

---

---

**Traditional Chinese medicine — *Coptis chinensis* and *Coptis japonica* rhizome**

*Médecine traditionnelle chinoise — Rhizome de Coptis chinensis et de Coptis japonica*

iTeh STANDARD PREVIEW  
(standards.iteh.ai)

ISO 7177:2023

<https://standards.iteh.ai/catalog/standards/sist/f84b9b3b-43ce-4431-99a0-6dbcf7aa62e7/iso-7177-2023>



iTeh STANDARD PREVIEW  
(standards.iteh.ai)

ISO 7177:2023

<https://standards.iteh.ai/catalog/standards/sist/f84b9b3b-43ce-4431-99a0-6dbcf7aa62e7/iso-7177-2023>



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2023

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 Description.....</b>	<b>2</b>
<b>5 Requirements.....</b>	<b>3</b>
5.1 General characteristics.....	3
5.2 Morphological features of rhizome.....	3
5.3 Microscopic identification.....	3
5.4 Thin-layer chromatography (TLC) identification.....	4
5.5 Moisture.....	4
5.6 Total ash.....	4
5.7 Acid-insoluble ash.....	4
5.8 Heavy metals.....	4
5.9 Pesticide residues.....	5
5.10 Marker compounds.....	5
<b>6 Sampling.....</b>	<b>5</b>
<b>7 Test methods.....</b>	<b>5</b>
7.1 Macroscopic identification.....	5
7.2 Microscopic identification.....	5
7.3 Thin-layer chromatography (TLC) identification.....	5
7.4 Determination of moisture.....	5
7.5 Determination of total ash.....	5
7.6 Determination of acid-insoluble ash.....	5
7.7 Determination of heavy metals.....	5
7.8 Determination of pesticide residues.....	5
7.9 Determination of marker compounds.....	5
<b>8 Test report.....</b>	<b>6</b>
<b>9 Packaging, storage and transportation.....</b>	<b>6</b>
<b>10 Marking and labelling.....</b>	<b>6</b>
<b>Annex A (informative) Thin-layer chromatography (TLC) identification of <i>Coptis</i> rhizome.....</b>	<b>7</b>
<b>Annex B (informative) Determination of marker compounds by high-performance liquid chromatography with an ultraviolet detector (HPLC-UV).....</b>	<b>9</b>
<b>Annex C (informative) National and regional requirements for <i>Coptis</i> rhizome.....</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 document 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)).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at [www.iso.org/patents](http://www.iso.org/patents). ISO shall not be held responsible for identifying any or all such patent rights.

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

*Coptis* rhizome is used as traditional Chinese medicine in China. The rhizome of *Coptis japonica* Makino is also used as herbal medicine in Japan and the Republic of Korea. As one of the most commonly used medicinal herbs, *Coptis* rhizome was listed in *Shennong materia Medica. Treatise on Febrile diseases* contains 113 prescriptions, including 12 containing *Coptis* rhizome.

However, there are still some concerns about the quality control of *Coptis* rhizome, outlined as follows, which affect the trade and use of this herb.

- a) The harvesting and processing methods and techniques have not been standardized. Issues such as low efficiency, large interference from human factors and poor controllability seriously affect the quality of *Coptis* rhizome materials.
- b) Even though many countries or regions, such as China, Japan, the Republic of Korea and Europe, have established pharmacopoeia standards for *Coptis* rhizome, the relevant requirements vary significantly, which limits the application of those standards in global trade.
- c) The lack of quality standards for certain processed products, such as *Coptis* rhizome products processed with wine, ginger or *Euodia* fruit, makes it difficult to control their quality. This can affect the efficacy and safety of these products.

*Coptis* rhizome is ranked the fourth in the priority list of single herbal medicines for developing standards in ISO/TR 23975:2019. Thus, it is essential to develop an International Standard for *Coptis* rhizome to ensure consistency in the quality of *Coptis* rhizome and safe use of this herb and also to promote international trade.

In this document, the identification of commonly adulterated species of *Coptis* rhizome is also introduced.

As national implementation can differ, national standards bodies are invited to modify the values given in [5.5](#), [5.6](#) and [5.7](#) based on their national standards. Examples of national values are given in [Annex C](#).

7177-2023



# Traditional Chinese medicine — *Coptis chinensis* and *Coptis japonica* rhizome

## 1 Scope

This document specifies the minimum requirements and test methods for *Coptis* rhizome (the dried rhizome of *Coptis chinensis* Franch. and *Coptis japonica* Makino.).

This document applies to *Coptis* rhizome sold and used as Chinese materia medica (whole medicinal materials) and decoction pieces derived from these plants.

This document does not apply to the processed *Coptis* rhizome, including products traditionally processed with different methods, or its processing methods.

## 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 22217:2020, *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 23723:2021, *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

#### ***Coptis* rhizome**

dried rhizome of *Coptis chinensis* Franch. and *Coptis japonica* Makino.

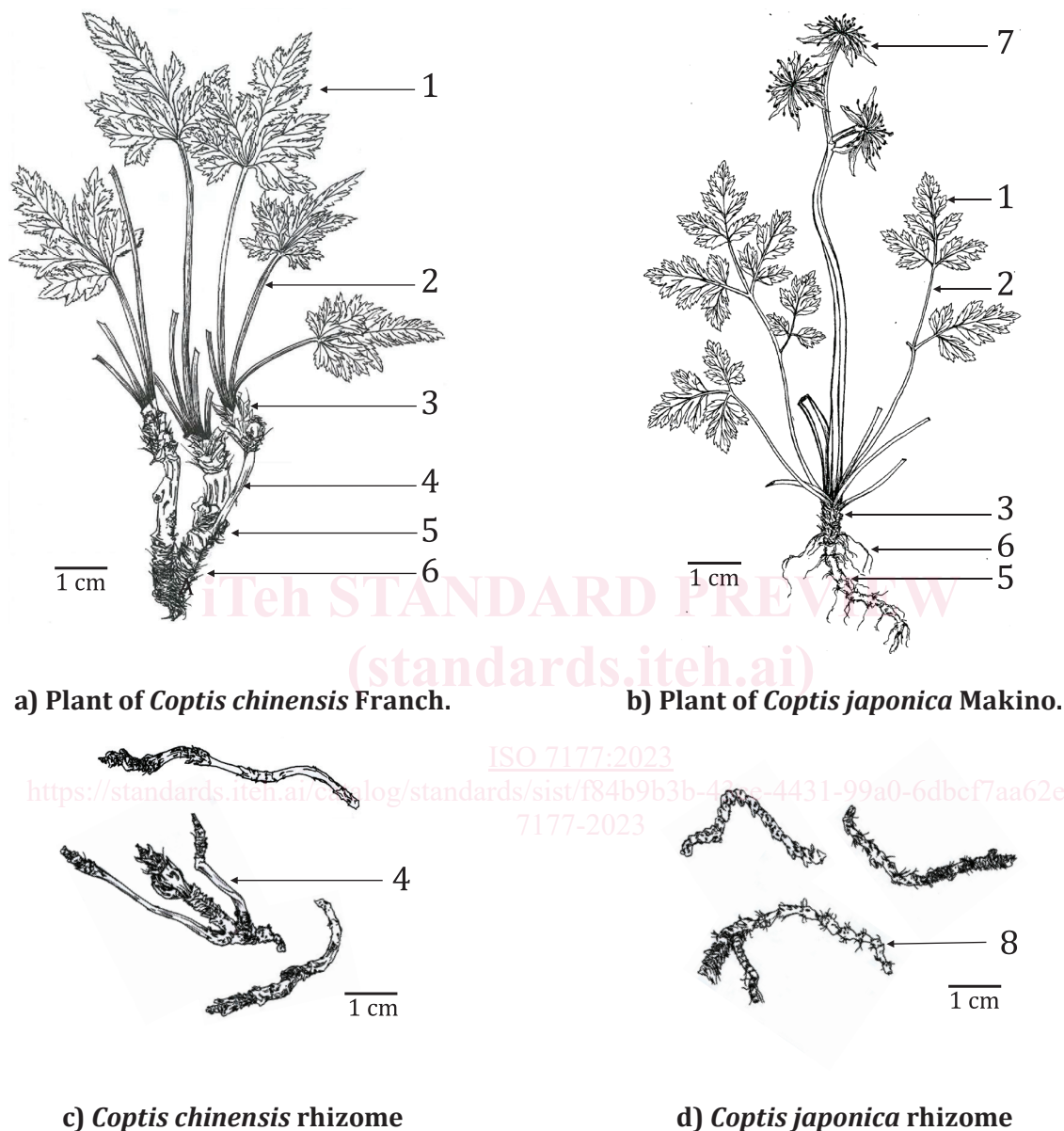
### 3.2

#### **bridge piece**

morphological feature of *Coptis* rhizome with its rhizome internodes as smooth as stem

## 4 Description

*Coptis* rhizome is the dried rhizome of *Coptis chinensis* Franch. and *Coptis japonica* Makino., collected in autumn, removed from rootlets and soil and dried, as shown in [Figure 1](#).



### Key

- 1 leaf
- 2 petiolate
- 3 phyllode
- 4 bridge piece
- 5 rhizome
- 6 fibrous root
- 7 flower
- 8 nodular bump

**Figure 1 — Structure of *Coptis* rhizome**



## 5 Requirements

### 5.1 General characteristics

The following requirements shall be met before sampling:

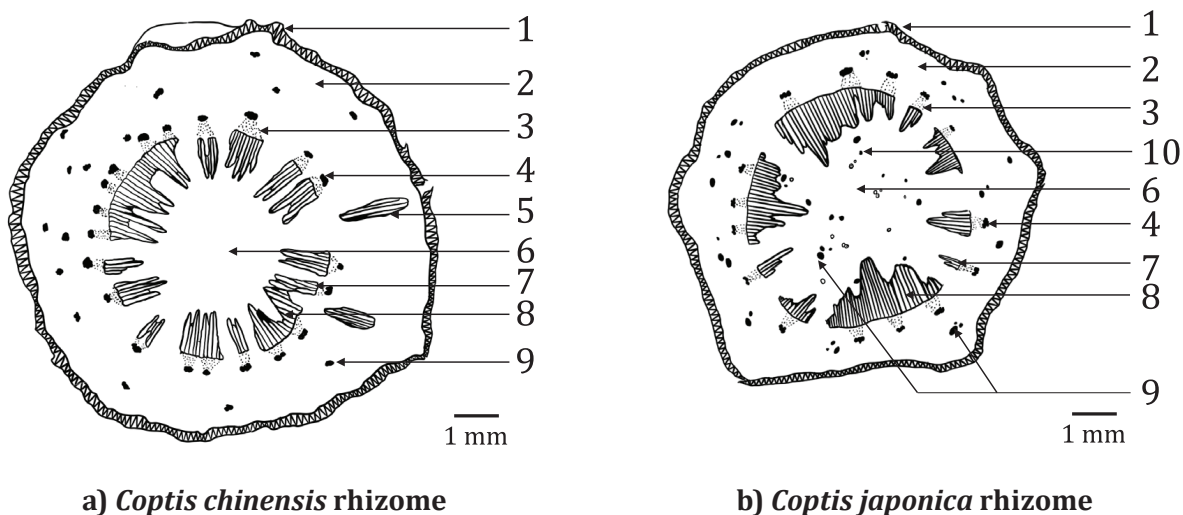
- a) *Coptis* rhizome shall be clean and free from leaves and foreign matter.
- b) The presence of living insects, mouldy fruit and external contaminants which are visible to the naked eye shall not be permitted.

### 5.2 Morphological features of rhizome

- a) *Coptis chinensis* rhizome is gathered in a cluster, curved like chicken feet. A single rhizome is 3 cm to 6 cm long and 0,3 cm to 0,8 cm in diameter. The outer surface is greyish-yellow or yellowish-brown, rough, bearing irregular nodular bumps, fibrous roots and their residues. Some internodes are as smooth as the stem and commonly known as bridge pieces. The upper part mostly retains brown scale leaves. The apex often bears the remains of stems or petioles. The rhizome has a hard texture and its fracture is uneven. The bark is orange-red or dark brown. The wood is bright yellow or orange-yellow, radially arranged. The pith is sometimes hollow. It has a slight odour and a very bitter taste.
- b) *Coptis japonica* rhizome is irregular and cylindrical. The rhizome is 2 cm to 4 cm long and 0,2 cm to 0,7 cm in diameter, slightly curved and short-branched. The outer surface is greyish yellow-brown, with ring nodes, without a bridge piece but with numerous remains of rootlets. The rhizome generally bears the remains of petiole at one end. It has a slight odour and an extremely bitter and lasting taste.

### 5.3 Microscopic identification

- a) *Coptis chinensis* rhizome contains cork cells of several layers, covered on the outside by epidermis which is often withered. The cortex is broader; stone cells are singly scattered or grouped. The pericycle fibres are in bundles or accompanied by a few stone cells; both are yellow. Collateral vascular bundles are arranged in a ring. The xylem is yellow and lignified and the xylem fibres are well developed. The pith consists of parenchymatous cells, but stone cells are absent (see [Figure 2 a](#)).
- b) *Coptis japonica* rhizome consists of a few stone cells in cortex and pith. The fractured surface is rather fibrous. Cork layer is light greyish brown. The cortex and pith are yellow-brown to reddish yellow-brown. The xylem is yellow to reddish-yellow (see [Figure 2 b](#)).



**Key**

- 1 cork layer
- 2 cortex
- 3 phloem
- 4 pericycle fibre
- 5 root-trace vascular bundle
- 6 pith
- 7 cambium
- 8 xylem
- 9 stone cells
- 10 starch grains

iTeh STANDARD PREVIEW  
(standards.iteh.ai)

ISO 7177:2023

<https://standards.iteh.ai/catalog/standards/sist/f84b9b3b-43ce-4431-99a0-6dbcf7aa62e7/iso-7177-2023>

**Figure 2 — Transverse section of *Coptis* rhizome**

**5.4 Thin-layer chromatography (TLC) identification**

The thin-layer chromatography (TLC) of *Coptis* rhizome shall present fluorescent spots with the same colour and positions corresponding to the chromatogram of reference drug solution and one spot corresponding to the reference solution in the chromatogram.

**5.5 Moisture**

The content of water should be a mass fraction of  $\leq 14,0$  %.

**5.6 Total ash**

The content of total ash should be a mass fraction of  $\leq 5,0$  %.

**5.7 Acid-insoluble ash**

The content of acid-insoluble ash should be a mass fraction of  $\leq 2,5$  %.

**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 compounds

The content of marker compounds, such as berberine, epiberberine, coptisine and palmatine, should be determined as a mass fraction.

# 6 Sampling

Sampling shall be carried out in accordance with the method described in ISO 23723:2021, Clause 8.

# 7 Test methods

## 7.1 Macroscopic identification

The samples shall be examined by the naked eye in sunlight and also for smell and taste as described in [5.2](#).

## 7.2 Microscopic identification

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

## 7.3 Thin-layer chromatography (TLC) identification

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

## 7.4 Determination of moisture

The testing method specified in ISO 23723:2021, 7.2.1 shall apply.

## 7.5 Determination of total ash

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

## 7.6 Determination of acid-insoluble ash

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

## 7.7 Determination of heavy metals

The testing method specified in ISO 18664 shall apply.

## 7.8 Determination of pesticide residues

The testing method specified in ISO 22258 shall apply.

## 7.9 Determination of marker compounds

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