
**Traditional Chinese medicine —
Gastrodia elata tuber**

Médecine traditionnelle chinoise — Tubercule de Gastrodia elata

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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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

Gastrodia elata tuber, the dried tuber of *Gastrodia elata* Bl. (Orchidaceae) after it has been steamed thoroughly, is a medicinal herb which has been used as an anticonvulsant, analgesic and sedative to treat general paralysis, epilepsy, tetanus and vertigo in Asian countries for thousands of years.

There are at least 16 countries and regions using *Gastrodia elata* tuber and its products. Major users include China, Japan, South Korea, the United State, Australia, Austria and Singapore. Due to its great demand and high price in the global market, trade in *Gastrodia elata* tuber has been complicated by adulteration, substitution and species identification issues. The toxic roots of other species, such as the plants of the Phytolaccaceae family, are sometimes misused as *Gastrodia elata* tuber, which can cause health risks. Factors including contamination, packaging and storage conditions also affect the quality of *Gastrodia elata* tuber.

The establishment of an international standard for *Gastrodia elata* tuber is therefore necessary to support its quality consistency, clinical effectiveness and safety in international trade.

As national implementation may differ, National Standards Bodies are invited to modify the values given in [5.3](#), [5.4](#), [5.5](#) and [5.7](#) in their national standards. Examples of national and regional values are given in [Annex F](#).

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Traditional Chinese medicine — *Gastrodia elata* tuber

1 Scope

This document specifies minimum requirements and test methods for *Gastrodia elata* tuber that is derived from cultivated and artificially propagated *Gastrodia elata* Bl.

It is applicable to *Gastrodia elata* tuber that is sold and used as Chinese materia medica, specifically excluding the wild forms of the species.

2 Normative references

ISO 1575, *Tea — Determination of total ash*

ISO 5379, *Starches and derived products — Determination of sulfur dioxide content — Acidimetric method and nephelometric 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*

CODEX STAN 229-1993, REV.1-2003, *Analysis of pesticide residues: Recommended methods*

CAC/MRL01-2009, *Maximum Residue Limits for Pesticides in Foods*

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

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

***Gastrodia elata* tuber**

dried tuber of *Gastrodia elata* Bl. (Orchidaceae) after it has been steamed or boiled thoroughly

3.2

bud

undeveloped or embryonic shoot in red-brown to dark brown, which is parrot-beak-shaped and grows on the apex of the tuber

Note 1 to entry: See [Figure 1](#).

3.3

latent bud

bud which remains undeveloped or dormant, arranged along the body of *Gastrodia elata* tuber

Note 1 to entry: See [Figure 1](#).

3.4

sample

portion taken from the *batch* (3.5) during one single sampling action

3.5

batch

samples (3.4) collected from the same particular place at the same time

Note 1 to entry: This is not more than 5 000 kg.

3.6

final sample

samples (3.4) for the test required in this standard

Note 1 to entry: Final samples may be packed in different materials meeting conditions for specific tests (e.g. moisture or total ash).

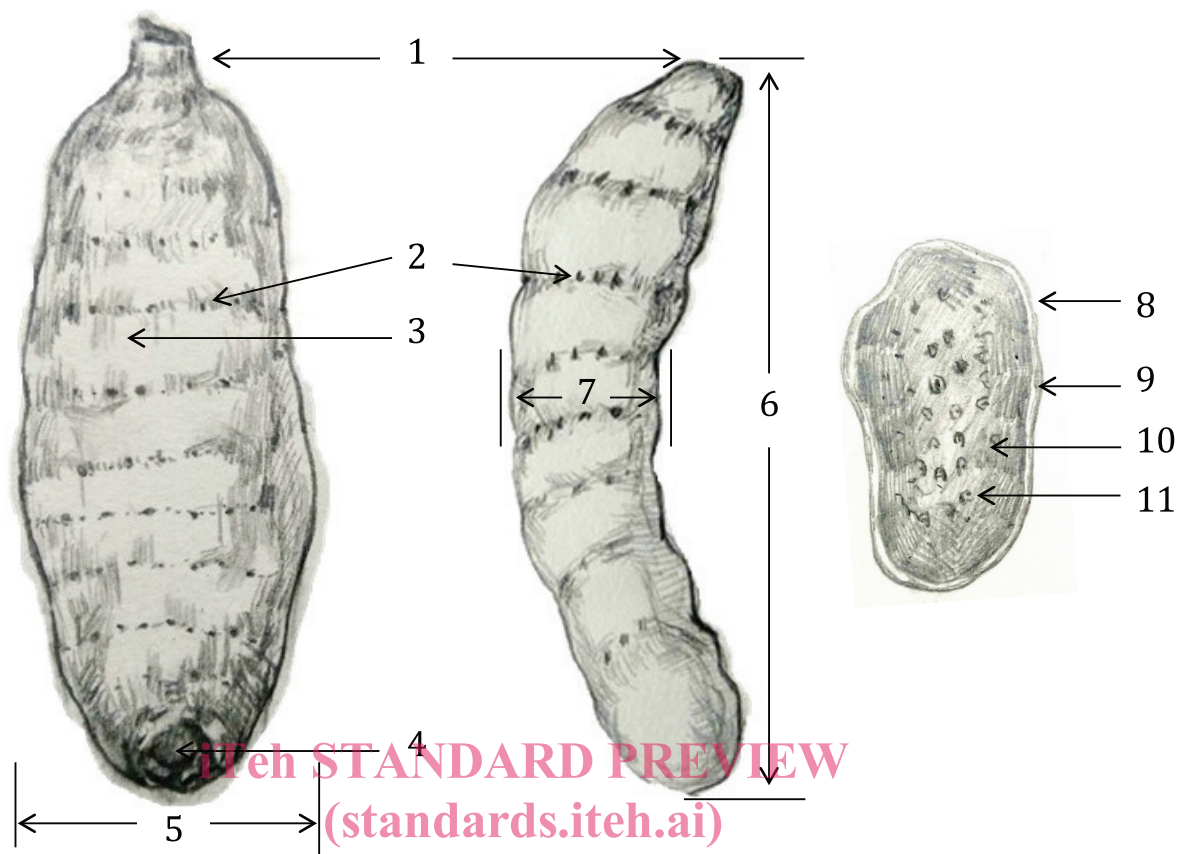
4 Descriptions

Gastrodia elata tuber is the dried tuber of *Gastrodia elata* Bl. (Orchidaceae) after it has been steamed or boiled thoroughly, as shown in [Figure 1](#).

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A

B

C

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Key

- A front view
- B lateral view
- C cross-sectional view
- 1 bud or remain of stem
- 2 latent bud
- 3 longitudinal wrinkle
- 4 rounded scar
- 5 tuber width
- 6 tuber length
- 7 tuber thickness
- 8 epidermis
- 9 hypodermis
- 10 stele
- 11 vascular bundle

Figure 1 — Structure of *Gastrodia elata* tuber

5 Requirements

5.1 General characteristics

The following requirements shall be met before sampling:

- a) *Gastrodia elata* tuber shall be clean and free from foreign matter;
- b) the presence of living insects, mouldy tuber and external contaminants which are visible to the naked eye shall not be permitted.

5.2 Morphological features

- a) The tuber is ellipsoid or spat-shaped, slightly compressed, shrunken and somewhat curved.
- b) The tuber is 3 cm to 15 cm long, 1,5 cm to 6 cm wide, and 0,5 cm to 4 cm thick.
- c) The tuber mass is no less than 12 g.
- d) The outer surface is yellowish-white to pale yellowish-brown, with longitudinal wrinkles and many transverse annulations arranged along latent buds. The brown thread is sometimes visible. There are reddish-brown to deep brown parrot-beak-shaped buds or remains of stem on the apex. There is a rounded scar at the lower end of the tuber.
- e) The texture is hard and uneasily broken.
- f) The fracture is fairly even, yellowish-white to brownish, and horny.
- g) The odour is slight, and the taste is sweetish.

5.3 Moisture

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

5.4 Total ash

The mass fraction of total ash should not be more than 4,5 %.

5.5 Dilute ethanol-soluble extract

The mass fraction of dilute ethanol-soluble extract should not be less than 15,0 %.

5.6 Identification of marker compound(s)

The identification of marker compound(s), such as gastrodin or *p*-hydroxybenzyl alcohol, with thin-layer chromatography (TLC) shall present the spots or bands obtained from the test and reference solutions in the same position with the same colour.

5.7 Content of marker compound(s)

The content of marker compound(s) should be determined. For example, the sum of the mass fraction of gastrodin and *p*-hydroxybenzyl alcohol should not be less than 0,25 %.

5.8 Heavy metals

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

5.9 Pesticide residues

The contents of pesticide residues including Benzex, DDT and quintozene shall be determined.

5.10 Sulfur dioxide

The content of sulfur dioxide shall be determined.

6 Sampling

Sampling of *Gastrodia elata* tuber shall be done with reference to the World Health Organization 2011, *Quality control methods for herbal materials*.

- a) Take a sample from each of a batch of five containers or packaging units.
- b) From a batch of 6 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. The three original samples should then be combined into a pooled sample that should be mixed carefully.
- e) The average sample is obtained by quartering. From the pooled sample, adequately mix into an even and square-shaped heap, and divide it 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](#).

Table 1 — Maximum mass of batch and minimum mass of the final sample

Maximum mass of tuber per batch kg	Minimum mass of final sample g		
	For macroscopic identification	For determination of marker compound(s) content	For other analyses
5 000	500	250	250

NOTE 1 The requirements are based on samples collected from different production regions of *Gastrodia elata* tuber.

NOTE 2 Other analyses include the identification of marker compound(s) and the determination of moisture content, total ash, ethanol-soluble extractives, heavy metals, pesticide residues and sulfur dioxide.

7 Test methods

7.1 Macroscopic identification

Samples of not less than 500 g are taken from each batch randomly and observed with the naked eye, smelt and tasted with the tongue.

7.2 Determination of moisture content

The testing method refers to [Annex A](#) for additional information.