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Traditional Chinese medicine — *Saposhnikovia divaricata* root and rhizome

Médecine traditionnelle chinoise — Racine et rhizome de Saposhnikovia divaricata

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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

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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 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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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

Saposhnikovia divaricata root and rhizome is the dried root and rhizome of *Saposhnikovia divaricata* (Turcz.) Schischk. It was first recorded in the book *Divine Farmer's Classic of Materia Medica*, a commonly used reference material in various countries. *Saposhnikovia divaricata* root and rhizome has long been used in traditional Chinese medicine for its multiple therapeutic properties (antipyretic, analgesic, sedative, anti-inflammatory, anti-allergic and anti-convulsion). It is a highly regarded traditional Chinese medicine with significant medicinal and economic value around the world. Due to annually increasing domestic and international demand, cultivated herbs have begun to replace wild herbs on the market. The markets of Japan, Korea, Germany, and China, amongst others, have a large circulation of *Saposhnikovia divaricata* root and rhizome.

Saposhnikovia divaricata root and rhizome is mainly distributed in the northeast China (Inner Mongolia, Heilongjiang, Liaoning, Jilin), which are the major production areas of China and account for more than 80 % of national production. It is also planted in Hebei and Shanxi Provinces. The qualities of *Saposhnikovia divaricata* root and rhizome from the producing areas differ in their appearance and chemical contents when comparing cultivated and wild ones. Therefore, the work for identification and quality evaluation of *Saposhnikovia divaricata* root and rhizome is highly important.

Although *Saposhnikovia divaricata* root and rhizome has been recorded in Chinese Pharmacopoeia (2020 edition), Japanese Pharmacopoeia (17th edition), and Korean Pharmacopoeia (10th edition), these standards are not harmonized and can be unsuitable for the purpose of international trade of *Saposhnikovia divaricata* root and rhizome. Therefore, it is of utmost urgency to standardize the quality of *Saposhnikovia divaricata* root and rhizome in the world. This action will benefit consumers (patients), farmers, enterprises and companies related to the planting, management and trade of *Saposhnikovia divaricata* root and rhizome.

As national implementation can differ, National Standards Bodies are invited to 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 D.

Traditional Chinese medicine — *Saposhnikovia divaricata* root and rhizome

1 Scope

This document specifies the quality and safety requirements of *Saposhnikovia divaricata* root and rhizome derived from the plant of *Saposhnikovia divaricata* (Turcz.) Schischk.

It is applicable to *Saposhnikovia divaricata* root and rhizome that is sold as natural medicine in international trade, including Chinese materia medica (whole medicinal materials) 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 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 terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

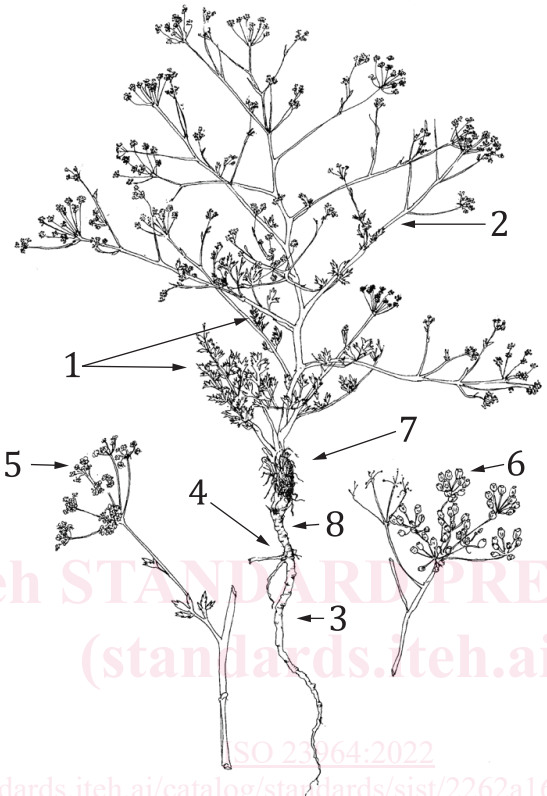
— IEC Electropedia: available at https://www.electropedia.org/

3.1
wild *Saposhnikovia divaricata* root and rhizome
dried root and rhizome of *Saposhnikovia divaricata* (Turcz.) Schischk that grows naturally without cultivation

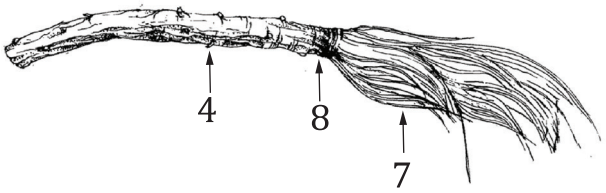
3.2
cultivated *Saposhnikovia divaricata* root and rhizome
dried root and rhizome of *Saposhnikovia divaricata* (Turcz.) Schischk that are artificially cultivated

4 Descriptions

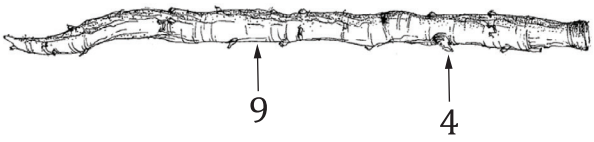
In this document, *Saposhnikovia divaricata* root and rhizome is the dried root and rhizome of *Saposhnikovia divaricata* (Turcz.) Schischk. in the family of *Apiaceae* as shown in Figure 1.



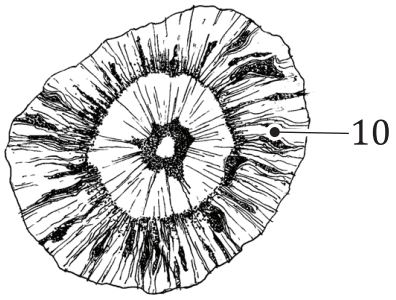
a) plant of *Saposhnikovia divaricata* (Turcz.) Schischk.



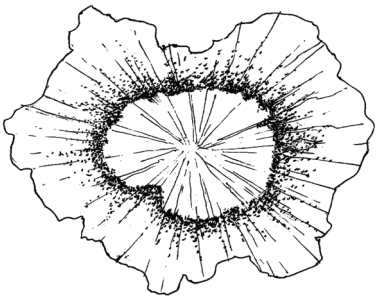
b) wild *Saposhnikovia divaricata* root and rhizome



c) cultivated *Saposhnikovia divaricata* root and rhizome



d) transverse section of wild herb



e) transverse section of cultivated herb

Key

1 leaf
2 stem
3 tap root
4 lateral root
5 inflorescence
6 seed
7 hair-like remains of leaf sheath
8 dense crosswise wrinkles
9 longitudinal wrinkles
10 lacunae

Figure 1 — Structure of *Saposhnikovia divaricata* and *Saposhnikovia divaricata* root and rhizome

5 Requirements

5.1 General characteristics

The following requirements should be met before the sampling.

a) *Saposhnikovia divaricata* root and rhizome should be clean and free from foreign matter.

b) The presence of living insects, mildew and external contaminants which are visible to the naked eye should not be permitted.

5.2 Macroscopic characteristics

5.2.1 Appearance

Long conical or cylindrical rhizome and root, some bend slightly; 15 cm to 30 cm in length, 0,5 cm to 2,0 cm in diameter.

5.2.2 Sensory identification

5.2.2.1 Wild Saposhnikovia divaricata root and rhizome

The surface is pale brown or brown; rhizome reveals dense crosswise wrinkles like ring nodes, and sometimes reveals brown and hair-like remains of leaf sheath; the root reveals many longitudinal

wrinkles and scars of rootlets; in a transverse section, cortex is greyish brown in colour and reveals many lacunae, and xylem is yellow in colour. Odour: slight; taste: slightly sweet.

5.2.2.2 Cultivated *Saposhnikovia divaricata* root and rhizome

The surface is light brown or faint yellow; rhizome's crosswise wrinkles are not distinct. Rhizome sometimes reveals brown and hair-like remains of leaf sheath; the root reveals many longitudinal wrinkles and scars of rootlets; in a transverse section, cortex is pale yellow or brown in colour and reveals few lacunae. Odour: subtle smells; taste: slightly sweet.

5.3 Moisture

The moisture content in percentage mass should not be more than 10,0 %.

5.4 Total ash

The total ash content in percentage mass should not be more than 7,0 %.

5.5 Acid-insoluble ash

The total ash content in percentage mass should not be more than 1,5 %.

5.6 Thin-layer chromatography identification

The identification of *Saposhnikovia divaricata* root and rhizome with thin-layer chromatography (TLC) should present spots or bands obtained from the test and the reference drug solution in the same position with the same colour.

5.7 Dilute ethanol-soluble extractives

The dilute ethanol-soluble extracts content in percentage mass should not be less than 16,0 %.

5.8 Content of marker compound

The contents of marker compounds, such as Prim-*O*-glucosylcimifugin and 5-*O*-methylvisamminoside shall be determined.

5.9 Heavy metals

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

5.10 Pesticide residues

The content of pesticide residues shall be determined.

5.11 Commercial grades

If commercial grades are necessary, see Annex E for additional information.

6 Sampling

Sampling of *Saposhnikovia divaricata* root and rhizome shall be carried out in accordance with ISO 23723.

7 Test methods

7.1 Macroscopic identification

Samples not less than 500 g are taken from each batch randomly. These samples are examined by naked-eye observation, smell and taste.

7.2 Determination of moisture content

The testing method specified in ISO 23723 shall apply.

7.3 Determination of total ash

The testing method specified in ISO 23723 shall apply.

7.4 Determination of acid-insoluble ash

The testing method specified in ISO 23723 shall apply.

7.5 Determination of dilute ethanol-soluble extractives content

See Annex A for additional information.

7.6 Thin-layer chromatography (TLC) identification

See Annex B for additional information.

7.7 Determination of maker compound content

See Annex C for additional information.

7.8 Determination of heavy metals content

The testing method specified in ISO 18664 shall apply.

7.9 Determination of pesticide residues content

The testing method specified in ISO 22258 shall apply.

8 Test report

For each test sample, the test report should record the sample quantity, sampling date, sale company, as well as producing area and commodity name in detail.

For each test method, the test report shall specify at least the following aspects:

a) all the information necessary for the complete identification of the sample;

b) a reference to this document, including its year of publication (i.e. ISO 23964:2022);

c) the sampling method used;

d) the test method used, with reference to the clause which explains how the results were calculated;

e) the test result(s) obtained;

f) all operating details that are not specified in this document, or regarded as optional, together with details of any deviations or incidents which can have influenced the test result(s);