
**Traditional Chinese medicine —
Zingiber officinale rhizome**

Médecine traditionnelle chinoise — Rhizome de Zingiber officinale



This document is a preview generated by EUS



COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

Contents

Page

Foreword.....	iv
Introduction.....	v
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 Descriptions.....	2
5 Requirements.....	3
5.1 General characteristics.....	3
5.2 <i>Zingiber officinale</i> rhizome.....	3
5.2.1 Morphological features of rhizome.....	3
5.2.2 Microscopic characteristics.....	3
5.2.3 Thin-layer chromatogram (TLC) identification.....	3
5.2.4 Moisture content.....	3
5.2.5 Total ash.....	3
5.2.6 Volatile oil.....	4
5.2.7 Marker compound.....	4
5.2.8 Water-soluble extractives.....	4
5.2.9 Heavy metals.....	4
5.2.10 Pesticide residues.....	4
5.2.11 Residue of sulfur dioxide.....	4
6 Sampling.....	4
7 Test methods.....	4
7.1 Macroscopic identification.....	4
7.2 Microscopic identification.....	5
7.3 Thin-layer chromatogram (TLC) identification.....	5
7.4 Determination of moisture content.....	5
7.5 Determination of total ash content.....	5
7.6 Determination of volatile oil.....	5
7.7 Determination of marker compound 6-gingerol.....	5
7.8 Determination of water-soluble extractives.....	5
7.9 Determination of heavy metals.....	5
7.10 Determination of pesticide residues.....	5
7.11 Determination of residue of sulfur dioxide.....	5
8 Test report.....	5
9 Packaging and storage.....	6
10 Marking and labelling.....	6
Annex A (informative) Thin-layer chromatogram (TLC) identification.....	7
Annex B (informative) Determination of moisture content.....	9
Annex C (informative) Determination of 6-gingerol.....	11
Annex D (informative) Determination of water-soluble extractives.....	13
Annex E (informative) Referenced values of moisture, total ash, gingerol, volatile oil and water-soluble extractives contents on <i>Zingiber officinale</i> rhizome in different national and regional standards.....	14
Bibliography.....	15

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

Zingiber officinale rhizome is one of the most commonly used traditional Chinese medicines in the world. At present the global scope of *Zingiber officinale* rhizome covers medicinal products in addition to raw materials, including powder, ginger tea, extract, capsule, tincture and other dosage forms. Quality standards are given in the pharmacopoeias of various countries, including the Chinese Pharmacopoeia, the European Pharmacopoeia, the United States Pharmacopoeia, the Japanese Pharmacopoeia, the Korean Pharmacopoeia and the British Pharmacopoeia. However, there are some differences between these pharmacopoeias, such as trait description, identification methods, inspection indicators and limits, methods and indicators of content determination and storage. ISO published the relevant standards of *Zingiber officinale* rhizome as a spice in 2018, such as ISO 1003, but these lacked an investigation of the medicinal components of *Zingiber officinale* rhizome. The identification and quality control of medicinal materials are also different in the various pharmacopoeia, which are therefore not suitable for the quality control of medicinal *Zingiber officinale* rhizome. In the international context of gradually improving the quality requirements of traditional Chinese medicine, it is particularly important to establish International Standards for *Zingiber officinale* rhizome in order to promote the international circulation of medicinal *Zingiber officinale* rhizome products.

Zingiber officinale rhizome is also widely used throughout the world as a food supplement and spice, which indicates a good safety profile. As national implementation can differ, national standards bodies are invited to modify the values given in [5.2.4](#), [5.2.5](#), [5.2.6](#), [5.2.7](#) and [5.2.8](#) in their national standards. Examples of national and regional values are given in [Annex E](#), [Table E.1](#).

Traditional Chinese medicine — *Zingiber officinale* rhizome

1 Scope

This document specifies the quality and safety requirements of *Zingiber officinale* rhizome derived from the plant *Zingiber officinale* Roscoe, including the minimum requirements and test methods.

This document applies to *Zingiber officinale* rhizome that is sold and used as natural medicines in international trade, including Chinese materia medica (whole medicinal materials) and decoction pieces derived from this plant. It is not applicable to *Zingiber officinale* rhizome sold and used as food or spices.

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 1003, *Spices — Ginger (Zingiber officinale Roscoe) — Specification*

ISO 6571, *Spices, condiments and herbs — Determination of volatile oil content (hydrodistillation method)*

ISO 18664, *Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine*

ISO/TS 21310, *Traditional Chinese medicine — Microscopic examination on medicinal herbs*

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

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 terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

batch

samples collected from the same particular place at the same time, of no more than 5 000 kg

3.2

volatile oil

substance of *Zingiber officinale* rhizome entrained by steam