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

Part 1: General requirements

Partie 1: Généralités

Reference number
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Foreword

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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.

Introduction

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

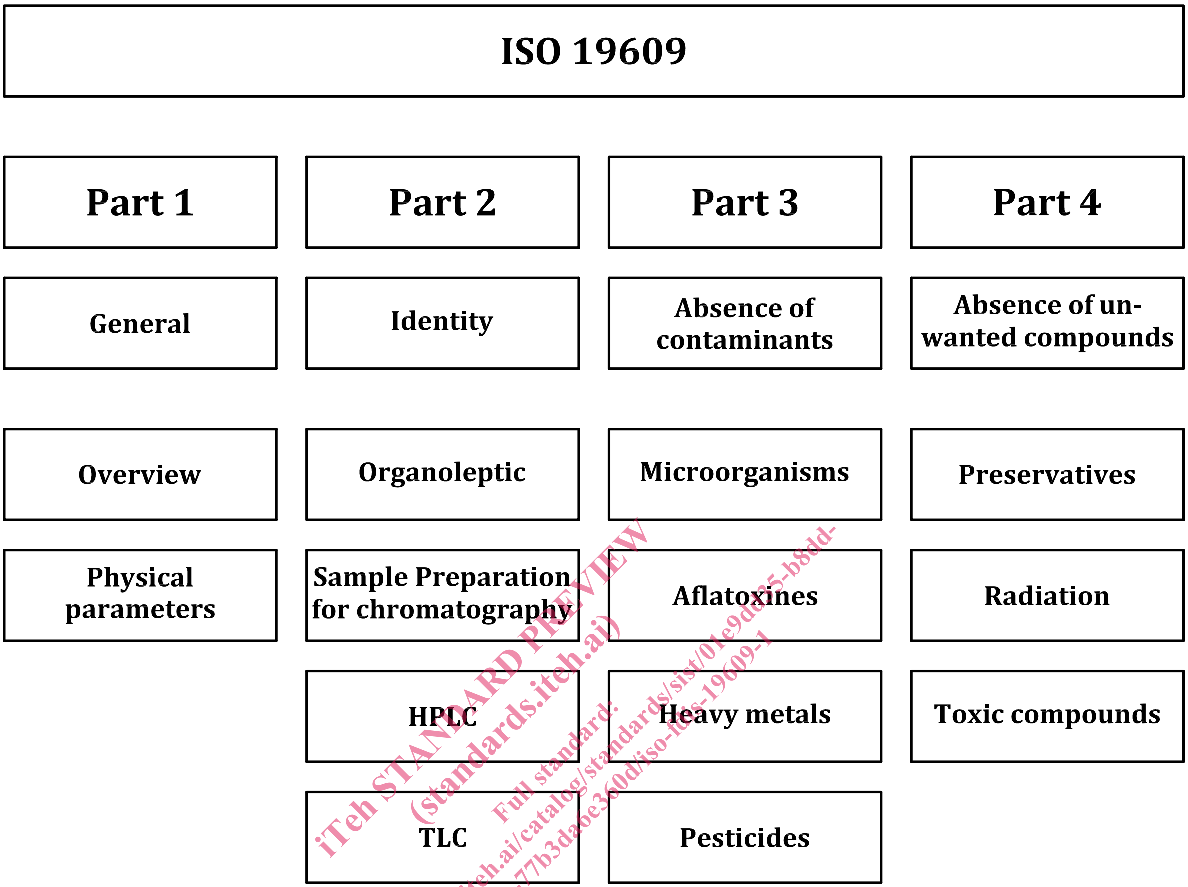

Figure 1 — Overview of the ISO 19609 series

Traditional Chinese medicine — Quality and safety of raw materials and manufacturing 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 manufacturing 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

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 organs (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.

4 Overview of herbal medicinal products

4.1 Raw materials

Raw materials of TCM are:

a) herbal material (e.g. flowers, herbs, seeds, fruits, roots and other parts of medicinal plants, fresh juices, gums, natural essential oils, resins);

b) parts of animals (e.g. mussels, bombyx);

c) minerals.

NOTE Herbal and animal material can be subject to CITES rules.

4.2 Products of raw materials

4.2.1 General

Products of raw materials are divided into three groups depending on the form of therapy:

a) decoction pieces, medical decoction prepared from decoction pieces and wine preparations or powders for traditional therapy;

b) finished products for modernized traditional therapy (e.g. capsules, coated and uncoated tablets, powders and granules);

c) non-traditionally produced finished products for phytotherapy (e.g. regulated formulas as remedies, made from extracts with other solvents instead of water).

Figure 2 shows the different types of products applied in the field of TCM. The categorization is necessary based on the different requirements of pharmaceutical products.

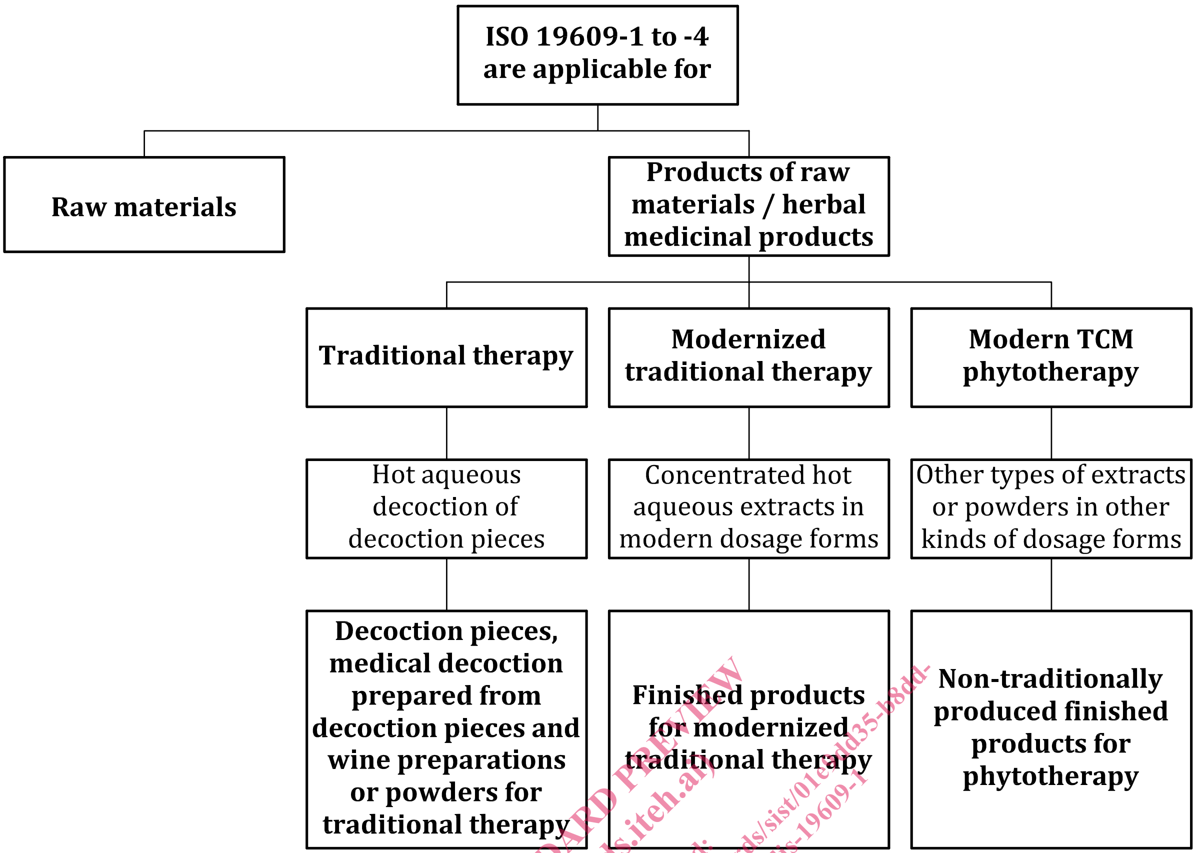

Figure 2 — Classification of products of raw materials

4.2.2 Decoction pieces, medicinal decoctions prepared from decoction pieces and wine preparations or powders

The typical raw materials used in and as TCM are decoction pieces in the form of cut raw materials. These are intended to produce a preparation using hot or boiling water.

NOTE 1 In the classical TCM therapy, herbal and animal material as well as minerals were cut into smaller pieces and used during or after a processing step (e.g. steaming, cooking, calcinating, paozhi) as a source for the individual mixture after a practitioner's and doctor's prescription.

NOTE 2 A special cutting is used for KAMPO herbals in Japan.

NOTE 3 In some cases, wine can be used as a solvent instead of water according to the Chinese[10], Japanese[11] and Korean[9] pharmacopoeias.

4.2.3 Finished products for modernized traditional therapy

Finished products for modernized traditional therapy are:

a) concentrates from hot aqueous preparations;

   NOTE 1 Only hot water decoctions can be seen as typically traditional, without toxicity risks.

   NOTE 2 Traditionally produced wine preparation can also be used.

b) powders made from raw materials which are described in the Chinese[10], Japanese[11] and Korean[9] pharmacopoeias;

   NOTE 3 In the case of powdered materials, there are risks for the patients because of the potential toxicity of the raw materials.

c) capsules, coated and uncoated tablets, powders and granules as dosage forms based on a) or b).

NOTE 4 The toxic risks cannot be extrapolated from traditional use of the decoctions. A lot of lipophilic compounds can be seen as toxic (e.g. aristolochic acid, which was not a problem in decoctions in TCM). The toxical risks of lipophilic compounds do not appear in water decoctions, but in powders, alcoholic extracts and lipophilic concentrates.

4.2.4 Non-traditionally produced finished products for phytotherapy

Non-traditionally produced finished products for phytotherapy are raw materials and products not listed in 4.2.2 and 4.2.3.

The pharmacology and toxicology of these products shall be tested by the producer before marketing.

NOTE 1 TCM products can be seen in parallel to the “European Phytomedicine”.

NOTE 2 KAMPO products extracted with up to 30 % ethanol do not need to be declared in Japan.

NOTE 3 For the markets in Europe and associated countries a registration is required for each product independent of specific dosage forms.

NOTE 4 Products made with supercritical carbon dioxide are not allowed in countries which apply the *European Pharmacopoeia*[14].

5 Quality testing

5.1 General

The quality of therapeutics is internationally defined with three general criteria: potency, safety and accuracy. These criteria are also relevant for TCM therapeutics (see Figure 3).

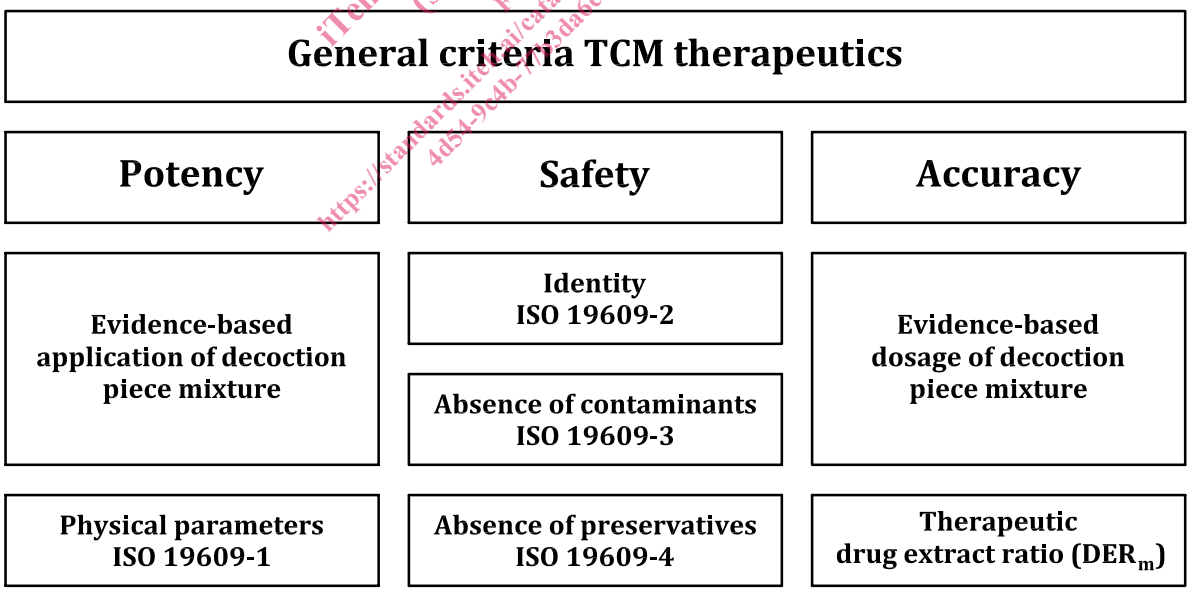

Figure 3 — General criteria for TCM therapeutics

Quality criteria of raw materials and products of raw materials are defined in the ISO 19609 series as follows:

— correct physical parameters;

— correct identity of herbal ingredients;