
**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.

Introduction

Ganoderma lucidum fruiting body is the dried fruiting body of *Ganoderma lucidum* (Leyss. 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](#).

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