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Traditional Chinese Medicine — *Glehnia littoralis* root

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Contents

Page

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 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

Glehnia littoralis root is the dried or dried peeled root of *Glehnia littoralis* Fr. Schmidt ex Miq. (Apiaceae), which is recorded in the Chinese, Japanese and Korean pharmacopoeias, Hong Kong Chinese Materia Medica Standards and Taiwan herbal pharmacopoeia. *Glehnia littoralis* root is internationally recognized as a medicinal material and there is great demand for it in the international market. However, there are many problems seriously affecting the international trade of *Glehnia littoralis* root, including the following:

1) Quality requirements for *Glehnia littoralis* root are different among different countries and regions.

2) *Glehnia littoralis* root is often substituted with fake and inferior *Glehnia littoralis* root.

3) Different collecting times, processing methods, packaging, transportation and storage conditions often result in different qualities of *Glehnia littoralis* root.

Therefore, the establishment of an International Standard for *Glehnia littoralis* root is necessary to guarantee the quality, safety and consistency of this valuable herbal medicine. This document includes sections on morphology evaluation (general, macroscopic and microscopic characteristics), physicochemical indexes (moisture, total ash, acid-insoluble ash, maker compounds, pesticide residues and sulfur dioxide residue) and heavy metal (lead, arsenic, cadmium and mercury) content.

As national implementation may differ, national standards bodies are invited to modify the values given in 5.4, 5.5, and 5.6 in their national standards. Examples of national and regional values are given in Annex D.

Traditional Chinese Medicine — *Glehnia littoralis* root

1 Scope

This document specifies the quality and safety requirements of *Glehnia littoralis* root, which is derived from the plant *Glehnia littoralis* Fr Schmidt ex Miq.

This document applies to *Glehnia littoralis* 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 1577, *Tea — Determination of acid-insoluble ash*

ISO 1666, *Starch — Determination of moisture content — Oven-drying method*

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

World Health Organization, *Quality control methods for herbal materials,* 2011

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
tap root
main root of *Glehnia littoralis* Fr. Schmidt ex Miq. that grows straight downwards and produces smaller side roots

Note 1 to entry: See Figure 1 B.

3.2
stem scar
scar left on the tap root when the stem is removed

Note 1 to entry: See Figure 1 B.

3.3
root length
longest distance from the bottom to the stem scar of the tap root

Note 1 to entry: See Figure 1 B.

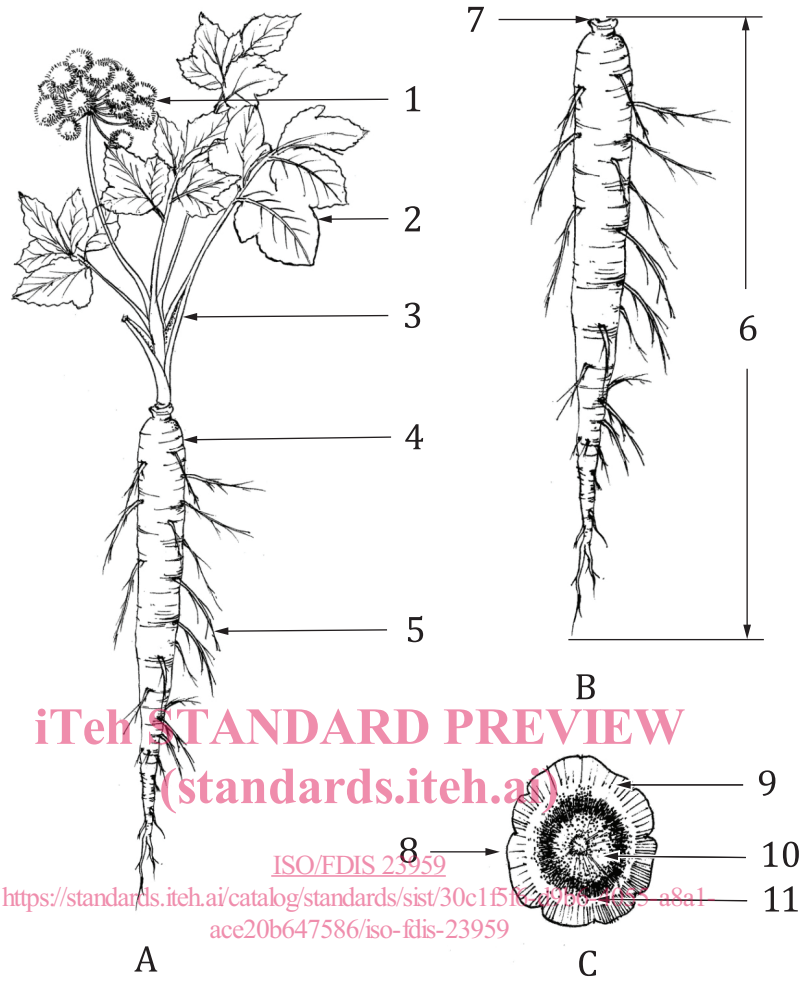
Note 2 to entry: Length is measured in centimetres.

3.4
batch
samples collected from the same particular place at the same time

[SOURCE: ISO 21317:2019, 3.5]

4 Descriptions

Glehnia littoralis root is the dried or dried peeled root of *Glehnia littoralis* Fr. Schmidt ex Miq. (Apiaceae), and the colour of its outer surface is pale yellowish-white to yellowish-brown (see Figure 1).



Key

A	plant of *Glehnia littoralis* Fr. Schmidt ex Miq.	5	lateral root
B	whole root of *Glehnia littoralis* Fr. Schmidt ex Miq.	6	tap root length
C	transverse section of the tap root	7	stem scar
1	inflorescence	8	epidermis
2	leaf	9	phloem
3	leaf sheath	10	xylem
4	tap root	11	cambium

Figure 1 — Structure of *Glehnia littoralis*

5 Requirements

5.1 General characteristics

The following requirements shall be met before sampling:

a) *Glehnia littoralis* root shall be clean and free from 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 Macroscopic characteristics

a) The root is slender-cylindrical. The top section of the root is slender, the greater portion of the middle section of the root is thick and the end section of the root becomes slender again towards the distal end (see Figure 1 A and B).

b) The top section of the root is often marked with remnants of yellowish-brown rhizome base.

c) The root is 9 cm to 45 cm long, 0,2 cm to 1,5 cm in diameter.

d) The outer surface is pale yellowish-white to yellowish-brown and somewhat rough. There are fine longitudinal wrinkles and grooves and brownish-yellow punctiform protuberance scars of rootlets across the surface of the root.

e) The bark (or cortex) section of the root's fracture is yellowish-white and the xylem section of the root's fracture is brown.

f) The texture is hard and fragile, and the root is easily broken.

g) The odour of the root is distinctively fragrant and the taste is slightly sweet.

5.3 Microscopic characteristics

5.3.1 Transverse section characteristics

a) Cortex consists of several rows of parenchyma cells.

b) Phloem is broad and has cleft. Phloem rays and groups of sieve tubes in the inner part are encrusted with densely arranged secretory canals. Secretory canals are 20 µm to 65 µm in diameter and contain yellowish-brown secretions. Each secretory canal is surrounded by 5 to 8 secretory cells.

c) Cambium is prominent and in a ring.

d) Xylem rays are broad and their width is 2 to 5 column cells. Vessels occur singly and are scattered or arranged in a V-shape configuration.

e) Parenchyma cells contain gelatinous starch masses.

5.3.2 Powder characteristics

a) The colour of the powder is yellowish-white.

b) Fragments of secretory canals containing yellowish-brown secretion are found frequently.

c) Yellowish-brown secretion and gelatinous starch masses are found frequently and their shape is irregular.

d) Vessel elements appear singly or in groups. The reticulate wall of the vessel elements is thick and the pits of the reticulate wall are long and wide.

e) Parenchyma cells are sub-rectangular and abundant.

5.4 Moisture

The content of moisture should not be more than 13,0 %.

5.5 Total ash

The content of total ash should not be more than 6,0 %.

5.6 Acid-insoluble ash

The content of acid-insoluble ash should not be more than 1,5 %.

5.7 Thin-layer chromatogram identification

The identification of *Glehnia littoralis* root with thin-layer chromatogram (TLC) shall present spot(s) of marker compound(s) such as falcarinol and other spots obtained from the test solution, reference standard solution and reference drug solution in the same positions with the same colour after evenly spraying the chromogenic agent.

5.8 Marker compounds

The content of marker compounds (e.g. polyacetylenes such as falcarinol) should be determined.

5.9 Heavy metals

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

5.10 Pesticide residues

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

5.11 Sulfur dioxide residue

The content of sulfur dioxide residue should be determined.

6 Sampling

Sampling of *Glehnia littoralis* root shall be in accordance with the World Health Organization's *Quality control methods for herbal materials*, 'General advice on sampling'.

a) From a batch of five containers or packaging units, take a sample from each one.

b) From a batch of between 6 and 50 units, take a sample from five units.

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 60 units; i.e. take samples from six packages.

d) From each selected container or package, take three original samples from the top, middle and bottom of the container or package. The three original samples should then be combined into a pooled sample that should be carefully mixed.

e) The average sample is obtained by quartering. Take some of the pooled sample, adequately mixed, place into an even, square-shaped heap, and divide this diagonally into four equal parts. Take two diagonally opposite parts and mix carefully.

f) 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 measurement and analyses specified in Table 1. Ground samples shall be used in the measurement and analyses, except the identification of macroscopic characteristics. The test samples shall be finely ground, carefully mixed and sealed.