

FINAL  
DRAFT

INTERNATIONAL  
STANDARD

ISO/FDIS  
22585

ISO/TC 249

Secretariat: SAC

Voting begins on:  
2021-12-14

Voting terminates on:  
2022-02-08

---

---

## Traditional Chinese medicine — *Codonopsis pilosula* root

iTeh STANDARD PREVIEW  
(standards.iteh.ai)

[ISO/FDIS 22585](https://standards.iteh.ai/catalog/standards/sist/c6d9cbc7-38d4-451c-ac25-86e607948429/iso-fdis-22585)

<https://standards.iteh.ai/catalog/standards/sist/c6d9cbc7-38d4-451c-ac25-86e607948429/iso-fdis-22585>

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.



Reference number  
ISO/FDIS 22585:2021(E)

© ISO 2021

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[ISO/FDIS 22585](https://standards.iteh.ai/catalog/standards/sist/c6d9cbc7-38d4-451c-ac25-86e607948429/iso-fdis-22585)

<https://standards.iteh.ai/catalog/standards/sist/c6d9cbc7-38d4-451c-ac25-86e607948429/iso-fdis-22585>



### **COPYRIGHT PROTECTED DOCUMENT**

© ISO 2021

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 Morphological features.....	3
5.1.1 Appearance.....	3
5.1.2 Colour.....	3
5.1.3 Dimensions.....	3
5.1.4 Texture.....	3
5.1.5 Odour and taste.....	3
5.2 Moisture.....	3
5.3 Total ash.....	3
5.4 Acid-insoluble ash.....	3
5.5 Ethanol-soluble extractives.....	3
5.6 Thin-layer chromatogram (TLC) identification.....	3
5.7 Contents of marker compound.....	3
5.8 Heavy metals.....	4
5.9 Pesticide residues.....	4
5.10 Sulfur dioxide residues.....	4
<b>6 Sampling.....</b>	<b>4</b>
<b>7 Test methods.....</b>	<b>4</b>
7.1 Macroscopic identification.....	4
7.2 Determination of moisture content.....	4
7.3 Determination of total ash content.....	4
7.4 Determination of acid-insoluble ash content.....	4
7.5 Determination of ethanol-solution extractives content.....	4
7.6 Thin-layer chromatogram (TLC) identification.....	4
7.7 Determination of lobetyolin content.....	4
7.8 Determination of heavy metals content.....	4
7.9 Determination of pesticide residues content.....	4
7.10 Determination of sulfur dioxide residues content.....	5
<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) Determination of ethanol-soluble extractives.....</b>	<b>6</b>
<b>Annex B (informative) Thin-layer chromatogram (TLC) identification.....</b>	<b>7</b>
<b>Annex C (informative) Determination of lobetyolin content.....</b>	<b>9</b>
<b>Annex D (informative) Referenced values of <i>Codonopsis pilosula</i> root in different countries and regions.....</b>	<b>12</b>
<b>Bibliography.....</b>	<b>14</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

*Codonopsis pilosula* root is dried root of *Codonopsis pilosula* (Franch.) Nannf. (Family: Campanulaceae). It has a long history of use in East Asian countries for invigorating the stomach and spleen and benefitting qi.

Clinically, *Codonopsis pilosula* root is effective for the treatment of anaemia and malnutrition. To date, *Codonopsis pilosula* root occupies a huge share of the international market. However, many problems affect the quality of *Codonopsis pilosula* root, such as limited wild resources, increasing demand, the high investment cost of planting, different quality requirements among different countries and regions, and different packaging, transportation and storage conditions. Therefore, standardization of *Codonopsis pilosula* root is required.

As national implementation can differ, national standards bodies are invited to modify the values given in [5.2](#), [5.3](#), [5.4](#), [5.5](#) and [5.7](#) in their national standards. Examples of national and regional values are given in [Annex D](#).

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[ISO/FDIS 22585](#)

<https://standards.iteh.ai/catalog/standards/sist/c6d9cbc7-38d4-451c-ac25-86e607948429/iso-fdis-22585>

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[ISO/FDIS 22585](https://standards.iteh.ai/catalog/standards/sist/c6d9cbc7-38d4-451c-ac25-86e607948429/iso-fdis-22585)

<https://standards.iteh.ai/catalog/standards/sist/c6d9cbc7-38d4-451c-ac25-86e607948429/iso-fdis-22585>

# Traditional Chinese medicine — *Codonopsis pilosula* root

## 1 Scope

This document specifies the minimum requirements and test methods for *Codonopsis pilosula* root derived from the plant of *Codonopsis pilosula* (Franch.) Nannf.

It is applicable to *Codonopsis pilosula* root that is sold as Chinese materia medica (whole medicinal materials) and decoction pieces derived from this plant.

## 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 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 20409, *Traditional Chinese medicine — Panax notoginseng root and rhizome*

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

<https://standards.iteh.ai/catalog/standards/sist/c6d9cbc7-38d4-451c-ac25-86e607948429/iso-fdis-22585>

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

ISO 23723:2021, *Traditional Chinese medicine — General requirements for herbal raw material and materia medica*

## 3 Terms and definitions

No terms and definitions are listed in this document.

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

#### ***Codonopsis pilosula* root**

dried root of *Codonopsis pilosula* (Franch.) Nannf. in the family of Campanulaceaea

### 3.2 marker compound

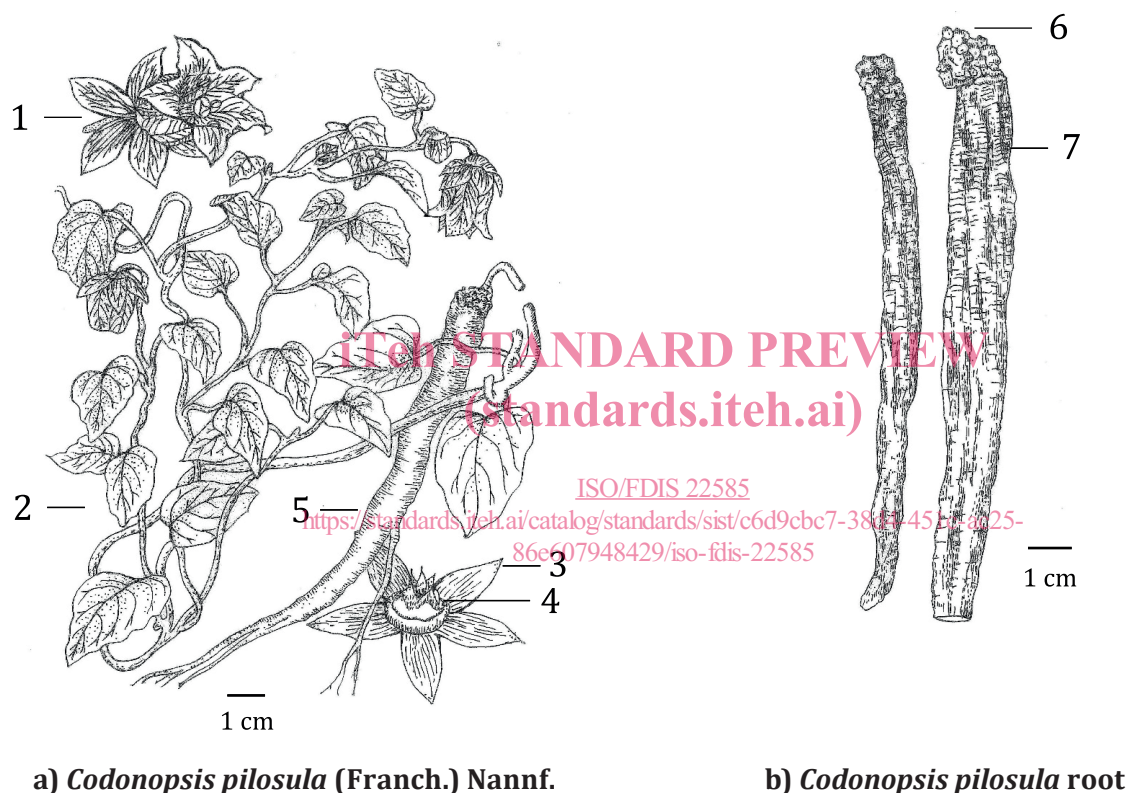
chemical constituent within a medicinal herb that can be used to verify its quality

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 may be one or more marker compounds for a medicinal herb.

## 4 Descriptions

*Codonopsis pilosula* root is dried root of *Codonopsis pilosula* (Franch.) Nannf. in the family of Campanulaceaea, as shown in [Figure 1](#).



#### Key

- 1 flower
- 2 plant
- 3 calyx
- 4 ovary
- 5 root
- 6 stem scars
- 7 lenticels

**Figure 1 — Structure of *Codonopsis pilosula* root**



## 5 Requirements

### 5.1 Morphological features

#### 5.1.1 Appearance

The whole root is cylindrical, slightly curved. The root crown, which is broader than the root, forms an irregular head with a convex centre consisting of buds and numerous prominent, rounded verrucose stem scars (Figure 1, key 6). The whole root from the base to the central part shows deep longitudinal wrinkles and prominent scattered protuberances, resembling lenticels (Figure 1, key 7), over its entire length.

#### 5.1.2 Colour

The external surface is brownish-yellow or brownish-grey. The colour of the transverse section is yellowish-white to light brown in the cortex, light yellow in the xylem, sometimes with a slit in the cortex. The cortex adheres tenaciously to the xylem and is difficult to remove.

#### 5.1.3 Dimensions

The root is 10 cm to 35 cm in length measured from the base to the end of the root and 0,4 cm to 2 cm in diameter measured at the base of the root (Figure 1 b).

#### 5.1.4 Texture

The texture is pliable and easily bendable on hard and easily breakable.

#### 5.1.5 Odour and taste

The odour is slight and characteristic; the taste is slightly sweet.

### 5.2 Moisture

The moisture content in percentage mass should not be more than 16,0 %.

### 5.3 Total ash

The total ash content in percentage mass should not be more than 5,0 %.

### 5.4 Acid-insoluble ash

The total ash content in percentage mass should not be more than 2,0 %.

### 5.5 Ethanol-soluble extractives

The ethanol-soluble extracts content in percentage mass should not be less than 35,0 %.

### 5.6 Thin-layer chromatogram (TLC) identification

The identification of marker compound, such as lobetyolin, with thin-layer chromatogram (TLC) shall present spots or bands obtained from the test and reference drug solution in the same position with the same colour.

### 5.7 Contents of marker compound

The content of the marker compound, such as lobetyolin, should be determined.

## 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 Sulfur dioxide residues

The content of sulfur dioxide residues should be determined.

## 6 Sampling

Sampling of *Codonopsis pilosula* root shall be carried out in accordance with ISO 23723:2021, Clause 8.

## 7 Test methods

### 7.1 Macroscopic identification

Samples of not less than 500 g are taken from each batch randomly. These samples are examined by unaided visual inspection, smell and taste.

### 7.2 Determination of moisture content

The testing method specified in ISO 20409 applies.

### 7.3 Determination of total ash content

The testing method specified in ISO 1575 applies.

### 7.4 Determination of acid-insoluble ash content

The testing method specified in ISO 1577 applies.

### 7.5 Determination of ethanol-solution extractives content

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

### 7.6 Thin-layer chromatogram (TLC) identification

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

### 7.7 Determination of lobetyolin content

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

### 7.8 Determination of heavy metals content

The testing method specified in ISO 18664 applies.

### 7.9 Determination of pesticide residues content

The testing method specified in ISO 22258 applies.

## 7.10 Determination of sulfur dioxide residues content

The testing method specified in ISO 22590 applies.

## 8 Test report

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

- a) all the 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

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

The storage requirements specified in ISO 22217 shall apply.

The *Codonopsis pilosula* root should be protected from light, moisture, pollution and the entry of foreign substances during long-distance delivery.

## 10 Marking and labelling

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

- a) product name;
- b) category of the product in the marketed country or region;
- c) net mass or quantity;
- d) contact information;
- e) name of raw materials;
- f) warning statements, if any;
- g) expiry date;
- h) storage method;
- i) batch or lot number;
- j) miscellaneous.