Form 36

DPC: 25/30488618 DC

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Date: 18 June 2025
Origin: International

Latest date for receipt of comments: 11 August 2025

Project No. 2024/00720

Responsible committee: CH/100 Healthcare and Medical Equipment

Interested committees:

Title: Draft BS ISO 24900 Traditional Chinese medicine. Sophora tonkinensis root and rhizome.

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Introduction

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For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex **(e.g. 3.1)**	Paragraph/ Figure/Table/Note	**Type of comment**	**Commend (justification for change) by the MB**	**Proposed change by the MB**	**Secretariat observations on each comment submitted**
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

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DRAFT International Standard

ISO/DIS 24900

Traditional Chinese medicine — *Sophora tonkinensis* root and rhizome

ICS: 11.120.10

ISO/TC **249**/SC **1**

Secretariat: **SAC**

Voting begins on:
2025-06-18

Voting terminates on:
2025-09-10

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Full document details: 25/30488618 DC

Contents

Page

Foreword ... **iv**
Introduction ... **v**
1 Scope ... **1**
2 Normative references ... **1**
3 Terms and definitions ... **1**
4 Description ... **1**
5 Requirements and recommendations ... **2**
5.1 General characteristics ... 2
5.2 Morphological features of root and rhizome ... 2
5.3 Microscopic identification ... 3
5.4 Thin-layer chromatogram (TLC) identification ... 3
5.5 Moisture ... 3
5.6 Total ash ... 4
5.7 Ethanol-soluble extractives ... 4
5.8 Heavy metals ... 4
5.9 Pesticide residues ... 4
5.10 Marker compounds ... 4
6 Sampling ... **4**
7 Test methods ... **4**
7.1 Macroscopic identification ... 4
7.2 Microscopic identification ... 4
7.3 Thin-layer chromatogram (TLC) identification ... 4
7.4 Determination of moisture ... 4
7.5 Determination of total ash ... 4
7.6 Determination of ethanol-soluble extractives ... 4
7.7 Determination of heavy metals ... 5
7.8 Determination of pesticide residues ... 5
7.9 Determination of marker compounds ... 5
8 Test report ... **5**
9 Packaging, storage, and transportation ... **5**
10 Marking and labelling ... **5**
Annex A (informative) **Thin-layer chromatogram (TLC) identification** ... **6**
Annex B (informative) **Determination of marker compounds by HPLC-UV** ... **8**
Annex C (informative) **Reference information for national and regional requirements** ... **10**
Bibliography ... **13**

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Foreword

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This document was prepared by Technical Committee ISO/TC*249*, *Traditional Chinese medicine*.

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Introduction

Sophora tonkinensis root and rhizome (Shandougen, 山豆根) 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, and called "solution throat swelling first medicine" in "Becao Qiuzhen" in the Qing Dynasty.

Sophora tonkinensis root and rhizome has the effect of clearing heat and detoxifying, reducing swelling and enhancing pharynx, and has various pharmacological effects such as anti-tumor, anti-inflammation, anti-oxidation, antibacterial, and enhancing immunity. 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. but 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 *Menispermun 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 the 54 in the ISO/TR 23975: 2025 Traditional Chinese medicine — Priority list of single herbal medicines for developing standards. Therefore, it is necessary to establish standards 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.

In addition, as the requirement and implementation may differ in different countries, the users are invited to modify the values given in 5.6 and 5.10 according to their national standards. Examples of national values are given in Annex C.

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