International Standard

ISO 21756

Traditional Chinese medicine — *Salvia miltiorrhiza* root and rhizome aqueous extract granules

Médecine traditionnelle chinoise — Granulés d'extrait aqueux de racine et de rhizome de Salvia miltiorrhiza

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Foreword

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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

Salvia miltiorrhiza root and rhizome (the Chinese Pinyin name: Danshen) has been used as traditional Chinese medicine for over 2 500 years and has been developed into various herbal medicinal products in many countries. *Salvia miltiorrhiza* root and rhizome aqueous extract granules are alternative forms of dosage for *Salvia miltiorrhiza* decoction pieces, which are obtained through modern pharmaceutical technology of extraction, concentration, drying and granulation. *Salvia miltiorrhiza* root and rhizome aqueous extract granules are well-suited for modern technological applications because they can be dosed accurately, quality controllable, ready-to-take, and easy to store, thereby replacing difficult dose calculation, poor portability, and longer decoction for *Salvia miltiorrhiza* decoction pieces.

ISO 21314 and ISO 23419 provide references for the quality assurance of *Salvia miltiorrhiza* root and rhizome aqueous extract granules. However, the manufacturing technology and quality control of *Salvia miltiorrhiza* root and rhizome aqueous extract granules have unique characteristics and requirements. Therefore, it is important to establish technical specifications for manufacturing technology and quality requirements of *Salvia miltiorrhiza* root and rhizome aqueous extract granules, to ensure their quality and safety, in accordance with international standards.

Traditional Chinese medicine — *Salvia miltiorrhiza* root and rhizome aqueous extract granules

1 Scope

This document specifies the technical requirements for the quality and safety of industrial manufacturing procedures and quality of *Salvia miltiorrhiza* root and rhizome aqueous extract granules. It is applicable to *Salvia miltiorrhiza* root and rhizome aqueous extract granules that are sold and used in international trade.

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 19609-1, *Traditional Chinese medicine — Quality and safety of raw materials and finished products made with raw materials — Part 1: General requirements*

ISO 21314, *Traditional Chinese medicine — Salvia miltiorrhiza root and rhizome*

ISO 22258, *Traditional Chinese medicine — Determination of pesticide residues in natural products by gas chromatography*

ISO 22467, *Traditional Chinese medicine — Determination of microorganisms in natural products*

ISO 23419, *Traditional Chinese medicine — General requirements for manufacturing procedures and quality assurance of granules*

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
granule
coated or uncoated small grains which range from approximately 0,2 mm to 4 mm in diameter, made from a uniform mixture of powdered extract and excipients

[SOURCE: ISO 23419: 2021, 3.3, modified — Notes to entry removed.]

3.2
extract
liquid preparation obtained by using water as a solvent for medicinal plants

[SOURCE: ISO 19617: 2018, 3.10, modified — The definition of "preparation" has been specified.]