



**International
Standard**

ISO 8071

**Traditional Chinese medicine —
Ligusticum chuanxiong rhizome**

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

**First edition
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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 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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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

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/>

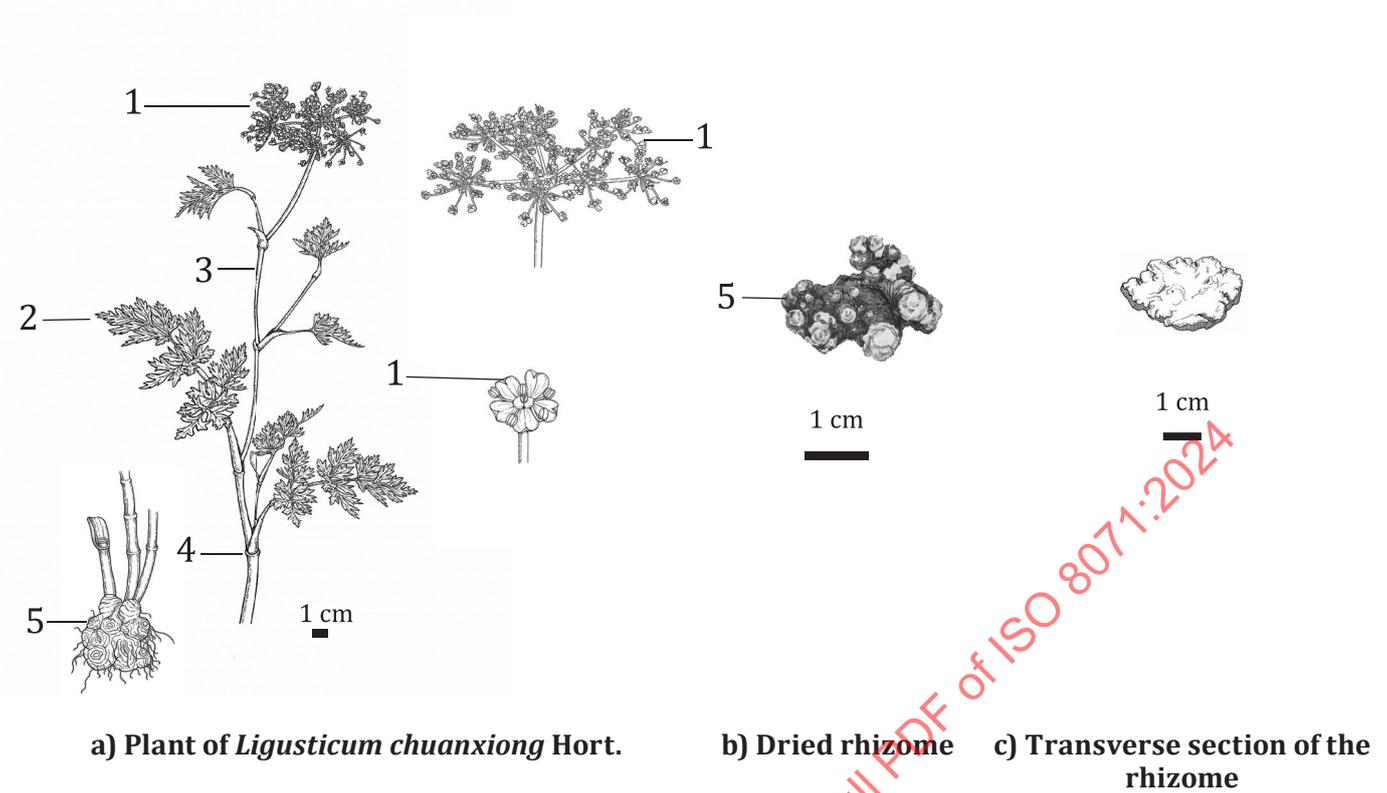
3.1

***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)

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.

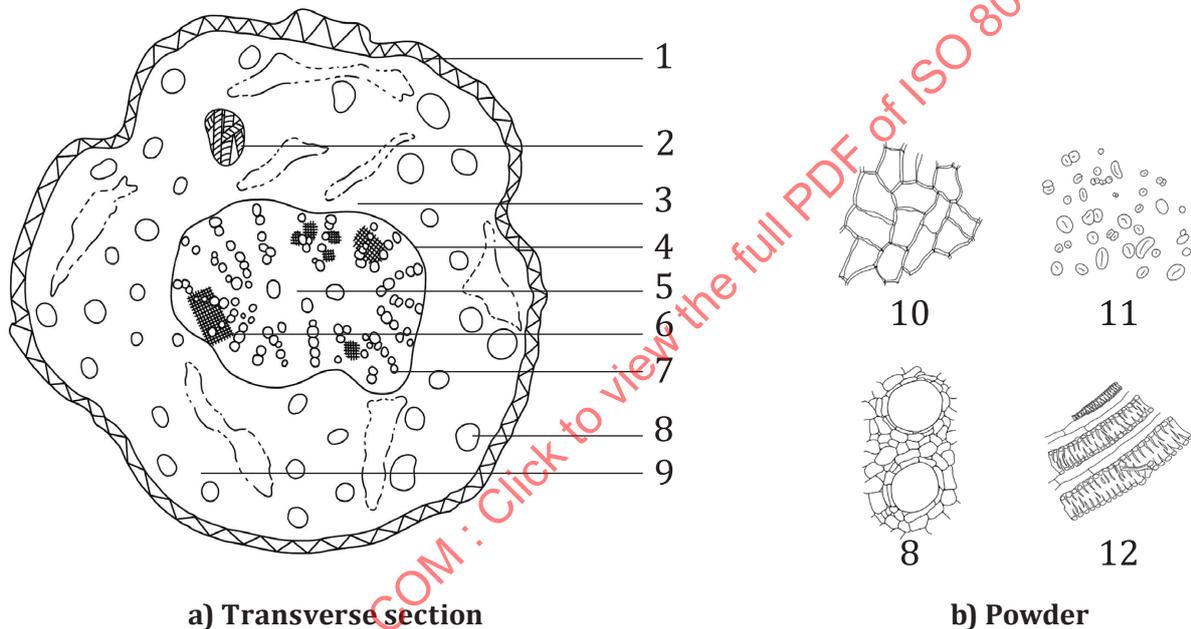
The section is greyish yellow or yellowish white, with scattered yellow-brown oil chambers, and the cambium is undulating ring grain, see [Figure 2 a\)](#).

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\)](#).



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.

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.

Determine whether the sample meets the requirements described in [5.1](#) and [5.2](#). If not, the subsequent tests may be stopped.

7.2 Microscopic identification

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

7.3 Determination of marker compound

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

7.4 Determination of extractives

The test method specified in ISO 23723 shall apply.

7.5 Determination of total ash

The test method of total ash specified in ISO 23723 shall apply.

7.6 Determination of acid-insoluble ash

The test method of acid-insoluble ash specified in ISO 23723 shall apply.

7.7 Determination of moisture

The test method specified in ISO 23723 shall apply.

7.8 Determination of essential oil

The test method specified in ISO 23723 shall apply.

7.9 Determination of foreign matter

The test method specified in ISO 23723 shall apply.

7.10 Determination of heavy metals

The test method specified in ISO 18664 shall apply.

7.11 Determination of pesticide residues

The test method specified in ISO 22258 shall apply.

7.12 Determination of sulfur dioxide

The test method specified in ISO 22590 shall apply.

7.13 Determination of aflatoxin

The test method specified in ISO 22283 shall apply.

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

9 Marking and labelling

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

- a) product name and Latin scientific name;
- b) all quality features indicated in [Clause 5](#), determined in accordance with methods specified in [Clause 7](#);
- c) gross mass and net mass of the package;
- d) country of origin and province or state of the products;
- e) date of production, batch number and expiry date of the products;
- f) storage and transportation method;
- g) any other information requested by the buyer, such as the harvest year and packaging date (if known).

10 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 the entry of foreign substances during long-distance delivery.

Annex A (informative)

Determination of ferulic acid

A.1 Preparation of reference solution

Weigh an appropriate amount of trans-ferulic acid (CAS Registry Number^{®1)} 537-98-4) reference and dissolve in 70,0 % methanol to make a solution containing 20 µg per 1 ml.

A.2 Preparation of test solution

Put about 0,5 g of ground sample (through a 65-mesh sieve) into a round-bottomed flask, add 50 ml of 70,0 % methanol, weigh, heat and reflux for 30 min. Cool to room temperature, weigh and add 70,0 % methanol to replenish the lost weight. Shake well, allow to stand, filter and take the filtrate as the test solution.

A.3 Chromatographic system condition and system adaptability

Liquid chromatograph:

- stationary phase: octadecyl silane bonded silica gel (4,6 × 250 mm, 5 µm);
- mobile phase: methanol-1 % acetic acid solution (30:70);
- detection wavelength: 321 nm;
- flow rate: 1,0 ml/min;
- injection volume: 10 µl;
- the theoretical plate number shall be no less than 4 000 according to ferulic acid peak.

A.4 Procedure of measurement

Prepare a five-point calibration curve by plotting the peak areas of the chemical reference substance against the corresponding concentrations (in milligrams per litre) of the standard solutions.

Obtain the slope, y-intercept, the regression equation and the r^2 value from the calibration curve.

With the calibration curve of the corresponding chemical reference substance, calculate the concentration (in milligrams per litre) of the analyte in the test solution by using [Formula \(A.1\)](#).

$$C = \frac{A-I}{m} \quad (\text{A.1})$$

1) Chemical Abstracts Service (CAS) Registry Number[®] is a trademark of the American Chemical Society (ACS). This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

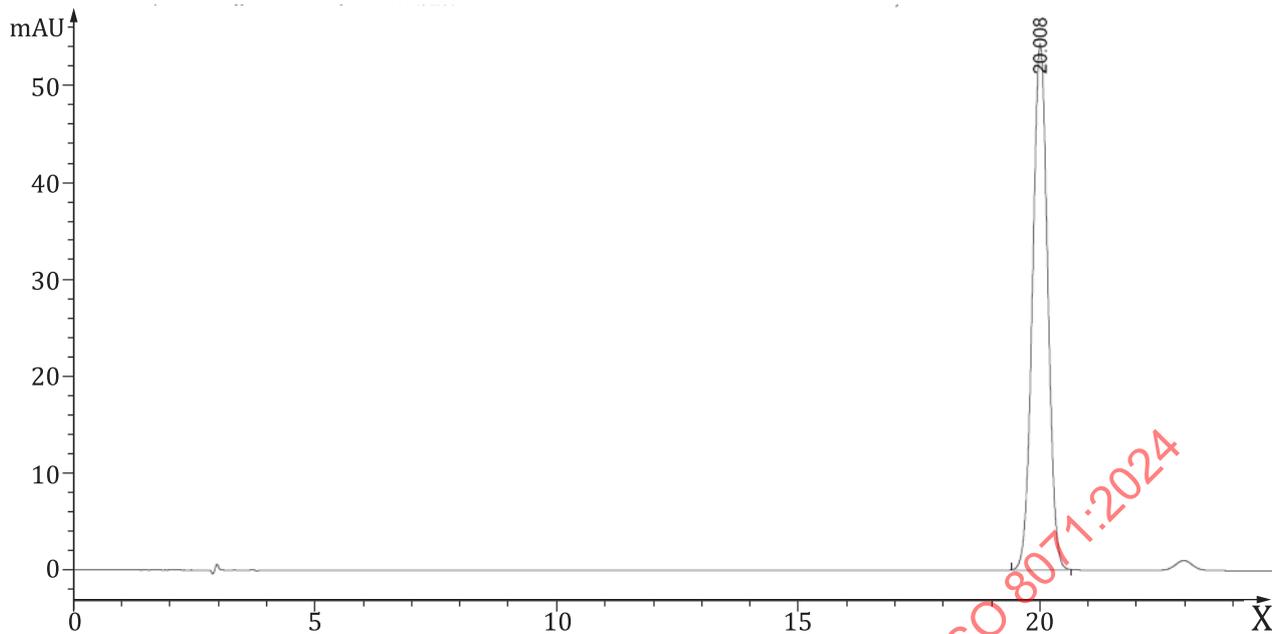
where

- C is the concentration of the analyte (mg/l);
- A is the peak area of the analyte in the test solution;
- I is the y-intercept of the five-point calibration curve;
- m is the slope of the five-point calibration curve.

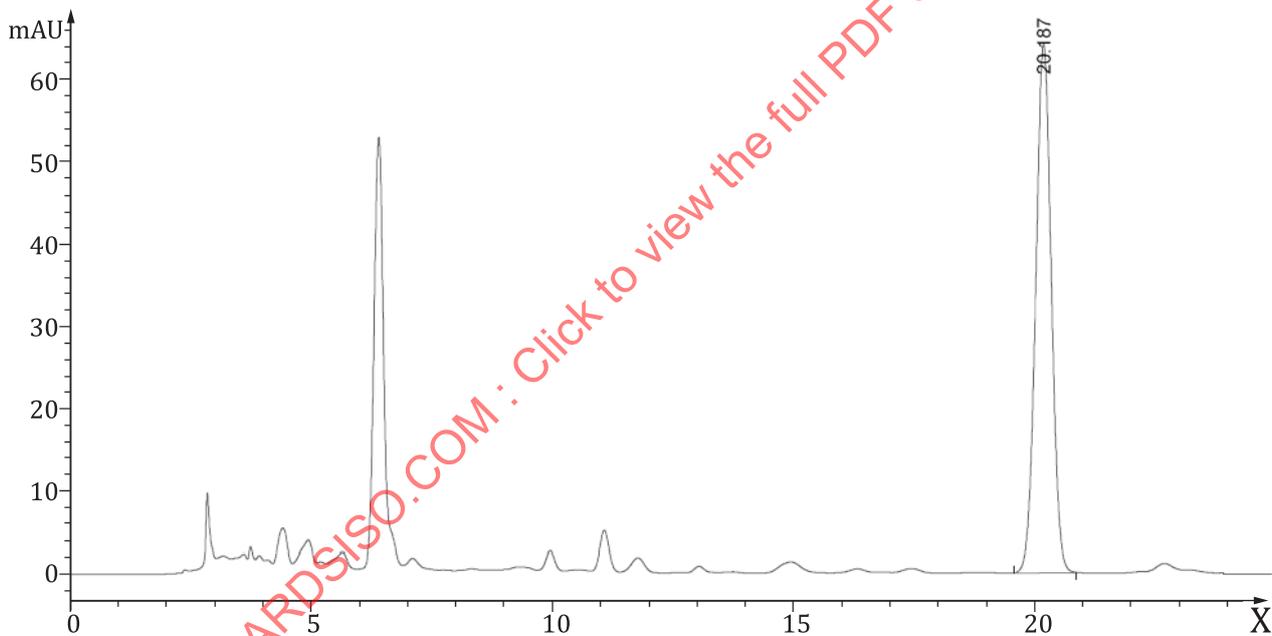
A.5 Expression of results

For the identification of samples, there should be a characteristic peak corresponding to the reference HPLC (high-performance liquid chromatography) chromatogram (see [Figure A.1](#)).

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a) Ferulic acid reference



b) Chuanxiong sample

Key
X min

Figure A.1 — HPLC chromatograms of ferulic acid

Ferulic acid content (calculated in trans-ferulic acid) is calculated with [Formula \(A.2\)](#).

$$X = \frac{C \times V \times D}{10\,000W} \tag{A.2}$$

where

- X is the percentage of the component to be measured in the sample;
- C is the concentration of the solution of the component measured in milligrams per litre (mg/l) from the standard curve;
- V is the sample extraction volume, in millilitres (50 ml for each sample);
- D is the dilution factor of the sample under test (if any);
- W is the mass of the sample represented by the sample solution in grams (g).

NOTE Dilution factor is the factor by which the sample solution is diluted. It is the ratio of the volume of the final diluted solution to the initial volume. When the content of the component to be tested in the sample is too high and beyond the detection range, it needs to be diluted.

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Annex B (informative)

Reference of national and regional requirements

The British, Chinese, European and Korean Pharmacopoeia and the Thai Herbal Pharmacopoeia have provisions on *Ligusticum chuanxiong* rhizome. The summarized maximum and minimum limits from previous references are listed in [Table B.1](#).

Table B.1 — Maximum and minimum limits for *Ligusticum chuanxiong* rhizome

Authority regulation		British Pharmacopoeia ^[2]	Chinese Pharmacopoeia ^[3]	European Pharmacopoeia ^[4]	Korean Pharmacopoeia ^[5]	Thai Herbal Pharmacopoeia ^[6]
Plant origin		<i>Conioselinum anthriscoides</i> (H.Boissieu) Pimenov & Kljuykov, syn/ <i>Ligusticum chuanxiong</i> Hort. (Umbelliferae)	<i>Ligusticum chuanxiong</i> Hort. (Umbelliferae)	<i>Conioselinum anthriscoides</i> (H.Boissieu) Pimenov & Kljuykov, syn/ <i>Ligusticum chuanxiong</i> Hort. (Umbelliferae)	<i>Cnidium officinale</i> Makino/ <i>Ligusticum chuanxiong</i> Hort. (Umbelliferae)	<i>Ligusticum chuanxiong</i> Hort. (Umbelliferae)
Medicinal part		rhizome				
Identification	Macroscopic	√	√	√	√	√
	Microscopic	√	√	√	√	√
	TLC (thin-layer chromatography)	√	√	√	√	√
Moisture		≤ 8,0 (loss on drying)	≤ 12,0 (toluene method)	≤ 8,0 (loss on drying)	×	≤12,0 (azeotropic distillation method)
Total ash (%)		≤ 6,0	≤ 6,0	≤ 6,0	≤ 6,0	≤ 6,0
Acid-insoluble ash (%)		≤ 2,0	≤ 2,0	≤ 2,0 %	≤ 1,0	≤ 2,0
Ethanol-soluble extractives (%)		×	≥ 12 % (hot-dip method)	×	×	≥18,0
Water-soluble extractives (%)		×	×	×	×	≥35,0
Essential oil Content (ml/kg)		≥ 3,5	×	≥ 3,5	×	×
Ferulic acid (%)		×	≥ 0,10	×	×	×
Residual sulfur dioxide (mg/kg)		×	≤150	×	≤30	×
Foreign matter (%)		×	≤ 3,0	×	×	≤ 2,0
Aflatoxin	Aflatoxin B1 (µg/kg)	2	5	2	×	×
	Aflatoxin (B1, B2, G1, G2) (µg/kg)	4	10	4	×	×