
**Traditional Chinese medicine —
Astragalus mongholicus root**

*Médecine traditionnelle chinoise — Racine d'astragalus
mongholicus*

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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.

Introduction

The *Astragalus* root (also called *Astragali Radix*, Milkvetch Root, Huang Qi in Mandarin, or 黄芪 or 黄耆 in Han characters) is one of the most frequently used herbal medicines in traditional Chinese medicine (TCM).

Of roughly 80 000 TCM formulae recorded in classic TCM books, around 7,3 % contain the *Astragalus* root as an ingredient. For example, of 1 493 formulae in the Chinese Pharmacopoeia (2015 edition), there are 202 which contain the *Astragalus* root (accounting for 13,53 %); among 148 kampo medicines for prescription from the Ministry of Health, Labour and Welfare (MHLW) of Japan, there are 15 formulae containing the *Astragalus* root (accounting for 10,14 %). In the United States, the *Astragalus* root is widely sold as a dietary supplement ingredient.

Based on the statistics report for the Department of Market Supervision, Ministry of Commerce of the People's Republic of China, the volume of *Astragalus* exported from China in 2015 was 4 477,2 tons, worth 28,330,614 US\$. The destination countries and regions included Malaysia, the United States, Japan, South Korea, Australia, Thailand, Singapore, Indonesia, Vietnam, Hong Kong and Taiwan.

The *Astragalus* root has been used in TCM for a very long time and remains a highly valued herb today because of its significant effects, which include:

- Efficacy supported by modern research: controls inflammation, boosts the immune system, slows or prevents the growth of tumours, protects the cardiovascular system, regulates and prevents diabetes and comorbidities related to diabetes, contains antioxidative and anti-ageing capabilities, heals wounds, alleviates symptoms of chemotherapy, treats COVID and flu, and provides supplemental therapy for chronic asthma.
- Traditional indications: qi deficiency and lack of strength, reduced food intake, sloppy stool, sunken middle qi, chronic diarrhoea, prolapse of the rectum, bloody stool, flooding and spotting, exterior deficiency with spontaneous sweating, qi deficiency oedema, interior heat wasting-thirst, blood deficiency and sallow complexion, hemiplegia, impediment pain, numbness, abscesses and long-term nonhealed cellulitis caused by diabetic complications.

Two species of *Astragalus*, namely *Astragalus mongholicus* and *Astragalus membranaceus*, are included in the British Pharmacopoeia^[1], the Pharmacopoeia of the People's Republic of China^[2], the European Pharmacopoeia^[3], the Japanese Pharmacopoeia^[4], the Korean Pharmacopoeia^[5] and the United States Pharmacopoeia^[6] (see [Table F.1](#)). This document deals with *Astragalus mongholicus*; while ISO/NP 21311 deals with *Astragalus membranaceus*. These two species are different in terms of morphology and identification. *Astragalus membranaceus* has small numbers of large leaflets, while *Astragalus mongholicus* has large numbers of small leaflets. These species can be identified and differentiated by the HPLC method^[7] and DNA barcoding^[8]. There are also many other *Astragalus* species that are morphologically similar to *Astragalus mongholicus*, some of which are toxic. The toxic species of *Astragalus* include *Astragalus emoryanus* var. *emoryanus*, *Astragalus emoryanus* var. *terlinguensis*, *Astragalus miser* var. *oblongifolius*, *Astragalus miser* var. *serotinus*, *Astragalus miser* var. *hylophilus*, *Astragalus michauxii*, *Astragalus Canadensis*, *Astragalus oreganus*, *Astragalus variabilis*, *Astragalus strictus*, *Astragalus hamiensis*, *Astragalus tibetanus*, *Astragalus confertus*, *Astragalus rigidulus*, and *Astragalus leucocephalus*, which can contain poisonous substances such as miserotoxin, karakin, cibarin and hiptugin^[9]. Thus, the establishment of an ISO standard for *Astragalus mongholicus* root is necessary to ensure the quality and safe use of this herb.

The misuse of such species in TCM remains a problem resulting in questions about the effectiveness or unexpected side-effects of *Astragalus mongholicus* and *Astragalus membranaceus*. The establishment of an international standard for *Astragalus mongholicus* root is therefore necessary to guarantee the clinical effectiveness, safety and controllability of this valuable medicine in global commerce and trade. Reference information on the use of *Astragalus* root in different countries and regions is included in [Annex F](#).

As national implementation may differ, national standards bodies are invited to modify the values given in [5.2](#), [5.3](#) and [5.4](#) in their national standards. Examples of national and regional values are given in [Annex F](#).

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Traditional Chinese medicine — *Astragalus mongholicus* root

1 Scope

This document specifies the quality and safety requirements of *Astragalus mongholicus* root [root of *Astragalus membranaceus* (Fisch.) Bge. var. *mongholicus* (Bge.) Hsiao].

This document applies to *Astragalus mongholicus* root that is sold and used as natural medicine in international trade, including Chinese materia medica (whole medicinal materials) and decoction pieces derived from this 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 1575, *Tea — Determination of total ash*

ISO 18664, *Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine* (standards.iteh.ai)

ISO 21371, *Traditional Chinese medicine — Labelling requirements of products intended for oral or topical use*

ISO 22217,¹⁾ *Traditional Chinese medicine — Storage requirements for raw materials and decoction pieces*

ISO 22258,²⁾ *Traditional Chinese medicine — Determination of pesticide residues in natural products by GC*

World Health Organization *Quality control methods for herbal materials, General advice on sampling*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

***Astragalus mongholicus* root**

dried root of *Astragalus membranaceus* (Fisch.) Bge. var. *mongholicus* (Bge.) Hsiao

Note 1 to entry: For synonyms of the *Astragalus membranaceus* (Fisch.) Bge. var. *mongholicus* (Bge.) Hsiao, see [Table F.1](#).

3.2

root length

distance from the bottom to the stem scar of the tap root, in centimetres

1) Under preparation. Stage at the time of publication: ISO/DIS 22217:2019.

2) Under preparation. Stage at the time of publication: ISO/DIS 22258:2019.

3.3

root diameter

diameter of the tap root, in centimetres

3.4

root top diameter

diameter of the tap root at the stem scar of the tap root, in centimetres

3.5

root mid-diameter

diameter of the tap root at the mid-length of the tap root, in centimetres

3.6

root bottom diameter

diameter of the tap root at the bottom of the tap root, in centimetres

3.7

marker compound

astragaloside I ($C_{45}H_{72}O_{16}$), astragaloside II ($C_{43}H_{70}O_{15}$), astragaloside IV ($C_{41}H_{68}O_{14}$), calycosin ($C_{16}H_{12}O_5$), calycosin-7-glucoside ($C_{22}H_{22}O_{10}$), formononetin ($C_{16}H_{12}O_4$), and ononin ($C_{22}H_{22}O_9$)

3.8

batch

samples collected from the same particular place at the same time, of no more than 5 000 kg

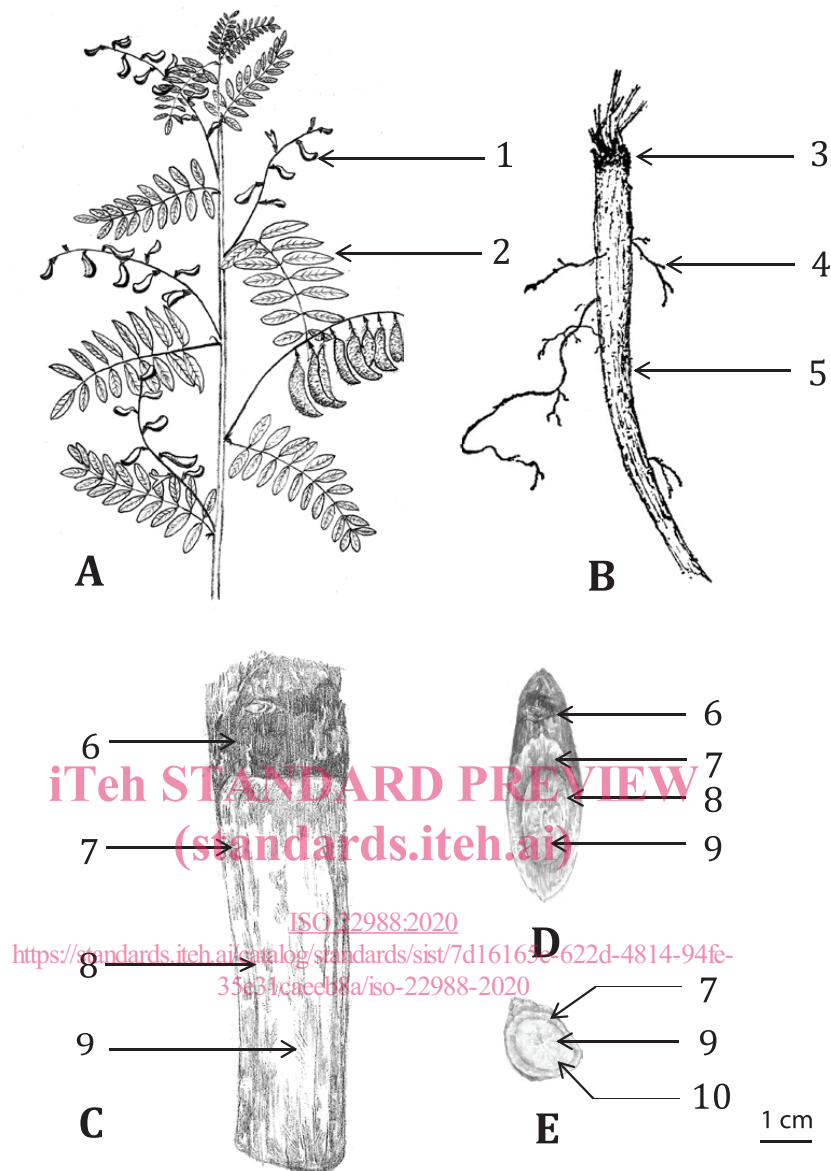
4 Descriptions

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In this document, *Astragalus mongholicus* root is the dried root of *Astragalus membranaceus* (Fisch.) Bge. var. *mongholicus* (Bge.) Hsiao in the family of Leguminosae shown in [Figure 1](#).

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Key

- | | | | |
|---|--|----|--------------------|
| A | plant of <i>Astragalus mongholicus</i> | 4 | fibrous root |
| B | dried tap root | 5 | tap root |
| C | longitudinal section of the tap root | 6 | epidermis |
| D | slanting section of the tap root | 7 | phloem |
| E | transverse section of the tap root | 8 | cambium |
| 1 | flower | 9 | xylem |
| 2 | leaf | 10 | radiate striations |
| 3 | stem scar | | |

Figure 1 — Structure of *Astragalus mongholicus* root

5 Requirements

5.1 Morphological features

- a) The roots are cylindrical, some branched, upper part relatively thick.

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- b) The roots are 30 cm to 90 cm long, 1 cm to 3,5 cm in diameter.
- c) The outer surface is pale brownish-yellow or pale brown, with irregular, longitudinal wrinkles or furrows.
- d) The texture is hard and tenacious, uneasily broken.
- e) The fracture is highly fibrous and starchy, bark yellowish-white, wood pale yellow, with radiate striations and fissures, the centre part of old root occasionally rotten wood-shaped, blackish-brown or hollowed.
- f) The odour is weak.
- g) The taste is slightly sweet and slightly bean-like on chewing.

5.2 Moisture

The content of moisture in percentage mass should not be more than 10,0 %.

5.3 Total ash

The content of total ash in percentage mass should not be more than 5,0 %.

5.4 Water-soluble extractives

The content of water-soluble extractives in percentage mass should not be less than 17,0 %.

5.5 Thin-layer chromatogram identification

The thin-layer chromatogram (TLC) of *Astragalus mongholicus* root shall present the spots and bands with the same colour and position corresponding to those of reference solutions.

5.6 Total polysaccharides

The content of total polysaccharides in percentage mass shall be determined.

5.7 Marker compounds

The content of marker compounds in percentage mass shall be determined.

For example, saponins (such as astragaloside I, astragaloside II or astragaloside IV) or isoflavonoids (such as calycosin, calycosin-7-glucoside, formononetin or ononin) shall be determined according to relevant national or regional pharmacopoeias.

5.8 Heavy metals

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

5.9 Pesticide residues

The content of pesticide residues shall be determined.

5.10 Grade

The grade of *Astragalus mongholicus* root shall be established only when all four requirements, i.e. root top diameter, root mid-diameter, root bottom diameter and root length, are met. The root diameter and root length of each batch of *Astragalus mongholicus* root shall conform to the requirements in [Table 1](#).

Table 1 — Grading requirements of *Astragalus mongholicus* root

Grade	Root diameter cm			Root length cm
	Root top diameter	Root mid-diameter	Root bottom diameter	
First	> 2	> 2	≥ 0,6	> 70
Second	> 1,5	> 1,5	≥ 0,5	> 50
Third	> 1	> 1	≥ 0,4	> 40
Fourth	> 0,7	> 0,7	≥ 0,3	—
Unqualified	≤ 0,7	≤ 0,7	< 0,3	—

NOTE 1 The requirements are based on roots collected from different production regions of *Astragalus mongholicus* root.

NOTE 2 The grading requirements are established according to the traditional grading system of *Astragalus mongholicus* root that has long been extensively used in the market and trading and that has also been adopted by the national standards of the People's Republic of China.

NOTE 3 Traditionally and practically, the market price of *Astragalus mongholicus* root is positively correlated with the grades. The higher the grade, the more expensive the price in the market.

NOTE 4 The grade merely reflects size and TCM knowledge of the product, which has no clear relationship with its efficacy and safety.

6 Sampling

Sampling shall be carried out in accordance with the method described in the World Health Organization, *Quality control methods for herbal materials, General advice on sampling*. Sampling of *Astragalus mongholicus* root shall be conducted according to the following steps:

- a) from a batch of five containers or packaging units, take a sample from each one;
- b) from a batch of six units to 50 units, take a sample from five;
- c) from a batch of over 50 units, sample 10 %, rounding up the number of units to the nearest multiple of 10. For example, a batch of 51 units would be sampled as for 60, i.e. take samples from six packages;
- d) from each container or package selected, take three original samples from the top, middle and bottom of the container or package;
- e) the three original samples shall then be combined into a pooled sample which shall be mixed carefully;
- f) the average sample is obtained by quartering:
 - mix the pooled sample into an even and square-shaped heap;
 - divide diagonally into four equal parts;
 - take two diagonally opposite parts and mix carefully;
 - repeat the process as necessary until the required quantity, to within ± 10 %, is obtained.
- g) using the same quartering procedure, divide the average sample into four final samples, taking care that each portion is representative of the bulk material;
- h) the final samples are tested for the measure and analyses specified in [Table 2](#).