



**International
Standard**

ISO 7835

**Traditional Chinese medicine —
Schisandra chinensis fruit**

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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 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

Schisandra chinensis fruit is a well-known traditional herbal medicine for thousands of years. *Schisandra chinensis* fruit has been used for the treatment of chronic cough and asthma, diabetes, and urinary tract disorders. Pharmacological studies have revealed that *Schisandra chinensis* fruit possesses various biological activities, including hepatoprotective, anti-inflammatory, antioxidant and antitumor activities.

Schisandra chinensis fruit has been officially documented as a traditional herbal medicine in the pharmacopoeias of several countries, including China (named wu wei zi),^[2] Japan (named gomishi),^[3] and Korea (named omija),^[1] as a traditional herbal medicine. Recently, the monograph of *Schisandra chinensis* fruit has also been included in the European pharmacopoeia and the United States Pharmacopoeia, where it is regulated as a dietary supplement.

The active medicinal constituents of *Schisandra chinensis* fruit contribute to its high market demand and utilization. Given the extensive cultivation and widespread use of this botanical, products in the herbal market are frequently adulterated with *Schisandra sphenanthera* fruit. This substitution occurs due to the morphological similarity between the two species and the lower cost of *Schisandra sphenanthera* fruit. Although the two *Schisandra* species differ significantly in their chemical profiles and biological activities, they are both commonly referred to as “Schisandra fruit” in commercial trade, leading to inconsistent quality in industrial applications.

Therefore, the establishment of an international standard for *Schisandra chinensis* fruit is necessary to support the clinical effectiveness, safety and quality consistency of this valuable traditional herbal medicine in international trade.

As national implementation can differ, national standards bodies are invited to modify the values given in [5.5](#) in their national standards. Examples of national and regional values are given in [Annex D](#).

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Traditional Chinese medicine — *Schisandra chinensis* fruit

1 Scope

This document specifies the minimum requirements and test methods for *Schisandra chinensis* fruit which is derived from *Schisandra chinensis* (Turcz.) Baill.

It is applicable to *Schisandra chinensis* fruit that is sold and used as a medicinal material in international trade, including Chinese materia medica.

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 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, *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 22590, *Traditional Chinese medicine — Determination of sulfur dioxide in natural products by titration*

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:

- IEC Electropedia: available at <https://www.iso.org/obp>
- ISO Online browsing platform: available at <https://www.electropedia.org/>

3.1

***Schisandra chinensis* fruit**

dried and ripe fruit from *Schisandra chinensis* (Turcz.) Baill. (Fam. Magnoliaceae).

3.2

***Schisandra sphenanthera* fruit**

dried and ripe fruit from *Schisandra sphenanthera* Rehd. et Wils. (Fam. Magnoliaceae).