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Traditional Chinese medicine — *Salvia miltiorrhiza* root and rhizome

Médecine traditionnelle chinoise — Racine et rhizome de Salvia miltiorrhiza

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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).

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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*

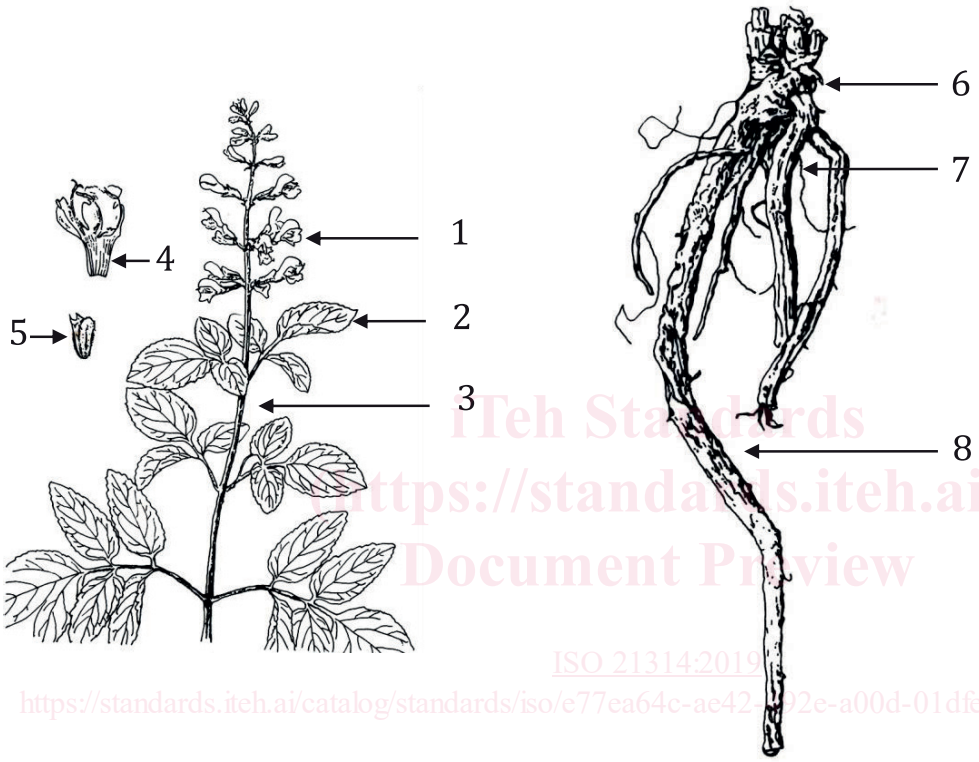
3.2
total ash
residue obtained after incineration at 525 ± 25 °C

3.3
acid-insoluble ash
part of the total ash remaining after treatment with hydrochloric acid

3.4
tanshinones
umbrella term of tanshinone IIA ($C_{19}H_{18}O_3$), cryptotanshinone ($C_{19}H_{20}O_3$) and tanshinone I ($C_{18}H_{12}O_3$)

4 Descriptions

Salvia miltiorrhiza root and rhizome is the dried root and rhizome of *Salvia miltiorrhiza* Bge. in the Lamiaceae (Labiatae) family as shown in Figure 1.



a) Aerial part of *Salvia miltiorrhiza* plant **b) Dried root and rhizome**

Key

1	raceme	5	calyx
2	leaf	6	rhizome
3	stem	7	fibrous root
4	flower (showing stamen)	8	root

Figure 1 — Structure of *Salvia miltiorrhiza*

5 Requirements

5.1 General characteristics

The following requirements shall be met before separating the bulk sample into test samples:

a) *Salvia miltiorrhiza* root and rhizome shall be clean and free from foreign matter.

b) The presence of living insects, mouldy root and rhizome and external contaminants which are visible to the naked eye shall not be permitted.

5.2 *Salvia miltiorrhiza* root and rhizome

5.2.1 Morphological features of root and rhizome

a) The rhizomes are short and stout, sometimes with a stem at the apex.

b) The roots are long, cylindrical and slightly curved. Some are branched and with rootlets.

c) The roots are 10 cm to 20 cm long, 0,3 cm to 1,5 cm in diameter.

d) The outer surface is brownish-red or dark brownish-red with rough and wrinkled longitudinal texture. The bark of old roots is loose, mostly purplish-brown and usually fall-off.

e) The texture is hard and fragile.

f) The fracture is loose with cleft or slightly flat and compact with brownish-red cortex, greyish-yellow or purplish-brown xylem and yellowish-white xylem rays arranged radially.

5.2.2 Thin-layer chromatogram (TLC) identification

The identification of *Salvia miltiorrhiza* root and rhizome by thin-layer chromatogram (TLC) shall present spots or bands with a colour and position corresponding to those of reference solutions.

5.2.3 Moisture

The mass fraction of moisture should not be more than 13,0 %.

5.2.4 Total ash

The mass fraction of total ash should not be more than 10,0 %.

5.2.5 Acid insoluble ash limit

The mass fraction of total ash should not be more than 3,0 %.

5.2.6 Extractives

5.2.6.1 Water-soluble extractives

The mass fraction of water-soluble extractives should not be less than 35,0 %.

5.2.6.2 Ethanol-soluble extractives

The mass fraction of ethanol-soluble extractives should not be less than 15,0 %.

5.2.7 Content of tanshinones

The sum of mass fraction of tanshinone IIA ($C_{19}H_{18}O_3$), cryptotanshinone ($C_{19}H_{20}O_3$), and tanshinone I ($C_{18}H_{12}O_3$) should not be less than 0,2 %. Annex C provides further information for the method.

5.2.8 Content of salvianolic acid B

The mass fraction of salvianolic acid B ($C_{36}H_{30}O_{16}$) should not be less than 3,0 %. Annex D provides further information for the method.

5.2.9 Heavy metals

The content of heavy metals including arsenic, mercury, lead and cadmium shall be determined.

5.2.10 Pesticide residues

The content of pesticide residues such as Benzex, DDT (dichloro-diphenyl-trichloroethane) and quintozene shall be determined.

6 Sampling

Sampling of *Salvia miltiorrhiza* root and rhizome shall be in accordance with the World Health Organization's *Quality control methods for herbal materials: General advice on sampling*.

7 Test methods

7.1 Macroscopic identification

Samples of not less than 500 g are taken from each batch randomly and observed by the naked eye.

7.2 TLC identification

See Annex A for additional information.

7.3 Determination of moisture content

The testing method specified in ISO 20409 applies.

7.4 Determination of total ash

The testing method specified in ISO 928 applies.

7.5 Determination of acid-insoluble ash

The testing method specified in ISO 930 applies.

7.6 Determination of extractives

See Annex B for additional information.

7.7 Determination of tanshinones

See Annex C for additional information.

7.8 Determination of salvianolic acid B

See Annex D for additional information.

7.9 Determination of heavy metals

The testing method specified in ISO 18664 applies.

7.10 Determination of pesticide residues

The testing methods specified in CODEX STAN 229-1993 and CAC/MRL01-2009 apply.