FINAL DRAFT International Standard

ISO/FDIS 5076

Traditional Chinese medicine — *Angelica dahurica* root

ISO/TC **249**

Secretariat: **SAC**

Voting begins on:
2024-03-07

Voting terminates on:
2024-05-02

Reference number
ISO/FDIS 5076:2024(en)

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Published in Switzerland

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Foreword

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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

Angelica dahurica root (also known as Angelicae dahuricae Radix or "baizhi") is one of the commonly used herbal medicines in traditional Chinese medicine (TCM). For instance, of 1607 formulae in the Pharmacopoeia of the People's Republic of China (2020 edition),[1] 131 (8,2 %) contain the *Angelica dahurica* root.

Angelica dahurica root was firstly recorded in “Shen Nong Ben Cao Jing” [2] (神农本草经), and has been used in TCM for a very long time to treat headache, supraorbital neuralgia, stuffy nose, nasosinusitis and toothache. Modern pharmacological studies demonstrate that *Angelica dahurica* root possesses anti-inflammatory, antioxidant, antibacterial, and anticancer properties. The main chemical constituents of *Angelica dahurica* root are coumarins and volatile oils. The coumarins contained in *Angelica dahurica* root, such as imperatorin and isoimperatorin, have been demonstrated to have anticancer, antiviral, antidepressive, antiallergic, anti–lipogenic, antioxidant, vasodilation and radical–scavenging effects.

In the global trade of *Angelica dahurica* root, mainland China is a main exporter. According to China customs data from 2015 to 2019, the average annual export volume of *Angelica dahurica* root was 2 557 tons, worth 11 891 630 US$. The main destination countries and regions included Japan, the Republic of Korea, Hong Kong, Taiwan, Vietnam, Malaysia, Thailand, New Zealand, the United States and Germany.

Angelica dahurica root has been recorded in the Pharmacopoeia of the People's Republic of China,[1] the European Pharmacopoeia,[3] the Japanese Pharmacopoeia[4] and the Korean Pharmacopoeia[5]; and the requirements of each pharmacopoeia are different. Currently, there's no globally unified standard for *Angelica dahurica* root; and regulators in many countries and regions have different levels of regulation. Therefore, the establishment of an International Standard is necessary to guarantee the quality, safety and consistency of the valuable herbal medicine.

As national implementation can differ, national standards bodies are invited to modify the values given in 5.5 and 5.7 in their national standards. Example of national values are given in Annex C.

Traditional Chinese medicine — *Angelica dahurica* root

1 Scope

This document specifies the quality and safety requirements of *Angelica dahurica* root [the dried root of *Angelica dahurica* (Fish.ex Hoffm.) Benth. et Hook. f. ex Franch. et Sav.].

This document applies to *Angelica dahurica* root that is sold and used as natural medicine in international trade, including Chinese materia medica (whole medicinal materials) and decoction pieces derived from the 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 18664, *Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine*

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 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:

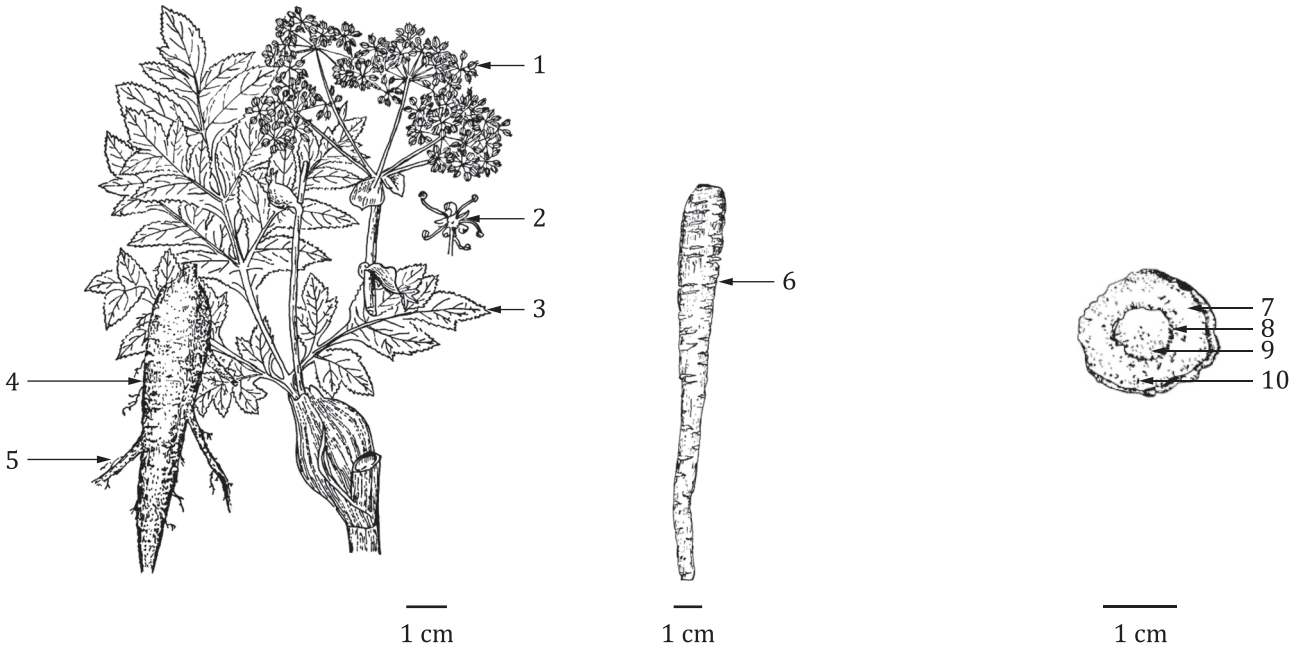
— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
***Angelica dahurica* root**
dried root of *Angelica dahurica* (Fish.ex Hoffm.) Benth. et Hook. f. ex Franch. et Sav.

4 Descriptions

Angelica dahurica root is collected in summer or autumn with rootlets removed and dried in the sun or with other appropriate methods (see Figure 1).



a) Plant of *Angelica dahurica* **b) Dried tap root** **c) Transverse section of the tap root**

Key

1 fruit
2 flower
3 leaf
4 tap root
5 secondary root
6 lenticel-like transverse protuberance
7 cortex
8 cambium
9 xylem
10 oil dot

Figure 1 — Structure of *Angelica dahurica*

5 Quality and safety requirements and recommendations

5.1 General characteristics

The following requirements shall be met before sampling.

a) *Angelica dahurica* root shall be clean and free from rootlets and foreign matter.

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

5.2 Morphological features

a) The roots are long and conical.

b) The roots are 10 cm to 25 cm long, with diameters of 1,5 cm to 2,5 cm.

c) The outer surface is greyish-brown or yellowish-brown, the root stock obtusely quadrangular or subrounded, with longitudinal wrinkles, rootlet scars and lenticel-like transverse protuberances.

d) The texture is compact.

e) The fracture is starchy, white or grey-white. The cambium occurs as a brown ring; and many brown oil dots are visible in the cortex.

f) The odour is aromatic.

g) The taste is pungent and slightly bitter.

5.3 Thin-layer chromatogram (TLC) identification

The thin-layer chromatogram (TLC) of *Angelica dahurica* root should present the spots with the same colour and position corresponding to those of the reference solutions.

5.4 Moisture

The content of moisture as a mass fraction should be determined.

5.5 Total ash

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

5.6 Acid-insoluble ash

The acid-insoluble ash content as a mass fraction should be determined.

5.7 Dilute ethanol-soluble extractives

When it is measured, the content of dilute ethanol (50 %)-soluble extract as a mass fraction should not be less than 15,0 %.

5.8 Heavy metals

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

5.9 Pesticide residues

The contents of pesticide residues should be determined.

5.10 Marker compound

The content of marker compound such as imperatorin ($C_{16}H_{14}O_4$) should be determined.

6 Sampling

Sampling of *Angelica dahurica* root shall be carried out in accordance with the method specified in ISO 23723.

7 Test methods

7.1 Macroscopic identification

Samples are examined by the naked eye, tasted and smelled.

7.2 Thin-layer chromatogram (TLC) identification

See Annex A for additional information on thin-layer chromatogram (TLC) identification.

7.3 Determination of moisture content

The test method specified in ISO 23723 shall apply.

7.4 Determination of total ash content

The test method specified in ISO 23723 shall apply.

7.5 Determination of acid-insoluble ash content

The test method specified in ISO 23723 shall apply.

7.6 Determination of dilute ethanol-soluble extractives content

The test method specified in ISO 23723 shall apply.

7.7 Determination of heavy metal contents

The test method specified in ISO 18664 shall apply.

7.8 Determination of pesticide residues contents

The test method specified in ISO 22258 shall apply.

7.9 Determination of marker compound

See Annex B for additional information on determination of marker compound.

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 international standard, or regarded as optional, together with details of any incidents which can 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

The packaging and transportation shall not transmit any odour or flavour to the product and shall not contain substances which can 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.