INTERNATIONAL STANDARD

ISO 19609-3

First edition
2022-11

Traditional Chinese medicine — Quality and safety of raw materials and finished products made with raw materials —

Part 3: Testing for contaminants

Médecine traditionnelle chinoise — Qualité et sécurité des matières premières et des produits finis fabriqués à partir de matières premières —

Partie 3: Essais pour la recherche de contaminants

Reference number
ISO 19609-3:2022(E)

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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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 Chinese medicine*.

A list of all parts in the ISO 19609 series can be found on the ISO website.

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.

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Introduction

The ISO 19609 series consists of four parts with different content, as shown in Figure 1.

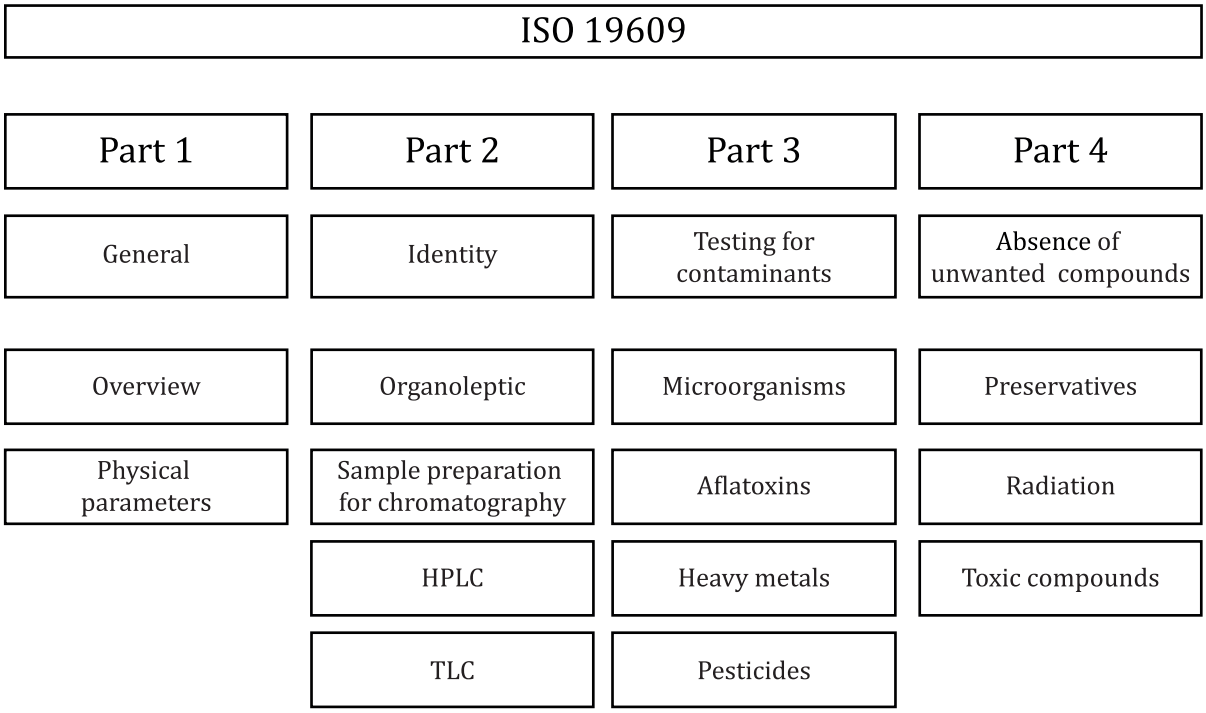


Figure 1 — Overview of the ISO 19609 series

To ensure the safety of herbal medicinal products, all raw materials and products must be analysed for possible contamination. In this field four main types of contaminants are controlled so that their absence or presence is lower than the relevant limit values defined by different target markets or nations.

Specific documents for heavy metals, pesticides, aflatoxins and microorganisms have been developed within the framework of ISO/TC 249.

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Traditional Chinese medicine — Quality and safety of raw materials and finished products made with raw materials —

Part 3: Testing for contaminants

1 Scope

This document specifies the sample preparation methods for the determination of contamination of natural products by heavy metals, pesticides, aflatoxins and microorganisms. It is applicable to raw materials and finished products used in traditional Chinese medicine.

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 19609-1:2021, *Traditional Chinese medicine — Quality and safety of raw materials and finished products made with raw materials — Part 1: General requirements*

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

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
aflatoxin
naturally occurring poisonous, carcinogenic and mutagenic mycotoxin, produced by certain fungi (mainly *Aspergillus* species), commonly found on agricultural crops

3.2
compactate
irregular-shaped agglomerate obtained directly from the dried extract-by-compaction

[SOURCE: ISO 23419: 2021, 3.4, modified — Note to entry removed.]

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3.3
heavy metal
metal with relatively high density as a natural constituent of the environment, commonly detected in air, water and soil

3.4
microbial contamination
presence of unintended bacteria, fungi, protozoa or viruses

Note 1 to entry: This can include extrinsic and/or intrinsic contamination.

[SOURCE: ISO 18362:2016, 3.17]

3.5
microorganism
entity of microscopic size, encompassing bacteria, fungi, protozoa and viruses

[SOURCE: ISO 11139:2018, 3.176]

3.6
pesticide
substance or mixture of substances intended to prevent, destroy, repel or mitigate any pest or weed

Note 1 to entry: Pesticides (plant protection products) approved for use in one country will not necessarily be approved in another country.

[SOURCE: ISO 18889:2019, 3.7, modified — Note to entry revised.]

4 Testing of contaminants

4.1 Determination of heavy metals in herbal medicines and products used in and as traditional Chinese medicine

4.1.1 General

The determination of heavy metals shall be done in accordance with ISO 18664.

4.1.2 Sample preparation

4.1.2.1 General

The quality and reliability of analytical results depend on both the analytical method and the sample preparation of the test sample. If a sample preparation is not appropriate, the analytical results can be slightly incorrect or completely wrong. Sample preparation methods depend on the constitution of the testing material. Typical established sample preparation techniques are listed in the following subclauses.

4.1.2.2 Sample size for the determination of heavy metals

Based on experiences with pharmaceuticals worldwide, and especially herbal-based phytopharmaceuticals, a typical amount of testing material is required. An appropriate sample size should be 250 mg of dry or dried material or equivalent.

4.1.2.3 Solid samples

The preparation of test samples shall be carried out in accordance with ISO 19609-1:2021, 6.2.

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