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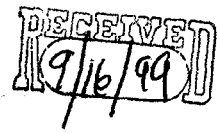

September 16, 1999

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. Uniweal, Ltd., Room 803, Corn Yan Center, 3 Jupiter Street, North Point, Hong Kong, People's Republic of China, plans to market a dietary supplement bearing the following statements on the label and/or in the labeling:

Name of supplement:	TIMYZOROLA™
Dietary ingredients:	Rehmannia (Di-Huang) (prepared root)
	Chinese Yam (Shan-Yao) (root)
	Asiatic Dogwood (Shan-Zhu-Yu) (fruit)
	Alisma (Ze-Xie) (root)
	Polyporus (Fu-Ling) (filament)
	Tree Peony Bark (Mu-Dan-Pi) (cortex)
	Cassia (cortex)
	Prepared Aconitum Tuber (Fu-Zi) (root)

97S-0162

LET 4429

Structure/function statements:

1. **This product supports healthy kidney and urinary function.** This statement is the subject of Guifu Dihuang Pills, which contains Rehmannia (Di-Huang) (root), Chinese Yam (Shan-Yao) (root), Asiatic Dogwood (Shan-Zhu-Yu) (fruit), Alisma (Ze-Xie) (root), Polyporus (Fu-Ling) (filament), Tree Peony Bark (Mu-Dan-Pi) (cortex), Cassia (cortex), and Prepared Aconitum Tuber (Fu-Zi) (root).

2. **This product promotes a healthy prostate.** This statement is the subject of TIMYZOROLA™, which contains Rehmannia (Di-Huang) (root), Chinese Yam (Shan-Yao) (root), Asiatic Dogwood (Shan-Zhu-Yu) (fruit), Alisma (Ze-Xie) (root), Polyporus (Fu-Ling) (filament), Tree Peony Bark (Mu-Dan-Pi) (cortex), Cassia (cortex), and Prepared Aconitum Tuber (Fu-Zi) (root).

3. **This product helps increase energy levels.** This statement is the subject of Guifu Dihuang Pills, which contains Rehmannia (Di-Huang) (root), Chinese Yam (Shan-Yao) (root), Asiatic Dogwood (Shan-Zhu-Yu) (fruit), Alisma (Ze-Xie) (root), Polyporus (Fu-Ling) (filament), Tree Peony Bark (Mu-Dan-Pi) (cortex), Cassia (cortex), and Prepared Aconitum Tuber (Fu-Zi) (root).

Summary of Substantiation:

The claims "this product supports healthy kidney and urinary function" and "helps increase energy levels" are based on and supported by reference to authoritative scientific literature. TIMYZOROLA™ is identical to Guifu Dihuang pills, the beneficial effects of which have been well characterized by authoritative scientific literature.

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 that Guifu Dihuang Pills is comprised of the above eight dietary ingredients (see attached).[1/] The Pharmacopoeia of the People's Republic of China states that the action of Guifu Dihuang Pills is to "reinforce the yang of the kidney," and that Guifu Dihuang Pills is indicated for "deficiency of the yang of the kidney marked by cold sensation in the loins and knees, edema of the limbs, oliguria, or on the

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1/ THE PHARMACOPOEIA COMMISSION OF PRC, PHARMACOPEIA OF THE PEOPLE'S REPUBLIC OF CHINA (English ed. 1997, Chemical Industry Press) at 288 (1997).

contrary polyuria, or marked by retention of fluid with cough and dyspnea, as well as diabetes."[2/]

Further, the Pharmacopoeia of the People's Republic of China states the following actions and indications for the component ingredients of Guifu Dihuang Pills:

- Rehmannia (Di-Huang) (root): Action—to reinforce the essence of life and marrow; Indications—yin deficiency of liver and kidney, aching and weakness of the loins and knees, emission, dizziness, uterine bleeding, etc.;

- Chinese Yam (Shan-Yao) (root): Action—to strengthen the kidney and restrain seminal discharge; Indications—seminal emission, excessive leukorrhea, frequency of urination or diabetes due to deficiency condition of the kidney;

- Asiatic Dogwood (Shan-Zhu-Yu) (fruit): Action—to replenish the liver and kidney, restrain seminal discharge and relieve collapse; Indications—dizziness, impotence, seminal emission, enuresis, frequency of urination, excessive uterine bleeding and leukorrhea, collapse with profuse sweating, and diabetes;

- Alisma (Ze-Xie) (root): Action—to cause diuresis; Indications—edema with oliguria, diarrhea with diminished discharge of urine, and acute urinary infection with difficult painful urination;

- Polyporus (Fu-Ling) (filament): Action—to cause diuresis and invigorate the spleen function; Indications—edema with oliguria, diminished function of the spleen marked by anorexia, restlessness, and insomnia;

- Cassia (cortex): Action—to supplement body fire and lead the fire to the kidney, and stimulate menstrual discharge; Indications—impotence, frigidity, dyspnea in deficiency syndrome of the kidney, dizziness, amenorrhea, and dysmenorrhea; and

- Prepared Aconitum Tuber (Fu-Zi) (root): Action—to cause restoration from collapse, to supplement body fire and reinforce yang, etc.; Indications—collapse with cold limbs and faint pulse, impotence, frigidity, etc.

2/ "Yang of the kidney implies the physiological energy of life, i.e., fire in its physiological sense, as well as the functions (growth, development, reproduction, metabolism, etc.) produced hereby." *Id.* at A-93.

Therefore, the proposed claims "this product supports healthy kidney and urinary function" and "helps increase energy levels" are proper and supported for Guifu Dihuang Pills, and therefore TIMYZOROLA™.

TIMYZOROLA™ has also been demonstrated to "promote a healthy prostate." This claim is based on a 1993-1996 clinical study performed on 302 male volunteers diagnosed with benign prostatic hyperplasia (BPH) and demonstrating high BPH symptom scores. The study was conducted by Uniweal Ltd. and its agents (see attached report titled "TIMYZOROLA™ Exhibits Positive Effects on the Prostate: Clinical Study in Support of the Dietary Supplement Claim, 'Promotes a Healthy Prostate'").

In this study, TIMYZOROLA™ was compared to an approved drug in the U.S., PROSCAR (finasteride), which is indicated in the treatment of BPH. In every measurement of BPH performed, including measurements of symptoms and actual prostate enlargement, TIMYZOROLA™ showed statistically significant differences from baseline measurements taken prior to use of TIMYZOROLA™. Symptomatic scoring using the International Prostate Symptom Score (IPSS) and Quality of Life (QOL) score (which are standards of prostate assessment promulgated by the World Health Organization) showed significant improvements as compared to baseline data with the use of TIMYZOROLA™ ($p<.01$). Also, urine flow rate increased significantly over baseline data ($p<.01$), and the volume of the prostate gland itself actually decreased over time as compared to baseline data with the use of TIMYZOROLA™ ($p<.01$). Finally, in a symptomatic category analysis of the study subjects, 98% of the subjects using TIMYZOROLA™ fall into categories of BPH where significant improvement is shown. TIMYZOROLA™ performed similarly to finasteride in these measurements. The weight of these results, demonstrating a positive effect on BPH-prostate, support the claim that TIMYZOROLA™ "promotes a healthy prostate."

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

Sincerely,

Stephen Paul Mahinka
Counsel for Uniweal, Ltd.

Attachment

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

test solution. Prepare a solution of 0.2 g of Radix Aristolochiae 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 G containing carboxymethylcellulose sodium as the coating substance and bezene-methanol-glacial acetic acid (10:1:0.05) as the mobile phase. Apply separately to the plate 10 μl of the two solutions. After developing for two times, and removal of the plate, dry it in air. The 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.

Other requirements Comply with the general requirements for pills (Appendix I A).

Action To regulate the flow of *qi* in the chest and relieve pain.

Indications Angina pectoris with stuffiness sensation in the chest.

Usage and dosage 1 pill, 1～3 times a day, or under direction of physician; to be taken orally by chewing.

Precaution Contraindicated in pregnancy.

Storage Preserve in tightly closed containers.

Guifu Dihuang Wan
(桂附地黄丸)

Guifu Dihuang Pills

Ingredients Cortex Cinnamomi 20 g; Radix Aconiti Lateralis Preparata (processed) 20 g; Radix Rehmanniae (steamed) 160 g; Fructus Corni (processed) 80 g; Cortex Moutan 60 g; Rhizoma Dioscoreae 80 g; Poria 60 g; Rhizoma Alismatis 60 g.

Procedure Pulverize the above eight ingredients to fine powder, sift, mix well. To each 100 g of the powder add 35～50 g of refined honey and a quantity of water to make pills and dry. Alternatively, add 80～110 g of refined honey to make small honeyed pills or big honeyed pills.

Description Blackish-brown water honeyed pills, small honeyed pills or big honeyed pills; taste, sweet with slightly sour and pungent.

Identification (1) Microscopical: Starch granules triangle-ovoid or oblong, 24～40 μm in diameter; hilum short-cleft or V-shaped. Gelatinized masses of starch granules whitish. Irregular branched masses colourless, dissolved in chloral hydrate solution; hyphae colourless or pale brown, 4～6 μm in diameter. Parenchyma greyish-brown to blackish-brown, cells mostly shrunken, and each containing a brown nucleus-like mass. Clusters of calcium oxalate occurring in colourless parenchymatous cells, sometimes several in a row. Epidermal cells of pericarp orange-yellow, subpolygonal in surface view, antielinal walls slightly beaded. Parenchymatous cells subrounded, with elliptic pits gathered in pit groups. Stone cells subsquare or subrounded, with thin walls at one side.
(2) Pulverize 9 g of big or small honeyed pills (or 6 g of water-honeyed pills), add 15 ml of ether, and shake for 15 minutes, stand for 1 hour, filter, evaporate the ether and dissolve the residue in 1 ml of acetone as the test solution. Dissolve paeonol CRS in acetone 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 cyclohexane-ethyl acearte (3:1) as the mobile phase. Apply in strip separately to the plate 10 μl of each of the two solutions. After developing and removal of the plate, dry it in air, spray with 5% solution of ferric chloride in ethanol (acidified with hydrochloic acid), visualize under a current of hot air. The bluish-brown strip in the chromatogram obtained with the test solution corresponds in position and colour to the strip in the chromatogram obtained with the reference solution.
(3) Pulverize 9 g of big or small honeyed pills (or 6 g of water-honeyed pills), add 10 ml of ethanol, shake for 15 minutes, stand for 1 hour, filter, use the filtrate as the test solution. Dissolve cinnamaldehyde CRS in ethanol to produce a solution containing 1 μl 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 (30－60℃)-ethyl acetate (17:3) as the mobile phase. Apply separately to the plate 15 μl of the test solution and 2μl of the reference solution. After developing and removal of the plate, dry it in air, and spray with 2, 4-dinitrophenyl hydrazine solution. The orange-red 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.

Other requirements Comply with the general requirements for pills (Appendix I A).

Action To reinforce *yang* of the *kidney*.

Indications *Deficiency of yang of the kidney* marked by cold sensation in the loins and knees, edema of the limbs, oliguria, or on the contrary, polyuria, or marked by retention of fluid with cough and dyspnea; diabetes.

Usage and dosage 6 g of water honeyed pills, 9 g of small honeyed pills or 1 big honeyed pill; 2 times a day.

Specification 9 g per big honeyed pill.

Storage Preserve in tightly closed containers.

Guifu Lizhong Wan
(桂附理中丸)

Guifu Lizhong Pills

Ingredients Cortex Cinnamomi 30 g; slices of Radix Aconiti Lateralis Preparata 30 g; Radix Codonopsis 90 g; Rhizoma Atractylodis Macrocephalae (stir-fried) 90 g; Rhizoma Zingiberis (processed) 90 g; Radix Glycyrrhizae (processed with honey) 90 g.

Procedure Pulverize the above six ingredients to fine powders, sift, and mix well. To each 100 g of the powder add 120～140 g of refined honey to make big honeyed pills.

Description Brown big honeyed pills; odour, slight; taste, sweet and pungent.

Identification (1) Microscopical: Fibres usually singly scattered, long fusiform, 24－50 μm in diameter, with thickened and lignified walls. Gelatinized starch masses whitish. Anastomosing laticiferous tubes 12～15 μm in diameter, containing fine granules. Needle crystals of calcium oxalate fine, 10～32 μm long, irregularly filling in parenchymatous cells. Starch granules long ovoid, broad ovoid, or irregular, some mucronate at the small end, 25～32 μm in diameter, up to about 50 μm long, hilum pointed at the small end. Fibre bundles surrounded by cells containing prisms of calcium oxalate, forming crystal fibres.
(2) To 9 g of the drug add 4.5 g of diatomite and 50 ml of

filled with starch granules.

Action To dissolve lumps and cause subsidence of swelling.

Indications Tuberculosis of lymph nodes without ulceration.

Usage and dosage 15～30 g; up to 120 g when used alone or as simple preparation.

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

Radix Rehmanniae (地黄, Dihuang)

Rehmannia Root

Rehmannia Root is the fresh or dried root tuber of *Rehmannia glutinosa* Libosch. (Fam. Scrophulariaceae). The drug is collected in autumn, removed from root stock, rootlet and soil, used either in fresh state or baked to almost dry. The former is known as "Xian Dihuang" (Fresh Rehmannia Root) and the latter is known as "Sheng Dishuang" (Unprocessed Rehmannia Root).

Description *Xian Dihuang* Fusiform or slat-shaped, 8～24 cm long, 2～9 cm in diameter, the outer bark thin, externally pale reddish-yellow, with curved longitudinal wrinkles, bud scars, elongated transverse lenticels and irregular scars. Texture fleshy, easily borken, yellowish-white, orange-red oil dots scattered in bark, fracture yellowish-white, with vessels arranged radially in wood. Odour, slight; taste, slightly sweet and bitterish.

Sheng Dihuang Mostly in irregular masses or oblong, swollen in the centre, slightly tapering at both ends, 6～12 cm long, 3～6 cm in diameter. Some small, slit-shaped, slightly compressed or twisted. Externally brownish-black or brownish-greyish, heavily shrunken, with irregular transverse wavy lines. Texture heavy, soft and tenacious, uneasily broken, fracture brownish-black or jet-black, lustrous, viscous, Odourless; taste, slightly sweet.

Identification (1) Transverse section: Cork consisting of several layers of cells. In cortex parenchymatous cells loosely arranged; scattered with more secretory cells, containing orange-yellow oil droplets; stone cells occasionally found. Phloem relatively broad, secretory cells less. Cambium in a ring. Xylem rays broad, vessels sparse, arranged radially.
Powder of Sheng Dihuang: Dark brown. Cork cells brownish, subrectangular in lateral view, regularly arranged. Parenchymatous cells subrounded, containing subrounded nuclei. Secretory cells mostly similar to ordinary parenchymatous cells in shape, containing orange or orange-red oil droplets. Bordered pitted and reticulate vessels up to about 92 μm in diameter.
(2) To 2 g of the powder add 20 ml of methanol, heat under reflux on water bath for 1 hour, cool, filter, distill the filtrate to recover methanol, until 5 ml of filtrate is remained, use the filtrate as the test solution. Dissolve catalpol CRS in methanol to produce a solution containing 0.5 mg per ml used as the reference solution. Carry out the method for thin layer chromatography (Appendix Ⅵ B) using silica gel G as the coating substance and a mixture of chloroform-methanol-water (70:30:5) as the mobile phase. Apply separately to the plate 5 μl of each of the above two solutions. After developing and removal of the plate, dry it in air, spray with anisaldehyde TS, heat a 105℃ for 5 minutes. A spot in the chromatogram obtained from the test solution corresponds in colour and position to spot in the chromatogram obtained from the reference solution.

Total ash Not more than 6.0% (Appendix Ⅸ K).

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

Water soluble extractives Carry out the method for determination of extractives-cold maceration method (Appendix Ⅹ A), not less than 65.0%.

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

Action Fresh Readix Rehmanniae: To remove *heat* and promote the production of body fluid, to reduce *heat* in blood, and to arrest bleeding.
Radix Rehmanniae (unprocessed): To reduce *heat* in blood, to nourish *yin* and promote the production of body fluid.

Indications Fresh Radix Rehmanniae: Impairment of *yin* in febrile diseases marked by deep red tongue and thirst; skin eruption and maculation; spitting of blood, epistaxis; sore throat.
Radix Rehmanniae (unprepared): Febrile diseases with deep red tongue and thirst; deficiency of *yin* with internal *heat*; consumptive fever; diabetes caused by internal *heat*; spitting of blood, epistaxis; skin eruption and maculation.

Usage and dosage Fresh Radix Rehmanniae: 12～30 g.
Radix Rehmanniae (unprocessed): 9～15 g.

Storage Embed Fresh Rehmannia Root in sand and protect from freezing; unprocessed Rhmannia Root is preserved in a ventilated dry place, protected from mould and moth.

Radix Rehmanniae Preparata (熟地黄, Shudihuang)

Prepared Rehmannia Root

The drug is the processed Radix Rehmanniae.

Procedure (1) Stew the clean Radix Rehmanniae as described under the method for stewing with wine (Appendix Ⅱ D) until the wine is absorbed entirely, take out, dry in the sun until the mucilage in bark is slightly dried, cut into thick slices or pieces, and dry thoroughtly.
To each 100 kg of Radix Rehmanniae add 30～50 kg of yellow rice wine.
(2) Steam the clean Radix Rehmanniae as described under the method for steaming (Appendix Ⅱ D) until it becomes blackish and shiny, take out, dry in the sun to be eighty percent dried, cut into thick slices or pieces, and dry thoroughly.

Description Occuring in irregular slices and pieces, broken lumps, varying in size and thickness. Externally jet-black, lustrous, more sticky. Texture soft and flexible, uneasily broken, fracture jet-black, lustrous. Odourless; taste, sweet.

Identification To 1 g of the powder add 10 ml of ethanol, macerate for 24 hours, filter, and use the filtrate as the test solution. Dissolve 5-(hydroxy methyl) furfural CRS in ethanol 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 gel GF_{254} as the coating substance and petroleum ether (60～90℃)-

dinitrophenyl hydrazine TS, the colour of the spot turns to orange-red gradually on standing.

Total ash Not more than 4.0% (Appendix Ⅸ K).

Processing *Rhizoma Cyperi* Remove fibrous matter and foreign matter, pound to pieces or cut into thin slices.

Rhizoma Cyperi (processed with vinegar) Stir-fry the pieces or slices of Rhizoma Cyperi as described under the method for stir-frying with vinegar (Appendix Ⅱ D) to dryness.

Action To remove stagnation of *qi*, regulate menstruation and relieve pain.

Indications Stagnation of the *liver qi* characterized by distending pain in the chest, hypochondria and epigastrium, indigestion, feeling of stuffiness in the chest and epigastrium, abdominal colic, distending pain in the breast, menstrual disorders, amenorrhea or dysmenorrhea.

Usage and dosage 6～9 g.

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

Rhizoma Dioscoreae (山药, Shanyao)

Common Yam Rhizome

Common Yam Rhizome is the dried rhizome of *Dioscorea opposita* Thunb. (Fam. Dioscoreaceae). The drug is collected in winter when the stem and leaf are withered, deprived of root stock, washed clean and deprived of outer bark and fibrous root, fumigated with sulfur, and then dried. Otherwise thick large straight and dried rhizome is sorted, soaked in clean water until the central portion of the drug gets wet and softened thoroughly, then fumigated with sulfur, cut two ends to smooth plane and rubbed on a board to become cylindrical in shape, dried in the sun and finally polished. It is known as "Guang Shanyao" (Polished Common Yam Rhizome).

Description Subcylindrical, curved or somewhat flattened, 15～30 cm long, 1.5～6 cm in diameter. Externally yellowish-white or pale yellow, longitudinally furrowed and wrinkled, and bearing fibrous root scars, with occasional patches of brownish cork. Texture heavy, compact and tough; uneasily broken, fracture white and starchy. Odourless; taste, weak, acidulous, and viscous when chewed. Guang Shaoyao cylindrical, the two ends even, 9～18 cm long, 1.5～3 cm in diameter, externally smooth, white or yellowish-white.

Identification Powder: Whitish. Simple starch granules compressed-ovoid, subrounded, deltoid-ovoid or oblong, 8～35 μm in diameter, hilum pointed, V-shaped, X-shaped or shortly cleft, striations visible. Compound starch granules less common, usually consisting of 2～3 granules. Mucilage cells containing raphides of calcium oxalate, up to 240 μm long and needle crystals 2～5 μm wide. Bordered-pitted, reticulate, spiral and annular vessels, 12～48 μm in diameter.

Processing *Rhizoma Dioscoreae* Eliminate foreign matter, grade according to size, soak and soften thoroughly, cut into thicker slices, and dry.

Rhizoma Dioscoreae (stir-fried with bran) Stir-fry the slices of Rhizoma Dioscoreae as described under the method for stir-frying with bran (Appendix Ⅱ D) to yellowish.

Action To replenish the *spleen* and stomach, to promote fluid secretion and benefit the *lung*, and to strengthen the *kidney* and restrain seminal discharge.
Rhizoma Dioscoreae (stir-fried with bran): To replenish the *spleen* and promote the stomach function.

Indications Anorexia and chronic diarrhea due to diminished function of the *spleen*; cough and dyspnea due to diminished function of the *lung*; seminal emission, excessive leukorrhea, frequency of urination or diabetes due to *deficiency* condition of the *kidney*.
Rhizoma Dioscoreae (stir-fried with bran): Diminished function of the *spleen* with anorexia, diarrhea and excessive leukorrhea.

Usage and dosage 15～30 g.

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

Rhizoma Dioscoreae Hypoglaucae (粉萆薢, Fenbixie)

Hypoglaucous Collett Yam Rhizome

Hypoglaucous Collett Yam Rhizome is the dried rhizome of *Dioscorea hypoglauca* Palibin (Fam. Dioscoreaceae). The drug is collected in autumn and winter, removed from the fibrous root, washed clean, cut into slice, and dried in the sun.

Description Irregularly thin slices, border uneven, varying in size, about 0.5 mm thick, some with brownish-black or greyish-brown outer bark. Slices yellowish-white or pale greyish-brown, vascular bundles scattered. Texture loose, slightly elastic. Odour, weak; taste, pungent and slightly bitter.

Identification (1) Transverse section: Suberized cells of more layers. Cortex narrow, cells tangentially elongated, walls slightly thickened, pits distinct, mucilage cells scattered, containing raphides of calcium oxalate. Collateral and amphivasal vascular bundles scattered in stele, parenchymatous cells walls slightly thickened, with pits, containing starch granules.
Powder: Yellowish-white. Simple starch granules rounded, ovoid or long-elliptical, 5～92 μm in diameter, up to 40 μm long, hilum pointed or cleft-like, compound granules less, mostly composed of two components. Sclerenchymatous cells abundant, walls lignified, pits distinct, some similar to stone cells, polygonal, fusiform or sub-rectangular, 40～80 μm in diameter, up to 224 μm long. Raphids of calcium oxalate 64～84 μm long.
(2) Macerate 10 g of the powder in 100 ml of water overnight, heat on a water bath at 60℃ for 10 minutes, filter while hot. Measure the filtrate, each of 2 ml, to two test tubes. To one tube add 2 ml of sodium hydroxide TS, and to another tube add 2 ml of hydrochloric acid solution (1→20), stopper well, shake vigorously for 1 minute, the foam produced in the alkaline solution is several times higher than that produced in the acid solution.

Action To remove turbid *damp*, and to relieve rheumatic conditions.

Indications Chyluria, turbid urine mixed with whitish substance or whitish discharge from urethra, excessive leukor-

ethyl acetate (1:1) as the mobile phase. Apply separately 10 μl of the test solution and 5 μl of the reference solution to the plate. After developing and removal of the plate, dry it in air. Examine under the ultra-violet light (254 nm), 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.

Extractives Comply with the test for Radix Rehmanniа.

Action To nourish *yin* and replenish blood, reinforce the essence of life and marrow.

Indications Yin deficiency of liver and kidney, aching and weakness of the loins and knees, hectic fever and bone-heat, night sweat, emission, internal heat and thirst. Anemia with sallow complexion, palpitation, menoxenia, uterine bleeding, dizziness, tinnitus, white hair and beard in young age.

Usage and dosage 9～15g.

Storage Preserve in a ventilated and dry place.

Radix Rhapontici (漏芦, Loulu)

Uniflower Swisscentaury Root

Uniflower Swisscentaury Root is the dried root of *Rhaponticum uniflorum* (L.) DC. (Fam. Compositae). The drug is collected in spring and autumn, removed from rootlet and soil, and dried in the sun.

Description Conical or flatted lumps, mostly twisted, varying in length, 1～2 cm in diameter. Externally greyish-brown or dark brown, rough, with longitudinal furrows and rhombic, netted clefts. Outer bark easily exfoliated. Root stock swollen, with the remains of stems and scaly leaf bases, top with greyish-white pubescences. Texture light, fragile, easily broken, fracture irregular, greyish-yellow, cleft, greyish-black or brownish-black in the centre. Odour, characteristic; taste, slightly bitter.

Identification To 1 g of the powder add 20 ml of methanol, ultra sonicate for 20 minutes, filter, evaporate the filtrate on a water bath to dryness, dissolve the residue in 1 ml of ethyl acetate and use it as the test solution. Prepare a solution of Radix Rhapontici 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 G as the coating substance and cyclohexane-butanone (4:1) as the mobile phase. Apply separately 5 μl of each of the two solutions to the plate. After developing and removal of the plate, dry it in air, examine under ultra-violet light (365 nm). A spot in the chromatogram obtained from the test solution corresponds in colour and position to spot in the chromatogram obtained from the solution of reference drug.

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

Action To remove *toxic heat* for treating subcutaneous infections, to promote lactation, and to relieve muscular contracture.

Indications Mastitis with swelling and pain, carbuncle, scrofula and ulcers; galactostasis; arthritis with ankylosis.

Usage and dosage 5～9 g.

Precaution Used with caution in pregnancy.

Storage Preserve in a ventilated and dry place.

Radix Rubiae (茜草, Qiancao)

Indian Madder Root

Indian Madder Root is the dried root and rhizome of *Rubia cordifolia* L. (Fam. Rubiaceae). The drug is collected in spring and summer, removed from soil, and dry.

Description Rhizomes nodular, marked with numerous fascicled roots varying in thickness. Roots cylindrical, somewhat curved, 10～25 cm long, 0.2～1 cm in diameter; externally reddish-brown or dark brown, with fine lingitudinal wrinkles and a few rootlet scars; the place where the outer bark has exfoliated appearing yellowish-red. Texture fragile, easily broken, fracture even, bark narrow and purplish-red, wood broad, pale yellowish-red, exhibiting numerous pores of vessels. Odourless; taste, bitterish with an irritating sensation to tongue when chewed for a long time.

Identification (1) Transverse section of root: Cork cells 6～12-layered, containing brown contents. Parenchymatous cells in cortex sometimes containing reddish-brown granules. Cells in phloem relatively small. Cambium ring less distinct. The majority of root occupied by wood, completely lignified, xylem rays indistinct. Parenchymatous cells containing raphides of calcium oxalate.
(2) Shake 0.2 g of the powder with 5 ml of ether for several minutes and filter. To the filtrate add 1 ml of sodium hydroxide TS, shake and allow to stand. The water layer shows a red colour; the ether layer is colourless, examine the ether layer under an ultra-violet light (365 nm), a sky-blue fluorescence is shown.

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

Processing *Radix Rubiae* Eliminate foreign matter, wash, soften thoroughly, cut into thick slices or sections, and dry.

Radix Rubiae (carbonized) Stir-fry the slices or the sections of Radix Rubiae as described under the method for carbonizing by stir-frying (Appendix II D) until the outer part is charred.

Action To remove *heat* from blood and arrest bleeding, to eliminate *blood stasis*, and to stimulate menstrual discharge.

Indications Spitting of blood, epistaxis, abnormal uterine bleeding, traumatic bleeding; amenorrhea with *blood stasis*; arthralgia, traumatic swelling and pain.

Usage and dosage 6～9 g.

Storage Preserve in a dry place.

tremely raised, with vascular bundles in the middle, surrounded by thick-walled and lignified reticulate cells; dorsal surface showing 1 ellipsoidal vitta between every 2 longitudianl ridges, commissural surface showing 2 vittae, altogether up to 6. Endocarp consisting of 1 layer of flattened cells with beaded walls. Testa consisting of 1 layer of pale brown cells. Cells of endosperm containing numerous aleurone grains, each embedding with fine clusters of calcium oxalate.

(2) To 2 g of the powder add 20 ml of ethanol, heat under reflux for 30 minutes and filter. Spot several drops of the filtrate on a white porcelain plate. Examine under ultra-violet light (365 nm), a bluish-purple fluorescence is shown. To 2 ml of the filtrate add an equal volume of 3% sodium carbonate solution and heat for 5 minutes. Allow to cool, add 1 ~ 2 drops of freshly prepared diazotized *p*-nitroaniline TS; a cherry colour is produced.

(3) To about 0.3 g of the coarse powder, add 5 ml of ethanol, ultrasonicate for 5 minutes, lay aside for a while, and use the supernate as the test solution. Dissolve osthol CRS with ethanol 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 containing sodium carboxymethylcellulose as the coating substance and benzene-ethyl acetate (30 : 1) 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, and examine it under ultra-violet light (365 nm). The fluroscent spot in the chromatogram obtained with the test solution corresponds in position and colour to spot in the chromatogram obtained with the reference solution.

Assay Weigh accurately 1 g of the powder (through No. 3 sieve), previously drided in vacuum in a phosphorus pentoxide desiccator to constant weight, into a stoppered conical flask, add accurately 20 ml of ethanol, shake and allow to stand overnight, filter, discard the primary filtrate, and collect the succesive filtrate as the test solution. Dissolve osthol CRS in ethanol 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 containing sodium carboxymethylcellulose as the coating substance and benzene-ethyl acetate (30 : 1) as the mobile phase. Apply separately 1μl of each of the two solution to the plate, after developing and removal of the plate, dry it in air. Carry out the method for thin layer chromatographic scanning (Appendix VI B), apply the linear fluorescent scanning at excitation wave λ =365 nm. Determine the integral fluorescence absorbance value of the test solution and reference solution respectively, and calculate the content of osthole.

It contains not less than 1.0% of osthole ($C_{16}H_{16}O_3$).

Action To warm the *kidney* and promote virility, to remove *damp*, to dispel *wind*, and to kill parasites.

Indications Impotence, frigidity, excessive leukorrhea caused by *cold-damp*; lumbago due to attack of *damp*; external use for eczema of external genitalia, vulval itching, trichomonas vaginitis.

Usage and dosage 3~9 g; appropriate quantity to be made into hot decoction for fuming and washing, or to be ground into powder for topical application after mix with liquid.

Storage Preserve in a dry place.

Fructus Corni
(山茱萸, Shanzhuyu)

Asiatic Cornelian Cherry Fruit

Asiatic Cornelian Cherry Fruit is the dried ripe sarcocarp of *Cornus officinalis* Sieb. et Zucc. (Fam. Cornaceae). The fruit is collected in later autumn and early winter when the pericarp turns red, baked over a soft fire or treated with boiling water for a moment, removed from kern in time and dried.

Description Irregularly flaky or bladdery, 1 ~ 1.5 cm long and 0.5 ~ 1 cm wide. Externally purplish-red to purplish-black, shrunken, lustrous. Sometimes with a rounded scar of persistent calyx at the apex and a scar of fruit stalk at the base. Texture soft. Odour, slight; taste, sour, astringent and slightly bitter.

Identification Powder: Raddish-brown. Epidermal cells of pericarp polygonal or subrectangular in surface view, 16 ~ 30 μm in diameter, anticlinal walls beaded, outer periclinal walls granularly cutinized and thickened, lumen containing pale orange-yellow contents. Cells of emsocarp orange-brown, mostly shrunken. Clusters of calcium oxalate rare 12 ~ 32 μm in diameter. Stone cells subsquare, ovoid or rectangular, pits obvious and with a large lumen.

Foreign matter (kerns and fruit stalks) Not more than 3% (Appendix IX A).

Assay Place about 1 g of the coarse powder, accurately weighed, in a Soxhlet's extractor, heat under reflux with a quantity of ether for 4 hours. Recover ether from the extract and evaporate to dryness. Macerate the residue with two quantities, each of 15 ml, of petroleum ether (30 ~ 60℃) for about 2 minutes each time, discard the petroleum ether solution, dissolve the residue in a solution of dehydrated ethanol-chloroform (3 : 2) by gentle heat. Transfer the solution to a 5 ml volumetric flask, dilute to volume, shake well, used as the test solution. Dissolve ursolic acid CRS, weighed accurately, in dehydrated ethanol to produce a solutin containing 0.5 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 cyclohexane-chloroform-ethyl acetate (20 : 5 : 8) as the mobile phase. Apply separately 5 μl and 10 μl of the test solution, and 4 μl and 8 μl of the reference solution to the plate. After developing and removal of the plate, dry it in air, spray with a 10% solution of sulfuric acid in ethanol, heat at 110℃ for 5 ~ 7 minutes until purplish-red spots appear. Cover the plate with a piece of glass of the same size, and fix with tape. Carry out the method for thin layer chromatography (thin layer chromatographic scanning method) (Appendix VI B), scan at the wavelengths of λ_S 520 nm and λ_R 700 nm. Determine the integral absorbence value of the test solution and reference solution respectively, and calculate the content of ursolic acid. It contains not less than 0.2% of ursolic acid ($C_{30}H_{48}O_3$).

Processing *Pulp of Fructus Corni* Eliminate foreign matter and remained kerns.

Pulp of Fructus Corni (processed with wine) Stew or steam the pulp of Fructus Corni as described under the method for stewing with wine or steaming with wine (Appendix II D) until the wine is absorbed entirely.

Action To replenish the *liver* and *kidney*, restrain seminal discharge and relieve collapse.

Indications Dizziness, tinnitus, soreness in the loins and knees, impotence, seminal emission, enuresis, frequency of urination, excessive uterine bleeding and leukorrhea; collapse with profuse sweating; diabetes.

Usage and dosage 6～12 g.

Storage Preserve in a dry place, protected from moth.

Fructus Crataegi (山楂, Shanzha)

Hawthorn Fruit

Hawthorn Fruit is the dried dripe fruit of *Crataegus pinnatifida* Bge. var *major* N. E. Br., or *Crataegus pinnatifida* Bge. (Fam. Rosaceae). The drug is collected in autumn when ripe, cut into slices, and dried.

Description Rounded slices shrunken and uneven, 1—2.5 cm in diameter, 2—4 mm thick. Externally red, wrinkled, with small greyish-white spots. Pulp dark yellow to pale brown. Transverse slices of the middle part showing 5 pale yellow kerns, mostly fallen off, and loculi hollowed. Some slices exhibiting a slender fruit stalk or remains of calyx. Odour, slightly aromatic; taste, sour and slightly sweet.

Assay Soak about 1 g of the fine powder, accurately weighed, in 100 ml of water, accurately measured, for 4 hours with occasional shaking, and filter. Determine the water content of the above powder (Appendix Ⅸ H, method 1) with another sample. To 25 ml of the filtrate, accurately measured, add 50 ml of water, 2 drops of phenolphthalein IS, titrate with sodium hydroxide (0.1 mol/L) VS and calculate the content. Each ml of sodium hydroxide (0.1 mol/L) VS is equivalent to 6.404 mg of $C_6H_8O_7$.
It contains not less than 5.0% of organic acids, calculated as citric acid ($C_6H_8O_7$), on the dried basis.

Processing *Fructus Crataegi* Eliminate foreign matter and fallen kernels.

Fructus Crataegi (stir-fried) Stir-fry the clean Fructus Crataegi as described under the method for simple stir-frying (Appendix Ⅱ D) until darkens in colour.

Fructus Crataegi (charred) Stir-fry the clean Fructus Crataegi as described under the method for simple stir-frying (Appendix Ⅱ D) until it becomes burnt-brown externally and yellowish-brown internally.

Action To stimulate digestion and promote the functional activity of the stomach; to improve the normal flow of *qi* and dissipate *blood stasis*.

Indications Stagnation of undigested meat with epigastric distension, diarrhea and abdominal pain; amenorrhea due to *blood stasis*, epigastric pain or abdominal colic, after childbirth; hernial pain; hyperlipemia.
Fructus Crataegi (charred): Has more digestant action and is particularly useful for stagnation of undigested meat and diarrhea with inadequate discharge from the bowels.

Usage and dosage 9—12 g.

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

Fructus Crotonis (巴豆, Badou)

Croton Fruit

Croton Fruit is the dried ripe fruit of *Croton tiglium* L. (Fam. Euphorbiaceae). The drug is collected in autumn when ripe, piled up for 2—3 days, spread out, and dried.

Description Ovoid, usually 3-ribbed, 1.8～2.2 cm long, 1.4～2 cm in diameter. Externally greyish-yellow or slightly deep, with 6 longitudinal lines, apex truncate, base with a fruit stalk scar, 3 loculi in the shell each containing 1 seed. Seed slightly flattened-elliptical, 1.2—1.5 cm long, 7～9 mm in diameter; Externally brown or greyish-brown, with a pointed hilum and a caruncle scar at one end, a slightly dented chalaza at other end, and a raphe between two ends; testa thin and brittle, tegmen white, membranous; kernels yellowish-white, oily. Odourless; taste pungent.

Identification Macerate about 0.5 g of the coarse powder in 10 ml of ether for 2 hours with constant shaking, filter. Evaporate the filtrate to dryness in a test tube, add 0.5 of saturated solution of hydroxylamine hydrochloride in methanol and 1 drop of thymolphthalein IS, add saturated solution of potassium hydroxide in methanol until a blue colour is produced, then an excess of 4 drops, boil and cool. Adjust the pH value to 2～3 by adding dilute hydrochloric acid solution, add 3 drops of ferric chloride TS and 1 ml of chloroform, shake; a purplish-red colour is produced in the lower layer.

Processing *Fructus Crotonis* Remove the coats to take the kernels.

Action To cause cauterization by external use.

Indications Malignant ulcer, scabies, wart.

Usage and dosage Appropriate quantity to be ground into powder for topical application or pounded into paste and wrapped in a piece of gauze for rubbing onto the affected skin.

Storage Preserve in a cool and dry place.

Fructus Evodiae (吴茱萸, Wuzhuyu)

Medicinal Evodia Fruit

Medicinal Evodia Fruit is the dried and nearly ripe fruit of *Evodia rutaecarpa* (Juss.) Benth., *Evodia rutaecarpa* (Juss.) Benth. var. *officinalis* (Dode) Huang or *Evodia rutaecarpa* (Juss.) Benth. var. *bodinieri* (Dode) Huang (Fam. Rutaceae). The fruit spur is cut off from August to November when the fruit indehiscent, dried in the sun or at a low temperature, removed from shoot, leaf, fruit stalk and foreign matter.

Description Spheroidal or slightly falttened-pentagon spheroidal, 2—5 mm in diameter. Externally dark yellowish-green to brown, rough, with numerous spotted protrudings or depressed oil dots. A pentagon-stellate cleft present at

Anemone raddeana Regel (Fam. Ranunculaceae). The drug is collected in summer, removed from rootelet, washed clean, and dried.

Description Long subfusiform, acute and pointed at two ends, slightly curved and one end somewhat expanded, 1～3 cm long, 2～7 mm in diameter, Externally brown to brownish-black, with fine longitudinal wrinkles, the expanded portion usually possessing 1～3 rootlet scars appearing finned-protruding, occasionally with 3～5 indistinct annulations. Texture hard and fragile, easily broken, fracture slightly even, whitish or greyish-brown, almost horny. Odourless; taste, weak and then slightly bitter and pungent.

Identification (1) Transverse section: Epidermis consisting of 1 row of cells, tangentially elongated, outer walls thickened. Cortex of 10 or more rows of subrounded parenchymatous cells. Vascular bundles collateral, 10 or more ones arranged in a ring, phloem cells shrunken, xylem vessels 6～24, cambium ring indistinct. Rays broad, pith relatively large and composed of subrounded parenchymatous cells. Parenchymatous cells filled with starch granules.
Powder: Greyish-brown. Starch granules numerous, simple granules subrounded or elliptical, 2～11 μm in diameter, hilum pointed or shortly cleft-like, striations indistinct; compound granules of 2～4 components. Epidermal cells reddish-brown, yellow or bright yellow, the outer walls suberized and thickened, frequently protruding into the cell to be ridge-like or tubercular. Reticular, spiral or scalariform vesseles more frequent, 10～33 μm in diameter, some with bordered pitted vessels.
(2) Warm 2 g of the coarse powder in 10 ml of methanol on a water bath, shake for 10 minutes and filter. To 2 ml of the filtrate add 2 ml of 1% solution of sodium hydroxide and heat on a water bath for 3 minutes. The solution shows a clear bright yellow colour; acidify with 1% hydrochloric acid solution, the bright yellow colour disappears and a turbid milk white colour is produced.
(3) Boil gently 1 g of the coarse powder with 10 ml of 70% ethanol on a water bath for 10 minutes and filter. Evaporate 2 ml of the filtrate to dryness and dissolve the residue in 1 ml of acetic anhydride. Add slowly sulfuric acid along the wall; a purplish colour is produced at the junction of the layers. The upper layer shows a dark green colour on standing.

Action To relieve rheumatic conditions, and to cure carbuncle.

Indications Rheumatoid arthritis with muscular contracture and joint pain; carbuncle with ulceration.

Usage and dosage 1.5～3 g; appropriate quantity for external use.

Storage preserve in a cool and dry place.

Rhizoma Alismatis (泽泻, Zexie)

Oriental Waterplantain Rhizome

Oriental Waterplantian Rhizome is the dried tuber of *Alisma orientalis* (Sam.) Juzep. (Fam. Alismataccae). The drug is collected in winter when the stem and turn withering, washed clean, dried, and removed from the fibrous root and coarse outer tissue.

Description Subspherical, elliptical or ovate, 2～7 cm long, 2～6 cm in diameter. Externally yellowish-white or yellowish-brown, with irregualr transverse-annular shallow furrows and numerous small raised fibrous root scars, occasionally tuberculate bud scars attached to the base. Texture compact, fracture yellowish-white, starchy, with numerous small pores. Odour, slight; taste, slightly bitter.

Identification Powder: Yellowish-brown. Starch granules numerous, simple granules long-ovoid, subspherical or ellipsoid, 3～14 μm in diameter, hilum V-shaped, shortly slit-shaped or Y-shaped; compound granules of 2～3 components. Parenchymatous cells subrounded, with many elliptical pits crowded into pitted areas. Anticlinal walls of endodermis cells sinuous, somewhat relatively thick, lignified, with sparse and minute pit-canals. Oil cavities mostly broken, whole ones subrounded, 54～110 μm in diameter, sometimes oil drops contained in secretory cells visible.

Total ash Not more than 5% (Appendix Ⅸ K).

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

Processing *Rhizoma Alismatis* Eliminate foreign matter, soak briefly, soften thoroughly, cut into thick slices, and dry.

Rhizoma Alismatix (Processed with salt) Stir-fry the slices of Rhizoma Alismatis as described under the method for stir-frying with salt-water (Appendix Ⅱ D) to dryness.

Action To cause diuresis, and to remove *damp-heat*.

Indications Edema with oliguria; diarrhea with diminished discharge of urine; vertigo due to retention of fluid; acute urinary infection with difficult painful urination; hyperlipemia.

Usage and dosage 6～9 g.

Storage Preserve in a dry place, protected from moth.

Rhizoma Alpiniae Officinarum (高良姜, Gaoliangjiang)

Lesser Galangal Rhizome

Lesser Galangal Rhizome is the dried rhizome of *Alpinia officinarum* Hance (Fam. Zingiberaceae). The drug is collected at the end of summer and the beginning of autumn, removed from fibrous root and remaining leaf scales, washed clean, cut into sections, and dried in the sun.

Description Cylindrical, often curved and branched, 5～9 cm long, 1～1.5 cm in diameter. Externally brownish-red to dark brown, with fine, numerous longitudinal wrinkles and grayish-brown sinuous, annular nodes, each node 0.2～1 cm long, bearing round root scars at the lower part. Texture hard and tenacious, uneasily broken, fracture greyish-brown or reddish-brown, fibrous. Stele occupying about 1/3 area of the rhizome. Odour, aromatic; taste, pungent.

Identification Transverse section: The outer walls of epidermal cells thickened, some cells containing reddish-brown non-crystalline masses. Vascular bundles of leaf trace relatively abundant in cortex, collateral. Endodermis distinct. Collateral vascular bundle numerous in stele, vascular bundle sheath fibres arranged in a ring and lignified. Secretory cells abundantly scattered in parenchyma of cortex and stele, containing yellow or reddish-brown resinous con-

Pollen Typhae
(蒲黄, Puhuang)

Cattail Pollen

Cattail Pollen is the dried pollen of *Typha angustifolia* L., *Typha orientalis* Presl or other plants of the same genus (Fam. Typhaceae). Yellow male inflorescence is gathered in summer, dried in the sun and ground. The drug is collected by sifting.

Description Yellow powder. Texture light, capable of floating on water, with satiny feeling when twisted and easily adsorbed on fingers. Odour, slight; taste, weak.

Identification (1) Powder: Yellow. Pollen grains subrounded or elliptical, 17～29 μm in diameter, exine with reticulate sculptures, single pore indistinct.
(2) Macerate warmly 0.1 g of powder in 5 ml of ethanol, on a water bath and filter. To 1 ml of the filtrate add a small quantity of magnesium powder and 2～3 drops of hydrochloric acid; a cherry red colour is produced.
(3) Macerate warmly 0.2 g in 10 ml of water, on a water bath and filter. To 1 ml of the filtrate add 1 drop of ferric chloride TS: a pale greenish-brown colour is produced.

Foreign matter Not more than 10% (Appendix Ⅸ A).

Processing *Pollen Typhae (unprocessed)* Pulverize and sift.

Pollen Typhae (carbonized) Stir-fry the clean Pollen Typhae as described under the method for carbonizing by stir-frying (Appendix Ⅱ D) until it becomes brown in colour.

Action To arrest bleeding, to remove *blood stasis*, and to relieve dysuria.

Indications Hematemesis, epistaxis, hemoptysis, abnormal uterine bleeding, traumatic bleeding; amenorrhea, dysmenorrhea, pricking pain in the epigastrium, traumatic swelling and pain; dysuria with difficult painful passage of bloody urine.

Usage and dosage 5～9 g; for external use, appropriate quantity to be applied topically.

Precaution Used with caution in pregnancy.

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

Polyporus
(猪苓, Zhuling)

Chuling

Chuling is the dried sclerotium of *Polyporus umbellatus* (Pers.) Fires (Fam. Polyporaceae). The drug is collected in spring and autumn, removed from soil, and dried.

Description Strip-shaped, subrounded or compressed-lumped, sometimes branched, 5～25 cm long, 2～6 cm in diameter. Externally black, greyish-black or brownish-black, crumpled or warty. Light. Texture, hard, fracture whitish or yellowish-white, somewhat granular. Odour, slight; taste, weak.

Identification (1) Section: All consisting of densely interweaved hyphae. The outer layer 27～54 μm thick, hyphae brown, uneasily separated; the inner hyphae colourless, sinuous, 2～10 μm in diameter, sometimes septa visible, with branches or tubercular swellings. Numerous prisms of calcium oxalate among the hyphae, mostly in octahedron cubes, regular double-conical octahedrons or irregular polyhedrons, 3～60 μm in diameter, up to 68 μm long, sometimes with several crystals aggregated.
(2) Boil 1 g of the powder with 10 ml of dilute hydrochloric acid on a water bath for 15 minutes, and stir; a viscose is produced. To a small quantity of powder, add a quantity of sodium hydroxide solution (1→5) and stir; a suspension is produced.

Total ash Not more than 12.0% (Appendix Ⅸ K).

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

Action To induce diuresis and remove *damp*.

Indications Oliguria, edema, diarrhea, dysuria, excessive leukorrhea.

Usage and dosage 6～12 g.

Storage Preserve in a ventilated and dry place.

Poria
(茯苓, Fuling)

Indian Bread

Indian Bread is the dried sclerotium of the fungus, *Poria cocos* (Schw.) Wolf (Fam. Polyporaceae). The drug is collected mostly in July to September, removed from soil, piled up, spread, and air-dried on the surface. Repeat this operation for several times until wrinkles appears and the inside water evaporated, then dried in the shade. It is known as "Fulingge". Or the fresh sclerotium is cut and dried in the air. According to the cut portions, and known as "Fulingpi" and "Fulingkuai", respectively.

Description *Fulingge* Subglobose, ellipsoid, oblate or irregular-shaped, variable in size. The outer skin thin and rough, brown to blackish-brown, conspicuously shrivelled and striated. Texture hard and compact, fracture granular, some cracked, the outer layer pale brown, inner part white, rarely reddish, some showing the penetrating roots of pine in the centre. Odourless; taste, weak and sticky when chewed.

Fulingpi (pared skin of Poria) variable in form and size. Externally brown to blackish-brown, internally white or pale brown. Relatively loose and soft, slightly elastic.

Fulingkuai (peeled and sliced Poria) occurring in pieces or slices, variable in size. White, pale red or pale brown.

Identification (1) Powder: Greyish-white. Irregularly granular masses and branched masses colourless, dissolved gradually on mounting in chloral hydrate solution. Hyphae colourless or pale brown, slender, slightly curved, branched, 3～8 μm (rarely up to 16 μm) in diameter.
(2) Heat under reflux 1 g of the powder in 10 ml of acetone for 10 minutes, filter. Evaporate the filtrate to dryness, dissolve the residue in 1 ml of glacial acetic acid, add 1 drop of sulfuric acid; a pale red colour is produced.

which turns to pale brown colour.
(3) To a few slices or small quantity of powder add 1 drop of iodine potassium idodide TS, a deep red colour is produced.

Processing Soak Poria in water, wash clean and steam briefly after softened. Cut into the skin, pieces, and thick slices separately in time, and then dry.

Action To cause diuresis, to invigorate the *spleen* function, and to calm the mind.

Indications Edema with oliguria; dizziness and palpitation caused by retained fluid; diminished function of the *spleen* marked by anorexia, loose stools or diarrhea; restlessness and insomnia.

Usage and dosage 9～15 g.

Storage Preserve in a dry place, protected from moisture.

Pseudobulbus Cremastrae seu Pleiones
(山慈菇, Shancigu)

Appendiculate Cremastra Pseudobulb or Common Pleione Pseudobulb

Appendiculate Cremastra Pseudobulb or Common Pleione Pseudobulb is the dried pseudobulb of *Cremastra appendiculata* (D. Don) Makino, *Pleione bulbocodioides* (Franch.) Rolfe or *Pleione yunnanensis* Rolfe (Fam. Urchidaceae). The former is known as "Maocigu", and the latter two are known as "Bingqiuzi". The drug is collected in summer and autumn, removed from the aerial part and soil, sorted according to size, steamed thoroughly with boiling water, and dried.

Description *Maocigu* Irregularly oblate or conical, top gradually protruding, base with rootlet scars. 1.8～3 cm long, the swollen part 1～2 cm in diameter. External yellowish-brown or brown, with longitudinal wrinkles and furrows, and exhibiting 2～3 slight prominents, ringed nodes with remainings of some filiform fibres, derived from the withering and decaying scaly leaves. Texture hard, not easily broken, fracture greyish-white or yellowish-white, slightly horny, Odour, Slight; taste, weak and sticky.

Bingqiuzi Conical, bottleneck-like or irregular masses, 1～2 cm in diameter, 1.5～2.5 cm high. Top acuminate, the broken tip dish-shaped, base swollen and rounded-flattened, dented at middle, with 1～2 ringed nodes, mostly inclined to one side. Externally yellowish-white for the peeled drug and brownish for the unpeeled, smooth with irregular wrinkles. Fracture yellowish, horny and translucent.

Identification Transverse section: *Maocigu* The outermost consisting of a layer of flattened epidermal cells, 2～3 layers of sclerenchymatous cells beneath, yellowish, the innermost consisting of large subrounded parenchymatous cells containing mucilage and starch granules. Parenchymatous cells near the epidermis containing raphides of calcium oxalate, 70～150 μm long. Vascular bundles scattered, collateral.

Bingqiuzi Epidermal cells tangentially elongated, starch granules occurring in small parenchymatous cells, vascular bundle sheath fibres crescent, occasionally double-crescent.

Processing Eliminate foreign matter, soak for about 1 hour, soften thoroughly, cut into thin slices, and dry, or dry after washing. Pound to pieces before use.

Action To remove toxic *heat*, and to dissolve lumps.

Indications Carbuncles, boils, tuberculosis of cervical lymph nodes; snake and insect-bite.

Usage and dosage 3～9 g; appropriate quantity for external use.

Storage Preserve in a dry place.

Pulvis Cornus Bubali Concentratus
(水牛角浓缩粉,Shuiniujiao Nongsuofen)

Condensed Buffalo Horn Powder

Condensed Buffalo Horn Powder is the semi-condensed powder of Cornu Bubali.

Procedure Take Cornu Bubali, wash clean, cut with a saw, eliminate the bony plug, split into small pieces, Select the solid tip part which is commonly known as "Jiaojian" (horn tip), immerse in 70% ethanol or sterilize with steam, then pulverize to fine powder. Break the rest which is commonly known as "Jiaozhuang"(horn stake) to coarse granules or thin slices. Decoct 810 g of coarse granules or slices of the horn stake with 10 times of water twice for 7～10 hours each time, supplement the evaporated water during decocting. Combine the decoctions and filter. Concentrate the filtrate to 80～160 ml, add 190 g of the fine powder of horn tip, mix well, dry below 80℃, pulverize to fine powder, and sift.

Description Pale greyish powder. Odour, slightly stinking; taste, slightly salty.

Water Carry out the method for the determination of water (Appendix Ⅸ H, method 1), not more than 11.0%.

Action and indications As described under Corni Bubali.

Usage and dosage 1.5～3 g, 2 times a day.

Storage Preserve in well closed containers, stored in a dry place, protected from moisture.

Pulvis Talci
(滑石粉, Huashifen)

Talc Powder

Talc Powder is a powder prepared from Talc by sorting, cleaning, pulverizing and drying.

Description A white or almost white, fine, sandless powder, unctuous to the touch. Odourless and tasteless. Insoluble in water and dilute solutions of mineral acid or alkali hydroxide.

Identification Complies with tests for Identification described under Talc.

Acidity or alkalinity Boil 10 g of powder with 50 ml of water for 30 minutes, supplement the water lost in evaporation frequently cool, filter, the filtrate is neutral to litmus paper.

Cortex Cinnamomi
(肉桂, Rougui)

Cassia Bark

Cassia Bark is the dried stem bark of *Cinnamomum cassia* Presl (Fam. Lauraceae). The drug is frequently collected in autumn, and dried in the shade.

Description Channelled or quilled, 30～40 cm long, 3～10 cm wide or in diameter, 2～8 mm thick. Outer surface greyesh-brown, slightly rough, with irregular fine wrinkles and transverse raised lenticels, some showing greyish-white streaks; inner surface reddish-brown, somewhat even, with fine longitudinal striations and exhibiting oily trace on scratching. Texture hard and fragile, easily broken, fracture uneven, outer layer brown and relatively rough, inner layer reddish-brown and oily and showing a yellowish-brown line between two layers. Odour, strongly aromatic; taste, sweet and pungent.

Identification (1) Transverse section: Cork cells several layers, the innermost layer of cells with thickened and lignified outer walls. Cortex scattered with stone cells and secretory cells. Pericycle stone cells in groups arranged in an interrupted ring, accompanied by fibre bundles at outer side, the outer walls of stone cells usually thinner. Phloem rays 1～2 rows of cells wide, containing minute needle crystals of calcium oxalate; usually 2～3 fibres in bundles; oil cells scattered throughout. Parenchymatous cells containing starch granules.
Powder: Reddish-brown. Most of fibres singly scattered, long fusiform, 195～920 μm long, up to 50 μm in diameter, walls thickened and lignified, pits indistinct. Stone cells subsquare or subrounded, 32～88 μm in diameter, walls thickened, some thin at one side. Oil cells subrounded or oblong, 45～108 μm in diameter. Needle crystals minute, scattered in ray cells. Cork cells polygonal, containing reddish-brown contents.
(2) Macerate 0.5 g of the powder with 10 ml of ethanol for 20 minutes with constant shaking in a stoppered flask and filter, use the filtrate as the test solution. Dissolve cinnamic aldehyde CRS in ethanol to produce a solution containing 1 μl per ml as the reference solution. Carry out the method for thin layer chromatography (Appendix ⅥB), using silica gel G as the coating substance, and petroleum ether (60—90℃)-ethyl acetate (85:15) as the mobile phase. Apply separately to the plate 2～5 μl of the test solution and 2 μl of the reference solution. After developing and removal of the plate, dry it in air, spray with ethanolic 2,4-dinitrophenyhydrazine 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.

Water Carry out the method for determination of water (Appendix ⅨH, method 2,), not more than 15.0%.

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

Processing Eliminate foreign matter and rough bark. Pound to pieces before use.

Action To supplement body *fire*, reinforce *yang*, and lead the *fire* back to the *kidney*, to dispel cold and relieve pain, and to activate blood circulation and stimulate menstrual discharge.

Indications Impotence, frigidity, feeling of coldness and pain in the loins and knees; dyspnea in *deficiency* syndrome of the *kidney*; dizziness, inflammation of the eye and sore throat due to *yang deficiency*; precordial and abdominal pain with cold sensation, vomiting and diarrhea in *deficiency-cold* syndromes; neurosis with a feeling of gas rushing up through the chest to the throat from the lower abdomen; amenorrhea, dysmenorrhea.

Usage and dosage 1～4.5 g.

Precaution Used with caution in patients with bleeding tendency or pregnancy. Incompatible with Halloysitum Rubrum.

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

Cortex Dictamni
(白鮮皮, Baixianpi)

Densefruit Pittany Root-bark

Densefruit Pittany Root-bark is the dried root bark of *Dictamnus dasycarpus* Turcz. (Fam. Rutaceae). The root is collected in spring and autumn, removed from soil and rough bark. The root bark is stripped off and dried.

Description Quilled, 5～15 cm long, 1～2 cm in diameter, 2～5 mm thick. Outer surface greyishp-white or pale greyish-yellow, with fine longitudinal wrinkles and rootlet scars, frequently with protruding small granular dots; inner surface whitish, with fine longitudinal wrinkles. Texture fragile, dusting on breaking, fracture uneven and somewhat lamellar, when outer layer peeled off, numorous glitter small spots observed on exposuring to light. Odour, muttony; taste, slightly bitter.

Identification Transverse section: Cork cells 10 or more rows. Cortex narrow, fibres mostly scattered singly, yellow, 25—100 μm in diameter, walls thickened and obviously striated. Phloem broad, rays 1～3 rows of cells in width; fibres singly scattered. Parenchyma containing abundant clusters of calcium oxalate, 5～30 μm in diameter.

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

Action To remove *damp-heat* detoxicating and dispel *wind*.

Indications Skin inflammation with yellowish watery discharge, eczema, rubella, tinea, scabies; acute rheumatic arthritis; jaundice with dark urine.

Usage and dosage 4.5—9 g; for external use, appropriate quantity to be decocted for washing or ground into powder for topical application.

Storage Preserve in a ventilated and dry place.

Cortex Eucommiae
(杜仲, Duzhong)

Eucommia Bark

Eucommia Bark is the dried stem bark of *Eucommia ulmoides* Oliv. (Fam. Eucommiaceae). The drug is collected from April to June.

Radix Aconiti Kusnezoffii Preparata (制草乌, Zhicaowu)

Prepared Kusnezoff Monkshood Root

The drug is the processed Radix Aconiti Kusnezoffii.

Procedure Grade clean Radix Aconiti Kusnezoffii according to size. Macerate it in water until there is no dry core. Take them out, boil in water until there is no white core in the larger root and the taste becomes slightly numb. After removal, allow it to dry in air appropriately, then cut into slices, and dry.

Description Irregularly rounded or nearly triangular slices. Externally dark brown, with a greyish-white polyangular cambium ring, dotted vascular bundles and clefts; the edges wrinkled or curved. Texture fragile. Odourless; taste, slightly pungent and numb.

Identification Complies with test (2)for Identification described under Radix Aconiti Kusnezoffii.

Diester-alkaloids Complies with the test for diester-alkaloids described under Radix Aconiti Preparata.

Assay Carry out the Assay described under Radix Aconiti Preparata, it complies with the requirements.

Action and indications As described under Radix Aconiti Kusnezoffii.

Usage and dosage 1.5～3 g; to be decocted for a long time before adding other ingredients.

Precaution, Storage As described under Radix Aconiti Preparata.

Radix Aconiti Lateralis Preparata (附子, Fuzi)

Prepared Common Monkshood Daughter Root

Prepared Common Monkshood Daughter Root is the processed daughter root of *Aconitum carmichaeli* Debx. (Fam. Ranunculaceae). The drug is collected in late June to early August, removed from the parent root, rootlet and soil. It is known as "Ni Fuzi", which can be processed into the following commercial varieties:

(1) Select the large and uniform Ni Fuzi, wash clean and soak over night in edible mother liquor of mineral salt preparation. Add salt, soak and take it out to sun-dry and air-dry every day. Gradually prolong the time for dryness until a lot of salt is crystallized on the surface of the drug and its texture becomes hard. It is known as "Yan Fuzi".

(2) Grade Ni Fuzi according to size, wash clean and soak in edible mother liquor of mineral salt preparation for several days. Boil in the infusion thoroughly. Take out, rinse in water, cut longitudinally into slices about 0.5 cm in thickness. Soak and rinse in water once again. Stain the slices dark brown and steam them until the slices turn to be oily and lustrous. Bake the slices to half-dryness, and then sun-dry or bake to complete dryness. It is known as "Hei Shunpian".

(3) Select the Ni Fuzi of uniform size, wash clean and soak in edible mother liquor of mineral salt preparation for several days, Boil in the infusion thoroughly. Take out, peel the bark and cut longitudinally into slices about 0.3 cm in thickness. After soaking and rinsing in water, take out, steam thoroughly, sun-dry to half-dryness, fume with sulfur and sun-dry completely. It is known as "Bai Fupian".

Description *Yan Fuzi (Salted Aconite Daughter Root)* Conical, 4～7 long, 3～5 cm in diameter. Externally greyish-black, covered with fine powder of salt, topped with depressed bud scars and encircled with tubercled short rootlets or rootlet scars. Texture heavy. Transversely cut surface greyish-brown, showing small clefts filled with fine powder of salt and a polyangular cambium ring, and vascular bundles arranged irregularly inside the ring. Odour, slight; taste, salty, numb and pungent.

Hei Shunpian (Black Slice) Longitudinal slices, the upper portion wide and the lower portion narrow, 1.7～5 cm long, 0.9～3 cm wide, 0.2～0.5 cm thick. The outer bark blackish-brown, cut surface dark yellow, oily and lustrous, translucent and showing longitudinal vascular bundles. Texture hard and fragile. Fracture horny. Odour, slight, taste, weak.

Bai Fupian (White Slice) Without outer bark, yellowish-white, translucent, about 3 mm thick.

Identification To 4 g of the coarse powder of Hei Shunpian or Bai Fupian add 30 ml of ether and 5 ml of ammonia TS, shake for 20 minutes, filter. Transfer the filtrate to a separator, extract with 20 ml of sulfuric acid solution (0.25 mol/L), separate the acid solution. Carry out the method for spectrophotometry (Appendix V A), the light absorption exhibits maxima at 231 nm and 274 nm.

Limit test for Aconitine Weigh 20 g of the coarse powder of Hei Shunpian, Bai Fupian or Dan Fupian to a stoppered conical flask, add 150 ml of ether, shake for 10 minutes, then add 10 ml of ammonia TS, shake for 30 minutes, allow to stand for 1～2 hours. Evaporate the ether layer to dryness. Dissolve the residue in 2 ml of dehydrated ethanol as the test solution. Dissolve aconitine CRS in dehydrated ethanol 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 alkaline aluminium oxide as the coating substance and *n*-hexane-ethyl acetate (1:1) as the mobile phase. Apply separately to the plate 6 μl of the test solution and 5 μl of the reference solution. After developing and removal of the plate, spray with a mixture of two equal volumes of potassium iodide-iodine TS and potassium iodobismuthate TS. The size of the spot in the chormatogram obtained with the test solution is less than the corresponding spot in the chromatogram obtained with the reference solution, or no spot reveals in the chromatogram obtained with the test solution.

Processing *Fapian* "Hei Shunpain" and "Bai Fupian" are used directly.

Dan Fupian Blanch "Yan Fuzi" with water, 2～3 times a day until all salt is rinsed out. Boil together with Radix Glycyrrhizae, black beans and water until the centre of the cut surface is devoid of white core and the cut slice is numb-

less to the tongue. Remove Radix Glycyrrhizae and black beans, cut the drug into slices, and dry.
To each 100 kg of "Yan Fuzi", add 5 kg of Radix Glycyrrhizae and 10 kg of black beans.

"Fupian" (Processed) Scald "Fupian" with sand as described under the method for scalding (Appendix Ⅱ D) until it is inflated and slightly discoloured.

Action To cause restoration from collapse, to supplement body *fire* and reinforce *yang*, and to dispel *wind*, *cold* and *damp*.

Indications Collapse with cold limbs and faint pulse; impotence, frigidity; precordial and abdominal pain with *cold* sensation; vomiting and diarrhea or edema accompanied by aversion to cold and cold extremities; colds in patients with *yang deficiency*; chronic arthritis due to attack of *cold* and *damp* (marked by persistent severe joint pain, fixed in place and accompanied by heaviness sensation and numbness).

Usage and dosage 3～15 g.

Precaution Contraindicated in pregnancy. Incompatible with Rhizoma Pinelliae, Fructus Trichosanthis, Bulbus Fritillariae and Rhizoma Bletillae.

Storage Preserve "Yan Fuzi" in well closed containers, stored in a cool and dry place. Preserve "Hei Fupian" and "Bai Fupian" in a dry place, protected from moisture.

Radix Aconiti Preparata
(制川乌, Zhichuanwu)

Prepared Common Monkshood Mother Root

The drug is the processed Radix Aconiti.

Procedure Grade clean Radix Aconiti according to size, macerate in water until there is no dry core. Take them out, boil in water for 4 to 6 hours (or steam for 6 to 8 hours) until there is no white core in the relatively large and solid root and the taste becomes slightly numb. After removal, dry in the air appropriately, cut into slices, and dry.

Description Irregular or elongated triangular slices. Externally dark brown or yellowish-brown, with a greyishbrown cambium ring. Texture light and fragile, fracture lustrous. Odourless, taste, slightly numb.

Identification Complies with test (2) for Identification described under Radix Aconiti.

Diester alkaloids *Reference preparation* Weigh accurately 20 mg of aconitine CRS to a 10 ml volumetric flask, add dehydrate ethanol to dissolve, and dilute to the volume.

Preparation of calibration curve Transfer accurately 0, 0.25, 0.50, 1.0, 1.5, 2.0, 2.5 ml of the reference solution to 25 ml volumetric flask respectively, add dehydrate ethanol to 2.5 ml, add accurately 1.5 ml of alkaline hydroxylamine hydrochloride TS, respectively, and mix well. Warm on a water bath at 60－65℃ for 10 minutes and allow to cool. Add 13 ml of ferric perchlorate TS, mix well, and stand for 5 minutes. Then add accurately 8 ml of perchloric acid TS, dilute with ferric perchlorate TS to volume, mix well, and allow to stand for 15 minutes. Carry out the method for spectrophotometry (Appendix Ⅴ B), using the first solution as the blank, measure the absorbance at 520 nm, and prepare the calibration curve with the absorbance as ordinate and the concentration as abscissa.

Procedure weigh accurately 10 g of the coarse powder to a stoppered conical flask, add 50 ml of ether and 4 ml of ammonia TS, stopper, shake thoroughly, allow to stand over night, and filter. The drug residue is shaken with 50 ml of ether for 1 hour, and filter. Wash the residue with 3～4 quantities, each of 15 ml, of ether, and filter. Combine the filtrate and washings, and evaporate to dryness at a lower temperature. Dissolve the residue in 2 ml of chloroform, and transfer to a separator. Wash the container with several quantities of 3 ml of chloroform, and transfer the washings to the separator. Extract with 3 quantities of 5 ml of sulfuric acid (0.05 mol/L). Wash the acid solution with the same 10 ml of chloroform, successively combine the acid solution, adjust to pH 9 with ammonia TS, and extract with 3 quantities, each of 10 ml, of chloroform, wash the chloroform solution with the same 20 ml of water successively, combine the chloroform solution, evaporate to dryness at a lower temperature. Dissolve the residue in a quantity of dehydrate ethanol, transfer the solution to a 5 ml volumetric flask, wash the container several times with dehydrate ethanol, combine the washings to the volumetric flask, dilute with dehydrated ethanol to volume, mix well. Transfer accurately 2.5 ml of each of the above solution and dehydrate ethanol used as blank solution, separately to 25 ml volumetric flask. Measure the absorbance, as described under calibration curve preparation, beginning at the words "add accurately 1.5 ml of alkaline hydroxylamine hydrochloride TS", Read and calculate the weight (μg) of diester-alkaloids in the test solution from the calibration curve.
It contains not more than 0.15% of diesteralkaloids, calculated as aconitine ($C_{34}H_{47}NO_{11}$), on the dried basis.

Assay Weigh accurately 10 g of the powder, and carry out the method described under procedure of Diester alkaloids, using a mixture of ether-chloroform (3:1) instead of ether, beginning at the words "add 50 ml of ether…" to "combine the filtrate and washings, evaporate to dryness at a lower temperature". Dissolve the residue in 5 ml of the mixture of ether-chloroform (3:1), evaporate to dryness. Dissolve the residue again in 5 ml of ethanol, add 15 ml of sulfuric acid (0.01 mol/L) VS, accurately measured, 15 ml of water and 3 drops of methyl red IS, and titrate with sodium hydroxide (0.02 mol/L) VS until a yellow colour is produced. Each ml of sulfuric acid (0.01 mol/L) VS is equivalent to 12.9 mg of $C_{34}H_{47}NO_{11}$.
It contains not less than 0.20% of alkaloide, calculated as aconitine ($C_{34}H_{47}NO_{11}$).

Action and Indications As described under Radix Aconiti.

Usage and dosage 1.5－3 g, to be decocted for a long time before other ingredients are added.

Precaution Used with caution in pregnancy. Incompatible with Bulbus Fritillariae, Rhizoma Pinelliae, Rhizoma Bletillae, Radix Ampelopsis, Radix Trichosanthis, Fructus Trichosanthis and Cornu Rhinoceri.

Storage Preserve in a ventilated dry place.

Radix Adenophorae
(南沙参, Nanshashen)

Fourleaf Ladybell Root

Fourleaf Ladybell Root is the dried root of *Adenophora tetraphylla* (Thunb.) Fisch. or *Adenophora stricta* Miq. (Fam. Campanu-

Appendix XVI
Explanation of Chinese Medical Terms

The following terms are used in traditional Chinese medicine and adopted in the individual monographs of crude drugs, dosage forms and Chinese patent medicines under the headings of "Action", "Indication", "Usage and dosage" and "Precaution".

blood stasis Local stoppage or slowness of the blood flow or general sluggishness of blood circulation. It is usually manifested by pricking or stabbing pain fixed in position and with tenderness, amenorrhea or diminished menstrual flow with discharge of dark blood clots, mass formation in the abdomen, dry scaly skin, purpura or ecchymosis, cyanosis of the tongue or purple dots or spots on the tongue. According to modern researches, blood stasis in traditional Chinese medicine may include the following pathological changes: ischemia, congestion, thrombosis, bleeding due to microcirculatory disturbance, inflammatory exudation, atrophy and hyperplasia, and even the formation of tumour. The principal treatment is to remove or eliminate blood stasis by activating or promoting the blood circulation.

channels and collaterals According to the theory of channels (or meridians), there exists in the human body a system of channels through which qi (vital energy) and blood circulate, and by which the internal organs are connected with the superficial organs and tissues. There are 12 regular channels (main meridians) and 8 extra channels. Collaterals are the branches of the channels. There are 15 main collaterals with subdivision of numerous secondary and tertiary collaterals. Many morbid conditions may be caused by obstruction of the collateral channels, e.g. obstruction by wind, cold and damp is believed be a common cause of arthritis with joint pain and limitation in motion, hemiplegia with numbness of the limbs is also due to obstruction in the collateral channels. Thus, removal of the obstructions from the affected collaterals is the main treatment of these morbid conditions.

cold (1) An exogenous pathogenic factor that brings on the syndrome marked by chilliness, mild fever, headache, general aching, but no sweating, when it invades the superficial portion of the body (also called wind-cold syndrome), or the syndrome marked by vomiting, abdominal pain, diarrhea, borborygmi and even shivering chills and syncope when it directly attacks the stomach and the intestines.
(2) An endogenous pathogenic factor due to deficiency of yang (vital function) that causes various morbid conditions marked by intolerance of cold, cold extremities, pale tongue with whitish coating, weak and slow pulse, also called deficiency-cold. Besides the above common features, each morbid condition caused by deficiency-cold has its own characteristics, such as relief by warmth in epigastric or abdominal pain of deficiency-cold type, difficulty in exhalation and expectoration of whitish thin sputum in dyspnea of deficiency-cold type, thin whitish discharge and discharge of pale red blood in leukorrhea and excessive menstrual flow of deficiency-cold type respectively. The principal treatment of the syndromes or morbid conditions caused by cold is to dispel cold. In case of deficiency-cold, drugs to warm the internal organs by invigorating the vital function (yang) are also necessary, but most of the drugs to dispel cold have warming effects.

cold-damp (1) Cold and damp in combination as a pathogenic fact or that causes muscle pain and arthralgia, chiefly rheumatic.
(2) A morbid condition marked by intolerance of cold, cold limbs, abdominal distention, diarrhea and edema either caused by attack of damp on the spleen resulting in lowered function of this organ (deficiency of yang) or due to deficiency of yang of the spleen and the kidney with accumulation of damp, e.g., cold-damp leukorrhea is characterized by incessant discharge of thin whitish mucus from the vagina, accompanied by lassitude, anorexia, loose bowels, aching in the lumbar regions and cold sensation in the lower abdomen.

collaterals (collateral channels) see channels and collaterals

damp (1) An exogenous pathogenic factor that causes syndromes with the following features: chills and persistent fever in spite of perspiration, headache as if the head were tightly bound, lassitude and heaviness sensation in the limbs, anorexia with feeling of stuffiness in the chest and epigastrium, and loose bowels, joint pains and swelling with sensation of heaviness, etc.
(2) Retention of water within the body caused by deficiency of yang (vital function of the spleen and the kidney, manifested by anorexia, diarrhea, abdominal distension, oliguria and edema.

damp-heat Heat and damp in combination as a pathogenic factor that causes morbid conditions usually characterized by inflammation with purulent discharges, e.g., acute urinary infection or urolithiasis accompanied by dysuria, passage of turbid urine and hematuria if it attacks the urinary bladder; acute dysentery or diarrhea with mucus and blood in the stools when it invades the large intestine; purulent leukorrhea with a foul smell or pyogenic inflammation of the leg or foot if it pours downward to the lower portion of the body. Furthermore, jaundice in acute cases is also attributed to damp-heat.

damp-warm An infectious disease prevalent in summer, marked by prolonged fever, general aching and sensation of heaviness, stuffiness in the chest and distension in the abdomen, and greasy tongue coating. Sometimes it is referred to typhoid or paratyphoid fever.

deficiency The state of being short of what is needed, especially of the functions, energy and essential materials needed for maintaining a healthy life and normal body resistance. Generally speaking, deficiency syndromes include deficiency of qi, of yang, of yin, of vital essence, and of blood.

deficiency-cold see cold.

deficiency-fire see fire.

deficiency of blood A morbid condition marked by pallor, dizziness, palpitation, insomnia, and numbness of the limbs. It roughly corresponds to anaemia, but it may also be found in other diseases (e.g. in neurosis), while a severe anaemic patient is usually deficient in both qi and blood.

deficiency of qi A general term for diminished function of the internal organs and lowered body resistance. Its common features are pallor, lassitude, listlessness, shortness of breath, spontaneous sweating, and weak pulse.

deficiency of yang A general term for lack of physiological energy of life with diminished functions, marked by pallor, intolerance of cold, cold extremities, loose bowels and feeble pulse.

deficiency of yin A general term for lack of body fluid, vital essence and blood, often resulting in endogenous heat (see **internal heat**).

deficiency of yin with flaming up of fire (see **fire**).

deficiency syndrome of the kidney A general term for deficiency of yin and yang of the kidney. The common features are aching and weakness in the loins and knees, seminal omission, impotence, dizziness, tinnitus, forgetfulness, etc. Edema and asthma may also be included in this syndrome.

deficiency syndrome of the liver A general term for deficiency of yin and blood of the liver. The common features are dizziness, headache, irritability, impairment of vision, dryness of the eyes, and menstrual disorders.

diabetes caused by internal heat A morbid condition marked by great thirst, the passage of a large amount of urine, and sometimes excessive eating, comprising diabetes mellitus and diabetes insipidus. According to traditional Chinese medicine, the pathogenesis of diabetes in most instances is deficiency of yin with formation of **internal heat**. In this book, some of the drugs indicated for diabetes may have a hypoglycaemic effect, but the others are used for relieving the symptoms such as polydipsia and polyuria.

dryness (1) An atmospheric pathogenic factor which prevails in dry seasons and impairs the body fluid, resulting in dryness syndrome marked by dryness of the nasal cavity, dry throat, thirst, parched lips, dry cough, and constipation.
(2) An endogenous pathogenic factor caused by impairment of body fluid and also the sydrome thus produced.

dryness-heat Dryness and heat in combination as a pathogenic factor causing sore throat, inflammation of the eyes, dry cough, or hemoptysis.

exogenous affection Morbid condition caused by excessive or untimely atmospheric influences and various infectious factors.

fire (1) Physiological energy of life. This definition is referred to in such expressions as "reinforce the fire" and "invigorate the fire".
(2) An exogenous pathogenic factor that causes morbid conditions marked by acute local inflammation or bleeding accompanied with constitutional manifestations such as aversion to heat, thirst, constipation, reddened tongue with yellowish coating, and forceful rapid pulse.
(3) A morbid condition caused either by hyperactivity of internal organ(s) or by yin deficiency with secondary fire symptoms (also called "deficiency-fire" or "deficiency of yin with flaming up of fire", which is manifested by flushed cheeks, daily recurring fever, heat sensation in the palms and soles, irritability, dryness in the mouth with sore throat, hemoptysis, hyperaphrodisea, etc.).

fire in the liver (liver-fire) A morbid condition of hyperactivity of the liver caused by strong emotional agitations and manifested by headache, dizziness, blood-shot eyes, flushed face, irritability, and hematemesis, hemoptysis or epistaxis. (see **fire**)

heart A viscus that maintains the blood circulation of the blood and controls the mental activities. Thus, not only the disturbance of blood circulation and irregularity in the sequence of the pulse beat but also various disorders of the higher central nervous system (such as insomnia, forgetfulness, impaired consciousness) are attributed to the dysfunction of the heart.

heat A pathogenic factor that causes morbid conditions characterized by feverishness, flushed face, thirst, craving for cold drink, constipation, reddened tongue with yellowish coating, and rapid pulse. When it causes inflammation with redness, heat and swelling, it is called **toxic heat**.

heat in blood (1) The late and severest stage of febrile diseases, marked by fever, restlessness, delirium, skin eruption and bleeding (hematemesis, epidstaxis, hematochezia, etc.).
(2) A common cause of bleeding, forcing the blood to flow out of the vessels.

heat in the lung A morbid condition that may be seen in various inflammatory diseases of the respiratory system, marked by cough with thick or yellowish (purulent) sputum, chest pain, dyspnea and even hemoptysis.

internal heat (1) The heat syndrom caused by consumption of yin or body fluid, usually manifested by fever in the afternoon or at night, heat sensation in the chest, palms and soles, night sweating, thirst, constipation, reddened tongue with scanty coating, and thready, rapid pulse.
(2) Invasion of exogenous pathogenic heat into the interior of the body. In this book, **internal heat** is usually referred to definition (1). It may also be a common cause of diabetes (see **diabetes caused by internal heat**).

kidney A viscus that stores the essence of life either congenital or acquired (from food) for growth and development, as well as semen for reproduction. It controls urine elimination and water metabolism and helps the lung in accomplishing respiration. It also has direct effect on the condition of the bone and marrow, activities of the brain, hearing of the ears, glossiness of the hair, and sexual power. Thus, in deficiency conditions of the kidney, the common symptoms are aching in the loins where the kidneys are seated, weakness in the knees and legs, impairment of hearing, premature greying of the hair and beard, impotence in male and frigidity in female. In addition, diminished function of the kidney may lead to edema (due to failure in eliminating urine) or dyspnea (due to failure in helping the lung to receive air). Some menstrual disorders, disturbances in mentality, osteopathies, and even looseness of the teeth (the teeth being considered as the odds and ends of the bone) may also be related to deficiency conditions of the kidney.

kidney yang The motive force of the functions of the kidney, including its reproductive function. Deficiency of the kidney yang is often marked by general debility, aversion to cold, cold limbs, listlessness, aching and weakness of the loins and knees, impotence, nocturia, pale tongue with whitish coating.

kidney yin The essential substances in the kidney, serving as the material basis of the kidney functions. Deficiency of the kidney yin is marked by lumbago, lassitude, dizziness, tinnitus, nocturnal emission, thirst, hot sensation in palms and soles, reddened tongue with little or no coating, thready and rapid pulse. Sterility is often attributed to deficiency of the kidney yin.

liver An internal organ that stores blood, smooths the flow of qi (vital energy), controls the function of the tendons, and communicates with the gall-bladder. Thus, dysfunction of the liver may lead to hematemesis or excessive uterine bleeding, stagnation of qi manifested by distending pain in the costal regions, irritability or depression, flaming up of the liver-fire manifested by headache, dizziness, tinnitus and congestion of the eyes, production of wind syndromes of the liver such as vertigo, tremors, spasms or even convulsions, and jaundice if the bile flow is obstructed. Since the essence of the liver and the kidney can reinforce

each other, and deficiency of the one will result in deficiency of the other. many of the drugs replenishing the kidney can replenish the liver at the same time. and vice versa. In addition, the liver has specific relationship with the eyes, and many eye diseases can be treated as liver diseases.

lung A viscus that performs the function of respiration, disseminates qi (vital energy), helps maintain normal water metabolism and controls perspiration, closely relating to the superficial body resistance. Thus, although it is mainly referred to the respiratory system including the upper respiratory tract, its implications are sometimes more extensive.

phlegm (1) Pathologic secretions of the respiratory system, synonymous to sputum if it is ejected from the mouth ("phlegm visible"). Retention of phlegm in the respiratory system is a common pathogenic factor that cause cough and asthma.
(2) A pathologic product of diseased internal organs, especially of the spleen, which in turn may cause various troubles, e.g., nausea and vomiting if it affects the stomach, palpitation, impairment of consciousness or even mania if it invades the heart, scrofula and other nodules under the skin if it accumulates subcutaneously. These troubles are thought to be caused by "phlegm invisible", as they can be effectively treated with the drugs used for the "phlegm visible".
Phlegm can be further classified into cold-phlegm, heat-phlegm, damp-phlegm, wind-phlegm and persistent phlegm. Cold-phlegm is characterized by frothy or watery sputum whitish in colour, accompanied with other cold manifestations such as aversion to cold or chilliness. Heat-phlegm is marked by sticky or purulent sputum accompanied with other heat manifestations such as fever, reddened tongue with yellowish greasy coating and rapid pulse. Dampphlegm is produced by retention of damp due to dysfunction of the spleen, bringing on symptoms such as profuse frothy sputum, epigastric distension, nausea and vomiting. Wind-phlegm usually causes headache, vertigo, numbness of the limbs, stroke or convulsions. Persistent phlegm is often seen in lingering cases of phlegm syndromes such as asthma with repeated attacks; mania and epilepsy are also attributed to persistent phlegm.

phlegm-fire Phlegm and fire in combination as a pathogenic factor that may cause palpitation, headache, vertigo, or mental disorders characterized by an expansive emotional state, hyperirritability, overtalkativeness, and increased motor activity.

phlegm-heat Phlegm and heat in combination as a pathogenic factor invading the respiratory system and causing fever, cough, expectoration of purulent sticky sputum and even dyspnea.

qi The basic element of energy that makes up the human body and supports the vital activities. Since the existence of qi in the human body can only be perceived through its resultant activities of the organs and tissues, it usually implies the functional activity. It circulates in the channels and collaterals. Stagnation of its circulation may result from emotional depression, improper diet, infection and injury, and is often manifested by distension and pain. Deficiency of qi is referred to decreased functional activity, usually manifested by lassitude, listlessness, shortness of breath, spontaneous sweating and weakened pulse. Since each internal organ has its own functional activities, deficiency of qi of different organs may have different manifestations. Drugs to promote the circulation of qi are indicated in the stagnation cases, while drugs to reinforce qi are used for the deficiency cases. To regulate the flow of qi is a general term for treating disorders in the flow of qi.

spleen A viscus that is believed to share with the stomach the function of digesting food, transport and distribute nutrients and water, reinforce the vital energy (qi), and keep the blood flowing within the blood vessels. In most cases, the spleen is referred to the digestive system, taken as the source of nutrients for growth and development, providing the material basis of the acquired constitution. However, dysfunction of the spleen is not confined to digestive disorders; it may also lead to retention of water (see damp) and hemorrhagic disorders such as excessive menstrual discharge and subcutaneous extravasation of blood.

summer-damp A morbid condition caused by summer heat and damp in combination and characterized by fever, fidgetness, feeling of stuffiness in the chest and epigastrium, thirst, diarrhea, and yellowish greasy tongue coating.

summer-heat An exogenous pathogenic factor that causes diseases in summer time, marked by high fever, thirst, profuse perspiration and lassitude.

vital essence (1) The fundamental substance that builds up the physical structure and maintains the body function.
(2) Semen. When this term is used in the context of the kidney, it is referred to both definitions, particularly to the latter.

wind An exogenous pathogenic factor characterized by upward and out-going dispersion, rapid change, and constant movement. Therefore, upper respiratory catarrh with headache and aversion to wind in common cold, morbid conditions with abrupt onset and sudden subsidence such as urticaria, those with wandering symptoms such as migratory pain in rheumatic arthritis, and those with abnormal motion such as convulsion, spasm, tremor, and facial paralysis with deviation of the eyes and the mouth are all believed to be caused by wind. Furthermore, attack of wind on the skin often results in itching.

wind-cold Wind and cold in combination as a pathogenic factor causing chilliness, headache, general aching and a stuffed, running nose.

wind-heat Wind and heat in combination as a pathogenic factor causing marked fever, mild chilliness, cough, thirst, sore throat, headache, or inflammation of the eyes.

wind-phlegm Wind and phlegm in combination as a pathogenic factor causing vertigo, numbness of the limbs, stroke, or epileptic convulsions.

yin and yang Yin-yang is one of the ancient philosophical concepts in China, which holds that anything in the universe is an entity of two aspects-yin and yang, ever opposing and complementing each other. This concept is used in traditional Chinese medicine as a guiding ideology referring to various antitheses in anatomy, physiology, pathology, diagnosis and treatment. In this book, yin and yang are only used in a specific sense, i.e., yin is referred to the material aspect of the body or internal organs, including vital essence, fluid, nutrients, etc., while yang to the functional aspect. For example, yin of the lung means the fluid nourishing and moistening the respiratory system; yang of the kidney implies the physiological energy of life, i.e., fire in its physiological sense, as well as the functions (growth, development, reproduction, metabolism, etc.) produced hereby. In healthy conditions, yin and yang are kept at normal levels and in a relative equilibrium. Breakdown of the balanced equilibrium due to deficiency or excess of either yin or yang will cause diseases. Furthermore, deficiency of the one may lead to excess of the other, e.g., diminished function of the spleen (deficiency of yang) may give rise to retention of water or damp (excess of yin); deficiency of yin of the liver may result in hyperactivity of the

liver or even flamming up of the liver-fire (excess of yang). On the other hand, excess of the one may lead to deficiency of the other, e.g., high fever (excess of yang) consumes the body fluid (yin).

TIMYZOROLA™ Exhibits Positive Effects On The Prostate: Clinical Study In Support Of The Dietary Supplement Claim, "Promotes A Healthy Prostate"

I. Methods

Clinical testing of TIMYZOROLA™ in humans was conducted between June of 1993 and July of 1996, by Uniweal Ltd. and its agents. This testing involved 302 male volunteers with benign prostatic hyperplasia (BPH) under a double-blinded protocol. The volunteers were between 40 and 80 years of age, exhibited an International Prostate Symptom Score (IPSS) (a standard of prostate assessment promulgated by the World Health Organization)[1] over 13 and maximum urine flow rate (Q_{max}) below 15 ml/s. They exhibited prostate specific antigen levels (PSA) within the normal range (<4 μg/L). The subjects exhibited no diseases including prostatic cancer, ureterostenosis, vesical diverticulum, sclerosis of bladder neck and neurogenic bladder, and other diseases including discharge of urine. Patients were excluded from the study who had dysfunction of the heart, liver, lung, and kidney, or orthostatic hypotension or mental diseases.

The 302 volunteers were divided randomly into two groups, with 202 in the TIMYZOROLA™ group and 100 in the finasteride group (finasteride is an approved drug in the U.S. (finasteride)). Both groups were physically similar as indicated by IPSS, Q_{max} and PSA measurements (Table 1).

Table 1. Group of Volunteers (X ± S)

Group	No	Average age	Average course[2]	IPSS	Q_{max} (ml/s)	PSA (μg/L)
TIMYZOROLA™ Group	202	71.4 ±9.3*	6.4 ±3.7*	27.6 ±4.2*	9.81 ±3.44*	2.2 ±0.49*
Finasteride group	100	69.5 ±8.4	6.1 ±4.2	26.3 ±3.9	10.38 ±2.56	1.9 ±0.31

* Student's t-test; two groups not significantly different at 95% confidence interval.

The volunteers in TIMYZOROLA™ group took two capsules orally per administration and four administrations per day for 180 days. One capsule contains 200 mg of TIMYZOROLA™.

The volunteers in the finasteride group orally took one 5 mg tablet per administration, one administration per day for 180 days. Finasteride tablets were provided by Merck SD (China) Ltd. Finasteride, an approved drug in the U.S. (finasteride), is an appropriate comparison drug for this study because it is the principal drug used in the treatment of BPH. See PHYSICIANS' DESK REFERENCE 1880 (53rd ed. 1999) (containing the PROSCAR (finasteride) package insert).

1 World Health Organization, International Prostate-Symptom Score (I-PSS): The Second International Consultation on Benign Prostatic Hyperplasia, Paris / June 27-30, 1993, ISBN 1 898452 05 9 (published by Scientific Communication International Ltd.).

2 "Average course" is the average time period of patients having BPH.

Starting from one week prior to treatment, the volunteers were not allowed to take any medicine which might influence the discharge of urine, such as sexual hormone inhibitors, 5∝-reductase inhibitors, and other 5∝-reductase receptor blockers. The volunteers were not allowed to take picklings, kimchi, sauerkraut, canned food, baked food, soy sauce, vinegar, food containing nitrites, excessive pesticide residues, preservative substances, and drinks containing alcohol.

The following observations were made according to the "Guidelines of Clinical Study of New Chinese Drug for Treating Prostate" published by the Ministry of Public Health of China in 1995:

(1) Safety Observation: normal physical examination, routine analysis of blood, urine and feces, and examination of heart, kidney and liver function.
(2) Effectiveness Observation: clinical symptoms, physical signs, routine analysis of blood, urine and feces, examination of heart, kidney and liver function, B mode ultrasonography on kidney, bladder and prostate, urodynamics test, and test of prostate specific antigen (PSA).

The above examinations were performed weekly before treatment and weekly during treatment. The examinations were taken a total of seven (7) times. Therapeutic effectiveness evaluations and comparisons were made were made a total of three times.

The standards of therapeutic effectiveness were defined and used according to the "Guidelines of Clinical Study of New Chinese Drug for Treating Prostate:"

(a) Clinically controlled: primary symptoms and physical signs disappear, IPSS score falls to 90% of its original value, and the physicochemical parameters become normal;
(b) Effectiveness: most primary symptoms and physical signs disappear, IPSS score falls to 60 to 89% of its original value, and the physicochemical property becomes substantially normal;
(c) Good: primary symptoms and physical signs partly decrease or disappear, IPSS score falls to 15 to 59% of its original value, and the physicochemical property begins to show good signs;
(d) Ineffectiveness: primary symptoms and physical signs show no changes or become worse.

Therapeutic effectiveness was analyzed using a Student's t-test to make pairwise comparisons between the before-treatment group and the after-treatment group, as well as within groups.

II. Results

1. IPSS Score and Quality of Life (QOL) Score[3]

IPSS and QOL Scores of the TIMYZOROLA™ and finasteride groups were determined one week prior to the treatment and at weeks 4, 8 12, 16, 20 and 24 after the treatment. The average scores are listed in Table 2. The data show that both IPSS and QOL scores improved throughout the duration of the study as compared to the baseline measurement ($p<.01$) for the TIMYZOROLA™ group. Having effects similar to the drug finasteride, TIMYZOROLA™ reduced the symptomatic effects of BPH and thus, supports the claim that "TIMYZOROLA™ promotes a healthy prostate."

3 See World Health Organization, The World Health Organization Quality of Life Assessment (WHOQOL): Position Paper from the WHO. Soc. Sci. Med. Vol. 41, No. 10, pp.1403-1409, 1995.

Table 2. Comparison of IPSS and QOL Scores Before and After Treatment (X±S)

Group	Weeks	IPSS	QOL
TIMYZOROLA™ Group (n=202)	1 week before treatment	27.6±4.2	4.71±0.63
	4 weeks after treatment	12.4±3.9□⊙	2.44 ±0.42□⊙
	8 weeks after treatment	9.7 ±2.1□⊙	2.15±0.36□⊙
	12 weeks after treatment	7.5±2.3□⊙	1.97±0.31□⊙
	16 weeks after treatment	5.4±1.9□@	1.91±0.35□@
	20 weeks after treatment	4.9±1.3□@	1.74±0.43□@
	24 weeks after treatment	4.4±1.3□@	1.82±0.41□@
Finasteride group (n=100)	1 week before treatment	26.3±3.9	4.45±0.70
	4 weeks after treatment	11.6±4.1	2.39 ±0.54
	8 weeks after treatment	8.4 ±3.4	2.23±0.39
	12 weeks after treatment	7.2±3.1	2.06±0.45
	16 weeks after treatment	6.3±3.4	2.01±0.42
	20 weeks after treatment	5.7±3.1	1.95±0.43
	24 weeks after treatment	5.8±3.4	1.97±0.42

Student's t-test

□ compared to baseline (within the group), $p<0.01$;

⊙ compared with finasteride group, $p<0.05$;

@ compared with finasteride group, $p<0.01$.

2. Urine Flow Rate

Maximum flow rate (MFR) and average flow rate (AFR) of urine for the two groups were tested one week prior to treatment and at weeks 4, 12 and 24 after commencing treatment. The results, listed in Table 3, show that MFR and AFR of the TIMYZOROLA™ group had statistically significant increases, compared to baseline ($p<0.01$), and compared to the finasteride group at 4 and 12 weeks after treatment ($p<0.05$) and at 24 weeks after treatment ($p<0.01$).

Table 3. Comparison of Urine Flow Rate Before and After Treatment ($X \pm S$)

	Number	Time of treatment	MFR (ml/s)	AFR (ml/s)
TIMYZOROLA™ group	202	1 week before treatment	9.81±2.76	5.61±2.68
		4 weeks after treatment	13.16±4.14□⊙	7.65 ±3.30□⊙
		12 weeks after treatment	15.22 ±5.17□⊙	9.24±3.43□⊙
		24 weeks after treatment	16.67±5.53□@	9.61±4.24□@
finasteride group	100	1 week before treatment	10.38±2.56	6.24±2.60
		4 weeks after treatment	13.60±3.59	7.80 ±3.60
		12 weeks after treatment	14.23±3.80	8.25±3.43
		24 weeks after treatment	14.79±5.46	8.51±3.94

Student's t-test

□ compared to baseline (within the group), $p<0.01$;

⊙ compared with finasteride group, $p<0.05$;

@ compared with finasteride group, $p<0.01$.

An analysis of rank-sum test was made on MFR and AFR for the two groups before and after treatment. The results show that both MFR and AFR improved for both the TIMYZOROLA™ group and the finasteride group (Table 4). Both groups exhibited similar reductions in urinary flow, which is associated with BPH.

Table 4. Comparison of Change Rate of Urine Flow Rate Before and After Treatment**

	Number	Time of Treatment	IPSS	MFR	AFR
TIMYZOROLA™ group	200	4 weeks after treatment	0.551	0.341*	0.364 @
		12 weeks after treatment	0.728*	0.551*	0.647 @
		24 weeks after treatment	0.841 @	0.699 @	0.713 @
Finasteride group	100	4 weeks after treatment	0.559	0.310	0.250
		12 weeks after treatment	0.726	0.371	0.332
		24 weeks after treatment	0.779	0.425	0.364

** Rank-sum test; change rate = (test value after treatment - test value before treatment) / test value before treatment.

* compared with finasteride group, $p<0.05$;
@ compared with finasteride group, $p<0.01$.

3. Prostate Gland Volume and Residual Bladder Urine

The volume of the prostate gland and the amount of urine remaining in the bladder were calculated using B mode ultrasonography via rectum for the two study groups before treatment and at weeks 4, 12, and 24 after commencing treatment. The results are presented in Table 5.

Table 5. Comparison of Prostate Volume and Residual Bladder Urine Between Groups Before and After Treatment (cm3/ml, X ± S)

Group	Time	Prostate volume (cm^3)	Change rate of prostate volume (%)**	Residual bladder urine (ml)	Change rate of residual urine of bladder (%)**
TIMYZOROLA™ group (n=202)	Before treatment	56.30 ±17.23		59.67 ±21.03	
	4 weeks after treatment	46.37 ±8.25□	-17.6	23.29 ±8.24□	-60.9
	12 weeks after treatment	37.66 ±6.24□@	-33.1	17.24 ±5.13□⊙	-71.1
	24 weeks after treatment	34.75 ±3.52□@	-38.3	6.52 ±2.47□⊙	-89.1
finasteride group (n=100)	Before treatment	54.29 ±18.24		58.24 ±22.15	
	4 weeks after treatment	51.67 ±15.43	-4.83	22.66 ±17.59	-61.1
	12 weeks after treatment	47.83 ±12.50	-11.9	19.82 ±13.43	-65.9
	24 weeks after treatment	43.45 ±8.24	-20.0	17.64 ±6.22	-69.7

** Change rate = (test value after treatment - test value before treatment) / test value before treatment

□ compared to baseline (within group), $p<0.01$;

⊙ compared with finasteride group, $p<0.05$;

@ compared with finasteride group, $p<0.01$.

The results show that the TIMYZOROLA™ group had statistically significant decreases in prostate volume, as compared to baseline ($p<0.01$). Compared to the finasteride group at 12 and 24 weeks after treatment, TIMYZOROLA™ also demonstrated similar effects in reducing residual bladder urine as finasteride.

4. Therapeutic Effectiveness

Various symptomatic criteria were weighed and an evaluation of clinical therapeutic effectiveness was performed (see Methods, therapeutic effectiveness scaling). These data are presented in Table 6. The results show that TIMYZOROLA™ has a therapeutic effect on BPH that is similar to finasteride.

Table 6. Comparison of Therapeutic Effectiveness Categories Between Study Groups

Group	Number	Clinically controlled (Number)	Effectiveness	Good (Number)	Ineffectiveness (Number)
TIMYZOROLA™ group	202	53.46% (108)@	42.08% (85)	2.48% (85)	1.98% (4)
Finasteride group	100	33.00% (33)	41.00% (41)	17.00% (17)	9.00% (9)

@ Student's t test, compared with finasteride group, $p<0.01$.

III. Conclusion

Subjects taking TIMYZOROLA™ had a statistically significant decrease in prostate volume and residual bladder urine, compared to baseline at 4, 12 and 24 weeks, and compared to the finasteride group at 12 and 24 weeks.

Subjects taking TIMYZOROLA™ had a statistically significant decrease in IPSS Score and QOL Score, both compared to baseline and finasteride group at 4, 8, 12, 16, 20, and 24 weeks. Subjects taking TIMYZOROLA™ had a statistically significant increase in urine flow rate, both compared to baseline and the finasteride group at 4, 12, and 24 weeks.

While only a traditional herbal remedy, TIMYZOROLA™ has strikingly similar effects at reducing the symptoms of BPH as compared to finasteride, which is an approved drug.

The data presented support the claim that "TIMYZOROLA™ promotes a health prostate."