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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 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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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* Linne., *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 materia medica*. *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*, *Yi xue zhong zhong can xi lu* and *Su Wen*.

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 diarrhoea; free anthraquinones are antibacterial and antitumour 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 against cardiovascular and cerebrovascular diseases.

In global trade, taking Chinese customs data as an example, *Rheum* root and rhizome in China is mainly exported to Japan, the Republic of Korea, the United States, Indonesia, Germany, Italy, Singapore, France, Thailand, Vietnam and Malaysia. From 2012 to 2016, the average annual export trade volume of *Rheum* root and rhizome in China was 7 128 400 US dollars, making it 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 two preparations in Japanese Pharmacopoeia (17th Edition). *Rheum* root and rhizome and its products have applications in a variety of medical fields, also involving 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 their doctor's instructions, which can lead to excessive and chronic irregular use of *Rheum* root and rhizome and liver and kidney damage.

As a globally used drug, *Rheum* root and rhizome is included in the pharmacopoeia of many countries and regions, such as China, Japan, the Republic of 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 priority list of single herbal medicines for developing standards in ISO/TR 23975, 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 necessary to guarantee the clinical effectiveness, safety and controllability of this valuable medicine in global commerce and trade.

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

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* Linne., *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 22217:2020, *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 23723:2021, *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

***Rheum* root and rhizome**

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

3.2

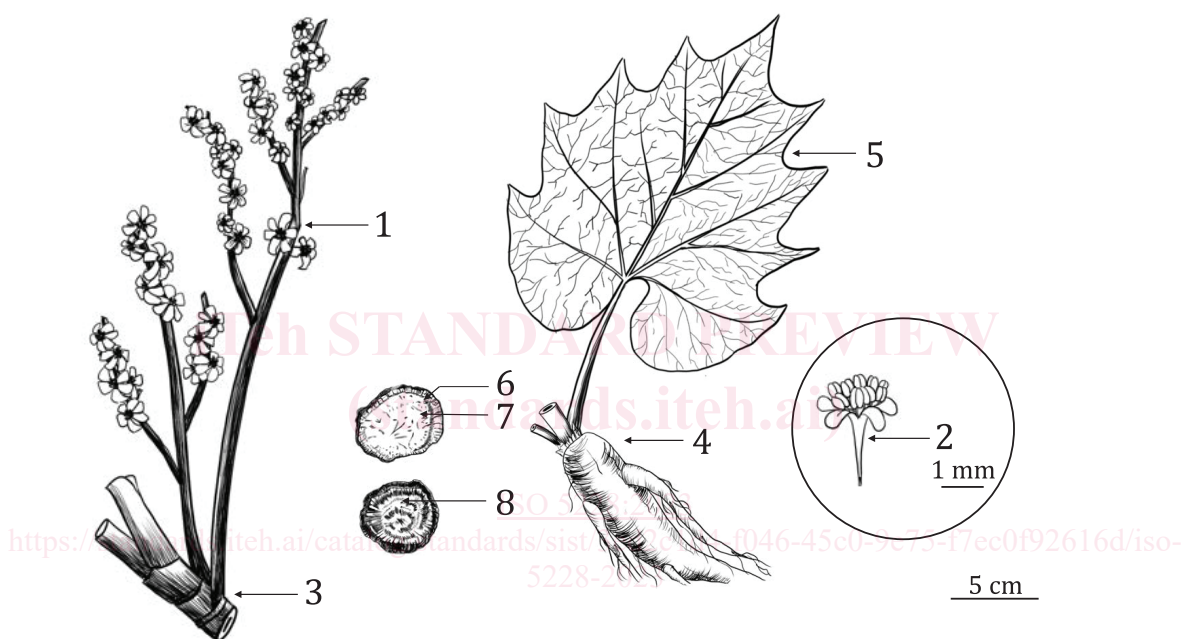
batch

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

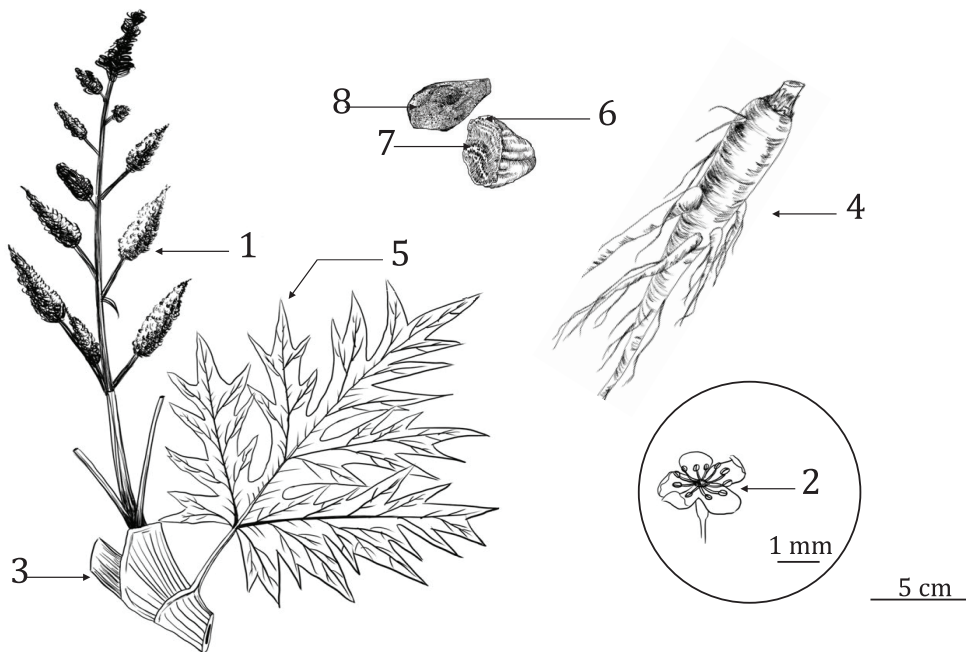
[SOURCE: ISO 22988:2020, 3.8]

4 Description

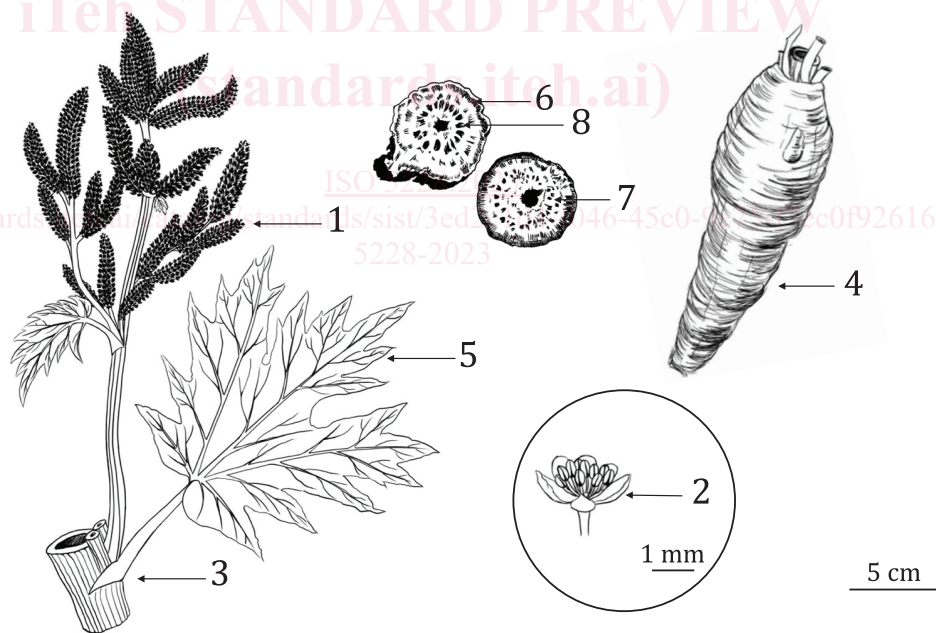
Rheum root and rhizome is the dried root and rhizome of *Rheum palmatum* Linne. (Figure 1 a), *Rheum tanguticum* Maxim. ex Balf. (Figure 1 b) and *Rheum officinale* Baill. (Figure 1 c). The crude drug is collected in late autumn when stem and leaves have withered or in spring just before budding. The crude drug is removed from rootlet and the outer bark, cut into segments or sections and either hung in line for drying or dried directly.



a) *Rheum palmatum* Linne.



b) *Rheum tanguticum* Maxim. ex Balf.



c) *Rheum officinale* Baill.

Key

- | | | | |
|---|------------------|---|---------------------------|
| 1 | inflorescence | 5 | leaf |
| 2 | flower | 6 | xylem, cambium and phloem |
| 3 | stem | 7 | pith |
| 4 | root and rhizome | 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 leaf 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 medicinal materials of *rheum* root and rhizome are subcylindrical, conical, ovoid or irregular pieces, 3 cm to 17 cm long and 3 cm to 10 cm in diameter. Externally, they are yellowish-brown to reddish-brown when peeled, sometimes with whitish reticulations and visible scattered star spots (abnormal vascular bundles), occasionally with brownish-black patches of cork, mainly with a hole through which the string is passed and coarse wrinkles. The texture of the medicinal parts is firm, sometimes loose and soft in the centre, the fracture pale reddish-brown or yellowish-brown and granular. The pith of the rhizome is broad, with star spots arranged in a ring or irregularly scattered. The wood of the root is well developed, lined radially, the cambium ring distinct and without star spots. The odour is delicately aromatic, the taste bitter and slightly astringent. It is sticky and gritty to chew.

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

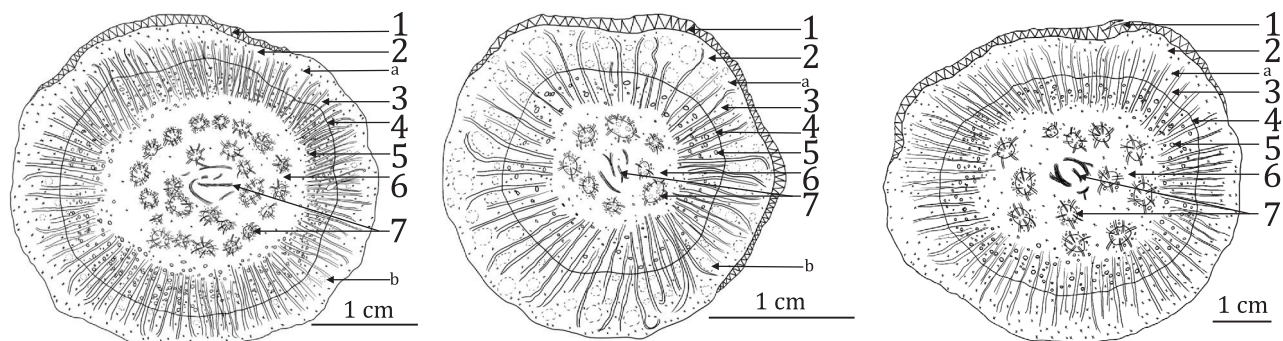
5.3 Identification

5.3.1 Microscopic identification

Transverse section of *Rheum palmatum* Linne. (Figure 2 a), *Rheum tanguticum* Maxim. ex Balf. (Figure 2 b) and *Rheum officinale* Baill. (Figure 2 c): the cork and phelloderm of root are mostly removed. In phloem, the sieve tube groups are distinct and the parenchyma is well developed. The cambium forms a ring. Xylem rays are relatively dense, two to four rows of cells wide, containing brown masses. The vessels are non-lignified, usually single or several grouped together and sparsely arranged. Parenchymatous cells contain clusters of calcium oxalate and abundant starch granules.

The rhizome pith is broad, usually showing mucilage cavities and containing reddish-brown masses, scattered with abnormal vascular bundles. The cambium forms a ring. Xylem is on the inside of the cambium and phloem on the outside. Rays are stellate.

The powder is yellowish-brown. Clusters of calcium oxalate are 20 µm to 160 µm in diameter, sometimes up to 190 µm in diameter. Bordered pitted vessels, reticulated vessels, spiral vessels and annular vessels are non-lignified. Starch granules are abundant, single granules are spheroid or polygonal, 3 µm to 45 µm in diameter, and hilum is stellate. The compound granules consist of two to eight components.

a) *Rheum palmatum* Linne.b) *Rheum tanguticum* Maxim. ex Balf.c) *Rheum officinale* Baill.**Key**

- 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 chromatography (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 TLC chromatogram.
- b) When high-performance liquid chromatography (HPLC) is performed, the chromatographic peak of the test solution shall not correspond at the retention time to the rhaponticin ($C_{21}H_{24}O_9$) chemical reference standard (CRS) of the HPLC chromatogram.

5.5 Moisture

The content of water should be a mass fraction of 15,0 %.

5.6 Total ash

The content of total ash should be a mass fraction of $\leq 13,0$ %.