



**International
Standard**

ISO 8071

**Traditional Chinese medicine —
Ligusticum chuanxiong rhizome**

*Médecine traditionnelle chinoise — Rhizome de livèche du
Sichuan (Ligusticum chuanxiong)*

**First edition
2024-03**

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Published in Switzerland

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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 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).

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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.

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Introduction

Ligusticum chuanxiong rhizome is one of the most commonly used Chinese materia medica in traditional Chinese medicine. The use of *Ligusticum chuanxiong* rhizome in medicine was first recorded in *Shennong Bencao Jing* (also called Shennong Emperor's Classic of Materia Medica) more than 2 000 years ago. And it has been artificially planted for traditional Chinese medicine (rhizome) or food (leaf) use as *Tao Hongjing* described 1 500 years ago.

Ligusticum chuanxiong rhizome has the effect of activating blood and dissolving stasis, dispelling wind and relieving pain. Clinically, it is often used with Chinese materia medica for the purpose of awakening, resuscitation and blood nourishing. It is the main active ingredient in many well-known prescriptions, such as Siwu decoction and Suxiao Jiuxin pills, and is present in about 30 % of traditional Chinese medicine prescriptions. For example, among 1 607 formulae in the Pharmacopoeia of the People's Republic of China^[3], 246 (15,3 %) contain *Ligusticum chuanxiong* rhizome.

Ligusticum chuanxiong rhizome and its products are widely used in 13 countries and regions, including Japan, Malaysia, Singapore, the Republic of Korea and Viet Nam. According to the 'Circulation Market Analysis Report for Traditional Chinese Medicinal Materials' by the Chinese ministry of commerce, the export volume of *Ligusticum chuanxiong* rhizome was 9 160,4 tons in 2014. Therefore, there is clearly a large demand for *Ligusticum chuanxiong* rhizome in the international market.

Currently, there is no globally unified standard on the quality, specification and grade of *Ligusticum chuanxiong* rhizome. Therefore, creating an International Standard for *Ligusticum chuanxiong* rhizome is of great significance.

As national implementation can differ, national standards bodies are invited to modify the values given in [5.4](#) to [5.10](#) according to their national requirements. Examples of national and regional values are given in [Annex B](#). An example of traditional grade information for *Ligusticum chuanxiong* rhizome is given in [Annex C](#).

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Traditional Chinese medicine — *Ligusticum chuanxiong* rhizome

1 Scope

This document specifies the quality requirements of *Ligusticum chuanxiong* rhizome (rhizome of *Ligusticum chuanxiong* Hort.).

This document applies to *Ligusticum chuanxiong* rhizome that is sold and used as natural medicine in international trade, including Chinese materia medica (whole medicinal materials) and decoction pieces derived from this rhizome.

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

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

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/>

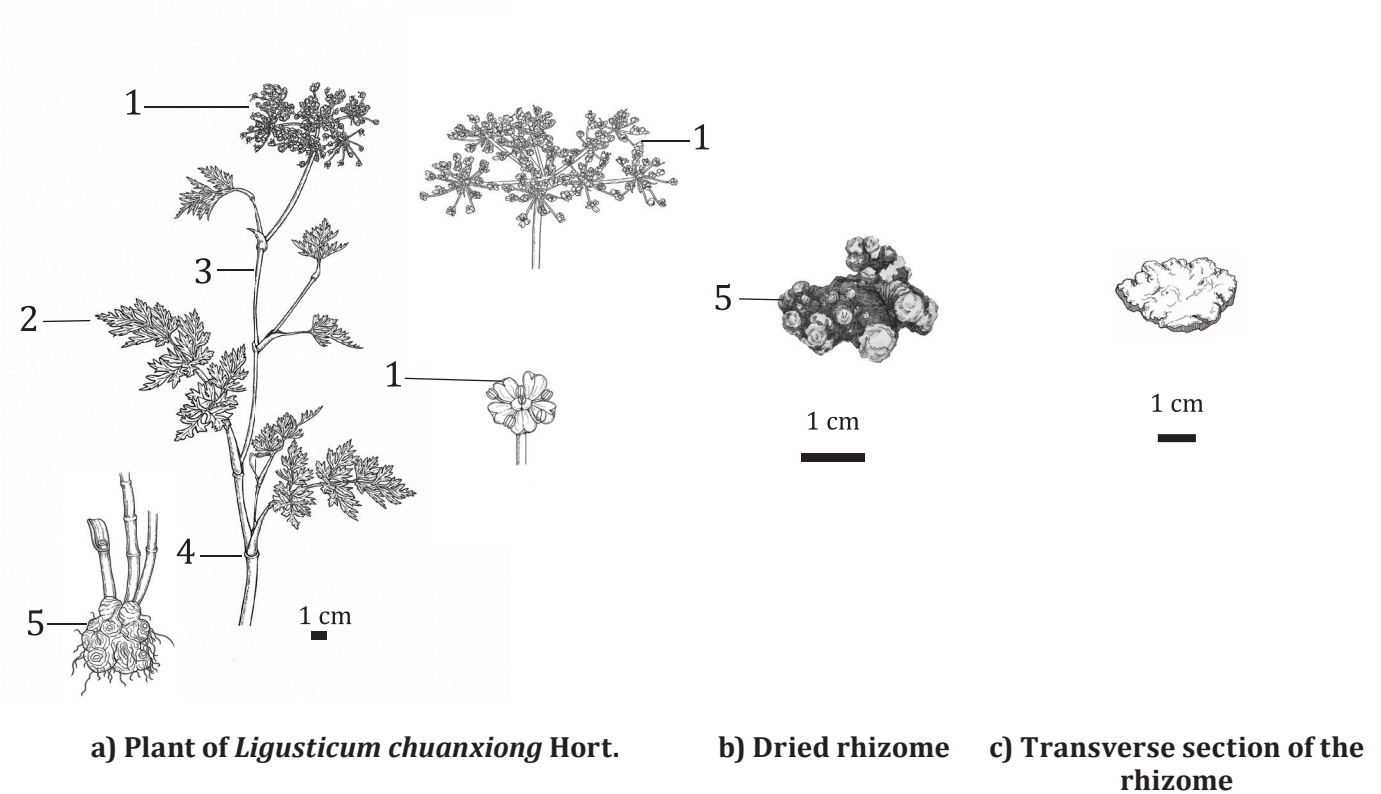
3.1

***Ligusticum chuanxiong* rhizome**

dried rhizome of *Ligusticum chuanxiong* Hort. (Apiaceae), after primary processing

4 Descriptions

Ligusticum chuanxiong rhizome is the dried rhizome of *Ligusticum chuanxiong* Hort. (Apiaceae), collected in summer, with rootlets removed, as shown in [Figure 1](#).



Key

- 1 flower
- 2 leaf
- 3 stem
- 4 stem node
- 5 stem scar (there are usually 5 to 20 stems on the rhizome)

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Figure 1 — Structure of *Ligusticum chuanxiong* Hort.

5 Requirements and recommendations

5.1 General

The presence of living insects, mouldy tuber and external contaminants which are visible to the naked eye shall not be permitted.

5.2 Morphological features

The rhizome is irregular knot and fist-like, 2 cm to 7 cm in diameter. The outer surface is coarse and wrinkled, with numerous parallel uplifted nodes. The top has concave rotund-like stem marks. The lower side and the nodes have numerous small tuberculous rhizome marks.

The surface colour is brown or dark brown.

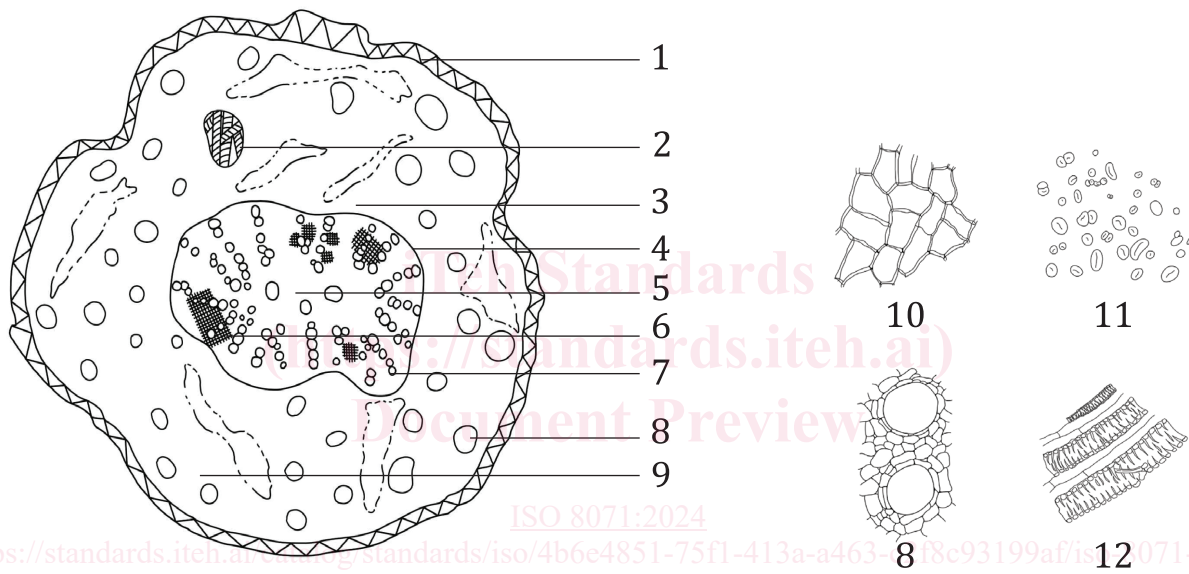
The section is greyish yellow or yellowish white, with scattered yellow-brown oil chambers, and the cambium is undulating ring grain, see [Figure 2 a\)](#).

The odour has intense aroma that is unique to the chuanxiong rhizome, it is slightly numbing to the tongue and has a slightly sweet aftertaste.

5.3 Microscopic features

In the transverse section, the cork consists of over 10 rows of flat cells; the cortex is narrow, scattered with root-trace vascular bundles. The phloem is broad. The cambium is undulated or irregularly polygonal. The xylem vessels are mostly uniseriate or arranged in a V shape; xylem fibres are occasionally found in bundles. The pith is broad. There are oil cavities scattered in the parenchyma, subround, ellipsoid or irregular in shape, pale yellowish-brown, smaller near the cambium, gradually becoming larger outwards. The parenchyma cells contain abundant starch grains, see [Figure 2 a](#)).

The powder is pale yellow to brown. Starch grains are abundant; simple grains are ellipsoid, elongated-rounded, oval or kidney-shaped, 3 µm to 19 µm in diameter and up to 22 µm long. The hilum is pointed, with a long cleft or V-shaped; there are a few compound grains, consisting of 2 to 4 units. Oil cavities are mostly broken, secretory cells containing numerous droplets of oil. Cork cells are closely arrayed, sub-polygonal in surface view, thin-walled, sinuately crooked, showing polyhedral cells with slightly sinuous walls. Cork cells are well-arranged in the lateral view. Spiral vessels are frequent, 14 µm to 50 µm in diameter, and the thickened wall of some spiral vessels are interconnected to form reticulated vessels. Clusters of calcium oxalate, in subround masses, are rarely observed, see [Figure 2 b](#)).



a) Transverse section

b) Powder

Key

- 1 cork
- 2 root trace vascular bundle
- 3 phloem
- 4 cambium
- 5 pith
- 6 fibre bundles
- 7 xylem
- 8 oil cavity
- 9 cortex
- 10 cork cells
- 11 starch granules
- 12 vessels

Figure 2 — Microscopic features of *Ligusticum chuanxiong* rhizome

5.4 Marker compound

The content of marker compound, such as ferulic acid, as a mass fraction should be determined. The content of ferulic acid should not be less than a mass fraction of 0,10 %.

5.5 Extractives

The content of water-soluble extractives (cold extraction method) and ethanol-soluble extractives (hot extraction method) as mass fractions should not be less than 27,0 % and 12,0 %, respectively.

5.6 Total ash

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

5.7 Acid-insoluble ash

The content of acid-insoluble ash as a mass fraction should not be more than 2,0 %.

5.8 Moisture

The content of moisture as a mass fraction should not be more than 12,0 %.

5.9 Essential oil

The content of essential oil should not be less than 3,5 ml/kg.

5.10 Foreign matter

The content of foreign matter as a mass fraction should not be more than 1,0 %.

5.11 Heavy metals

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

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5.12 Pesticide residues

The content of pesticide residues, such as DDT (dichloro-diphenyl-trichloroethane, sum of), dimethoate and omethoate (sum of) shall be determined.

5.13 Sulfur dioxide

The content of sulfur dioxide should be determined.

5.14 Aflatoxin

The content of aflatoxin B1 and total aflatoxin should be determined.

6 Sampling

Sampling shall be carried out in accordance with the method described in ISO 23723.

7 Test methods

7.1 Macroscopic identification

The samples shall be observed with the naked eye, smelled and tasted with the tongue.