



**International
Standard**

ISO 24898

**Traditional Chinese medicine —
General requirements for the
cultivation and primary processing
of herbal materials**

*Médecine traditionnelle chinoise — Exigences générales relatives
à la culture et à la transformation primaire des matières issues
des plantes*

**First edition
2026-03**

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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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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

The efficacy and safety of traditional Chinese medicine (TCM) is largely influenced by the quality of medicinal plants that are used as the starting materials for TCM. And the changes in components of medicinal parts during cultivating, harvesting, processing, storage and transportation ultimately also affect the quality of medicinal plants.

Good agricultural and collection practices (GACP) are crucial to ensuring the quality of medicinal plants (herbal medicine). World Health Organization (WHO) guidelines on GACP for medicinal plants was issued in 2004. Several countries and regions, like the European Union, the United State, Canada and China, have established or improved their own GACP standards subsequently, e.g. EU-GACP, AHPA-GACP, CHSNC-GACP, China-GACP. However, all these standards include both management and technical content. There is currently a lack of guidelines based on WHO-GACP that mainly focus on the production process of herbal materials, including their cultivation and collection. Such guidelines can enable practitioners to better grasp the technical aspects and obtain medicinal plants that are more in line with market demand.

The current GACP have played an important role in guiding the production of medicinal plants for TCM in those regions such as the EU, USA, Canada and China. With the improvement of people's living standards, herbal materials with preventive and health-care functions are gradually becoming more and more popular, and the demand for herbal materials is increasing. However, due to the long growth period and poor accessibility of wild populations of many medicinal plants, wild resources are not enough to support the growing demand. Hence, the demand for cultivated medicinal plants has increased sharply. However, the allelopathic or autotoxic effects of medicinal plants cause continuous cropping obstacles, making them difficult to cultivate. There is an urgent need for more clarifications on the cultivation techniques and a global general reference for medicinal materials cultivation. The specifications of some techniques in the current GACP are either too detailed and lack operability, or no longer applicable due to the updates and changes in production techniques over time. Therefore, in order to promote safety and quality at the first and most important stage of the production process of herbal medicines, it is necessary to develop globally applicable technical requirements for medicinal plant growers, collectors and processors to fulfill the current situation and demand. This document is developed to address this need. [Annexes A](#) to [E](#) provide templates for recording content during the production and processing of herbal materials. [Annex A](#) provides an example of an identification record for seeds and other propagation materials. [Annex B](#) gives an example of a record for the entire cultivation process. [Annex C](#) contains examples of records for the use of fertilizers and pesticides. [Annex D](#) provides an example of a record of the entire collection process. [Annex E](#) provides an example of a processing record.

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Traditional Chinese medicine — General requirements for the cultivation and primary processing of herbal materials

1 Scope

This document specifies the general technical requirements for the process of cultivation and collection of medicinal plants, including selection of site, seeds and other propagation materials, cultivation, harvest and collection, post-harvest processing, packaging and labelling, storage and transportation.

This document applies to the cultivation, harvest and collection of medicinal plants used as the source for herbal medicines, including certain post-harvest operations.

This document also provides practical record formats for the entire process.

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 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*

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

medicinal plant

plant (wild or cultivated) used for medical purposes

Note 1 to entry: Medicinal plants include fungi such as mushrooms.

[SOURCE: ISO 19617:2018, 3.6, modified — Note 1 to entry has been added.]

3.2

identification

method to determine the medicinal plant species, cultivars and varieties based on genetic information or external morphological characteristics