International Standard

ISO 19842

Traditional Chinese medicine — *Dioscorea opposita* rhizome

Médecine traditionnelle Chinoise — Rhizome de Dioscorea opposita

First edition
2025-05

Reference number
ISO 19842:2025(en)

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Published in Switzerland

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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 document 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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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

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 acting as an 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 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 a 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 5.4 and 5.5 in their national standards. Examples of national and regional values are given in Annex B.

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Traditional Chinese medicine — *Dioscorea opposita* rhizome

1 Scope

This document specifies the quality and safety requirements and test methods of *Dioscorea opposita* rhizome (dried rhizome of *Dioscorea opposita* Thunb.).

It is applicable to *Dioscorea opposita* rhizomes that are sold and used as natural medicines in international trade, including Chinese materia medica (whole medicinal material) and decoction pieces derived from this plant.

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

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

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

ISO 22217, *Traditional Chinese medicine —Storage requirements for raw materials and decoction pieces*

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*

ISO 23723, *Traditional Chinese medicine — General requirements for herbal raw material and materia medica*

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
***Dioscorea opposita* rhizome**
dried rhizome of *Dioscorea opposita* Thunb. (syn. *Dioscorea batatas* Decne. or *Dioscorea polystachya* Turcz.) in the family of *Dioscoreaceae.*

4 Descriptions

The features of *Dioscorea opposita* Thunb. plant in the family of Dioscoreaceae are shown in Figure 1.

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