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Traditional Chinese Medicine — *Rheum palmatum*, *Rheum tanguticum*, and *Rheum officinale* root and 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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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

Rheum root and rhizome is the dry root and rhizome of *Rheum palmatum* L., *Rheum tanguticum* Maxim. ex Balf. and *Rheum officinale* Baill. As one of the four traditional Chinese medicines in China, *Rheum* root and rhizome is documented in *Shennong material medica* (神农本草经). *Rheum* root and rhizome has a wide range of clinical applications, high frequency of use, and a long history of medicinal use. It is recorded in traditional Chinese medicine books such as *Yao pin hua yi*(药品化义), *Yi xue zhong zhong can xi lu*(医学衷中参西录) and *Su Wen*(素问).

Rheum root and rhizome has a cold property and bitter flavour. Its meridian distribution in the theory of TCM belongs to the spleen, stomach, large intestine, liver, and pericardium meridians. It can remove accumulation with purgation, clear heat, purge fire, cool the blood, remove toxin, expel stasis, unblock the meridians, and drain dampness to abate jaundice, for accumulation, stagnation and constipation caused by excess heat, hematemesis caused by intestinal abscess, blood-stasis amenorrhea, postpartum stasis and obstruction, traumatic injuries, dampness-heat dysentery, jaundice, red urine, stranguria, and edema, topical application for burn and scald. Wine-fried *Rheum* root and rhizome is good at clearing heat toxin in the upper energizer blood aspect, which can be applied for red eyes, swollen throat, and painful swollen gums. The purgation power of prepared *Rheum* root and rhizome is mild, and it can purge fire and remove toxins to treat soreness and ulcers caused by fire-toxin. Charred *Rheum* root and rhizome can cool the blood, resolve stasis and stop bleeding, which can be applied to bleeding symptoms caused by blood heat and stasis.

Rheum root and rhizome has a complex chemical composition, including various compounds such as anthraquinone, anthrone, tannin, and polysaccharide. Modern pharmacological studies have shown that sennoside and anthraquinone glucosides are the main components of *Rheum* root and rhizome that can induce diarrhea; free anthraquinones are antibacterial and antitumor active ingredients of *Rheum* root and rhizome; n-butyrophenones have good anti-inflammatory and analgesic effects; gallic acid glucosides and galloyl proanthocyanidins in the tannins have hypolipidemic effects; and d-catechin and gallic acid have haemostatic effects. Moreover, *Rheum* root and rhizome also has the functions of relieving phlegm, protecting the liver and gallbladder, and protecting cardiovascular and cerebrovascular diseases.

In global trade, taking China Customs data as an example, *Rheum* root and rhizome in China is mainly exported to Japan, South Korea, the United States, Indonesia, Germany, Italy, Singapore, France, Thailand, Vietnam, Malaysia and so on. From 2012 to 2016, the average annual export trade volume of *Rheum* root and rhizome in China was 7.128.400 US dollars, which is one of the main Chinese herbal medicines exported by China.

There are 152 Chinese patent medicines containing *Rheum* root and rhizome in the Chinese Pharmacopoeia (2015 Edition) and 2 preparations in Japanese Pharmacopoeia (17th Edition). *Rheum* root and rhizome and its products have applications in a variety of medical fields, and also involve detoxification and beauty, lipid-lowering, weight-loss health products and food additives. Many users believe that "Chinese medicine is non-toxic" and fail to take it strictly according to the doctor's instructions, which leads to excessive and chronic irregular use of *Rheum* root and rhizome and liver and kidney damage.

As a worldwide drug, *Rheum* root and rhizome is included in the pharmacopoeia of many countries and regions, such as China, Japan, Korea, and Europe. At present, the quality control of *Rheum* root and rhizome and its preparations is mostly based on the content of anthraquinones. However, the medicinal ingredients of *Rheum* root and rhizome are not just anthraquinones. The diversity of ingredients in traditional Chinese medicine determines that quality control should adopt a multi-index quality evaluation model.

Furthermore, *Rheum* root and rhizome is ranked tenth in the ISO/TR 23975: 2019 *Traditional Chinese medicine — Priority list of single herbal medicines for developing standards*, which indicates its high priority. Therefore, it is necessary to establish an international standard of *Rheum* root and rhizome, which unifies the quality and safety of *Rheum* root and rhizome, ensures the safety and effectiveness of the medication, and regulates trade in the international market. The establishment of an international

standard for *Rheum* root and rhizome is therefore necessary to guarantee the clinical effectiveness, safety, and controllability of this valuable medicine in global commerce and trade.

As national implementation may differ, national standards bodies are invited to modify the values given in [5.5](#), [5.6](#), [5.7](#), [5.8](#), [5.9](#), [5.10](#), and [5.11](#) in their national standards. Examples of national and regional values are given in [Annex C](#).

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Traditional Chinese Medicine — *Rheum palmatum*, *Rheum tanguticum*, and *Rheum officinale* root and rhizome

1 Scope

This document specifies the quality and safety requirements of *Rheum* root and rhizome [the dried root and rhizome of *Rheum palmatum* L., *Rheum tanguticum* Maxim. ex Balf., and *Rheum officinale* Baill.].

This document applies to *Rheum* root and rhizome that is sold and used as natural medicines in international trade, including Chinese materia medica (whole medicinal materials) and decoction pieces derived from these plants.

This document does not apply to the processing methods and processed products of *Rheum* root and rhizome.

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 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

***Rheum* root and rhizome**

dried root and rhizome of *Rheum palmatum* L., *Rheum tanguticum* Maxim. ex Balf., and *Rheum officinale* Baill.

3.2

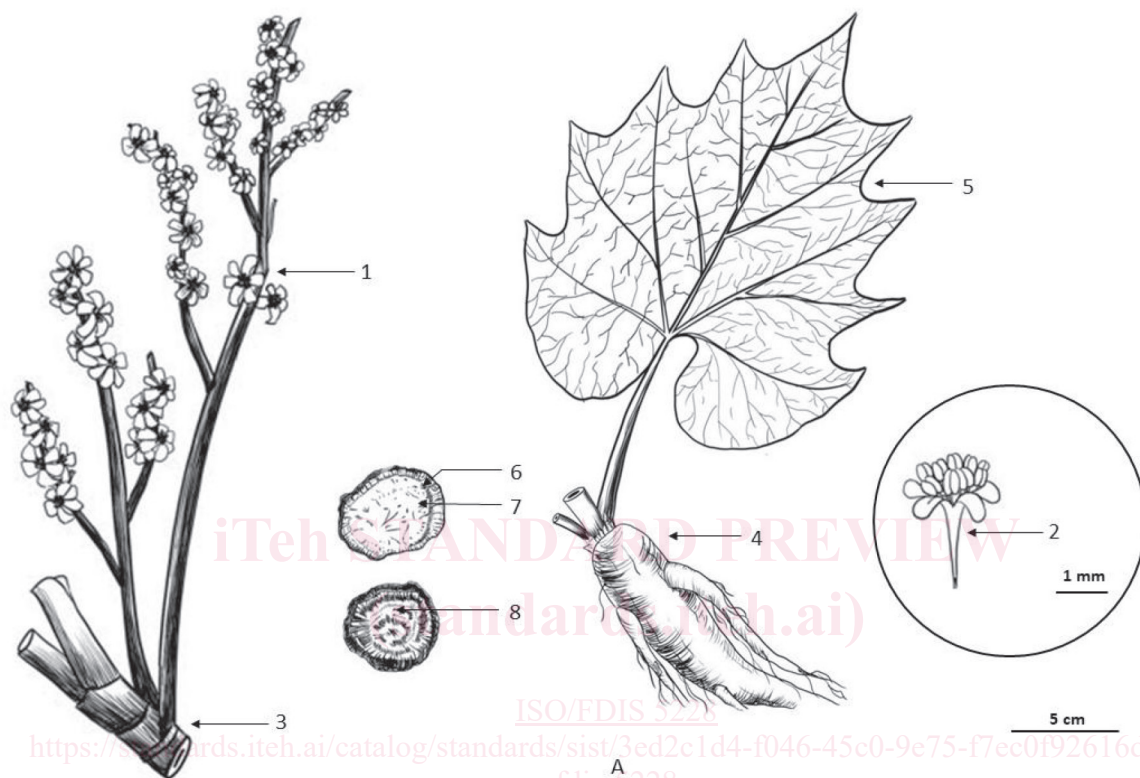
batch

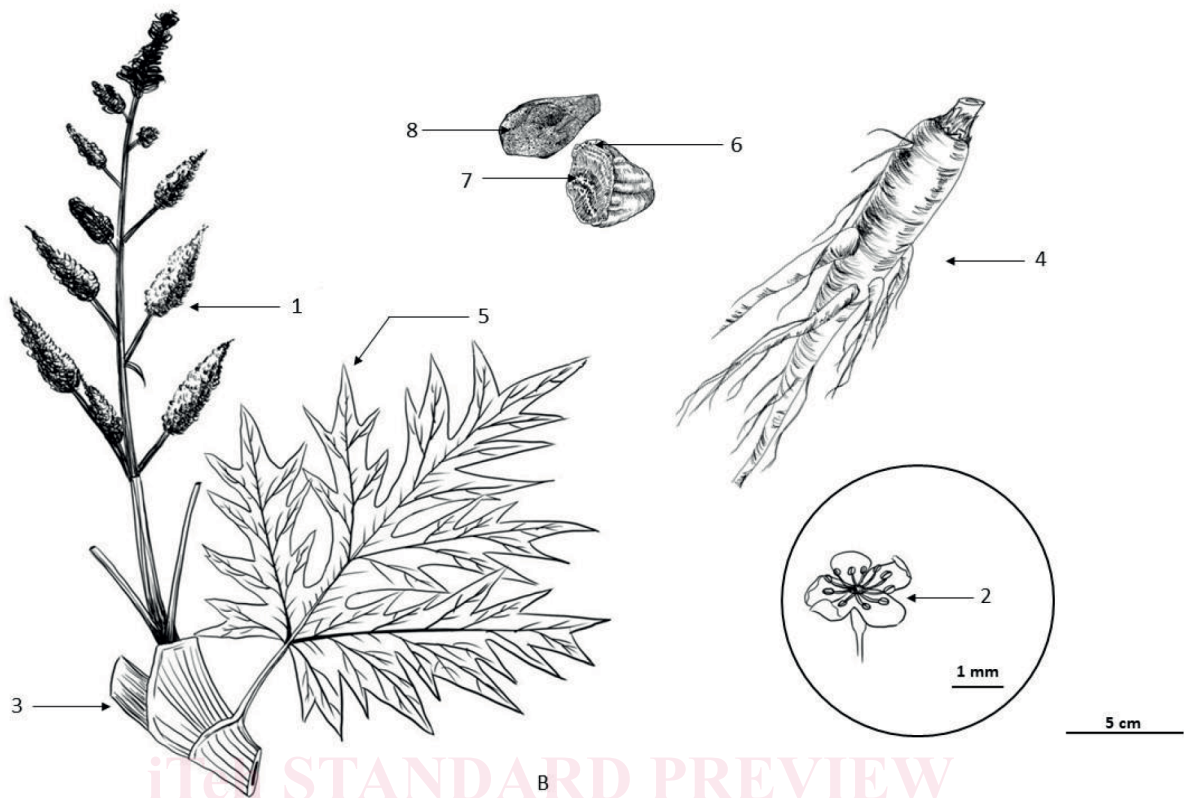
samples collected from the same particular place at the same time, no more than 5 000 kg

[SOURCE: ISO 22988:2019, 3.8]

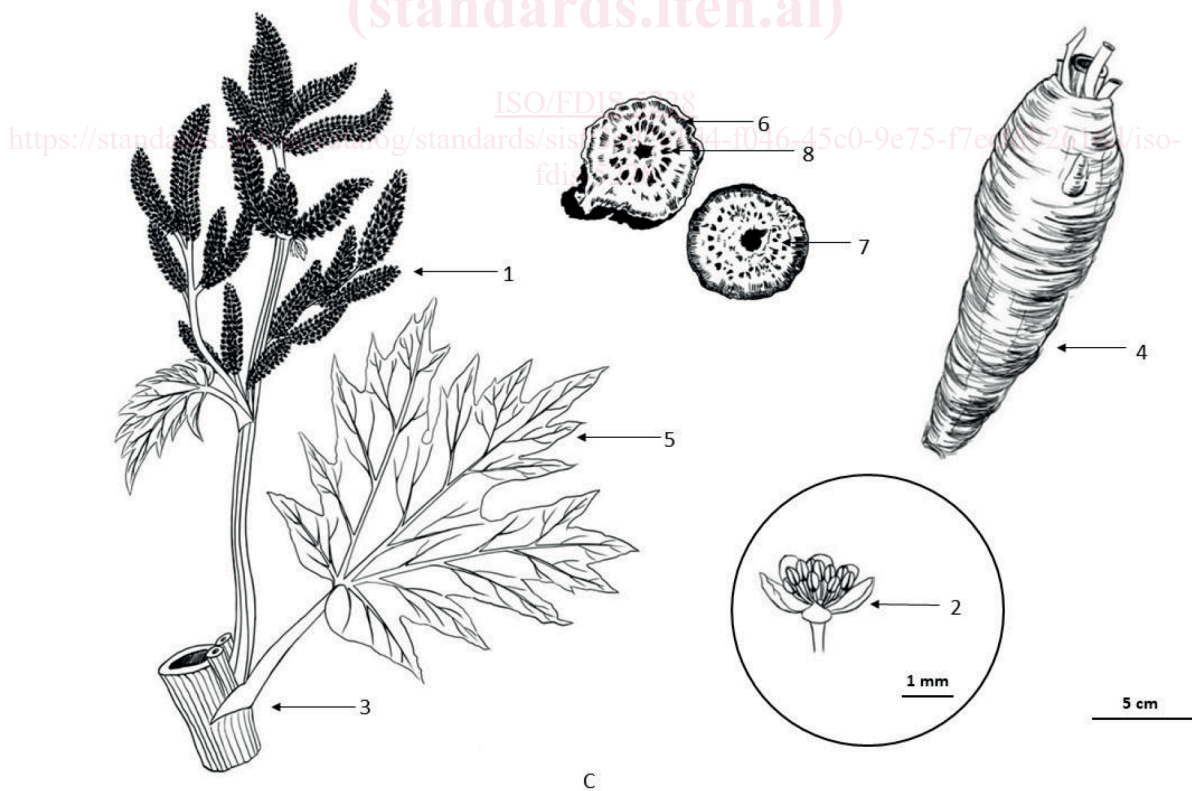
4 Description

Rheum root and rhizome is the dried root and rhizome of *Rheum palmatum* L., *Rheum tanguticum* Maxim. ex Balf., and *Rheum officinale* Baill., as shown in [Figure 1](#). The crude drug is collected in late autumn when stem and leaves have withered or in spring just before budding. The crude drug is removed from rootlet and the outer bark, cut into segment or section, and either hung in line for drying or dried directly.





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Key

- A *rheum palmatum* L.
- B *rheum tanguticum* Maxim. ex Balf.
- C *rheum officinale* Baill.
- 1 inflorescence

- 2 flower
- 3 stem
- 4 root and rhizome
- 5 leaf
- 6 xylem, cambium and phloem
- 7 pith
- 8 abnormal vascular bundles

Figure 1 — Structure of *Rheum* root and rhizome

5 Requirements

5.1 General characteristics

The following requirements shall be met before sampling.

- a) *Rheum* root and rhizome shall be clean and free from leave and foreign matter.
- b) 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

The appearance of the medicinal materials of *rheum* root and rhizome is subcylindrical, conical, ovoid, or irregular pieces, 3 cm to 17 cm long, 3 cm to 10 cm in diameter. Externally yellowish-brown to reddish-brown when peeled, sometimes whitish reticulations and scattered star spots (abnormal vascular bundles) visible, occasionally with brownish-black patches of cork, mainly with a hole through which the string passed, and coarse wrinkles. The texture is compact and sometimes loose and soft in the center, fracture pale reddish-brown or yellowish-brown, granular. The pith of the rhizome broad, with star spots arranged in a ring or irregularly scattered. The wood of the root is well developed, lined radially, cambium ring distinct, without star spots. Odour, delicately aromatic; taste bitter and slightly astringent, sticky, and gritty on chewing.

NOTE The hole and the string are for hanging *Rheum* root and rhizome when dry.

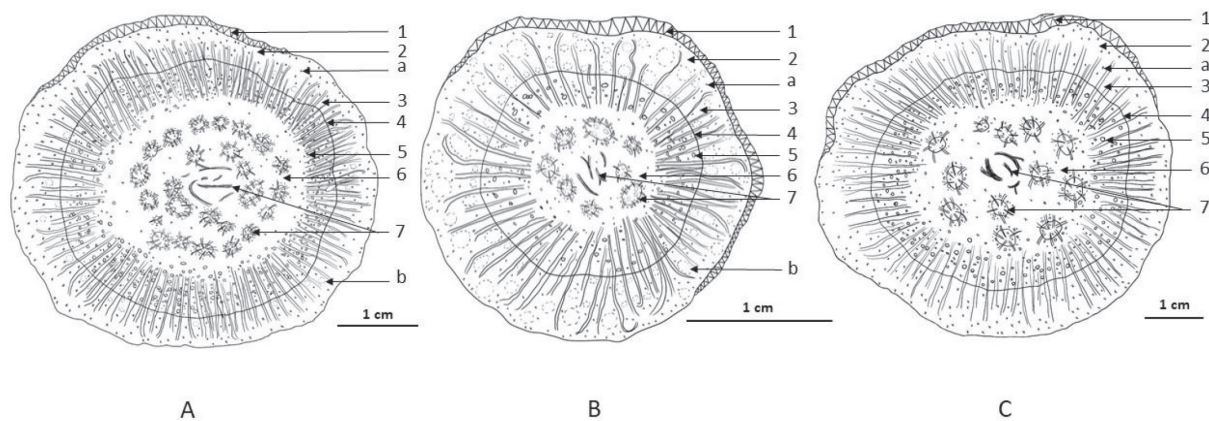
5.3 Identification

5.3.1 Microscopic identification

Transverse section, as shown in [Figure 2](#): most cork and phelloderm of root removed. In phloem, sieve tube groups distinct, parenchyma well developed. Cambium in a ring. Xylem with relatively dense rays, 2 to 4 cells wide containing brown masses; vessels non-lignified, usually single or several grouped, sparsely arranged. Parenchymatous cells have clusters of calcium oxalate and abundant starch granules.

The pith of the rhizome is broad, usually showing mucilage cavities, containing reddish-brown masses; abnormal vascular bundles are scattered; cambium is in a ring; xylem is at the inside of cambium, and phloem is outside. Stellate rays radiate.

Powder: Yellowish-brown. Clusters of calcium oxalate are 20 µm to 160 µm, sometimes up to 190 µm in diameter. Bordered pitted vessels, reticulated vessels, spiral vessels, and annular vessels are non-lignified. Starch granules are fairly abundant, single granules are spheroid or polygonal, 3 µm to 45 µm in diameter, and hilum stellate; compound granules consist of 2 to 8 components.



Key

- A *rheum palmatum* L.
 B *rheum tanguticum* Maxim. ex Balf.
 C *rheum officinale* Bail.
- 1 cork
 2 cortex
 3 phloem
 4 cambium
 5 xylem
 6 pith
 7 abnormal vascular bundles
 a clusters of calcium oxalate
 b mucilage cavities

Figure 2 — Transverse section of *Rheum* root and rhizome

5.3.2 Thin-layer chromatogram (TLC) identification

Spots in the chromatogram obtained with the test solution should correspond in position and colour to the spots in the chromatogram obtained from the reference drug solution or reference solution.

5.4 Rhaponticin

- a) The bright blue fluorescence spot in the chromatogram obtained with the test solution shall not correspond in position and colour to the spot in the chromatogram obtained with the reference solution in TLC chromatogram.
- b) When HPLC is performed, the chromatographic peak of the test solution shall not correspond at the retention time to rhaponticin ($C_{21}H_{24}O_9$) Chemical Reference Standard (CRS) in HPLC chromatogram.

5.5 Moisture

The content of water in percentage mass should not be more than 15,0 % (w/w).

5.6 Total ash

The content of total ash in percentage mass should not be more than 13,0 % (w/w).