
**Traditional Chinese medicine —
Angelica sinensis root**

Médecine traditionnelle chinoise — Racine d'Angélique chinoise

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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 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).

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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

Angelica root is a traditional herbal remedy, derived from the dried root of *Angelica sinensis* (Oliv.) Diels, *Angelica acutiloba* (Sieb. et Zucc.) Kitagawa and *Angelica gigas* Nakai, of the Umbelliferae family, as recorded by the Chinese Pharmacopoeia, the Japanese Pharmacopoeia and the Korean Pharmacopoeia, respectively, and has a long medicinal history. *Angelica sinensis* is still one of the herbs most commonly used by traditional Chinese medicine practitioners in Asia, North America and Europe. It is commonly known as female ginseng, and widely used to invigorate blood circulation and replenish blood in treating women's reproductive problems, such as dysmenorrhea, amenorrhoea and menopause. It has also been used in over 20 countries for its significant effectiveness in the pharmaceutical and cosmetic fields.

The quality of *Angelica sinensis* root is crucial for efficacy and safety for consumers. Until now, there have been no unique requirements for *Angelica sinensis* root, although *Angelica sinensis* root has also been recorded by the American Herbal Pharmacopoeia, the European Pharmacopoeia, the British Pharmacopoeia and the Hong Kong Chinese Materia Medica Standards. It is therefore important to standardize the quality of *Angelica sinensis* root globally in order to benefit farmers, enterprises and companies involved in the planting, management and trade of *Angelica sinensis* root.

As national implementation may differ, national standards bodies are invited to modify the values given in [5.4](#), [5.5](#), [5.6](#), [5.7](#), [5.8](#), [5.9](#) and [5.10](#) in their national standards. Examples of national and regional values are given in [Annex D](#).

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3.4

acid-insoluble ash

part of the *total ash* (3.3) remaining after treatment with hydrochloric acid

4 Description

Angelica sinensis root is shown in [Figure 1](#).



A iTeh Standards B

Key

A *Angelica sinensis* plant

B *Angelica sinensis* dried root

1 leaf

2 flowering branch

3 root stock

4 branching root

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Figure 1 — Structure of *Angelica sinensis* (Oliv.) Diels

5 Requirements

5.1 General characteristics

The following requirements shall be met before separating the bulk sample into test samples.

- a) *Angelica sinensis* root shall be clean and free from foreign matter.
- b) The presence of living insects, mould and external contaminants which are visible to the naked eye shall not be permitted.

5.2 Morphological features of *Angelica sinensis* root

- a) The root is slightly cylindrical.
- b) The outer surface is yellowish brown to reddish brown with longitudinal wrinkles and transversely elongated lenticels.

- c) The root stock is known as "Angelica head" (or *guitou*). The main root is known as "Angelica body" (or *guishen*). The branching root is known as "Angelica tails" (or *guiwei*). The entire root is known as "entire Angelica" (or *quanguai*).
- d) The root stock is 15 mm to 40 mm in diameter, annulated with obtuse and rounded apex or with purple or yellowish green remains of stems and leaf sheaths.
- e) The main root is thick and short with numerous branching roots in the lower part. The upper portion of the branching root is thick, while the lower portion of the branching root is thin and mostly twisted with a few rootlet scars.
- f) The texture is flexible.
- g) The fracture is yellowish white or pale yellowish brown with numerous brown-spotted secretory cavities in the thick bark. The wood is paler in colour than the bark with radial lines. The cambium ring is yellowish brown.
- h) The core of the root stock contains a pith and a cavity.
- i) The odour is strongly aromatic; the taste is sweet, pungent and slightly bitter.

5.3 Identification of *Angelica sinensis* root

The identification of *Angelica sinensis* root by a thin-layer chromatogram (TLC) shall present spots or bands with the same colour and positions corresponding to those of reference solutions.

5.4 Moisture

The mass fraction of moisture should not be more than 15,0 %.

5.5 Total ash

The mass fraction of total ash should not be more than 7,0 %.

5.6 Acid-insoluble ash

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

5.7 Extractives

The mass fraction of 70 % ethanol-soluble extractives should not be less than 40,0 %.

5.8 Content of marker compound

The content of marker compound shall be determined. For example, ferulic acid shall be determined taking into account relevant national or regional pharmacopoeias, legislation and norms.

The mass fraction of ferulic acid (C₁₀H₁₀O₄) should not be less than 0,050 %.

5.9 Heavy metal

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

The limit value should take into account the requirements of the regulatory bodies of the destination country or region. If there is none, the limit value of a national or regional pharmacopoeia listed in ISO 18664 shall be chosen.

5.10 Pesticide residues

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

6 Sampling

Sampling of *Angelica sinensis* root shall be carried out according to the World Health Organization's *Quality control methods for herbal materials, General advice on sampling*.

7 Test methods

7.1 Macroscopic identification

Samples not less than 500 g are taken from each batch randomly and observed with the naked eye.

7.2 TLC identification

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

7.3 Determination of moisture content

The testing method specified in ISO 20409 applies.

7.4 Determination of total ash

The testing method specified in ISO 1575 applies.

7.5 Determination of acid-insoluble ash

The testing method specified in ISO 1577 applies.

7.6 Determination of extractives

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

7.7 Determination of ferulic acid

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

7.8 Determination of heavy metal

The testing method specified in ISO 18664 applies.

7.9 Determination of pesticide residues

The testing methods specified in CODEX STAN 229 and CAC/MRL01 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) a reference to this document, for example "determined in accordance with ISO 22584:2019";