medicine to remove "heat" and dampness from the body, and as an anthelmintic and antipruitic. It is also used to treat irregular heart beat, exzema, acute dysentery, otitis media, acute and chronic conjunctivitis, and trichomoniasis. Its protective effect against X-irradiation[21] also allows its use against leukopenia, while its diuretic effects are useful for edema treatment.

Several preparations of the herb are used. In tablet form (2 g), general dosage is 3 to 10 tabs t.i.d.; the *Ku Seng* alkaloid may be administered in 50 mg tablet form at a dose of 1 to 2 tablets t.i.d. In syrup form, 100 ml of syrup is equivalent to 50 g of raw herb.

For treatment of leukopenia, intramuscular injection is used at 100 mg/ml, 200 to 400 mg daily. Asthma patients may inhale the herb in aerosol form, at 400 to 600 mg of alkaloid per 12-ml vial.

For external uses, a *Ku Seng* preparation in oily form is applied on infected skin; in douche form, it is used for vaginal trichomoniasis.

GAN CAO (甘草), OR LICORICE ROOT

The dried root and rhizome of *Glycyrrhiza uralensis, G. inflata,* or *G. glabra*

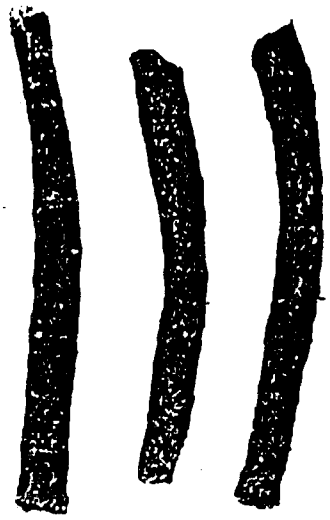
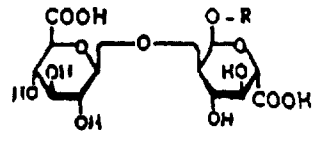


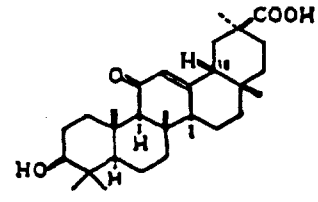
Figure 34.1 ***Gan Cao,* the licorice root.**

Chemistry: Between 6 and 14% of the herb by weight consists of glycyrrhizin, which is the Ca^{2+} or K^{+} salt of glycyrrhinic acid. Glycyrrhizin is about 170% sweeter than cane sugar. After water hydrolysis, it gives one molecule of glycyrrhetic acid and two molecules of glycuronic acid.

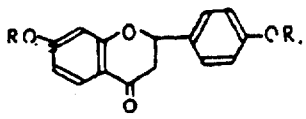
The plant also contains small amounts of glycosides called liquiritin, isoliquiritin, and neoliquiritin. Recently, an antiulcerative FM 100 fraction, or licorione, which is a glycyrrhizin-free isoflavone and chalcone, has been isolated from the root. In addition, licochalcone A, an oxygenated chalcone, and an immunosuppressant substance called LX were also isolated from the plant.



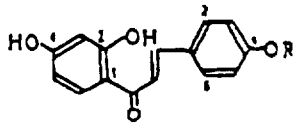
Glycyrrhizic acid
R = glycyrrhetic acid



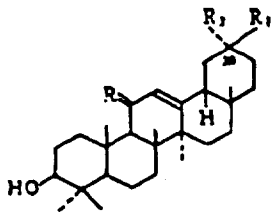
18 β-Glycyrrhetic acid



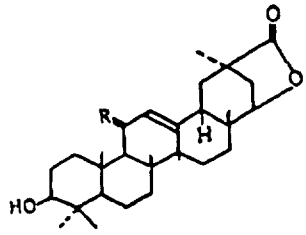
	R=	R_1=
Liquiritigenin	H	H
Liquiritin	H	-glucose
Neo-liquiritin	-glu.	H



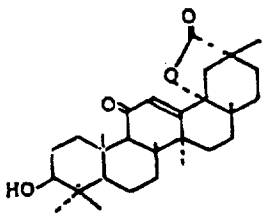
	R=
Isoliquiritigenin	H
Isoliquiritin	-glucose



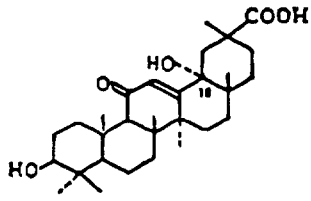
	R=	R_1=	R_2=
Acid I	H_2	COOH	CH_3
Liquiritic acid	O	CH_3	COOH
Glycyrrhetol	O	CH_2OH	CH_3



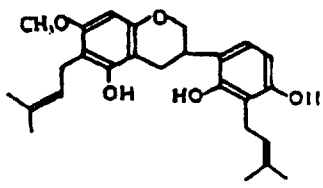
	R=
Glabrolide	O
Deoxyglabrolide	H_2



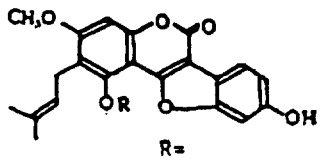
Isoglabrolide



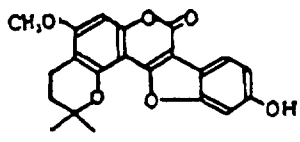
18α-Hydroxyglycyrrhetic acid



Licoricidin



	R=
Glycyrol	H
5-O-Methyl-glycyrol	CH_3



Isoglycyrol

Actions:

Endocrine System — Licorice root possesses a steroid-like activity. Chronic administration of this herb produces symptoms of hypertension, transient reduction of kalemia, increase of body weight, and depression of plasma renin activity.[2] There is an increase in the plasma levels of mineralocorticoid, which leads to a decrease in urinary Na^+ excretion and an increase in urinary K^+. An increase of plasma Na^+ ion and retention of body fluid then results. In addition, blood Ca^{2+} decreases. Such effects were not observed in bilateral adrenalectomized animals or in dexamethasone-treated rats.

Licorice can potentiate and prolong the action of cortisol and increase the urinary excretion of 17-ketosterone. It inhibits the release of melanin-stimulating hormone from the pituitary. It causes a fall in vitamin C levels in the adrenal gland and an increase in adrenal weight. It also causes a decrease in eosinophil and leukocyte counts.

It is known that glycyrrhizin, the active principle of the herb, is a potent inhibitor of 11-β-hydroxysteroid dehydrogenase (11-β-OHSD) in man. This enzyme plays an important role in conversion of aldosterone into inactive steroid. Thus, the inhibition of 11-β-OHSD by licorice results in a pseudohyperaldosteronism. Hypertension is observed, which can be reduced by spironolactone.[14] This hypertensive effect may be partially mediated through the CNS.[8]

Hypokalemic myopathy and rhabdomyolysis have also been observed in chronic ingestion of this herb. Elderly persons susceptible to the effect of licorice may show a rapid deterioration of renal functions.[10]

Anti-Inflammation and the Immune System — Licorice and glycyrrhizin also inhibit the conversion of cortisol to cortisone in the kidney by inhibition of renal 11-β-OHSD. The urinary cortisone excretion is down and the plasma level of cortisol is up. This exerts an anti-inflmmatory effect and can counteract the activity of burn-associated suppressor T cell activity.

Licorice can reduce hypersensitivity reactions and capillary permeability. In addition, it can prolong the survival time of transplanted tissue and inhibit the production of antibodies. The active principle responsible for this effect belongs to the heat-stable LX immunosuppressant.

The herb is a promotor that modulates the proliferation and IL-2 production of murine thymocytes in response to anti-CD3 monoclonal antibody.[8] The herb selectively activates extrathymic T cells in the liver, but does not affect regular T cells in the thymus.[15]

The water-based extract of licorice can increase proliferation of human fibroblasts. This is attributed mainly to the glycoside of this herb, isoliquiritin, which can inhibit granuloma angiogenesis and shows an antigranulomatosis effect.[16,20]

Digestive System — Gan Cao has remarkable antigastric ulcer activity. It inhibits gastric secretion and ulcer formation. This activity is due to the FM 100 fraction, which can lower gastric acidity and reduce pepsin activity and inhibit gastric secretion. The FM 100 fraction is a potent inhibitor of 15-hydroxyprostaglandin dehydrogenase (15-OHPGD) and δ-13-prostaglandin reductase. These enzymes play an role in regulating the PGE_2 and $PGF_{2\alpha}$ level in the human body. Inhibition of the enzymes by the FM 100 fraction would raise the local concentration of

PGE_2 which in turn promotes mucous secretion and cell proliferation in the stomach, leading to healing process of the ulcer.[1]

Licorice and glycyrrhizin are widely used in patients with chronic liver diseases. They have a protective effect against CCl_4 hepatotoxicity and can reduce cisplatin-induced hepatotoxicity, nephrotoxicity, and reticulotoxicity without affecting its anticancer efficacy.[31,34]

The Japanese used licorice to treat chronic hepatitis B infection. Patients taking this herb show an improvement of liver function, with occasional complete recovery from hepatitis. It is been shown that glycyrrhizin can suppress the reaction of hepatitis B surface antigen (HBsAg).[26]

Other Effects — The herb is a potent antitoxin. The classic Chinese medical texts stated that "*Gan Cao* can detoxify hundreds of toxic substances...." Experiments showed that glycyrrhinic acid can lower the toxicity of strychnine, histamine, chloral hydrate, arsenate, snake venom, diphtheria toxin, tetanus toxin, etc. In isolated perfused heart experiments, *Gan Cao* can antagonize the actions of physostigmine and acetylcholine.

It was claimed that *Gan Cao*, through its glycyrrhinic acid and water hydrolysis products, can transform several toxins in the liver into insoluble products.

In small doses, the herb stimulates biosynthesis of cholesterol in rat liver and can lower the plasma levels of cholesterol and triglycerol in hypertensive patients by increasing excretion. It can have a preventive effect on arteriosclerosis formation.

Gan Cao is an effective antitussive and expectorant. Oral administration of *Gan Cao* can reduce inflammation of the laryngeal mucosa and exert a protective action to reduce irritation. 18-β-Glycyrrhetic acid definitely has an antitussive effect, acting both locally and centrally.

In addition, the herb has analgesic and anticonvulsive effects.

Glycyrrhizin inhibits Na/K ATPase and exhibits a significant antioxidant, antitumor, and antimutagenic activity.[7,33] When it is given to animals in combination with saikosaponin, the herb can reduce mutagenicity of mutagen AF-2 in the animal and produces a chemopreventive effect.

Licochalcone A inhibits the growth of both *Leishmania major* and *L. donovani* promastigotes and amastigotes. It is also found to inhibit the human malaria parasite, *Plasmodium falciparum*.[21]

Abuse or chronic use of *Gan Cao* can result in hypertension, similar to Cushing's syndrome. A regular daily intake of 100 mg glycyrrhizin (approximately corresponding to 50 g licorice root) would be enough to produce such a hyperaldosteronism effect. The herb also has a tendency to lower the basal metabolite rate and decrease thyroid function.

Pharmacokinetic — Glycyrrhizin is binding with human serum albumin and can competitively be displayed by ibuprofen, warfarin, salicylate, or deoxycholic acid.[13]

The herb is absorbed readily from the intestine and is generally metabolized in glucuronate form in the liver. Only 1% of the dose taken is excreted in the urine.

The half-life ($t_{1/\beta}$) of 18-β-glycyrrhetic acid in the human is 11.5 ± 1.2 h. In patients suffering with chronic hepatitis, the half-life of this agent is prolonged to 5 h.[18]

Therapeutic Uses: Chinese medical texts describe *Gan Cao* as an agent to "improve the tone of the 'middle *Jiao*' (the digestive system) and replenish *qi*, to remove 'heat' and toxic substance, to moisturize the lungs and arrest coughing, and to relieve spasms and pain."

Licorice root candy is a favorite snack for children. It is also used in many food or drug preparations as a flavoring adjuvant, an ingredient in cigarette or chewing tobacco for its taste and property to reduce irritation. Alexander the Great distributed the root to his soldiers to alleviate thirst.

Gan Cao is effective in the treatment of mild or moderate cases of hypocorticosteroidism or Addison's disease. It can be used alone or in combination with cortisol to produce a synergistic effect.

Licorice pills are sold in overseas Chinese stores as an antigastric ulcer product.

The herb is also used to treat bronchitis, tuberculosis, and peptic ulcers. It is administered in doses of 30 g, decocted and taken twice a day in the treatment of thrombocytopenia purpurea. In addition, it is used as an adjuvant to other herbs, to smooth their taste and reduce their side effects.

Glycyrrhizin and IFN-α are synergistic in antiviral action against hepatitis A virus (HAV).[3] Therapeutically it is also found to be effective in the treatment of interferon-resistant chronic hepatitis C infection.[22]

The herb is used as an adjuvant in the treatment of organophosphorous pesticide poisoning and in preventing the complications.[11]

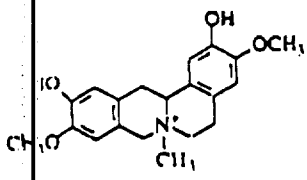
In combination with spironolactone, this herb is effective in treating hirsutism.[9]

There are many formulas in which *Gan Cao* serves as the principal adjuvant, or supporting herb. Standard preparations include a *Gan Cao* extract, which is administered in doses of 5 to 15 ml t.i.d. In tablet form, the herb is administered in doses of 3 to 4 tablets t.i.d. The drug biogastrone contains glycyrrhetic acid (50 mg/tablet); it is taken in doses of 2 tablets t.i.d.

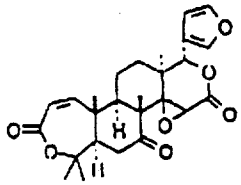
HUANG BAI (黄柏)

The dried bark of *Phellodendron chinense* or *P. amurense*

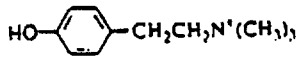
Chemistry: The bark contains many alkaloids; the major ones are berberine (0.6 to 2.5% of total content), palmatine, and phellodendrine.



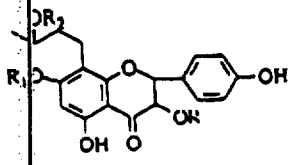
Phellodendrine



Obacunone



Candicine



	R=	R_1=	R_2=	C_2 C_3
Phellodendroside	-gluc.	H	H	-
Phellamurin	H	-gluc	H	-
Dihydrophelloside	H	-gluc	-gluc	-
Phelloside	H	-gluc	-gluc	double bond
Nor-icariside	H	H	-gluc	double bond

Actions: Like *Huang Lian, Huang Bai* exerts an antibacterial effect and is especially effective against diphtheria bacilli, streptococci, and dysentery bacilla. In addition, it can stimulate the phagocytic activity of leukocytes. It also has a vasodilatory effect, increasing coronary flow and lowering blood pressure.

The alkaloid of this herb, phellodendrine, is found to have immunosuppressive action against cellular immune response, but unlike prednisolone and cyclophosphamide, it does not affect antibody production in the red blood cells of mice or sheep.[25]

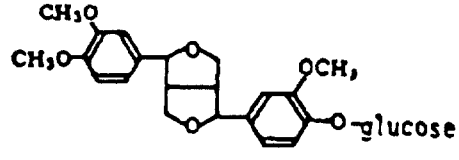
Therapeutic Uses: The Chinese pharmacopocia recommended the herb to purge intensive "heat" and to remove "dampness" and toxic substances. Therapeutically, it is effective against dysentery and used in jaundice, tuberculosis, epidemic meningitis, acute conjunctivitis, and trachoma.

The herb is available as an extract, equivalent to 1 g of raw material, and as a 0.2% injection solution for intramuscular administration.

LIAN QIAO (連翹)

The dried fruit of *Forsythia suspensa* (Thunb.) Vahl.

Chemistry: The fruit contains forsythol ($C_{15}H_{18}O_7$), phillyroside ($C_{27}H_{34}O_{11}$), oleanolic acid, and rutoside.



Phillyrin or Phillyroside

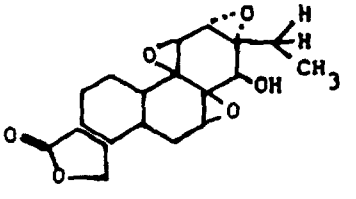
Actions: The herb has antibacterial action against *Salmonella typhi*, cholera, *E. coli*, diphtheria, plague, tuberculosis, staphylococci, and pneumococci. It has anti-inflammatory properties and can lower body temperature. It can increase body immunity. It protects hepatic function and is an effective choleretic. In the cardiovascular system, it can produce vasodilatation and a hypotensive effect. It is a diuretic and antiemetic; the latter effect occurs via inhibition of the chemoreceptor trigger zone (CTZ).

Therapeutic Uses: In the treatment of early influenza and cold, the herb is administered in doses of 9 to 16 g prepared in a decoction. It is also used in the treatment of encephalitis, hepatitis, carbuncle, and tuberculosis.

...network.

TRIPTOLIDE (雷公藤)

A diterpenoid tripoxide isolated from *Tripterygium wilfordii* Hook.
(*See Chapter 29 and Chapter 43.*)



Triptolide

Actions: Triptolide is one of the active nonalkaloid principles isolated from *Tripterygium* and possesses an extensive suppressive effect on immune function, especially on T and B lymphocytes. The inhibitory effect is direct and nonselective. It inhibits IL-2 production and IL-2R (receptor) expression by interferring with signal transduction of IL-2.[5,16,24]

Figure 3.1 illustrates the effect of triptolide and tripdiolide on IL-2 production of T-cells.

At high doses, it exerts an anti-inflammatory effect by stimulating the pituitary-adrenal axis with little effect on PGE content of the inflammatory tissues.[30]

Clinical trials show that it significantly inhibits the proliferation of peripheral blood mononuclear cells of rheumatic arthritis patients.[25] After medication, patients usually indicate that their stiffness, walking, and hand grasping strength are improved and their inflammation index goes down.[30]

Triptolide can synergize the pharmacological effect of other immunosuppressing agents, especially cyclosporine.

Toxicity: Triptolide is quite toxic. A dog or rat receiving a dose of triptolide of 10 mg/kg/d would show significant toxic symptoms, including a high blood urea level and damage to the heart, liver, and kidney. This is usually reversible when administration stops.

Approximately 28% of the patients taking this compound show some types of side effects, such as gastrointestinal disturbance, nausea and vomiting, ulceration of mouth mucosa, anemia, hypotension, and edema. Long-term therapy may cause mental fatigue and agranulocytic anemia.

Therapeutic Uses: This agent has a potential therapeutic effect on some types of solid tumors, including breast and stomach carcinoma.[21] It is also used in the treatment of SLE nephritis patients at a dose of 30 mg/d, resulting in a significant lowering of $CD8^+VV^+$ cell level.[28]

Because of its synergistic effect with cyclosporine, it is recommended to be used together with cyclosporine in allograft organ transplant, aiming to reduce the toxicity and resistance development of cyclosporine.

Siegesbeckia orientalis L.
NAMES: Pinyin: xī xiān.
English: divine herb.
USES: *Root:* Analgesic, antirheumatic, used externally for abscesses, boils and ulcers. *Plant:* Whole plant used for arthritis, bad back, boils, dermatitis, hemiplegia, hypertension, leg ache, rheumatism, side ache, sciatica, weak knees. Ground and taken alone or with *Acanthopanax* (or *Periploca*), *Clerodendron* and *Xanthium*, for convulsions, paralytic stroke, and rheumatoid arthritis. For bugbites, dog bites, malaria, numbness, snakebites, tiger bites, and ulcers. Decocted for malignant tumors, mentioned as a tumor remedy in the T'ang Pent'sao (659 AD).

豨莶草

5321 豨莶 xī xiān (<湿木草>)

Ref: 4, 12, 15, 16, 35, 36, 37.

CHEM.: The root contains essential oil, a white substance suggesting salicylic acid, and a bitter glucoside (darutoside, $C_{26}H_{44}O_8$) which on hydrolysis yields an aglucone, darutigenol and on acid hydrolysis yields a mixture of aglucones and isodarutigenals B and C. Extracts are said to have antiviral, hypoglycemic and insecticidal activities. The fresh juice, dressed over a wound, leaves a varnish-like coating as it dries.

通脱木
1.花枝 2.果序及苞片

4050 通草 tōng cǎo (《本草拾遗》)

perium (Indochina). *Ref:* 16.
NOTES: In India, the roots, mixed with rice, are eaten by the Mundas to "cure dropsy." The leaves are said to contain saponins. Ref: 1.

4057 七叶莲 qī yè lián (广州部队《常用中草药手册》)

Tetrapanax papyriferus (Hook.) K. Koch
NAMES: Pinyin: tōng cǎo.
English: rice-paper plant.
USES: *Flowers:* Pollen applied to hemorrhoids and infections. *Stem:* Pith antidotal, deobstruent, diuretic, febrifuge, lactagogue, sedative, vermifuge, decocted for bronchitis,

Coix lacryma-jobi L.
NAMES: Pinyin: yi yǐ rén.
English: Job's tears, pearl barley.
USES: Decoction believed to benefit the blood and breath, used for washing the newly borne to prevent disease. *Fruit:* Used for intestinal or lung cancers and warts. Wine made from fermented grains given in rheumatism. Vermifuge; for gonorrhea, hypertension. *Seed:* Antirheumatic, diuretic, refrigerant; decoction for appendicitis, arthritis, beri-beri, bronchitis, cancer, diarrhea, dry skin, dysuria, edema, hydrothorax, inflammation, pleurisy, pneumonia, pulmonary abscess, rheumatism, and tuberculosis. *Plant:* Anticancer.

Ref: 4, 12, 15, 25, 33, 35, 37, 68.

CHEM.: Per 100 g, the seed is reported to contain 380 calories, 11.2 g H_2O, 15.4 g protein, 6.2 g fat, 65.3 g total carbohydrate, 0.8 g fiber, 1.9 g ash, 25 mg Ca, 435 mg P, 5.0 mg Fe, 0 mg beta-carotene equivalent, 0.28 mg thiamine, 0.19 mg riboflavin, 4.3 mg niacin, and 0 mg ascorbic acid. There is 50-60% starch, 18.7% protein (with glutamic-acid, leucine, tyrosine, arginine, histidine, and lysine) and 5-10% fatty oil with glycerides of myristic- and palmitic-acids. The herbage (ZMB) contains 8.5% protein, 2.8% fat, 79.8% total carbohydrate, 27.9% fiber, and 8.9% ash.

5548 薏苡仁 yi yi rén (《本經》)

Ref: 33 142