



**International
Standard**

ISO 24900

**Traditional Chinese medicine —
Sophora tonkinensis root and
rhizome**

*Médecine traditionnelle chinoise — Racine et rhizome de
Sophora tonkinensis*

**First edition
2026-08**

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Published in Switzerland

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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 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 medicine*, Subcommittee SC 1, *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

Sophora tonkinensis root and rhizome (the Chinese Pinyin name: Shandougen) is the dried root and rhizome of *Sophora tonkinensis* Gagnep. (Fam. Leguminosae). It is mainly produced in southwest China and Vietnam, belongs to one of the toxic traditional Chinese medicines. *Sophora tonkinensis* root and rhizome is first recorded in "Kaibao Bencao" in the Song Dynasty,^[1] and called "solution throat swelling first medicine" in "Becao Qiuzhen" in the Qing Dynasty^[2].

Sophora tonkinensis root and rhizome can clear heat and detoxify, reduce swelling and enhance pharynx. It demonstrates anti-tumour, anti-inflammation, anti-oxidation, antibacterial and immunity-enhancing effects. It is often used in the clinical treatment of pharyngitis and tonsillitis, and its preparations are also used in the treatment of chronic hepatitis and liver cancer as adjuvant therapy.

More than 200 compounds have been identified from the *Sophora tonkinensis* root and rhizome, mainly include alkaloids, flavonoids, triterpenoids, triterpenoid saponins, and polysaccharides, where alkaloids both serve as the important material basis for the pharmacodynamic action and the main substances causing toxicity. The adverse events induced by *Sophora tonkinensis* root and rhizome and its alkaloids include nerve injury, hepatic injury, cardiovascular injury, kidney injury and reproductive injury, and gastrointestinal reaction. Quinolizidine alkaloids are the main toxic components, mainly including matrine, oxymatrine, cytisine, sophocarpine, oxysophocarpine, sophoridine, sophoramine, and lehmannine. The mechanism of toxicity needs further study. Because of the coexisting of its efficacy and poison, long-term or high-dose administration often leads to a series of safety problems in the clinical application process.

At present, the quality of *Sophora tonkinensis* root and rhizome varies greatly. It is mainly represented by the substitution of other varieties in medicine, such as *Menispermum dauricum*, *Indigofera fortunei*, *Mogjanin philippinensis*. There are also the above-ground parts (non-medicinal parts) adulterated with *Sophora tonkinensis* sold as *Sophora tonkinensis* root and rhizome.

Moreover, *Sophora tonkinensis* root and rhizome is ranked no. 54 in the priority list of single herbal medicines for developing standards in ISO/TR 23975.^[3] Therefore, it is necessary to standardize the quality and safety control of *Sophora tonkinensis* root and rhizome, so as to provide reference for studying the toxicity of *Sophora tonkinensis* root and rhizome.

As national implementation can differ, national standards bodies are invited to modify the values given in [5.6](#) and [5.10](#) in their national standards. Examples of national and regional values are given in [Annex C](#).

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Traditional Chinese medicine — *Sophora tonkinensis* root and rhizome

1 Scope

This document specifies the minimum requirements and test methods for *Sophora tonkinensis* root and rhizome.

This document applies to *Sophora tonkinensis* root and rhizome sold and used as 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/TS 21310, *Traditional Chinese medicine — Microscopic examination of medicinal herbs*

ISO 21371, *Traditional Chinese medicine — Labelling requirements of products intended for oral or topical use*

ISO 22217:2020, *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 23723:2021, *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

***Sophora tonkinensis* root and rhizome**

dried root and rhizome of *Sophora tonkinensis* Gagnep. (Fam. Leguminosae)

3.2

marker compound

matrine (C₁₅H₂₄N₂O) and oxymatrine (C₁₅H₂₄N₂O₂)