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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

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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 22467[1)], *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 B_1 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.

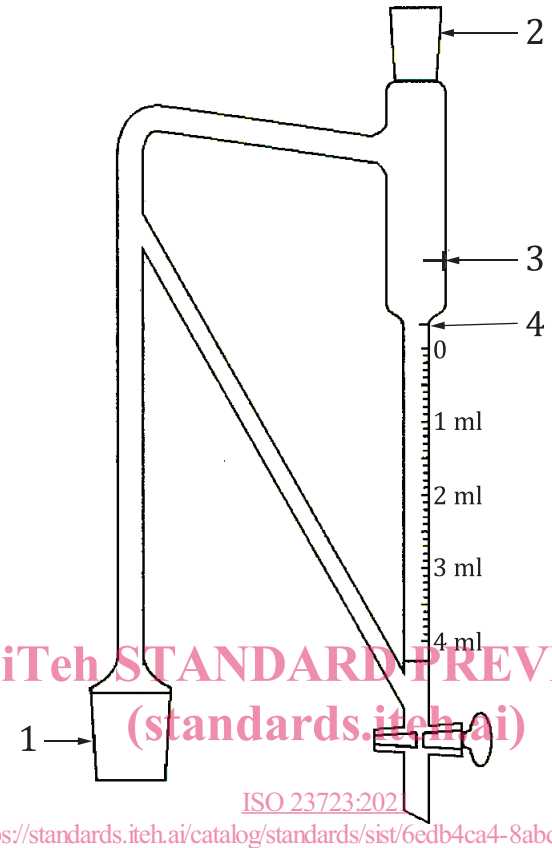
7.2.5 Extractives

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 lower

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 22467[2)] 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.

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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.