
**Traditional Chinese medicine —
General requirements for herbal raw
material and materia medica**

*Médecine traditionnelle chinoise — Exigences générales relatives aux
matières premières issues des plantes et à la matière médicale*



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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.

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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

Chinese herbal medicine, as an important component of traditional Chinese medicine, is widely used in many countries because of its high value to human health and huge market. The annual sales of Chinese herbal medicine are worth more than USD 16 billion and are increasing at a rate of 10 % to 20 % per year, with great future potential. Such great opportunities for trade call for International Standards specifying the requirements for herbal medicines, in order to ensure their quality and safety, and to avoid misuse due to varietal complexity, harmful foreign matter and adverse drug reactions.

There are specific standards for important species, such as ISO 20409 for *Panax notoginseng* root and rhizome. However, it is impractical to develop one-on-one standards for the thousands of species of herbal medicine used in traditional Chinese medicine in the different traditions and regions. It is preferable to have one International Standard of general requirements for herbal medicine, because herbal medicines have many aspects in common.

The purpose of this document is to:

- a) provide a standard for the species not covered in the existing International Standards for single species of herbal medicine;
- b) provide an outline and reference for International Standards for single species of herbal medicine.

The principles that were followed in preparing this document are as follows:

- 1) cover all general requirements of herbal medicine recorded by national, regional and organizational pharmacopoeia, such as the *Pharmacopoeia of the People's Republic of China*,^[1] the *Japanese Pharmacopoeia*,^[2] the *Korean Pharmacopoeia*^[3] and the *European Pharmacopoeia*^[4];
- 2) distill the common characteristics of herbal medicine and formulate general requirements;
- 3) fully consider and respect the testing method and specific requirements on national or regional pharmacopoeias, legislation and standards.

The general requirements do not define general limit values. [Annex A](#) provides additional information as it lists the monographs for specific herbs in national and regional pharmacopoeias, including the items that are covered, meaning that limit values can be searched.

Traditional Chinese medicine — General requirements for herbal raw material and materia medica

1 Scope

This document specifies the general requirements and test methods for herbal raw material and materia medica.

This document provides minimum requirements for those herbal materials that are not covered by individual standards.

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 1573, *Tea — Determination of loss in mass at 103 °C*

ISO 1575, *Tea — Determination of total ash*

ISO 1577, *Tea — Determination of acid-insoluble ash*

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

ISO 19609-2, *Traditional Chinese medicine — Quality and safety of raw materials and finished products made with raw materials — Part 2: Identity testing of constituents of herbal origin*

ISO/TS 21310, *Traditional Chinese medicine — Microscopic examination of medicinal herbs*

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 22283, *Traditional Chinese medicine — Determination of aflatoxins in natural products by LC-FLD*

ISO 22467¹⁾, *Traditional Chinese Medicine — Determination of microorganism in natural products*

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

ISO 23190, *Traditional Chinese medicine — Determination of aristolochic acids in natural products by HPLC*

ISO 23191, *Traditional Chinese medicine — Determination of selected Aconitum alkaloids by high-performance liquid chromatography (HPLC)*

World Health Organization. *Quality Control Methods for Herbal Materials*. World Health Organization, 2011

3 Terms and definitions

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

1) Under preparation. Stage at the time of publication: ISO/FDIS 22467:2021.