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Traditional Chinese medicine — *Zingiber officinale* rhizome

Médecine traditionnelle chinoise — Rhizome de Zingiber officinale

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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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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

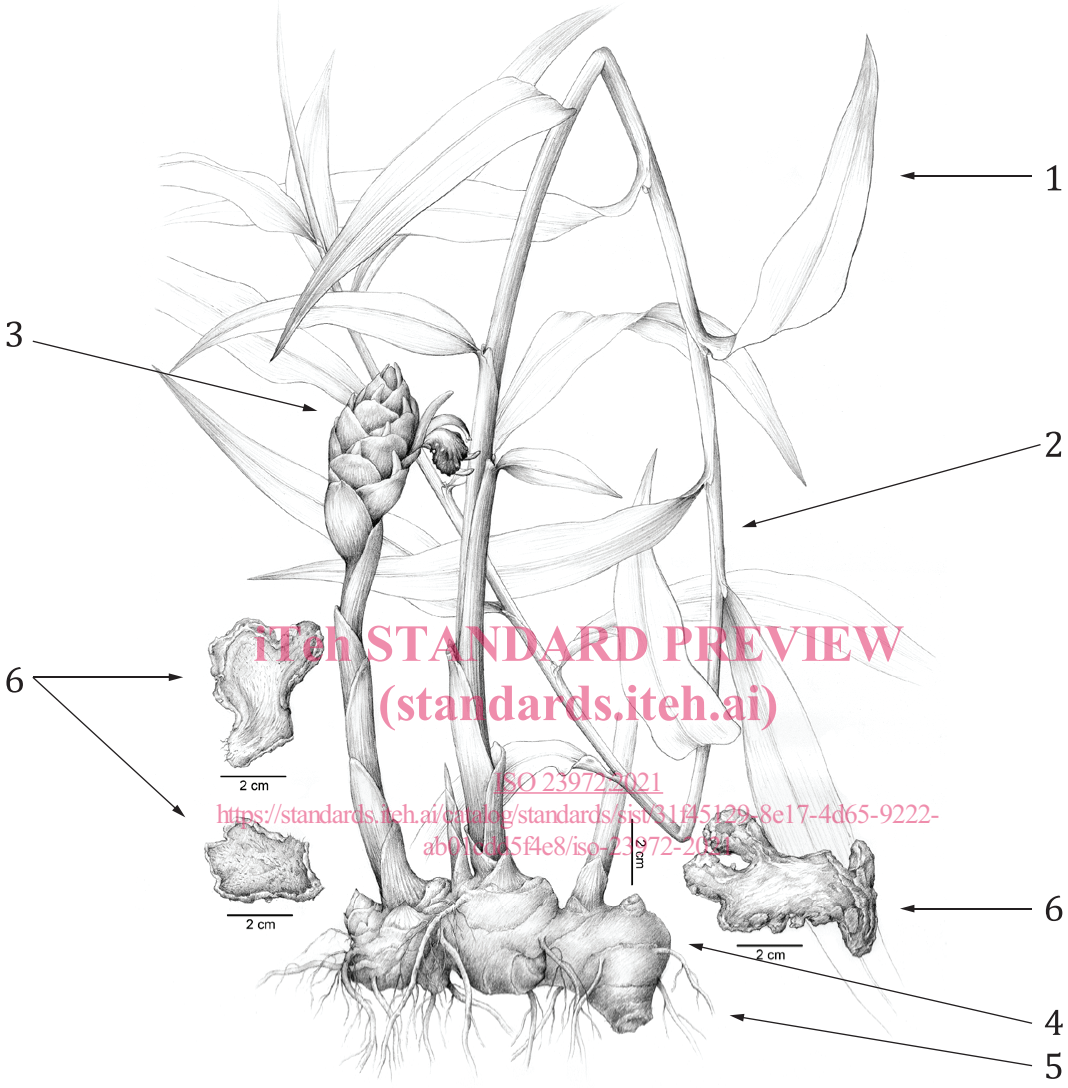
— IEC Electropedia: available at https://www.electropedia.org/

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

4 Descriptions

Zingiber officinale rhizome is the dried rhizome of *Zingiber officinale* Roscoe as shown in Figure 1.



Key

1 leaf
2 pseudostem
3 inflorescence
4 rhizome
5 root
6 dried sliced rhizome

Figure 1 — *Zingiber officinale* Roscoe plant and dried rhizome

5 Requirements

5.1 General characteristics

The following requirements shall be met before sampling.

a) *Zingiber officinale* rhizome shall be clean and free from rootlets and foreign matter.

b) The presence of living insects, mouldy rhizome and external contaminants which are visible to the naked eye shall not be permitted.

5.2 *Zingiber officinale* rhizome

5.2.1 Morphological features of rhizome

a) *Zingiber officinale* rhizome in flattened pieces with fingered branches.

b) The rhizomes are 3 cm to 7 cm long and 1 cm to 2 cm thick.

c) The outer surface is greyish-yellow or pale greyish-brown, rough, with longitudinal wrinkles and distinct annulated nodes.

d) Branched parts usually produce scale leaves and the apex of branches produce stem scars or buds.

e) The texture is compact fracture yellowish-white or greyish-white, starchy and granular, exhibiting a distinct ring of endodermis, scattered with vascular bundles and yellow oil drops.

f) The odour is aromatic and characteristic. The taste is pungent.

5.2.2 Microscopic characteristics

a) Starch granules fairly abundant, long ovate, triangular-ovoid elliptical, subrounded or irregular, 5 µm to 40 µm in diameter, pointed hilum at the small end, sometimes cleft, striations obvious.

b) Oil cells and resin cells scattered in parenchyma, containing pale-yellow oil drops or a dark reddish-brown substance.

c) Fibres in bundles or scattered, apex obtusely acute, few branches, some undulate or serrate on one side, 15 µm to 40 µm in diameter, walls slightly thickened, non-lignified, with fine oblique pits, frequently with thin septa.

d) Vessels mostly scalariform, spiral and reticulate, few annular, 15 µm to 70 µm in diameter.

e) Tubular cells containing a dark reddish-brown substance, 12 µm to 20 µm in diameter, occasionally found beside vessels and fibres.

5.2.3 Thin-layer chromatogram (TLC) identification

The identification of *Zingiber officinale* rhizome with thin-layer chromatogram (TLC) shall present the spot or band with the same colour and position corresponding to those of reference standard solution.

5.2.4 Moisture content

The mass fraction of moisture should not be more than 12,0 %.

5.2.5 Total ash

The mass fraction of total ash should not be more than 8,0 %.

5.2.6 Volatile oil

The mass fraction of assay volatile oil should not be less than 0,8 %.

5.2.7 Marker compound

A marker compound such as 6-gingerol shall be determined; its mass fraction should not be less than 0,6 %.

5.2.8 Water-soluble extractives

The mass fraction of water-soluble extractives should not be less than 10,0 %.

5.2.9 Heavy metals

The contents of heavy metals, namely arsenic, mercury, lead and cadmium, should be determined.

5.2.10 Pesticide residues

The contents of pesticide residues referred to in ISO 22258 should be determined.

5.2.11 Residue of sulfur dioxide

The contents of sulfur dioxide should be determined.

6 Sampling

Sampling of rhizome shall be done with reference to the World Health Organization's *Quality control methods for herbal materials*, 'General advice on sampling'.

a) From a batch of five containers or packaging units, take a sample from each one.

b) From a batch of six to 50 units, take a sample from five.

c) From a batch of over 50 units, sample 10 %, rounding up the number of units to the nearest multiple of 10. For example, a batch of 51 units would be sampled as for 60, i.e. take samples from six packages.

d) From each container or package selected, take three original samples from the top, middle and bottom of the container or package. The three original samples should then be combined into a pooled sample that should be mixed carefully.

e) The average sample is obtained by quartering. From the pooled sample, adequately mix into an even, square-shaped heap and divide it diagonally into four equal parts. Take two diagonally opposite parts and mix carefully.

f) Repeat the process as necessary until the required quantity, to within ± 10 %, is obtained. Using the same quartering procedure, divide the average sample into four final samples, taking care that each portion is representative of the bulk material.

7 Test methods

7.1 Macroscopic identification

Samples of not less than 500 g are taken from each batch randomly and observed with the naked eye.

7.2 Microscopic identification

The testing method specified in ISO/TS 21310 applies.

7.3 Thin-layer chromatogram (TLC) identification

See Annex A for information.

7.4 Determination of moisture content

See Annex B for information.

7.5 Determination of total ash content

The testing method specified in ISO 1003 applies.

7.6 Determination of volatile oil

The testing method specified in ISO 6571 applies.

7.7 Determination of marker compound 6-gingerol

See Annex C for information.

7.8 Determination of water-soluble extractives

See Annex D for information.

7.9 Determination of heavy metals

The testing method specified in ISO 18664 applies.

7.10 Determination of pesticide residues

The testing method specified in ISO 22258 applies.

7.11 Determination of residue of sulfur dioxide

The testing method specified in ISO 22590 applies.

8 Test report

For each test method, the test report shall specify the following:

a) all information necessary for the complete identification of the sample;

b) the sampling method used;

c) the test method used, with reference to this document;

d) the test result(s) obtained;

e) all operating details not specified in this document, or regarded as optional, together with details of any incidents which possibly influenced the test result(s);

f) any unusual features (anomalies) observed during the test;

g) the date of the test.