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**Traditional Chinese medicine —
Paeonia lactiflora root — White peony
root**

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Contents

	Page
Foreword.....	iv
Introduction.....	v
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 Descriptions.....	2
5 Requirements.....	2
5.1 Morphological features.....	2
5.1.1 Appearance.....	2
5.1.2 Colour.....	3
5.1.3 Dimension.....	3
5.1.4 Fracture.....	3
5.1.5 Odour.....	3
5.1.6 Taste.....	3
5.2 Microscopical characteristics.....	3
5.3 Moisture.....	4
5.4 Total ash.....	4
5.5 Acid-insoluble ash.....	4
5.6 Thin-layer chromatogram (TLC) identification.....	4
5.7 Content of marker compounds.....	4
5.8 Heavy metals.....	5
5.9 Pesticide residues.....	5
5.10 Sulfur dioxide residues.....	5
6 Sampling.....	5
7 Test methods.....	5
7.1 Macroscopic identification.....	5
7.2 Determination of moisture content.....	5
7.3 Determination of total ash content.....	5
7.4 Determination of acid-insoluble ash content.....	5
7.5 Thin-layer chromatogram (TLC) identification.....	5
7.6 Determination of paeoniflorin content.....	5
7.7 Determination of heavy metal content.....	5
7.8 Determination of pesticide residue content.....	5
7.9 Determination of sulfur dioxide residue content.....	5
8 Test report.....	6
9 Packaging, storage and transportation.....	6
10 Marking and labelling.....	6
Annex A (informative) Thin-layer chromatogram (TLC) identification.....	7
Annex B (informative) Determination of paeoniflorin content.....	9
Annex C (informative) Reference values of <i>Paeonia lactiflora</i> root in different countries and regions.....	11
Bibliography.....	13

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

Paeonia lactiflora root, dried root of *Paeonia lactiflora* Pallas (Fam. Paeoniaceae), has a long history of use in East Asian countries. There are two kinds of peony root: white peony root and red peony root, which are used for different therapeutic purposes. White peony root is used to tonify the blood and preserve the yin, to nourish the liver and assist in the smooth flow of qi, and to regulate the meridians and ease pain.

White peony root is known as clinically effective for the treatment of blood deficiency and sallowness, menstrual irregularities, spontaneous sweating, night sweating and chronic pain. Different quality requirements between different countries and regions, different packaging, transportation and storage conditions can affect the quality of white peony root.

Therefore, the harmonization of requirements of white peony root is required to ensure quality and safety. As national implementation can differ, national standards bodies can modify the values given in 5.3, 5.4, 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 — *Paeonia lactiflora* root — White peony root

1 Scope

This document specifies the minimum requirements and test methods for white peony root derived from the plant of *Paeonia lactiflora* Pallas.

It is applicable to white peony root that is sold as Chinese material medica (whole medicinal materials) and decoction pieces derived from this plant.

It is not applicable to red peony root.

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 1575, *Tea — Determination of total ash*

ISO 1577, *Tea — Determination of acid-insoluble ash*

ISO 18664, *Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine*

ISO 20409, *Traditional Chinese medicine — Panax notoginseng root and rhizome*

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 23723:2021, *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

***Paeonia lactiflora* root**

dried root of *Paeonia lactiflora* Pallas in the family of Paeoniaceae

3.2 marker compound

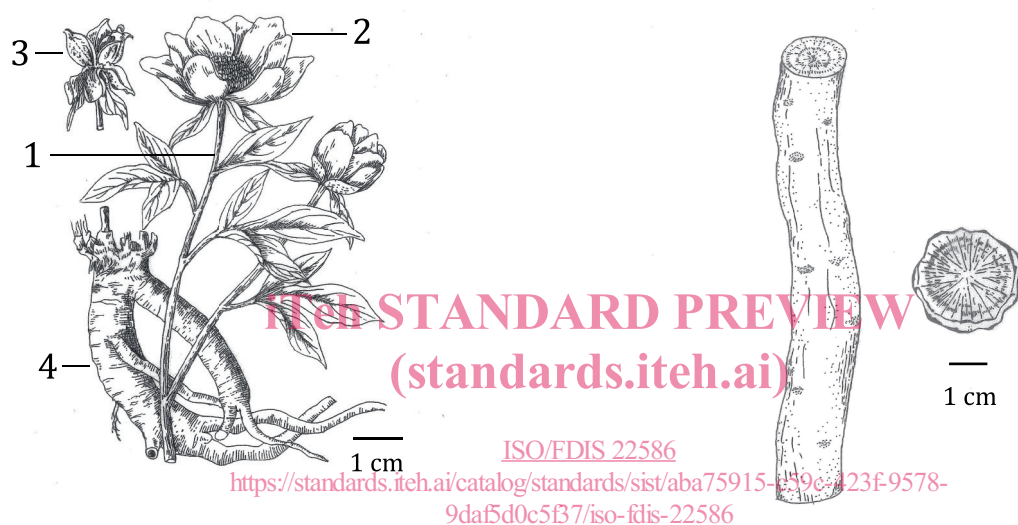
chemical constituent within a medicinal herb that can be used to verify its quality

Note 1 to entry: Usually described as active ingredients or chemicals that confirm the correct botanical identity of the starting material.

Note 2 to entry: There may be one or more marker compounds for a medicinal herb.

4 Descriptions

Paeonia lactiflora root is the dried root of *Paeonia lactiflora* Pallas in the family of Paeoniaceae, as shown in [Figure 1](#).



a) *Paeonia lactiflora* Pallas

b) White peony root

Key

- 1 spray
- 2 flower
- 3 fruit
- 4 root

Figure 1 — Structure of *Paeonia lactiflora* Pallas and white peony root

5 Requirements

5.1 Morphological features

5.1.1 Appearance

The root is cylindrical, the shape is straight or slightly curved and the root is smooth and glossy or with longitudinal wrinkles, see [Figure 1](#) b).

5.1.2 Colour

The external surface is brown to light grayish-brown, with rootlet scars and occasional remains of brown cork at the base, see [Figure 1 b](#)).

5.1.3 Dimension

The root is 5 cm to 18 cm in length measured from the base to the end of the root and 1 cm to 2,5 cm in diameter measured at the base of the root.

5.1.4 Fracture

The fractured surface is dense in texture and there are light grayish-brown or light brown radial lines in xylem. The texture is compact, relatively even and not easily broken.

5.1.5 Odour

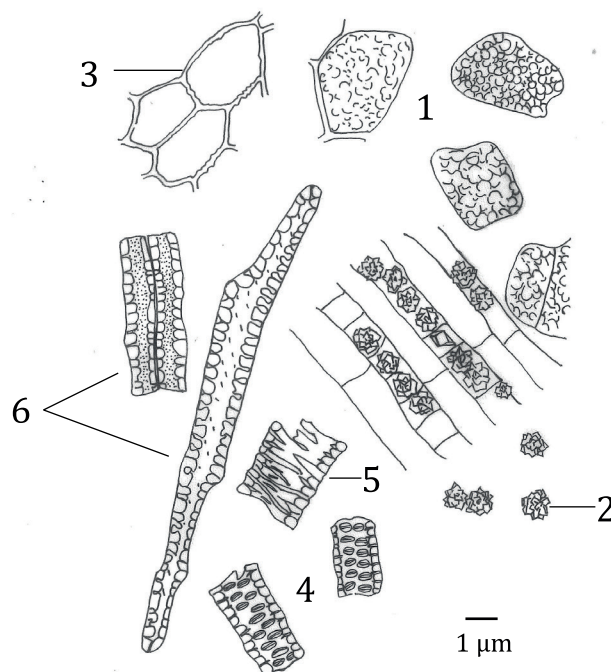
The odour is slight and characteristic.

5.1.6 Taste

The taste is slightly bitter and sour.

5.2 Microscopical characteristics

The powder is greyish-white to pale brown. Gelatinized starch grains are fairly abundant. Cluster crystals of calcium oxalate are 11 µm to 35 µm in diameter, are often arranged in rows or one-to-several cluster crystals in parenchyma cells and show polychrome when examined under a polarized microscope. Bordered-pitted vessels or reticulate vessels are 20 µm to 65 µm in diameter. Xylem fibres are long fusiform with a thickened and slightly lignified wall, which is large, round-pitted or oblique-pitted (see [Figure 2](#)).



Key

- 1 gelatinized starch grains
- 2 calcium oxalate
- 3 parenchyma cells
- 4 bordered-pitted vessels
- 5 reticulate vessels
- 6 xylem fibres

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Figure 2 — Structure of powdered white peony root

5.3 Moisture

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

5.4 Total ash

The total ash content in percentage mass should not be more than 6,5 %.

5.5 Acid-insoluble ash

The total ash content in percentage mass should not be more than 1,0 %.

5.6 Thin-layer chromatogram (TLC) identification

The identification of marker compound, such as paeoniflorin, with TLC shall present spots or brands obtained from the test and reference drug solution in the same position with the same colour.

5.7 Content of marker compounds

The content of marker compounds such as paeoniflorin should be determined.

5.8 Heavy metals

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

5.9 Pesticide residues

The content of pesticide residues such as benzene hexachloride, DDT and pentachloronitrobenzene shall be determined.

5.10 Sulfur dioxide residues

The content of sulfur dioxide residues should be determined.

6 Sampling

Sampling of white peony root shall be carried out in accordance with ISO 23723:2021, Clause 8.

7 Test methods

7.1 Macroscopic identification

Samples of not less than 500 g are taken from each batch randomly. These samples are examined by unaided visual inspection, smell and taste.

7.2 Determination of moisture content

The testing method specified in ISO 20409 applies.

7.3 Determination of total ash content

The testing method specified in ISO 1575 applies.

7.4 Determination of acid-insoluble ash content

The testing method specified in ISO 1577 applies.

7.5 Thin-layer chromatogram (TLC) identification

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

7.6 Determination of paeoniflorin content

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

7.7 Determination of heavy metal content

The testing method specified in ISO 18664 applies.

7.8 Determination of pesticide residue content

The testing method specified in ISO 22258 applies.

7.9 Determination of sulfur dioxide residue content

The testing method specified in ISO 22590 applies.