### ISO/FDIS 19842:2025(en)

ISO/TC 249<del>/ WG 1</del>

Secretariat: SAC

Date: 2024-12-232025-01-27

Traditional Chinese medicine—<u></u>Dioscorea opposita rhizome

# FDIS stage

## **Document Preview**

**ISO/FDIS 19842** 

https://standards.iteh.ai/catalog/standards/iso/85202af5-38c3-4671-91e7-f8019735a5af/iso-fdis-19842

Edited DIS - MUST BE USED FOR FINAL DRAFT

#### © ISO 2024 2025

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 <u>EmailE-mail</u>: copyright@iso.org Website: <u>www.iso.org</u>

Published in Switzerland

# iTeh Standards (https://standards.iteh.ai) Document Preview

**ISO/FDIS 19842** 

https://standards.iteh.ai/catalog/standards/iso/85202af5-38c3-4671-91e7-f8019735a5af/iso-fdis-19842

## Contents Page

For	eword	Error! Bookmark not defined.	
Introduction		Error! Bookmark not defined.	
1	Scope	Error! Bookmark not defined.	
2	Normative references	Error! Bookmark not defined.	
3	Terms and definitions	Error! Bookmark not defined.	
4	Descriptions	Error! Bookmark not defined.	
5 5.1 5.2 5.3	Quality and safety requirements and recommendations General characteristics Morphological features Microscopic characteristics	Error! Bookmark not defined. Error! Bookmark not defined. Error! Bookmark not defined. Error! Bookmark not defined.	
5.4	Moisture	Error! Bookmark not defined.	
5.5 5.6	1 Otal asn Water-soluble extractives	Fror! Bookmark not defined.	
5.7	Thin-layer chromatogram (TLC) identification	Error! Bookmark not defined.	
5.8	Heavy metals	Error! Bookmark not defined.	
5.9	Pesticide residues	Error! Bookmark not defined.	
5.10	Sulfur dioxide	Error! Bookmark not defined.	
6	Sampling	Error! Bookmark not defined.	
7	Test methods	Error! Bookmark not defined.	
7.1 7.2	Macroscopic identification	Error! Bookmark not defined.	
7.3	Determination of moisture	Error! Bookmark not defined.	
7.4	Determination of total ash	Error! Bookmark not defined.	
7.5	Determination of water-soluble extractives	Error! Bookmark not defined.	
7.6	Thin-layer chromatogram (TLC) identification	Error! Bookmark not defined.	
7.7	Determination of heavy metals	Error! Bookmark not defined.	
7.8	Determination of pesticide residues	Error! Bookmark not defined.	
7.9	Determination of sulfur dioxide	Error! Bookmark not defined.	
8	Test report	Error! Bookmark not defined.	
9	Packaging, storage and transportation	Error! Bookmark not defined.	
10	Marking and labelling	Error! Bookmark not defined.	
(informative) Thin-layer chromatogram (TLC) identification Error! Bookmark not defined.			
(informative) Referenced values of national and regional limits for Dioscorea opposita rhizomeError! Bookmark not defined.			
Bibl	iography	Error! Bookmark not defined.	

© ISO-2024-2025 – All rights reserved iii Edited DIS - MUST BE USED FOR FINAL DRAFT

#### 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 document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see <a href="https://www.iso.org/directives">www.iso.org/directives</a>).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at <u>www.iso.org/patents</u>. ISO shall not be held responsible for identifying any or all such patent rights.

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 <u>www.iso.org/iso/foreword.html</u>.

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 <u>www.iso.org/members.html</u>. 8019735a5af/iso-fdis-19842

#### ISO/FDIS 19842:2025(en)

#### Introduction

*Dioscorea opposita* rhizome is the dried rhizome of *Dioscorea opposita* Thunb. It has a long history of application as a traditional Chinese herb in China, the Republic of Korea, Japan, etc. It is widely used clinically for its efficacy in nourishing the spleen and stomach, generating body fluid and benefiting the lungs, and tonifying the kidneys and <u>acting as an</u> astringent essence. *Dioscorea opposita* rhizome is mostly processed into *Dioscorea opposita* rhizome decoction pieces, bran-fried *Dioscorea opposita* rhizome and other products circulating in the market. *Dioscorea opposita* rhizome has a long history of cultivation and is grown all over the world. In 2020, the global *Dioscorea opposita* rhizome cultivation area is about 9,205 million hectares and *Dioscorea opposita* rhizome production is about 76,031 million tonnes, both of which are on a growing trend.

To date, *Dioscorea opposita* rhizome has been widely recorded in the established pharmacopoeias such as the Chinese Pharmacopoeia, Korean Pharmacopoeia, Japanese Pharmacopoeia, and the European Pharmacopoeia. But different quality requirements in different countries and regions, different packaging, transportation and storage conditions can affect the quality of *Dioscorea opposita* rhizome. Meanwhile, *Dioscorea opposita* rhizome occupies the No. 65 place on the priority list of ISO/TR 23975. Therefore, it is urgent and necessary to establish ana unified international standard for *Dioscorea opposita* rhizome to ensure its quality and safety.

As national implementation can differ, national standards bodies are invited to modify the values given in 5.45.4 and 5.55.5 in their national standards. Examples of national and regional values are given in Annex BAnnex B.

# iTeh Standards (https://standards.iteh.ai) Document Preview

**ISO/FDIS 19842** 

https://standards.iteh.ai/catalog/standards/iso/85202af5-38c3-4671-91e7-f8019735a5af/iso-fdis-19842

© ISO-2024-2025 – All rights reserved Edited DIS - MUST BE USED FOR FINAL DRAFT

## iTeh Standards (https://standards.iteh.ai) Document Preview

<u>ISO/FDIS 19842</u> https://standards.iteh.ai/catalog/standards/iso/85202af5-38c3-4671-91e7-f8019735a5af/iso-fdis-19842