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Traditional Chinese medicine — *Poria cocos* sclerotium

Médecine traditionnelle chinoise — Poria cocos *sclerotium*

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This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

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Introduction

Poria cocos sclerotium is the dried sclerotium of the fungus *Poria cocos* (Schw.) Wolf (Polyporaceae). It is a medicinal herb which has been widely used as functional food and crude drug to promote urination to drain dampness, fortify the spleen and calm the heart in Asian countries for thousands of years.

The products of *Poria cocos* sclerotium are sold all over the world. There are at least 23 countries and regions using *Poria cocos* sclerotium and its products. Major users include China, Japan, the Republic of Korea, Viet Nam, Malaysia and Singapore. Factors including producing areas, processing, packaging and storage conditions affect the quality of *Poria cocos* sclerotium. The quality of *Poria cocos* in the market can be unstable.

Poria cocos sclerotium is recorded in the Pharmacopoeia of the People's Republic of China[1], the European Pharmacopoeia[5], the Japanese Pharmacopoeia[2] and the Korean Pharmacopoeia[4]. However, the requirements and test methods of *Poria cocos* in these national and regional standards are varied and can cause barriers to international trade. In addition, due to its great demand in the global market, trade in *Poria cocos* sclerotium can be complicated by adulteration and substitution issues. The establishment of an International Standard for *Poria cocos* sclerotium is therefore necessary to ensure quality consistency, support clinical safety and effectiveness and promote international trade.

As national implementation can differ, national standards bodies are invited to modify the values given in 5.6 and 5.7 in their national standards. Examples of national and regional values are given in Annex C.

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Traditional Chinese medicine — *Poria cocos* sclerotium

1 Scope

This document specifies the quality, safety requirements and test methods for *Poria cocos* sclerotium that is derived from the fungus *Poria cocos* (Schw.) Wolf.

It is applicable to *Poria cocos* sclerotium sold and used as natural medicines in international trade, including Chinese materia medica (whole medicinal materials) and decoction pieces.

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*

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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
***Poria cocos* sclerotium**
dried sclerotium of the fungus *Poria cocos* (Schw.) Wolf (Polyporaceae) (syn. *Wolfiporia cocos* (F.A. Wolf) Ryvarden & Gilb.; *Wolfiporia extensa* (Peck) Ginns)

3.2
whole poria
whole dried *Poria cocos sclerotium* (3.1) with *skin* (3.5)

3.3
cubic poria
peeled *Poria cocos sclerotium* (3.1) without *skin* (3.5) cut in cubic pieces, variable in size

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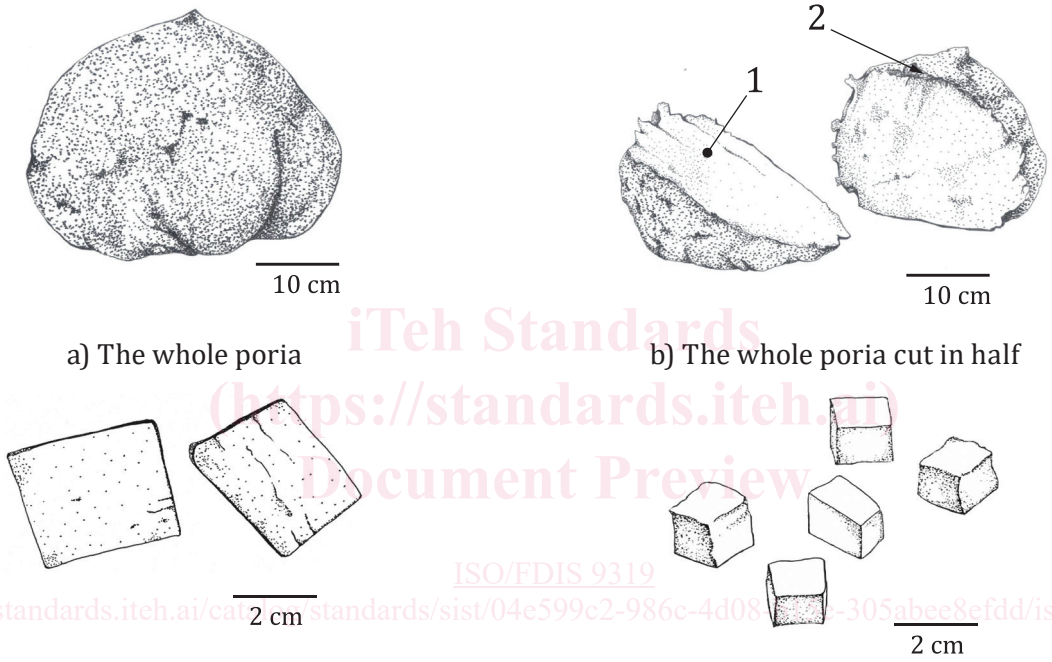
3.4
sliced poria
peeled *Poria cocos sclerotium* (3.1) without *skin* (3.5) cut in irregular thick slices, varying in thickness

3.5
skin
outer layer of the *whole poria* (3.2)

4 Descriptions

Poria cocos sclerotium is the dried sclerotium of the fungus *Poria cocos* (Schw.) Wolf (Polyporaceae) and has different trade forms, including whole poria, cubic poria, sliced poria and powdered poria, as shown in Figure 1.



a) The whole poria

b) The whole poria cut in half

c) Sliced poria

d) Cubic poria

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Key
1 inner part
2 skin

Figure 1 — Structure of *Poria cocos* sclerotium

5 Quality and safety requirements and recommendations

5.1 General characteristics

The following requirements shall be met before sampling:

a) *Poria cocos* sclerotium shall be clean and free from foreign matter.

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

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5.2 Morphological features

5.2.1 Whole poria

Whole poria is subglobose, ellipsoid, oblate or irregular-shaped and variable in size. The skin is thin and rough, brown to blackish-brown, conspicuously shrivelled and striated. The texture is hard and compact, the fracture granular, sometimes cracked, the outer layer pale brown, the inner part white or occasionally reddish, with some showing the penetrating roots of pine in the centre. The odour is slight, the taste weak and it is sticky when chewed.

5.2.2 Cubic poria

Cubic poria are cubic pieces or cubic thick slices, variable in size. The colour is white, pale red or pale brown. The odour is slight, the taste weak and they are sticky when chewed.

5.2.3 Sliced poria

Sliced poria are irregular thick slices, variable in thickness. The colour is white, pale red or pale brown. The odour is slight, the taste weak and they are sticky when chewed.

5.3 Microscopic identification

The powdered *Poria cocos* sclerotium is whitish with a pale brown hue. Examined under a microscope using chloral hydrate solution, the powder shows an irregularly shaped and occasionally granular and branched colourless mass, which dissolves gradually in chloral hydrate solution. The hyphae are colourless or pale brown, slender, slightly curved, branched and 3 µm to 8 µm (occasionally up to 16 µm) in diameter, as shown in Figure 2.

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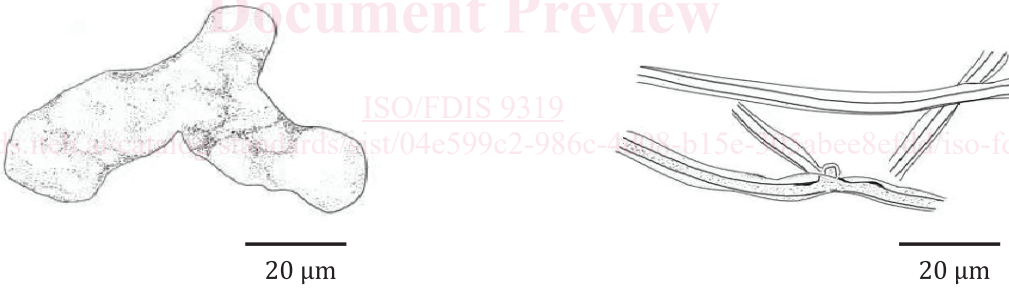

a) Granular and branched mass

b) Hyphae

Figure 2 — Structure of granular and branched mass and hyphae

5.4 Thin-layer chromatography (TLC)

The main spots in the chromatogram obtained with the test solution correspond in position and colour to the spots obtained with the reference solutions.

5.5 Chemical colour reaction

When one drop of iodinated potassium iodide solution is added to a small piece or powder of sample, a deep red colour shall be produced.

5.6 Moisture

The moisture should not be more than a mass fraction of 15,0 %.

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5.7 Total ash

The total ash should not be more than a mass fraction of 2,0 %.

5.8 Extractives

5.8.1 Ethanol-soluble extractives

The mass fraction of dilute ethanol-soluble extract should be determined.

5.8.2 Water-soluble extractives

The mass fraction of water-soluble extract should be determined.

5.9 Content of marker compound(s)

The content of marker compound(s) such as pachymic acid should be determined.

5.10 Heavy metals

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

5.11 Pesticide residues

The contents of pesticide residues such as total BHC (benzene hexachloride), DDT (dichlorodiphenyltrichloroethane), aldrin, dieldrin and endrin shall be determined.

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5.12 Sulfur dioxide

The content of sulfur dioxide should be determined.

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6 Sampling

Sampling of *Poria cocos* sclerotium shall be in accordance with ISO 23723.

7 Test methods

7.1 Macroscopic identification

Samples of not less than 500 g shall be taken from each batch randomly, observed with the naked eye, smelled and tasted.

7.2 Microscopic identification

The testing method specified in ISO/TS 21310 shall apply.

7.3 Thin-layer chromatographic identification

See Annex A for additional information on thin-layer chromatographic identification.

7.4 Determination of moisture

The testing method specified in ISO 23723 shall apply.

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