
**Traditional Chinese medicine —
Saposhnikovia divaricata root and
rhizome**

*Médecine traditionnelle chinoise — Racine et rhizome de
Saposhnikovia divaricata*



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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

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