
Traditional Chinese medicine — General requirements for herbal raw material and materia medica

*Médecine traditionnelle chinoise — Exigences générales relatives aux
matières premières issues des plantes et à la matière médicale*





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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Chinese herbal medicine, as an important component of traditional Chinese medicine, is widely used in many countries because of its high value to human health and huge market. The annual sales of Chinese herbal medicine are worth more than USD 16 billion and are increasing at a rate of 10 % to 20 % per year, with great future potential. Such great opportunities for trade call for International Standards specifying the requirements for herbal medicines, in order to ensure their quality and safety, and to avoid misuse due to varietal complexity, harmful foreign matter and adverse drug reactions.

There are specific standards for important species, such as ISO 20409 for *Panax notoginseng* root and rhizome. However, it is impractical to develop one-on-one standards for the thousands of species of herbal medicine used in traditional Chinese medicine in the different traditions and regions. It is preferable to have one International Standard of general requirements for herbal medicine, because herbal medicines have many aspects in common.

The purpose of this document is to:

- a) provide a standard for the species not covered in the existing International Standards for single species of herbal medicine;
- b) provide an outline and reference for International Standards for single species of herbal medicine.

The principles that were followed in preparing this document are as follows:

- 1) cover all general requirements of herbal medicine recorded by national, regional and organizational pharmacopoeia, such as the *Pharmacopoeia of the People's Republic of China*,^[1] the *Japanese Pharmacopoeia*,^[2] the *Korean Pharmacopoeia*^[3] and the *European Pharmacopoeia*^[4];
- 2) distill the common characteristics of herbal medicine and formulate general requirements;
- 3) fully consider and respect the testing method and specific requirements on national or regional pharmacopoeias, legislation and standards.

The general requirements do not define general limit values. [Annex A](#) provides additional information as it lists the monographs for specific herbs in national and regional pharmacopoeias, including the items that are covered, meaning that limit values can be searched.

Traditional Chinese medicine — General requirements for herbal raw material and materia medica

1 Scope

This document specifies the general requirements and test methods for herbal raw material and materia medica.

This document provides minimum requirements for those herbal materials that are not covered by individual standards.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1573, *Tea — Determination of loss in mass at 103 °C*

ISO 1575, *Tea — Determination of total ash*

ISO 1577, *Tea — Determination of acid-insoluble ash*

ISO 18664, *Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine*

ISO 19609-2, *Traditional Chinese medicine — Quality and safety of raw materials and finished products made with raw materials — Part 2: Identity testing of constituents of herbal origin*

ISO/TS 21310, *Traditional Chinese medicine — Microscopic examination of medicinal herbs*

ISO 22217, *Traditional Chinese medicine — Storage requirements for raw materials and decoction pieces*

ISO 22258, *Traditional Chinese medicine — Determination of pesticide residues in natural products by gas chromatography*

ISO 22283, *Traditional Chinese medicine — Determination of aflatoxins in natural products by LC-FLD*

ISO 22467¹⁾, *Traditional Chinese Medicine — Determination of microorganism in natural products*

ISO 22590, *Traditional Chinese medicine — Determination of sulfur dioxide in natural products by titration*

ISO 23190, *Traditional Chinese medicine — Determination of aristolochic acids in natural products by HPLC*

ISO 23191, *Traditional Chinese medicine — Determination of selected Aconitum alkaloids by high-performance liquid chromatography (HPLC)*

World Health Organization. *Quality Control Methods for Herbal Materials*. World Health Organization, 2011

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

1) Under preparation. Stage at the time of publication: ISO/FDIS 22467:2021.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1 **Chinese materia medica** medicinal parts of medicinal plants, animals and minerals after preliminary processing, which are used in traditional Chinese medicine as decoction pieces and raw materials to make decoction pieces

Note 1 to entry: The different nomenclatures of the Chinese materia medica in use are described as follows:

- Latin name: Latin pharmaceutical name of the Chinese materia medica. In the Latin name, the genus name or genus name plus species name is followed by the applicable medicinal parts. Items are listed in alphabetical order of the Latin name for easy and convenient searching.
- Chinese name: Han (Chinese) character name of the Chinese materia medica. Han characters include both the simplified character and the traditional character, which is given in parentheses.
- Pinyin name: Pinyin name (Chinese phonetic) of the Chinese materia medica. The “four tones” have been added in Pinyin to facilitate practice by users. Pinyin syllabication (in parentheses) is provided to facilitate correct pronunciation.
- Scientific name: Latin scientific name of the source of the Chinese materia medica.
- English name: commonly used English name of the Chinese materia medica.

[SOURCE: ISO 18662-1:2017, 3.1, modified.]

3.2 **foreign matter** non-medicinal parts or components which can be carried or mixed in herbal raw material and materia medica

EXAMPLE Material consisting of any or all of the following:

- Parts of the herbal material or materials other than those named with the limits specified for the herbal material concerned.
- Any organism, part or product of an organism, other than that named in the specification and description of the herbal material concerned.
- Mineral admixtures such as soil, stones, sand and dust, and glass, metal and plastics or any other extraneous materials. These can be loose or adhering to these herbal materials.

4 General principle

For single herbs with existing International Standards, these International Standards apply.

For single herbs without existing International Standards, this document applies.

For single herbs with existing International Standards, but in which some requirements are not specified, this document applies.

Requirements in Chapter 5 shall apply to all herbal materials.

Requirements in Chapter 6 shall apply to some specific herbal materials, of which the test items covered by monographs of national and regional pharmacopoeias are listed in [Table A.1](#) of [Annex A](#) for information. The herbal name, pharmaceutical name, regional expressions and English name of these herbal materials are listed in [Table A.2](#) of [Annex A](#) for information.

5 Requirements for all Chinese materia medica

5.1 General

The presence of mouldy plant material, obvious deterioration of physical appearance, external contaminants and living insects which are visible to the naked eye shall not be permitted.

The presence of mouldy smells or taste shall not be permitted.

5.2 Identification

The identity shall be authenticated based on one of the following:

- macroscopic features of the whole material, fragmented material or both;
- microscopic features of the powdered material;
- a thin layer chromatography (TLC) or high-performance liquid chromatography (HPLC) fingerprint to verify the presence of characteristic compounds and, where applicable, to exclude characteristic compounds of known adulterations.

5.3 Quality requirements

5.3.1 Moisture and loss on drying

The content of water or loss on drying shall be determined.

5.3.2 Foreign matter

The percentage and nature of foreign matter shall be determined.

5.4 Safety requirements

5.4.1 Heavy metals and arsenic

The content of heavy metals such as lead, cadmium, mercury and arsenic shall be determined.

5.4.2 Pesticide residues

The content of pesticide residues listed in ISO 22258 shall be determined.

6 Requirements for specific Chinese materia medica

6.1 Quality requirements

6.1.1 Total ash and acid-insoluble ash

To limit the content of inorganic impurities (such as clay and sand) in some specific herbal materials, the content of total ash and acid insoluble ash shall be determined.

6.1.2 Assay

For some specific herbal materials that contain chemical substance(s) that serve as marker compounds, an assay shall be applied.

6.1.3 Extractives

For some specific herbal materials, the content of water-soluble extractive, ethanol-soluble extractive or ether-soluble extractives shall be determined.

6.1.4 Essential oil

For some specific herbal materials containing volatile oils, the content of essential oil shall be determined.

6.1.5 Rancidity

For some specific herbal materials containing volatile oils or fatty oils which are liable to become rancid, rancidity shall be determined.

6.1.6 Degree of colouration

For some specific herbal materials containing volatile oils or fatty oils which are liable to get oil extravasation, degree of colouration shall be determined.

6.2 Safety requirements

6.2.1 Sulfur dioxide residues

For some specific herbal materials where the contamination with sulfur dioxide is a known safety issue, sulfur dioxide shall be determined.

6.2.2 Aflatoxins

For some specific herbal materials where the contamination with aflatoxins is a known safety issue, aflatoxin B₁ and total aflatoxins shall be determined according to ISO 22283.

6.2.3 Aristolochic acids

For some specific herbal materials originated from the *Aristolochia* genus, aristolochic acids shall be determined according to ISO 23190.

6.2.4 Aconitum alkaloids

For some specific herbal materials originated from the *Aconitum* genus, aconitum alkaloids shall be determined according to ISO 23191.

6.2.5 Microbial contamination

For some specific herbal materials where the contamination with microorganism is a known safety issue, microbial contamination shall be determined.

7 Methods

7.1 Identification

7.1.1 Macroscopic identification

Macroscopic identification includes shape, size, colour, texture, odour and taste of herbal material. Perform macroscopic identification according to ISO 19609-2.

7.1.2 Microscopic identification

The testing method specified in ISO/TS 21310 applies.

7.1.3 TLC identification and HPLC identification

The testing methods specified in monographs of existing national or regional pharmacopoeias apply.

7.2 Quality tests

7.2.1 Moisture and loss on drying

The testing method of water content specified in the World Health Organization's *Quality Control Methods for Herbal Materials* applies.

The testing method of loss on drying specified in ISO 1573 applies.

7.2.2 Foreign matter

Weigh a quantity of the substance to be examined and spread it out in a thin layer. Examine for foreign matter by inspection with the unaided eye or by use of a lens (5× to 10×). To separate the foreign matter, a suitable sieve can be used if necessary. Weigh separately each kind of foreign matter and calculate its percentage content.

NOTE 1 When the foreign matter closely resembles the official drug and it is difficult to distinguish between them, the microscopical, chemical or physical methods can be used to identify the foreign matter.

Cut the big crude drugs and examine for the occurrence of insects, mould and deterioration.

NOTE 2 Unless otherwise specified, the quantity of substance to be examined for the determination of foreign matter is in accordance with the requirements for the sampling of crude drugs.

7.2.3 Total ash and acid-insoluble ash

The testing methods specified in ISO 1575 and ISO 1577 apply for total ash and acid-insoluble ash, respectively.

7.2.4 Assay

For chemical characterization, an assay can be suitable if methods and technologies are available, for example, in monographs of existing national or regional pharmacopoeias. When the method of a certain pharmacopoeia is chosen, the limit value of that pharmacopoeia monograph shall apply.

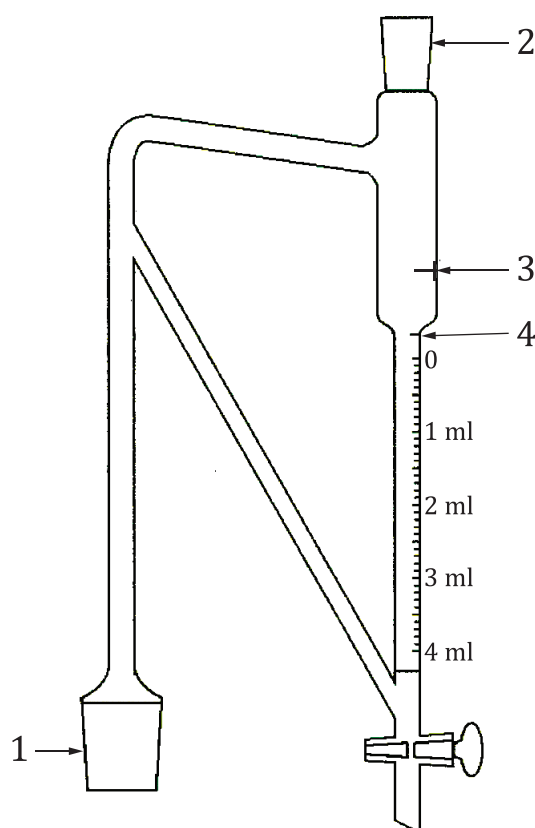
7.2.5 Extractives

Extractives include water-soluble extractives, ethanol-soluble extractives and ether-soluble extractives. The testing methods specified in the World Health Organization's *Quality Control Methods for Herbal Materials* apply.

7.2.6 Essential oil

Weigh the quantity of the test sample for analysis in a 1-l hard glass-stoppered flask and add from 5 times to 10 times as much water as the drug. Set up the apparatus for essential oil determination ([Figure 1](#)); insert the left-lower mouth (1) into the flask and insert a reflux condenser into the upper mouth (2), then heat the contents of the flask in an oil bath of between 130 °C and 150 °C to boiling. Fill the graduated tube of the apparatus with water to the standard line (3) and add 2,0 ml of xylene. Unless otherwise specified, continue boiling for 5 hours, allow to stand for some time then open the stopper of the apparatus. Draw off the water slowly until the surface of the oil layer corresponds to the preparation line (4) and allow it to stand for more than 1 hour at ambient temperature. Then, use

the surface of the oil layer to the zero line and read the volume (ml) of the oil at ambient temperature. Subtract the volume (ml) of xylene from the volume of the total oil.



Key

- 1 left-lower mouth
- 2 upper mouth
- 3 standard line
- 4 preparation line

Figure 1 — Apparatus for essential oil determination

7.2.7 Rancidity

Rancidity includes acid value, peroxide value and carbonyl value. The testing method specified in the World Health Organization's *Quality Control Methods for Herbal Materials* applies.

7.2.8 Degree of colouration

The testing method specified in the World Health Organization's *Quality Control Methods for Herbal Materials* applies.

7.3 Safety test

7.3.1 Heavy metal and arsenic

The testing method specified in ISO 18664 applies.

7.3.2 Pesticide residues

The testing method specified in ISO 22258 applies.

7.3.3 Sulfur dioxide residues

The testing method specified in ISO 22590 applies.

7.3.4 Aflatoxins

The testing method specified in ISO 22283 applies.

7.3.5 Aristolochic acids

The testing method specified in ISO 23190 applies.

7.3.6 Aconitum alkaloids

The testing method specified in ISO 23191 applies.

7.3.7 Microbial contamination

The testing method specified in ISO 22467²⁾ applies.

8 Sampling

Sampling shall be carried out in accordance with the method described in the World Health Organization's *Quality Control Methods for Herbal Materials*. Sampling shall be conducted according to the following steps:

- a) From a batch of five containers or packaging units, take a sample from each one.
- b) From a batch of 6 to 50 units, take a sample from five.
- c) From a batch of over 50 units, sample 10 %, rounding up the number of units to the nearest multiple of 10. For example, a batch of 51 units would be sampled as for 60, i.e. take samples from six packages.
- d) From each container or package selected, take three original samples from the top, middle and bottom.
- e) Combine the three original samples into a pooled sample and mix carefully.
- f) Obtain the average sample by quartering:
 - take the pooled sample, adequately mixed into an even and square-shaped heap;
 - divide diagonally into four equal parts;
 - take two diagonally opposite parts and mix carefully;
 - repeat the process as necessary until the required quantity, to within ± 10 %, is obtained.
- g) Using the same quartering procedure, divide the average sample into four final samples, taking care that each portion is representative of the bulk material.
- h) Use the final samples for the tests, measurements and analyses.

2) Under preparation. Stage at the time of publication: ISO/FDIS 22467:2021.

9 Test report

For each test method, the test report shall specify the following:

- a) all information necessary for the complete identification of the sample;
- b) the sampling method used;
- c) the test method used, with reference to this document, i.e. ISO 23723:—;
- d) the test result(s) obtained;
- e) all operating details not specified in this document, or regarded as optional, together with details of any incidents which may have influenced the test result(s);
- f) any unusual features (anomalies) observed during the test;
- g) the date of the test.

10 Packaging

The packaging and transportation shall not transmit any odour or flavour to the product and shall not contain substances which can damage the product or constitute a health risk. The packaging shall be strong enough to withstand normal handling and transportation.

11 Labelling

See the label content specified in ISO 21371. The following items shall be marked or labelled on the packages:

- a) all quality features indicated in [Clause 5](#) and [Clause 6](#), determined in accordance with methods specified in [Clause 7](#);
- b) gross weight and net weight of the package;
- c) country of origin and province or state of the products;
- d) date of production and expiry date of the products;
- e) storage method;
- f) any items required by the regulatory bodies of the destination country.

12 Storage and transportation

The requirements given in ISO 22217 shall apply.

Annex A (informative)

Test information of single herbs in national and regional pharmacopoeias

A.1 Test items

In total, the test items of 903 herbs were collected from the *Pharmacopoeia of the People's Republic of China*,^[1] the *Japanese Pharmacopoeia*,^[2] the *Korean Pharmacopoeia*^[3] and the *European Pharmacopoeia*^[4], valid in March 2020. These are summarized and listed in alphabetical order by herbal name in [Table A.1](#). The test items include:

- 1) moisture
- 2) loss on drying
- 3) foreign matter
- 4) heavy metals
- 5) arsenic
- 6) pesticide residues
- 7) total ash
- 8) acid-insoluble ash
- 9) assay
- 10) water-soluble extractives
- 11) ethanol-soluble extractives
- 12) ether-soluble extractives
- 13) essential oil
- 14) rancidity
- 15) degree of colouration
- 16) sulfur dioxide residues
- 17) aflatoxins
- 18) aristolochic acids
- 19) aconitum alkaloids

The item numbers refer to the codes of the test items in [Table A.1](#). The limit value in each test item for each herb can be referred to the corresponding requirements in each pharmacopoeia.

Table A.1 — Test items of single herbs in national and organizational pharmacopoeias

Herbal name	Pharmacopoeia	Test item																		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Abelmoschus manihot corolla	CP	X					X	X	X		X									
Abrus cantoniensis herb	CP	X					X				X									
Abutilon theophrastii seed	CP	X		X			X				X									
Acanthopanax gracilistylus root bark	CP	X					X	X			X									
Acanthopanax senticosus root and rhizome or stern	CP	X					X		X		X									
Acanthopanax sessilifolium root bark and stem bark	KP			X	X	X	X	X		X						X				
Achillea aplina herb	CP	X					X	X	X		X									
Achillea millefolium herb	EP		X	X			X	X	X				X							
Achyranthes bidentata root	CP	X					X		X	X	X					X				
Achyranthes bidentata root	EP		X				X	X	X	X										
Achyranthes fauriei root/Achyranthes bidentata root	JP		X	X	X	X	X	X												
Achyranthes japonica root/Achyranthes bidentata root	KP		X	X	X	X	X	X								X				
Aconitum carmichaeli parent root tuber	CP	X					X	X	X											X
Aconitum carmichaeli prepared daughter root	KP				X	X										X				X
Aconitum kusnezoffii leaf	CP																			
Aconitum kusnezoffii root tuber	CP	X		X			X		X											X
Acorus calamus rhizome	CP	X					X						X							
Acorus tatarinowii rhizome	CP	X					X		X	X	X		X							
Actium lappa fruit	CP	X					X		X											
Adenophora tetraphylla root/Adenophora strucria root	CP	X					X	X			X									
Aesculus chinensis seed/Aesculus chinensis var. chekiangensis seed/Aesculus wilsonii seed	CP	X					X		X	X										

Table A.1 (continued)

Herbal name	Pharmacopoeia	Test item																		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Agrimonia pilosa herb	CP	X					X													
Ailanthus altissima bark	CP	X					X	X			X									
Ajuga decumbens herb	CP	X					X	X	X											
Akebia quinata fruit/Akebia trifoliata fruit/Akebia trifoliata var. australis fruit	CP	X					X		X											
Akebia quinata stem	KP				X	X	X									X				
Akebia quinata stem/Akebia trifoliata stem	JP						X													
Akebia quinata stem/Akebia trifoliata stem/Akebia trifoliata var. australis stem	CP	X					X		X											
Akebia quinata stem/Akebia trifoliata stem	EP		X				X		X									X		
Albizia julibrissin inflorescence or flower bud	CP	X		X			X	X			X									
Albizia julibrissin stem bark	CP	X					X		X		X									
Alisma orientale tuber	CP	X					X		X		X									
Alisma orientale tuber	JP				X	X	X	X												
Alisma orientale tuber	KP				X	X	X									X				
Allium macrostem bulb/Allium chinensis bulb	CP	X					X				X									
Allium sativum bulb	CP						X		X	X										
Allium tuberosum seed	CP																			
Aloe barbadensis juice	EP		X				X		X											
Aloe barbadensis juice/Aloe ferox juice	CP	X					X		X											
Aloe ferox juice	EP		X				X		X											
Aloe ferox juice/Aloe africana juice/Aloe spicata juice	JP		X				X		X	X										
Alpina officinarum rhizome	CP	X					X		X											

Table A.1 (continued)

Herbal name	Pharmacopoeia	Test item																		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Alpinia galanga fruit	CP													X						
Alpinia katsumadai seed	CP									X				X						
Alpinia katsumadai seed	KP		X		X	X	X										X			
Alpinia officinarum rhizome	JP		X		X	X	X	X				X								
Alpinia officinarum rhizome	KP		X		X	X	X	X				X		X			X			
Alpinia oxyphylla fruit	CP						X	X						X						
Alpinia oxyphylla fruit	JP							X	X					X						
Alpinia oxyphylla fruit	KP						X	X						X			X			
Amomum kravanh fruit/Amomum compactum fruit	KP		X	X	X	X	X	X						X			X			
Amomum kravanh fruit/Amomum compactum fruit	CP	X		X					X					X						
Amomum krervanh fruit/Amomum compactum fruit	EP	X					X		X					X						
Amomum tsao-ko fruit	CP	X						X						X						
Amomum tsao-ko fruit	KP		X		X	X	X	X						X			X			
Amomum villosum fruit/Amomum longiligulare fruit	EP	X					X		X					X						
Amomum villosum fruit/Amomum villosum var. xanthioides fruit/Amomum longiligulare fruit	CP	X							X					X						
Amomum villosum var. xanthioides fruit or seed/Amomum villosum fruit or seed	KP				X	X	X	X						X			X			
Amomum xanthioides seed	JP						X	X						X						
Ampelopsis japonica root tuber	CP	X					X	X				X								
Andrographis paniculata herb	CP								X			X								
Andrographis paniculata herb	EP		X				X		X											
Anemarrhena asphodeloides rhizome	CP	X					X	X	X											

Table A.1 (continued)

Herbal name	Pharmacopoeia	Test item																		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Anemarrhena asphodeloides rhizome	EP		X					X	X	X										
Anemarrhena asphodeloides rhizome	JP			X	X			X	X											
Anemarrhena asphodeloides rhizome	KP			X	X	X	X	X	X	X							X			
Anemone raddeana rhizome	CP	X						X	X	X		X								
Angelica biserrata (syn. Angelica pubescens f. biserrata) root	EP		X					X	X	X										
Angelica dahurica root	EP		X					X	X	X										
Angelica dahurica root	JP			X	X	X		X	X			X								
Angelica dahurica root/Angelica dahurica var. formosana root	KP			X	X	X	X	X	X	X		X					X			
Angelica dahurica root/Angelica dahurica var. formosana root	CP	X						X		X		X								
Angelica pubescens f. biserrata root	CP	X						X	X	X										
Angelica sinensis root	CP	X						X	X	X		X		X						
Angelica sinensis root	EP		X					X	X	X										
Apocynum venetum leaf	CP	X						X	X	X		X								
Aquilaria sinensis resin	CP									X		X								
Arctium lappa fruit	JP		X					X	X			X								
Arctium lappa fruit	KP		X		X	X	X	X	X			X					X			
Ardisa japonica herb	CP	X						X		X										
Ardisia crenata root	CP	X						X	X	X		X								
Dreca catechu pericarp	CP	X																		
Dreca catechu pericarp	KP		X	X	X	X	X	X				X					X			
Dreca catechu seed	CP	X							X									X		
Dreca catechu seed	JP			X				X												
Dreca catechu seed	KP			X	X	X	X	X									X	X		

Table A.1 (continued)

Herbal name	Pharmacopoeia	Test item																		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Arisaema amurense tuber/Arisaema erubescens tuber/Arisaema heterophyllum tuber	KP		X		X	X	X	X									X			
Arisaema erubescens tuber/Arisaema heterophyllum tuber/Arisaema amurense tuber	CP	X					X		X		X									
Aristolochia contorta fruit/Aristolochia debilis fruit	CP																			
Aristolochia debilis herb/Aristolochia contorta herb	CP	X					X			X									X	
Arnebia euchroma root/Arnebia guttata root	CP	X							X											
Artemisia annua herb	CP	X					X				X									
Artemisia argyi leaf	CP	X					X	X	X											
Artemisia scoparia herb/Artemisia capillaris herb	CP	X							X	X										
Asarum heterotropoides var. mandshuricum root and rhizome/Asarum sieboldii var. seoulense root and rhizome/Asarum sieboldii root and rhizome	CP	X						X	X	X		X		X					X	
Asparagus cochinchinensis root	JP		X		X	X														
Asparagus cochinchinensis root tuber	CP	X					X				X						X			
Asparagus cochinchinensis tuber	KP		X		X	X	X				X						X			
Aster tataricus root and rhizome	CP	X					X	X	X	X										
Aster tataricus root and rhizome	KP		X	X	X	X	X	X			X						X			
Astragalus complanatus seed	CP	X					X	X	X											
Astragalus membranaceus root/Astragalus membranaceus var. mongholicus root	KP		X		X	X	X	X									X			
Astragalus membranaceus root/Astragalus mongholicus root	JP		X		X	X	X	X												

Table A.1 (continued)

Herbal name	Pharmacopoeia	Test item																		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Astragalus membranaceus var. mongholicus root/Astragalus membranaceus root	CP	X			X	X	X		X	X										
Astragalus mongholicus root	EP		X	X			X	X	X											
Atractylodes japonica rhizome/Atractylodes macrocephala rhizome	JP				X	X	X	X					X							
Atractylodes japonica rhizome/Atractylodes macrocephala rhizome	KP				X	X	X	X					X				X			
Atractylodes lancea (syn. Atractylodes chinensis, Atractylodes japonica) rhizome	EP	X					X	X					X							
Atractylodes lancea rhizome/Atractylodes chinensis rhizome	CP	X					X		X											
Atractylodes lancea rhizome/Atractylodes chinensis rhizome	JP				X	X	X	X					X							
Atractylodes lancea rhizome/Atractylodes chinensis rhizome	KP				X	X	X	X					X				X			
Atractylodes macrocephala rhizome	CP	X					X					X				X	X			
Atractylodes macrocephala rhizome	EP	X					X	X					X							
Atropa belladonna herb	CP	X		X					X											
Atropa belladonna leaf	EP			X			X	X	X											
Aucklandia lappa root	CP						X		X											
Bambusa textilis secretion/Schizostachyum chinense secretion	CP																			
Bambusa tuldoidea stem/Sinocalamus beecheyanus var. pubescens stem/phyllostachys nigra var. henonis stem	CP	X									X									

Table A.1 (continued)

Herbal name	Pharmacopoeia	Test item																		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Baphicacanthus cusia rhizome and root	CP	X					X				X									
Belamcanda chinensis rhizome	CP	X					X		X		X									
Belamcanda chinensis rhizome	EP		X				X	X												
Benincasa hispida exocarp	CP	X					X													
Berberis soulieana root/Berberis wilsonae root/Berberis poirerii root/Berberis verna root	CP	X					X		X		X									
Bergenia purpurascens rhizome	CP	X					X		X		X									
Bletilla striata tuber	CP	X					X										X			
Bolbostemma paniculatum tuber	CP	X					X		X		X									
Boswellia carterii bark resin/Boswellia bhawdajiana bark resin	CP			X					X											
Broussonetia papyrifera fruit	CP	X					X				X									
Brucea javanica fruit	CP	X		X			X		X											
Buddleja officinalis flower bud and inflorescence	CP								X											
Bupleurum chinense root	EP		X				X	X		X										
Bupleurum chinense root/Bupleurum scorzonifolium root	CP	X					X	X		X	X									
Bupleurum falcatum root	JP		X	X	X	X	X	X		X		X								
Bupleurum falcatum root	KP			X	X	X	X	X	X	X							X			
Caesalpinia sappan duramen	JP		X				X				X									
Caesalpinia sappan heart wood	CP	X									X									
Caesalpinia sappan heartwood	KP		X	X	X	X	X				X						X			
callicarpa formosana leaf	CP	X					X		X		X									
Callicarpa kwangtungensis stem and leaf	CP	X					X		X	X										
Callicarpa macrophylla leaf or branch	CP	X					X		X		X									

Table A.1 (continued)

Herbal name	Pharmacopoeia	Test item																		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Campsis grandiflora flower/ Campsis radicans flower	CP	X						X	X											
Canarium album fruit	CP	X						X			X									
Canavalia gladiata seed	CP																			
Cannabis sativa fruit	CP																			
Cannabis sativa fruit	JP		X	X				X	X											
Capsicum annuum fruit	CP									X										
Capsicum annuum fruit	JP		X	X				X	X	X										
Capsicum annuum fruit	KP			X	X	X	X	X	X			X								
Capsicum annuum var. minimum fruit	EP		X	X				X		X										
Carpesium abrotanoides fruit	CP																			
Carthamus tinctorius flower	CP	X		X				X	X	X	X									
Carthamus tinctorius flower	EP		X					X	X	X										
Carthamus tinctorius flower	JP			X				X												
Carthamus tinctorius tubulous flower	KP			X	X	X	X	X								X	X			
Cassia acutifolia leaf/Cassia an- gustifolia leaf	EP		X	X				X	X	X										
Cassia angustifolia leaf/Cassia acutifolia leaf	JP		X	X			X	X	X	X										
Cassia angustifolia leaf/Cassia acutifolia leaf	KP		X	X	X	X	X	X	X	X										
Cassia angustifolia leaflet/Cassia acutifolia leaflet	CP	X		X						X										
Cassia obtusifolia seed/Cassia toro seed	CP	X						X		X								X		
Cassia obtusifolia seed/Cassia toro seed	JP			X				X												
Cassia tora seed/Cassia obtusifolia seed	KP			X	X	X	X	X								X	X			

Table A.1 (continued)

Herbal name	Pharmacopoeia	Test item																		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Celosia argentea seed	CP																			
Celosia cristata capitulum	CP	X					X	X		X										
Centella asiatica herb	CP	X					X	X	X		X									
Centella asiatica herb	EP		X	X			X	X	X											
Centipeda minima herb	CP	X		X						X										
Chaenomeles speciosa fruit	CP	X					X		X		X									
Changium smyrnioides root	CP	X					X			X										
Chelidonium majus herb	CP	X					X		X			X								
Chelidonium majus herb	EP		X	X			X		X											
Choerospondias axillaris fruit	CP	X					X		X		X									
Chrysanthemum indicum capitulum	CP	X					X	X	X											
Chrysanthemum morifolium capitulum	CP	X							X											
Chrysanthemum morifolium capitulum/Chrysanthemum indicum capitulum	JP		X				X	X			X									
Cibotium barometz rhizome	CP	X					X													
Cibotium barometz rhizome	KP		X		X	X	X				X						X			
Cichorium glandulosum herb or root/Cichorium intybus herb or root	CP	X					X				X									
Cimicifuga heracleifolia rhizome/Cimicifuga dahurica rhizome/Cimicifuga foetida rhizome	CP	X		X			X	X	X			X								
Cimicifuga heracleifolia rhizome/Cimicifuga simplex rhizome/Cimicifuga dahurica rhizome/Cimicifuga foetida rhizome	KP				X	X	X	X									X			

Table A.1 (continued)

Herbal name	Pharmacopoeia	Test item																		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Cimicifuga simplex rhizome/ Cimicifuga dahurica rhizome/Ci- micifuga foetida rhizome/Cimicif- uga heracleifolia rhizome	JP				X	X		X	X			X								
Cinnamomum cassia bark	KP		X		X	X	X	X		X							X			
Cinnamomum cassia stem bark	CP	X					X	X		X				X						
Cinnamomum cassia trunk bark	JP		X				X	X						X						
Cinnamomum cassia young branch	CP	X						X		X		X								
Cinnamomum verum bark	EP							X						X						
Cirsium japonicum herb	CP	X		X					X	X		X								
Cirsium setosum herb	CP	X		X					X	X		X								
Cissampelos pareira herb	CP																			
Cistanche deserticola stem/Cis- tanche tubulosa stem	CP	X						X		X		X								
Cistanche salsa stem/Cistanche deserticola stem/Cistanche tubu- losa stem	JP		X			X		X	X			X								
Citrus aurantium immature fruit	CP	X						X		X										
Citrus aurantium var. daidai immature fruit/Citrus aurantium immature fruit/Citrus natsuda- idai immature fruit	JP							X												
Citrus grandis 'Tomentosa' exo- carp/Citrus grandis exocarp	CP	X						X		X										
Citrus medica fruit/Citrus wilsonii fruit	CP									X										
Citrus medica var. sarcodactylis fruit	CP	X								X		X								
Citrus reticulata epicarp and mesocarp	EP		X					X		X										
Citrus reticulata exocarp	CP	X						X		X										

Table A.1 (continued)

Herbal name	Pharmacopoeia	Test item																		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Citrus reticulata ripe pericarp	CP	X								X								X		
Citrus reticulata unripe pericarp	CP	X					X		X											
Citrus reticulata seed	CP																			
Citrus unshiu pericarp/Citrus reticulata pericarp	JP		X			X	X		X		X		X							
Citrus unshiu ripe pericarp/Citrus reticulata ripe pericarp	KP		X		X	X	X		X								X			
Citrus unshiu unripe pericarp/Citrus reticulata unripe pericarp	KP		X		X	X	X	X			X		X				X			
Citrus aurantium young fruit/Citrus sinensis young fruit	CP	X					X		X		X									
Clematis armandii stem	EP		X				X		X										X	
Clematis armandii stem/Clematis montana stem	CP	X					X				X									
Clematis chinensis root and rhizome/Clematis manshurica root and rhizome/Clematis hexapetala root and rhizome	CP	X					X	X	X		X									
Clematis chinensis root with rhizome/Clematis manshurica root with rhizome/Clematis hexapetala root with rhizome	JP		X		X	X	X	X			X									
Clinopodium polycephalum herb/clinopodiurn chinensis herb	CP	X					X				X									
Cnidium monnieri fruit	CP	X					X	X	X		X									
Cnidium monnieri fruit	JP		X				X	X			X									
Codonopsis pilosula root	EP		X				X	X	X		X									
Codonopsis pilosula root/Codonopsis pilosula var. modesta root/Codonopsis tangshen root	CP	X					X				X						X			
Codonopsis pilosula root/Codonopsis pilosula var. modesta root/Codonopsis tangshen root	KP		X		X	X	X	X			X						X			

Table A.1 (continued)

Herbal name	Pharmacopoeia	Test item																		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Codonopsis pilosula root/Codonopsis tangshen root	JP		X		X	X		X	X			X								
Coix lachryma-jobi var. mayuen seed	JP		X				X													
Coix lachryma-jobi var. mayuen seed	KP		X		X	X	X										X			
Coix lacryma-jobi subsp. mayuen kernel	EP		X				X		X											
Coix lacrymajobi var. mayuen kernel	CP	X		X			X		X		X							X		
Commelina communis herb	CP	X									X									
Commiphora molmol gum-resin/Commiphora myrrha gum-resin	KP						X		X											
Commiphora molmol resin/Commiphora myrrha resin	CP			X			X		X				X							
Commiphora myrrha (syn. Commiphora molmol) resin	EP		X				X													
Conyza blinii herb	CP	X					X		X	X										
Coptis chinensis rhizome/Coptis deltoidea rhizome/Coptis teeta rhizome	CP	X					X		X	X		X								
Coptis chinensis rhizome/Coptis deltoidea rhizome/Coptis teeta rhizome	EP		X	X			X		X	X										
Coptis japonica rhizome/Coptis chinensis rhizome/Coptis deltoidea rhizome/Coptis teeta rhizome	KP		X		X	X	X		X	X							X			
Coptis japonica rhizome/Coptis chinensis rhizome/Coptis deltoidea rhizome/Coptis teeta rhizome	JP		X		X		X		X	X										
Cordyceps sinensis composite	CP									X										

Table A.1 (continued)

Herbal name	Pharmacopoeia	Test item																		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Coriolus versicolour sporophore	CP	X					X	X	X	X	X									
Cornus officinalis fruit	KP			X	X	X	X		X	X							X			
Cornus officinalis pulp	JP			X		X	X		X	X		X								
Cornus officinalis sarcocarp	CP	X		X			X		X	X	X									
Corydalis bungeana herb	CP	X		X					X	X	X									
Corydalis decumbens tuber	CP	X					X		X	X		X								
Corydalis ternata tuber/Corydalis yanhusuo tuber	KP				X	X	X		X	X							X			
Corydalis turttschaninovii forma yanhusuo tuber	JP		X		X	X	X		X	X										
Corydalis yanhusuo tuber	CP	X					X		X	X		X								
Corydalis yanhusuo tuber	EP		X				X	X	X	X								X		
Crataegus cuneata pseudocarp/Crataegus pinnatifida var. major pseudocarp	JP		X				X					X								
Crataegus monogyna flower-bearing branches/Crataegus laevigata (syn. Crataegus oxyacantha/Crataegus oxyacanthoides) flower-bearing branches/Crataegus pentagyna flower-bearing branches/Crataegus nigra flower-bearing branches/Crataegus azarolus flower-bearing branches	EP		X	X			X		X											
Crataegus monogyna fruit/Crataegus laevigata (syn. Crataegus oxyacantha) fruit	EP		X	X			X		X											
Crataegus pinnatifida fruit	KP				X	X	X	X									X			
Crataegus pinnatifida var. major fruit/Crataegus pinnatifida fruit	CP	X			X	X	X	X	X		X									
Crataegus pinnatifida var. major leaf/Crataegus pinnatifida leaf	CP	X						X	X	X	X									

Table A.1 (continued)

Herbal name	Pharmacopoeia	Test item																		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Cremastra appendiculata pseudobulb/Pleione bulbocodioides pseudobulb/Pleione yunnanensis pseudobulb	CP																			
	CP		X				X		X		X									
	JP		X	X			X													
Crocus sativus stigma	KP		X	X	X	X	X													
Croton tiglium fruit	CP	X					X		X											
Croton tiglium seed	KP				X	X	X				X							X		
Cucumis melo seed	CP						X													
Curculigo orchioideis rhizome	CP	X		X			X	X	X		X									
Curcuma domestica rhizome	EP	X					X		X				X							
Curcuma longa rhizome	CP	X					X		X		X		X							
Curcuma longa rhizome	JP		X		X	X	X	X	X		X									
Curcuma longa rhizome	KP				X	X	X	X	X								X			
Curcuma phaeocaulis rhizome/ Curcuma kwangsiensis rhizome/ Curcuma wenyujin rhizome	CP	X					X	X			X			X						
Curcuma phaeocaulis rhizome/ Curcuma kwangsiensis rhizome/ Curcuma wenyujin rhizome	KP				X	X	X						X			X				
Curcuma wenyujin rhizome	CP																			
Curcuma wenyujin rhizome	CP												X							
Curcuma wenyujin root tuber/ Curcuma longa root tuber/ Curcuma kwangsiensis root tuber/ Curcuma phaeocaulis root tuber	CP	X					X													
Curcuma wenyujin root tuber/ Curcuma longa root tuber/ Curcuma kwangsiensis root tuber/ Curcuma phaeocaulis root tuber	KP		X		X	X	X										X	X		
Curcuma zedoaria rhizome	JP				X	X							X							

Table A.1 (continued)

Herbal name	Pharmacopoeia	Test item																		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Cuscuta australis seed/Cuscuta chinensis seed	CP	X					X	X	X											
Cyathula officinalis root	CP	X					X		X	X										
Cynanchum atratum root and rhizome/Cynanchum versicolour root and rhizome	CP	X		X			X	X			X									
Cynanchum paniculatum root and rhizome	CP	X					X	X	X		X									
Cynanchum stauntonii rhizome and root/Cynanchum glaucescens rhizome and root	CP																			
Cynomorium songaricum stem	CP	X		X			X				X									
Cynomorium songaricum succulent stem	KP		X	X	X	X	X				X						X			
Cyperus rotundus rhizome	CP	X					X					X		X						
Cyperus rotundus rhizome	JP				X	X	X						X							
Cyperus rotundus rhizome	KP				X	X	X	X						X			X			
Daemonorops draco resin	CP						X		X											
Dalbergia odorifera heart wood	CP											X								
Daphne genkwa flower bud	CP								X		X									
Datura metel flower	CP	X					X	X	X											
Daucus carota fruit	CP																			
Dendrobium nobile stem/Dendrobium chrysotoxum stem/Dendrobium fimbriatum stem	CP	X					X		X											
Dendrobium officinale stem	CP	X					X		X		X									
Descurainia sophia seed/Lepidium apetalum seed	CP	X					X	X	X											
Desmodium styracifolium herb	CP	X					X	X	X											
Dianthus superbus herb/Dianthus chinensis herb	CP	X					X													

Table A.1 (continued)

Herbal name	Pharmacopoeia	Test item																		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Dichroa febrifuga root	CP	X					X													
Dictamnus dasycarpus root bark	CP	X							X	X										
Dimorcarpus longan aril	CP	X					X			X										
Dimorcarpus longan aril	KP		X		X	X	X									X				
Dioscorea hypoglauca rhizome	CP	X					X				X									
Dioscorea japonica rhizome/Dioscorea batatas rhizome	JP		X		X	X	X	X												
Dioscorea japonica rhizome/Dioscorea batatas rhizome	KP		X		X	X	X									X				
Dioscorea nipponica rhizome	CP	X					X		X		X									
Dioscorea nipponica rhizome	EP		X				X	X												
Dioscorea opposita rhizome	CP	X					X			X							X			
Dioscorea opposita rhizome	EP		X				X	X		X										
Dioscorea panthaica rhizome	CP	X					X		X	X										
Dioscorea spongiosa rhizome/Dioscorea futschauensis rhizome	CP	X					X				X									
Diospyros kaki calyx	CP	X					X													
Dipsacus asper root	CP	X					X	X	X	X										
Dolichos lablab seed	CP	X																		
Dolichos lablab seed	JP		X				X				X									
Dolichos lablabseed	KP		X		X	X	X	X		X						X	X			
Drynaria fortunei rhizome	CP	X					X		X		X									
Drynaria fortunei rhizome	EP		X				X	X	X											
Drynaria foutunei rhizome	KP				X	X										X				
Dryopteris crassirhizoma rhizome and frond bases	CP	X					X	X			X									
Echinops latifolius root/Echinops grijisii root	CP	X					X	X			X									
Eclipta prostrata herb	CP	X					X	X	X											
Eclipta prostrata herb	EP		X				X	X	X											

Table A.1 (continued)

Herbal name	Pharmacopoeia	Test item																		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Eleutherococcus nodiflorus (syn. Acanthopanax gracilistylus) root bark	EP		X					X	X			X								
Eleutherococcus senticosus (Acanthopanax senticosus) rhizome	JP		X		X			X	X			X								
Entada phaseoloides seed	CP	X										X								
Ephedra sinica herb/Ephedra intermedia herb/Ephedra equisetina herb	EP		X				X	X	X											
Ephedra sinica root and rhizome/Ephedra intermedia root and rhizome/Ephedra equisetina root and rhizome	CP	X					X	X		X										
Ephedra sinica stem/Ephedra intermedia stem/Ephedra equisetina stem	CP	X		X			X	X	X											
Ephedra sinica stem/Ephedra intermedia stem/Ephedra equisetina stem	JP		X	X			X	X	X											
Ephedra sinica terrestrial stem/Ephedra intermedia terrestrial stem/Ephedra equisetina terrestrial stem	KP			X	X	X	X	X	X								X			
Epimedium brevicornum leaf/Epimedium sagittatum leaf/Epimedium pubescens leaf/Epimedium koreanum leaf	CP	X		X			X	X	X		X									
Epimedium koreanum herb/Epimedium brevicornum herb/Epimedium pubescens herb/Epimedium wushanense herb/Epimedium sagittatum herb	KP		X		X	X	X	X	X		X						X			

Table A.1 (continued)

Herbal name	Pharmacopoeia	Test item																		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Epimedium pubescens herb/ Epimedium brevicornu herb/Epimedium wushanense herb/Epimedium sagittatum herb/Epimedium koreanum herb/Epimedium grandiflorum var. thunbergianum herb/Epimedium sempervirens herb	JP		X					X	X			X								
Epimedium wushanense leaf	CP	X		X			X		X			X								
Equisetum arvense herb	EP		X	X			X	X												
Equisetum hyemale herb	CP	X							X			X								
Eriobotrya japonica leaf	CP	X					X		X			X								
Erigeron breviscapus herb	CP	X					X	X	X			X								
Eriobotrya japonica leaf	JP		X				X	X				X								
Eriobotrya japonica leaf	KP		X		X	X	X					X					X			
Eriocaulon buergerianum capitulum	CP																			
Erodium stephanianum herb/Geranium wilfordii herb/geranium carolinianum herb	CP	X		X			X			X										
Erycibe obtusifolia stem/Erycibe schmidtii stem	CP	X					X			X		X								
Eucommia ulmoides bark	EP		X				X			X										
Eucommia ulmoides bark	JP		X				X	X				X								
Eucommia ulmoides leaf	CP	X								X		X								
Eucommia ulmoides stem bark	CP									X		X								
Eucommia ulmoides stem bark	KP		X		X	X	X	X	X	X		X					X			
Eugenia caryophyllata flower bud	CP	X		X						X										
Eugenia caryophyllata flower bud	JP			X			X	X						X						
Eugenia caryophyllata fruit	CP	X					X		X			X								
Eugenia caryophyllus flower bud	EP			X			X						X							