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(English Edition 1988)

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of

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PREFACE TO THE PHARMACOPŒIA OF THE PEOPLE'S REPUBLIC OF CHINA (ENGLISH EDITION 1988)

The 1985 edition of the "Pharmacopœia of the People's Republic of China" (generally known as the 1985 edition of Chinese Pharmacopœia) was brought into effect on 1 April 1986. It is approved by the Ministry of Public Health to publish an English version so as to facilitate the broad understanding of Chinese Pharmacopœia and to promote the international exchange of the experience of drug standardization. It comes out as "Pharmacopœia of the People's Republic of China (English edition 1988)", may also be useful to manufacturers and drug importers and exporters in commerce.

The total number of monographs admitted to the original Chinese Pharmacopœia is 1489, it was published in two volumes: volume 1 consists of the monographs on traditional medicaments, and volume 2 consists of the monographs on modern medicaments, each volume has its own general notice, appendix and index. The total number of monographs admitted to the Pharmacopœia of the People's Republic of China (English edition 1988) is 1211, 278 monographs have been deleted (involving mainly seldom used drugs and excipients, in which 138 monographs were deleted from volume 1 and 140 monographs deleted from volume 2), and it is published in a single volume, but the monographs on traditional and/or modern medicaments are compiled separately so as to facilitate consultation. General notices, appendices and indices have been combined to avoid duplication.

The actions and indications of a traditional medicament were originally written on the basis of the theory and practice of traditional Chinese medicine, using traditional medical terminology. Unfortunately, it is extremely difficult to express the meaning of these terms concisely and precisely in English. Therefore, an explanation of terms of Chinese traditional medicine adopted in the Pharmacopœia of the People's Republic of China (English edition 1988) is incorporated in the appendix. If the English version is still found to be obscure, the original text should be consulted.

GENERAL NOTICES

1. The Pharmacopœia of the People's Republic of China (English edition 1988) is the English version of the 1985 edition of "Pharmacopœia of the People's Republic of China", generally known as the 1985 edition of Chinese Pharmacopœia (Ch. P. 1985).

2. Monographs are grouped into 3 parts: the first part consists of the specifications for crude drugs including oils, fats, etc., and their simple preparations; the second part consists of the specifications for the traditional Chinese medicinal formularies; the third part consists of the specifications for chemical drugs, antibiotics etc. and their preparations. The appendices describe the general requirements for pharmaceutical dosage forms, general methods of analysis, reagents, test solutions, indicators, volumetric solutions etc.

3. In the original Ch.P., the Chinese title of a drug is used as the official designation, its Latin name is used as a synonym; but in the English version, the Latin name is used as the official designation and its English name is used as a synonym.

4. The specification of a Chinese crude drug is based on the dried substance in general, quality standard and the dosage of fresh substance are also specified if it is to be used fresh.

5. The botanical nomenclature of a medicinal plant/animal, and its family name which it is originated from, the part used for pharmaceutical purposes, the appropriate season for its collection and the requirements for on-the-spot treatment are described under the heading "Source".
   "The part used of a plant for pharmaceutical purposes" refers to the commercially available crude drug which is free from extraneous matter. Therefore, in this Pharmacopœia, the collection and on-the-spot treatment of a crude drug involves that particular part of a plant only.

6. On-the-spot drying or drying during collection of crude drugs is described as follows:
   (1) When only the word "dry" is used, it means that drying can be done either by baking, exposure to sun light or standing in the shade;
   (2) The term "dry in the sun light" or "dry at a low temperature (not exceeding 60°C) is used for those undersirable to dry at a high temperature.
   (3) The term "dry in the shade" or "dry in air" is used for those unsuitable to dry by baking or by exposure to sun light.
   (4) In a few cases, the crude drugs are preferable to dry within a short time, the term "dry in strong sun light" or "dry timely" is used.

7. Crude drugs of different origins and of different characteristics are described respectively in details for one variety, followed by the unique characteristics of the others so as to help in differentiation.
   In certain cases, they are described under separate monographs and their conventional name is used as the title; or the name of the mother plant/animal origin is used as the title, but the description refers to the appropriate crude drug only, not to the original plant/animal.

8. Crude drugs used for the manufacture of a preparation should be cleaned. If processing is required, they must be processed with the method specified in individual monograph, unless otherwise indicated.

9. The quantity specified for the ingredient in a preparation refers to the quantity of pulverized clean crude drug or its processed product. In the manufacture of a preparation, the input of raw material in the form of clean powder must comply with the quantity specified in individual monograph.

10. The microscopical characteristics of the cross section, surface view and powder of a crude drug, and the microscopical characteristics of a preparation are the characteristics of the sample (prepared as directed in Appendix 4.1) observed under a microscope.

11. Crude drugs, drug substances, excipients and additives used in a preparation must comply with the requirements of this Pharmacopœia. Those are not admitted to this Pharmacopoeia must

comply with the specifications stipulated by the Ministry of Public Health or the health authorities of provinces, autonomous regions and municipalities. The identity and quantity of excipients and additives used should not prejudice the safety and efficacy of the medicament, and care should be taken to avoid the interruption of analytical methods specified in the monograph concerned.

12. When the specified upper limit of the content of a drug substance is above 100%, it represents the assay value which can be obtained using the method described in this Pharmacopœia; if no upper limit is specified, the assay value should not exceed 101.0%.

13. Crude drugs, drug substances and preparations admitted to this Pharmacopœia must be analysed with the official assay procedures given in individual monographs, alternative assay method can only be adopted as it is shown to be comparable to that of the official assay. However, the official assay shall be conclusive in case of dispute.

14. Chemical reagents used in the laboratory must comply with the national standards of the People's Republic of China, or the standards promulgated by the Ministry of Chemical Industry. Test solutions, indicator solutions, volumetric solutions, buffer solutions and standard colour-matching solutions must be prepared and standardized as directed in the Appendix of this Pharmacopœia. Measuring apparatus and equipments used in the laboratory must comply with the specified requirements of the State Bureau of Weights and Measures, and be calibrated periodically or whenever necessary.

15. The official system of units is adopted for physical measurements, the symbols used for the international system of units are:
Units of lenth: m (meter)
dm (decimeter) = 0.1 meter
cm (centimeter) = 0.01 meter
mm (millimeter) = 0.001 meter
μm (micrometer) = 10^{-6} meter
nm (nanometer) = 10^{-9} meter
Units of volume: L (liter)
ml (milliliter) = 0.001 liter
μl (microliter) = 10^{-6} liter
Units of mass: g (gram)
kg (kilogram) = 1 000 gram
mg (milligram) = 0.001 gram
μg (microgram) = 10^{-6} gram
Units of pressure: Pa (pascal)
kPa (kilopascal) = 1 000 pascal
1 atm = 760 mm Hg = 101.3 kPa
1 mm Hg = 133.322 Pa
1 Pa = 7.5×10^{-3} mm Hg
1 kPa = 7.5 mm Hg
Units of viscosity: kinetic viscosity is expressed in Pa·S
1 cP (centipoise) = 0.01 Pa·S
kinematic viscosity is expressed in mm^2/s
Units of radioactivity: Bq (becquerel)
1 Ci (curie) = 3.7×10^{10} Bq

16. The strength of volumetric solutions is expressed in mol/L, the expressions "Normality (N)" and "Molarity (M)" have been abandoned, e.g., 0.1 N sulfuric acid = sulfuric acid (0.05 mol/L) and 0.1 M sodium nitrite = sodium nitrite (0.1 mol/L).

17. Temperature is expressed in °C (degree Celsius).
The temperature of water bath is 98--100°C, unless otherwise indicated.
The temperature of hot water is 70—80°C.
The temperature of warm water or moderately warm water is 40—50°C.
"Cool place" refers to a place below 20°C.
"Cold place" refers to a place at 2—10°C.
When there is no indication of the temperature at which a test is to be conducted, it should be

performed at 10—30°C, but if the temperature has a pronounced impact on the test results, the test should be performed at 25 ± 2°C, unless otherwise indicated.

18. The symbol used for percentage is %, the purity of a substance expressed in percentage refers to % (wt/wt); the strength of a solution expressed in percentage refers to % (wt/vol); the strength of ethanol expressed in percentage refers to % (vol/vol).
% (g/g) indicates the number of grams of a solute in 100 g of solution.
% (ml/ml) indicated the number of milliliters of a solute in 100 ml of solution.
% (g/ml) indicates the number of grams of a solute in 100 ml of solution.
100% indicates a percentage not less than 99.5% and not more than 100.4%.
100.0% indicates a percentage not less than 99.95% and not more than 100.04%.

19. The solubility of a drug substance is a physical property reflecting its purity to some extent. The following expressions are used to describe the solubility of drug substances:
Very soluble ..... 1 part of solute is soluble in less than 1 part of solvent.
Freely soluble ..... 1 part of solute is soluble in 1—less than 10 parts of solvent.
Soluble ..... 1 part of solute is soluble in 10—less than 30 parts of solvent.
Sparingly soluble ..... 1 part of solute is soluble in 30—less than 100 parts of solvent.
Slightly soluble ..... 1 part of solute is soluble in 100—less than 1 000 parts of solvent.
Very slightly soluble ..... 1 part of solute is soluble in 1 000—less than 10 000 parts of solvent.
Insoluble or practically insoluble ..... 1 part of solute cannot be dissolved completely in 10 000 parts of solvent.
Determination of solubility: Weigh (or measure) accurately a definite quantity of the sample, finely powdered for solids, with a precision of ±2%, add a definite amount of the solvent, allow to stand at 25 ± 2°C for 30 minutes, shaking for 30 seconds at every 5-minutes intervals. If no solute particles or droplets can be observed at the end of 30 minutes, the sample is considered to be completely dissolved.

20. The expression (1→10) means 1 g or 1 ml of the solute is dissolved in a solvent to make a solution of 10 ml.
The symbol ":" inserted between two or more numerical figures indicates the parts by volume of each liquid in a mixture. The symbol ":" is also used to denote the strength of an injection, e.g. 1 ml: 10 mg indicates that 1 ml of the injection contains 10 mg of the active drug substance.

21. The drop of liquid is defined as such that 1 ml of water at 20°C is equivalent to 20 drops.

22. When the strength of ethanol is not indicated, it is understood to be 95% (ml/ml).

23. When the word "about" is used to express the quantity of a substance is to be weighed, a deviation of ± 10% of the specific quantity is usually permissible; when the substance is to be accurately weighed, the limit of error of weighing should not exceed ± 0.1%.

24. The expression "dry/ignite to constant weight" means that the drying/igniting process should be repeated until the results of two consecutive weighings do not differ by more than 0.3 mg. The second weighing being made after an additional hour of drying at the prescribed conditions, or after an additional 30 minutes of ignition.

25. Distilled water or demineralized water should be used in all the tests, unless otherwise indicated. When the solvent is not indicated, it is understood to be water.
Freshly boiled and cooled water should be used in tests for acidity or alkalinity.

26. When the indicator is not specified in a test for acidity or alkalinity, it is understood to be litmus paper.

27. Standard sieves of R40/3 series are used in this Pharmacopoeia, the sieves are numbered as follows:

Sieve No.	Average size of aperture (μm)
1	2 000 ± 70
2	850 ± 13
3	355 ± 13
4	250 ± 9.9
5	180 ± 7.6

6	150 ±6.6
7	125 ±5.8
8	90 ±4.6
9	75 ±4.1

Powders are graded as follows:
Very coarse powder: A powder in which all the particles pass through a No. 1 sieve, and not more than 20% pass through a No. 3 sieve.
Coarse powder: A powder in which all the particles pass through a No. 2 sieve, and not more than 40% pass through a No. 4 sieve.
Medium powder: A powder in which all the particles pass through a No. 4 sieve, and not more than 60% pass through a No. 5 sieve.
Fine powder: A powder in which all the particles pass through a No. 5 sieve, and not more than 95% pass through a No. 6 sieve.
Very fine powder: A powder in which all the particles pass through a No. 6 sieve, and not more than 95% pass through a No. 7 sieve.
Ultra fine powder: A powder in which all the particles pass through a No. 8 sieve, and not more than 95% pass through a No. 9 sieve.

28. The Action and use of a drug described in this Pharmacopœia is intended only as information on the main pharmacological action and principal therapeutic use of that drug substance concerned. There is no indication that additional therapeutic usage may not be approached on the basis of clinical practice.

29. Crude drugs are used for oral administration in form of a decoction, unless otherwise indicated. The dose of a drug specified in this Pharmacopœia is the usual dose for adults, appropriate adjustment may be necessary depending on the condition of individual patients. The maximum dose of a drug is the highest dose tolerable to adults and should not be exceeded except under special conditions.

30. The contraindications and side effects stated under the heading "Precaution" are the chief contraindications and chief side effects, general precautions are not enumerated as a rule.

31. The basic requirements for the preservation of drugs are stated under the heading "Storage". "Protected from light" means that the drug should be kept in an amber coloured glass container, a colourless glass container wrapped with black paper or any light-resistant container.
"Well closed" means that the container should be able to protect the contents from soil and extraneous matter.
"Tightly closed" means that the container should be able to avoid the efflorescence, deliquescence or evaporation of the contents and protect the contents from extraneous matter.
"Hermetically sealed" means that the container should be air-tight and be able to protect the contents from moisture and micro organisms.

32. The abbreviations are adopted as follows:

BS	buffer solution
CRS	chemical reference substance
IS	indicator solution
RS	reference standard
TP	test paper
TS	test solution
VS	volumetric solution

CONTENTS

PART I

Chinese Materia Medica, Oil, Fats, etc. and Their Simple Preparations

Agkistrodon (蕲 蛇, Qishe)

Long-noded Pit Viper (Moccasin)

Long-noded Pit Viper is the dried body of *Agkistrodon acutus* (Guenther) (Fam. Viperidae). Usually captured in summer and autumn, the abdomen cut open and the viscera excised, washed, the abdomen is held open with bamboo pieces, winded up in a coil. The bamboo pieces were removed when dried.

Description Winded up in a coil, the diameter of the coil 17—34 cm in diameter, body up to 2 m long. The head located in the center of the coil and upward slightly, triangular and flat, tip of the snout bend upwad, idiomatically known as "Qiaobitou (nostril upward)". 24 "Λ" shaped blotches, blackish-brown and light brown occurring on each side of the dorsum. The top of the "Λ" shaped blotches contacting each other at the mid-dorsal line, idiomatically known as "Fangshengwen (Fangsheng stripes)". Some being not contact with each other, but interlaced alternately. The abdomen held open or not, greyish-white. Scales relatively larger, with black subround spots, idiomatically known as "Lianzhuban (pearl lace stripes)". The inner wall of the abdomen yellowish-white, the vertebrae distinctively projected, bearing a number of ribs on both sides. The tail tapers abruptly. One dark grey triangle horny scale at the end of the tail. Odour, stinking; taste, slightly salty.

Processing *Agkistrodon*: Remove the heads and scales, and cut into segments.

Agkistrodon Meat: Remove the heads, soften thoroughly with yellow rice wine, eliminate the scales and bones, and dry.

Agkistrodon (processed with wine): Stir-fry Agkistrodon segments with yellow rice wine as described under the method of stir-fry with wine (Appendix 2.2) to dryness. To each 100 kg of Agkistrodon add 20 kg of yellow rice wine.

Action To dispel *wind*, to remove obstruction of *collaterals*, and to arrest spasm.

Indications Chronic rheumatic or rheumatoid arthritis with numbness and contracture of joints; hemiplegia in stroke; convulsion, tetanus; leprosy, scabies ringworm.

Usage and dosage 3—9 g; 1—1.5 g to be gound into powder and swallowed with liquids.

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

Alumen (白 礬, Baifan)

Alum

Alum is produced by alumstone in the mineral of sulfates. It contains mainly potassium aluminium sulfate [$KAl(SO_4)_2 \cdot 12H_2O$].

Description Irregular masses or granular, colourless or pale yellowish-white, transparent or semitransparent. Surface slight smooth or uneven, close wrinkled longitudinally, glossy. Texture hard and brittle. Odour, slight; taste, sour, sweetish and most astringent.

Identification The aqueous solution yields the characteristic reactions of the aluminium salts, potassium salts and sulfates (Appendix 7).

Ammonium salts Dissolve 0.1g in 100 ml of ammonia-free water. Transfer 10 ml of the solution to a Nessler tube, add 40 ml of ammonia-free water and 2 ml of alkaline potassium mercuric iodide TS, any colour produced is not more intense than that of a mixture of 1 ml of ammonium chloride solution (dissolve 31.5 mg of ammonium chloride in 1000 ml of ammonia-free water), 2 ml of alkaline potassium mercuric iodide TS and 49 ml of ammonia-free water.

Copper and Zinc To 1 g add 100 ml of water and slight excess of ammonia TS, boil and filter, the filtrate should not be blue. Acidify the solution with acetic acid, add hydrogen sulfide TS, it should not be turbid.

Iron Dissolve 0.35 g in 20 ml of water, add 2 drops of nitric acid, boil for 5 minutes, neutralized by adding sodium hydroxide TS dropwise to produce slightly turbidity, add 1 ml of dilute hydrochloric acid, 1 ml of potassium ferrocyanide TS and sufficient quantity of water to make 50 ml, mix well, it shows no blue colour within 1 hour.

Heavy metals Dissolve 1 g in 20 ml of water, add 2 ml of dilute acetic acid and sufficient quantity of water to make 25 ml, carry out the limit test for heavy metals (Appendix 8.7, method 1), not more than 20 ppm.

Assay Dissolve about 0.3 g, weigh accurately, in 20 ml of water, add 10 ml of acetic acid-ammonium acetate BS (pH 4.8) and add 25 ml, measure accurately, of disodium edetate (0.05 mol/L) VS. Boil gently for 10 minutes, cool to room temperature, add 55 ml of ethanol, using 2 ml of diphenylthiocarbazone IS, titrate with zinc solution (0.05 mol/L) VS, until the pale greenish-yellow colour turns to pink. Repeat the operation without the alum. The difference between the titrations represents the amount of disodium edetate (0.05 mol/L) VS required. Each ml of disodium edetate (0.05 mol/L) VS is equivalent to 23.72 mg of $KAl(SO_4)_2 \cdot 12H_2O$.
It contains not less than 99.0% of potassium aluminium sulfate [$KAl(SO_4)_2 \cdot 12H_2O$].

Processing *Alumen*: Eliminate the foreign matter, pound to pieces.

Alumen (calcined): Calcine the clean alumm as described under the method for calcining openly (Appendix 2.2) to loose and brittle.

Action To counteract toxicity, to kill parasites, to arrest discharges, and to relieve itching by external use; to arrest bleeding, to relieve diarrhea, and to dispel *wind-phlegm* by internal adminstration.

Alumen (calcined): to arrest discharges, promote the healing of ulcers, arrest bleeding, and cause cauterization.

Indications External use for eczema, scabies, otits media with purulent discaharge; internal use for chronic diarrhea, hematochezia, abnormal uterine bleeding, epilepsy and mania.

Alumen (calcined): Eczema, discharge from wound, otitis media with purulent discharge, excessive leukorrhea

with pudendal itching, bleeding from the nose or gums; nasal polyp.

Usage and dosage For external use, appropriate quantity to be ground into powder for topical application or dissolved in water for washing; 0.6—1.5 g for oral administration.

Storage Preserve in a dry place.

Arisaema cum Bile (胆南星, Dannanxing)

Bile Arisaema

Bile Arisaema is prepared from finely powdered *Rhizoma Arisaematis* (processed) and the bile of oxen, sheeps or pigs; or fermented with finely powder unprocessed Rhizoma Arisaematis.

Description Cubic or cylindrical, brownish-yellow, greyish-brown or brownish-black. Texture, hard. Odour, slightly fishy; taste, bitter.

Identification (1) Powder: Pale yellowish-brown. Parenchymatous cells subround, filled with gelatinized starch grains. Raphides of calcium oxalate 20—90 μm long. Spiral and annular vessels 8—60 μm in diameter.
(2) To 0.2 g, in powder, add 5 ml of water, stir and filter. Transfer 2 ml of the filtrate to a test tube, add 0.5 ml of a solution of furfural prepared freshly (1→100) and add 2 ml of sulfuric acid along the tube wall, a brownish-red ring is produced at the junction of two layers.

Action To remove *heat* and resolve *phlegm*, and to calm the nerves.

Indications Cough with yellowish sticky expectoration; stroke, mania, epilepsy.

Dosage 3—6 g.

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

Benzoinum (安息香, Anxixiang)

Benzoin

Benzoin is the dried resin obtained from *Styrax tonkinensis* (Pierre) Craib ex Hart. (Fam. Styracaceae). The resin is collected from the trunk injured naturally, or from incisions made through the bark of the trunk in summer and autumn, and dried in the shade.

Description Small irregular pieces, slightly compressed, sometimes agglutinated into a mass. Externally orange-yellow, waxy-glossy (natural exuding resin). Or irregularly cylindrical or flattened lumps, externally greyish-white to pale yellowish-white (resin exuding by artificial incisions). Brittle, breakable, fractured surface even, white and becoming gradually into pale yellowish-brown to reddish-brown on keeping. Softened and melted upon heating. Odour, aromatic; taste, slightly acrid, with a gritty sensation when chewed.

Identification (1) Place about 0.25 g in a dry test tube, heat gently, a stimulant aromatic smell is perceptible and a sublimate with the majority of the prismatical crystals is produced.
(2) To about 0.1 g of the drug, add 5 ml of ethanol, grind, filter. To the filtrate add 0.5 ml of 5% ferric chloride solution in ethanol; a bright green colour is produced, then turning to yellowish-green colour.

Loss on drying When dried over sulfuric acid in a vaccum desiccator to constant weight, loses not more than 2% of its weight (Appendix 9.2).

Total ash Not more than 0.5% (Appendix 4.3).

Ethanol-insoluble matter Place 2.5 g of the fine powder, weigh accurately, in a Soxhlet extractor, reflux with ethanol, until the extraction is completed. Allow the residue to dry to constant weight at 100°C, calculate the quantity of ethanol-insoluble matter in the sample.
It contains not more than 2%.

Assay Place about 1.5 g of the powder, weigh accurately, in a conical flask, add 25 ml of ethanolic potassium hydroxide (0.5 mol/L) VS, reflux for 1.5 hours and remove ethanol in a water bath. To the residue add 50 ml of hot water, allow it to diffuse evenly, cool. Add 150 ml of water and 50 ml of magnesium sulfate solution (1→20), stir thoroughly, then stand for 10 minutes. Filter through a Buchner funnel, wash the residue with 20 ml of water. Combine the washings with the filtrate, acidified with hydrochloric acid and transfer to a separator, then extract with four quantities, 50 ml, 40 ml, 30 ml, 30 ml, of ether. Extract the combined ether solutions with five quantities, 20 ml, 20 ml, 10 ml, 10 ml, 10 ml, of sodium bicarbonate solution (1→20). Wash each of the aqueous solution with the same 20 ml of ether. Combine the aqueous solution and acidify with hydrochloric acid. Extract the aqueous solution with four quantities, 30 ml, 20 ml, 10 ml, 10 ml, of ether. Combine the ether extracts to a weighed flask and allow to stand until most of ether evaporated. Turn round the flask and allow the residue to distribute evenly in the inside wall of the flask. Dry to constant weight in a vaccum desiccator (with sulfuric acid) and weigh accurately, calculate the percentage of balsamic acid in the sample and converted to the content of total balsamic acid accordingly with reference to the dried substance and its ethanol insoluble extractives.
It contains not less than 30% of total balsamic acid, with respect to dried ethanol-soluble extractive.

Action To restore consciousness, to activate the flow of *qi* and blood, and to relieve pain.

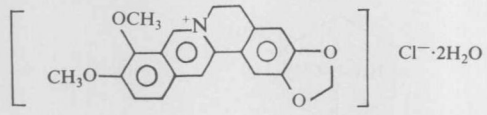
Indications Loss of consciousness in stroke and attack of noxious factors, syncope due to violent excitement or postpartem anemia; pain in the chest and epigastrium; infantile convulsion.

Usage and dosage 0.6—1.5 g; mostly used in making pills or powder.

Storage Preserve in a cool and dry place.

Berberini Hydrochloridum (鹽酸黃連素, Yansuan Huangliansu)

Berberine Hydrochloride



$[C_{20}H_{18}ClNO_4 \cdot 2H_2O = 407.85]$

The extracted product contains not less than 97.0% of the alkaloid and the synthetic product contains not less than 98.0% of the alkaloid, both calculated as berberine hydrochloride ($C_{20}H_{18}ClNO_4$), on the dried basis.

Description A yellow crystalline powder; odourless; taste, very bitter.
Soluble in hot water; slightly soluble in water or ethanol; very slightly soluble in chloroform; insoluble in ether.

Identification (1) Dissolve 50 mg in 5 ml of water on gentle heating, add 2 drops of sodium hydroxide TS, an orange red colour is produced. Cool, add 4 drops of acetone, a turbidity is produced and a yellow precipitate is produced on standing; to the supernant liquid add a quantity of acetone to precipitate the alkaloid completely, filter, the filtrate yields the reactions characteristic of chlorides (Appendix 7).
(2) Stir about 5 mg with dilute hydrochloric acid, add a few of bleaching powder, a cherry-red colour is produced.
(3) Dissolve about 2 mg in 1 ml of sulfuric acid, add 5 drops of 5% solution of gallic acid in ethanol, heat on a water bath, an emerald green colour is produced.

Loss on drying When dried for 5 hours at 100°C, loses not more than 12% of its weight (Appendix 9.2).

Residue on ignition Carry out the method for determination of residue on ignition (Appendix 9.4), using 1 g; not more than 0.2% (extracted product) or 1.0% (synthetic product) of its residue.

Other alkaloids Prepare a solution containing 2 mg in 1 ml of ethanol as the test solution and a solution containing 0.1 mg each of jatrorrhizine CRS and palmatine CRS in 1 ml of ethanol as the reference solution. Carry out the method for thin layer chromatography (Appendix 6.3), using silica gel G containing 0.1% of sodium carboxymethylcellulose as the coating substance and ethyl acetate-chloroform-methanol-diethylamine (8:2:2:1) as the mobile phase. Apply separately to the plate, 3 μl of each of these two solutions. After developing, examine it immediately. The spot due to jatrorrhizine in the chromatogram obtained with the test solution is not intense in colour, than the corresponding spot in the chromatograme obtained with the reference solution. To another plate, apply separately 15 μl of test solution and 6 μl of palmatine solution, using n-butanol-glacial acetic acid-water (7:1:2) as a mobile phase, after developing and removal of the plate, dry it in air, spray with dilute potassium iodobismuthate TS and examine immediately. The spot due to palmatine in the chromatogram obtained with the test solution is not more intense in colour than the corresponding spot in the chromatogram obtained with the reference solution (no necessity to examine the synthetic product).

Heavy metals Carry out the limit test for heavy metals (Appendix 8.7, method 2), using the residue from Residue on ignition; not more than 20 ppm (no necessity to examine for the extracted product).

Assay Dissolve about 0.3 g, weighed accurately, in a breaker in 150 ml of boiling water, cool and transfer the solution to a 250 ml volumetric flask, add accurately 50 ml of potassium dichromate (0.01667 mol/L) VS and water to volume. Shake for 5 minutes, filter with dry filter paper. Discard the initial filtrate, transfer accurately 100 ml of the successive filtrate to a 250 ml iodine flask. Add 2 g of potassium iodide, shake to dissolve, add 10 ml of hydrochloric acid solution (1→2), well-stoppered, shake well and allow to stand for 10 minutes in the dark. Titrate with sodium thiosulfate (0.1 mol/L) VS, add 2 ml of starch IS towards the end of titration and continue to titrate until the blue colour disappears and a bright green colour persists. Perform a blank determination and make any necessary correction. Each ml of potassium dichromate (0.01667 mol/L) VS is equivalent to 12.39 mg of $C_{20}H_{18}ClNO_4$.

Action Antibacterial.

Indications Bacillary dysentery.

Dosage 0.1—0.3 g; 0.3—0.9 g, daily.

Storage Preserve in well closed containers.

Preparation Berberine Hydrochloride Tablets

Tabellae Berberini Hydrochloridi (鹽酸黃連素片, Yansuan Huangliansu Pian)

Berberine Hydrochloride Tablets

Berberine Hydrochloride Tablets contain not less than 93.0% and not more than 107.0% of the labelled amount of berberine hydrochloride ($C_{20}H_{18}ClNO_4 \cdot 2H_2O$).

Description A yellow or sugar-coated tablets.

Identification To a quantity of fine powder (equivalent to about 0.1 g of berberine hydrochloride) add 10 ml of water, heat gently to dissolve, filter. The filtrate complies with tests for Identification described under Berberine Hydrochloride.

Other requirements Comply with the general requirements for tablets (Appendix 1.8).

Assay Weigh accurately 20 tablets (remove the sugar coat for sugar-coated tablets) and pulverize to fine powder. Place a quantity equivalent to about 0.3 g of berberine hydrochloride, weighed accurately, to a 250 ml beaker. Add 150 ml of boiling water, stir to dissolve the berberine hydrochloride, cool, then transfer to a 250 ml volumetric flask. Carry out the assay described under Berberine Hydrochloride, beginning at the words "add accurately 50 ml of potassium dichromate solution (0.01667 mol/L) VS, and water to volume...". Each ml of potassium dichromate solution (0.01667 mol/L) VS is equivalent to 13.59 mg of $C_{20}H_{18}ClNO_4 \cdot 2H_2O$.

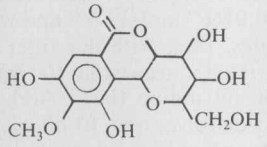
Action, Indications, Dosage As described under Berberini Hydrochloridum.

Specification (1) 0.025 g (2) 0.05 g (3) 0.1 g

Storage Preserve in well closed containers, protected from light.

Bergeninum (岩白菜素, Yanbaicaisu)

Bergenin



[$C_{14}H_{16}O_9$ = 328.27]

Bergenin contains not less than 97.0% and not more than 103.0% of $C_{14}H_{16}O_9$, calculated on the dried basis.

Description A white, loosen needle crystals or crystalline powder; odourless; taste, bitter; discoloured gradually on exposure to light and heat.
Soluble in methanol; slightly soluble in water or ethanol.

Melting point 232—240°C, dried at 130°C (Appendix 5.3).

Specific optical rotation -38° to -45°, in a solution of 20 mg per ml in methanol (Appendix 5.5), calculated on the dried basis.

Identification (1) Heat to dissolve about 50 mg in 10 ml of water and cool. To 1 ml of the solution add 2 drops of potassium ferricyanide TS containing 1 drop of ferric chloride TS per ml; an emerald green colour is produced.
(2) Dissolve about 5 mg in 1 ml of methanol, add several drops of 7% hydroxyamine hydrochloride solution in methanol, make alkaline with 10% potassium hydroxide solution in methanol and boil gently, allow to cool, acidify with dilute hydrochloric acid, add 1—2 drops of 1% ferric chloride solution in ethanol; a purple colour is produced.
(3) The light absorption of the solution obtained in the Assay, exhibits maxima at 275±1 nm and 220±1 nm (Appendix 5.8).

Loss on drying When dried to constant weight at 130°C, loses not more than 6.0% of its weight (Appendix 9.2).

Residue on ignition Not more than 0.1% (Appendix 9.4).

Assay Dissolve about 20 mg of bergenin, accurately weighed, in methanol in a 50 ml volumetric flask, dilute with methanol to volume and shake well. Measure accurately 1 ml of the solution in a 25 ml volumetric flask, add methanol to volume and shake well. Measure the absorbance at 275±1 nm (Appendix 5.8), calculate the content of $C_{14}H_{16}O_9$, taking 248 as the value of A (1%, 1 cm).

Action Antitussive and expectorant.

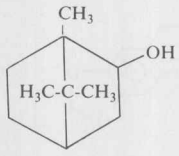
Indications Chronic bronchitis.

Dosage 0.125 g, three times a day.

Storage Preserve in well closed containers, protected from light.

Borneolum Syntheticum (冰片, Bingpian)

Borneol



[$C_{10}H_{18}O$ = 154.25]

Description Colourless or white, trasparent or semitransparent, loose plate crystals; odour, delicated aromatic; taste, spicy followed by a sensation of cold; volatilises at ordinary temperature, burns readily with a dense smoke and bright flame.
Freely soluble in ethanol, chloroform or ether; practically insoluble in water.

Melting point 205—210°C (Appendix 5.3).

Identification (1) Dissolve about 10 mg in several drops of ethanol, add 1—2 drops of freshly prepared 1% solution of vanillin in sulfuric acid; a purple colour is produced.
(2) To 3 g of the powder, add 10 ml of nitric acid; a reddish-brown gas is produced immediately. After the evolution of gas add 20 ml of water, shake and filter, wash the residue with water; a smell resembling camphor is perceptible.

Acidity or alkalinity To 2.5 g of the drug, finely powdered, add 25 ml of water, shake and filter. Separate the filtrate into two parts (10 ml of each part). To one part, add 2 drops of methyl red IS; to another part, add 2 drops of phenolphthalein IS, both solutions should not show red colour.

Non-volatile matter Place 10 g in a weighed porcelain dish, evaporate on a water bath, dry at 105°C to constant weight, leaves not more than 3.5 mg (0.035%).

Water Dissolve 1 g in 10 ml of petroleum ether, shake, a clear solution is obtained.

Heavy metals Dissolve 2 g in 23 ml of ethanol, add 2 ml of dilute acetic acid, carry out the limit test for heavy metals (Appendix 8.7, method 1), not more than 5 ppm.

Arsenic To 1 g add 0.5 g of calcium hydroxide and 2 ml of water, shake thoroughly. Heat on a water bath to volatilise, cool, neutralize with hydrochloric acid, then add 5 ml of hydrochloric acid and sufficient quantity of water to make 28 ml, carry out the limit test for arsenic (Appendix 8.8), not more than 2 ppm.

Action To restore consciousness, to remove *heat*, and to relieve pain.

Indications Loss of consciousness in febrile diseases, stroke, syncope or attack of noxious factors; inflammation of the eye, ulcers in the mouth, sore throat, purulent discharge from the auditory canal.

Usage and dosage 0.15—0.3 g, used in making pills or powder; for external use, appropriate quantity to be ground into powder and applied topically.

Precaution Used with caution in pregnancy.

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

Bulbus Allii Macrostemi (薤 白, Xiebai)

Longstamen Onion Bulb

Longstamen Onion Bulb is the dried bulb of *Allium macrostemon* Bge. (Fam. Liliaceae). The drug is collected in summer and autumn, washed clean, removed from rootlets, steamed thoroughly or scalded thoroughly in boiling water, and dried in the sun.

Description Irregularly oval, 0.5—1cm high, 0.5—1.8 cm in diameter. Externally yellowish-white or pale yellowish-brown, crumpled, translucent, bearing whitish membranous scales, bulged plateau at the base. Texture hard, horny. Odour, alliaceous; taste, slightly hot.

Action To remove obstructions from the chest, promote the flow of *qi* and relieve its stagnation.

Indications Angina pectoris; cough and dyspnea caused by retained phlegm; tenesmus in dysentery.

Dosage 4.5—9 g.

Storage Preserve in a dry place, protected from moth.

Bulbus Fritillariae Cirrhosae (川貝母, Chuanbeimu)

Tendrilleaf Fritillary Bulb

Tendrilleaf Fritillary Bulb is the dried bulb of *Fritillaria cirrhosa* D.Don, *Fritillaria unibracteata* Hsiao et K.C. Hsia, *Fritilleria przewalskii* Maxim. or *Fritillaria delavayi* Franch. (Fam. Liliaceae). According to the different characters in the commercial varieties the former three are known as "Songbei" and "Qingbei", respectively, and the latter is known as "Lubei". The drug is collected in summer and autumn, or when the snow melts, removed from fibrous roots, tunics and adhering soil, and dried in the sun or at low temperature.

Description *Songbei*: Subconical or subspherical, 0.3—0.8 cm high, 0.3—0.9 cm in diameter. Externally whitish. Outer scales 2, of considerable variation in size, with the large scale closely embracing the small one, the part of which is not enclosed appearing crescent. It is known as "Huaizhong Baoyue" (holding the moon in the arms). Summit closed, with subcylindrical and slightly tapering buds and 1—2 small scales inside; apex obtuse or slightly acute, base even and slightly depressed, with a greyish-brown disk at central part, remains of fibrous roots occasionally found. Hard and brittle, fractured surface white, starchy. Odour, slight; taste, bitterish.

Qingbei: Nearly oblate, 0.4—1.4 cm high, 0.4—1.6 cm in diameter. Outer scales 2, fairly uniform in size, embraced. Summit open, with buds and 2—3 small scales inside and slender cylindrical remains of stem.

Lubei: Long conical, 0.7—2.5 cm high, 0.5—2.5 cm in diameter. Externally whitish or pale brownish-yellow, some brown-maculate. Outer scales 2, fairly uniform in size. Summit open and somewhat tapering, base slightly acute or relatively obtuse.

Identification Powder: Whitish.

Songbei and Qingbei: Starch grains numerous, broadly ovoid, long spherical or irregularly spherical, some with uneven or slightly branch-like edges, 5—64 μm in diameter, hilum shortly slit-shaped, pointed, V-shaped or U-shaped, and faint striations visible. Epidermal cells subrectangular, anticlinal walls sinuous, rounded or oblate anomocytic stomata occasionally found. Spiral vessels 5—26 μm in diameter.

Lubei: Starch grains broadly ovoid, conchoidal, reniform or ellipsoid, up to 60 μm in diameter, hilum V-shaped, stellate or pointed, striations distinct. Spiral and reticulate vessels even up to 64 μm in diameter.

Action To remove *heat*, moisten the *lung*, resolve sputum and relieve cough.

Indications Dry cough due to *heat* in the *lung*; cough with bloody sputum in consumptive diseases.

Usage and dosage 3—9 g; or 1—2 g ground into powder and taken with water.

Precaution Incompatible with aconite and allied drugs.

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

Bulbus Fritillariae Pallidiflorae (伊貝母, Yibeimu)

Sinkiang Fritillary Bulb

Sinkiang Fritillary Bulb is the dried bulb of *Fritillaria walujewii* Regel or *Fritillaria pallidiflora* Schrenk (Fam. Liliaceae). The drug is collected from May to July, freed from soil, dried and then removed from fibrous roots and tunics.

Description *Bulbus Fritillariae Walujewii*: Oblate, 0.5—1.5cm high. Externally whitish and smooth. Outer scales 2, crescent, plump and fleshy, fairly uniform in size, close together. Summit spread and open out, base rounded and obtuse, with larger scales, remains of a stem and a bud. Texture hard and brittle, fractured surface white, starchy. Odour, slight; taste, slightly bitter.

Bulbus Fritillariae Pallidiflorae: Conical, relatively large. Externally somewhat rough, pale yellowish-white. Outer scales cordate, plump and large, significantly varying in size, closely embraced. Summit slightly acute with a few open, base slightly depressed.

Identification Powder: Whitish, mainly consisting of starch grains.

Bulbus Fritillariae Walujewii: Starch grains simple, broadly ovoid, ovoid or conchoidal, 5—54 μm in diameter, hilum pointed, V-shaped or shortly slit-shaped, striations distinct; compound grains less, of 2 components. Epidermal cells subrectangular, with sinuous anticlinal walls, containing small calcium oxalate prisms. Stomata anomocytic, subsidiary cells 4—6, spiral and annular