



**International
Standard**

ISO 21314

**Traditional Chinese medicine —
Salvia miltiorrhiza root and rhizome**

*Médecine traditionnelle chinoise — Racine et rhizome de Salvia
miltiorrhiza*

**Second edition
2026-08**

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Published in Switzerland

Contents

Page

Foreword.....	iv
Introduction.....	v
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 Descriptions.....	2
5 Requirements and recommendations.....	3
5.1 General characteristics.....	3
5.2 <i>Salvia miltiorrhiza</i> root and rhizome.....	3
5.2.1 Morphological features of root and rhizome.....	3
5.2.2 Thin-layer chromatogram (TLC) identification.....	3
5.2.3 Moisture.....	3
5.2.4 Total ash.....	3
5.2.5 Acid-insoluble ash limit.....	3
5.2.6 Extractives.....	3
5.2.7 Content of marker compounds.....	3
5.2.8 Heavy metals.....	4
5.2.9 Pesticide residues.....	4
6 Sampling.....	4
7 Test methods.....	4
7.1 Macroscopic identification.....	4
7.2 Thin-layer chromatogram(TLC) identification.....	4
7.3 Determination of moisture content.....	4
7.4 Determination of total ash.....	4
7.5 Determination of acid-insoluble ash.....	4
7.6 Determination of extractives.....	4
7.7 Determination of tanshinones.....	4
7.8 Determination of salvianolic acid B.....	4
7.9 Determination of heavy metals.....	4
7.10 Determination of pesticide residues.....	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 extractives.....	8
Annex C (informative) Determination of tanshinones.....	9
Annex D (informative) Determination of salvianolic acid B.....	12
Annex E (informative) National and regional requirements for <i>Salvia miltiorrhiza</i> root and rhizome.....	14
Bibliography.....	15

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).

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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*.

This second edition cancels and replaces the first edition (ISO 21314:2019), which has been technically revised.

The main changes are as follows:

- 5.2.7 and 5.2.8: combination of 5.2.7 and 5.2.8 in to a single subclause with the title “Content of compound markers”;
- [Annex E](#) : update of the edition of the Chinese Pharmacopoeia and the Korea Pharmacopoeia;
- update of [Clause 2](#) and Bibliography.

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

Salvia miltiorrhiza Bge. is a perennial herbal plant in the Lamiaceae family. The root and rhizome of this plant have been used as traditional Chinese medicines for more than 2 500 years. Used as raw material, *Salvia miltiorrhiza* root and rhizome (Danshen) have been developed into various kinds of herbal medicine products and used in at least 19 countries or regions for their therapeutic value and market potential in the treatment of cardiovascular diseases, neurasthenic insomnia, liver fibrosis and cancer. It has also been used as an ingredient in health supplements and cosmetics.

Salvia miltiorrhiza Bge. is mainly grown and cultivated in China, but is also cultivated in the USA, Germany, Great Britain and Australia. However, the quality of *Salvia miltiorrhiza* root and rhizome (Danshen) provided by different cultivators is quite different, which can affect the safety and efficacy of this herb.

Salvia miltiorrhiza root and rhizome (Danshen) has been recorded by [1], [2], [3], [4], [5] and [6]. However, these national or regional standards are not harmonized and can be unfavourable for the international trade of *Salvia miltiorrhiza* root and rhizome (Danshen). One of the significant differences between them is that different chemical markers, or the same chemical markers with different limitations, are used. These chemical markers provide a vital index for judging the quality of *Salvia miltiorrhiza* root and rhizome. Therefore, the establishment of an international standard for *Salvia miltiorrhiza* root and rhizome (Danshen) is important for the international trade of this herb and also for ensuring the consistent quality and safety of this herb in clinical use.

As national implementation can differ, national standards bodies are invited to modify the values given in 5.2.3, 5.2.4, 5.2.5, 5.2.6.1, 5.2.6.2 and 5.2.7 in their national standards. Examples of national and regional values are given in Annex E.

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Traditional Chinese medicine — *Salvia miltiorrhiza* root and rhizome

1 Scope

This document specifies the requirements and test methods for *Salvia miltiorrhiza* root and rhizome, which are derived from the *Salvia miltiorrhiza* Bge. plant.

It is applicable to *Salvia miltiorrhiza* root and rhizome that are sold and used as a natural medicine in international trade, including unprocessed and traditionally processed materials.

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 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

***Salvia miltiorrhiza* root and rhizome**

underground part of *Salvia miltiorrhiza*

3.2

total ash

residue obtained after incineration at $(525 \pm 25) ^\circ\text{C}$

3.3

acid-insoluble ash

part of the *total ash* (3.2) remaining after treatment with hydrochloric acid

3.4

tanshinones

tanshinone IIA ($\text{C}_{19}\text{H}_{18}\text{O}_3$), cryptotanshinone ($\text{C}_{19}\text{H}_{20}\text{O}_3$) and tanshinone I ($\text{C}_{18}\text{H}_{12}\text{O}_3$)