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Traditional Chinese Medicine — *Coptis chinensis* and *Coptis japonica* rhizome

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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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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

Coptis rhizome is the dried rhizome of *Coptis chinensis* Franch., *Coptis deltoidea* C.Y. Cheng et Hsiao, and *Coptis teeta* Wall. used in traditional Chinese medicine (TCM) in China. The rhizome of *Coptis japonica* Makino. is also used as an herbal medicine in Japan and South Korea. As one of the commonly used medicinal herb, *Coptis* rhizome was listed in *Shennong materia Medica. Treatise on February-related diseases* contains 113 prescriptions, including 12 containing *Coptis* rhizome.

In TCM, *Coptis* rhizome has a cold property and bitter flavour. It belongs to heart, spleen, stomach, liver, gallbladder, and large intestine meridians. And it is often used to clear heat, dry dampness, purge fire and remove the toxin. Its main chemical components are alkaloids, including berberine, coptisine, palmatine and epiberberine. It also contains ferulic acid, chlorogenic acid, quercetin, and other non-alkaloid components. Modern pharmacological studies have shown that the alkaloids in *Coptis* rhizome can resist pathogenic microorganisms and inhibit various diseases and conditions, including arrhythmia, cancer, diabetes, and inflammation. It can also regulate immune and platelet functions, and protect the gastric mucosa. The alkaloids of *Coptis* rhizome have been widely used clinically for treating digestive, respiratory, and dermatological infectious diseases, and certain cardiovascular conditions,

In the global trade of *Coptis* rhizome, according to the China Customs data, *Coptis* rhizome from the mainland of China is mainly exported to Japan, South Korea, the United States, India, Singapore, Thailand, Vietnam, Malaysia, Hong Kong, Macao, and Taiwan. From 2012 to 2016, the average annual export trade of *Coptis* rhizome amounted to US\$ 4,12 million, which was one of the main Chinese herbal medicines exported from China.

However, there are still some concerns on the quality control of *Coptis* rhizome as follows, which affects the trade and use of this herb.

1. The harvesting and processing methods and techniques have not been standardized. The problems, such as low efficiency, large interference from human factors, and poor controllability, seriously affect the quality of *Coptis* rhizome materials.
2. Even though many countries or regions, e.g., China, Japan, Korea, and Europe, have established Pharmacopoeia standards for *Coptis* rhizome, the relevant requirements vary significantly, which limits the application of those standards in the global trade.
3. The lack of quality standards for certain processed products, such as *Coptis* rhizome products processed with wine, ginger, or *Euodia* fruit, makes it difficult to control their quality. This may affect the efficacy and safety of these products.

Moreover, *Coptis* rhizome is ranked the fourth in the ISO/TR 23975: 2019 Traditional Chinese medicine — Priority list of single herbal medicines for developing standards. Thus, it is essential to develop the international standard for *Coptis* rhizome to ensure the consistency in the quality of *Coptis* rhizome, which is for the safe use of this herb and also promote the international trade.

In this document, the identification of commonly adulterated species of *Coptis* rhizome is also introduced.

In addition, as the requirement and implementation may differ in different countries, the users are invited to modify the values given in [5.5](#), [5.6](#), [5.7](#), and [5.10](#) according to their national standards. Examples of national values are given in [Annex C](#).

Traditional Chinese Medicine — *Coptis chinensis* and *Coptis japonica* rhizome

1 Scope

This document specifies the minimum requirements and test methods for *Coptis* rhizome [the dried rhizome of *Coptis chinensis* Franch. and *Coptis japonica* Makino.].

This document applies to *Coptis* rhizome sold and used as Chinese materia medica (whole medicinal materials) and decoction pieces derived from these plants.

This document does not apply to the processed *Coptis* rhizome, including the products traditionally processed with different methods, and its processing methods.

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 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 terminological 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

Coptis rhizome

dried rhizome of *Coptis chinensis* Franch. and *Coptis japonica* Makino.

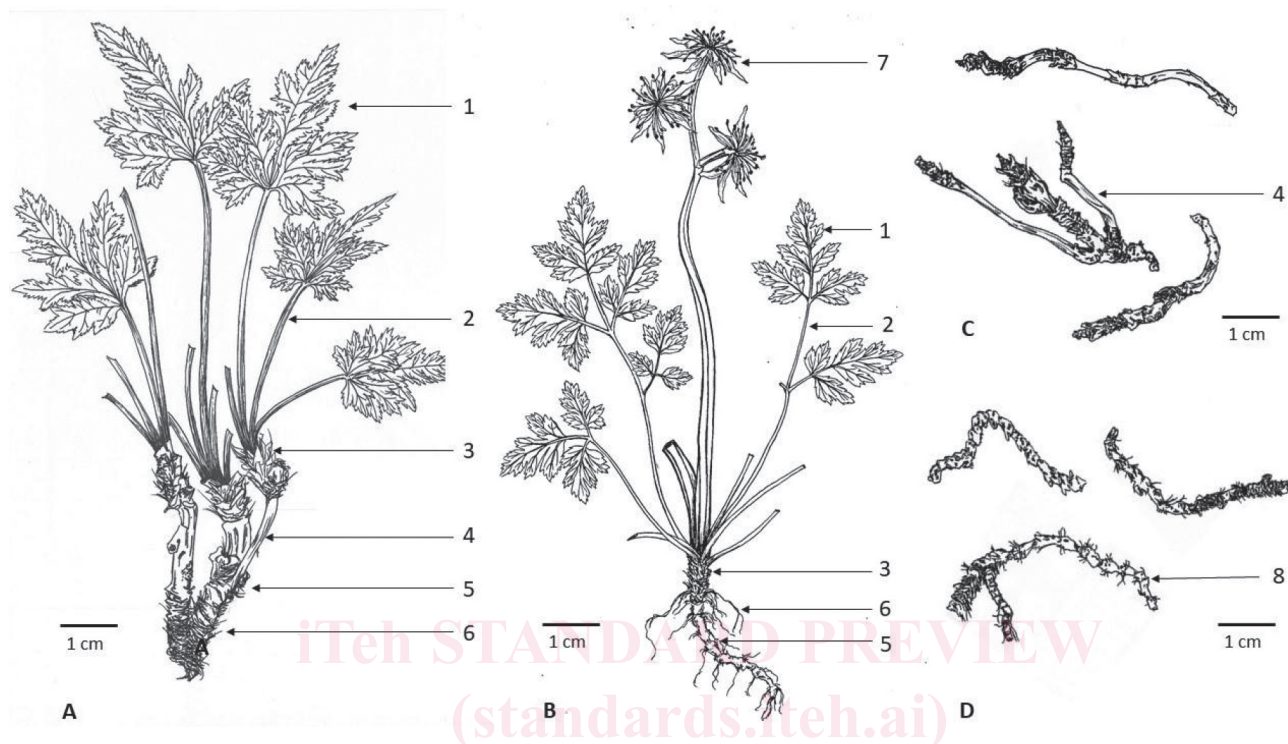
3.2

bridge piece

morphological feature of *Coptis* rhizome with its rhizome internodes as smooth as stem

4 Description

Coptis rhizome is the dried rhizome of *Coptis chinensis* Franch. and *Coptis japonica* Makino., collected in autumn, removed from rootlets and soil, and dried, as shown in [Figure 1](#).



Key

A plant of *Coptis chinensis* Franch.

B plant of *Coptis japonica* Makino.

C *Coptis chinensis* rhizome

D *Coptis japonica* rhizome

1 leaf

2 petiolate

3 phyllode

4 bridge piece

5 rhizome

6 fibrous root

7 flower

8 nodular bump

Figure 1 — Structure of *Coptis* rhizome

5 Requirements

5.1 General characteristics

The following requirements shall be met before sampling.

- Coptis* rhizome shall be clean and free from leave and foreign matter.
- The presence of living insects, mouldy fruit and external contaminants which are visible to the naked eye shall not be permitted.

5.2 Morphological features of rhizome

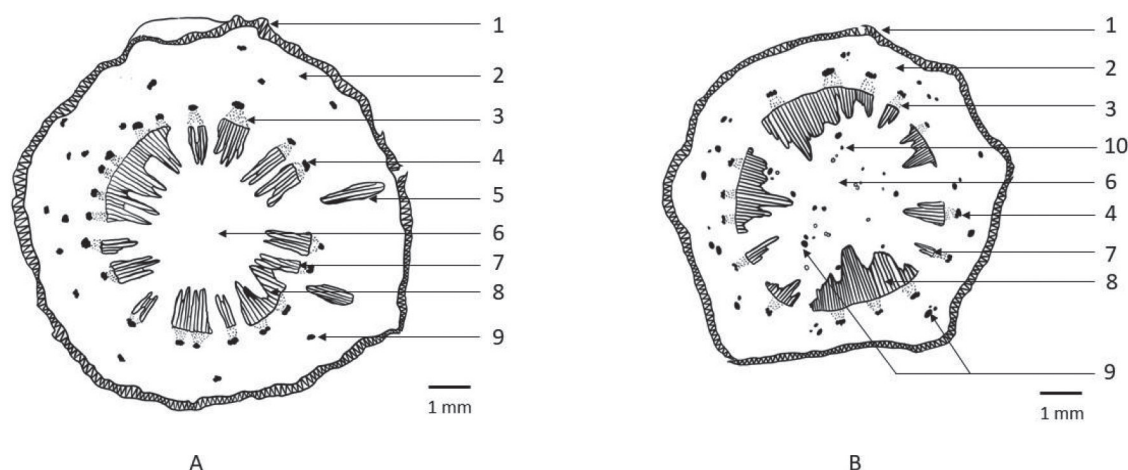
- a) *Coptis chinensis* rhizome is mostly gathered to a cluster, curved, like “chicken’s feet”. Single rhizome is 3 cm to 6 cm long, 0,3 cm to 0,8 cm in diameter. The outer surface is greyish-yellow or yellowish-brown, rough, bearing irregular nodular bumps, fibrous roots, and their residues. Some internodes are as smooth as stem, commonly known as “bridge piece”. The upper part is mostly remained with brown scale leaves. The apex often bears the remains of stems or petioles. Texture is hard. Fracture is uneven. Bark is orange-red or dark brown. Wood is brightly yellow or orange-yellow, radially arranged. Pith sometimes is hollowed. Odour is slight. Taste is very bitter.
- b) *Coptis japonica* rhizome is irregular and cylindrical. The rhizome is 2 cm to 4 cm long, rarely up to 10 cm in length, 0,2 cm to 0,7 cm in diameter, slightly curved and shortly branched; The outer surface is grayish yellow-brown, with ring nodes without "bridge piece", and with numerous remains of rootlets; The rhizome generally bears remains of petiole at one end. Odour is slight. Taste is extremely bitter and lasting.

5.3 Microscopic identification

- a) *Coptis chinensis* rhizome contains cork cells of several layers, covered outside by epidermis which is often withered. Cortex is broader, stone cells are singly scattered or grouped. Pericycle fibres are in bundles or accompanied with a few stone cells, both are yellow. Collateral vascular bundles are arranged in a ring. Xylem is yellow, lignified, and xylem fibers are well developed. Pith consists of parenchymatous cells, but stone cells are absent. (See [Figure 2A](#))
- b) *Coptis japonica* rhizome consists of a few stone cells in cortex and pith. Fractured surface is rather fibrous. Cork layer is light greyish brown. Cortex and pith are yellow-brown to reddish yellow-brown. Xylem is yellow to reddish yellow in colour. (See [Figure 2B](#))

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Key

A *Coptis chinensis* rhizome

B *Coptis japonica* rhizome

1 cork layer

2 cortex

3 phloem

4 pericycle fibre

5 root-trace vascular bundle

6 pith

7 cambium

8 xylem

9 stone cells

10 starch grains

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Figure 2 — Transverse section of *Coptis* rhizome

5.4 Thin-layer chromatogram (TLC) identification

The thin-layer chromatogram (TLC) of *Coptis* rhizome shall present fluorescent spots with the same colour and positions corresponding to the chromatogram of reference drug solution, and one spot corresponding to the reference solution in the chromatogram.

5.5 Moisture

The content of water in percentage mass should not be more than 14,0 % (w/w).

5.6 Total ash

The content of total ash in percentage mass should not be more than 5,0 % (w/w).

5.7 Acid-insoluble ash

The content of acid-insoluble ash in percentage mass should not be more than 2,5 % (w/w).

5.8 Heavy metals

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

5.9 Pesticide residues

The content of pesticide residues shall be determined.

5.10 Marker compounds

- a) The content of marker compounds, such as berberine, epiberberine, coptisine, and palmatine, in percentage mass should be determined.
- b) *Coptis chinensis* rhizome should not contain less than 5,5 % of berberine($C_{20}H_{17}NO_4$), 0,80 % of epiberberine ($C_{20}H_{17}NO_4$), 1,6 % of coptisine($C_{19}H_{13}NO_4$), and 1,5 % of palmatine($C_{21}H_{21}NO_4$), calculated as berberine hydrochloride($C_{20}H_{18}ClNO_4$) with reference to the dried drug.
- c) *Coptis japonica* rhizome should not contain less than 4,2 % of berberine($C_{20}H_{17}NO_4$), calculated as berberine hydrochloride($C_{20}H_{18}ClNO_4$) with reference to the dried drug.

6 Sampling

Sampling shall be carried out in accordance with the method described in the Clause 8 of ISO 23723.

7 Test methods

7.1 Macroscopic identification

The samples shall be examined by naked eyes observation in sunlight, and also on smell and taste as described above in [section 5.2](#).

7.2 Microscopic identification

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

7.3 Thin-layer chromatogram (TLC) identification

See [Annex A](#) for additional information.

7.4 Determination of moisture

The testing method specified in the Clause 7.2.1 of ISO 23723 shall apply.

7.5 Determination of total ash

The testing method specified in the Clause 7.2.3 of ISO 23723 shall apply.

7.6 Determination of acid-insoluble ash

The testing method specified in the Clause 7.2.3 of ISO 23723 shall apply.

7.7 Determination of heavy metals

The testing method specified in ISO 18664 shall apply.

7.8 Determination of pesticide residues

The testing method specified in ISO 22258 shall apply.