
Traditional Chinese medicine — *Salvia miltiorrhiza* root and rhizome

Médecine traditionnelle chinoise — Racine et rhizome de Salvia miltiorrhiza



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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 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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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

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 has 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 provided by different cultivators is quite different, which may affect the safety and efficacy of this herb.

Salvia miltiorrhiza root and rhizome has been recorded by the United States of America Pharmacopoeia, the European Pharmacopoeia, the British Pharmacopoeia, the Chinese Pharmacopoeia, the Hong Kong Chinese Materia Medica Standard and the Taiwan Chinese Materia Medica Standard. However, these national or regional standards are not harmonized and may be unfavourable for the international trade of *Salvia miltiorrhiza* root and rhizome. One of the significant differences between them is that different chemical markers, or the same chemical markers with different limitations, are used in multiple standards. 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 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 may 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](#), [5.2.7](#) and [5.2.8](#) in their national standards. Examples of national and regional values are given in [Annex E](#).

Traditional Chinese medicine — *Salvia miltiorrhiza* root and rhizome

1 Scope

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

It is applicable to *Salvia miltiorrhiza* root and rhizome that is 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 928, *Spices and condiments — Determination of total ash*

ISO 930, *Spices and condiments — Determination of acid-insoluble ash*

ISO 18664, *Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine*

ISO 20409, *Traditional Chinese medicine — Panax notoginseng root and rhizome*

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

CODEX STAN 229-1993: *Analysis of pesticide residues: Recommended methods*

CAC/MRL01-2009: *Maximum Residue Limits for Pesticides in Foods*

World Health Organization. *Quality control methods for herbal materials: General advice on sampling*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at <https://www.iso.org/obp>

— IEC Electropedia: available at <http://www.electropedia.org/>

3.1

root and rhizome

underground part of *Salvia miltiorrhiza*

3.2

total ash

residue obtained after incineration at 525 ± 25 °C

3.3

acid-insoluble ash

part of the total ash remaining after treatment with hydrochloric acid