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Traditional Chinese medicine — *Pinellia ternata* tuber

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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.

Introduction

Pinellia ternata tuber, the dried tuber of *Pinellia ternata* (Thunb.) Breit. (Fam. Araceae), has a long history of medicinal use in China, Japan, Korea and other Southeast Asian countries. *P. ternata* tuber is commonly used for drying dampness, resolving phlegm and descending counterflow to relieve nausea and vomiting.

Owing to its effectiveness, there has recently been an increasing demand for *P. ternata* tuber in China and worldwide. According to data from Chinese customs, the average annual demand for *P. ternata* tuber from 2015 to 2019 was about 1 800 tons and overseas trade counts for as much as USD 1 million per year. *P. ternata* tuber is ranked no. 3 in the priority list of single herbal medicines for developing standards (see ISO/TR 23975).

P. ternata tuber has a pungent taste with a numbing and irritating sensation in the gastrointestinal mucosa, throat and oral cavity. Its properties are warm, pungent and toxic. Indeed, unprocessed *P. ternata* tuber, or its insufficiently boiled decoction, causes acrid irritation of the oral and laryngopharynx mucosa when taken by mistake. The toxicity and side effects of raw *P. ternata* tuber can be reduced dramatically with proper processing and dose control. Three kinds of processed *P. ternata* tuber with different processing methods are available and traded on the market, as well as applied in clinical treatments: liquorice-limewater-processed *P. ternata* tuber, ginger-alum-processed *P. ternata* tuber and alum-processed *P. ternata* tuber. However, a unified International Standard regarding the characteristics of and test methods for raw and processed *P. ternata* tuber is not yet available. The regulatory authorities in many countries have not adequately differentiated high-toxic forms of *P. ternata* tuber from less-toxic forms (or even non-toxic forms). Additionally, the quality of raw and processed *P. ternata* tuber provided from different areas varies a lot. Therefore, an International Standard for raw and processed *P. ternata* tuber in terms of quality control of this herb and its products is urgently required to ensure the safe use of these medicinal materials.

This document aims to build a systematic and practical International Standard for *P. ternata* tuber to control and supervise its stable quality, to ensure its safe and effective application in clinics, to regulate the trade in the global market and to reduce cases of Pinellia poisoning.

As national implementation can differ, national standards bodies are invited to modify the values given in 5.4, 5.5 and 5.8 in their national standards. Examples of national and regional values are given in Annex E.

Traditional Chinese medicine — *Pinellia ternata* tuber

1 Scope

This document specifies the quality and safety requirements and test methods of *Pinellia ternata* tuber, including raw and processed *Pinellia ternata* tuber [dried tuber of *Pinellia ternata* (Thunb.) Breit.].

This document does not cover processing methods of *Pinellia ternata* tuber.

This document is applicable to raw and processed *Pinellia ternata* tuber that are sold and used as natural medicines in international trade, including Chinese materia medica (whole medicinal material) and decoction pieces derived from this 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/TS 21310, *Traditional Chinese medicine — Microscopic examination of medicinal herbs*

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 22467, *Traditional Chinese medicine — Determination of microorganisms in natural products*

ISO 22590, *Traditional Chinese medicine — Determination of sulfur dioxide in natural products by titration*

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

raw *Pinellia ternata* tuber

dried tuber of *Pinellia ternata* (Thunb.) Breit

3.2

processed *Pinellia ternata* tuber

dried tuber of *Pinellia ternata* (Thunb.) Breit after traditional processing

Note 1 to entry: Commonly used varieties include liquorice-limewater-processed *Pinellia ternata* tuber, ginger-alum-processed *Pinellia ternata* tuber and alum-processed *Pinellia ternata* tuber.

3.3

liquorice-limewater-processed *Pinellia ternata* tuber

processed *Pinellia ternata* tuber in liquorice and limewater

Note 1 to entry: Liquorice-limewater-processed *Pinellia ternata* tuber is processed with the following method: soak the dried raw *Pinellia ternata* tuber in water until the tuber is fully wet, decoct proper liquorice (*Glycyrrhiza* root and rhizome) with water twice, mix the decoction solutions then pour into the limewater; add the soaked *Pinellia ternata* tuber and stir it one to two times per day, maintaining a pH value over 12,0; gradually prolong the time for processing until the colour of the longitudinal section becomes evenly yellow and tasting it leaves the tongue slightly numb; take it out then wash and dry it in the shade or an oven.

Note 2 to entry: The mass ratio of raw *Pinellia ternata* tuber, liquorice and quicklime powder is 20:3:2.

3.4

ginger-alum-processed *Pinellia ternata* tuber

processed *Pinellia ternata* tuber in ginger and alum

Note 1 to entry: Ginger-alum-processed *Pinellia ternata* tuber is processed with the following method: soak the dried raw *Pinellia ternata* tuber in water until the tuber is fully wet then remove; decoct ginger slices to prepare the ginger solution; add raw *Pinellia ternata* tuber and alum to boil thoroughly, then take it out and dry in the air or cut it into slices and then dry in the air.

Note 2 to entry: The mass ratio of raw *Pinellia ternata* tuber, ginger and alum is 8:2:1.

3.5

alum-processed *Pinellia ternata* tuber

processed *Pinellia ternata* tuber in alum

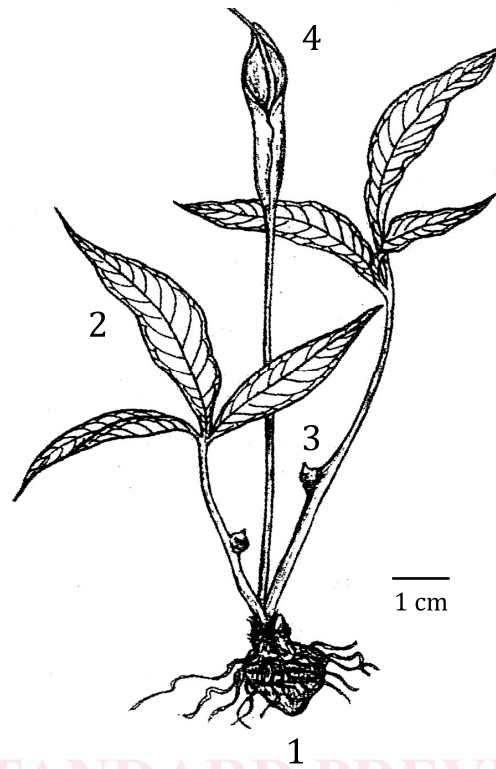
Note 1 to entry: Alum-processed *Pinellia ternata* tuber is processed with the following method: soak the dried raw *Pinellia ternata* tuber in 8 % alum solution until the tuber is fully wet and tasting it leaves the tongue slightly numb; take it out, wash it, cut into thick slices and dry in the air.

Note 2 to entry: The mass ratio of raw *Pinellia ternata* tuber and alum is 5:1.

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4 Description

The features of *Pinellia ternata* (Thunb.) Breit. plant in the family of Araceae are shown in [Figure 1](#).

**Key**

- 1 tuber
- 2 leaf
- 3 bulbil
- 4 spadix

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Figure 1 — Structure of *Pinellia ternata* plant

5 Quality and safety requirements and recommendations

5.1 General characteristics

The following requirements shall be met before sampling:

- a) *Pinellia ternata* tuber shall be clean and free from fibrous roots and foreign matter.
- b) The presence of living insects, mouldy tuber and external contaminants which are visible to the naked eye shall not be permitted.

5.2 Morphological features of the tuber

5.2.1 Raw *Pinellia ternata* tuber

Tubers have a spheroidal shape, some being slightly oblique, and of 1 cm to 1,5 cm in diameter. Externally, they are white or pale yellow, with a dented stem scar at the apex, densely surrounded by pocked and dotted root scars; the base is obtuse, rounded and relatively smooth. Its texture is hard and the cross-section of the root is white and starchy. Its odour is slight and the taste is pungent, with a numbing and irritating sensation [see [Figure 2 a](#)].

5.2.2 Liquorice-limewater-processed *Pinellia ternata* tuber

The tuber is spheroidal or broken into irregular granules. Externally, the tuber is pale yellowish-white, yellow or brownish yellow. The texture is fragile and loose or hard, the granules are relatively hard and fragile and the fracture is yellow or pale greyish yellow. The odour is slight and the taste is slightly sweet and numbing [see [Figure 2 b](#)].

5.2.3 Ginger-alum-processed *Pinellia ternata* tuber

The tuber is slice-shaped with irregular grains, or spheroidal. Externally, the tuber is brown or dark brown. The texture is hard and fragile. The fracture is pale yellowish-brown, frequently horny and lustrous. The odour is slightly aromatic and the taste is bland and slightly numbing; the texture is viscous while chewing [see [Figure 2 c](#)].

5.2.4 Alum-processed *Pinellia ternata* tuber

The tuber has elliptical, rounded or irregular slices. The vertical section is pale grey or greyish-white, showing greyish-white and dotted or short line-shaped vascular bundles, sometimes with purplish-red dapples under the remaining cork. The texture is fragile and easily broken; the fracture is slightly cutin-like. The odour is slight and the taste astringent, with a slight numbing sensation [see [Figure 2 d](#)].

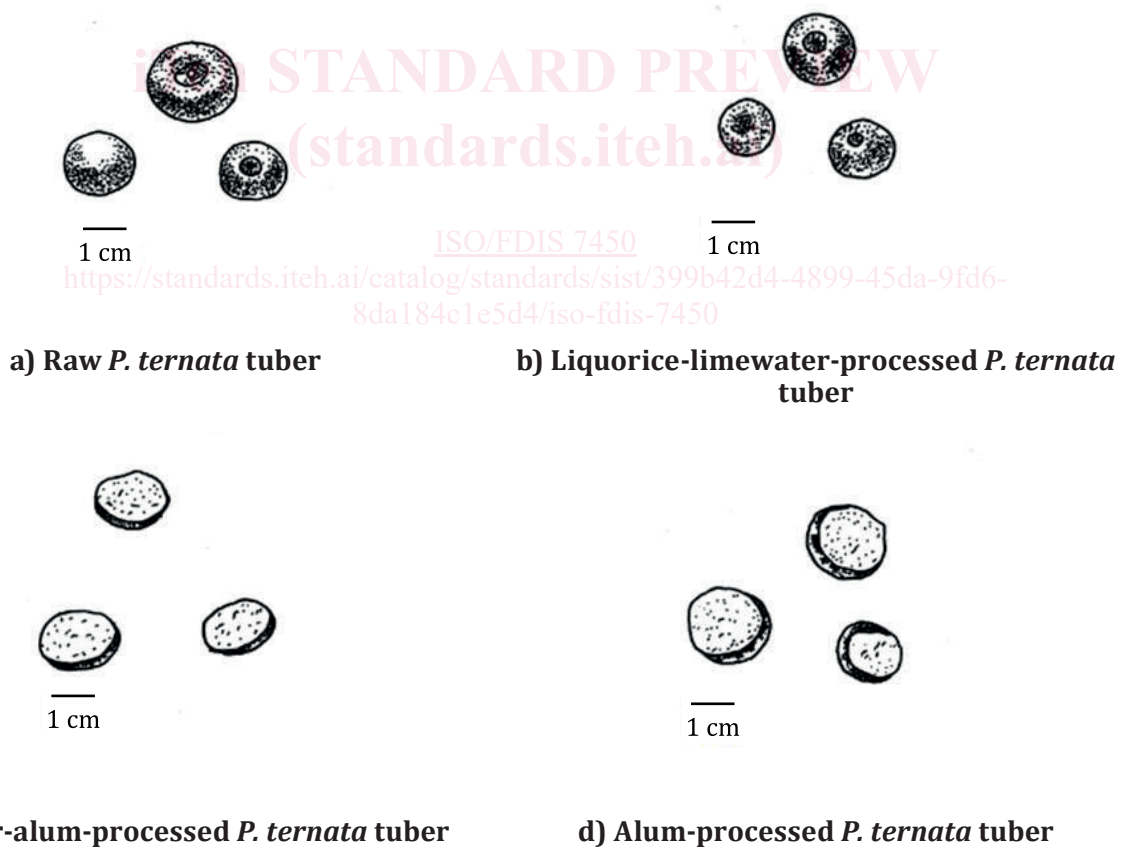


Figure 2 — Illustration of a *Pinellia ternata* tuber

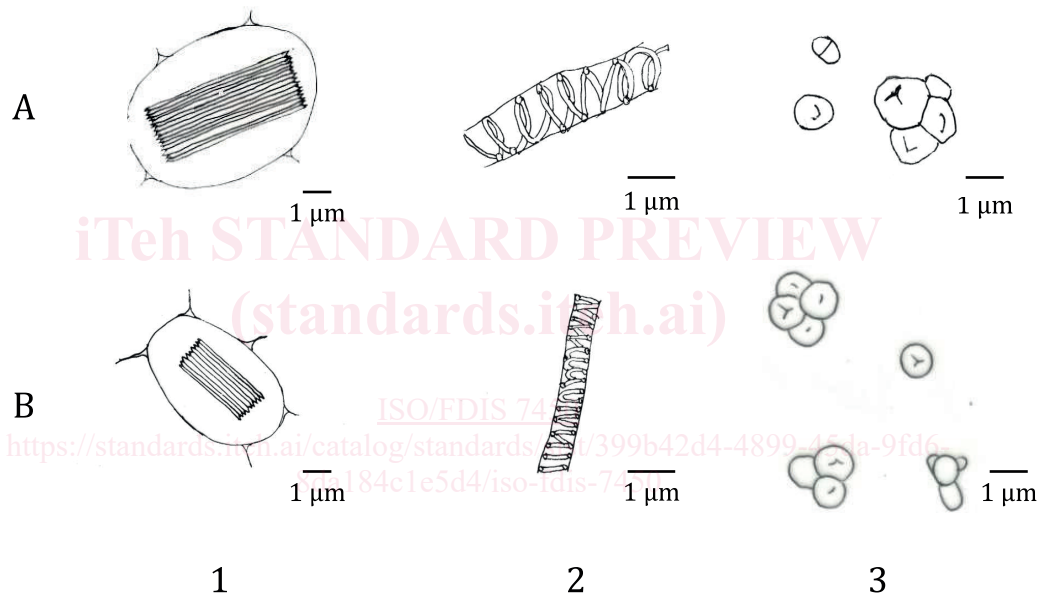
5.3 Microscopical characteristics

5.3.1 Raw *Pinellia ternata* tuber

The powder is almost white. Starch granules are abundant; simple granules are rounded, semi-circular or rounded-polygonal, 2 µm to 20 µm in diameter, hilum slit-shaped, V-shaped or stellate; compound granules consist of two to six components. Raphides of calcium oxalate are embedded in elliptical mucilage cells or scattered throughout; needle crystals are 20 µm to 144 µm long. Spiral vessels have a diameter of 10 µm to 24 µm (see [Figure 3](#), key A).

5.3.2 Processed *Pinellia ternata* tuber

The powder is yellowish-brown to pale yellowish-brown gelatinized starch granules in parenchymatous cells. Raphides of calcium oxalate are embedded in elliptical mucilage cells or scattered throughout; needle crystals are 20 µm to 144 µm long. Spiral vessels have a diameter of 10 µm to 24 µm (see [Figure 3](#), key B).



Key

- A raw *Pinellia ternata* tuber
- B processed *Pinellia ternata* tuber
- 1 acicular crystal
- 2 vascular
- 3 starch granules

Figure 3 — Microscopical characteristics of raw and processed *Pinellia ternata* tuber

5.4 Moisture

5.4.1 Raw *Pinellia ternata* tuber

The moisture content in percentage mass should not be more than 14,0 %.

5.4.2 Processed *Pinellia ternata* tuber

The moisture content in percentage mass should not be more than 13,0 %.