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

Part 4: Testing for preservatives and unwanted compounds

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

Partie 4: Essais des conservateurs et composés indésirables

Reference number
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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).

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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 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 different parts with different content as shown in Figure 1.

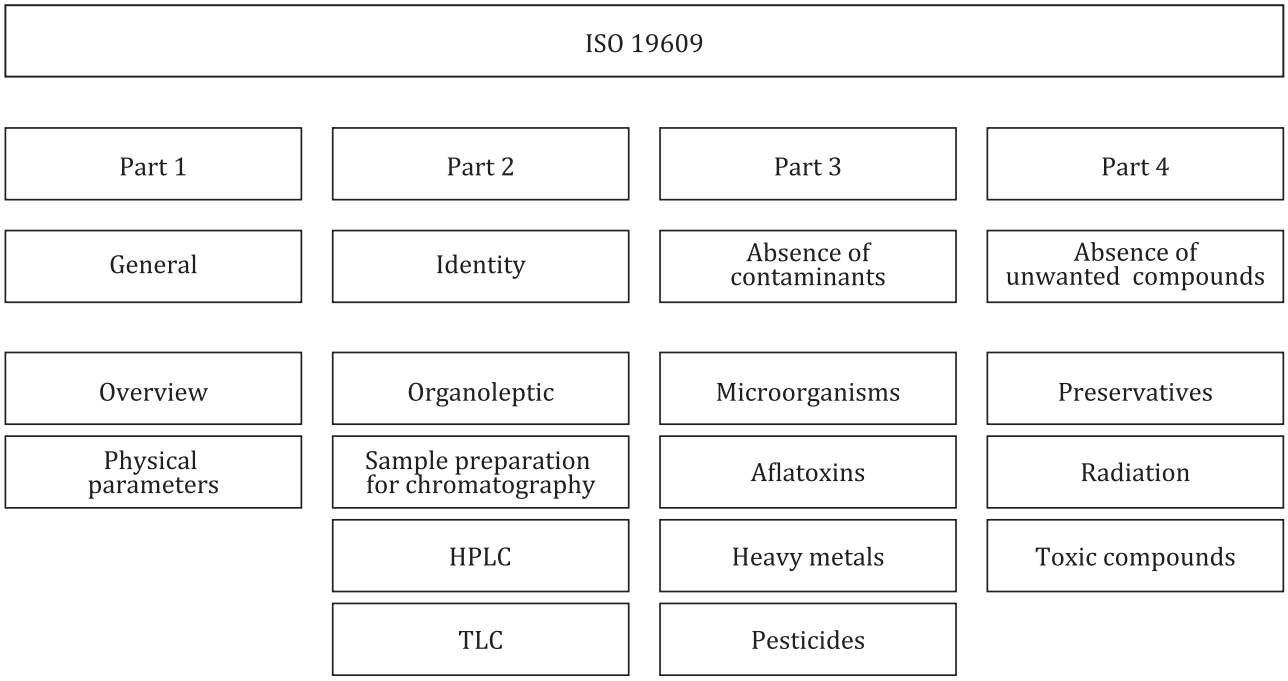


Figure 1 — Overview of the ISO 19609 series

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

Part 4:
Testing for preservatives and unwanted compounds

1 Scope

This document specifies the testing of preservatives and unwanted compounds within a quality control framework for starting materials and finished products used in and as 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 22256, *Traditional Chinese medicine — Detection of irradiated natural products by photostimulated luminescence*

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 high-performance liquid chromatography (HPLC)*

ISO 23956, *Traditional Chinese medicine — Determination of benzopyrene in processed natural products*

ISO 23962, *Traditional Chinese medicine — Processed Aconitum carmichaelii lateral root*

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
unwanted compound
Constituent of a product which is unsuitable or unsafe for the intended use of that product.

Note 1 to entry: Such compounds can be those added for preservation or which result from a degradation process. Toxic natural compounds can also be considered unwanted compounds.

3.2
preservative
component intended to prevent the growth of microorganisms in or on a product

[SOURCE: ISO 18369-1:2017, 3.1.11.7]

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3.3
excipient
material that is present in a therapeutic product administered to a patient, other than the active substance(s)

[SOURCE: ISO/TS 20399-1:2018, 3.7, modified — Definition revised, example and note to entry removed.]

4 Testing for the absence of unwanted compounds and radiation

4.1 General

For the risk assessment of traditional Chinese medicine products, the presence and/or the amount of unwanted compounds shall be estimated.

4.2 Overview

These unwanted compounds and radiation can be categorized in three main groups:

a) preservatives;

b) radiation;

c) toxic compounds:

— natural toxins;

— toxins resulting from degradation reactions;

d) other additives.

4.3 Determination of preservatives

4.3.1 General

Preservatives are pharmaceutical excipients added to therapeutic products to extend their shelf life and prevent contamination with microorganisms such as bacteria and fungi. Their possible adverse effects include allergic reactions and irritation.

4.3.2 Determination of preservatives

4.3.2.1 General

The determination and quantification should be done by specific and valid analytical procedures.

Preservatives in traditional Chinese medicine products are listed on the product ingredient list.

4.3.2.2 Sulfur and sulfur derivatives

Sulfur and sulfur derivatives include elemental sulfur and sulfites such as potassium sulfide and sodium sulfite, as well as sulfur dioxide and other sulfur-containing additives.

NOTE Sulfur dioxide or sulfite formed in aqueous solution has a preserving effect by irretrievably inhibiting metabolism and damage to the cell membranes from microorganisms as well as destroying the secondary and tertiary structure of microbial enzymes.

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