

ISO/FDIS 13615:~~2024~~(E)

ISO/TC 249/~~WG1~~

Secretariat: SAC

Date: 2024-~~03-26~~04-24

Traditional Chinese medicine — *Atractylodes macrocephala* rhizome

Médecine traditionnelle chinoise — Rhizome d'*Atractylodes macrocephala*

iTeh Standards

(<https://standards.itih.ai>)
FDIS stage

ISO/FDIS 13615

<https://standards.itih.ai/catalog/standards/iso/6bf0ba35-b9d0-4590-8db3-11e3787bf970/iso-fdis-13615>

© ISO ~~2023~~2024

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

~~Fax: +41 22 749 09 47~~

~~Email~~E-mail: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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

ISO/FDIS 13615

<https://standards.iteh.ai/catalog/standards/iso/6bf0ba35-b9d0-4590-8db3-11e3787bf970/iso-fdis-13615>

Contents

Foreword.....	iv
Introduction	v
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions	1
4 Descriptions.....	2
5 Quality and safety requirements and recommendations.....	4
5.1 General characteristics.....	4
5.2 Morphological features.....	4
5.2.1 <i>Atractylodes macrocephala</i> rhizome.....	4
5.2.2 Decoction pieces.....	4
5.3 Identification	4
5.3.1 Thin-layer chromatography (TLC) identification	4
5.3.2 High performance liquid chromatography (HPLC) identification	4
5.4 Moisture	4
5.5 Total ash	4
5.6 Sulfur dioxide residues.....	5
5.7 Ethanol-soluble extractives.....	5
5.8 Essential oil.....	5
5.9 Heavy metals	5
5.10 Pesticide residues.....	5
6 Sampling.....	5
7 Test methods	5
7.1 Macroscopic identification	5
7.2 Thin-layer chromatography (TLC) identification	5
7.3 High performance liquid chromatography (HPLC) identification	5
7.4 Determination of moisture content	5
7.5 Determination of total ash content	5
7.6 Determination of sulfur dioxide residues content	5
7.7 Determination of ethanol-soluble extractives content.....	6
7.8 Determination of essential oil content.....	6
7.9 Determination of heavy metals content	6
7.10 Determination of pesticide residues content	6
8 Test report.....	6
9 Packaging, storage and transportation.....	6
10 Marking and labelling	6
Annex A (informative) Thin-layer chromatography (TLC) identification.....	8
Annex B (informative) High performance liquid chromatography (HPLC) identification.....	11
Annex C (informative) Reference values of national and regional limits.....	15
Bibliography	17

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).

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 www.iso.org/patents. 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 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

Atractylodes macrocephala rhizome, the dried rhizome of *Atractylodes macrocephala* Koidz., is a widely used herbal medicine in China and many other countries. In traditional Chinese medicine, this herb can tonify the Spleen-Qi, and is used to treat distension in the abdomen, loose stools, and diarrhoea. Modern pharmacological studies also demonstrate its great potential in immuno-enhancement and indigestion treatment. The market, yield, and trade volume of *Atractylodes macrocephala* rhizome are large and develop rapidly in recent years.

Atractylodes macrocephala rhizome has been recorded in several pharmacopoeias, including Chinese Pharmacopoeia^{[1][4]}, European Pharmacopoeia^{[2][2]}, Korean Pharmacopoeia^{[3][3]}, Japanese Pharmacopoeia^{[4][4]} and Hong Kong Chinese Materia Medical Standards^{[5][5]}. The requirements and specifications in these standards have differences. Therefore, it is important to develop an International Standard for harmonizing the existing standards, as well as ensuring the safety and effectiveness of *Atractylodes macrocephala* rhizome, which can benefit farmers, consumers, enterprises and governments involved in the cultivation, regulation and trade of *Atractylodes macrocephala* rhizome.

As national implementation may differ, national standards bodies are invited to modify the values given in 5.4.5.4 and 5.5.5.5 in their national standards. Examples of national and regional values are given in Annex C. Annex C.

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

ISO/FDIS 13615

<https://standards.iteh.ai/catalog/standards/iso/6bf0ba35-b9d0-4590-8db3-11e3787bf970/iso-fdis-13615>

Traditional Chinese medicine — *Atractylodes macrocephala* rhizome

1 Scope

This document specifies requirements and test methods for *Atractylodes macrocephala* rhizome that is derived from *Atractylodes macrocephala* Koidz.

It is applicable to *Atractylodes macrocephala* rhizome that is sold and used as a natural medicine in international trade, including Chinese materia medica (whole medicinal materials) and decoction pieces derived from the 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 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

Atractylodes macrocephala rhizome

dried rhizome (3.2(3.2)) of *Atractylodes macrocephala* Koidz in the family of Atractylodes.

3.2

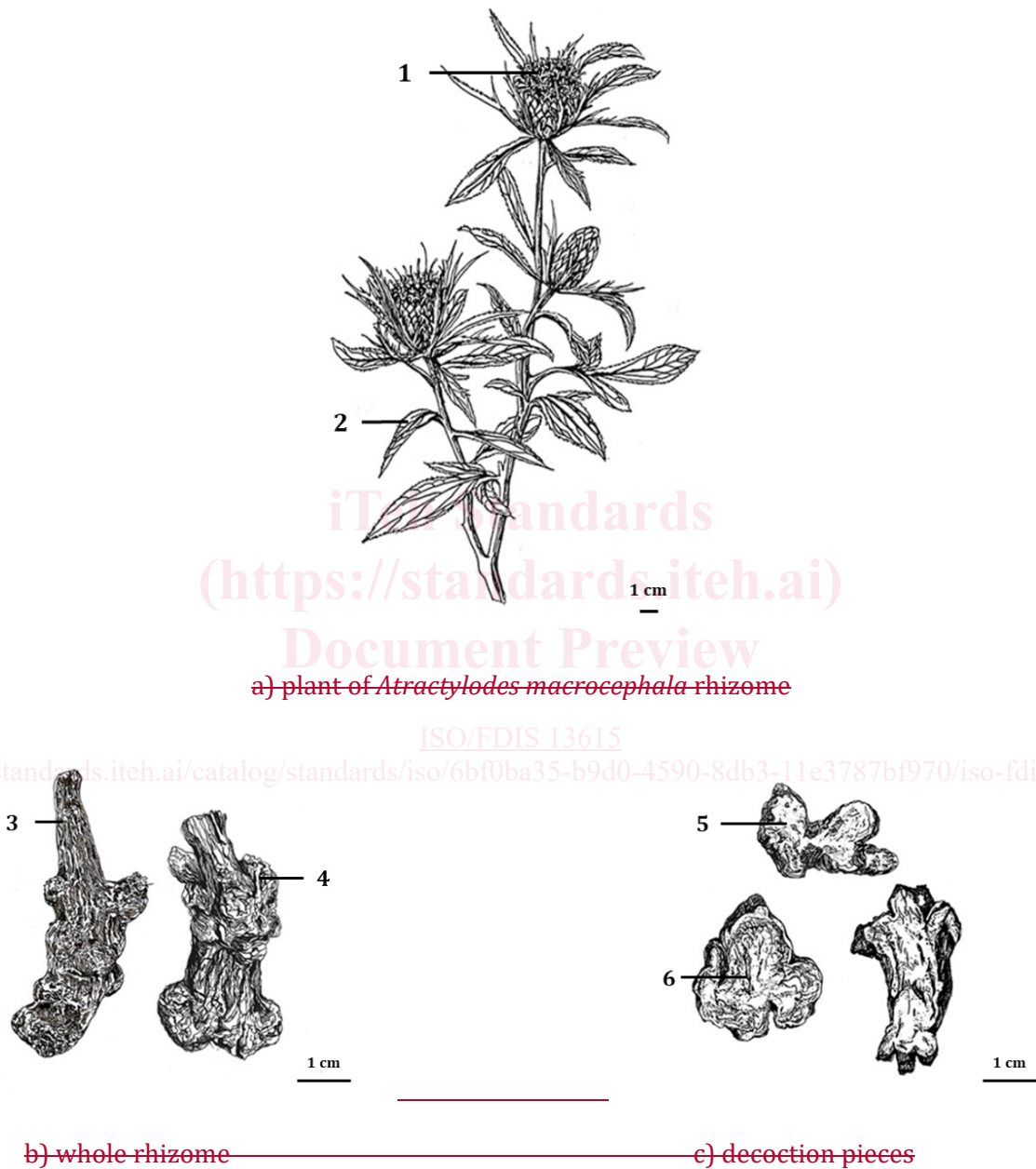
rhizome

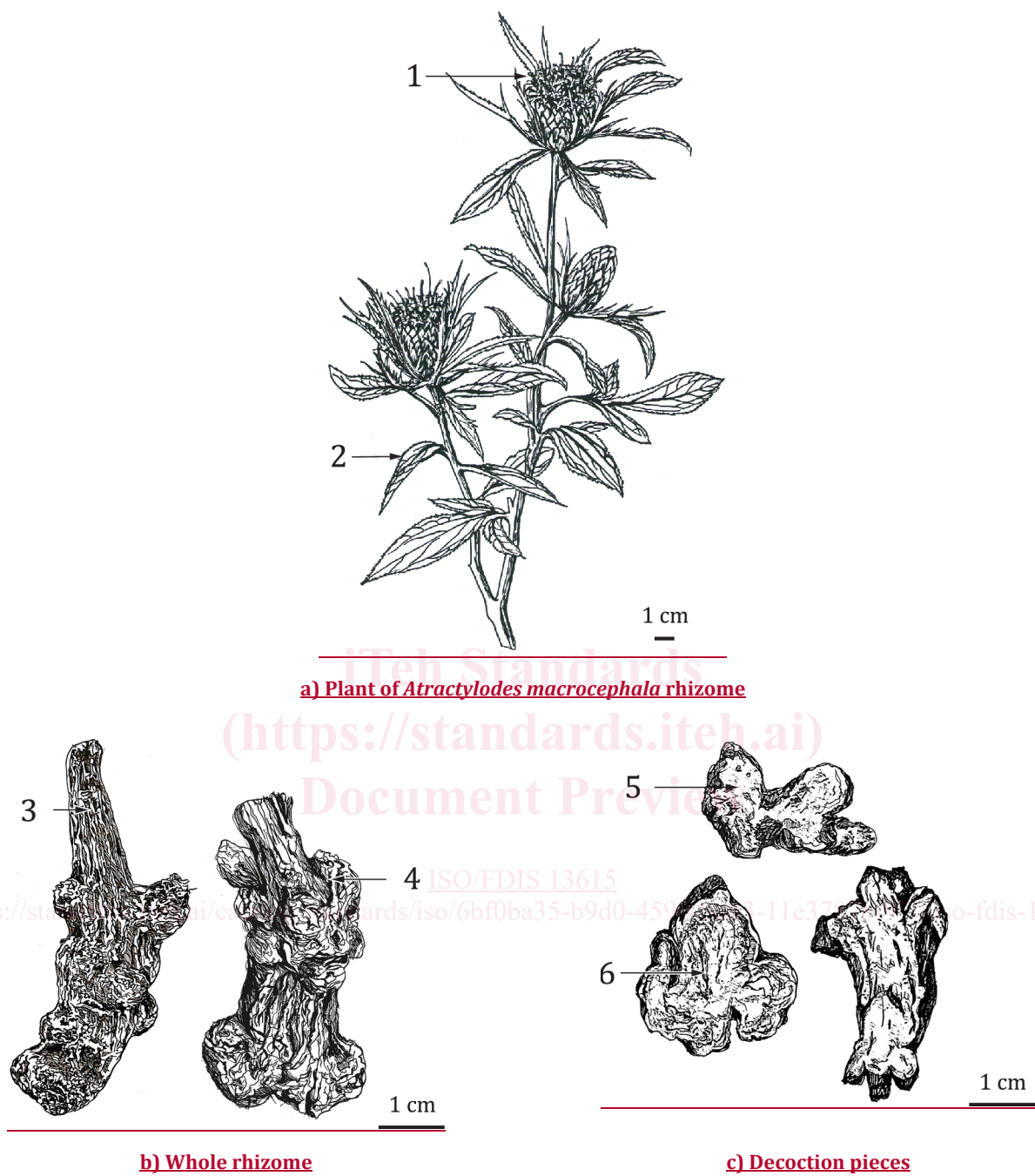
creeping rootstalk

main stem of a plant that sends out roots and shoots from its nodes

4 Descriptions

~~Figure 1~~ ~~Figure 1~~ illustrates the structure of *Atractylodes macrocephala* rhizome. The crude drug is collected in winter, when the leaves at the lower part of the plant turn yellow and those at the upper part become fragile; ~~with~~ soil removed ~~and, it is~~ baked over low heat or dried under the sun; the fibrous roots are removed to obtain *Atractylodes macrocephala* rhizome.





Key

- 1 flower
- 2 foliage
- 3 wrinkles and grooves
- 4 warty protrudings
- 5 dotted oil cavities
- 6 chrysanthemum-shaped cracks

Figure 1 — Structure of *Atractylodes macrocephala* rhizome

5 Quality and safety requirements and recommendations

5.1 General characteristics

The following requirements shall be met before sampling.

- a) ~~a)~~ *Atractylodes macrocephala* rhizome shall be clean and free from foreign matter.
- b) ~~b)~~ The presence of living insects, moulds and external contaminants which are visible to the naked eye shall not be permitted.

5.2 Morphological features

5.2.1 *Atractylodes macrocephala* rhizome

Atractylodes macrocephala rhizomes are irregularly plump masses, frog, drumstick or ruyi-shaped, 3 cm to 13 cm long and 1,5 cm to 7 cm in diameter. The external colour is greyish yellow or greyish brown, with warty protrudings, interrupted longitudinal wrinkles and grooves, and scars of fibrous rootlets; remains of stems and bud scars are attached to the apex. The texture is hard, not easily broken; the fracture is uneven, yellowish-white to pale brown, scattered with obvious brownish-yellow dotted oil cavities. The bake-dried material is horny and relatively dark coloured or cracked in section view. The odour is aromatic. The taste is sweet and slightly pungent. It gets viscous when chewed.

5.2.2 Decoction pieces

The decoction pieces are irregular thick slices. The external is greyish yellow or greyish brown. The cut surface is yellowish-white to pale brown, scattered with obvious brownish-yellow dotted oil cavities, xylem with radial striations; the cut surface is horny and with deeper colour and clefts when dried by oven. The odour is faintly aromatic. The taste is sweet and slightly pungent. It gets slightly viscous when chewed.

5.3 Identification

5.3.1 Thin-layer chromatography (TLC) identification

The identification of *Atractylodes macrocephala* rhizome by thin-layer chromatogram (TLC) should present spots or bands with the same colour and positions corresponding to those of the reference solution. Furthermore, other faint zones may be present in the chromatogram obtained with the test solution.

5.3.2 High performance liquid chromatography (HPLC) identification

When TLC bands are not clearly identified, HPLC identification can be applied. The chromatogram of the test solution should exhibit 3 characteristic peaks (atractylenolide II, atractylenolide III and atractylon), corresponding in the retention times to those in chromatogram of the reference solution.

5.4 Moisture

The moisture content should not be more than 15,0 %.

5.5 Total ash

The total ash content should not be more than 7,0 %.