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

**Part 1:
General requirements**

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

Partie 1: Exigences générales



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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Overview of herbal medicinal products	3
4.1 Raw materials	3
4.2 Products of raw materials	3
4.2.1 General	3
4.2.2 Decoction pieces, medicinal decoctions prepared from decoction pieces and wine preparations or powders	4
4.2.3 Finished products for modernized traditional therapy	4
4.2.4 Non-traditionally produced finished products for phytotherapy	5
5 Quality testing	5
5.1 General	5
5.2 Testing procedure	6
6 Testing of physical parameters	6
6.1 General	6
6.2 Sampling	7
6.2.1 General	7
6.2.2 Bulk sampling method	7
6.2.3 Test sampling method	7
6.3 Estimation of the water content of herbals and resulting products	8
6.3.1 General	8
6.3.2 Testing methods	8
6.4 Requirements and testing methods for finished products for modernized traditional therapy and non-traditionally produced finished products for phytotherapy	11
6.4.1 General	11
6.4.2 Estimation of the uniformity of dosage units	11
6.4.3 Disintegration test for solid dosage forms like tablets and capsules	12
6.4.4 Estimation of particle size for powders and other small dosage forms	14
6.4.5 Estimation of the pH-value of liquids, solutions or suspensions by potentiometric determination	15
6.4.6 Dissolution test for solid dosage forms	15
6.5 Estimation of the content of residual solvents	17
6.5.1 General	17
6.5.2 Types of typically used solvents	17
6.5.3 Reagents	19
6.5.4 Sample preparation	19
6.5.5 Apparatus	19
6.5.6 Procedure	19
6.5.7 System suitability	21
6.5.8 Calculation	21
6.6 Stability of TCM products	21
6.6.1 General	21
6.6.2 Estimation of the stability of TCM products	21
Bibliography	22

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.

Introduction

The ISO 19609 series consists of four parts with different content as shown in [Figure 1](#).

ISO 19609			
Part 1	Part 2	Part 3	Part 4
General	Identity	Absence of contaminants	Absence of unwanted compounds
Overview	Organoleptic	Microorganisms	Preservatives
Physical parameters	Sample Preparation for chromatography	Aflatoxins	Radiation
	HPLC	Heavy metals	Toxic compounds
	TLC	Pesticides	

Figure 1 — Overview of the ISO 19609 series

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

Part 1: General requirements

1 Scope

This document specifies general requirements within a quality control framework for raw materials and finished products used in and as traditional Chinese medicine (TCM) and derivative forms, and the comparison between the starting materials and the finished products, if necessary.

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 760, *Determination of water — Karl Fischer method (General method)*

ISO 3310-1, *Test sieves — Technical requirements and testing — Part 1: Test sieves of metal wire cloth*

ISO 10523, *Water quality — Determination of pH*

ISO 12937, *Petroleum products — Determination of water — Coulometric Karl Fischer titration method*

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 22217, *Traditional Chinese medicine — Storage requirements for Chinese materia medica and decoction pieces*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

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

3.1

active substance

substance of physiological or pharmacological action

3.2

finished product for modernized traditional therapy

concentrated product from hot aqueous decoctions of *decoction pieces* (3.3) or other starting materials (3.11) as well as powder made from starting materials described in pharmacopoeias, applied in the dosage forms of capsules, granules or tablets