INTERNATIONAL STANDARD

ISO 19609-1

First edition
2021-01

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

Reference number
ISO 19609-1:2021(E)

© ISO 2021



COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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**

© ISO 2021 – All rights reserved

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.

© ISO 2021 – All rights reserved

Introduction

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

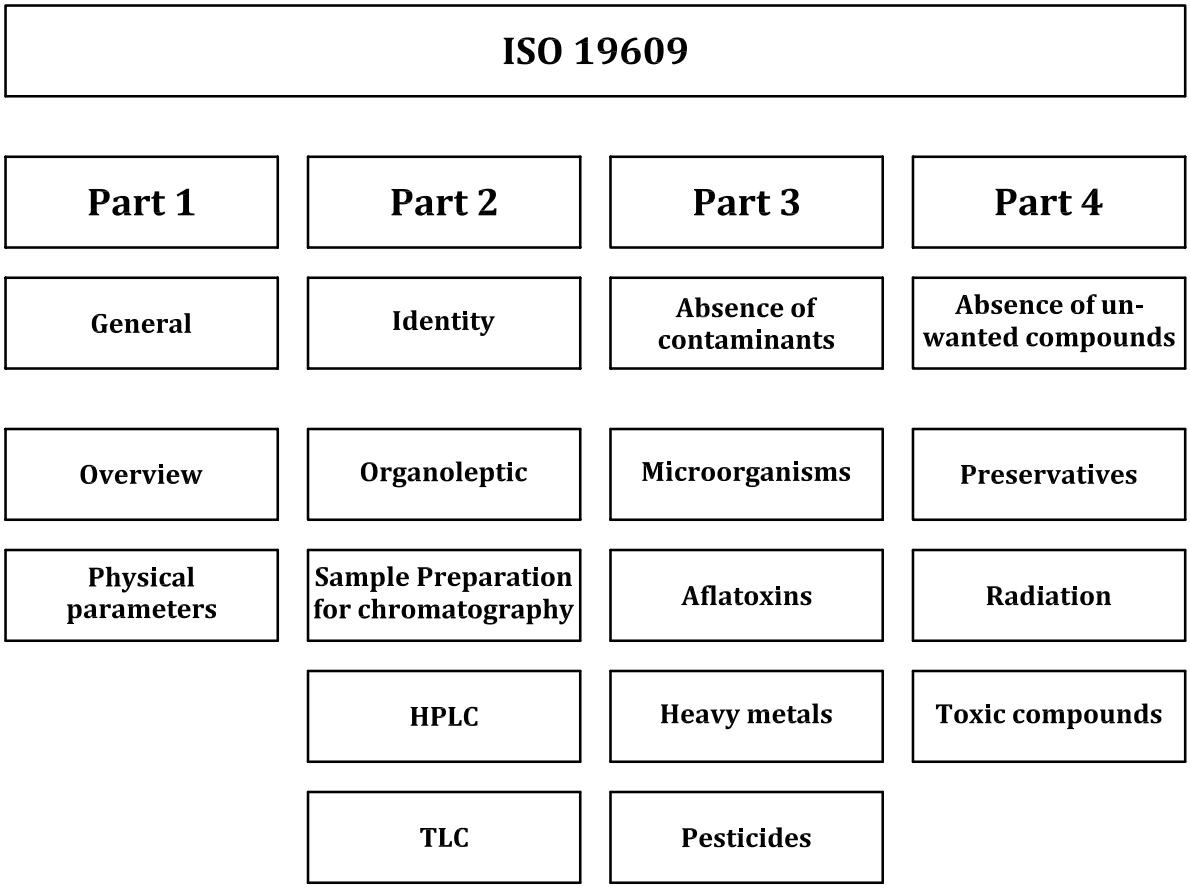


Figure 1 — Overview of the ISO 19609 series

© ISO 2021 – All rights reserved

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

© ISO 2021 – All rights reserved

3.3
decoction piece
prescription medicinal processed from Chinese Materia Medica under the direction of TCM and processing methods for Chinese medicines and derivative forms, which can be directly used in clinical practice or the production of prepared medicines

[SOURCE: ISO 18668-1:2016, 3.3, modified — Note 1 to entry amalgamated with definition.]

3.4
disintegration
physical breakdown of a material into very small fragments in a pharmaceutical context except insoluble coating materials or broken capsule shell

[SOURCE: ISO 17088:2012, 3.6, definition modified.]

3.5
dissolution
process of obtaining a solution containing the analyte of interest in a pharmaceutical context

[SOURCE: ISO/TR 19057:2017, 3.6, definition modified.]

3.6
finished product
commercial product intended for sale and use, including *decoction pieces* (3.3)

3.7
foreign matter
material consisting of any or all foreign tissues (matter coming from the source plant but not defined as the right herbal material) and foreign elements (other matter of vegetable, animal or mineral origin)

3.8
non-traditionally produced finished product for phytotherapy
product made from TCM raw materials (3.9) which are not *decoction pieces* (3.3) or *finished products for modernized traditional therapy* (3.2)

EXAMPLE Organic extracts and products made from these extracts.

3.9
raw material
substance going into or involved in the manufacturing of a bulk product

[SOURCE: ISO 22716:2007, 2.28]

3.10
residual solvent
organic volatile chemical used or produced in the manufacturing of extracts or excipients or in the preparation of medicinal products, and not completely removed by practical manufacturing techniques

3.11
starting material
material received by a manufacturer to be commercially processed, manufactured or packaged

Note 1 to entry: This includes raw materials (3.9) and other materials, for example solvents, excipients and capsule shells.

© ISO 2021 – All rights reserved