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ISO/FDIS 13615

Traditional Chinese medicine — *Atractylodes macrocephala* rhizome

*Médecine traditionnelle chinoise — Rhizome d'Atractylodes
macrocephala*

ISO/TC 249

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Foreword

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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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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

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] European Pharmacopoeia,^[2] Korean Pharmacopoeia^[3] Japanese Pharmacopoeia^[4] and Hong Kong Chinese Materia Medical Standards.^[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](#) and [5.5](#) in their national standards. Examples of national and regional values are given in [Annex C](#).

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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) of *Atractylodes macrocephala* Koidz in the family of Atractylodes.

3.2

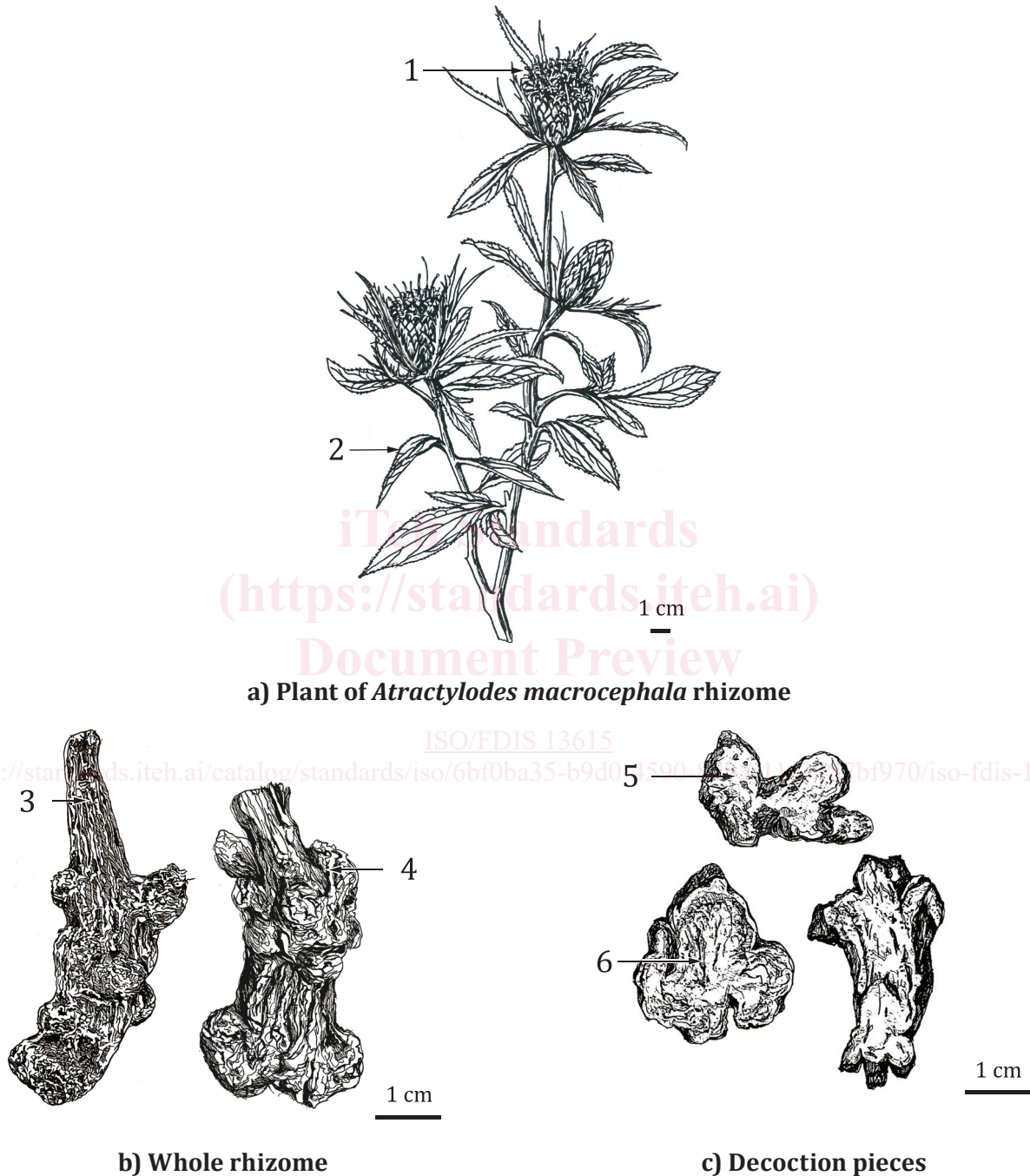
rhizome

creeping rootstalk

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

4 Descriptions

[Figure 1](#) 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, 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) *Atractylodes macrocephala* rhizome shall be clean and free from foreign matter.
- 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 %.

5.6 Sulfur dioxide residues

The content of sulfur dioxide residues should be determined.

5.7 Ethanol-soluble extractives

The ethanol-soluble extractives content should be determined.

5.8 Essential oil

The essential oil content should be determined.

5.9 Heavy metals

The contents of heavy metals such as arsenic, cadmium, lead and mercury shall be determined.

5.10 Pesticide residues

The contents of pesticide residues such as hexachlorocyclohexane (BHC), dichloro-diphenyl-trichloroethane (DDT) and quintozone should be determined.

6 Sampling

Sampling of *Atractylodes macrocephala* rhizome shall be in accordance with ISO 23723.

7 Test methods

7.1 Macroscopic identification

[ISO/FDIS 13615](https://standards.iteh.ai/catalog/standards/iso/6bf0ba35-b9d0-4590-8db3-11e3787bf970/iso-fdis-13615)

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The samples are examined by the naked eye, smelled and tasted.

7.2 Thin-layer chromatography (TLC) identification

See [Annex A](#) for additional information on thin-layer chromatography (TLC) identification.

7.3 High performance liquid chromatography (HPLC) identification

See [Annex B](#) for additional information on high performance liquid chromatography (HPLC) identification.

7.4 Determination of moisture content

The test method specified in ISO 23723 shall apply.

7.5 Determination of total ash content

The test method specified in ISO 23723 shall apply.

7.6 Determination of sulfur dioxide residues content

The test method specified in ISO 22590 shall apply.