



**International
Standard**

ISO 21590

**Traditional Chinese medicine —
*Crocus sativus stigma***

Médecine traditionnelle chinoise — Stigmate de Crocus sativus

**First edition
2026-02**

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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 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

Crocus sativus stigma (Xihonghua) is originally native to Europe and was introduced in China via the Silk Road for application in traditional Chinese medicine. In China, *Crocus sativus* stigma was first recorded in Bencao Pinhui Jingyao [1] in 1505. The primary producers of *Crocus sativus* stigma include countries such as Iran, India, Spain, Afghanistan, Greece and Italy, with emerging countries like China gaining prominence. *Crocus sativus* stigma is utilized medicinally in over 100 countries, thereby facilitating its global trade and its significant role in pharmaceutical applications. However, no international standard exists to evaluate the quality of *Crocus sativus* stigma as a raw material of traditional Chinese medicine.

The main chemical constituents of *Crocus sativus* stigma include carotene and volatile oil. Modern pharmacological studies have shown that crocin-I and crocin-II in *Crocus sativus* stigma have definite benefits for neurodegenerative diseases, mental disorders, epilepsy, seizures and insomnia, as well as several cardiovascular system conditions including hypertension, hyperlipidemia and atherosclerosis.

China, Japan, South Korea, India and Europe have established standards for *Crocus sativus* stigma in their respective pharmacopoeias. But each pharmacopoeia's requirements are different. The *Crocus sativus* stigma standard has not been unified at the international level, and many countries have different regulation levels.

As national implementation can differ, national standards bodies are invited to modify the values given in [5.5](#) and [5.6](#) in their national standards. An example of national values is given in [Annex C](#).

Traditional Chinese medicine — *Crocus sativus* stigma

1 Scope

This document specifies the minimum quality and safety requirements for *Crocus sativus* stigma.

It applies to *Crocus sativus* stigma that is sold and used as natural medicines in international trade, including in Chinese materia medica and decoction pieces.

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 3632-2, *Spices — Saffron (Crocus sativus L.) — Part 2: Test methods*

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

ISO/TS 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 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:

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

3.1

***Crocus sativus* stigma**

dried *stigma* (3.2) of *Crocus sativus* L., usually joined by the base to a short style

3.2

stigma

section of the aerial part of the pistil

3.3

reference medicine

authentic medicine from *Crocus sativus stigma* (3.2) used for reference in TLC analyses of the sample