

INTERNATIONAL  
STANDARD

ISO  
4154

First edition  
2022-05

---

---

**Traditional Chinese medicine —  
*Sinomenium acutum* stem**

*Médecine traditionnelle chinoise — Tige de Sinomenium acutum*

STANDARDSISO.COM : Click to view the full PDF of ISO 4154:2022



Reference number  
ISO 4154:2022(E)

© ISO 2022

STANDARDSISO.COM : Click to view the full PDF of ISO 4154:2022



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2022

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

Page

Foreword.....	iv
Introduction.....	v
<b>1 Scope.....</b>	<b>1</b>
<b>2 Normative references.....</b>	<b>1</b>
<b>3 Terms and definitions.....</b>	<b>1</b>
<b>4 Descriptions.....</b>	<b>2</b>
<b>5 Requirements.....</b>	<b>3</b>
5.1 General characteristics.....	3
5.2 Morphological features of <i>Sinomenium acutum</i> stem.....	3
5.3 Microscopic identification.....	3
5.3.1 Transverse section.....	3
5.3.2 Powder.....	3
5.4 Thin-layer chromatogram identification.....	3
5.5 Moisture.....	3
5.6 Total ash.....	3
5.7 Acid-insoluble ash.....	3
5.8 Heavy metals.....	4
5.9 Pesticide residues.....	4
5.10 Marker compound.....	4
<b>6 Sampling.....</b>	<b>4</b>
<b>7 Test methods.....</b>	<b>4</b>
7.1 Macroscopic identification.....	4
7.2 Microscopic identification.....	4
7.3 Thin-layer chromatogram identification.....	4
7.4 Determination of moisture content.....	4
7.5 Determination of total ash content.....	4
7.6 Determination of acid-insoluble ash content.....	4
7.7 Determination of heavy metals content.....	4
7.8 Determination of pesticide residues content.....	4
7.9 Determination of marker compound.....	4
<b>8 Test report.....</b>	<b>5</b>
<b>9 Packaging, storage and transportation.....</b>	<b>5</b>
<b>10 Marking and labelling.....</b>	<b>5</b>
<b>Annex A (informative) Thin-layer chromatogram identification.....</b>	<b>6</b>
<b>Annex B (informative) Determination of moisture content.....</b>	<b>7</b>
<b>Annex C (informative) Determination of marker compound by HPLC-UV.....</b>	<b>8</b>
<b>Annex D (informative) Referenced information of national and regional requirements.....</b>	<b>9</b>
<b>Bibliography.....</b>	<b>10</b>

## 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](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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](http://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](http://www.iso.org/members.html).

## Introduction

*Sinomenium acutum* stem is mainly produced in China and is also distributed in Japan. It has a long history as one of the most commonly used traditional Chinese medicines to treat rheumatism and arthralgia. *Sinomenium acutum* stem was first recorded in *Bencao tujing*<sup>[1]</sup> (本草图经) and also called qingteng or xunfengteng in *Bencao gangmu*<sup>[2]</sup> (本草纲目).

The main chemical constituents of *Sinomenium acutum* stem include alkaloids, volatile oils, sterols and lipids. Modern pharmacological studies have shown that the sinomenine in *Sinomenium acutum* stem has definite benefits for analgesia, anti-inflammation, sedation, lowering blood-pressure, anti-arrhythmia and immunosuppression. It is mainly used to treat rheumatoid arthritis, arrhythmia, ankylosing spondylitis, pain and other diseases. At present, there are more than 10 kinds of Chinese proprietary medicine, including zhengqing fengtongning pills, analgesic wine and qingtengteng tablets.

Although the curative effect of *Sinomenium acutum* stem is definite, side effects include allergic skin rash, gastrointestinal reactions and granulocyte reduction. This is a reminder to the industry to be cautious about the safety of *Sinomenium acutum* stem.

China, Japan, South Korea and Europe have established a standard for *Sinomenium acutum* stem in their respective pharmacopoeias. But each pharmacopoeia's requirements are different. The *Sinomenium acutum* stem standard has not been unified at the international level, and many countries have different regulation levels.

As national implementation can differ, national standards bodies are invited to modify the values given in [5.5](#), [5.6](#) and [5.7](#) in their national standards. An example of national values is given in [Annex D](#).

The purpose of this document is to establish an International Standard for the quality and safety control of *Sinomenium acutum* stem, ensure the safety and effectiveness of clinical drug use, regulate the international market and reduce the occurrence of adverse events.

[STANDARDSISO.COM](https://standardsiso.com) : Click to view the full PDF of ISO 4154:2022

# Traditional Chinese medicine — *Sinomenium acutum* stem

## 1 Scope

This document specifies the minimum quality and safety requirements of *Sinomenium acutum* stem [the dried lianoid stem of *Sinomenium acutum* (Thunb.) Rehd. et Wils. and *Sinomenium acutum* (Thunb.) Rehd. et Wils. var. *cinereum* Rehd. et Wils.].

This document applies to *Sinomenium acutum* stem that is sold and used as natural medicines in international trade, including Chinese materia medica (whole medicinal materials) and decoction pieces derived from these plants.

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

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

ISO 21371, *Traditional Chinese medicine — Labelling requirements of products intended for oral or topical use*

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 23723, *Traditional Chinese medicine — General requirements for herbal raw material and materia medica*

## 3 Terms and definitions

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

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

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

### 3.1

#### ***Sinomenium acutum* stem**

dried lianoid stem of *Sinomenium acutum* (Thunb.) Rehd. et Wils. and *Sinomenium acutum* (Thunb.) Rehd. et Wils. var. *cinereum* Rehd. et Wils

### 3.2

#### **marker compound**

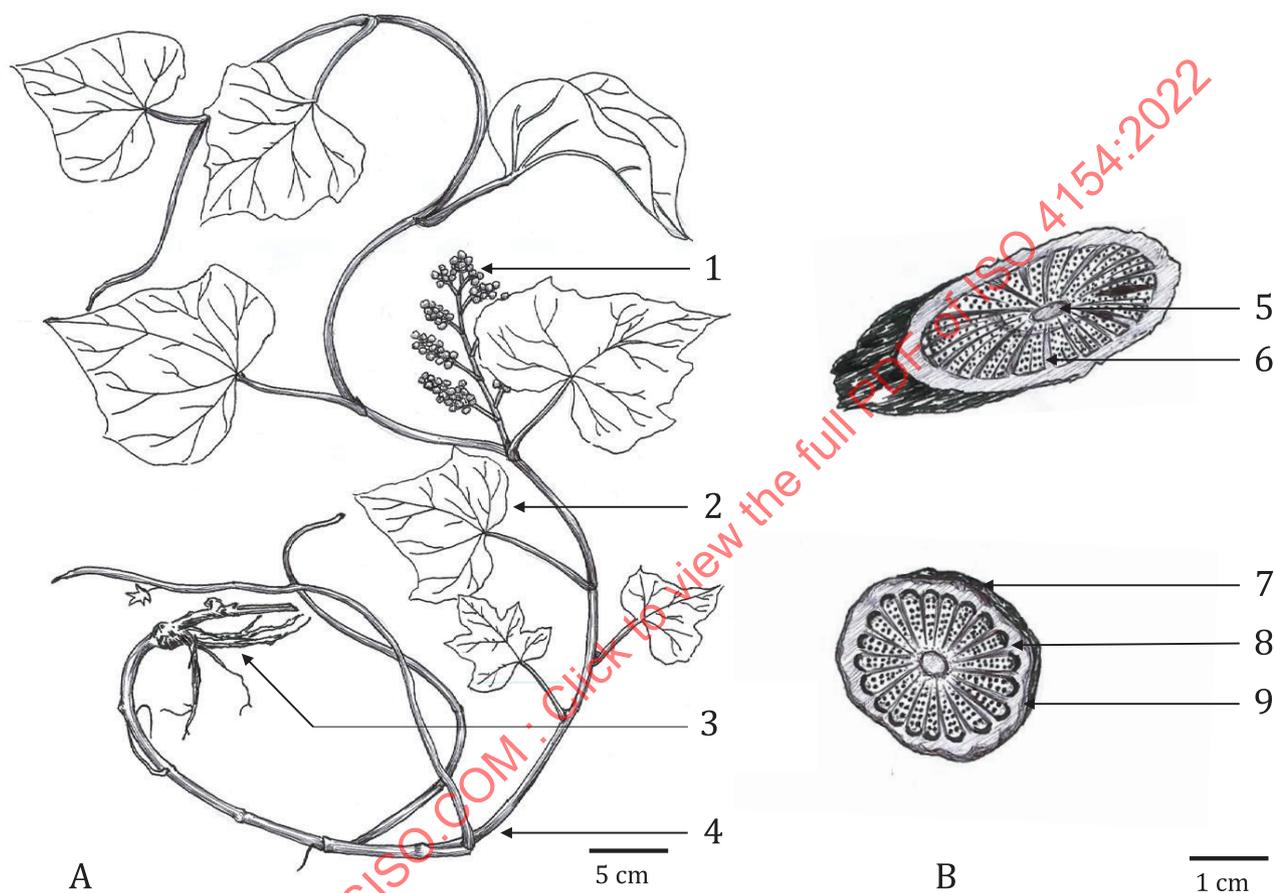
chemical constituent within a medicinal herb that can be used to verify its quality

Note 1 to entry: Usually described as active ingredients or chemicals that confirm the correct botanical identity of the starting material.

Note 2 to entry: There can be one or more marker compounds for a medicinal herb.

## 4 Descriptions

*Sinomenium acutum* stem is the lianoid stem of *Sinomenium acutum* (Thunb.) Rehd. et Wils. and *Sinomenium acutum* (Thunb.) Rehd. et Wils. var. *cinereum* Rehd. et Wils. collected in late autumn and early winter, tied up in a bundle or cut into a long section and dried in the sun or by another appropriate method, as shown in [Figure 1](#).



### Key

- A plant of *Sinomenium acutum*
- B decoction pieces of *Sinomenium acutum* stem
- 1 inflorescence
- 2 leaf
- 3 root
- 4 stem
- 5 pith
- 6 wood ray
- 7 epidermis
- 8 xylem
- 9 phloem

Figure 1 — Structure of *Sinomenium acutum* stem

## 5 Requirements

### 5.1 General characteristics

The following requirements shall be met before sampling:

- a) *Sinomenium acutum* stem shall be clean and free from leaves and foreign matter.
- b) The presence of living insects, mouldy fruit and external contaminants which are visible to the naked eye shall not be permitted.

### 5.2 Morphological features of *Sinomenium acutum* stem

This raw materia medica is long and cylindrical, usually somewhat curved, 20 cm to 70 cm long or more and 0,5 cm to 2 cm in diameter. The exterior is greenish-brown to brown. Some are greyish-brown, with fine longitudinal striations and lenticels. The nodes are slightly swollen and branched. The texture is uneven and greyish-yellow or pale greyish-brown. The bark is narrow. Wood rays are arranged radially. The pith is pale yellowish-white or yellowish-brown. The odour is slight. The taste is bitter.

### 5.3 Microscopic identification

#### 5.3.1 Transverse section

The outmost is the epidermis, covered with thick cuticle or cork. The cortex is scattered with fibres and stone cells. Pericyclic fibre groups are in a crescent shape. The inner sider of the fibre groups usually possesses two to five layers of stone cells, tangentially elongated and linked with stone cell groups in rays to a ring. Vascular bundles are collateral. The phloem rays gradually widen outwards, with conical or branched stone cells. The cells of phloem are mostly collapsed, sometimes scattered with one to three fibres. Xylem vessels are individually scattered or several linked up tangentially. The walls of the cells surrounding the pith are relatively thick and distinctly pitted. Parenchymatous cells contain starch granules and needle crystals of calcium oxalate.

#### 5.3.2 Powder

The powder is yellowish-brown or greyish-brown. Epidermal cells are yellow or yellowish-brown, subrounded or oblong in lateral view, 24  $\mu\text{m}$  to 78  $\mu\text{m}$  in diameter, covered with cuticles. Stone cells are pale yellow or yellow, subsquare, fusiform, elliptical or irregular. The walls are relatively thick. Pit canals are distinct. Cortex fibres are pale yellow or yellow, 27  $\mu\text{m}$  to 70  $\mu\text{m}$  in diameter, with heavy, thick walls and a narrow lumen. Needle crystals of calcium oxalate are small, occurring in parenchymatous cells.

### 5.4 Thin-layer chromatogram identification

When thin-layer chromatogram (TLC) identification is performed, the TLC of *Sinomenium acutum* stem shall present the spots with the same colour and position as those of the reference solutions.

### 5.5 Moisture

The mass fraction of moisture should not be more than 13,0 %.

### 5.6 Total ash

The mass fraction of total ash should not be more than 6,0 %.

### 5.7 Acid-insoluble ash

The mass fraction of acid-insoluble ash should not be more than 0,5 %.

## 5.8 Heavy metals

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

## 5.9 Pesticide residues

The content of pesticide residues shall be determined.

## 5.10 Marker compound

When sinomenine (C<sub>19</sub>H<sub>23</sub>NO<sub>4</sub>) is used as a marker compound, its content should not be less than 0,50 % of dried *Sinomenium acutum* stem.

## 6 Sampling

Sampling of *Sinomenium acutum* stem shall be carried out in accordance with the method described in ISO 23723:2021, Clause 8.

## 7 Test methods

### 7.1 Macroscopic identification

Samples are examined by naked eye observation in sunlight, and by smell and taste.

### 7.2 Microscopic identification

The testing method specified in ISO/TS 21310 shall apply.

### 7.3 Thin-layer chromatogram identification

See [Annex A](#) for additional information.

### 7.4 Determination of moisture content

See [Annex B](#) for additional information.

### 7.5 Determination of total ash content

The testing method specified in ISO 23723:2021, 7.2.3 shall apply.

### 7.6 Determination of acid-insoluble ash content

The testing method specified in ISO 23723:2021, 7.2.3 shall apply.

### 7.7 Determination of heavy metals content

The testing method specified in ISO 18664 shall apply.

### 7.8 Determination of pesticide residues content

The testing method specified in ISO 22258 shall apply.

### 7.9 Determination of marker compound

See [Annex C](#) for additional information.

## 8 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;
- 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 might have influenced the test result(s);
- f) any unusual features (anomalies) observed during the test;
- g) the date of the test.

## 9 Packaging, storage and transportation

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

The storage conditions specified in ISO 22217 shall apply.

The products shall be protected from light, moisture, pollution and foreign substances during long-distance delivery. Carriers should be well ventilated and moisture-proof to keep the products dry.

## 10 Marking and labelling

The method specified in ISO 21371 shall apply. The following items shall be marked or labelled on the packages:

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

## Annex A (informative)

### Thin-layer chromatogram identification

- a) Heat 2 g of the powdered *Sinomenium acutum* stem sample being examined (through no. 3 sieve) with 25 ml of ethanol under reflux for 60 min and filter. Evaporate the filtrate to dryness and dissolve in 1 ml of ethanol as the test solution.
- b) Heat 2 g of the powdered reference drug of *Sinomenium acutum* stem with 25 ml of ethanol under reflux for 60 min and filter. Evaporate the filtrate to dryness and dissolve in 1 ml of ethanol as the herbal reference solution.
- c) Dissolve a quantity of sinomenine CRS in ethanol to produce a solution containing 1 mg per ml as the CRS reference solution.
- d) Use silica gel G as the coating substance and the upper layer of a mixture of toluene, ethyl acetate, methanol and water (2:4:2:1) placed below 10 °C as the mobile phase before use.
- e) Pipette 5 µl of each test solution and the reference solution and spot them on the same silica gel G thin layer plate, respectively. Develop at room temperature in a developing cylinder with the concentrated ammonia test solution presaturated for 20 min.
- f) After developing, remove the plate, dry the plate in air and successively spray with bismuth potassium iodide TS and sodium nitrite in ethanol TS.
- g) The spots in the chromatogram obtained with the test solution correspond in position and colour to the spots in the chromatogram obtained with the reference solutions.

## Annex B (informative)

### Determination of moisture content

Determination can be conducted by the oven-drying method with the following steps:

- a) Place 2 g to 5 g of the powdered *Sinomenium acutum* stem sample (through no. 3 sieve) in a flat weighing bottle, previously dried to a constant weight, to form a smooth layer not exceeding 5 mm in thickness and then weigh accurately.
- b) Dry in an oven at 100 °C to 105 °C for 5 h with the stopper of the bottle removed.
- c) Upon opening the oven, close the bottle promptly and allow it to cool in a desiccator for 30 min.
- d) Weigh accurately and dry it again under similar conditions for 1 h, cool and weigh.
- e) Repeat the operation until the difference between two successive samples is not more than 5 mg.
- f) Calculate the percentage content of water in the test sample according to the mass loss on drying.

STANDARDSISO.COM : Click to view the full PDF of ISO 4154:2022

## Annex C (informative)

### Determination of marker compound by HPLC-UV

#### C.1 Preparation of test solution

- a) Weigh accurately 0,5 g of the powdered *Sinomenium acutum* stem sample (through no. 3 sieve) in a conical flask with stopper.
- b) Accurately add 20 ml of 70 % ethanol, stopper well and weigh.
- c) Ultrasonicate for 20 min (power 150 W, frequency 20 kHz), cool, weigh again and compensate the loss of the mass with 70 % ethanol.
- d) Shake thoroughly, filter and use the successive filtrate as the test solution.

#### C.2 Preparation of reference solution

Dissolve a quantity of sinomenine CRS in [Table C.1](#) and weigh accurately in methanol to produce a solution containing 0,5 mg per ml as the reference solution.

**Table C.1 — Chemical information of sinomenine**

Name	Molecular formula	CAS no.	Molar mass g/mol
sinomenine	$C_{19}H_{23}NO_4$	115-53-7	329,39

#### C.3 Chromatographic conditions

- a) Stationary phase: octadecyl-silane bonded silica gel or equivalent as analysing column.
- b) Column size: 4,6  $\mu\text{m}$ , 5 mm  $\times$  150 mm.
- c) Mobile phase A: 55 % methanol and 45 % phosphate buffer (the buffer is adjusted to pH 8,0 with 0,005 mol/l sodium dihydrogen phosphate solution then to pH 9,0 with 1 % triethylamine).
- d) Flow rate: 1 ml/min.
- e) Injection volume: 10  $\mu\text{l}$ .
- f) Temperature of column oven: 30  $^{\circ}\text{C}$ .
- g) Detector: a spectrophotometer set at 262 nm.

#### C.4 Determination

Inject accurately 10  $\mu\text{l}$  each of the reference solution and the test solution into the column and calculate the mass fraction of sinomenine with reference to the dried drug. Validate the methodology for accuracy, precision and repeatability, if necessary.