



International
Standard

ISO 24902

**Traditional Chinese medicine —
Zanthoxylum nitidum root**

*Médecine traditionnelle chinoise — Racine de Zanthoxylum
nitidum*

**First edition
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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	2
5.3 Microscopic identification	3
5.4 Thin-layer chromatogram (TLC) identification	3
5.5 Moisture	4
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 Toddalolactone identification	4
7.7 Determination of ethanol-soluble extractives	5
7.8 Determination of heavy metals	5
7.9 Determination of pesticide residues	5
7.10 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 of national and regional requirements	10
Bibliography	12

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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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 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

Zanthoxylum nitidum root (the Chinese Pinyin name: Liang-Mian-Zhen) is the dried root of *Zanthoxylum nitidum* (Roxb.) DC., which is known in China as Liang-Mian-Zhen. It is mainly distributed in southern China and Viet Nam. *Zanthoxylum nitidum* root and its products are sold in China, Japan, Thailand, Myanmar, Singapore, Malaysia, the United States, Uganda, and many other countries. It is widely used in traditional Chinese medicine for treating stomachache, toothache, rheumatic arthralgia, traumatic injury, and venomous snake bites. Additional medical applications include the treatment of inflammations, various types of cancer, bacterial and viral infections, gastric and oral ulcers, and liver damage.

Zanthoxylum nitidum root contains a variety of effective chemical components, including alkaloids, coumarins, lignans, sterols, flavonoids, and volatile oils, among which alkaloids have the highest content, accounting for about 0,7 %. Modern pharmacological studies have shown that *Zanthoxylum nitidum* root has anti-inflammatory, analgesic, antioxidant and anti-tumour effects. The anti-inflammatory and analgesic effects of *Zanthoxylum nitidum* root are widely used in the treatment of bruises, stomach pain, toothache, and rheumatism.

The alkaloids are the main active components of *Zanthoxylum nitidum* root. Nitidine chloride is one of the most frequently used alkaloids in *Zanthoxylum nitidum* root to study its various pharmacological effects.

At the same time, studies have also shown that the alkaloids in *Zanthoxylum nitidum* root have a certain degree of toxicity and can cause toxic effects such as hepatocyte toxicity, renal cytotoxicity, developmental toxicity and cardiotoxicity.

On the market, the quality of *Zanthoxylum nitidum* root is uneven. There are forgeries and adulterations. The common forgeries and confused products of *Zanthoxylum nitidum* root are the stem of *Zanthoxylum nitidum* (Roxb.) DC. and roots from the plants of *Toddalia asiatica* (L.) Lam., *Zanthoxylum armatum* DC., *Zanthoxylum dimorphophyllum* Hemsl. var. *spinifolium* Rehd. et Wils..

The quality evaluation of *Zanthoxylum nitidum* root in Chinese Pharmacopoeia has inspection items that are different from *Zanthoxylum nitidum* (Roxb.) DC. prodr. var. *tomentosum* Huang..

The development of standards for the quality and safety control of *Zanthoxylum nitidum* root can provide a reference for better development and use of *Zanthoxylum nitidum* root. Moreover, *Zanthoxylum nitidum* root is ranked no. 94 in the priority list of single herbal medicines for developing standards in ISO/TR 23975. [1] Thus, it is essential to develop an International Standard for *Zanthoxylum nitidum* root to ensure the consistency in the quality of *Zanthoxylum nitidum* root, which can contribute to the safe use of this herb and also promote the international trade.

In this document, the identification of commonly adulterated species of *Zanthoxylum nitidum* root is also introduced.

As national implementation can differ in different countries, national standards bodies are invited to modify the values given in 5.8 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 — *Zanthoxylum nitidum* root

1 Scope

This document specifies the minimum requirements and test methods for *Zanthoxylum nitidum* root.

This document applies to *Zanthoxylum nitidum* root 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

***Zanthoxylum nitidum* root**

dried root of *Zanthoxylum nitidum* (Roxb.) DC.

3.2

marker compound

nitidine chloride ($C_{21}H_{18}ClNO_4$)

4 Description

Zanthoxylum nitidum root is collected all year round, washed clean, sliced, or sectioned, and dried, as shown in [Figure 1](#).