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

*Médecine traditionnelle chinoise — Racine de Paeonia lactiflora —
Racine de pivoine blanche*

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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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 sallow complexion, 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](#), [5.5](#) 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 materia 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

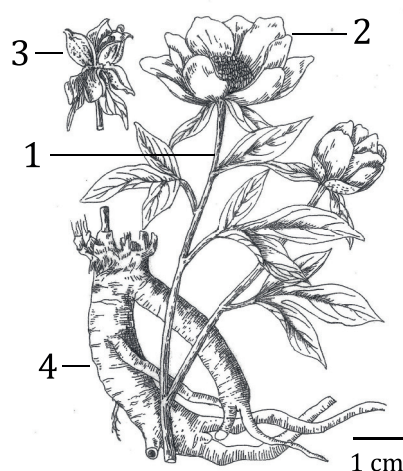
chemical constituent within a medicinal herb that can be used to verify its quality

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

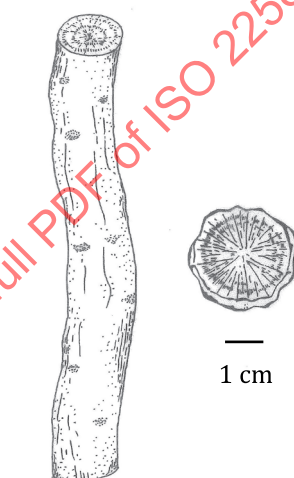
Note 2 to entry: There may be one or more marker compounds for a medicinal herb.

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

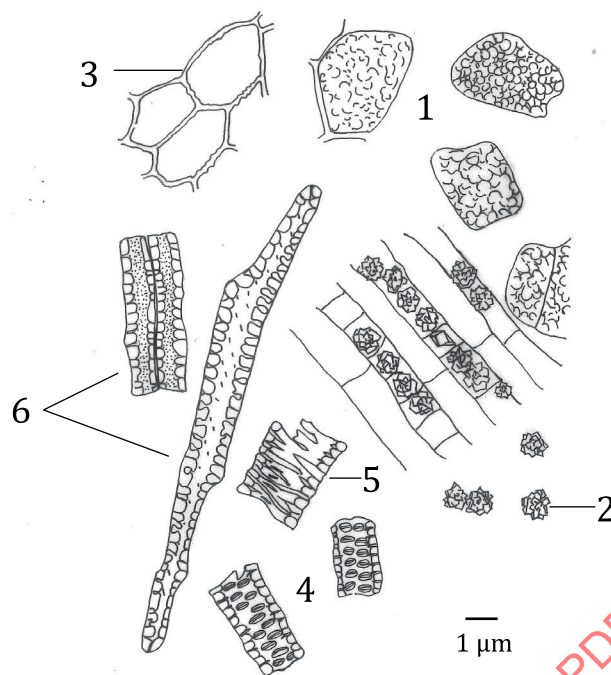
The odour is slight and characteristic.

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

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 acid-insoluble 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 bands 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.

8 Test report

For each test method, the test report shall specify the following:

- a) all the information necessary for the complete identification of the sample;
- b) the sampling method used;
- c) the test method used, with reference to this document;
- d) the test result(s) obtained;
- e) all operating details not specified in this document, or regarded as optional, together with details of any incidents which might have influenced the test result(s);
- f) any unusual features (anomalies) observed during the test;
- g) the date of the test.

9 Packaging, storage and transportation

Packaging should not transmit any odour or flavour to the product and should not contain substances which have the potential to damage the product or constitute a health risk. The packaging should be strong enough to withstand normal handling and transportation.

The storage requirements specified in ISO 22217 shall apply.

The white peony root should be protected from light, moisture, pollution and the entry of foreign substances during long-distance delivery.

10 Marking and labelling

The general requirements specified in ISO 21371 shall apply. The following items shall be marked or labelled on the packages:

- a) product name;
- b) category of the product in the marketed country or region;
- c) net mass or quantity;
- d) contact information;
- e) name of raw materials and species;
- f) warning statements, if any;
- g) expiry date;
- h) storage method;
- i) batch or lot number;
- j) miscellaneous.

Annex A (informative)

Thin-layer chromatogram (TLC) identification

A.1 Preparation of test solution and reference solution

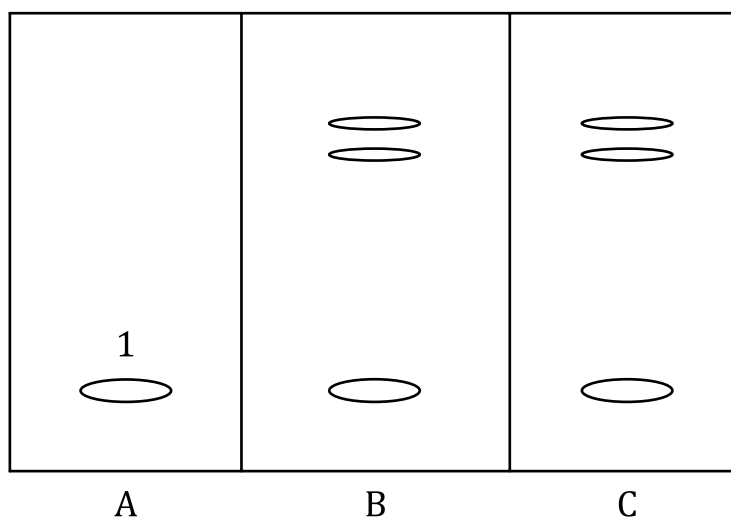
- a) Weigh 250 g of white peony root to grind and pass it through an 80-mesh or finer sieve. Weigh approximately 0,5 g of the powder, add 10 ml of 95 % ethanol-water (volume fraction), shake thoroughly for 5 min then filter. Evaporate the filtrate to dryness then dissolve the residue in 1 ml of ethanol as the sample solution.
- b) Weigh 0,5 g of white peony root reference drug powder and treat it in the same manner as in a) as the reference drug solution.
- c) Dissolve a quantity of paeoniflorin chemical reference substance (CRS) in ethanol to produce a solution containing 1 mg per ml as the reference solution.

A.2 Developing solvent system

Prepare a mixture of acetone, ethyl acetate and acetic acid (100) in the volume ratio of 10:10:1 (volume fraction) as the mobile phase.

A.3 Procedure

Apply 10 µl each of the reference drug solution and the test solution on the same TLC plate (silica gel binder) previously dried at 110 °C for 15 min in the oven. Develop the plate in the mobile phase, then remove it from the oven and dry in air. Spray with a 5 % solution of vanillin in ethanolic sulfuric acid (10 %) and heat at 105 °C until the colours of the zones become visible. Examine the plate in daylight. Identify the spots of the test solution by comparing the positions and colours with those of the reference drug solution. Typical reference TLC chromatograms are shown in [Figure A.1](#).



Key

- 1 paeoniflorin
- A reference solution
- B *Paeonia lactiflora* root — White peony root reference drug solution
- C *Paeonia lactiflora* root — White peony root test solution

Figure A.1 — Schematic diagram of typical TLC chromatogram of white peony root

Annex B (informative)

Determination of paeoniflorin content

B.1 Preparation of reference standard solution

Dissolve a quantity of paeoniflorin CRS with methanol in a brown volumetric flask to produce a solution containing 0,06 mg per ml as the reference solution.

B.2 Preparation of test solution

Weigh 250 g of white peony root to grind and pass it through an 80-mesh or finer sieve. Weigh approximately 0,1 g of the powder in a 50-ml round-bottomed flask. Accurately add 35 ml of 50 % ethanol water (volume fraction). Weigh and give ultrasonic treatment for 30 min (240 W, 45 KHz). Cool and weigh again. Replenish the loss of solvent with 50 % ethanol and mix well, filter and use the successive filtrate. Filter through 0,45 µm membrane filter as the test solution.

B.3 Chromatographic system

B.3.1 Column

B.3.1.1 Stationary phase: octadecylsilane chemically bonded to porous silica particles, 5 µm in diameter as analysing column or equivalent.

B.3.1.2 size: $l = 250$ mm, $\phi = 4,6$ mm.

B.3.2 Mobile phase

B.3.2.1 Mobile phase A: 0,1 % (volume fraction) phosphoric acid in water for chromatography R.

B.3.2.2 Mobile phase B: acetonitrile for chromatography R.

B.3.2.3 Isocratic elution: a mixture of mobile phases A and B (86:14, volume fraction).

B.3.3 Flow rate: 1,0 ml/min.

B.3.4 Detection wavelength: 230 nm.

B.3.5 Column temperature: 30 °C.

B.3.6 Injection volume: 10 µl.

B.4 Content calculation of paeoniflorin

B.4.1 The percentage content of paeoniflorin, M_{PF} , is calculated with [Formula \(B.1\)](#):

$$M_{PF} = \frac{C_s \times 10^{-3} \times 100}{M \times (1 - C_m)} \times 100 \% \quad (\text{B.1})$$

where:

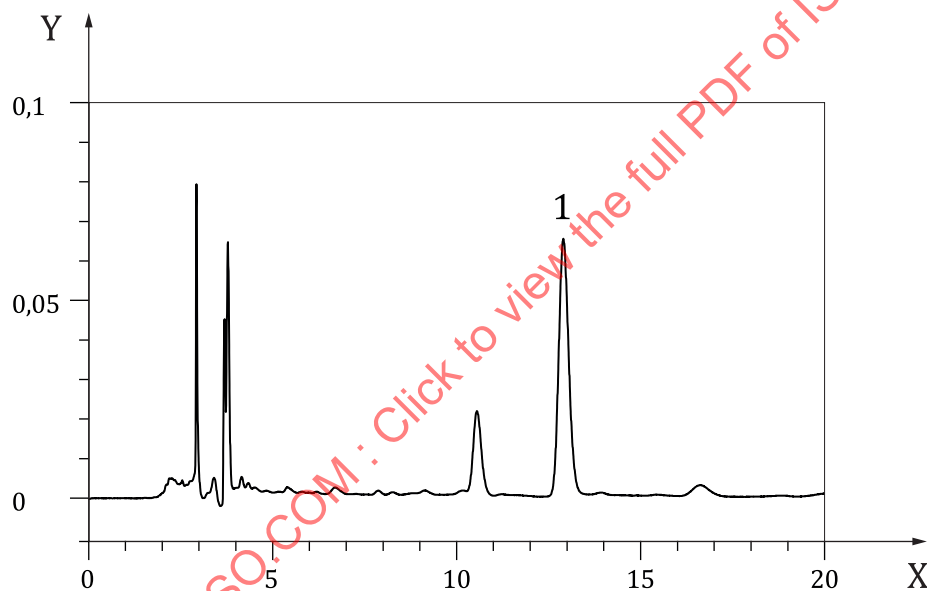
M_{PF} is the content of paeoniflorin (%);

C_s is the average content of the sample (mg/ml);

M is the mass of white peony root taken to prepare the sample solution (g);

C_m is the moisture content of the sample (%).

B.4.2 A typical reference HPLC chromatogram is shown in [Figure B.1](#).



Key

X retention time (min)

Y absorbance unit

1 paeoniflorin

Figure B.1 — Typical reference HPLC chromatogram of white peony root