
**Traditional Chinese medicine —
Ganoderma lucidum fruiting body**

*Médecine traditionnelle chinoise — Organe fructifère de
Ganoderma lucidum*

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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).

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

Ganoderma lucidum fruiting body is the dried fruiting body of *Ganoderma lucidum* (Leys. ex Fr.) Karst., which is also known as Lingzhi or Reishi. It has been used as a medicinal mushroom in many Asian countries for more than 2000 years, such as China, Japan and Korea, making it one of the oldest mushrooms known to have been used medicinally. This fungus can tonify Qi, and is traditionally used to treat fatigue, cough and insomnia in traditional Chinese medicine. Modern pharmacological studies also demonstrate its great potential in tumour treatment and immuno-enhancement. Therefore, the market of *Ganoderma lucidum* has developed very rapidly, as indicated by the increase in yield, production output and trade volume.

However, there remain many challenges, such as adulteration of similar species, and lack of suitable testing methods for quality assessment. In addition, though *Ganoderma lucidum* has been recorded in several pharmacopoeias, such as Chinese Pharmacopoeia, United States Pharmacopeia Herbal Medicines Compendium and the Korean Herbal Pharmacopoeia, the specifications and quality requirements in these standards vary. Therefore, there is a clear and urgent need to develop an international standard for harmonizing the existing standards, as well as ensuring the safety and effectiveness of *Ganoderma lucidum* fruiting body.

As national implementation may differ, National Standards Bodies are invited to modify the values given in [5.2.3](#), [5.2.4](#) and [5.2.5](#) in their national standards. Examples of national and regional values are given in [Annex E](#).

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Traditional Chinese medicine — *Ganoderma lucidum* fruiting body

1 Scope

This document specifies minimum requirements and test methods for *Ganoderma lucidum* fruiting body that is derived from *Ganoderma lucidum* (Leyss. ex Fr.) Karst.

It is applicable to *Ganoderma lucidum* fruiting body that is sold and used as Chinese materia medica (whole medicinal materials) and decoction pieces derived from this fungus.

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*

ISO 20409, *Traditional Chinese medicine — Panax notoginseng root and rhizome*

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

CAC/MRL01, *Maximum Residue Limits for Pesticides in Food*

CODEX STAN 229, *Analysis of pesticide residues: Recommended methods*

World Health Organization. 2011, *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

fruiting body

dried sporocarp of *Ganoderma lucidum* (Leyss. ex Fr.) Karst.

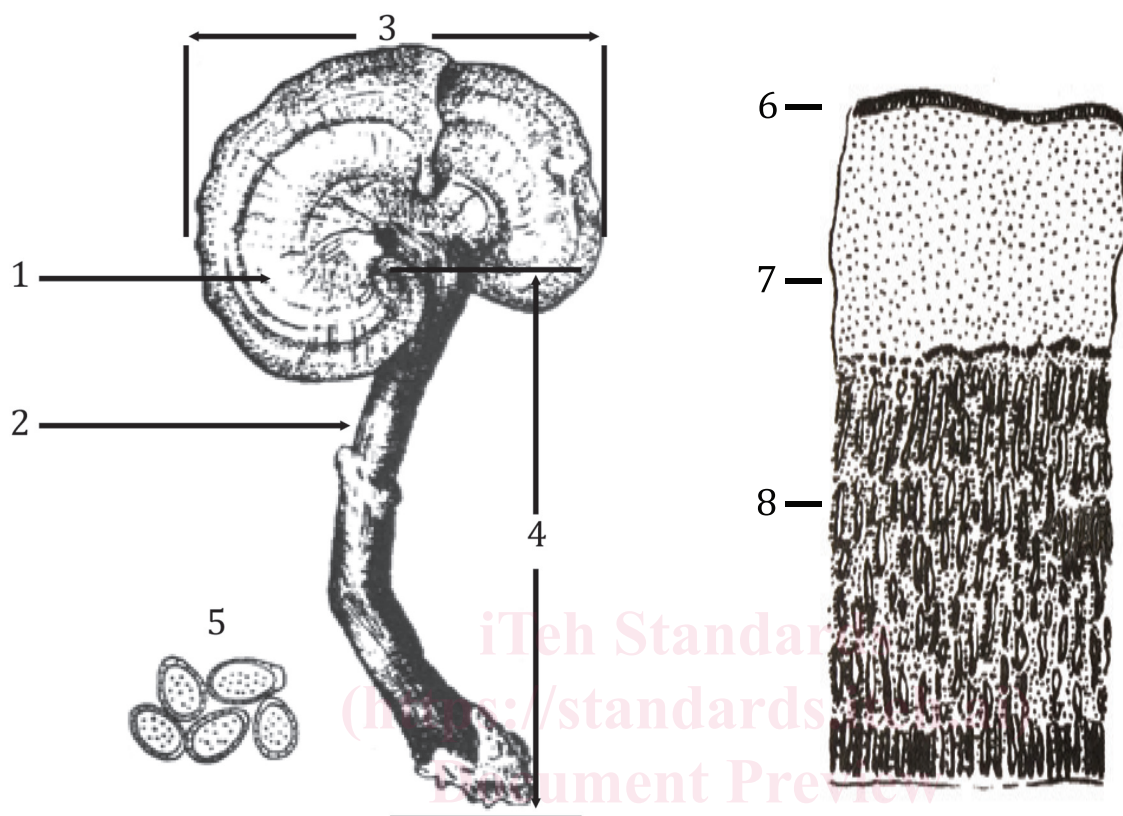
3.2

reference standard

authentic substance used as a measurement base for TLC identification or marker compound quantification

4 Descriptions

Ganoderma lucidum fruiting body is the dried fruiting body of *Ganoderma lucidum* (Leyss. ex Fr.) Karst. in the family of Ganodermataceae shown in [Figure 1](#).



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<https://standards.iso.org/standards/info/05390de8-bdb> **a) Fruiting body of *Ganoderma lucidum*** **b) Vertical section of pileus** iso-21315-2018

Key

- 1 pileus
- 2 stipe
- 3 pileus diameter
- 4 stipe length
- 5 spore
- 6 crust
- 7 context
- 8 tube

Figure 1 — Structure of *Ganoderma lucidum*

5 Requirements

5.1 General characteristics

The following requirements shall be met before sampling.

- a) *Ganoderma lucidum* fruiting body shall be clean and free from foreign matter.

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

5.2 *Ganoderma lucidum* fruiting body

5.2.1 Morphological features of fruiting body

- a) Outline of fruiting body umbrella-shaped, pileus reniform, semi-rounded or surrounded, 10 cm to 30 cm in diameter, 1 cm to 4 cm thick.
- b) Colour of pileus varies, yellowish-brown to reddish-brown, lustrous, with circular stripe and radiate wrinkle.
- c) Stipe cylinder, usually 4 cm to 15 cm long, 1 cm to 3,5 cm in diameter, reddish-brown, luminous; attachment of the stipe to the pileus varies from lateral to nearly central.
- d) Spore small and fine, yellowish-brown.
- e) Odour slightly aromatic, taste slightly bitter.
- f) Crust hard, colour similar to pileus or darker, the context varies in colour from yellowish-brown to dark brown, the length of tube layer varies from short (less than one-third of the pileus thickness) to long (more than one-third of the pileus thickness).

5.2.2 Thin-layer chromatogram (TLC) identification

The identification of *Ganoderma lucidum* fruiting body with thin-layer chromatogram (TLC) shall present the spot or band with the same colour and position corresponding to those of reference standard solution.

5.2.3 Moisture

The mass fraction of moisture should not be more than 17,0 %.

5.2.4 Total ash

The mass fraction of total ash should not be more than 4,0 %.

5.2.5 Water-soluble extractives

The mass fraction of water-soluble extractives should not be less than 3,0 %.

5.2.6 Marker compounds

Marker compounds such as polysaccharides and ganoderic acid A shall be determined.

5.2.7 Heavy metals

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

5.2.8 Pesticide residues

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

6 Sampling

Sampling of *Ganoderma lucidum* fruiting body shall be in accordance with the World Health Organization 2011 *Quality Control Methods for Herbal Materials, General Advice on Sampling*.

7 Test methods

7.1 Macroscopic identification

Samples not less than 500 g are taken from each batch randomly. These samples are examined by the naked eye, smell and taste.

7.2 TLC identification

See [Annex A](#) for additional information.

7.3 Determination of moisture content

The testing method specified in ISO 20409 shall apply.

7.4 Determination of total ash

The testing method specified in ISO 1575 shall apply.

7.5 Determination of water-soluble extractives

See [Annex B](#) for additional information.

7.6 Determination of marker compounds

See [Annex C](#) and [D](#) for additional information. [ISO 21315:2018
https://standards.iteh.ai/catalog/standards/iso/05390dc8-bd03-4b08-8fad-a21b1fd1b055/iso-21315-2018](https://standards.iteh.ai/catalog/standards/iso/05390dc8-bd03-4b08-8fad-a21b1fd1b055/iso-21315-2018)

7.7 Determination of heavy metals

The testing method specified in ISO 18664 shall apply.

7.8 Determination of pesticide residues

The testing method specified in CAC/MRL01 and CODEX STAN 229 shall apply.

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(s) used;
- d) the test result(s) obtained;
- e) all operating details not specified in this document, or regarded as optional, together with details of any incidents which may have influenced the test result(s);
- f) any unusual features (anomalies) observed during the test;