Draft for Public Comment

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Interested committees:

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at **https://standardsdevelopment.bsigroup.com/**. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex **(e.g. 3.1)**	Paragraph/ Figure/Table/Note	**Type of comment**	**Commend (justification for change) by the MB**	**Proposed change by the MB**	**Secretariat observations on each comment submitted**
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

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DRAFT International Standard

ISO/DIS 21315

Traditional Chinese medicine — *Ganoderma lucidum* fruiting body

Médecine traditionnelle chinoise — Organe fructifère de Ganoderma lucidum

ICS: 11.120.10

ISO/TC **249**/SC **1**

Secretariat: **SAC**

Voting begins on:
2025-06-17

Voting terminates on:
2025-09-09

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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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This document was prepared by Technical Committee ISO/TC 249/SC 1, *Traditional Chinese medicine*.

This second edition cancels and replaces the first edition (ISO 21315:2018) which has been technically revised.

The main changes are as follows:

— add a NOTE to elucidate the correct name for the widely cultivated medicinal fungus *Ganoderma lucidum* in China in clause 3.1;

— revise the requirement for the moisture content from “should not be more than 17,0 %” to “should be determined” in clause 5.4;

— revise the requirement for the water-soluble extractives content from “should not be less than 3,0 %” to “should be determined” in clause 5.6;

— add the principle of the test method, a table of relative retention time and correction factor of ganoderic acids in Annex C;

— update the edition date and requirements of the Chinese Pharmacopoeia, the United States Pharmacopoeia and the Korean Herbal Pharmacopoeia, and add the requirements from the European Pharmacopoeia in Annex E;

— minor editorial changes.

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* (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. Though *Ganoderma lucidum* has been recorded in several pharmacopoeias, such as Chinese Pharmacopoeia,[1] the Korean Herbal Pharmacopoeia,[2] the European Pharmacopoeia,[3] and the United States Pharmacopoeia,[4] 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 can differ, national standards bodies are invited to modify the values given in 5.5 in their national standards. Examples of national and regional values are given in Annex D.

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