INTERNATIONAL STANDARD

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Traditional Chinese medicine — *Glehnia littoralis* root

Médecine traditionnelle chinoise — *racine de* Glehnia littoralis

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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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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

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.

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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 Mig.

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.

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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

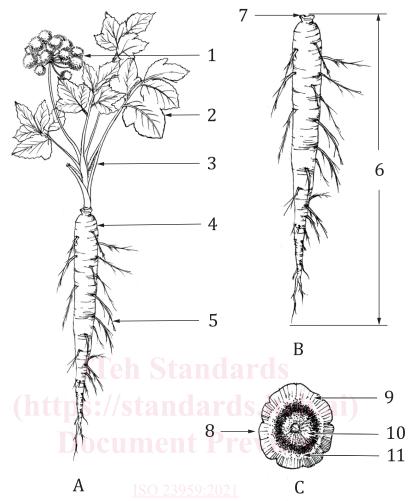
[SOURCE: ISO 21317:2019, 3.5]

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).

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Key

Α plant of Glehnia littoralis Fr. Schmidt ex Mig. lateral root В whole root of Glehnia littoralis Fr. Schmidt ex Miq. 6 tap root length C transverse section of the tap root stem scar 1 inflorescence epidermis 2 leaf phloem 3 leaf sheath xylem 10 4 11 cambium tap root

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 %.